

DENTAL BOARD OF CALIFORNIA

REPORT TO CALIFORNIA STATE LEGISLATURE REGARDING

FINDINGS RELEVANT TO INFORM DENTAL ANESTHESIA AND SEDATION STANDARDS

December 2021

(As required by SB 501 (Glazier, Ch 929, Stats. 2018); Bus. & Prof. Code, § 1601.4, subd. (a)(2))

Members of the Dental Board of California

Joanne Pacheco, RDH, MAOB, President

Rosalinda Olague, RDA, BA, Vice President

Alan Felsenfeld, MA, DDS, Secretary

Fran Burton, MSW

Steven Chan, DDS

Lilia Larin, DDS

Meredith McKenzie, Esq.

Angelita Medina

Mark Mendoza

Sonia Molina, DMD, MPH

Alicia Montell, DDS

Steven Morrow, DDS, MS

Thomas Stewart, DDS

James Yu, DDS, MS

Table of Contents

EXECUTIVE SUMMARY	1
NTRODUCTION	2
STATISTICAL FINDINGS	3
Hospitalization Incident Reports by Age Group	4
Sex of Hospitalized Patients by Age Group	9
ASA Physical Status of Hospitalized Patients by Age Group	10
Number of Hospitalized Patients With and Without Coexisting Diagnosis I	
Dental Setting of Those Who Were Hospitalized	14
Category of Provider Responsible for Anesthesia or Sedation Oversight for Patients Who Were Hospitalized	
Hospitalization Incident Reports: Investigative Outcomes	15
Death Incident Reports by Age Group	17
Sex of Deceased Patients by Age Group	22
ASA Physical Status Classification (I, II, or III) of Deceased Patients by Ag	•
Number of Deceased Patients by Age Group With and Without Coexisting Diagnosis	
Dental Setting Where Anesthesia and/or Sedation May Have Resulted in P	
Category of Provider Responsible for Anesthesia or Sedation Oversight of Deceased Patient	
Death Incident Reports: Investigative Outcomes	28
RELEVANT PROFESSIONAL GUIDELINES, RECOMMENDATIONS, OR BEST	
PRACTICES FOR THE PROVISION OF DENTAL ANESTHESIA AND SEDATION	
COMPARATIVE REVIEW	
CONCLUSION	37

EXECUTIVE SUMMARY

The Dental Board of California (Board) submits this Report to California State Legislature Regarding Findings Relevant to Inform Dental Anesthesia and Sedation Standards as required by Senate Bill (SB) 501 (Glazer, Chapter 929, Statutes of 2018) and Business and Professions Code (BPC) section 1601.4, subdivision (a)(2).

The first half of the report summarizes the Board's statistical findings regarding adverse events reported to the Board after the administration of anesthesia and/or sedation before or during dental procedures. The adverse events reported to the Board were submitted by dental licensees, physicians and surgeons, anesthesiologists, and other various reporting sources from the period of January 1, 2017, to June 30, 2021. The Board will continue to collect information on adverse effects of all sedation levels in dentistry, and the next Board report regarding pediatric deaths related to general anesthesia and deep sedation in dentistry will be submitted to the California State Legislature at the time of the Board's Sunset Review pursuant to the requirements of BPC section 1601.4, subdivision (b).

The second half of the report discusses relevant professional guidelines, recommendations, or best practices for the provision of dental anesthesia and sedation care and how they compare to California laws and regulations effective January 1, 2022.

This report concludes that with the implementation of new minimal, moderate, and deep sedation and general anesthesia provisions enacted by SB 501 that become effective on January 1, 2022, California will have some of the highest patient monitoring standards for the administration of minimal, moderate, and deep sedation and general anesthesia to dental patients of all age groups and especially for children. California statutes meet and generally exceed the guidelines of all the organizations that are involved in the administration of anesthesia to children in dental offices.

INTRODUCTION

In 2018, SB 501 (Glazer, Chapter 929, Statutes of 2018) amended BPC section 1601.4, subdivision (a), to require the Board to review available data on all adverse events related to general anesthesia and deep sedation, moderate sedation, and minimal sedation in dentistry and relevant professional guidelines, recommendations, or best practices for the provision of dental anesthesia and sedation care. SB 501, among other things, also required the Board, by January 1, 2022, to report to the California State Legislature any findings relevant to inform dental anesthesia and sedation standards. This report is submitted in accordance with this requirement.

BPC section 1680, subdivision (z), requires licensees to report the death of a patient during the performance of any dental or dental hygiene procedure, the discovery of a death of a patient whose death is related to dental or dental hygiene procedure performed by the licensee, or, except for a scheduled hospitalization, the removal to a hospital or emergency center for medical treatment 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. In addition, this section requires the licensee to report a death or hospitalization when sedation and/or anesthesia is used for a dental procedure on a form approved by the Board and include all of the following information:

- the date of the procedure;
- the patient's age in years and months, weight, and sex;
- the patient's American Society of Anesthesiologists (ASA) physical status;
- the patient's primary diagnosis;
- the patient's coexisting diagnoses;
- the procedures performed;
- the sedation setting;
- the medications used;
- the monitoring equipment used;
- the category of the provider responsible for sedation oversight;
- the category of the provider delivering sedation;
- the category of the provider monitoring the patient during sedation;
- whether the person supervising the sedation performed one or more of the procedures;
- the planned airway management;
- the planned depth of sedation;
- the complications that occurred;
- a description of what was unexpected about the airway management;
- whether there was transportation of the patient during sedation;
- the category of the provider conducting resuscitation measures; and
- the resuscitation equipment utilized.

In response to Assembly Bill (AB) 2235 (Thurmond, Chapter 519, Statutes of 2016), the Board created the "Courtesy Form for Reporting of Anesthesia Death or Hospitalization". The form is available on the Board's website.

STATISTICAL FINDINGS

The Board attempted to gather information from other state dental boards, however data regarding adverse events associated with anesthesia and/or sedation varies from state to state which therefore limits the value of the data. Instead, the Board will focus this report on the data received via the "Courtesy Form for Reporting of Anesthesia Death or Hospitalization" within the State of California.

Below are charts showing the statistical findings regarding adverse events after the administration of anesthesia and/or sedation before or during dental procedures. The data is based on the incident reports submitted by dental licensees, physicians and surgeons, anesthesiologists and other various reporting sources from the period of January 1, 2017, to June 30, 2021.

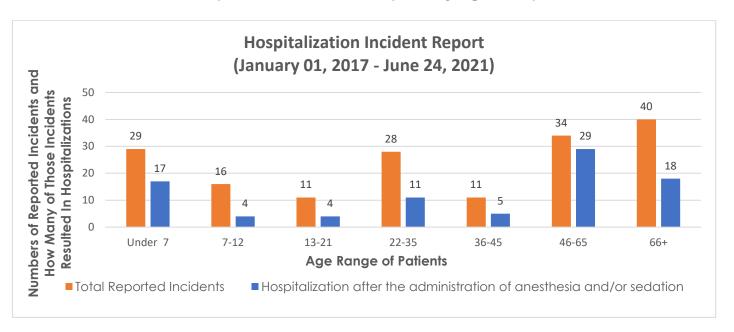
The Board presents its findings and provides a breakdown of the incident reports, which include the number of patient deaths and hospitalizations that may have been a result of complications due to any anesthesia and/or sedation used for the patient's dental procedure. For this reporting period, the Board has received a total of 210 incident reports. Of the 210 incident reports received, the Board has determined that a total of 88 reports included incidents in which anesthesia or sedation was administered and the patient was hospitalized, and 23 reports in which anesthesia or sedation was administered and the patient passed away during or shortly after the dental procedure. The data has been categorized by age group with the assistance of the Board's subject matter experts.

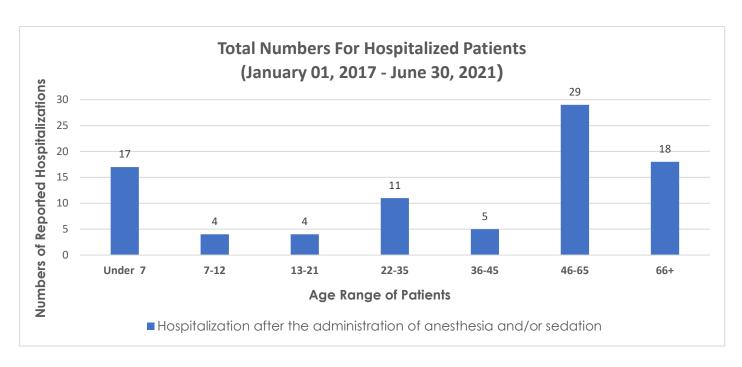
The different age groups are broken down as follows:

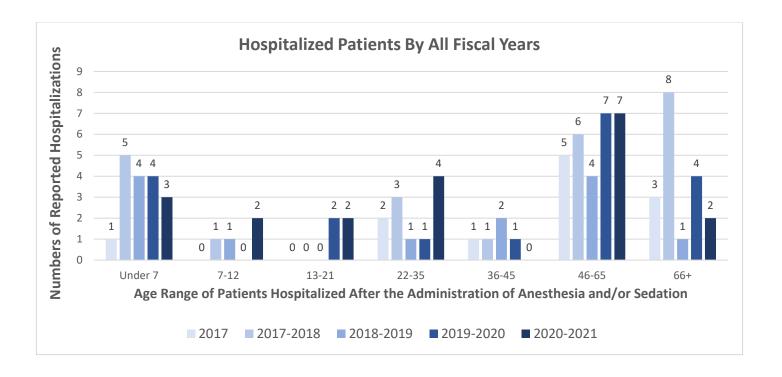
- Pediatric (Under 7 years)
- Older Pediatric (Ages 7-12)
- Adolescents (Ages 13-21)
- Young Adults (Ages 22-35)
- Adults (Ages 36-45)
- Middle-Aged (Ages 46-65)
- Senior (Ages 66+)

The data is sorted by fiscal year and includes the patient's age, sex, ASA physical status, if the patient had any coexisting diagnoses, the setting where the sedation and dental procedure took place, and the category of the provider responsible for sedation oversight.

Hospitalization Incident Reports by Age Group

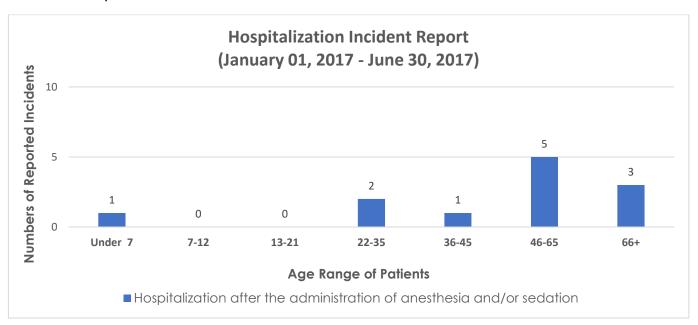


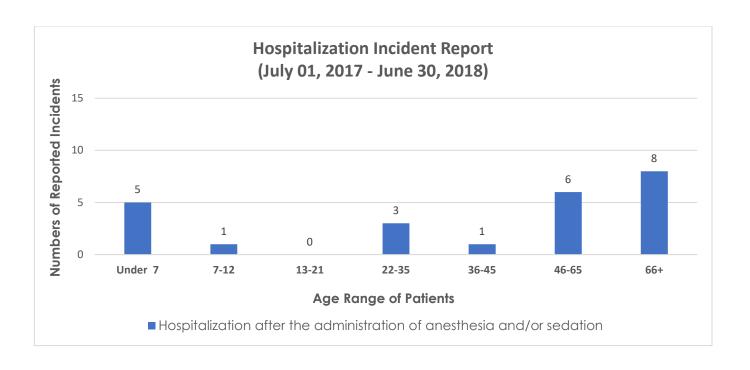


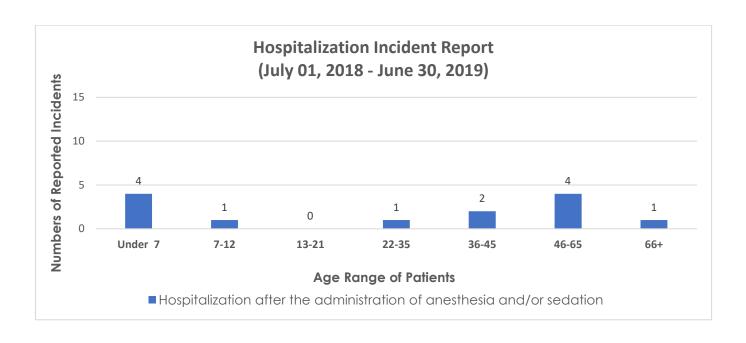


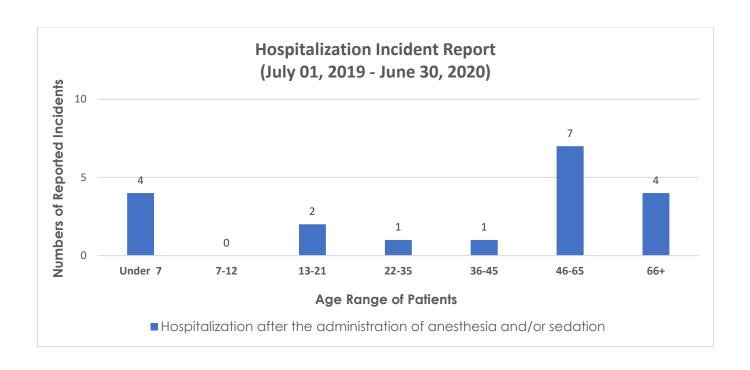
- The first chart reflects the total numbers of incident reports, and of those reports, how many patients were hospitalized after the administration of anesthesia and/or sedation during a four and one half-year span. The second chart is a reiteration of the first chart but represents the total numbers of reported hospitalizations for that same time frame. The third chart represents the numbers of patients hospitalized throughout the various fiscal years via their age groups. This chart is presented to provide a comparison of any possible trends during this period.
- The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age, there were a total of 29 incident reports, and of those of 29, 17 were hospitalized possibly due to anesthesia and/or sedation related treatment.
 - For older pediatric patients ages 7-12, there were a total of 16 incident reports, and of those 16, six were hospitalized possibly due to anesthesia and/or sedation related treatment.
 - For adolescent patients ages 13-21, there were a total of 11 incident reports, and of those 11, four were hospitalized possibly due to anesthesia and/or sedation related treatment.
 - For young adult patients ages 22-35, there were a total of 28 incident reports and of those 28, 11 were hospitalized possibly due to anesthesia and/or sedation related treatment.

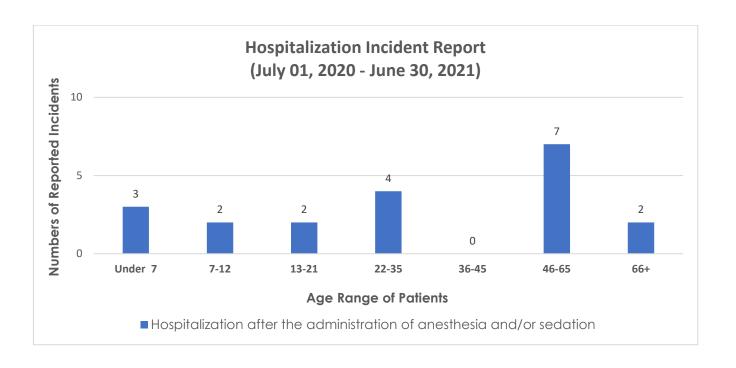
- For adult patients ages 36-45, there were a total of 11 incident reports, and of those 11, five were hospitalized possibly due to anesthesia and/or sedation related treatment.
- For middle-aged patients ages 46-65, there were a total of 34 incident reports, and of those 34, 29 were hospitalized possibly to due anesthesia and/or sedation related treatment.
- For senior patients ages 66 and up, there were a total of 40 incident reports, and of those 40, 18 were hospitalized possibly to due anesthesia and/or sedation related treatment.
- From the date of the initial mandate (January 2017) through June 24, 2021, this is the data that the Board has for hospitalization due to possible complications from the administration of anesthesia and/or sedation before and during the patient's dental procedure. The specific reports indicate that anesthesia and/or sedation were given before or during the procedure prior to hospitalization. However, the reason for hospitalization may have been due to outside factors and not due to administration of anesthesia and/or sedation. Accordingly, the term "possibly" is used to accommodate for hospitalization that may or may not have been the result of anesthesia and/or sedation administered to the patient.
- The charts below show the numbers of hospitalizations during each fiscal period:



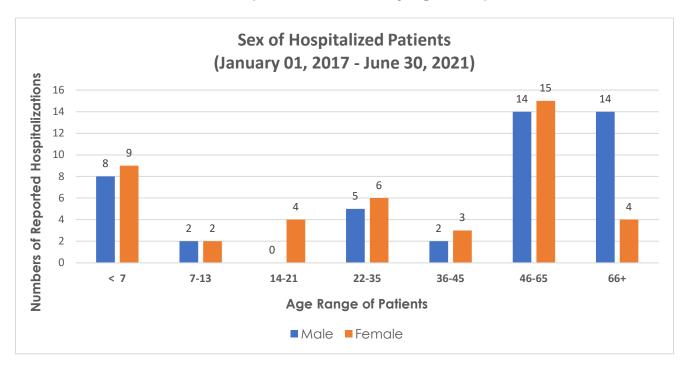


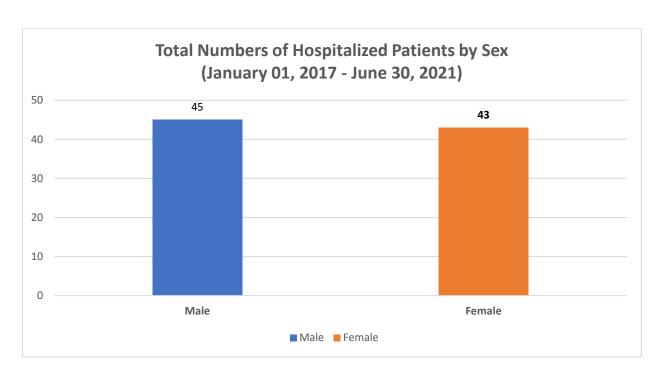






Sex of Hospitalized Patients by Age Group

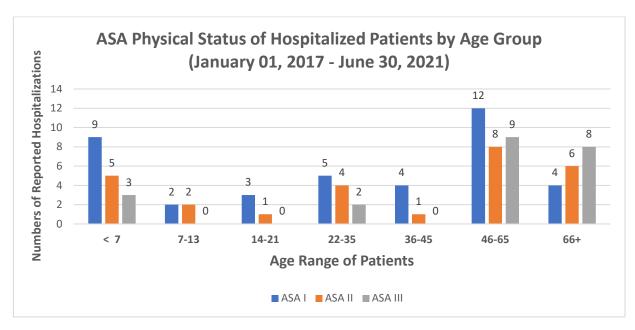


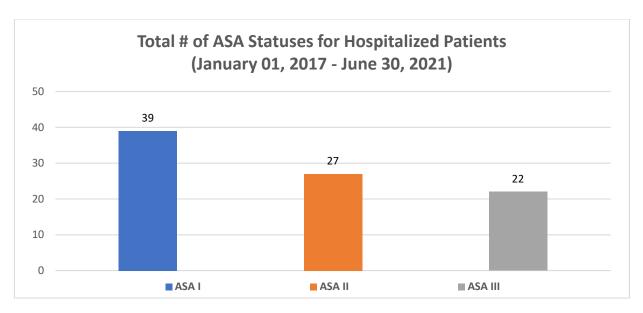


- o The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age, there were a total of 17 hospitalization reports (8 were males, and 9 were females).
 - For older pediatric patients ages 7-12, there were a total of four hospitalization reports (2 were males and 2 were females).

- For adolescent patients ages 13-21, there were a total of four hospitalization reports (no males; all 4 were females).
- For young adult patients ages 22-35, there were a total of 11 hospitalization reports (5 were males, and 6 were females).
- For adult patients ages 36-45, there were a total of five hospitalization reports (2 were males, and 3 were females).
- For middle-aged patients ages 46-65, there were a total of 29 hospitalization reports (14 were males, and 15 were females).
- For senior patients ages 66 and up, there were a total of 17 hospitalization reports (8 were males, and 9 were females).
- According to the data collected, the ratio of males to females was overall similar in number, except for senior patients ages 66 and up. In this group, the number of males was 3.5 times more than that of females (14 to 4). Overall, there did not appear to be any significant discrepancy among the numbers to indicate that one sex is more prone than another when it comes to the number of those hospitalized due to possible anesthesia and or sedation related incidents.

ASA Physical Status of Hospitalized Patients by Age Group

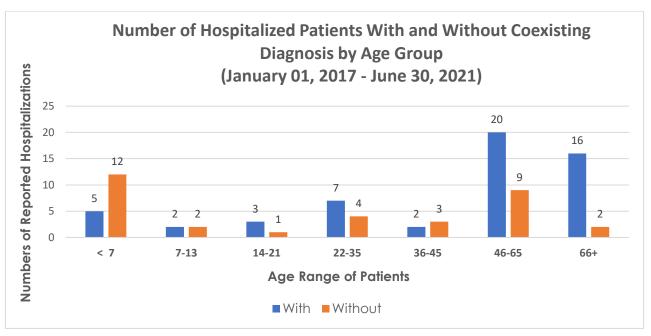


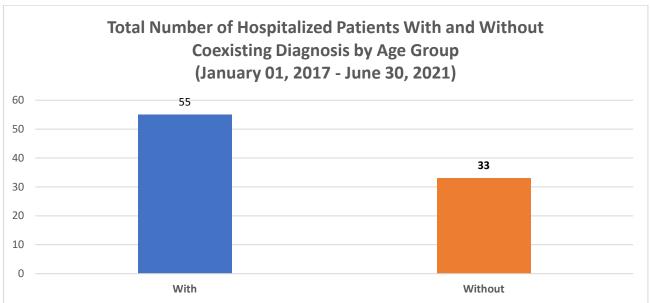


- According to the ASA, the ASA Physical Status Classification System has been in use for over 60 years. The purpose of the system is to assess and communicate a patient's pre-anesthesia medical co-morbidities. The classification does not predict the perioperative risks, but used with other factors (e.g., type of surgery, facility, level of deconditioning), it can be helpful in predicting perioperative risks.
- A general guidelines of the ASA Physical Status Classification System are outlined below:
 - ASA I: A normal healthy patient
 - ASA II: A patient with mild systemic disease
 - ASA III: A patient with severe systemic disease
 - ASA IV: A patient with severe systemic disease that is a constant threat to life (none reported)
 - ASA V: A moribund patient who is not expected to survive without the operation (none reported)
 - ASA VI: A declared brain-dead patient whose organs are being removed for donor purposes (none reported)
- The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age: nine patients were considered healthy, five as having mild systemic disease, and three with severe systemic disease.

- For older pediatric patients ages 7-12: two patients were considered healthy, two as having mild systemic disease, and none with severe systemic disease.
- For adolescent patients ages 13-21: three patients were considered healthy, one as having mild systemic disease, and none with severe systemic disease.
- For young adult patients ages 22-35: five patients were considered healthy, four as having mild systemic disease, and two with severe systemic disease.
- For adult patients ages 36-45: four patients were considered healthy, one as having mild systemic disease, and none with severe systemic disease.
- For middle-aged patients ages 46-65: 12 patients were considered healthy, eight as having mild systemic disease, and nine with severe systemic disease.
- For senior patients ages 66 and up: four patients were considered healthy, six as having mild systemic disease, and eight with severe systemic disease.
- According to the data collected, the total number of patients in every age group combined that were considered "normal healthy patient" were 39; 27 were considered as those with mild systemic disease, and 22 were considered as those with severe systemic disease. Most younger patients hospitalized were normal healthy patients, but beginning with the middle-aged group, there are higher numbers of ASA statuses of II and III. It is known that health declines as one gets older. Although the ASA guidelines go up to level VI, there were no reports of any hospitalized patients who were considered greater than level III.

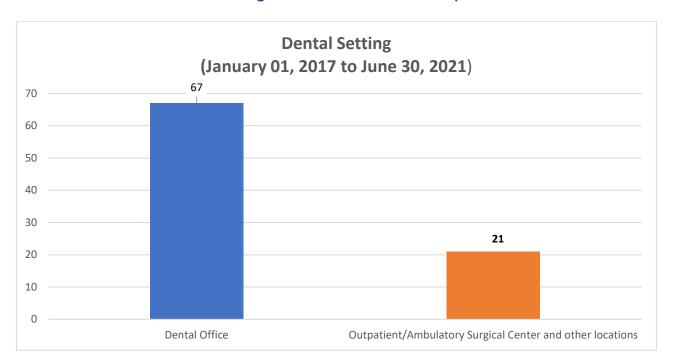
Number of Hospitalized Patients With and Without Coexisting Diagnosis by Age Group





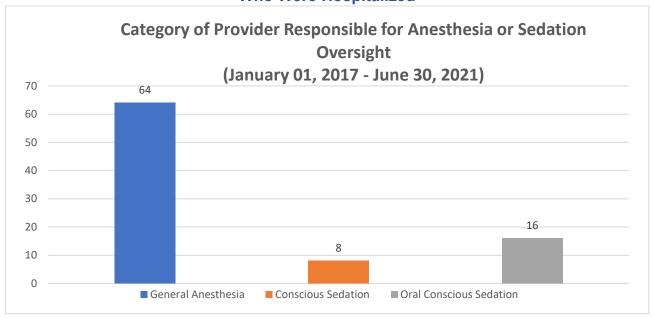
These charts represent hospitalized patients who, before their dental procedure, either had or did not have coexisting diagnosis. A total of 55 hospitalized patients were found to have a coexisting diagnosis, while 33 did not. Predictably, there were higher numbers of serious coexisting diagnoses, such as hypertension, diabetes, liver disease, and other serious conditions, from age 46 and older. These numbers are for hospitalizations possibly due to the anesthesia and/or sedation administered, but the patients' coexisting diagnoses also could have played a role in their hospitalization, and this could hold truer for the older age groups.

Dental Setting of Those Who Were Hospitalized



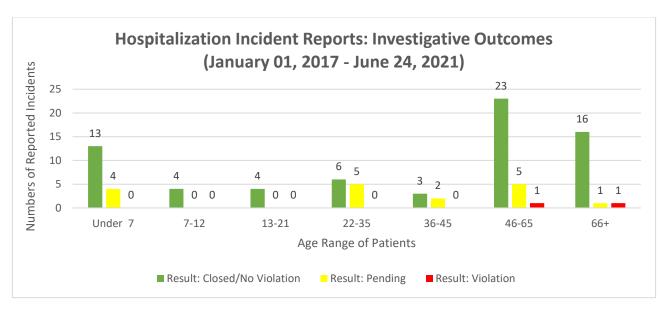
This chart represents the setting of the dental procedures that resulted in hospitalization possibly due to the administration of anesthesia and/or sedation treatment. Out of the total 88 reports of dental treatment that resulted in hospitalization, 67 were conducted in a dental office; 21 were conducted in outpatient/ambulatory surgical centers and other locations that were not a dental office.

Category of Provider Responsible for Anesthesia or Sedation Oversight for Patients
Who Were Hospitalized



- This chart represents the category (anesthesia or sedation certification) of the provider responsible for anesthesia or sedation oversight in cases where the patients were hospitalized possibly due to the administration of anesthesia and/or sedation under the dental provider's care or after they had left the premises.
 - Of the 88 cases of reported hospitalizations, 64 of the care providers possessed a current general anesthesia permit.
 - Eight of the care providers possessed a current conscious sedation permit.
 - Sixteen of the care providers possessed a current oral conscious sedation permit.
- Note that the provider responsible for anesthesia or sedation oversight was also the same provider who delivered the anesthesia and/or sedation and monitored the patient during the procedure. In the case of monitoring, aside from the provider, there were cases where registered dental assistants also participated in the monitoring.

Hospitalization Incident Reports: Investigative Outcomes

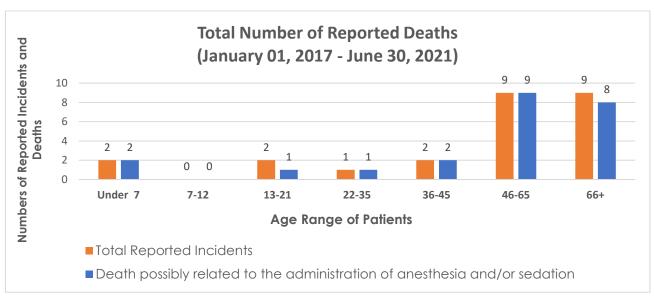


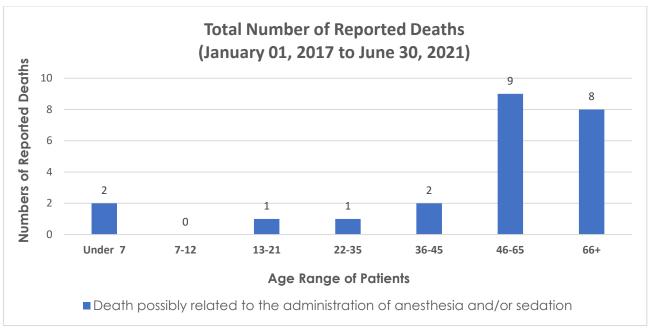


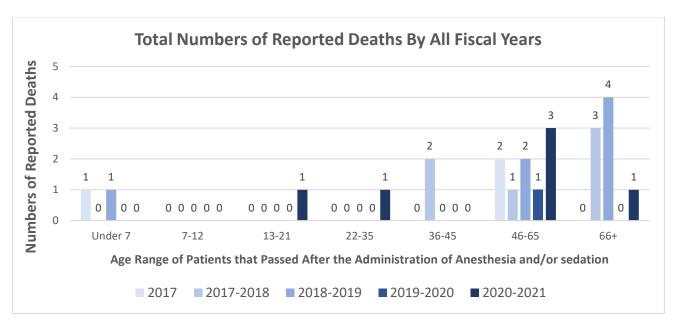
- These two charts represent the Board's investigative outcomes from January 1, 2017, to June 30, 2021, for all reported hospitalizations where anesthesia and/or sedation was given.
- The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age, there were a total of 17 incident reports of hospitalization. Of those 17, 13 cases resulted in no violations, and four cases are currently pending.
 - For older pediatric patients ages 7-12, there were a total of four incident reports of hospitalization; all four cases resulted in no violations occurring.
 - For adolescent patients ages 13-21, there were a total of four incident reports of hospitalization; all four cases resulted in no violations occurring.
 - For young adult patients ages 22-35, there were a total of 11 incident reports of hospitalization. Of those 11, six cases resulted in no violations, and five cases are currently pending.
 - For adult patients ages 36-45, there were a total of five incident reports of hospitalization. Of those five, three cases resulted in no violations, and two cases are currently pending.
 - For middle-aged patients ages 46-65, there were a total of 29 incident reports of hospitalization. Of those 29, 23 cases resulted in no violations, one case resulted in a violation, and five cases are currently pending.

- For senior patients ages 66 and up, there were a total of 18 incident reports of hospitalization. Of those 18, 16 cases resulted in no violations, one case resulted in a violation, and one case is currently pending.
- Percentages of the case results are broken down as follows:
 - 78.4% of cases were "Closed No Violations"
 - 19.3% of cases are in "Pending" status
 - 2.3% of cases were "Violations"

Death Incident Reports by Age Group

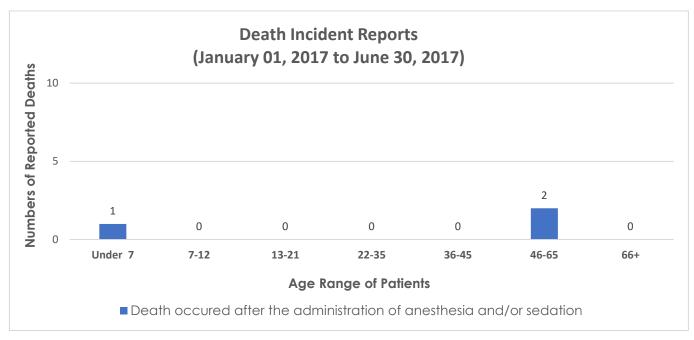


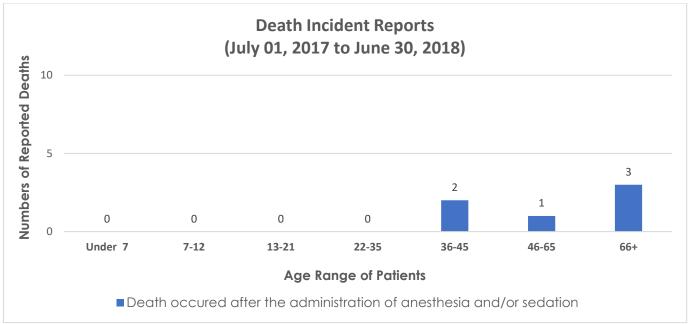


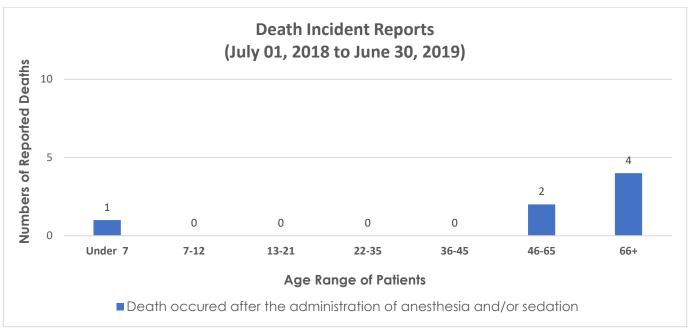


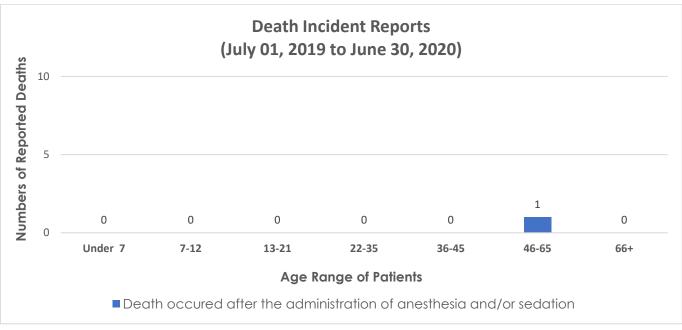
- The first chart reflects the total number of incident reports and how many resulted in deaths possibly related to the administration of anesthesia and/or sedation during dental treatments in a four and one half-year span. The second chart is a reiteration of the first chart, but represents only the total numbers of reported deaths for that same time frame. The third chart represents the numbers of reported deaths throughout the various fiscal years via their age groups. This chart is presented to provide a comparison of any possible trends throughout this period of review.
- o The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age, there were a total of two incident reports, and of those of 2, both resulted in death possibly due to anesthesia and/or sedation related treatment.
 - For older pediatric patients ages 7-12, there were no reported deaths.
 - For adolescent patients ages 13-21, there were a total of two incident reports, and of those two, one resulted in death possibly due to anesthesia and/or sedation related treatment.
 - For young adult patients ages 22-35, there was only one incident report, which was reported as a death that was possibly due to anesthesia and/or sedation related treatment.
 - For adult patients ages 36-45, there were a total of two incident reports, and of those two, both resulted in death possibly to due to anesthesia and/or sedation related treatment.

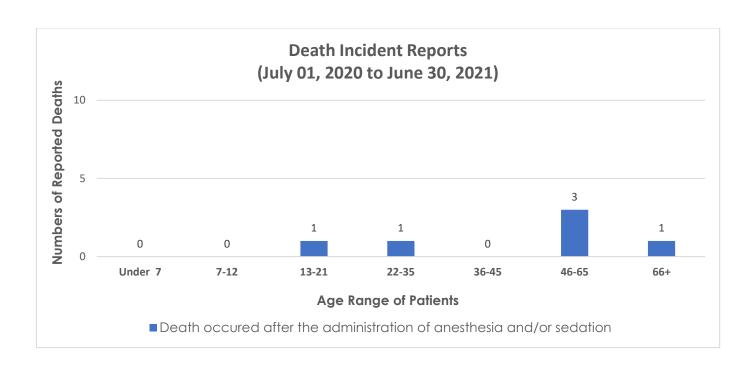
- For middle-aged patients ages 46-65, there were a total of nine incident reports, and all nine resulted in death possibly to due anesthesia and/or sedation related treatment.
- For senior patients ages 66 and up, there were a total of nine incident reports, and of those nine, eight resulted in death possibly to due anesthesia and/or sedation related treatment.
- o Below is a breakdown of the numbers of deaths for each fiscal period:



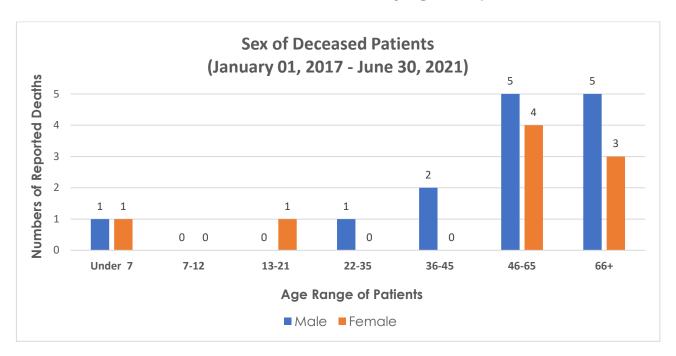






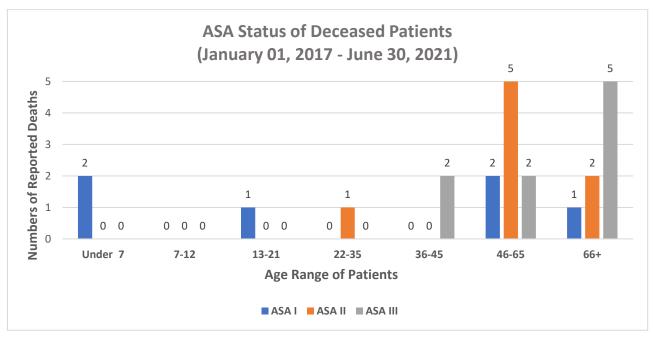


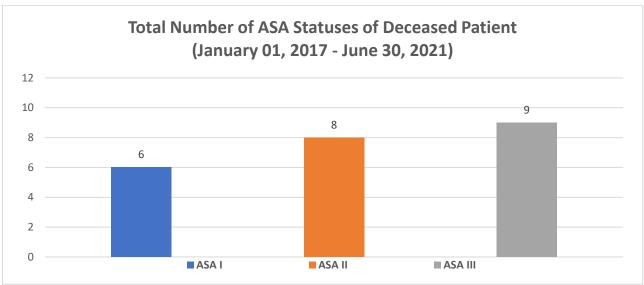
Sex of Deceased Patients by Age Group



- The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age, there were a total of two death reports (1 male and 1 female).
 - For older pediatric patients ages 7-12, there were no reported deaths.
 - For adolescent patients ages 13-21, there was one death report (1 female).
 - For young adult patients ages 22-35, there was one hospitalization report (1 male).
 - For adult patients ages 36-45, there were a total of two death reports (2 males).
 - For middle-aged patients ages 46-65, there were a total of nine death reports (5 males and 4 females).
 - For senior patients ages 66 and up, there were a total of eight death reports (5 males and 3 females).
- The ratio of males to females was overall similar in number throughout the various age groups.

ASA Physical Status Classification (I, II, or III) of Deceased Patients by Age Group

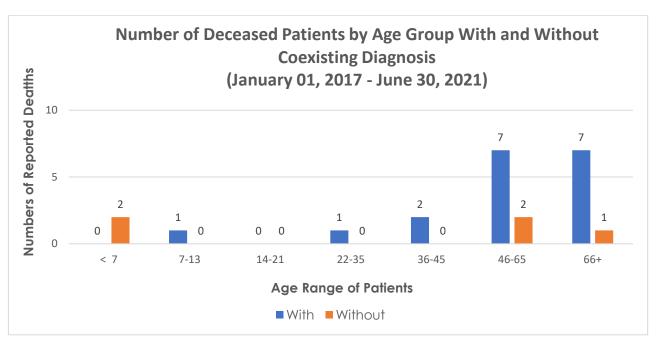


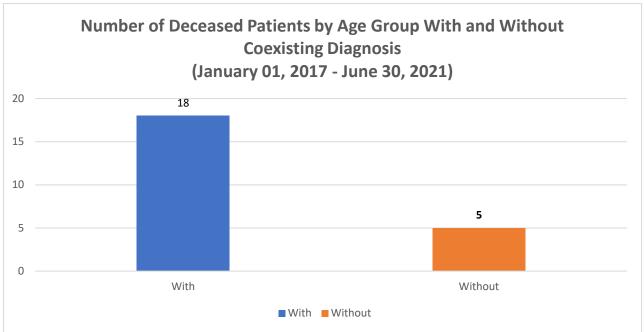


- The general guidelines of the ASA Physical Status Classification System are outlined below:
 - ASA I: A normal healthy patient
 - ASA II: A patient with mild systemic disease
 - ASA III: A patient with severe systemic disease
 - ASA IV: A patient with severe systemic disease that is a constant threat to life (none reported)

- ASA V: A moribund patient who is not expected to survive without the operation (none reported)
- ASA VI: A declared brain-dead patient whose organs are being removed for donor purposes (none reported)
- The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age: both patients were considered healthy.
 - For older pediatric patients ages 7-12: there no reports of death.
 - For adolescent patients ages 13-21: one patient was considered healthy.
 - For young adult patients ages 22-35: one patient was considered as having mild systemic disease.
 - For adult patients ages 36-45: two patients were considered as having severe systemic disease.
 - For middle-aged patients ages 46-65: two patients were considered healthy, five as having mild systemic disease, and two with severe systemic disease.
 - For senior patients ages 66 and up: one patient was considered healthy, two as having mild systemic disease, and five with severe systemic disease.
- In every age group combined, there were six patients considered "normal healthy patient," eight were considered as those with mild systemic disease, and nine were considered as those with severe systemic disease. Both of the patients from the younger age group were considered healthy, but in the adult patients age group, there were higher numbers of ASA status of II and III similar to the hospitalization statistics. Although the ASA guidelines go up to level VI, there were no reports of any hospitalized patients who were considered a level IV, V, or VI.

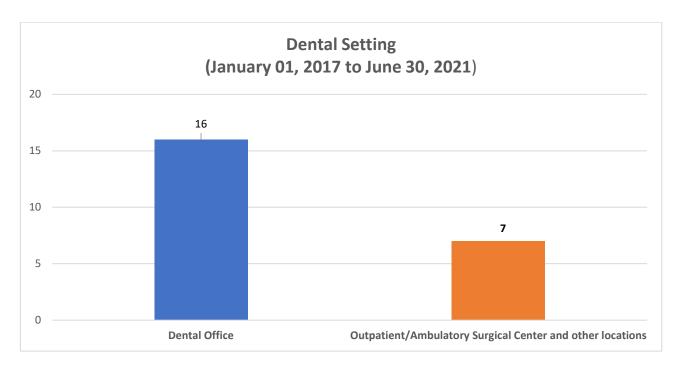
Number of Deceased Patients by Age Group With and Without Coexisting Diagnosis





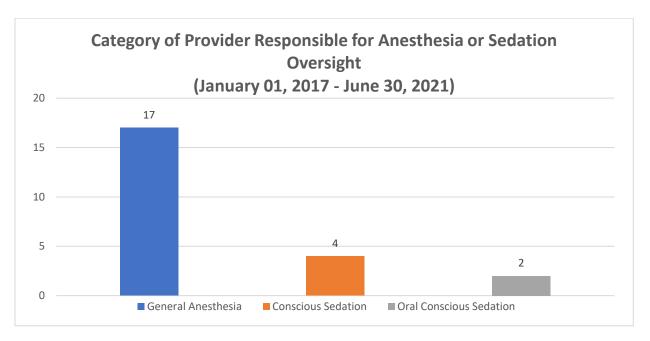
These charts represent deceased patients who, before their dental procedure, either had or did not have coexisting diagnosis. A total of 18 deceased patients were found to have a coexisting diagnosis; only five did not. Predictably, there were higher numbers of serious coexisting diagnoses, such as hypertension, diabetes, liver disease, and other serious conditions, beginning at age 46 and older.

Dental Setting Where Anesthesia and/or Sedation May Have Resulted in Patient's Death



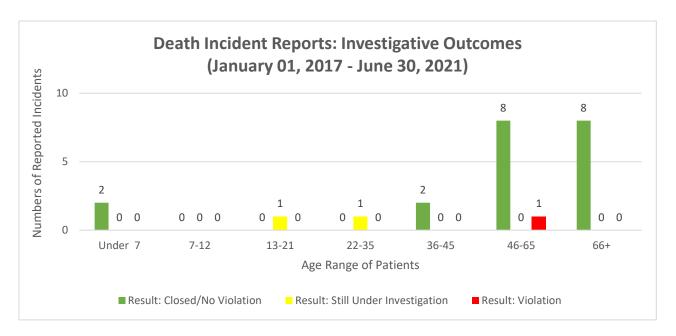
This chart represents the setting of the dental procedures that resulted in the death of patients possibly due to the administration of anesthesia and/or sedation. Out of the total 23 dental treatments that possibly resulted in death, 16 were conducted in a dental office, while seven were conducted in outpatient/ambulatory surgical centers and other locations that were not a dental office.

Category of Provider Responsible for Anesthesia or Sedation Oversight of Deceased Patient



- This chart represents the permit category (anesthesia or sedation) of the provider responsible for anesthesia or sedation oversight in cases where the patient had passed away possibly due to the administration of anesthesia and/or sedation under the dental provider's care or after they had left the premises.
 - Of the 23 cases of reported deaths, 17 of the care providers possessed a current general anesthesia permit at the time of the procedure.
 - Four of the care providers possessed a current conscious sedation permit
 - Two of the care providers possessed a current oral conscious sedation permit
- The provider responsible for anesthesia or sedation oversight was also the same provider who delivered the anesthesia and/or sedation and monitored the patient during the procedure. In the case of monitoring, aside from the provider, there were cases where registered dental assistants also participated in the monitoring.

Death Incident Reports: Investigative Outcomes



- This chart represents the Board's investigative outcomes from January 1, 2017, to June 30, 2021, for all reported deaths where anesthesia and/or sedation was administered.
- The Board has compiled and presents the following data:
 - For pediatric patients under 7 years of age, there were a total of two incident reports of death, and both of those cases resulted in no violations.
 - For older pediatric patients ages 7-12, there were no reported cases of death.
 - For adolescent patients ages 13-21, there was one incident report of death, which is pending further investigation.
 - For young adult patients ages 22-35, there was one incident report of death, which is pending further investigation.
 - For adult patients ages 36-45, there were a total of two incident reports of death, and both of those cases resulted in no violations.
 - For middle-aged patients ages 46-65, there were a total of nine incident reports of death. Of those nine, eight cases resulted in no violations, and only one case resulted in violation.
 - For senior patients ages 66 and up, there were a total of eight incident reports of death, none of which resulted in violations.

- Percentages of the case results are broken down as follows:
 - 86.96% of cases were "Closed No Violations"
 - 8.69% of cases are in "Pending" status
 - 4.35% of cases were "Violations"

RELEVANT PROFESSIONAL GUIDELINES, RECOMMENDATIONS, OR BEST PRACTICES FOR THE PROVISION OF DENTAL ANESTHESIA AND SEDATION CARE

To prepare its findings relevant to inform dental anesthesia and sedation standards, the Board reviewed the following professional organization guidelines, with pertinent highlights and excerpts.

American Dental Association (ADA) "Guidelines for Use of Sedation and General Anesthesia by Dentists" (2016)

- These guidelines defer to the American Academy of Pediatrics (AAP) and American Academy of Pediatric Dentistry (AAPD) guidelines relative to children.
- Sedation and anesthesia are categorized as minimal sedation, moderate sedation, deep sedation, and general anesthesia with attendant definitions and physiologic parameters.
- Concerns are raised about the continuum of anesthesia levels and that providers need to be able to identify and rescue patients who have gone to a level deeper than initially intended.
- For minimal sedation, all providers and their staff need to be certified in Basic Life Support (BLS). A focused physical examination, including vital signs, must be performed on patients before this level of sedation. Positive pressure oxygen must be available and pulse oximetry should be considered for some patients.
- For moderate sedation, providers must complete a training program consistent with the ADA guidelines for training programs or a Commission on Dental Accreditation (CODA) approved residency with appropriate training. Patients must be appropriately evaluated with the necessity of physician consultation when appropriate. Positive pressure oxygen must be available and end tidal carbon dioxide and auscultation of breath sounds must be available as well. Pulse oximetry, heart

- rate, respiratory rate, blood pressure, and level of consciousness must be continually monitored.
- For deep sedation and general anesthesia, certification and BLS and Advanced Cardiac Life Support (ACLS) is indicated, and only providers who have completed a CODA-approved training program that includes deep sedation and general anesthesia as part of the curriculum may administer those levels of anesthesia. Patients must be physically assessed prior to anesthesia, including Body-Mass Index (BMI). Three individuals must be present in the operatory at the time of anesthesia, including two in addition to the operator who are BLS certified, one of whom needs to be designated to monitor the patient only during the procedure if the operator is doing the anesthetic as well. End tidal carbon dioxide and a precordial stethoscope are not mandated but must be immediately available.

AAP "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (2019)

- These guidelines are a collaborative effort of the AAP and AAPD for the monitoring and management of pediatric patients undergoing sedation.
- Appropriate physiologic monitoring by personnel not involved in the procedure allow for accurate and rapid diagnosis of complications.
- Children younger than six years pose the greatest risk for adverse problems.
- It is common for children to pass from levels of sedation to deeper unintended levels.
- The patient chart shall contain a time-based record that includes the name, route, site, time, dosage, and patient effect of administered drugs.
- Level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, end tidal carbon dioxide, and oxygen saturation must be documented in the chart.

- For moderate sedation, the practitioner must have Pediatric Advanced Life Support (PALS) certification, and a support person must be designated to monitor the physiologic parameters of the patient under sedation or anesthesia. This individual must have PALS certification. Monitoring includes oxygen saturation and heart rate. When communication is possible, capnography or precordial stethoscope is recommended. When communication is not possible, capnography (is required and preferred) or a precordial stethoscope is required.
- For deep sedation and general anesthesia, two individuals must be present throughout the procedure. Each of them must have appropriate training and PALS certification. One of these two needs to be an independent member of the team to administer drugs and observe the patient. The guidelines suggest this individual must be a physician anesthesiologist, certified registered nurse anesthetist, oral and maxillofacial surgeon, or dentist anesthesiologist.

American Society of Anesthesiology – "Standards for Basic Anesthetic Monitoring" (2015)

- Standards apply to all anesthesia care, including general anesthesia and monitored anesthesia care (moderate sedation).
- Oxygenation (pulse oximetry), ventilation (patient observation, breath sounds, and end tidal carbon dioxide monitoring), circulation (EKG with every five-minute evaluation of blood pressure and heart rate), and temperature shall be continually evaluated during all anesthetics.
- Temperature should be monitored when clinically indicated.

ADA "Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students" (2016)

- Emphasizes that level of sedation and anesthesia is not dependent on the route of administration. Training must be consistent with protecting the patient.
- Supports the AAP/AAPD guidelines for pediatric sedation and anesthesia.

- Deep sedation and general anesthesia must be taught in CODA-accredited postgraduate programs.
- Offers definitions for minimal sedation, moderate sedation, deep sedation, and general anesthesia.
- Supports the ASA classification of patients for anesthesia.
- Reiterates ASA fasting guidelines.
- Provides a suggested curriculum content for teaching minimal and moderate sedation at the pre-doctoral level.

ADA "Guidelines for Teaching Pediatric Pain Control and Sedation to Dentists and Dental Students" (2021)

- The guidelines are very similar to the ADA guidelines for teaching pain control and sedation dentist and dental students with emphasis on the fact that pediatric patients are particularly difficult to deal with in the dental office.
- Provides direction for teaching minimal and moderate sedation to dentist and dental students for office care of pediatric patients.
- Reinforces support of the AAP/AAPD guidelines for pediatric anesthesia.
- Identifies pediatric patients as under 10 to 13 years of age with emphasis on increased risk with patients under six.
- Suggest a pre-doctoral curriculum should include education in pharmacological and nonpharmacological methods of managing pediatric patients.
- Stresses the need to understand maximal doses of local anesthesia for children.
- Recognizes that training for moderate sedation is not within the normal scope of a pre-doctoral educational program.
- Stresses the continuum of levels of anesthesia and potential need for rescue during the administration of any anesthetic.
- Reiterates the definitions for levels of anesthesia and routes of administration.
- Offers curriculum guidelines for teaching pain control for

- pediatric patients at the pre-doctoral level.
- Offers curriculum guidelines for an extended course of education in moderate sedation with a specific number of hours and clinical cases to determine competency including the number of patients who must be under six years of age.

Practice Guidelines for Moderate Procedural Sedation and Analgesia (2018)

- Prepared by a task force of six organizations, including the American Association of Oral and Maxillofacial Surgeons (AAOMS), ADA, and American Society of Dentist Anesthesiologists (ASDA).
- Specific for moderate sedation and does not provide suggestions as to the educational requirements to be able to administer moderate sedation.
- Each of the participating organizations sent representatives to serve as members of the task force.
- Emphasizes the need for potential rescue of patients from deeper levels of anesthesia.
- Used published research analysis to validate the guidelines.
- Stresses the importance of pre-procedural patient evaluation for adequate history and physical findings.
- Charting includes level of consciousness, ventilation by clinical signs capnography and pulse and oximetry, hemodynamic monitoring by blood pressure, heart rate and EKG, and availability of an individual responsible for patient monitoring.
- Supports use of capnography, pulse oximetry, and EKG for monitoring based on literature review.
- Literature is insufficient to determine whether or not an individual dedicated to patient monitoring will reduce adverse outcomes.
- Survey of panel members differed somewhat from literature findings. Task force opinion survey served as a basis for practice parameters.
- Recommends:

- Periodic monitoring of patient response to verbal commands.
- Using capnography for all patients under moderate sedation unless precluded.
- Pulse oximetry for all patients.
- Continuous monitoring of blood pressure and heart rate.
- EKG monitoring in patients with clinically significant cardiovascular disease.
- Record level of consciousness filtering oxygenation status and hemodynamic variables on record.
- Designating an individual with appropriate training other than the practitioner to monitor the patient throughout but not be part of the procedural team.
- Benzodiazepines and opioids are acceptable pharmacologic methods of providing moderate sedation.
- Propofol, ketamine, and etomidate are considered general anesthetic agents and not part of moderate sedation.

o ASA "Guidelines for Office-Based Anesthesia (2019)

- Written by and for medical anesthesiologists who plan to perform ambulatory anesthesia in outpatient offices.
- Places the responsibility on their members to investigate the areas where they are going to be practicing.
- Significant infrastructure or comments, such as having a medical director or written policies and procedures, included in the document.
- Suggest that all operating room personnel are qualified to do what they are doing.
- Discharge of patients is the responsibility of the physician.
- Personnel with advanced resuscitative technique training, such as ACLS and PALS, should be available until all patients are discharged.

- Generic statement that if children are being treated, all equipment, medication, and resuscitative capacities should be appropriately sized.
- Nothing specific relative to dental offices.

ASDA: Parameters of Care (2018)

- Written specifically for dentist anesthesiologists.
- Reinforces the concept of a continuum of anesthetic levels and supports the ASA definitions of levels of anesthesia.
- Anesthesiologist must maintain ACLS certification for all patients and PALS certification for patients under 13.
- For deep sedation or general anesthesia, three individuals must be present: operating dentist; dentist anesthesiologist; and a trained dental assistant.
- If the dentist anesthesiologist is the operator, then a second licensed anesthesia provider should be present for deep sedation and general anesthesia.
- For moderate sedation, the dentist anesthesiologist can be the operator but needs one appropriately trained support staff to help monitor the patient.
- Agrees with ASA preoperative fasting guidelines.
- Monitoring includes pulse oximetry, end tidal carbon dioxide, observation of chest excursions, EKG, and arterial blood pressure.
- If triggering agents for malignant hyperthermia are used, monitoring of body temperature should be done, and agents to correct the emergency must be present.
- A licensed general anesthesia provider is responsible for determining and documenting the criteria for discharge have been met.

COMPARATIVE REVIEW

Since the Board submitted its Pediatric Anesthesia Study in December 2016, there have been several statutory changes due to the enactment of SB 501. This report provides

comment on contemporary California law in comparison to the above-referenced guidelines from other organizations where they are relevant.

The review of the guidelines did not produce significant differences in most of the publications as they were unchanged from prior to 2016. Several of the guidelines did put additional emphasis concerning pediatric anesthesia and are contrasted below with the minimal, moderate, and deep sedation and general anesthesia statutes enacted in SB 501 that become effective on January 1, 2022.

Monitoring Equipment

Most of the above guidelines reference the use of specific patient monitoring equipment or recommend specific monitoring information to be charted for the patient. Once the new statutes in SB 501 go into effect on January 1, 2022, California law will be more prescriptive in the monitoring equipment required to be used for both adults and children undergoing deep sedation or general anesthesia. SB 501 expanded an existing ground for discipline for unprofessional conduct and will require any dentist with patients undergoing deep sedation, general anesthesia, or moderate sedation to have the patients continuously monitored during the dental procedure with a pulse oximeter or similar or superior monitoring equipment and ventilation continuously monitored using at least two of the three following methods: (1) auscultation of breath sounds using a precordial stethoscope; (2) monitoring for the presence of exhaled carbon dioxide with capnography; and (3) verbal communication with a patient under moderate sedation (not applicable for a patient under deep sedation or general anesthesia). In addition, for patients under 13 years of age undergoing deep sedation or general anesthesia, SB 501 will require the additional dental personnel monitoring the patient to be trained to read and respond to monitoring equipment including, but not limited to, pulse oximeter. cardiac monitor, blood pressure, pulse, capnograph, and respiration monitoring devices.

<u>Personnel</u>

Although the above guidelines vary with respect to the number of individuals (two or three) required to attend each patient under deep sedation, general anesthesia, or moderate sedation, California law will require three members for the operating/anesthesia team for children under the age of 13 undergoing moderate sedation, deep sedation, or general anesthesia. The operating dentist and one assistant must be PALS certified, with the PALS-certified assistant solely dedicated to monitoring the patient and trained to read and respond to monitoring equipment. For operating dentists who administer moderate sedation to children under 13, a pediatric endorsement will be required. For administration of deep sedation and general anesthesia to children under seven, the dentist must possess a pediatric endorsement.

Education

The above guidelines generally recommend ACLS certification of operators treating all patients and PALS certification of operators treating patients under 13 years of age. The SB 501 education requirements for operating dentists are consistent with prior legislation in that a dentist who wishes to administer deep sedation or general anesthesia must have graduated either from a CODA-approved program in dental anesthesia or oral and maxillofacial surgery. Those who wish to administer moderate sedation to children under the age of 13 must complete a program that teaches moderate sedation with statutory requirements as to the number of hours and cases and obtain a pediatric endorsement, which further requires ACLS and PALS certification. Dental assistants who are involved in deep sedation, general anesthesia, or moderate sedation cases must undergo additional education, including PALS or other board-approved training in pediatric life support and airway management.

California law is more prescriptive than the above-referenced guidelines from the various organizations that are concerned about anesthesia and sedation administered in dental offices. California law provides a robust and articulated series of requirements to provide the best environment with potentially higher safety standards for in-office anesthesia and sedation in general and specifically for pediatric patients.

CONCLUSION

This report concludes that with the implementation of new minimal, moderate, and deep sedation and general anesthesia provisions enacted by SB 501 that become effective on January 1, 2022, California will have some of the highest patient monitoring standards for the administration of minimal, moderate, and deep sedation and general anesthesia to dental patients of all age groups and especially for children. California statutes meet and generally exceed the guidelines of all the organizations that are involved in the administration of anesthesia to children in dental offices.