

**List of Written Comments Received from Stakeholders and Interested Parties in  
Response to the Dental Board of California Pediatric Anesthesia Study**

(June 1 – November 30, 2016)

**AMERICAN ACADEMY OF PEDIATRIC DENTISTRY (AAPD)**

1. August 19, 2016 Letter from Jade Miller, DDS, President of AAPD and David Okawachi, DDS, President of California Society of Pediatric Dentistry

**AMERICAN ACADEMY OF PEDIATRICS (AAP)**

1. June 17, 2016 Letter from Karen Remley, MD, MBA, MPH, FAAP, CEO/Executive Director with Attachment
  - Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016
2. July 22, 2016 Letter from Roger F. Suchyta, MD, FAAP, Associate Executive Director
3. July 27, 2016 Letter Regarding AAP-CA Comment on Dental Board of California Pediatric Anesthesia Study
4. October 12, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016.
5. October 28, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016
6. November 30, 2016 Letter Regarding Response to DBC Subcommittee Final Recommendations

**AMERICAN ASSOCIATION OF ORAL AND MAXILLOFACIAL SURGEONS (AAOMS)**

1. Testimony Before the Board on October 13, 2016.

**AMERICAN SOCIETY OF DENTIST ANESTHESIOLOGISTS (ASDA)**

1. July 25, 2016 Letter from Steve Nguyen, DDS, ASDA President with Attachment
  - Periodontal Abstract, Volume 53, Number 2 – 2005 – Summary of the California Blue Ribbon Panel Report on Anesthesia

**CALIFORNIA ACADEMY OF GENERAL DENTISTS (CAGD)**

1. October 12, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

## CALIFORNIA ASSOCIATION OF NURSE ANESTHETISTS

1. November 14, 2016 Letter and Attachments

## CALIFORNIA DENTAL ASSOCIATION (CDA)

1. June 30, 2016 Letter from Brianna Pittman, Legislative Director
2. October 14, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016
3. October 28, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

## CALIFORNIA SOCIETY OF ANESTHESIOLOGISTS (CSA)

1. June 30, 2016 Cover Letter and Attachments Submitted by Mark Zakowski, MD, President
  - 42 C.F.R. § 482.52 Condition of Participation: Anesthesia Services: *Please note the five classes of healthcare practitioners who may provide anesthesia services. The five classes are: physician anesthesiologists; other doctors of medicine or osteopathy; certain dentists, oral surgeons and podiatrists; nurse anesthetists; and anesthesiologist assistants.*
  - ASA Policy on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (October 15, 2014)
  - ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (October 17, 2012)
  - ASA Statement on the Anesthesia Care Team (October 16, 2013)
  - ASA Standards for Basic Anesthetic Monitoring (October 28, 2015)
  - 42 C.F.R. § 482.13 Condition of Participation: Patient's Rights
  - *"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists"* Anesthesiology 2002; 96:1004–17
  - *"Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures"* developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (adopted 2006; reaffirmed 2011)
  - CSA Patient Safety Bill of Rights: Patient Safety Across the Continuum for Deep Sedation/General Anesthesia (adopted June 5, 2016)
  - AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016 (***Did not reprint – Refer to AAP for Document***)
2. July 28, 2016 Comments Delivered at Dental Board Workshop and submitted via fax by Dr. Mark Singleton
3. August 17, 2016 Letter from Mark Zakowski, MD, President
4. October 26, 2016 Letter from Mark Zakowski, MD, President

**CALIFORNIA SOCIETY OF DENTIST ANESTHESIOLOGISTS (CSDA)**

1. October 28, 2016 Letter from Richard Stafford, DDS, President

**CALIFORNIA SOCIETY OF PEDIATRIC DENTISTRY (CSPD)** – See American Academy of Pediatric Dentists Comment Above

1. October 13, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

**CALIFORNIA SOCIETY OF PERIODONTISTS**

1. October 23, 2016 Letter from Nicholas Caplanis, DMD, MS, President Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

**HERMAN OSTROW SCHOOL OF DENTISTRY OF USC**

1. October 28, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

**LOMA LINDA UNIVERSITY – PEDIATRIC DENTISTRY DEPARTMENT – SCHOOL OF DENTISTRY**

1. November 10, 2016 Letter from Samah Omar, BDS, DDS, MSD on behalf of the LLU Pediatric Dentistry Department with attachments

**ORAL AND FACIAL SURGEONS OF CALIFORNIA**

1. August 11, 2016 Letter from Leonard M. Tyko II, DDS, MD, FACS, President with Attachment
  - Report, References, and Appendix A
2. October 13, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

**INDIVIDUALS**

1. Diana Belli, DDS (Dental Anesthesiologist) – Emails dated July 21, 2016 and July 22, 2016
2. David Crippen, DDS (Pediatric Dentist) – Email dated July 26, 2016
3. Skip Harris, DDS (Oral and Maxillofacial Surgeon in Arizona) – Email dated July 22, 2016
4. Annie Kaplan, MD – Emails dated June 15, 2016 and July 18, 2016 – Attachments
  - August 11, 2010, 12 page letter signed by Janet Woodcock, MD Center for Drug Evaluation and Research.
  - Caleb's Law – White Paper, March 29, 2016 (Author Unknown)

**EMAILS RECEIVED IN RESPONSE TO NBC BAY AREA MEDIA REPORT ON  
OCTOBER 24, 2016 RELATING TO THE PEDIATRIC ANESTHESIA ISSUE**

Alahwal, Jennifer  
Anonymous  
Belcher, Naomi  
Bentley, John and Ann  
Berlet, John  
Blucher, Debbie  
Brereton Mondanlou, Karen  
Brown, B.  
Butwick, Dr. Alex  
Chan, Nancy  
Chiba, Michelle  
Civitello, Linda  
Collins, Lorraine  
Cruciani, Michelle  
DeRooy, Jessica  
DeSimone, Joseph  
Dolan, Patricia  
Elder, Desmond  
Elder, Pamela  
Fernandez, Lissette  
Fernandes, Ross  
Fontes, David  
Friedman, Dr. Laura  
GG  
Gagne, Dr. Richard  
Geraghy, Grace  
Giraud, Judy  
Hancock, Valerie  
Haynes, Charlotte  
Herrera, Daisy  
Jensky, Britt  
Jolivette, Robin  
Kaloyanova, Elena  
Kantor, Cathy  
Kaplan, Dr. Anna  
Kaplan, Laurence  
Kaplan, Noa  
Leibowitz, Dr. Howard  
Lilly, Laura  
Lund, Stephanie  
Mashni, Dr. Michael  
McCarthy, Linda  
McCormick, Gail  
McLean, Barbara  
McLean, Jennifer  
McLean, Alex & Jennifer  
Miller, Megan  
Molloy, John

Moretti, Carolina  
Munro, Katy  
Munro, Kristine  
Myers, Sara  
Nino-Murcia, Anamaria  
Nino-Murcia, Dr. Matilde  
Packer, Dr. Leslie  
Palacios, Diane  
Paluska, Karen  
Phelan, Shirley  
Pine, Bruce  
Pine, Wendy  
Ptaszynski, Andre  
Rodriguez, Jesus  
Rudolf, Sally  
Sanghi, Vivek & Rashi  
Schneider, Karen  
Scholnick, Nadia  
Selchau-Hansen, Lou  
Sunzeri, Debbie  
Sykes, Joy  
Tan, Corrine  
Tang, Lien  
Thomas, Ajit  
Tong, J  
Turner, Susan  
Walke, B. Blaine  
Welcome, Jessika  
Wong, Sheri Glucoft

# **AMERICAN ACADEMY OF PEDIATRIC DENTISTRY (AAPD)**

1. August 19, 2016 Letter from Jade Miller, DDS, President of AAPD and David Okawachi, DDS, President of California Society of Pediatric Dentistry



## AMERICA'S PEDIATRIC DENTISTS

THE BIG ADVOCACY ON Little Kids



August 19, 2016

Dental Board of California  
2005 Evergreen St, Suite 1550  
Sacramento, CA 95815

Attn: Pediatric Anesthesia Subcommittee  
Re: Progress of the Pediatric Anesthesia Study Requested by Senator Jerry Hill

The American Academy of Pediatric Dentistry (AAPD)<sup>1</sup> and the California Society of Pediatric Dentistry (CSPD)<sup>2</sup> commend the Dental Board of California and the Pediatric Anesthesia Subcommittee on the depth, breadth and attention to important detail contained in the *Anesthesia Working Document* of July 2016. It is evident the Board is addressing seriously its mandate of public protection and is researching responsibly what measures in law or regulation could make pediatric dental anesthesia even safer in the future than it is today.

We would respectfully submit a correction to the reference on page 26 of the *Working Document* regarding the process by which the joint American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* ([http://www.aapd.org/media/Policies\\_Guidelines/G\\_Sedation.pdf](http://www.aapd.org/media/Policies_Guidelines/G_Sedation.pdf)) is developed and approved by the governing bodies of both organizations. The document states:

*It is unclear whether input is solicited from non-member dentists, outside organizations or the public. Detailed information is available to AAPD members only. AAPD guidelines are subsequently forwarded to the American Academy of Pediatrics for endorsement and are then published as a joint document.*

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<sup>1</sup>The **American Academy of Pediatric Dentistry** is the recognized authority on children's oral health. As advocates for children's oral health, the AAPD promotes evidence-based policies and clinical guidelines; educates and informs policymakers, parents and guardians, and other health care professionals; fosters research; and provides continuing professional education for pediatric dentists and general dentists who treat children. Founded in 1947, the AAPD is a not-for-profit professional membership association representing the specialty of pediatric dentistry. Its 10,000 members provide primary care and comprehensive dental specialty treatments for infants, children, adolescents and individuals with special health care needs

<sup>2</sup>The **California Society of Pediatric Dentistry** is the state's leading advocate and recognized authority on oral health issues affecting infants, children, adolescents and patients with special health care and developmental needs. The Society interacts with the state legislature, regulatory bodies, licensing bureaus, institutions of dental education, media outlets, and policy makers at all levels of public and private participation to promote and ensure optimal pediatric oral health throughout the state. CSPD is the professional membership organization of California's over 900 pediatric dental practitioners, educators and researchers.

This is incorrect. The guidelines are developed jointly by the both organizations and not merely forwarded to the AAP by the AAPD for endorsement. 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.

The AAPD and CSPD look forward to the completion of the comprehensive and impartial analysis by the DBC of pediatric dental sedation and the laws, regulations and policies which govern its administration. We support and applaud the open and transparent process by which the subcommittee is moving forward to identify any necessary statutory or other changes to the administration of office-based sedation which improve the margin of safety for pediatric patients. We believe this information is essential in determining the course of action necessary to ensure the highest level of care for the patients we treat.



Jade Miller, DDS  
President  
American Academy of Pediatric Dentistry



David Okawachi, DDS  
President  
California Society of Pediatric Dentistry

# AMERICAN ACADEMY OF PEDIATRICS (AAP)

1. June 17, 2016 Letter from Karen Remley, MD, MBA, MPH, FAAP, CEO/Executive Director with Attachment
  - Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016
2. July 22, 2016 Letter from Roger F. Suchyta, MD, FAAP, Associate Executive Director
3. July 27, 2016 Letter Regarding AAP-CA Comment on Dental Board of California Pediatric Anesthesia Study
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June 17, 2016

The Dental Board of California  
c/o Ms. Karen Fischer  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 91815

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Dear Members of the The Dental Board of California,

Thank you for your letter dated June 1, 2016, regarding the anesthesia project you have underway. As you review the present laws, regulations, and policies in California to determine whether they provide sufficient protection to pediatric patients during dental anesthesia, we would encourage you to review the American Academy of Pediatrics (AAP)/American Academy of Pediatric Dentistry (AAPD) "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016" (Guidelines).

The AAP/AAPD Joint Guidelines are set to be released online on June 27, 2016, and to subsequently be published in the e-pages of *Pediatrics* on July 1, 2016. Enclosed with this letter is a pre-publication, embargoed copy of the Guidelines for your review and consideration. We ask that you please abide by the embargo and not publish, post, broadcast or distribute any details of the embargoed document before the embargo date and time (12:01 A.M. ET Monday June 27, 2016). Please review the Embargo Policy at [www.aap.org/embargo](http://www.aap.org/embargo).

If you should have any further questions, please contact Roger Suchyta, MD, FAAP, Associate Executive Director, at 800-433-9016, ext. 7111, or via email at [rsuchyta@aap.org](mailto:rsuchyta@aap.org).

Thank You.

A handwritten signature in cursive script that reads "Karen Remley MD".

Karen Remley, MD, MBA, MPH, FAAP  
CEO/Executive Director

KR/jgr

CC: John Rutkauskas, DDS, MBA, CAE, CEO, American Academy of  
Pediatric Dentistry;  
Stuart Alan Cohen, MD, MPH, FAAP, Chair, AAP California District IX;  
Kris Calvin, MA, Chief Executive Officer, AAP California District IX

# PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

## **Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016**

Charles J. Coté, Stephen Wilson, AMERICAN ACADEMY OF PEDIATRICS and  
AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

*Pediatrics*; originally published online June 27, 2016;  
DOI: 10.1542/peds.2016-1212

The online version of this article, along with updated information and services, is  
located on the World Wide Web at:  
[/content/early/2016/06/24/peds.2016-1212.full.html](http://content.early/2016/06/24/peds.2016-1212.full.html)

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# Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016

Charles J. Coté, MD, FAAP, Stephen Wilson, DMD, MA, PhD, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

The safe sedation of children for procedures requires a systematic approach that includes the following: no administration of sedating medication without the safety net of medical/dental supervision, careful presedation evaluation for underlying medical or surgical conditions that would place the child at increased risk from sedating medications, appropriate fasting for elective procedures and a balance between the depth of sedation and risk for those who are unable to fast because of the urgent nature of the procedure, a focused airway examination for large (kissing) tonsils or anatomic airway abnormalities that might increase the potential for airway obstruction, a clear understanding of the medication's pharmacokinetic and pharmacodynamic effects and drug interactions, appropriate training and skills in airway management to allow rescue of the patient, age- and size-appropriate equipment for airway management and venous access, appropriate medications and reversal agents, sufficient numbers of staff to both carry out the procedure and monitor the patient, appropriate physiologic monitoring during and after the procedure, a properly equipped and staffed recovery area, recovery to the presedation level of consciousness before discharge from medical/dental supervision, and appropriate discharge instructions. This report was developed through a collaborative effort of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry to offer pediatric providers updated information and guidance in delivering safe sedation to children.

## abstract



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*The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical/dental care. Variations, taking into account individual circumstances, may be appropriate.*

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## INTRODUCTION

The number of diagnostic and minor surgical procedures performed on pediatric patients outside of the traditional operating room setting has increased in the past several decades. As a consequence of this change and the increased awareness of the importance of providing analgesia and anxiolysis, the need for sedation for procedures in physicians' offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, other inpatient hospital settings, and ambulatory surgery centers also has increased markedly.<sup>1-52</sup> In recognition of this need for both elective and emergency use of sedation in nontraditional settings, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) have published a series of guidelines for the monitoring and management of pediatric patients during and after sedation for a procedure.<sup>53-58</sup> The purpose of this updated report is to unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities, particularly regarding continuous expired carbon dioxide measurement; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes. This document uses the same language to define sedation categories and expected physiologic responses as The Joint Commission, the American Society of Anesthesiologists (ASA), and the AAPD.<sup>56,57,59-61</sup>

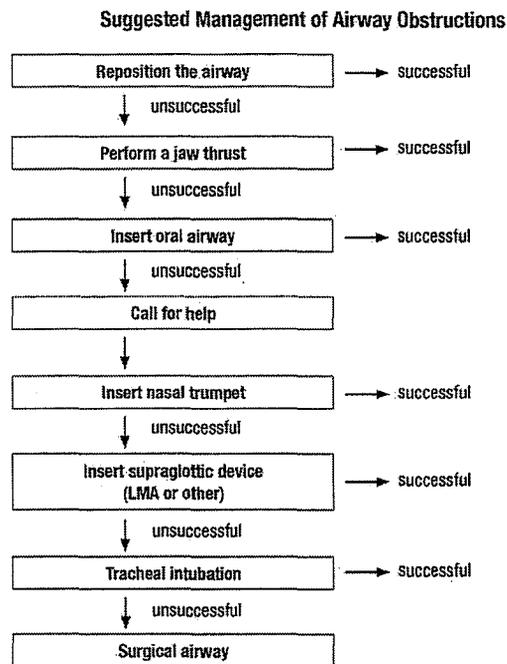
This revised statement reflects the current understanding of appropriate monitoring needs of pediatric patients both during and after sedation for a procedure.<sup>3,4,11,18,20,21,23,24,33,39,41,44,47,51,62-73</sup> The monitoring and care outlined may be exceeded at any time on the basis of the judgment of the

responsible practitioner. Although intended to encourage high-quality patient care, adherence to the recommendations in this document cannot guarantee a specific patient outcome. However, structured sedation protocols designed to incorporate these safety principles have been widely implemented and shown to reduce morbidity.<sup>11,23,24,27,30-33,35,39,41,44,47,51,74-84</sup> These practice recommendations are proffered with the awareness that, regardless of the intended level of sedation or route of drug administration, the sedation of a pediatric patient represents a continuum and may result in respiratory depression, laryngospasm, impaired airway patency, apnea, loss of the patient's protective airway reflexes, and cardiovascular instability.<sup>38,43,45,47,48,59,62,63,85-112</sup>

Procedural sedation of pediatric patients has serious associated risks.<sup>2,5,38,43,45,47,48,62,63,71,83,85,88-105,107-138</sup> These adverse responses during and after sedation for a diagnostic or therapeutic procedure may be minimized, but not completely eliminated, by a careful preprocedure review of the patient's underlying medical conditions and consideration of how the sedation process might affect or be affected by these conditions: for example, children with developmental disabilities have been shown to have a threefold increased incidence of desaturation compared with children without developmental disabilities.<sup>74,78,103</sup> Appropriate drug selection for the intended procedure, a clear understanding of the sedating medication's pharmacokinetics and pharmacodynamics and drug interactions, as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are critical.<sup>42,48,62,63,92,97,99,125-127,132,133,139-158</sup> Appropriate physiologic monitoring and continuous observation by personnel not directly involved with

the procedure allow for the accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.<sup>44,63,64,67,68,74,90,96,110,159-174</sup> The work of the Pediatric Sedation Research Consortium has improved the sedation knowledge base, demonstrating the marked safety of sedation by highly motivated and skilled practitioners from a variety of specialties practicing the above modalities and skills that focus on a culture of sedation safety.<sup>45,83,95,128-138</sup> However, these groundbreaking studies also show a low but persistent rate of potential sedation-induced life-threatening events, such as apnea, airway obstruction, laryngospasm, pulmonary aspiration, desaturation, and others, even when the sedation is provided under the direction of a motivated team of specialists.<sup>129</sup> These studies have helped define the skills needed to rescue children experiencing adverse sedation events.

The sedation of children is different from the sedation of adults. Sedation in children is often administered to relieve pain and anxiety as well as to modify behavior (eg, immobility) so as to allow the safe completion of a procedure. A child's ability to control his or her own behavior to cooperate for a procedure depends both on his or her chronologic age and cognitive/emotional development. Many brief procedures, such as suture of a minor laceration, may be accomplished with distraction and guided imagery techniques, along with the use of topical/local anesthetics and minimal sedation, if needed.<sup>175-181</sup> However, longer procedures that require immobility involving children younger than 6 years or those with developmental delay often require an increased depth of sedation to gain control of their behavior.<sup>86,87,103</sup> Children younger than 6 years (particularly those younger than 6 months) may be at greatest risk of an adverse event.<sup>129</sup> Children in this age group are particularly vulnerable



**FIGURE 1**  
Suggested management of airway obstruction.

to the sedating medication's effects on respiratory drive, airway patency, and protective airway reflexes.<sup>62,63</sup> Other modalities, such as careful preparation, parental presence, hypnosis, distraction, topical local anesthetics, electronic devices with age-appropriate games or videos, guided imagery, and the techniques advised by child life specialists, may reduce the need for or the needed depth of pharmacologic sedation.<sup>29,46,49,182-211</sup>

Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation,<sup>85,88,212,213</sup> making the concept of rescue essential to safe sedation. Practitioners of sedation must have the skills to rescue the patient from a deeper level than that intended for the procedure. For example, if the intended level of sedation is "minimal," practitioners must be able to rescue from "moderate sedation"; if the intended level of sedation is "moderate," practitioners must have the skills to rescue from "deep sedation"; if the

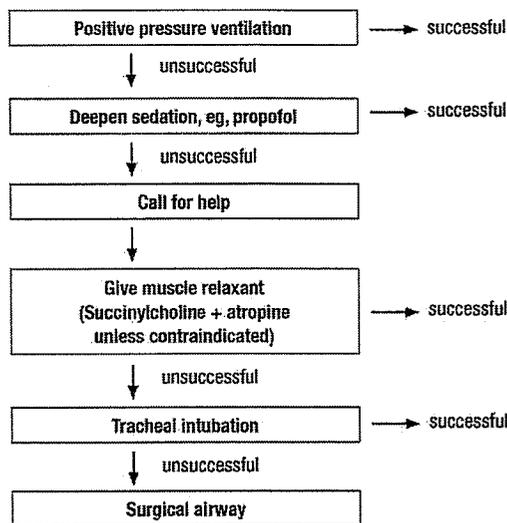
intended level of sedation is "deep," practitioners must have the skills to rescue from a state of "general anesthesia." The ability to rescue means that practitioners must be able to recognize the various levels of sedation and have the skills and age- and size-appropriate equipment necessary to provide appropriate cardiopulmonary support if needed.

These guidelines are intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office). Sedation and anesthesia in a nonhospital environment (eg, private physician's or dental office, freestanding imaging facility) historically have been associated with an increased incidence of "failure to rescue" from adverse events, because these settings may lack immediately available backup. Immediate activation of emergency medical services (EMS) may be required in such settings, but the practitioner is responsible for life-support measures while awaiting

EMS arrival.<sup>63,214</sup> Rescue techniques require specific training and skills.<sup>63,74,215,216</sup> 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. These skills are likely best maintained with frequent simulation and team training for the management of rare events.<sup>128,130,217-220</sup> Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue (see Figs 1, 2, and 3).<sup>215,216,221-223</sup>

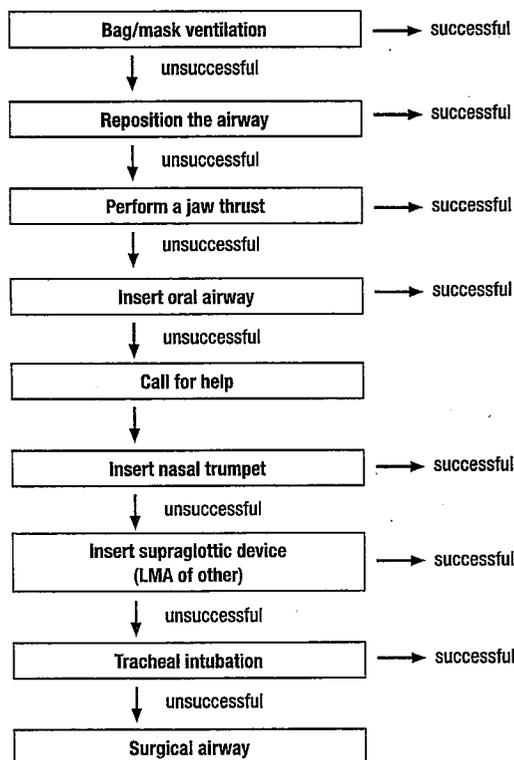
Practitioners should have an in-depth knowledge of the agents they intend to use and their potential complications. A number of reviews and handbooks for sedating pediatric patients are available.<sup>30,39,65,75,171,172,201,224-233</sup> There are specific situations that are beyond the scope of this document. Specifically, guidelines for the delivery of general anesthesia and monitored anesthesia care (sedation or analgesia), outside or within the operating room by anesthesiologists or other practitioners functioning within a department of anesthesiology, are addressed by policies developed by the ASA and by individual departments of anesthesiology.<sup>234</sup> In addition, guidelines for the sedation of patients undergoing mechanical ventilation in a critical care environment or for providing analgesia for patients postoperatively, patients with chronic painful conditions, and patients in hospice care are beyond the scope of this document.

### Suggested Management of Laryngospasm



**FIGURE 2**  
Suggested management of laryngospasm.

### Suggested Management of Apnea



**FIGURE 3**  
Suggested management of apnea.

### GOALS OF SEDATION

The goals of sedation in the pediatric patient for diagnostic and therapeutic

procedures are as follows: (1) to guard the patient's safety and welfare; (2) to minimize physical discomfort and pain; (3) to control

anxiety, minimize psychological trauma, and maximize the potential for amnesia; (4) to modify behavior and/or movement so as to allow the safe completion of the procedure; and (5) to return the patient to a state in which discharge from medical/dental supervision is safe, as determined by recognized criteria (Supplemental Appendix 1).

These goals can best be achieved by selecting the lowest dose of drug with the highest therapeutic index for the procedure. It is beyond the scope of this document to specify which drugs are appropriate for which procedures; however, the selection of the fewest number of drugs and matching drug selection to the type and goals of the procedure are essential for safe practice. For example, analgesic medications, such as opioids or ketamine, are indicated for painful procedures. For nonpainful procedures, such as computed tomography or magnetic resonance imaging (MRI), sedatives/hypnotics are preferred. When both sedation and analgesia are desirable (eg, fracture reduction), either single agents with analgesic/sedative properties or combination regimens are commonly used. Anxiolysis and amnesia are additional goals that should be considered in the selection of agents for particular patients. However, the potential for an adverse outcome may be increased when 2 or more sedating medications are administered.<sup>62,127,136,173,235</sup> Recently, there has been renewed interest in noninvasive routes of medication administration, including intranasal and inhaled routes (eg, nitrous oxide; see below).<sup>236</sup>

Knowledge of each drug's time of onset, peak response, and duration of action is important (eg, the peak electroencephalogram [EEG] effect of intravenous midazolam occurs at ~4.8 minutes, compared with that of diazepam at ~1.6 minutes<sup>237-239</sup>). Titration of drug to effect is an important concept;

one must know whether the previous dose has taken full effect before administering additional drugs.<sup>237</sup> Drugs that have a long duration of action (eg, intramuscular pentobarbital, phenothiazines) have fallen out of favor because of unpredictable responses and prolonged recovery. The use of these drugs requires a longer period of observation even after the child achieves currently used recovery and discharge criteria.<sup>62,238-241</sup> This concept is particularly important for infants and toddlers transported in car safety seats; re-sedation after discharge attributable to residual prolonged drug effects may lead to airway obstruction.<sup>62,63,242</sup> In particular, promethazine (Phenergan; Wyeth Pharmaceuticals, Philadelphia, PA) has a "black box warning" regarding fatal respiratory depression in children younger than 2 years.<sup>243</sup> Although the liquid formulation of chloral hydrate is no longer commercially available, some hospital pharmacies now are compounding their own formulations. Low-dose chloral hydrate (10–25 mg/kg), in combination with other sedating medications, is used commonly in pediatric dental practice.

## GENERAL GUIDELINES

### Candidates

Patients who are in ASA classes I and II are frequently considered appropriate candidates for minimal, moderate, or deep sedation (Supplemental Appendix 2). Children in ASA classes III and IV, children with special needs, and those with anatomic airway abnormalities or moderate to severe tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation.<sup>68,244-249</sup> Practitioners are encouraged to consult with

appropriate subspecialists and/or an anesthesiologist for patients at increased risk of experiencing adverse sedation events because of their underlying medical/surgical conditions.

### Responsible Person

The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person. It is preferable to have 2 adults accompany children who are still in car safety seats if transportation to and from a treatment facility is provided by 1 of the adults.<sup>250</sup>

### 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, laryngospasm, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from the inadequate recognition and treatment of respiratory compromise.<sup>42,48,92,97,99,125,132,139-155</sup> Other rare complications also may include seizures, vomiting, and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.

### Back-up Emergency Services

A protocol for immediate access to back-up emergency services shall be clearly outlined. For nonhospital facilities, a protocol for the immediate activation of the EMS system for life-threatening complications must be established and maintained.<sup>44</sup> It should be understood that the availability of EMS does not replace the practitioner's responsibility to

provide initial rescue for life-threatening complications.

### On-site Monitoring, Rescue Drugs, and Equipment

An emergency cart or kit must be immediately accessible. This cart or kit must contain the necessary age- and size-appropriate equipment (oral and nasal airways, bag-valve-mask device, LMAs or other supraglottic devices, laryngoscope blades, tracheal tubes, face masks, blood pressure cuffs, intravenous catheters, etc) to resuscitate a nonbreathing 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/dental facility or to another area within the facility. All equipment and drugs must be checked and maintained on a scheduled basis (see Supplemental Appendices 3 and 4 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 probes, end-tidal carbon dioxide monitors, and defibrillators with size-appropriate patches/paddles, must have a safety and function check on a regular basis as required by local or state regulation. The use of emergency checklists is recommended, and these should be immediately available at all sedation locations; they can be obtained from <http://www.pedsanesthesia.org/>.

### Documentation

Documentation prior to sedation shall include, but not be limited to, the following recommendations:

1. Informed consent: The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.<sup>251,252</sup>
2. Instructions and information provided to the responsible

person: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation.<sup>163,253-255</sup> Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Transportation in a car safety seat poses a particular risk for infants who have received medications known to have a long half-life, such as chloral hydrate, intramuscular pentobarbital, or phenothiazine because deaths after procedural sedation have been reported.<sup>62,63,238,242,256,257</sup> Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (eg, only 1 adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem, an underlying medical condition such as significant obstructive sleep apnea (OSA), or a former preterm infant younger than 60 weeks' postconceptional age. A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.

### **Dietary Precautions**

Agents used for sedation have the potential to impair protective airway reflexes, particularly during deep sedation. Although a rare occurrence, pulmonary aspiration may occur if the child regurgitates and cannot protect his or her airway.<sup>95,127,258</sup> Therefore, the practitioner should

evaluate preceding food and fluid intake before administering sedation. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulations.<sup>259,260</sup> However, the absolute risk of aspiration during elective procedural sedation is not yet known; the reported incidence varies from ~1 in 825 to ~1 in 30 037.<sup>95,127,129,173,244,261</sup> Therefore, standard practice for fasting before elective sedation generally follows the same guidelines as for elective general anesthesia; this requirement is particularly important for solids, because aspiration of clear gastric contents causes less pulmonary injury than aspiration of particulate gastric contents.<sup>262,263</sup>

For emergency procedures in children undergoing general anesthesia, the reported incidence of pulmonary aspiration of gastric contents from 1 institution is ~1 in 373 compared with ~1 in 4544 for elective anesthetics.<sup>262</sup> Because there are few published studies with adequate statistical power to provide guidance to the practitioner regarding the safety or risk of pulmonary aspiration of gastric contents during procedural sedation,<sup>95,127,129,173,244,259-261,264-268,</sup> it is unknown whether the risk of aspiration is reduced when airway manipulation is not performed/anticipated (eg, moderate sedation). However, if a deeply sedated child requires intervention for airway obstruction, apnea, or laryngospasm, there is concern that these rescue maneuvers could increase the risk of pulmonary aspiration of gastric contents. For children requiring urgent/emergent sedation who do not meet elective fasting guidelines, the risks of sedation and possible aspiration are as-yet unknown and must be balanced against the benefits of performing the procedure promptly. For example, a prudent practitioner would be unlikely

to administer deep sedation to a child with a minor condition who just ate a large meal; conversely, it is not justifiable to withhold sedation/analgesia from the child in significant pain from a displaced fracture who had a small snack a few hours earlier. Several emergency department studies have reported a low to zero incidence of pulmonary aspiration despite variable fasting periods<sup>260,264,268</sup>; however, each of these reports has, for the most part, clearly balanced the urgency of the procedure with the need for and depth of sedation.<sup>268,269</sup> Although emergency medicine studies and practice guidelines generally support a less restrictive approach to fasting for brief urgent/emergent procedures, such as care of wounds, joint dislocation, chest tube placement, etc, in healthy children, further research in many thousands of patients would be desirable to better define the relationships between various fasting intervals and sedation complications.<sup>262-270</sup>

### *Before Elective Sedation*

Children undergoing sedation for elective procedures generally should follow the same fasting guidelines as those for general anesthesia (Table 1).<sup>271</sup> It is permissible for routine necessary medications (eg, antiseizure medications) to be taken with a sip of clear liquid or water on the day of the procedure.

### *For the Emergency Patient*

The practitioner must always balance the possible risks of sedating nonfasted patients with the benefits of and necessity for completing the procedure. In particular, patients with a history of recent oral intake or with other known risk factors, such as trauma, decreased level of consciousness, extreme obesity (BMI  $\geq 95\%$  for age and sex), pregnancy, or bowel motility dysfunction, require careful evaluation before the administration of sedatives. When proper fasting has not been ensured,

the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. In this circumstance, additional techniques for achieving analgesia and patient cooperation, such as distraction, guided imagery, video games, topical and local anesthetics, hematoma block or nerve blocks, and other techniques advised by child life specialists, are particularly helpful and should be considered.<sup>29,49,182-201, 274,275</sup>

The use of agents with less risk of depressing protective airway reflexes, such as ketamine, or moderate sedation, which would also maintain protective reflexes, may be preferred.<sup>276</sup> Some emergency patients requiring deep sedation (eg, a trauma patient who just ate a full meal or a child with a bowel obstruction) may need to be intubated to protect their airway before they can be sedated.

#### Use of Immobilization Devices (Protective Stabilization)

Immobilization devices, such as papoose boards, must be applied in such a way as to avoid airway obstruction or chest restriction.<sup>277-281</sup> The child's head position and respiratory excursions should be checked frequently to ensure airway patency. If an immobilization device is used, a hand or foot should be kept exposed, and the child should never be left unattended. If sedating medications are administered in conjunction with an immobilization device, monitoring must be used at a level consistent with the level of sedation achieved.

#### Documentation at the Time of Sedation

1. Health evaluation: Before sedation, a health evaluation shall be performed by an appropriately licensed practitioner and reviewed by the sedation team at the time of treatment for possible interval changes.<sup>282</sup> The purpose of this evaluation is not only to document baseline status

**TABLE 1** Appropriate Intake of Food and Liquids Before Elective Sedation

Ingested Material	Minimum Fasting Period, h
Clear liquids: water; fruit juices without pulp, carbonated beverages, clear tea, black coffee	2
Human milk	4
Infant formula	6
Nonhuman milk: because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.	6
Light meal: a light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.	6

Source: American Society of Anesthesiologists. 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 Committee on Standards and Practice Parameters. Available at: <https://www.asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx>. For emergent sedation, the practitioner must balance the depth of sedation versus the risk of possible aspiration; see also Mace et al<sup>272</sup> and Green et al.<sup>273</sup>

but also to determine whether the patient has specific risk factors that may warrant additional consultation before sedation. This evaluation also facilitates the identification of patients who will require more advanced airway or cardiovascular management skills or alterations in the doses or types of medications used for procedural sedation.

An important concern for the practitioner is the widespread use of medications that may interfere with drug absorption or metabolism and therefore enhance or shorten the effect time of sedating medications. Herbal medicines (eg, St John's wort, ginkgo, ginger, ginseng, garlic) may alter drug pharmacokinetics through inhibition of the cytochrome P450 system, resulting in prolonged drug effect and altered (increased or decreased) blood drug concentrations (midazolam, cyclosporine, tacrolimus).<sup>283-292</sup> Kava may increase the effects of sedatives by potentiating  $\gamma$ -aminobutyric acid inhibitory neurotransmission and may increase acetaminophen-induced liver toxicity.<sup>293-295</sup> Valerian may itself produce sedation that apparently is mediated through the modulation of  $\gamma$ -aminobutyric acid neurotransmission and receptor function.<sup>291,296-299</sup> Drugs such as erythromycin, cimetidine, and others may also inhibit the cytochrome

P450 system, resulting in prolonged sedation with midazolam as well as other medications competing for the same enzyme systems.<sup>300-304</sup> Medications used to treat HIV infection, some anticonvulsants, immunosuppressive drugs, and some psychotropic medications (often used to treat children with autism spectrum disorder) may also produce clinically important drug-drug interactions.<sup>305-314</sup> Therefore, a careful drug history is a vital part of the safe sedation of children. The practitioner should consult various sources (a pharmacist, textbooks, online services, or handheld databases) for specific information on drug interactions.<sup>315-319</sup> The US Food and Drug Administration issued a warning in February 2013 regarding the use of codeine for postoperative pain management in children undergoing tonsillectomy, particularly those with OSA. The safety issue is that some children have duplicated cytochromes that allow greater than expected conversion of the prodrug codeine to morphine, thus resulting in potential overdose; codeine should be avoided for postprocedure analgesia.<sup>320-324</sup>

The health evaluation should include the following:

- age and weight (in kg) and gestational age at birth (preterm infants may have associated

sequelae such as apnea of prematurity); and

- health history, including (1) food and medication allergies and previous allergic or adverse drug reactions; (2) medication/drug history, including dosage, time, route, and site of administration for prescription, over-the-counter, herbal, or illicit drugs; (3) relevant diseases, physical abnormalities (including genetic syndromes), neurologic impairments that might increase the potential for airway obstruction, obesity, a history of snoring or OSA,<sup>325-328</sup> or cervical spine instability in Down syndrome, Marfan syndrome, skeletal dysplasia, and other conditions; (4) pregnancy status (as many as 1% of menarchal females presenting for general anesthesia at children's hospitals are pregnant)<sup>329-331</sup> because of concerns for the potential adverse effects of most sedating and anesthetic drugs on the fetus<sup>329,332-338</sup>; (5) history of prematurity (may be associated with subglottic stenosis or propensity to apnea after sedation); (6) history of any seizure disorder; (7) summary of previous relevant hospitalizations; (8) history of sedation or general anesthesia and any complications or unexpected responses; and (9) relevant family history, particularly related to anesthesia (eg, muscular dystrophy, malignant hyperthermia, pseudocholinesterase deficiency).

The review of systems should focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications. A specific query regarding signs and symptoms of sleep-disordered breathing and OSA may be helpful. Children with severe OSA who have experienced repeated episodes of desaturation will likely have altered mu receptors and be

analgesic at opioid levels one-third to one-half those of a child without OSA<sup>325-328,339,340</sup>; lower titrated doses of opioids should be used in this population. Such a detailed history will help to determine which patients may benefit from a higher level of care by an appropriately skilled health care provider, such as an anesthesiologist. The health evaluation should also include:

- vital signs, including heart rate, blood pressure, respiratory rate, room air oxygen saturation, and temperature (for some children who are very upset or noncooperative, this may not be possible and a note should be written to document this circumstance);
- physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy [eg, mandibular hypoplasia], high Mallampati score [ie, ability to visualize only the hard palate or tip of the uvula]) to determine whether there is an increased risk of airway obstruction<sup>74,341-344</sup>;
- physical status evaluation (ASA classification [see Appendix 2]); and
- name, address, and telephone number of the child's home or parent's, or caregiver's cell phone; additional information such as the patient's personal care provider or medical home is also encouraged.

For hospitalized patients, the current hospital record may suffice for adequate documentation of pre-sedation health; however, a note shall be written documenting that the chart was reviewed, positive findings were noted, and a management plan was formulated. If the clinical or emergency condition of the patient precludes acquiring complete information before sedation, this health evaluation should be obtained as soon as feasible.

2. Prescriptions. When prescriptions are used for sedation, a copy of the prescription or a note describing the content of the prescription should be in the patient's chart along with a description of the instructions that were given to the responsible person. **Prescription medications intended to accomplish procedural sedation must not be administered without the safety net of direct supervision by trained medical/dental personnel.** The administration of sedating medications at home poses an unacceptable risk, particularly for infants and preschool-aged children traveling in car safety seats because deaths as a result of this practice have been reported.<sup>63,257</sup>

#### Documentation During Treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage/kilogram, 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 laterality and site of the procedure.<sup>59</sup> During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administration, special attention must be paid to the calculation of dosage (ie, mg/kg); for obese patients, most drug doses should likely be adjusted lower to ideal body weight rather than actual weight.<sup>345</sup> When a programmable pump is used for the infusion of sedating medications, the dose/kilogram per minute or hour and the child's weight in kilograms should be double-checked and confirmed by a separate individual. 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, expired carbon dioxide values, and oxygen saturation

were monitored. Standard vital signs should be further documented at appropriate intervals during recovery until the patient attains predetermined discharge criteria (Appendix 1). A variety of sedation scoring systems are available that may aid this process.<sup>212,238,346-348</sup> Adverse events and their treatment shall be documented.

#### Documentation After Treatment

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 (see Appendix 1). Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure. Because some sedation medications are known to have a long half-life and may delay a patient's complete return to baseline or pose the risk of re-sedation<sup>62,104,256,349,350</sup> and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (eg, a step-down observation area) before discharge from medical/dental supervision may be indicated.<sup>239</sup> Several scales to evaluate recovery have been devised and validated.<sup>212,346-348,351,352</sup> 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.<sup>238</sup>

#### CONTINUOUS QUALITY IMPROVEMENT

The essence of medical error reduction is a careful examination of index events and root-cause analysis of how the event could be avoided in the future.<sup>353-359</sup>

Therefore, each facility should maintain records that track all adverse events and significant interventions, such as desaturation; apnea; laryngospasm; need for airway interventions, including the need for placement of supraglottic devices such as an oral airway, nasal trumpet, or LMA; positive-pressure ventilation; prolonged sedation; unanticipated use of reversal agents; unplanned or prolonged hospital admission; sedation failures; inability to complete the procedure; and unsatisfactory sedation, analgesia, or anxiolysis.<sup>360</sup> Such events can then be examined for the assessment of risk reduction and improvement in patient/family satisfaction.

#### PREPARATION FOR SEDATION PROCEDURES

Part of the safety net of sedation is using a systematic approach so as to not overlook having an important drug, piece of equipment, or monitor immediately available at the time of a developing emergency. To avoid this problem, it is helpful to use an acronym that allows the same setup and checklist for every procedure. A commonly used acronym useful in planning and preparation for a procedure is **SOAPME**, which represents the following:

**S** = Size-appropriate suction catheters and a functioning suction apparatus (eg, Yankauer-type suction)

**O** = an adequate Oxygen supply and functioning flow meters or other devices to allow its delivery

**A** = size-appropriate Airway equipment (eg, bag-valve-mask or equivalent device [functioning]), nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (checked and functioning), endotracheal tubes, stylets, face mask

**P** = Pharmacy: all the basic drugs needed to support life during an

emergency, including antagonists as indicated

**M** = Monitors: functioning pulse oximeter with size-appropriate oximeter probes,<sup>361,362</sup> end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, ECG, stethoscope)

**E** = special Equipment or drugs for a particular case (eg, defibrillator)

#### SPECIFIC GUIDELINES FOR INTENDED LEVEL OF SEDATION

##### Minimal Sedation

Minimal sedation (old terminology, "anxiolysis") is 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. 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.<sup>85,363</sup>

##### Moderate Sedation

Moderate sedation (old terminology, "conscious sedation" or "sedation/analgesia") is 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. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation; drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Because the patient who

receives moderate sedation may progress into a state of deep sedation and obtundation, the practitioner should be prepared to increase the level of vigilance corresponding to what is necessary for deep sedation.<sup>85</sup>

#### *Personnel*

**THE PRACTITIONER.** 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 described in these guidelines, 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 rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation should the child progress to a level of deep sedation. Training in, and maintenance of, advanced pediatric airway skills is required (eg, pediatric advanced life support [PALS]); regular skills reinforcement with simulation is strongly encouraged.<sup>79,80,128,130,217-220, 364</sup>

**SUPPORT PERSONNEL.** The use of moderate sedation shall include the provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration, such as holding an instrument or troubleshooting equipment.<sup>60</sup> 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.<sup>133,365-367</sup> It is recommended that at least 1 practitioner be skilled in obtaining vascular access in children.

#### *Monitoring and Documentation*

**BASELINE.** Before the administration of sedative medications, a baseline determination of vital signs shall be documented. For some children who are very upset or uncooperative, this may not be possible, and a note should be written to document this circumstance.

**DURING THE PROCEDURE** The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the qualified health care provider administering the medication to confirm the dose verbally before administration. 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)<sup>368-371</sup> 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. Heart rate, respiratory rate, blood pressure, oxygen saturation, and

expired carbon dioxide values should be recorded, at minimum, every 10 minutes in a time-based record. Note that the exact value of expired carbon dioxide is less important than simple assessment of continuous respiratory gas exchange. In some situations in which there is excessive patient agitation or lack of cooperation or during certain procedures such as bronchoscopy, dentistry, or repair of facial lacerations capnography may not be feasible, and this situation should be documented. For uncooperative children, it is often helpful to defer the initiation of capnography until the child becomes sedated. Similarly, the stimulation of blood pressure cuff inflation may cause arousal or agitation; in such cases, blood pressure monitoring may be counterproductive and may be documented at less frequent intervals (eg, 10-15 minutes, assuming the patient remains stable, well oxygenated, and well perfused). Immobilization devices (protective stabilization) should be checked to prevent airway obstruction or chest restriction. If a restraint device is used, a hand or foot should be kept exposed. The child's head position should be continuously assessed to ensure airway patency.

**AFTER THE PROCEDURE.** The child who has received moderate sedation must be observed in a suitably equipped recovery area, which must have a functioning suction apparatus as well as the capacity to deliver >90% oxygen and positive-pressure ventilation (bag-valve mask) with an adequate oxygen capacity as well as age- and size-appropriate rescue equipment and devices. The patient's vital signs should be recorded at specific intervals (eg, every 10-15 minutes). If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met (see Appendix 1). Because sedation medications with a long half-life

may delay the patient's complete return to baseline or pose the risk of re-sedation, some patients might benefit from a longer period of less intense observation (eg, a step-down observation area where multiple patients can be observed simultaneously) before discharge from medical/dental supervision (see section entitled "Documentation Before Sedation" above).<sup>62,256,349,350</sup> 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.<sup>238</sup> Patients who have received reversal agents, such as flumazenil or naloxone, will require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, resulting in re-sedation.

### **Deep Sedation/General Anesthesia**

"Deep sedation" ("deep sedation/analgesia") is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (eg, purposefully pushing away the noxious stimuli). Reflex withdrawal from a painful stimulus is not considered a purposeful response and is more consistent with a state of general anesthesia. 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. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may pass from a state of deep sedation to the state of general anesthesia. In some situations, such as during MRI, one is not usually able to assess responses to stimulation, because this would defeat the purpose of sedation, and one should assume that such patients are deeply sedated.

"General anesthesia" is 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.

### *Personnel*

During deep sedation, there must be 1 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 1 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.

### *Equipment*

In addition to the equipment needed for moderate sedation, an ECG monitor and a defibrillator for use in pediatric patients should be readily available.

### *Vascular Access*

Patients receiving deep sedation should have an intravenous line placed at the start of the procedure or

have a person skilled in establishing vascular access in pediatric patients immediately available.

### *Monitoring*

A competent individual shall observe the patient continuously. Monitoring shall include all parameters described for moderate sedation. Vital signs, including heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide, must be documented at least every 5 minutes in a time-based record. Capnography should be used for almost all deeply sedated children because of the increased risk of airway/ventilation compromise. Capnography may not be feasible if the patient is agitated or uncooperative during the initial phases of sedation or during certain procedures, such as bronchoscopy or repair of facial lacerations, and this circumstance should be documented. For uncooperative children, the capnography monitor may be placed once the child becomes sedated. Note that if supplemental oxygen is administered, the capnograph may underestimate the true expired carbon dioxide value; of more importance than the numeric reading of exhaled carbon dioxide is the assurance of continuous respiratory gas exchange (ie, continuous waveform). Capnography is particularly useful for patients who are difficult to observe (eg, during MRI or in a darkened room).<sup>64,67,72,90,96,110,159-162,164-166,167-170,372-375</sup>

The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the nurse administering the medication to confirm the dose verbally before administration. The inspired

concentrations of inhalation sedation agents and oxygen and the duration of administration shall be documented.

*Postsedation Care*

The facility and procedures followed for postsedation care shall conform to those described under "moderate sedation." The initial recording of vital signs should be documented at least every 5 minutes. Once the child begins to awaken, the recording intervals may be increased to 10 to 15 minutes. Table 2 summarizes the equipment, personnel, and monitoring requirements for moderate and deep sedation.

**Special Considerations**

*Neonates and Former Preterm Infants*

Neonates and former preterm infants require specific management, because immaturity of hepatic and renal function may alter the ability to metabolize and excrete sedating medications,<sup>376</sup> resulting in prolonged sedation and the need for extended postsedation monitoring. Former preterm infants have an increased risk of postanesthesia apnea,<sup>377</sup> but it is unclear whether a similar risk is associated with sedation, because this possibility has not been systematically investigated.<sup>378</sup>

Other concerns regarding the effects of anesthetic drugs and sedating medications on the developing brain are beyond the scope of this document. At this point, the research in this area is preliminary and inconclusive at best, but it would seem prudent to avoid unnecessary exposure to sedation if the procedure is unlikely to change medical/dental management (eg, a sedated MRI purely for screening purposes in preterm infants).<sup>379-382</sup>

*Local Anesthetic Agents*

All local anesthetic agents are cardiac depressants and may

**TABLE 2** Comparison of Moderate and Deep Sedation Equipment and Personnel Requirements

	Moderate Sedation	Deep Sedation
Personnel	An observer who will monitor the patient but who may also assist with interruptible tasks; should be trained in PALS	An independent observer whose only responsibility is to continuously monitor the patient; trained in PALS
Responsible practitioner	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation; recommended that at least 1 practitioner should be skilled in obtaining vascular access in children; trained in PALS	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation; training in PALS is required; at least 1 practitioner skilled in obtaining vascular access in children immediately available
Monitoring	Pulse oximetry ECG recommended Heart rate Blood pressure Respiration Capnography recommended	Pulse oximetry ECG required Heart rate Blood pressure Respiration Capnography required
Other equipment	Suction equipment, adequate oxygen source/supply	Suction equipment, adequate oxygen source/supply, defibrillator required
Documentation	Name, route, site, time of administration, and dosage of all drugs administered Continuous oxygen saturation, heart rate, and ventilation (capnography recommended); parameters recorded every 10 minutes	Name, route, site, time of administration, and dosage of all drugs administered; continuous oxygen saturation, heart rate, and ventilation (capnography required); parameters recorded at least every 5 minutes
Emergency checklists	Recommended	Recommended
Rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4)	Required	Required
Dedicated recovery area with rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4) and dedicated recovery personnel; adequate oxygen supply	Recommended; initial recording of vital signs may be needed at least every 10 minutes until the child begins to awaken, then recording intervals may be increased	Recommended; initial recording of vital signs may be needed for at least 5-minute intervals until the child begins to awaken, then recording intervals may be increased to 10–15 minutes
Discharge criteria	See Appendix 1	See Appendix 1

cause central nervous system excitation or depression. Particular weight-based attention should be paid to cumulative dosage in all children.<sup>118,120,125,383-386</sup> To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (eg, mg/kg) should be calculated before

administration. There may be enhanced sedative effects when the highest recommended doses of local anesthetic drugs are used in combination with other sedatives or opioids (see Tables 3 and 4 for limits and conversion tables of commonly used local anesthetics).<sup>118,125,387-400</sup> In general, when administering local

**TABLE 3** Commonly Used Local Anesthetic Agents for Nerve Block or Infiltration: Doses, Duration, and Calculations

Local Anesthetic	Maximum Dose With Epinephrine, <sup>a</sup> mg/kg		Maximum Dose Without Epinephrine, mg/kg		Duration of Action, <sup>b</sup> min
	Medical	Dental	Medical	Dental	
<b>Esters</b>					
Procaine	10.0	6	7	6	60–90
Chloroprocaine	20.0	12	15	12	30–60
Tetracaine	1.5	1	1	1	180–600
<b>Amides</b>					
Lidocaine	7.0	4.4	4	4.4	90–200
Mepivacaine	7.0	4.4	5	4.4	120–240
Bupivacaine	3.0	1.3	2.5	1.3	180–600
Levobupivacaine <sup>c</sup>	3.0	2	2	2	180–600
Ropivacaine	3.0	2	2	2	180–600
Articaine <sup>d</sup>	—	7	—	7	60–230

Maximum recommended doses and durations of action are shown. Note that lower doses should be used in very vascular areas.

<sup>a</sup> These are maximum doses of local anesthetics combined with epinephrine; lower doses are recommended when used without epinephrine. Doses of amides should be decreased by 30% in infants younger than 6 mo. When lidocaine is being administered intravascularly (eg, during intravenous regional anesthesia), the dose should be decreased to 3 to 5 mg/kg; long-acting local anesthetic agents should not be used for intravenous regional anesthesia.

<sup>b</sup> Duration of action is dependent on concentration, total dose, and site of administration; use of epinephrine; and the patient's age.

<sup>c</sup> Levobupivacaine is not available in the United States.

<sup>d</sup> Use in pediatric patients under 4 years of age is not recommended.

**TABLE 4** Local Anesthetic Conversion Chart

Concentration, %	mg/mL
4.0	40
3.0	30
2.5	25
2.0	20
1.0	10
0.5	5
0.25	2.5
0.125	1.25

anesthetic drugs, the practitioner should aspirate frequently to minimize the likelihood that the needle is in a blood vessel; lower doses should be used when injecting into vascular tissues.<sup>401</sup> If high doses or injection of amide local anesthetics (bupivacaine and ropivacaine) into vascular tissues is anticipated, then the immediate availability of a 20% lipid emulsion for the treatment of local anesthetic toxicity is recommended (Tables 3 and 5).<sup>402–409</sup> Topical local anesthetics are commonly used and encouraged, but the practitioner should avoid applying excessive doses to mucosal surfaces where systemic uptake and possible toxicity (seizures, methemoglobinemia) could result and to remain within the manufacturer's recommendations regarding allowable surface area application.<sup>410–415</sup>

**TABLE 5** Treatment of Local Anesthetic Toxicity

1. Get help. Ventilate with 100% oxygen. Alert nearest facility with cardiopulmonary bypass capability.
2. Resuscitation: airway/ventilatory support, chest compressions, etc. Avoid vasopressin, calcium channel blockers,  $\beta$ -blockers, or additional local anesthetic. Reduce epinephrine dosages. Prolonged effort may be required.
3. Seizure management: benzodiazepines preferred (eg, intravenous midazolam 0.1–0.2 mg/kg); avoid propofol if cardiovascular instability.
4. Administer 1.5 mL/kg 20% lipid emulsion over ~1 minute to trap unbound amide local anesthetics. Repeat bolus once or twice for persistent cardiovascular collapse.
5. Initiate 20% lipid infusion (0.25 mL/kg per minute) until circulation is restored; double the infusion rate if blood pressure remains low. Continue infusion for at least 10 minutes after attaining circulatory stability. Recommended upper limit of ~10 mL/kg.
6. A fluid bolus of 10–20 mL/kg balanced salt solution and an infusion of phenylephrine (0.1  $\mu$ g/kg per minute to start) may be needed to correct peripheral vasodilation.

Source: <https://www.asra.com/advisory-guidelines/article/3/checklist-for-treatment-of-local-anesthetic-systemic-toxicity>.

#### Pulse Oximetry

Newer pulse oximeters are less susceptible to motion artifacts and may be more useful than older oximeters that do not contain updated software.<sup>416–420</sup> Oximeters that change tone with changes in hemoglobin saturation provide immediate aural warning to everyone within hearing distance. The oximeter probe must be properly positioned; clip-on devices are easy to displace, which may produce artifactual data (under- or overestimation of oxygen saturation).<sup>361,362</sup>

#### Capnography

Expired carbon dioxide monitoring is valuable to diagnose the simple

presence or absence of respirations, airway obstruction, or respiratory depression, particularly in patients sedated in less-accessible locations, such as in MRI machines or darkened rooms.<sup>64,66,67,72,90,96,110,159–162,164–170,372–375,421–427</sup> In patients receiving supplemental oxygen, capnography facilitates the recognition of apnea or airway obstruction several minutes before the situation would be detected just by pulse oximetry. In this situation, desaturation would be delayed due to increased oxygen reserves; capnography would enable earlier intervention.<sup>161</sup> One study in children sedated in the emergency department found that the use of capnography reduced the incidence of hypoventilation and desaturation

(7% to 1%).<sup>174</sup> The use of expired carbon dioxide monitoring devices is now required for almost all deeply sedated children (with rare exceptions), particularly in situations in which other means of assessing the adequacy of ventilation are limited. Several manufacturers have produced nasal cannulae that allow simultaneous delivery of oxygen and measurement of expired carbon dioxide values.<sup>421,422,427</sup> Although these devices can have a high degree of false-positive alarms, they are also very accurate for the detection of complete airway obstruction or apnea.<sup>164,168,169</sup> Taping the sampling line under the nares under an oxygen face mask or nasal hood will provide similar information. The exact measured value is less important than the simple answer to the question: Is the child exchanging air with each breath?

#### *Processed EEG (Bispectral Index)*

Although not new to the anesthesia community, the processed EEG (bispectral index [BIS]) monitor is slowly finding its way into the sedation literature.<sup>428</sup> Several studies have attempted to use BIS monitoring as a means of noninvasively assessing the depth of sedation. This technology was designed to examine EEG signals and, through a variety of algorithms, correlate a number with depth of unconsciousness: that is, the lower the number, the deeper the sedation. Unfortunately, these algorithms are based on adult patients and have not been validated in children of varying ages and varying brain development. Although the readings correspond quite well with the depth of propofol sedation, the numbers may paradoxically go up rather than down with sevoflurane and ketamine because of central excitation despite a state of general anesthesia or deep sedation.<sup>429,430</sup> Opioids and benzodiazepines have minimal and variable effects on the BIS. Dexmedetomidine has minimal effect with EEG patterns, consistent

with stage 2 sleep.<sup>431</sup> Several sedation studies have examined the utility of this device and degree of correlation with standard sedation scales.<sup>347,363,432-435</sup> It appears that there is some correlation with BIS values in moderate sedation, but there is not a reliable ability to distinguish between deep sedation and moderate sedation or deep sedation from general anesthesia.<sup>432</sup> Presently, it would appear that BIS monitoring might provide useful information only when used for sedation with propofol<sup>363</sup>; in general, it is still considered a research tool and not recommended for routine use.

#### *Adjuncts to Airway Management and Resuscitation*

The vast majority of sedation complications can be managed with simple maneuvers, such as supplemental oxygen, opening the airway, suctioning, placement of an oral or nasopharyngeal airway, and bag-mask-valve ventilation. Rarely, tracheal intubation is required for more prolonged ventilatory support. In addition to standard tracheal intubation techniques, a number of supraglottic devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the LMA, the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.<sup>436,437</sup>

The largest clinical experience in pediatrics is with the LMA, which is available in multiple sizes, including those for late preterm and term neonates. The use of the LMA is now an essential addition to advanced airway training courses, and familiarity with insertion techniques can be life-saving.<sup>438-442</sup> The LMA can also serve as a bridge to secure airway management in children with anatomic airway abnormalities.<sup>443,444</sup> Practitioners are encouraged to gain

experience with these techniques as they become incorporated into PALS courses.

Another valuable emergency technique is intraosseous needle placement for vascular access. Intraosseous needles are available in several sizes; insertion can be life-saving when rapid intravenous access is difficult. A relatively new intraosseous device (EZ-IO Vidacare, now part of Teleflex, Research Triangle Park, NC) is similar to a hand-held battery-powered drill. It allows rapid placement with minimal chance of misplacement; it also has a low-profile intravenous adapter.<sup>445-450</sup> Familiarity with the use of these emergency techniques can be gained by keeping current with resuscitation courses, such as PALS and advanced pediatric life support.

#### *Patient Simulators*

High-fidelity patient simulators are now available that allow physicians, dentists, and other health care providers to practice managing a variety of programmed adverse events, such as apnea, bronchospasm, and laryngospasm.<sup>133,220,450-452</sup> The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events.<sup>128,131,451,453-455</sup> 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.<sup>456</sup>

#### *Monitoring During MRI*

The powerful magnetic field and the generation of radiofrequency emissions necessitate the use of special equipment to provide

continuous patient monitoring throughout the MRI scanning procedure.<sup>457-459</sup> MRI-compatible pulse oximeters and capnographs capable of continuous function during scanning should be used in any sedated or restrained pediatric patient. Thermal injuries can result if appropriate precautions are not taken; the practitioner is cautioned to avoid coiling of all wires (oximeter, ECG) and to place the oximeter probe as far from the magnetic coil as possible to diminish the possibility of injury. ECG monitoring during MRI has been associated with thermal injury; special MRI-compatible ECG pads are essential to allow safe monitoring.<sup>460-463</sup> If sedation is achieved by using an infusion pump, then either an MRI-compatible pump is required or the pump must be situated outside of the room with long infusion tubing so as to maintain infusion accuracy. All equipment must be MRI compatible, including laryngoscope blades and handles, oxygen tanks, and any ancillary equipment. All individuals, including parents, must be screened for ferromagnetic materials, phones, pagers, pens, credit cards, watches, surgical implants, pacemakers, etc, before entry into the MRI suite.

#### *Nitrous Oxide*

Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100% and never less than 25% oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide >50% to oxygen that covers the mouth and nose must be used in conjunction with

a calibrated and functional oxygen analyzer. All nitrous oxide-to-oxygen inhalation devices should be calibrated in accordance with appropriate state and local requirements. Consideration should be given to the National Institute of Occupational Safety and Health Standards for the scavenging of waste gases.<sup>464</sup> Newly constructed or reconstructed treatment facilities, especially those with piped-in nitrous oxide and oxygen, must have appropriate state or local inspections to certify proper function of inhalation sedation/analgesia systems before any delivery of patient care.

Nitrous oxide in oxygen, with varying concentrations, has been successfully used for many years to provide analgesia for a variety of painful procedures in children.<sup>14,36,49,98,465-493</sup> The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide of  $\leq 50\%$  with the balance as oxygen, without any other sedative, opioid, or other depressant drug before or concurrent with the nitrous oxide to an otherwise healthy patient in ASA class I or II. The patient is able to maintain verbal communication throughout the procedure. It should be noted that although local anesthetics have sedative properties, for purposes of this guideline they are not considered sedatives in this circumstance. If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations >50%, the likelihood for moderate or deep sedation increases.<sup>107,197,492,494,495</sup>

In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response.<sup>496</sup>

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#### **ABBREVIATIONS**

AAP: American Academy of Pediatrics  
AAPD: American Academy of Pediatric Dentistry  
ASA: American Society of Anesthesiologists  
BIS: bispectral index  
CPAP: continuous positive airway pressure  
ECG: electrocardiography  
EEG: electroencephalogram/electroencephalography  
EMS: emergency medical services  
LMA: laryngeal mask airway  
MRI: magnetic resonance imaging  
OSA: obstructive sleep apnea  
PALS: pediatric advanced life support

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**Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016**

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Phone: 847/434-4000  
Fax: 847/434-8000  
E-mail: kidsdocs@aap.org  
www.aap.org

Steven G. Morrow, DDS, MS, President  
Dental Board of California  
2005 Evergreen Street, Suite 1550,  
Sacramento, California 95815

Dear Dr Morrow,

Thank you for your letter of July 18.

The American Academy of Pediatrics is deeply committed to ensuring infants, children and adolescents receive the proper care to attain optimal health. For many years, the Academy has been concerned with the protection of pediatric patients during dental sedation, and have updated our "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016," a copy of which we recently submitted to the Dental Board.

We thank you for the invitation to participate in your July and August meetings. Inasmuch as our California District is as invested in this issue as the National Office, we defer to and are fully supportive of their efforts in California. By copy of this letter, I am asking Kris Calvin, MA, Executive Director, AAP-CA, to identify appropriate participants for the sessions.

We look forward to assisting you in promoting the best practices in dental sedation consistent with our Guidelines.

Sincerely,

A handwritten signature in black ink, appearing to read "Roger F Suchyta".

Roger F Suchyta, MD, FAAP  
Associate Executive Director

RFS/dc

cc: Karen Remley, MD, MBA, MPH, FAAP, Executive Director/CEO  
Stu Cohen, MD, FAAP, District IX Chairperson  
Yasuko Fukuda, MD, FAAP, District IX Vice Chairperson  
Kris Calvin, MA, CEO, AAP-CA  
Judy Dolins, Associate Executive Director/Director, Department of Community, Chapter and State Affairs  
Lauran Barone, Manager, Oral Health

Zoey J. Goore, MD, MPH, FAAP, President, CA Chapter 1  
Beverly Busher, Executive Director, CA Chapter 1  
Edward S. Curry, MD, FAAP President, CA Chapter 2  
Tomas Torices, MD, Executive Director, CA Chapter 2  
Patricia E. Cantrell, MD, FAAP, President, CA Chapter 3  
Meredith Kennedy, MPH, Executive Director, CA Chapter 3  
Dean S. Jacobs, MD, FAAP, President, CA Chapter 4  
Jamie S. McDonald, MPH, Executive Director, CA Chapter 4

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# American Academy of Pediatrics



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AMERICAN ACADEMY OF PEDIATRICS, CALIFORNIA

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Email office@aap-ca.org | Website www.AAP-CA.org

July 27, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

## RE: AAP-CA Comment on Dental Board of California Pediatric Anesthesia Study

Dear Dr. Morrow:

**The mission of the AAP-CA is to protect and promote the health and well-being of all children and youth living in California.** Our mission applies in any circumstance and setting in which a child's health and well-being is nurtured or is at risk. Pediatricians' interest, expertise and training extend to the health of the whole child, and while distinct in important aspects, overlap with that of pediatric dentistry and oral surgery.

In situations where anesthesia is used on a child, it is often the pediatrician who clears the patient for anesthesia beforehand and the pediatrician who treats any adverse consequences that may arise afterwards.

It is also often the pediatrician who counsels and comforts a parent when a child dies, a child who that pediatrician has cared for since birth, irrespective of the circumstances in which the tragedy occurs.

**It is important to note that pediatricians have absolutely no financial stake in how anesthesia is administered in a dental office; we gain no income regardless of who administers the anesthesia. In making our recommendations in this area, we are, therefore, able to consider only the evidence as it relates to the child's safety and well-being.**

Given our primary involvement in children's health, we are disappointed that pediatricians have been relegated to act as external stakeholders in the California Dental Board's review of anesthesia practices for children, restricted to commenting on a draft report for which the issue has been framed and the questions have been asked in an internal and exclusionary process in which, as we understand it, an oral surgeon and a lawyer (with a seat on the dental board) have been the only primary authors, supported by Board staff.

**We hope that enactment of AB 2235 (Thurmond)—supported not only by the AAP-CA as sponsors, but also by the California Dental Association— will occur, and that at that time the California Dental Board will establish a collaborative and inclusive process, through which the houses of medicine and dentistry will be able to step out of our respective silos and combine our knowledge and expertise to determine what is truly best for California's children who undergo anesthesia in a dental setting.**

With respect to the Board's draft report, we have not had sufficient time to review line-by-line the recently released 150 page document or to put it through our formal process. **We can, however make initial comments, and greatly appreciate the careful work done by the Dental Board in the draft report on Appendix 2, in which current definitions/requirements in California law are compared to policy as put forth in the joint guidelines established by the American Academy of Pediatrics (AAP) in collaboration with the American**

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**Academy of Pediatric Dentistry (AAPD).** (For purposes of comparison, it appears the Board's draft report utilizes an older version of these guidelines, which have since been updated and published in the July 2016 issue of the journal *Pediatrics* as "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016," by Charles J. Coté and Stephen Wilson.)

The AAP-AAPD guidelines, publicly available online, reflect our current position on addressing the needs of pediatric patients before, during, and after the administration of anesthesia.

With respect to the report under discussion here, we are deeply concerned by an area of disagreement between the AAP-AAPD guidelines and current CA law with respect to Personnel. California law requires that Personnel for deep sedation/general anesthesia only be the "same as moderate sedation". In contrast, The AAP-AAPD personnel guidelines for deep sedation/general anesthesia have additional requirements:

*"There must be one person available 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. At least one individual must be present who is trained in, and capable of, providing advanced pediatric life support, and who is skilled in airway management and cardiopulmonary resuscitation; training in pediatric advanced life support is required."*

The notion that the personnel necessary to monitor and administer anesthesia for a child under deep sedation/general anesthesia in a dental chair is no more than that required for moderate sedation seems, frankly, woefully inadequate. That would seem to hold true *only if there were no greater risk to the child under deep sedation/general anesthesia than under moderate sedation.*

In addition to asking that the above-referenced guidelines issued jointly by the American Academy of Pediatrics and the American Association of Pediatric Dentists (as updated in 2016) be adopted in their entirety as the basis for recommendations for improving California's laws and regulations in the area of pediatric anesthesia and dental care, we also endorse the position of the California Society of Anesthesiologists "...the standard of care regarding the administration and monitoring of anesthesia services must be consistent... whether anesthesia care is delivered in a dental office, ambulatory surgery center or acute care hospital."

The above requires that a dentist performing a dental procedure not be simultaneously responsible for anesthesia care, much as a surgeon does not perform anesthesia while operating but rather requires the assistance of an anesthesiologist. The fact that dental offices are typically located at some distance from hospital facilities means that more, rather than fewer, precautions should be taken with the use of pediatric anesthesia, as the relative inaccessibility of potentially life-saving emergency assistance stands to have disastrous consequences.

Please note: our national organization (the American Academy of Pediatrics based in Illinois) forwarded your request for comment to us, the American Academy of Pediatrics, California (AAP-CA). **We ask that any further communications regarding this issue be directed to our CEO, Kris Calvin at 626-796-1632/office@aap-ca.org.**

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October 12, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

## **RE: AAP-CA Response to Dental Board of California Subcommittee Preliminary Recommendations for Discussion as Published on October 3, 2016**

Dear Dr. Morrow:

The American Academy of Pediatrics, California (AAPCA), representing 5000 board-certified California pediatricians statewide, appreciates the opportunity to comment on the important work that the Dental Board of California has undertaken to review current laws and regulations pertaining to pediatric dental anesthesia.

The mission of the AAP-CA is to protect and promote the health and well-being of all children and youth living in California. Our mission applies in any circumstance and setting in which a child's health and well-being is nurtured or is at risk.

**Pediatricians have no financial interest in who administers and monitors anesthesia in a dental office—our interest stems solely from our mission to protect and promote the health and well-being of every child in California.**

Our letters to you on July 29, 2016 and August 19, 2016 expressed the AAP-CA's deep concerns that the subcommittee's draft report fails to address serious shortcomings in current California law relative to recommendations on standards for administration and monitoring of anesthesia use in children in a dental setting, as set forth jointly by the American Academy of Pediatrics and the American Association of Pediatric Dentists (AAP-AAPD).

**These preliminary recommendations still fall short in guaranteeing pediatric patient safety.**

In particular, California currently permits use of the single operator-anesthetist model in a dental setting. In this single operator-anesthetist model, the professional responsible for performing the dental procedure is simultaneously charged with administering and monitoring anesthesia, as well as performing emergency rescue procedures on the child, if necessary. As quoted from the AAP-AAPD guidelines, **"This individual must, at minimum, be trained in Pediatric Advanced Life Support (PALS) and capable of assisting with any emergency event."** Experience in other health care settings clearly shows that having a second trained person, per the AAP-AAPD guidelines and as described in the letter dated August 2016 sent by the California Society of Anesthesiologists promotes safe outcomes.

Finally, we would note that the "access argument", i.e., that somehow children will fail to receive care at all if we require that the care is administered safely, is not a defensible position, nor is it adequately supported by the evidence. Access issues that may already exist (e.g., in rural areas) warrant a separate conversation; pediatricians will gladly join you in developing and seeking strategies to address those.

**California pediatricians ask that the California Dental Board stand with us as partners with anesthesiologists, with parents, and with policymakers to address the dangers of inadequate safeguards**

# American Academy of Pediatrics



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## for pediatric anesthesia in the dental setting now.

We hope you agree that we cannot, in good conscience, tell the parents of one more healthy child that goes into a dental office for a routine procedure and dies while under anesthesia that we were unwilling to do anything proactive to prevent that tragedy.

*That we were able to do nothing but wait.*

## To that end, we respectfully request that the California Dental Board:

- 1- Urge all dentists and oral surgeons in California to comply with the AAP-AAPD guidelines on pediatric anesthesia in dental settings;
- 2- Integrate into your subcommittee report, in full, the recommendations of the California Society of Anesthesiologists (CSA) in their August 17, 2016 letter of comment (in particular the qualifications of the "sole monitor"); and
- 3- Publicly support an immediate and full moratorium on the single operator-anesthetist model when a child is placed under moderate to deep sedation in a dental office.

Not one more healthy California child should die in a dental chair if anything can be done to prevent it.

*Not one more.*

We look forward to working with you to publicize and promote these changes.

Sincerely,

A handwritten signature in cursive script that reads "Kris E. Calvin".

Kris Calvin  
Chief Executive Officer  
American Academy of Pediatrics, California

cc: Karen Fischer, Executive Director, Dental Board of California  
Honorable Jerry Hill (D-San Mateo)  
Honorable Tony Thurmond (D-Richmond)  
Bryce Docherty, KP Public Affairs  
Vanessa Cajina, KP Public Affairs  
AAP-CA Leadership  
Lydia Bourne



October 28, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: AAP-CA Response to Dental Board of California Subcommittee Preliminary Recommendations for Discussion as Published on October 3, 2016**

Dear Dr. Morrow:

The American Academy of Pediatrics, California (AAPCA), representing 5000 board-certified California pediatricians statewide, appreciates the opportunity to comment on the important work that the Dental Board of California has undertaken to review current laws and regulations pertaining to pediatric dental anesthesia.

The mission of the AAP-CA is to protect and promote the health and well-being of all children and youth living in California. Our mission applies in any circumstance and setting in which a child's health and well-being is nurtured or is at risk.

Pediatricians have no financial interest in who administers and monitors anesthesia in a dental office—our interest stems solely from our mission to protect and promote the health and well-being of every child in California.

Our letters to you on July 29, 2016 and August 19, 2016 expressed the AAP-CA's deep concerns that the Dental Board of California's subcommittee draft report fails to address serious shortcomings in current California law relative to administration and monitoring of anesthesia used in children in a dental setting.

While we appreciate the continued work that has been done by the subcommittee, pediatricians' serious concerns for child safety in dental settings relative to anesthesia are not adequately addressed by the preliminary recommendations of the Board.

In particular, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentists (AAPD) have jointly developed and issued guidelines regarding the appropriate administration and monitoring of anesthesia for children in the dental setting. **The preliminary recommendations from the subcommittee do not meet these reasonable and important guidelines.** To remedy that, we respectfully request that the California Dental Board:

- 1. Urge all dentists and oral surgeons in California to voluntarily comply with the AAP-AAPD guidelines on pediatric anesthesia in dental settings (updated 2016); and*
- 2. Work with interested stakeholders to enact appropriate changes to California statute and regulations to phase out the operator-anesthetist model for children undergoing dental procedures in California.*
- 3. Integrate into your subcommittee report, in full, the recommendations of the California Society of Anesthesiologists (CSA) in their August 17, 2016 letter of comment (in particular the qualifications of the "sole monitor").*

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Through the above actions, California pediatricians urge the California Dental Board stand with us as partners with anesthesiologists, with parents, and with policymakers to address the dangers of inadequate safeguards for pediatric anesthesia in the dental setting now.

Sincerely,

A handwritten signature in black ink that reads "Kris E. Calvin". The signature is fluid and cursive.

Kris Calvin  
Chief Executive Officer  
American Academy of Pediatrics, California

cc: Karen Fischer, Executive Director, Dental Board of California  
Honorable Tony Thurmond (D-Richmond)  
Honorable Jerry Hill (D-San Mateo)  
Bryce Docherty, KP Public Affairs  
Anna Kaplan, MD  
AAP-CA Leadership  
Lydia Bourne

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November 30, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: AAP-CA Response to Dental Board of California Subcommittee Final Recommendations for Discussion as Published on October 3, 2016**

Dear Dr. Morrow:

Our letters to you on July 29, August 19, and October 28, 2016 expressed the AAP-CA's deep concerns that the subcommittee's draft report fails to address serious shortcomings in current California law relative to recommendations on standards for administration and monitoring of anesthesia use in children in a dental setting, as set forth jointly by the American Academy of Pediatrics and the American Association of Pediatric Dentists (AAP-AAPD).

**Despite rearticulating our concerns numerous times over the course of several months, these final recommendations still fall short in guaranteeing pediatric patient safety.** The final report before the Dental Board today still fails to address the unusual exception to widely-accepted standards of care with regard to pediatric sedation.

As quoted from the AAP-AAPD guidelines, "[The administering professional] must, at minimum, be trained in Pediatric Advanced Life Support (PALS) and capable of assisting with any emergency event." Experience in other health care settings clearly shows that having a second trained person, per the AAP-AAPD guidelines and as described in the letter dated August 2016 sent by the California Society of Anesthesiologists promotes safe outcomes.

To that end, we respectfully, once again, request that the California Dental Board:

1. **Urge all dentists and oral surgeons in California to comply with the AAP-AAPD guidelines on pediatric anesthesia in dental settings;**
2. **Integrate into your subcommittee report, in full, the recommendations of the California Society of Anesthesiologists (CSA) in their August 17, 2016 letter of comment (in particular the qualifications of the "sole monitor"); and**
3. **Publicly support an immediate and full moratorium on the single operator-anesthetist model when a child is placed under moderate to deep sedation and general anesthesia in a dental office.**

Sincerely,

Kris Calvin  
Chief Executive Officer  
American Academy of Pediatrics, California

cc: Karen Fischer, Executive Director, Dental Board of California  
Honorable Jerry Hill (D-San Mateo)  
Honorable Tony Thurmond (D-Richmond)  
Bryce Docherty, KP Public Affairs  
Vanessa Cajina, KP Public Affairs  
AAP-CA Leadership  
Lydia Bourne

# **AMERICAN ASSOCIATION OF ORAL AND MAXILLOFACIAL SURGEONS (AAOMS)**

1. Testimony Before the Dental Board of California on October 13, 2016.

## **Testimony to the Dental Board of California Subcommittee on Pediatric Dental Sedation**

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On behalf of the 9,500 fellows and members of the American Association of Oral and Maxillofacial Surgeons (AAOMS), including the 725 oral and maxillofacial surgeons who practice in California, we appreciate the opportunity to provide written testimony regarding the Dental Board of California Subcommittee on Pediatric Dental Sedation preliminary recommendations. In an effort to ensure safe delivery of anesthesia and improve outcomes, the AAOMS supports the subcommittee recommendations to increase patient safety particularly in the delivery of anesthesia to pediatric patients.

Training, expertise and experience are of paramount importance in establishing a culture of safety. This should include not only the doctor, but all members of the anesthetic team. The oral and maxillofacial surgeon in conjunction with their team of skilled dental sedation assistants, provide a comfortable and safe office-based delivery of dental sedation. The team members are trained and current in the management of the anesthetic patient through programs like the DAANCE (Dental Anesthesia Assistants National Certification Exam) or similar programs.

Despite the best of efforts, unanticipated events, unfortunately, occur. Therefore the anesthetic team should be well prepared and practiced to respond in a timely and effective manner to any adverse events that may occur. This should include regular mock safety drills covering the spectrum of potential pre-emergency and emergency situations. Even with the best efforts in patient selection and risk assessment, diligent monitoring provides the anesthetic team the best opportunity to recognize and manage a potential adverse event. The environment in which anesthetic care is provided is important in the effort to ensure patient safety. Every office should be designed and maintained with patient safety in mind and members of the anesthetic teams should be intimately familiar not only with all rescue drugs, equipment and protocols, but also with the facility to allow a seamless response to any pre-emergent or emergent event.

It is important to appreciate that children are not simply 'small adults', but have many unique and constantly changing anatomic, physiologic, pharmacologic and psychological differences. We appreciate the higher standards that are being proposed relative to pediatric anesthesia care. The AAOMS anesthesia goals for the pediatric patient are safety, cooperation, elimination of pain, reduction of anxiety, and control of behavior to allow completion of the planned intervention. All AAOMS providers must maintain ACLS certification and PALS is recommended for those who provide anesthesia to children.

The *Oral and Maxillofacial Surgery Parameters of Care*, which reflects clinical practice guidelines necessary for practice by the oral and maxillofacial surgeon, discuss the standards for treating patients receiving office-based anesthesia, including the monitoring procedures and equipment that should be followed by the surgeon and staff. The AAOMS is pleased that the proposed subcommittee recommendations include all the necessary monitoring equipment to provide advance warning of hypoxic events. Surgical suites of oral and maxillofacial surgeons must be equipped with emergency drugs and monitoring equipment that allow appropriate ACLS intervention, including a device to confirm exhaled CO<sub>2</sub>. Capnography equipment, such as that required in the oral and maxillofacial surgery office, goes beyond what is found in most office-based surgical facilities.

Safety is paramount to pediatric anesthetic care. Therefore, the age of the patient and preoperative evaluation, difficulty of the planned procedure, as well as the training and experience of the practitioner guide the oral and maxillofacial surgeon as to the choice of technique and most suitable environment to provide safe anesthetic care. As demonstrated through decades of experience, the oral and maxillofacial surgery anesthesia team model has provided patients with safe, dependable, high quality specialty dental care.

# **AMERICAN SOCIETY OF DENTIST ANESTHESIOLOGISTS (ASDA)**

1. July 25, 2016 Letter from Steve Nguyen, DDS, ASDA President with Attachment
  - Periodontal Abstract, Volume 53, Number 2 – 2005 – Summary of the California Blue Ribbon Panel Report on Anesthesia



**American Society of  
Dentist Anesthesiologists**

**RECEIVED**

**JUL 26 2016**

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abrown@asdahq.org

July 25, 2016

Steven G. Morrow, DDS, MS  
President  
Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Dear Dr. Morrow:

The American Society of Dentist Anesthesiologists (ASDA) would like to thank the Dental Board of California for the invitation to provide comments to the California dental anesthesia issues surrounding the proposed AB2235, otherwise known as "Caleb's Law."

The ASDA is in accord with the California Society of Anesthesiologists' recommendation, as stated by Dr. Zakowski's letter to the Dental Board of California. The ASDA supports limiting deep sedation and general anesthesia to the most qualified providers. We also concur with Dr. Zakowski that the foundation for safe anesthesia practice is adequate training and continued training.

Few people outside of dentistry are aware of the wide range of anesthesia training across the dental profession: Dentist anesthesiologists, oral and maxillofacial surgeons, pediatric dentists, dentists with sedation training, and dental assistants and auxiliaries. In dentistry, the Commission on Dental Accreditation (CODA) develops and enforces standards that foster continuous quality improvements of dental and dental related educational programs.

Descriptions of CODA accredited programs are illustrated below (taken from CODA website and Standard):

- **Dental Anesthesiology:** These educational programs are designed to train the dental resident, in the most comprehensive manner, to use pharmacologic and non-pharmacologic methods to manage anxiety and pain of adults, children, and patients with special care needs undergoing dental, maxillofacial and adjunctive procedures, as well as to be qualified in the diagnosis and non-surgical treatment of acute orofacial pain and to participate in the management of patients with chronic orofacial pain.

*Improving Access to Care for Dental Patients and Their Dentists*

4411 Bee Ridge Road, #172 ■ Sarasota, FL 34233 ■ (phone) 312.624.9591 ■ (fax) 773.304.9894 ■

www.asdahq.org

CODA Standard 2-6: The following list represents the minimum clinical experiences that **must** be obtained by each resident in the program: Eight hundred (800) total cases of deep sedation/general anesthesia to include one hundred and twenty five (125) children aged *seven (7) and under*. Standard 2-7: General anesthesia experience/anesthesia service must include, at a minimum, a total of twenty-four (24) months over a thirty-six (36) month period **must** be devoted exclusively to clinical training in anesthesiology, of which a minimum of six (6) months are devoted to dental anesthesiology.

- Oral and Maxillofacial Surgery: Oral and maxillofacial surgery is the specialty of dentistry which includes the diagnosis, surgical and adjunctive treatment of diseases, injuries and defects involving both the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial region.

CODA Standard 4-3.1: Anesthesia Service: The assignment **must** be for a minimum of 5 months, should be consecutive and one of these months should be dedicated to pediatric anesthesia. The resident **must** function as an anesthesia resident with commensurate level of responsibility.

CODA Standard 4-9: The off-service rotation in anesthesia **must** be supplemented by longitudinal and progressive experience throughout the training program in all aspects of pain and anxiety control. The outpatient surgery experience must ensure adequate training to competence in general anesthesia/deep sedation for oral and maxillofacial surgery procedures on adult and pediatric patients. This includes the competence on managing the airway.

CODA Standard 4-9.1: The cumulative experience of each graduating resident **must** include administration of general anesthesia/deep sedation to a minimum of 300 patients. A minimum of 150 of these cases must be ambulatory anesthetics for oral and maxillofacial surgery. A minimum of 50 of the 300 patients must be pediatric (*18 years of age or younger*).

- **Pediatric Dentistry:** Pediatric Dentistry is an age-defined specialty that provides both primary and comprehensive preventive and therapeutic oral health care for infants and children through adolescence, including those with special health care needs. Pediatric dentists are dedicated to improving the oral health of infants, children, adolescents and patients with special health care needs.

CODA Standard 4-6: Clinical experiences in behavior guidance **must** enable students/residents to achieve competency in patient management using behavior guidance: A. Experiences must include infants, children and adolescents including patients with special health care needs, using: 1) Non-pharmacological techniques. 2) Sedation; and 3) Inhalation analgesia. B. Students/Residents **must** perform adequate patient encounters to achieve competency: 1) Students/Residents **must** complete 20 nitrous oxide analgesia patient encounters as primary operator; and 2) Students/Residents **must** complete a minimum of 50 patient encounters in which sedative agents other than nitrous oxide. The agents may be administered by any route. All sedation cases **must** be completed in accordance with the recommendations and guidelines of AAPD/AAP, the ADA's *Teaching of Pain Control and Sedation to Dentists and Dental Students*, and relevant institutional policies.

- **Dentists with Moderate Sedation Permit:** Currently, the American Dental Association (ADA) is revising its ADA's *Teaching of Pain Control and Sedation to Dentists and Dental Students*. The un-revised Standard: To administer moderate sedation, the dentist must demonstrate competency by having have successfully completed: A. 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 B. An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines.

The practice mode in which dental anesthesia services are delivered also varies widely across dentistry and dental settings. Dentist anesthesiologists practice primarily as independent anesthesia providers congruent with their physician-based training model and standards. In contrast, nearly all oral and maxillofacial surgeons practice the operator-anesthetist mode in providing general anesthesia and oral surgery simultaneously. The majority of other dentists primarily perform minimal or moderate sedation also as operator anesthetists.

Further, the ASDA supports current AAP-AAPD guidelines on the training and personnel guidelines for deep sedation and general anesthesia. Specifically, the recommendation of prescribed by the AAP-AAPD where

During deep sedation, there **must** be one person whose only responsibility is to 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 skilled to rescue a child who has 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. The definition of a pediatric patient, for intents and purposes, is any individual below or at the age of 18 years.

The ASDA also recommends that the Dental Board of California explicitly follow the recommendations of the Blue Ribbon Panel convened to thoroughly examine dental anesthesia within the State of California. The very first recommendation by the Blue Ribbon Panel was to establish a Dental Board-sponsored or independent "Anesthesia Review Committee" composed of a multidisciplinary panel that included dentist and physician anesthesiologists, general dentists, pediatric dentists, periodontists, oral surgeons, and other healthcare professionals. This recommendation has not been initiated from the time of the 2005 report (*see attached*).

The ASDA recommends that the California statutes and regulations be updated to delete the archaic terms "conscious sedation" and "anxiolysis" to avoid any ambiguity with current and accepted American Dental Association and American Society of Anesthesiologists' terms describing the continuum of sedation and anesthesia. Additionally, the statutes and regulations must be revised to conform to current training standards and educational requirements of CODA and ADA.

Dental Board of CA Letter  
Page 5  
July 25, 2016

Removal of one year training requirements for general anesthesia permits must be revised to accurately reflect the current 36 month, CODA-accredited standards for dental anesthesiology residency programs.

The ASDA explicitly recommends, for the purpose of longitudinal data collection and outcomes based research in patient safety, that the Dental Board of California begin to collect the following information regarding any 1680(z) reports from practitioners and the subsequent investigations that follow:

- a) Patient age and intended procedure
- b) Medical history and pertinent co-morbidities
- c) Training of practitioner and auxiliaries (if applicable)
- d) Medications, dosages, and techniques used in the conduct of the anesthetic
- e) Intended level of sedation or anesthesia
- f) Intervening actions to rescue the patient
- g) Conclusions and determinations made by the Dental Board of CA.

In closing, the American Society of Dentist Anesthesiologists would like to thank the Dental Board of California and the California Legislature for their continuing efforts to improve the safe delivery of office-based anesthesia services to the citizens of California.

Sincerely,



Steve Nguyen, DDS  
ASDA President

Enclosure

## Summary of the California Blue Ribbon Panel Report on Anesthesia

### Abstract

At the request of the Dental Board of California, a panel reviewed mortality data from the Dental Board, lawsuits from a major California malpractice insurance company, anesthesia regulations from other states, and the published scientific literature. In California between 1991 and 2000, there were 12 deaths related to general anesthesia permits, 0 deaths related to conscious sedation permits, and 8 deaths related to nonpermit holders (four deaths with oral sedation in children and four deaths with local anesthesia alone). The panel was concerned about the increased use of repeated oral or sublingual doses of sedatives and recommended a certificate process. The panel recommended a standing committee to access significant anesthesia/sedation-related misadventures and to determine how such mishaps could be prevented. The data reviewed and recommendations made are summarized in this report.

The purpose of the panel was to perform a comprehensive review of all aspects of dental anesthesia and sedation, then make recommendations to the Dental Board that would potentially benefit the citizens of California.

The panel reviewed all pertinent state laws and regulations pertaining to the delivery of general anesthesia and sedation services by dentists in California.<sup>1,2</sup> In performing this review, the panel also considered guidelines and data from several other organizations.<sup>3-14</sup> The panel used an evidence-based approach in making recommendations for changes and improvements in existing state regulations and procedures pertaining to anesthesia and sedation for dentistry in California. As a result of this review, the panel recommended a series of actions it believed would improve the health and safety of Californians.

### Recommendations of the Blue Ribbon Panel on Anesthesia

#### ANESTHESIA REVIEW COMMITTEE

The panel recommends that an Anesthesia Review Committee be established as a standing committee, either of the Dental Board or as an independent body, to assist the profession and public in all areas pertaining to anxiety and pain control in dentistry. This committee would seek access to data on all significant anesthesia/sedation-related misadventures. The committee would evaluate cases with respect to how such mishaps might be prevented in the future. The committee could also function as a sounding board for anesthesia difficulties and issues that do not formally reach the attention of the Dental Board. It is the hope of the panel that committee feedback would improve anesthesia/sedation practices in private dental offices much as quality control measures improve patient care in hospitals and related institutions.

#### IN-OFFICE EXAMINATIONS

Panel members reported inconsistencies in how in-office evaluations are performed for conscious sedation and general anesthesia permits. In particular, two issues were found to deserve attention from the Dental Board. First, defined criteria should be established with regard to proper emergency manage-

\* Member, Blue Ribbon Panel on Anesthesia

ment. A checklist of required and permissible actions by permit level would be most helpful in providing some standardization to the examination process. Another useful suggestion is to require all permit examinees to give the Dental Board or its examination surrogate a list of emergency medications maintained by the examinee prior to the exam. This information would be most helpful to examiners in evaluating the appropriateness of an examinee's response to a simulated emergency (e.g., correct dosage).

#### BUSINESS AND PROFESSIONS CODE

The panel has several suggestions for modifying the *Business and Professions Code*. Recognizing that none of these suggestions requires immediate attention, except for a proposed new article dealing with oral conscious sedation in adults (described below under Adult Oral Sedation), the most opportune time for implementing these changes might be during the sunset review process.

#### CODE OF REGULATIONS

Numerous changes pertaining to general anesthesia, conscious sedation, and oral sedation were suggested in the *California Code of Regulations*. The definition of conscious sedation should be modified to make it in line with that of the American Dental Association. Changes also reflect the opinion of the panel that more rigorous physical evaluation and recording of vital signs, as recommended by many dental and anesthesia groups, would improve patient safety without adversely affecting access to care.

#### ORAL CONSCIOUS SEDATION

In recent years, increasing numbers of dentists have begun to use sedative regimens recommended by a group known as DOCS.<sup>15</sup> These techniques of sedative drug administration by repeated oral and/or sublingual doses at intervals that are often shorter than the time for peak effect of the previous dose are a nontraditional approach to conscious sedation. The panel found no published data available to evaluate the safety or efficacy of this form of sedation.

The panel feels that oral sedatives (with or without inhalation of nitrous oxide and oxygen) used traditionally in adults to produce anxiolysis should remain exempt from oral sedation regulations when the total dosage administered in a single dental appointment is less than or equal to the single maximum recommended dose that can be prescribed for home use. Otherwise, the dentist wishing to use oral conscious sedation in adults should obtain a certificate from the Dental Board in a manner currently required for oral conscious sedation in children. Ongoing monitoring of the safety of oral conscious sedation would include reports of adverse events made to the Dental Board and could then be used to assess the safety of this and other nontraditional approaches to oral conscious sedation.

#### ACTION NOT RECOMMENDED

In reviewing potential changes to existing anesthesia and sedation rules and regulations, the panel

#### Blue Ribbon Panel on Anesthesia

JOHN A. YAGIELA, DDS, PHD  
Chair

MICHAEL E. CADRA, DMD, MD  
California Association of Oral and Maxillofacial Surgeons

GARY H. CHAN, DDS  
California Dental Society of Anesthesiology

STUART I. GREEN, DDS  
California Association of Oral and Maxillofacial Surgeons

GARY KLUGMAN, DDS  
Representing the Dental Organization for Conscious Sedation

ROBERT L. MERIN, DDS, MS  
California Society of Periodontists

DAVID ROTHMAN, DDS  
California Society of Pediatric Dentists

STANLEY R. SURABIAN, DDS, JD  
California Dental Association

LARRY TRAPP, DDS, MS  
California Society of Dentist Anesthesiologists

BRUCE VALENTINE, DDS  
California Dental Association

used an evidence-based approach. The panel reviewed anesthesia-related deaths in California<sup>10</sup> since 1991 and found the following:

General anesthesia permits	12 deaths
Conscious sedation permits	0 deaths
No permits	4 deaths with oral sedation in children
	4 deaths with local anesthesia alone

Data from The Dentists Insurance Company<sup>11</sup> for conscious sedation providers were also available for the study period, which identified four claims resulting in indemnity payments. These claims involved two patients not being adequately escorted when walking, phlebitis at the intravenous site, and an alleged allergic reaction.

The panel was asked to consider the desirability of requiring automated external defibrillators (AEDs) in conscious-sedation provider offices. Accordingly, the panel reviewed a recent article entitled "Cardiac arrest in medical and dental practices: implications for automated external defibrillators."<sup>16</sup> The panel agreed with the authors that "It would appear that there are too few cardiac arrests in dental practices and other medical specialties to justify their routine placement at this time." Moreover, in reviewing the available dental literature on conscious sedation, the panel could not find any death that would have been avoided by use of an AED. This finding, consistent with the aforementioned mortality data in California, is understandable since conscious sedation does not promote ventricular arrhythmias directly, generally reduces the amount of local anesthetic (with epinephrine) required, and commonly decreases endogenous activation of the sympathetic nervous system.

In summary, the panel concluded that conscious-sedation patients were either at the same or lower risk for cardiac problems as patients receiving local anesthetics only, then decided not to recommend at this time that cardiac monitoring or AEDs be required for conscious-sedation providers.

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# **CALIFORNIA ACADEMY OF GENERAL DENTISTS (CAGD)**

1. October 12, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016



October 12, 2016

Dental Board of California  
2005 Evergreen St., Suite 1550  
Sacramento, CA 95815

Attn: Pediatric Anesthesia Subcommittee  
Re: California Academy of General Dentistry's Statement of the DBC's Review of Sedation Guidelines

The California Academy of General Dentistry (CAGD) appreciates being included in the Dental Board of California's review of the regulation of Deep Sedation and General Anesthesia for pediatric dental patients. The DBC has gone to great lengths to solicit input from virtually every group of providers involved in delivering sedation to pediatric dental patients and we want to acknowledge that effort and say, "Thank you."

The California Academy of General Dentistry feels that the current guidelines published by the American Academy of Pediatric Dentistry satisfy our opinions on training, personnel, and monitoring requirements for deep sedation and general anesthesia provided to pediatric patients in dental offices.

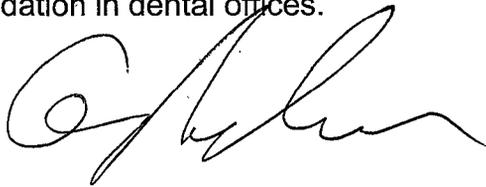
CAGD agrees with making the use of capnography mandatory for sedation when the intended level of sedation is deep sedation or general anesthesia. However, for adult moderate sedation we feel that the use of a precordial stethoscope should carry equal weight to capnography and the choice should be up to the practitioner delivering the sedation. There should not be any language suggesting a preference for capnography in moderate sedation.

Where CAGD feels there could be improvements in how California regulates the use of sedation for all dental patients is in requiring periodic completion of a high fidelity course in advanced airway management by practitioners and support staff that provide moderate sedation, whether delivered parenterally or enterally.

The primary departure of CAGD with the proposed workgroup consensus has to do with potentially having only one permit for adult moderate sedation. The California system has recognized that purely enterally administered moderate sedation is different than

parenterally administered moderate sedation. The vast majority of general dentists who provide moderate sedation do so under the enteral certification and training. There are significant differences in skill sets, training programs, equipment needs, patient management for induction and recovery, and drug distribution and metabolism concerns for enteral and parenteral sedation. We feel that requiring the vast majority of general dentists who provide adult moderate sedation under the purely enteral technique will be dissuaded from continuing to provide this service if they are required to have training equal to that required for parenteral moderate sedation (demonstrating intravenous sedation cases) and this will have a significant negative impact on access to care for those patients who require moderate sedation for dental care. Furthermore, we see no evidence that the existing differentiation of enteral and parenteral moderate sedation puts the public's safety at risk.

In addition, it is difficult to assess the morbidities associated with delivery of sedation in dental offices because of the lack of accurate numbers of sedations delivered. Reporting of total sedations provided by each permitted/certificated provider at the time of their permit/certificate renewal would allow a more objective assessment of the safety of sedation in dental offices.

A handwritten signature in black ink, appearing to read 'Guy E. Acheson', written in a cursive style.

Guy E. Acheson, DDS, MAGD  
Past-President  
California Academy of General Dentistry

# **CALIFORNIA ASSOCIATION OF NURSE ANESTHETISTS (CANA)**

1. November 14, 2016 Letter and Attachments



# California Association of Nurse Anesthetists, Inc.

## CRNAs: The solution for a healthier California

November 14, 2016

Steven G. Morrow  
President, Dental Board of California  
2005 Evergreen St., Suite 1550  
Sacramento, CA 95815

Dear Dr. Morrow,

The California Association of Nurse Anesthetists (CANA) appreciates the invitation to provide comment to the Dental Board of California regarding dental office anesthesia. CANA is the professional, not-for-profit organization representing Certified Registered Nurse Anesthetists (CRNAs) in California; our ongoing mission is to advance patient safety and foster access to the highest quality anesthesia care. Nurse anesthetists have provided anesthesia services in the U.S. for over 150 years and administer over 40 million anesthetics annually in every setting anesthesia is delivered. Currently, over 2,300 licensed CRNAs provide safe, high quality services to Californians, especially in rural and medically underserved communities.

We would like to thank the Dental Board of California for their leadership in analyzing the dental anesthesia issues raised by Senator Hill. We also agree that an evidence-based approach is key to identification of issues and solutions.

CRNAs are in the unique position to be able to help fulfill the need for safe and effective anesthesia services by California dentists. The superb safety record of CRNAs is underscored by a growing body of independent research in top ranked healthcare journals as well as the continued reduction in both CRNA liability insurance premiums and premiums for dental providers working with CRNAs (TDIC, 2014). There is also a significant cost-savings to patients, dental providers and health care systems such as Medi-Cal, because CRNAs provide high quality services at a reduced cost. Please find attached reports of CRNA safety and quality.

Many other states are helping their dental providers increase access through statutory and regulatory language that does not serve as a disincentive toward the use of safe and qualified CRNA providers, or limit access to needed care (e.g. Oregon; Washington).

We hope the attached documents will suggest further input into the utilization of CRNAs to increase access to safe dental anesthesia services in California. CANA looks forward to discussing this important issue to benefit Californians in the access, delivery, and safety of dental anesthesia services.

Sincerely,

Maricel Isidro-Reighard, DNAP, CRNA  
President

cc: Karen Fischer, Executive Officer, Dental Board of California  
Honorable Jerry Hill  
Honorable Tony Thurmond

*President*  
Maricel Reighard, DNAP, CRNA

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*Association Manager*  
Mary Davis, BS

*Mission Statement*  
CANA - the leader in advancing patient safety, fostering access to the highest quality anesthesia care, and supporting the profession of nurse anesthesia in California.

By Brian Dulisse and Jerry Cromwell

# No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians

DOI: 10.1377/hlthaff.2008.0966  
HEALTH AFFAIRS 29,  
NO. 8 (2010): 1469-1475  
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The People-to-People Health  
Foundation, Inc.

**ABSTRACT** In 2001 the Centers for Medicare and Medicaid Services (CMS) allowed states to opt out of the requirement for reimbursement that a surgeon or anesthesiologist oversee the provision of anesthesia by certified registered nurse anesthetists. By 2005, fourteen states had exercised this option. An analysis of Medicare data for 1999–2005 finds no evidence that opting out of the oversight requirement resulted in increased inpatient deaths or complications. Based on our findings, we recommend that CMS allow certified registered nurse anesthetists in every state to work without the supervision of a surgeon or anesthesiologist.

Brian Dulisse is a health economist at the Research Triangle Institute, in Waltham, Massachusetts.

Jerry Cromwell (jcromwell@rti.org) is a senior fellow in health economics at the Research Triangle Institute.

**S**urgical anesthesia in the United States is administered by both anesthesiologists and certified registered nurse anesthetists (CRNAs). For almost 150 years, these nurses were the dominant providers of anesthesia services, but by 1986 the rapid influx of physicians into the specialty resulted in a greater number of anesthesiologists who practiced alone or in a team arrangement with nurse anesthetists.<sup>1,2</sup> Even so, 37,000 certified registered nurse anesthetists provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals.<sup>3</sup>

## Background On The Issue

Until recently, the Centers for Medicare and Medicaid Services (CMS) reimbursement rules for anesthesia providers prohibited payments to certified registered nurse anesthetists who administered anesthesia in the absence of physician supervision. This supervision could be provided by either an anesthesiologist or the surgeon,<sup>4</sup> although surgeons now largely defer to anesthetists at the operating table during the administration of anesthesia and immediately after surgery.

In December 1997, CMS published a proposed rule to, in the words of the final version, “let State law determine which professionals would be permitted to administer anesthetics, and the level of supervision required for practitioners [seeing Medicare patients] in each category.”<sup>5</sup> The agency later reported basing its decision on a “lack of evidence to support...[the] requirement for [surgeon or anesthesiologist] supervision of Certified Registered Nurse Anesthetists.”<sup>6</sup>

It should be noted that except for the extra training that anesthesiologists receive in medical school and residency in specialties other than the direct provision of anesthesia, both certified registered nurse anesthetists and anesthesiologists undergo similar classroom and clinical training in anesthesia care.<sup>7</sup>

Anesthesiologists opposed the proposed rule, arguing that they provide anesthesia care superior to that of certified registered nurse anesthetists,<sup>8</sup> even though adverse events related to anesthesia are rare regardless of the provider.<sup>5,9-11</sup> The final CMS rule of November 2001 maintained physician supervision of nurse anesthetists “unless the governor of a State, in consultation with the State’s Boards of Medicine & Nursing, exercises the option of exemption from this requirement” through a written request

signed by the governor.<sup>6</sup>

As of 1998, eighteen states permitted certified registered nurse anesthetists to practice independently of any physician,<sup>12</sup> although for reimbursement purposes, Medicare still required physician supervision at least by the surgeon if not by an anesthesiologist.<sup>6</sup> By 2005, fourteen governors in mostly rural states<sup>13</sup> had submitted written requests to Medicare and opted out of the supervised anesthesia requirement. Solo practice by certified registered nurse anesthetists is especially important in rural areas, where anesthesiologists are in short supply.

This article explores whether the change in CMS policy toward anesthesia supervision had a negative impact on patient outcomes. We begin by examining the absolute level and time trends of adverse patient outcomes within the states that opted out and those that did not.

It is important to note, however, that differences in these gross measures do not constitute prima facie evidence of a response to the policy change. The act of opting out of the supervision requirement does not necessarily imply any changes in the actual practice of anesthesia within any hospital in a state. The opt-out exemption does not mandate that hospitals allow certified registered nurse anesthetists to provide anesthesia without supervision by a surgeon or an anesthesiologist. It means only that Medicare would not require such supervision as a condition of reimbursement.

Nonetheless, if patient outcomes are unchanged after a state has opted out, as we show to be the case, then the requirement that governors petition CMS to exempt certified registered nurse anesthetists from physician supervision is unnecessary and should be rescinded.

### Study Data And Methods

For the opt-out policy to affect outcomes, two conditions must be fulfilled. First, the opt-out policy must result in a shift in anesthesia arrangements. If the policy change does not affect anesthesia arrangements, then it alone could not affect patient outcomes.

Second, there must be some systematic difference in the outcomes associated with the different anesthetist arrangements. If the outcomes across the different arrangements are the same, then even if the policy change affected anesthesia arrangements, it would not affect overall patient outcomes in opt-out states.

We therefore examined whether there was a material change in the provision of anesthesia services away from anesthesiologists in favor of certified registered nurse anesthetists and, separately, whether there is evidence of different

outcomes associated with the two types of anesthetists. In examining outcomes, we first determined whether case-mix complexity differed between opt-out and non-opt-out states and by anesthetist training.

**DATA SOURCE** To address the research questions, we used the 5 percent Medicare Inpatient (Part A) and Carrier (Part B) Medicare limited data set files for 1999–2005. The files include all Part A claims from facilities and Part B claims from physicians and suppliers for a 5 percent sample of beneficiaries.

Given the distribution of states opting out of physician supervision at different times, we used seven calendar years of Medicare 5 percent data. This gives three full years of post-opt-out data for six of fourteen opt-out states and at least two full years of data for eleven opt-out states. Any deleterious effects of shifts to more anesthesia by unsupervised nurse anesthetists should be seen soon after a state opts out because more anesthesia complications would occur during the patient's inpatient hospital stay.

We abstracted Part A claims for each study year for all admissions in all Medicare surgical diagnosis-related groups (DRGs), which were 98,000–114,000 claims per year. Procedures taking place in ambulatory surgery centers were excluded because of uncertainty in measuring mortality or complications in those cases.

Because the 5 percent limited data sets do not contain the patient's measurement on the physical status scale of the American Society of Anesthesiologists, we merged onto the claims the anesthesia base units for the most complex anesthesia procedure (*International Classification of Diseases, Ninth Revision, or ICD-9*) code for each admission. For example, the base unit for a thyroid biopsy is 3; for cardiac catheterization, 8; and for tracheobronchial reconstruction, 18.<sup>14</sup>

We used the two Part B procedure modifier fields to identify three anesthesia provider arrangements: anesthesiologists practicing solo, certified registered nurse anesthetists practicing solo, and team anesthesia in which anesthesiologists supervise or direct nurse anesthetists. If a modifier on either a nurse anesthetist or an anesthesiologist claim indicated supervision or direction of the nurse anesthetist, then the anesthesia category was defined as team anesthesia.

Any nonteam hospitalization with a certified registered nurse anesthetist claim but no anesthesiologist claim was coded as certified registered nurse anesthetist solo. Finally, any procedure with an anesthesiologist claim not already characterized as team or certified registered nurse anesthetist solo was considered anesthesiologist solo.

Because all date fields in the data are aggreg-

gated to the quarter level, it was not possible to accurately link inpatient Part B anesthesia claims to specific hospitalizations for patients who had multiple hospitalizations in the same quarter. Therefore, we excluded patients with more than one hospitalization in a quarter.

The resulting seven-year pooled file contained 741,518 surgical discharges. Roughly one-third did not have any anesthetist claim. The majority of cases without anesthesia bills were for procedures that often do not require an anesthetist, such as percutaneous transluminal coronary angioplasty, pacemaker lead inserts, sigmoidoscopies, bronchoscopies, diagnostic catheterizations, and endoscopic surgeries.

Hospitalizations without a Part B anesthesia claim were excluded unless a surgical procedure took place in a Medicare "pass-through" hospital. In these hospitals, claims for services by nurse anesthetists are rolled into ("passed through") the Part A hospital claims. Therefore, observations from these hospitals were assigned to the certified registered nurse anesthetist solo category.

Hospitalization claims were also deleted if a Part B inpatient anesthetist claim was present in the previous quarter for the same beneficiary with no admission claim in that quarter. We assumed in those cases that the anesthetist filed his or her claim earlier than the hospital's claim for the same admission.

This left us with 481,440 hospitalizations for analysis, of which 412,696 were in non-opt-out states and 68,744 were in opt-out states. Of the latter, 41,868 hospitalizations occurred before the state had opted out.

**ANALYTIC METHODS** We analyzed two outcomes measures: inpatient mortality and complications. Mortality is reported on the Medicare discharge abstract. To measure possible anesthesia complications, we identified seven relevant patient safety indicators developed by the Agency for Healthcare Research and Quality:<sup>15</sup> complications of anesthesia (patient safety indicator 1); death in low-mortality diagnoses (indicator 2); failure to rescue from a complication of an underlying illness or medical care (indicator 4); iatrogenic pneumothorax, or collapsed lung (indicator 6); postoperative physiologic and metabolic derangements, or physical or chemical imbalances in the body (indicator 10); postoperative respiratory failure (indicator 11); and transfusion reaction (indicator 16). (Descriptions of each complication are provided in the online Appendix.)<sup>16</sup>

Each of these complications occurred only infrequently. Therefore, we used a single no/yes indicator (0 for no, 1 for yes) to show if any one of them occurred on a single admission.

State-level analyses cannot completely answer the question of whether allowing certified registered nurse anesthetists to provide anesthesia without supervision exposes patients to meaningful additional risks. By focusing on individual hospitalizations, however, it is possible to use Medicare claims to isolate any impact of opting out by anesthesia provider type.

It is possible that hospital managers systematically refer more difficult procedures to anesthesiologists and less difficult ones to nurse anesthetists. We therefore controlled for patient characteristics and procedure complexity.

We compared inpatient mortality rates between opt-out and non-opt-out states, stratifying by year and anesthesia arrangement. Anesthesiologists practicing alone were involved in more complex surgical procedures than certified registered nurse anesthetists practicing alone. Therefore, we adjusted anesthesiologist solo mortality rates by applying to the anesthesiologist solo group the nurse anesthetist case-mix for surgeries that the two providers had in common.

Frequency weighting was done at the diagnosis-related group level for each state, separately. T-tests were used to measure the differences in the adjusted mortality rates between opt-out and non-opt-out states within each stratum.

We also estimated logistic regressions using indicators for state opt-out status before and after opt-out and for anesthesia provider, to determine the effects of these variables on the probability of mortality and complications. Also included were the patient's age, sex, and race, along with year indicators and the procedure's anesthesia base units, to measure its complexity. The model was applied to surgical admissions pooled across all seven years in all opt-out and non-opt-out states.

## Results

**WHO PROVIDES ANESTHESIA** We examined whether a state's decision to opt out of the supervision requirement resulted in different anesthesia arrangements. In our sample, the certified registered nurse anesthetist solo group provided anesthesia in 21 percent of surgeries in opt-out states and about 10 percent in non-opt-out states (Exhibit 1). Solo provision of anesthesia by nurse anesthetists increased over time in opt-out and non-opt-out states.

Although the absolute increase was roughly five percentage points in both opt-out and non-opt-out states, the proportional increase was larger in non-opt-out states (71 percent) than in opt-out states (28 percent). The growth of the solo share by certified registered nurse anesthetists in opt-out states came at the expense of

EXHIBIT 1

Percentages Of Surgical Anesthetics By Anesthesia Provider, In States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	17.6	40.7	41.7	7.0	47.3	45.8
2000	18.4	42.5	39.1	8.3	46.7	45.0
2001	20.2	42.0	37.8	9.2	45.3	45.5
2002	22.2	41.7	36.1	9.9	44.7	45.4
2003	22.9	42.5	34.7	10.3	43.7	46.0
2004	23.4	42.0	34.6	11.3	42.3	46.5
2005	22.5	42.8	34.7	12.0	41.5	46.5
1999–2005	21.0	42.0	37.0	9.7	44.5	45.8

**SOURCE** Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** Not all totals equal 100 percent because of rounding. CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together.

team anesthesia, while in the non-opt-out states it came at the expense of anesthesiologist solo anesthesia.

**DIFFERENCES BY PATIENT TYPE OR PROCEDURE**

Before comparing trends in outcomes, we examined whether the case-mix of certified registered nurse anesthetists and anesthesiologists differed by type of patient or procedure. Exhibit 2 shows patient characteristics as of 2005, stratified by anesthesia provider and state opt-out status. The figures have not been adjusted for the different diagnosis-related group surgical cases that are typical of the two types of anesthesia providers. With the exception of base units, the differences in patient characteristics between the certified registered nurse anesthetist solo and anesthesiologist solo groups, although statistically significant, were clinically minor and would not explain large differences in patient outcomes within opt-out and non-opt-out states.

With the exception of the prevalence of African American patients, the differences within provider groups across opt-out status were also

minimal.

In opt-out and non-opt-out states, the mean number of base units in the anesthesiologist solo group was about a full point higher than in the certified registered nurse anesthetist solo group ( $p < 0.05$ , or unlikely to be due to chance). This indicates that solo anesthesiologists were performing more complex or difficult procedures than the nurse anesthetist solo group. One might have expected higher relative complexity by nurse anesthetists practicing solo in opt-out states, given their higher proportion of cases.

However, many opt-out states are rural, and surgery and anesthesia in those states may be less complex overall than in more urban states. This is because patients with more difficult surgical procedures are referred to major urban hospitals with experienced surgical teams and technologies.

**OUTCOMES FOR PATIENTS** Given that the solo practice of nurse anesthetists did increase in opt-out states, we next determined whether there were any differences in patient outcomes by

EXHIBIT 2

Characteristics Of Anesthesia Patients In States That Did And Did Not Opt Out Of Physician Supervision, 2005

Characteristic	Opt-out states			Non-opt-out states		
	CRNA solo (n = 2,310)	MDA solo (n = 4,605)	Team (n = 3,736)	CRNA solo (n = 7,554)	MDA solo (n = 26,354)	Team (n = 29,511)
Age 75+	51%	48%	45%	44%	47%	44%
Male	41%	45%	44%	43%	45%	44%
African American	1%	2%	2%	8%	7%	11%
Base units <sup>a</sup>	7.2	8.3	7.6	7.2	8.4	7.6

**SOURCE** Authors' analysis of Medicare Parts A and B claims, 2005 limited data set. **NOTES** CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. All comparisons of CRNA solo with MDA solo are significant at the 95 percent confidence level. <sup>a</sup>Base units indicate the severity of the case; see text.

anesthesia arrangement. We started with mortality rates within each hospital for procedures that the two provider types had in common in opt-out and non-opt-out states.

In non-opt-out states, mortality rates for the three anesthesia arrangements followed a general downward trend throughout the seven-year period, from 3.1–3.5 percent to 2.2–2.8 percent (Exhibit 3). A general downward trend is also apparent in opt-out states. Of particular interest is the mortality trend for the certified registered nurse anesthetist solo group in opt-out states. The rate increased from 1999 to 2001—prior to the introduction of the opt-out provision—and decreased from 2001 to 2005. December 2001 was when the first state, Iowa, opted out of the supervision requirement.

**MULTIVARIATE ANALYSES** Exhibit 4 shows the results of the multivariate analyses for inpatient mortality and complications. It presents the odds ratios for each of the three provider groups in three different opt-out status conditions: non-opt-out states, opt-out states prior to opting out, and opt-out states after opting out. In addition to the provider group and opt-out status indicators, the model controlled for patients' age categories, sex, and race; anesthesia procedure base units; indicators for the ten highest-mortality diagnosis-related groups; and an annual time trend.

The reference group for the odds ratios for both mortality and complications was the anesthesiologist solo group in non-opt-out states. All eight comparison cells for mortality had odds ratios less than 1.0, which indicates that mortality occurred with lower probability in all other combinations of provider and opt-out status than it did with solo anesthesiologists in non-opt-out states (the differences are all significant at the 0.05 level). In opt-out states, there were no

statistically significant mortality differences between the periods before and after opting out.

Unlike mortality, complication rates did not differ between anesthesiologist and certified registered nurse anesthetist solo groups in non-opt-out states (Exhibit 4).<sup>17</sup> Yet, as with mortality, nurse anesthetists practicing solo in opt-out states had a lower incidence of complications (odds ratios were 0.798 before opting out and 0.813 after) relative to solo anesthesiologists in non-opt-out states. These differences were statistically significant for both time periods.

In opt-out states, complication rates for the nurse anesthetist solo group were essentially identical to those for the anesthesiologist solo group. The difference between complication rates for nurse anesthetist solo and team anesthesia was also not statistically different in opt-out states.

## Discussion

Linking the change in CMS reimbursement policy to changes in patient outcomes requires both that the proportion of surgical procedures for which certified registered nurse anesthetists alone provided anesthesia changed as a consequence of the policy change, and that the type of anesthesia provider affects the likelihood of in-hospital mortality or other adverse event. Our analysis does not support either of the two.

Instead, we found that from 1999 to 2005, the proportion of surgeries in which anesthesia was provided by nurse anesthetists with no anesthesiologist involvement increased by five percentage points in both opt-out and non-opt-out states. However, the rate of increase was nearly three times as great in non-opt-out states as in opt-out states because nurse anesthetist solo rates initially were lower in the former than in

### EXHIBIT 3

**Surgical Inpatient Mortality Rates (Per 100 Patients) By Anesthetist Arrangement, in States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005**

Year	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	1.76	3.45	2.92	3.10	3.50	3.19
2000	2.50	3.67	1.79	3.16	3.21	2.58
2001	3.01	2.80	1.94	3.54	3.68	3.19
2002	2.26	2.72	2.15	3.09	3.44	2.95
2003	2.49	2.39	2.01	3.21	3.58	2.86
2004	1.86	3.82	2.03	2.84	3.20	3.08
2005	2.03	1.32	1.45	2.34	2.76	2.20

**SOURCE** Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. MDA solo and team mortality rates are based on CRNA case-mix. Inpatient mortality is attributable to anesthesia and all other causes.

## EXHIBIT 4

## Likelihood Of Death And Complications From Anesthesia, For Different Combinations Of Anesthesia Provider Groups And States' Opt-Out Status: Odds Ratios

Anesthesia provider	Mortality			Complications		
	Non-opt-out states	Opt-out states		Non-opt-out states	Opt-out states	
		Before opting out	After opting out		Before opting out	After opting out
MDA solo	1.00	0.797 <sup>a</sup>	0.788 <sup>a</sup>	1.00	0.824 <sup>a</sup>	0.818 <sup>a</sup>
CRNA solo	0.899 <sup>a</sup>	0.651 <sup>a</sup>	0.689 <sup>a</sup>	0.992	0.798 <sup>a</sup>	0.813 <sup>a</sup>
Team	0.959 <sup>a</sup>	0.708 <sup>a</sup>	0.565 <sup>a</sup>	1.067 <sup>a</sup>	0.927	0.903

**SOURCE** Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** MDA solo is anesthesiologist without certified registered nurse anesthetist (CRNAs). CRNA solo is CRNA without anesthesiologist. Team is anesthesiologist and CRNA working together. The model includes year, base units, diagnosis-related groups, and the patient's age, race, sex. Complications include patient safety indicators 1, 2, 4, 6, 10, 11, and 16 of the Agency for Healthcare Research and Quality; see text. <sup>a</sup>Odds ratio is significantly different from 1 for MDA solo ( $p = 0.05$ ).

the latter. This implies that the increase in the certified registered nurse anesthetist solo share in opt-out states cannot be ascribed wholly, if at all, to the change in the CMS supervision policy.

Whatever forces are driving the growing share of nurse anesthetist solo cases, they appear to be different in the fourteen opt-out states than in the non-opt-out states. In opt-out states, the seven-percentage-point decline in team anesthesia resulted in more solo practice by both types of anesthetists. Anesthesiologists practicing solo explained about one-third of the decline in team anesthesia, and nurse anesthetists practicing solo accounted for the other two-thirds. Elsewhere in the country, team anesthesia rates were constant.

Despite the shift to more anesthetics performed by nurse anesthetists, no increase in adverse outcomes was found in either opt-out or non-opt-out states. In fact, declining mortality was the norm. Moreover, the mortality rate for the nurse anesthetist solo group was lower than for the anesthesiologist solo group in opt-out states both before and after opting out, although the difference was statistically significant only before the state opted out.

These results do not support the hypothesis that allowing states to opt out of the supervision requirement resulted in increased surgical risks to patients. Nor do the results support the claim that patients will be exposed to increased risk as a consequence of more nurse anesthetists' practicing without physician supervision.

We did find that case-mix complexity was different for the two types of providers. Anesthesia base units for procedures in which anesthesiologists practiced solo were a full point higher than for procedures in which certified registered nurse anesthetists worked alone.

Although base units might not completely de-

scribe the complexity of either surgical or anesthetic procedures, base units were associated with a statistically greater mortality risk in our multivariate model. We estimate that each one-point increase in procedure base units is associated with a 7 percent higher mortality risk.

To this extent, base units can capture a sizable part of the complexity and risk of the procedures. Moreover, we believe that using additional measures of complexity would not qualitatively change our results.

There were clearly differences between the opt-out and non-opt-out states that were not a consequence of their opt-out status. With the exception of the proportion of African American patients, it does not appear that these differences were primarily caused by patient characteristics such as sex and age.

Yet opt-out states had lower mortality and complication rates than non-opt-out states, even prior to opting out. This suggests that some unobserved difference existed between opt-out and non-opt-out states, perhaps related to the fact that opt-out states were more rural and tended to be located in the West and Midwest.

In any case, the policy conclusions supported by this study remain valid. In opt-out states, mortality and complication rates for the certified registered nurse anesthetist solo group did not vary greatly between the period before opting out and the period after. That means that our data do not support the hypothesis that patients are exposed to increased surgical risk if nurse anesthetists work without physician supervision.

### Policy Recommendations

Our analysis of seven years of Medicare inpatient anesthesia claims suggests that the change in CMS policy allowing states to opt out of the

physician supervision requirement for certified registered nurse anesthetist reimbursement was not associated with increased risks to patients. In particular, the absolute increase in the provision of anesthesia by unsupervised nurse anesthetists in opt-out states was virtually identical to the increase in non-opt-out states, and the proportional increase was smaller in opt-out states.

This lends no support to the belief that a meaningful shift in provider shares occurred as a consequence of the policy change. Similarly, our analysis found no evidence to suggest that there is an increase in patient risk associated with anesthesia provided by unsupervised certified registered nurse anesthetists.

Both a change in the proportion of anesthesia provided by the different groups—nurse anesthetists alone, anesthesiologists alone, and

nurse anesthetists and anesthesiologists working in teams—and a difference in the outcomes of the different groups are necessary to conclude that the change in CMS policy led to changes in patient safety. Because our data provide no evidence to support either of these conditions, we conclude that patient safety was not compromised by the opt-out policy.

We recommend that CMS return to its original intention of allowing nurse anesthetists to work independently of surgeon or anesthesiologist supervision without requiring state governments to formally petition for an exemption. This would free surgeons from the legal responsibility for anesthesia services provided by other professionals. It would also lead to more-cost-effective care as the solo practice of certified registered nurse anesthetists increases. ■

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# Scope of Practice Laws and Anesthesia Complications

## *No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications*

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**Background:** Scope of practice (SOP) laws governing Certified Registered Nurse Anesthetists (CRNAs) vary by state and drive CRNA practice and reimbursement.

**Objective:** To test whether the odds of an anesthesia complication vary by SOP and delivery model (CRNA only, anesthesiologist only, or mixed anesthesiologist and CRNAs team).

**Methods:** Anesthesia claims and related complications were identified in a large commercial payor database, including inpatient and ambulatory settings. Logit regression models were estimated by setting to determine the impact of SOP and delivery model on the odds of an anesthesia-related complication, while controlling for patient characteristics, patient comorbidities, procedure and procedure complexity, and local area economic factors.

**Results:** Overall, 8 in every 10,000 anesthesia-related procedures had a complication. However, complications were 4 times more likely in the inpatient setting (20 per 10,000) than the outpatient setting (4 per 10,000). In both settings, the odds of a complication were found to differ significantly with patient characteristics, patient comorbidities, and the procedures being administered. The odds of an anesthesia-related complication are particularly high for procedures related to childbirth. However, complication odds were not found to differ by SOP or delivery model.

**Conclusions:** Our research results suggest that there is strong evidence of differences in the likelihood of anesthesia complications by patient characteristics, patient comorbidities, and the procedures

being administered, but virtually no evidence that the odds of a complication differ by SOP or delivery model.

**Key Words:** scope of practice, anesthesia complications, anesthesia delivery model, CRNA, anesthesiologist

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### BACKGROUND

Advance Practice Registered Nurses (APRNs) are an important resource to the health care system; however, barriers to full APRN practice limit the full utilization of the APRN workforce.<sup>1,2</sup> According to the 2008 APRN Consensus Model, APRN professional activities are overseen by state nursing boards, which determine their legal scope of practice (SOP).<sup>3</sup> Both the APRN Consensus Model and the Institute of Medicine expressed the value of APRNs being able to practice to the full extent of their training.<sup>3,4</sup>

Both Certified Registered Nurse Anesthetists (CRNAs) and anesthesiologists are trained to provide the full range of anesthesia-related care. CRNAs face barriers similar to other APRNs, and state SOP restrictions play a crucial role in how anesthesia is delivered.

The issue regarding CRNA SOP entails restrictive language specifying the extent of physician involvement in the delivery of anesthesia. A restrictive SOP for CRNAs is a scope containing a requirement for physician involvement (at facility level or in the state law). Examples of such restrictions include supervision, immediate presence, timely onsite consultation, and physically present and available on the premises. A nonrestrictive SOP is a scope containing no or minimal requirements for physician involvement. In this case, minimal involvement may come in the form of requirements for collaboration and/or direction.

The rationale for CRNA SOP restrictions often focuses on years of training and anesthesia quality outcomes. Several studies have compared anesthesia-related complications or mortality by anesthesia delivery model.<sup>5–9</sup> These studies explored the implications of anesthesia provider type on inpatient outcomes in subsets of the population, including Medicare beneficiaries or women of child-bearing age. With 1 exception,<sup>9</sup> the current literature suggests no difference in quality based on anesthesia provider type.<sup>5–8</sup> Nevertheless, many states still maintain restrictive CRNA SOP.

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## PURPOSE

The purpose of this study is to determine whether there are differences in anesthesia-related complications across delivery models and CRNA SOP among inpatients and outpatients of all ages in a commercial payor database. No existing studies have examined whether anesthesia complications are related to SOP laws. We test whether states with SOP laws allowing CRNAs to practice independently experience the same risk of anesthesia complications as states that require supervision or direction/collaboration. We also test whether risk varies across anesthesia delivery models, which include anesthesia delivered by CRNAs acting alone, anesthesiologists acting alone, and teams of anesthesiologists and CRNAs.

Past studies find that the incidence of anesthesia-related complications is very low. Power tests (available from the authors upon request) indicate that the sample must contain at least 1 million observations to detect an actual difference in the odds of a complication of 10% (or more) between 2 SOP classifications or 2 delivery models with a high degree of confidence (probability of a type II error of  $\leq 0.1$ ). Our 5.7 million observation database is over 5 times larger than the largest sample used in previous studies. It is national in scope, covers patients of both sexes and all age ranges, and contains procedures performed in all settings. By contrast, previous studies were limited to specific states or regions<sup>6-9</sup> or to Medicare patients,<sup>5</sup> and none have studied anesthesia-related complications in the outpatient setting.

## METHODS

### Study Sample

This study is based on 2011–2012 data from the Optum Research Database, a database of deidentified health care claims of individuals insured by United Healthcare, a major US health insurer, and other claims processed by Optum. Our database includes approximately 4.6 million covered lives associated with an anesthesia-related claim and 5.7 million anesthesia-related claims. Anesthesia-specific Current Procedural Terminology (CPT) codes (ie, 00100–01999) along with modifier fields were used to identify anesthesia claims. Place of service codes were used to classify outpatient, inpatient, and emergency room settings. The anesthesia base units (BU) identified by CMS corresponding to each anesthesia CPT code were attached to each claim.<sup>10</sup> BUs reflect procedure difficulty and skills necessary to perform a procedure; higher BUs reflect increasing complexity.<sup>10</sup>

Our database contains 5,740,470 anesthesia-specific procedures in 2011–2012. About 75% of them occurred in an outpatient setting (4,273,122) and the rest (1,467,348) were in the inpatient setting. The mean age of the study population was 52 and 60% of the patients were female. The average BUs for anesthesia procedures was 6.7 in the inpatient setting and 4.7 in the outpatient setting. Approximately 6% (355,103) procedures were administered in rural areas (Table 1).

### Key Variables

The dependent variable in the logit regression models described below is an indicator for whether the procedure had an anesthesia-related complication. The key explanatory

variables in these models are indicators for anesthesia delivery model and state SOP classification. Furthermore, to mitigate bias in the estimated effects of the key variables, the models controlled for (1) the patient's age and sex, (2) the patient's health as measured by 6 comorbidity indicators, (3) procedure and BUs, and (4) local area economic factors, including a rural indicator, local area poverty rate, and median income. Summary statistics for the key variables other than procedure are shown in Table 1. Procedures are discussed in more detail below.

### Anesthesia Delivery Model

Anesthesia delivery models were defined by the procedure modifiers on the claim (Supplementary Table 1, Supplemental Digital Content 1, <http://links.lww.com/MLR/B181>). Using these modifiers, 5 delivery models were identified: CRNA only, Anesthesiologist only, Medical Direction 1:1, Medical Direction 1:2–4, and Supervision 1:>4. The latter 3 models are characterized as “team” models where the notation 1:1, 1:2–4, and 1:>4 refer to the anesthesiologist-to-CRNA ratio (Supplementary Table 2, Supplemental Digital Content 1, <http://links.lww.com/MLR/B181>).

In both settings combined, the distribution of the anesthesia procedures by delivery model was as follows: 21.7% by CRNAs only, 49.9% by anesthesiologists only, 3.8% under Medical Direction 1:1, 24.4% under Medical Direction 1:2–4, and 0.3% under Supervision 1:>4. Table 1 shows that the distribution varies somewhat by setting, with relatively more outpatient procedures administered by CRNAs acting alone and relatively more inpatient procedures administered by anesthesiologists acting alone.

### State SOP Classification

CRNA SOP laws vary by state as well as by setting or facility type within the state. An analysis conducted by the AANA classified states into 3 categories: (1) supervision in state nursing or facility statutes, rules, or regulations; (2) direction/collaboration in state nursing or facility statutes, rules, or regulations; and (3) no supervision or direction in nursing or facility statutes, rules, or regulations. Table 2 displays AANA's classification of states by SOP.

“Supervision” SOP means supervision by a physician such as an anesthesiologist, but it can also be by another physician, typically a surgeon. Hence, in states that require “supervision” a CRNA-only delivery model is possible when, for example, the surgeon agrees to accept the responsibility of supervision. “Direction/collaboration” means that there must be an anesthesiologist involved at some level in the procedure. This can range from direction of the CRNA(s) by an anesthesiologist, but it can also mean that the CRNA is simply affiliated with an anesthesiologist practice, and collaborates with that practice. In this case, the “collaboration” does not necessarily imply that the anesthesiologist will be present for any part of the procedure. Finally, “no supervision” means that an anesthesiologist is not required to be involved in any part of the anesthesia procedure, nor is a physician required to accept supervisory responsibility for the CRNA. Note that none of the SOP categories necessarily define or eliminate the types of

**TABLE 1. Summary Statistics for Optum Data**

Variables	Inpatient (N = 1,467,348)		Outpatient (N = 4,273,122)	
	Mean	SD	Mean	SD
Complication	0.002	0.044	0.0004	0.021
Age 0–4	0.011	0.102	0.027	0.163
Age 5–14	0.016	0.124	0.034	0.181
Age 15–24	0.057	0.231	0.046	0.210
Age 25–34	0.198	0.398	0.069	0.253
Age 35–44	0.128	0.334	0.115	0.319
Age 45–54	0.113	0.316	0.189	0.391
Age 55–64	0.155	0.362	0.215	0.411
Age 65–74	0.158	0.364	0.179	0.383
Age 75–84	0.117	0.321	0.102	0.302
Age 85+	0.049	0.216	0.0246	0.155
Female	0.660	0.474	0.567	0.495
CRNA only	0.130	0.336	0.247	0.431
AA only	0.558	0.497	0.478	0.500
Medical direction 1:1	0.050	0.217	0.033	0.180
Medical direction 1:2–4	0.259	0.438	0.239	0.426
Supervision 1:1 > 4	0.004	0.060	0.002	0.048
Direction/collaboration	0.363	0.481	0.306	0.461
Supervision	0.394	0.489	0.436	0.496
Arrhythmia	0.234	0.424	0.126	0.332
Aortic stenosis	0.056	0.231	0.027	0.161
Diabetes	0.222	0.415	0.183	0.387
Cancer	0.256	0.436	0.249	0.433
Hypertension	0.502	0.500	0.464	0.499
COPD	0.226	0.418	0.179	0.383
Rural indicator	0.052	0.222	0.065	0.247
Base units	6.668	3.293	4.723	1.222
Percent below poverty	15.941	5.041	15.712	5.069
Median family income (in “000s”)	67.680	16.058	68.101	17.182

Data on percent in poverty and median family income at the 3-digit zip code level were obtained from the American Community Survey and are available at <https://www.census.gov/programs-surveys/acs/data/summary-file.2012.html>.

**TABLE 2. Classification of Scope of Practice State Laws or Regulations by Setting**

No Supervision or Direction		Direction/Collaboration in Nursing Statute or Hospital Rules		Supervision in Either Nursing or Hospital Statute, State Rules or Hospital Rules, or Both	
Inpatient and ER	Ambulatory	Inpatient and ER	Ambulatory	Inpatient and ER	Ambulatory
Alaska	Alaska	Arizona	Arizona	Alabama	Alabama
California	California	Connecticut	Connecticut	Arkansas	Arkansas
Colorado	Colorado	Delaware			Delaware
Hawaii			District of Columbia	District of Columbia	
Idaho	Idaho	Georgia	Georgia	Florida	Florida
Iowa	Iowa	Illinois	Illinois		Hawaii
Kansas	Kansas	Indiana			Indiana
Montana	Montana	Kentucky	Kentucky	Louisiana	Louisiana
New Hampshire	New Hampshire	Maryland	Maryland	Maine	Maine
New Mexico	New Mexico	Massachusetts	Massachusetts	Michigan	Michigan
North Dakota	North Dakota	Mississippi			Mississippi
Oregon	Oregon	Minnesota	Minnesota	Missouri	Missouri
Tennessee	Tennessee	Nebraska	Nebraska	New Jersey	New Jersey
Texas	Texas	Nevada	Nevada	New York	New York
Vermont	Vermont	North Carolina	North Carolina	Ohio	Ohio
Washington	Washington		Pennsylvania	Oklahoma	Oklahoma
		South Dakota	South Dakota	Pennsylvania	
		Wisconsin	Wisconsin	Rhode Island	Rhode Island
				South Carolina	South Carolina
				Utah	Utah
				Virginia	Virginia
				West Virginia	West Virginia
				Wyoming	

delivery models observed in the state. However, in states with “no supervision” we do observe a higher proportion of cases with a CRNA-only delivery model, compared with the mix of models in the other 2 categories.

In our data, about 32% of all anesthesia procedures were identified as “direction/collaboration,” 43% “supervision,” and 25% “no supervision.”

### Comorbidities and Procedures

We used all International Classification of Diseases, 9th Revision (ICD-9) diagnosis codes reported on patients' claims to identify comorbid conditions for patients undergoing anesthesia procedures. Following the literature,<sup>9</sup> we identify and control for the following comorbidities: arrhythmia (ICD-9 code 417), aortic stenosis (ICD-9 code 424.1), hypertension (ICD-9 codes 401, 405), cancer (ICD-9 codes 140–209, 230–239), diabetes (ICD-9 codes 250, 357.2, 362.0, 366.41, 648.0), and chronic obstructive pulmonary disease (COPD) (ICD-9 codes 490–496, 500–505, 506.4).

Comorbidities are similarly represented in both settings with the exception of arrhythmia and aortic stenosis, which are almost twice as prevalent in the inpatient setting (Table 1). Hypertension is a condition that affects half of our inpatient sample and 46% of our outpatient sample. Cancer is a comorbid condition for around 26% of observations in both settings, whereas the incidence of diabetes and COPD ranges from 18% (outpatient) to 22% (inpatient).

There are 280 currently active anesthesia-specific CPT codes, and our database contains all but 2. The codes contain descriptions of the reason for the anesthesia. Codes were analyzed to determine the frequency of each procedure overall as well as their frequency by delivery model and setting. Table 3 shows the top 60 procedures in each setting. Frequency of all procedures by delivery model and setting are available in the Supplemental Digital Content 2 (see Supplementary Tables 6, 6a, and 6b, Supplemental Digital Content 2, <http://links.lww.com/MLR/B182>).

The most frequently performed inpatient procedure is normal child delivery, which accounts for 15.6% of all inpatient procedures. The most frequent outpatient procedure is “lower intestine scope,” which accounts for 19.5% of all outpatient procedures. The supplementary tables referenced above show that all delivery models perform all procedures and that the frequency (and ranking) of procedures by delivery model does not vary significantly. That is to say, it is not the case that delivery models specialize in select procedures.

Table 3 indicates that the top 60 procedures performed in each setting account for over 90% of all procedures performed in that setting. Furthermore, the same 60 procedures account for 89%, or more, of the procedures performed by each delivery model. Therefore, we controlled for procedure risk using indicators for the top 60 procedures performed in that setting. Each procedure effect thus estimates the average difference in the odds of a complication between the given procedure and the omitted procedures.

### Anesthesia-related Complications

Li et al<sup>11</sup> constructed a list of anesthesia-related complications using ICD-10 codes for medical conditions

that we matched to ICD-9 codes in the Optum research database (Supplementary Table 3, Supplemental Digital Content 1, <http://links.lww.com/MLR/B181>). Matched ICD-9 codes were grouped into major categories according to Li et al<sup>11</sup>: (1) overdose of anesthetics; (2) complications of anesthesia during pregnancy, labor, and puerperium; and (3) other complications of anesthesia (Supplementary Table 4, Supplemental Digital Content 1, <http://links.lww.com/MLR/B181>). We also used ICD-9 codes from AHRQ's Experimental Quality Indicator #1 for rate of complications of anesthesia<sup>12</sup> (Supplementary Table 5, Supplemental Digital Content 1, <http://links.lww.com/MLR/B181>).

Patients who underwent an anesthesia procedure in the calendar year were linked to all identified anesthesia complications, except complications from spinal and epidural anesthesia, which occurred at or before 3 days post-procedure. Complications resulting from spinal and epidural anesthesia procedures were assessed for complications up to 7 days postoperatively since, unlike the majority of complications, a spinal and/or epidural complication may not be recognized within 72 hours.

### Regression Methodology

A complication occurring during or after a medical procedure is a binary outcome. Consistent with past studies, we use logistic regression to analyze whether a complication occurred during or after a procedure involving anesthesia delivery. In our models, the probability of an anesthesia complication is based on the key variables of interest (3 state SOP classification indicators and 5 delivery model indicators) plus control variables to account for other observable factors that might affect the risk of an anesthesia complication. The reference category for SOP classification is “no supervision” and the reference category the delivery model categories is “Anesthesiologist only.” The controls for procedure risk include (1) indicators for patient age group and sex, (2) BUs, (3) 6 patient comorbidity indicators, (4) indicators for the top 60 most frequent procedures, and (5) 2 measures of local area economic conditions (% below poverty and median family income in the provider's 3-digit zip code). Models were estimated separately by setting.

Models were estimated by setting separately. The model specification includes the following key variables: (1) indicators for delivery model, (2) indicators for state SOP classification, (3) patient age and sex, (4) 6 patient comorbidity indicators, (5) indicator variables for the top 60 most frequent procedures, and (6) BUs. The reference category for the delivery model categories is “Anesthesiologist only” and the reference category for SOP classification is “no supervision.”

Logit model coefficients show how each variable affects the natural logarithm of the odds of the outcome, where odds equal  $p/(1-p)$  and  $p$  is the probability of an anesthesia-related complication. Following past studies, our logit model coefficient estimates are presented in Table 4 as odds ratios (OR). An OR estimate larger (smaller) than 1.0 and statistically significant indicates that the variable in question increases (reduces) the odds of a complication. A coefficient insignificantly different from 1.0 indicates that the variable

TABLE 3. Top 60 Inpatient and Outpatient Procedures for All Delivery Models

Rank	Inpatient				Outpatient			
	CPT Description	CPT Code	%	Cumulative %	CPT Description	CPT Code	%	Cumulative %
1	Analg, vag delivery	01967	0.156	0.156	Low intestine scope	00810	0.195	0.195
2	Surg lower abdomen	00840	0.071	0.227	Upper GI visualize	00740	0.101	0.296
3	Surg upper abdomen	00790	0.068	0.295	Lens surgery	00142	0.100	0.396
4	Cs delivery	01961	0.068	0.363	Knee joint surgery	01400	0.040	0.436
5	Knee arthroplasty	01402	0.057	0.420	Surg lower abdomen	00840	0.030	0.467
6	Upper GI visualize	00740	0.052	0.472	Skin, ext/per/atruunk	00400	0.028	0.495
7	Spine, cord surgery	00670	0.037	0.509	Lower arm surgery	01810	0.026	0.521
8	Hip arthroplasty	01214	0.029	0.539	lower leg bone surg	01480	0.026	0.547
9	Analg cs deliv add-on	01968	0.024	0.562	N block/inj, prone	01992	0.026	0.573
10	Skin, ext/per/atruunk	00400	0.022	0.584	Procedure on mouth	00170	0.025	0.598
11	Low intestine scope	00810	0.021	0.605	Surg upper abdomen	00790	0.024	0.622
12	Spine, cord surgery	00630	0.016	0.622	Hysteroscope/graph	00952	0.021	0.643
13	Surgery of femur	01230	0.015	0.636	Surgery of shoulder	01630	0.020	0.663
14	Lower leg bone surg	01480	0.015	0.651	Head/neck/ptruunk	00300	0.018	0.681
15	Neck organ, 1 and over	00320	0.013	0.664	Nose/sinus surgery	00160	0.017	0.698
16	Bladder surgery	00910	0.012	0.676	Bladder surgery	00910	0.017	0.715
17	Hrt surg w/pmp ag>1	00562	0.011	0.687	Repair of hernia	00830	0.013	0.728
18	CAT or MRI scan	01922	0.010	0.697	Anorectal surgery	00902	0.012	0.739
19	Hip joint surgery	01210	0.010	0.707	Tympanotomy	00126	0.012	0.751
20	CABG w/pump	00567	0.010	0.717	Lower arm surgery	01830	0.011	0.762
21	Cranial surg nos	00210	0.009	0.725	procedures on eye	00140	0.010	0.772
22	Head/neck/ptruunk	00300	0.008	0.733	Neck organ, 1 and over	00320	0.010	0.782
23	Neck vessel surgery	00350	0.008	0.741	Vaginal procedures	00940	0.009	0.791
24	Surgery for obesity	00797	0.008	0.749	CAT or MRI scan	01922	0.009	0.799
25	1 lung ventilation	00541	0.008	0.757	Perc img tx sp proc	01936	0.008	0.808
26	Vaginal hysterectomy	00944	0.008	0.764	Kidney stone destruct	00873	0.008	0.816
27	Kidney/ureter surg	00862	0.008	0.772	Spine, cord surgery	00630	0.008	0.824
28	Removal of prostate	00865	0.007	0.779	Vitreoretinal surg	00145	0.008	0.832
29	Electroshock	00104	0.007	0.786	Surgery of breast	00402	0.006	0.839
30	Cardiac electrophys	00537	0.006	0.792	Blepharoplasty	00103	0.006	0.845
31	Vascular access	00532	0.006	0.799	Genitalia surgery	00920	0.006	0.851
32	Thigh arteries surg	01270	0.006	0.805	Lower leg surgery	01470	0.006	0.858
33	Knee joint surgery	01400	0.006	0.810	Inc/missed ab proc	01965	0.006	0.864
34	Chest procedure	00520	0.006	0.816	vascular access	00532	0.006	0.870
35	Surgery of abdomen	00860	0.005	0.821	Stone removal	00918	0.006	0.876
36	Tx interv rad hrt/cran	01926	0.005	0.826	Surgery of shoulder	01610	0.006	0.882
37	Stone removal	00918	0.005	0.831	Surgery of abdomen	00860	0.005	0.887
38	Shoulder replacement	01638	0.005	0.835	Electroshock	00104	0.005	0.893
39	Surgery of breast	00402	0.004	0.840	ear surgery	00120	0.005	0.898
40	Anorectal surgery	00902	0.004	0.844	Repair of hernia	00750	0.004	0.902
41	Surgery of shoulder	01630	0.004	0.848	Bladder tumor surg	00912	0.004	0.906
42	Spine, cord surgery	00600	0.004	0.852	Removal of prostate	00914	0.004	0.910
43	Pacemaker insertion	00530	0.004	0.856	Spine, cord surgery	00670	0.003	0.913
44	Revise hip repair	01215	0.004	0.860	Repair of hernia	00752	0.003	0.916
45	Removal of prostate	00914	0.004	0.864	Cardiac electrophys	00537	0.003	0.919
46	Correct heart rhythm	00410	0.004	0.867	Elbow area surgery	01710	0.003	0.922
47	Lower arm surgery	01830	0.004	0.871	Correct heart rhythm	00410	0.003	0.925
48	Lower leg surgery	01470	0.003	0.875	Vascular shunt surg	01844	0.003	0.928
49	Procedure on mouth	00170	0.003	0.878	Lower arm procedure	01820	0.003	0.931
50	Repair of hernia	00752	0.003	0.881	Vag hysterectomy	00944	0.003	0.933
51	Heart surg w/o pump	00560	0.003	0.884	chest procedure	00520	0.003	0.936
52	Vascular shunt surg	01844	0.003	0.887	Tubal ligation	00851	0.003	0.939
53	Vaginal procedures	00940	0.003	0.889	Nerve block/inj	01991	0.003	0.941
54	Intrcm nerve	00220	0.003	0.892	Upper arm surgery	01740	0.002	0.943
55	Chest surgery	00540	0.003	0.895	Repair of hernia	00832	0.002	0.945
56	Surgery of shoulder	01610	0.003	0.897	Perc img dx sp proc	01935	0.002	0.947
57	Knee area surgery	01392	0.003	0.900	Ther interven rad, vei	01930	0.002	0.949
58	CABG w/o pump	00566	0.003	0.903	Kidney/ureter surg	00862	0.002	0.950
59	Perc img tx sp proc	01936	0.002	0.905	Knee arthroplasty	01402	0.002	0.952
60	Repair of hernia	00830	0.002	0.907	Surgery of breast	00404	0.002	0.954

has no statistically detectable impact on complications. To avoid potential bias in the estimation of SEs due to unobservable factors that may be correlated across observations, SEs are clustered at the state level. Hypotheses

involving single coefficients are tested by z tests. ORs were determined to be significant with a P-value at the 0.10 level or lower. Joint tests involving multiple coefficients are tested by  $\chi^2$  tests with degrees of freedom equal to the number of

**TABLE 4.** Logistic Regressions for Likelihood of an Anesthesia-related Complication (Odds Ratio Form)

Variable	Inpatient Procedures					Outpatient Procedures				
	Parameters Estimation	SE	P	Lower 95% CI	Upper 95% CI	Parameters Estimation	SE	P	Lower 95% CI	Upper 95% CI
SOP indicators										
Direction/collaboration	0.972	0.085	0.749	0.819	1.155	0.753	0.186	0.252	0.463	1.223
Supervision	1.046	0.082	0.563	0.897	1.221	0.864	0.162	0.437	0.599	1.248
Delivery model indicators										
CRNA only	1.149	0.109	0.142	0.954	1.384	1.009	0.160	0.954	0.740	1.377
MD 1:1	1.042	0.123	0.730	0.826	1.313	1.122	0.183	0.482	0.814	1.545
MD 1:2-4	1.160	0.118	0.144	0.951	1.415	1.320	0.208	0.077	0.970	1.797
Supervision 1:>4	1.080	0.385	0.830	0.537	2.173	1.363	0.604	0.485	0.572	3.249
Patient characteristics										
Age 0-4	0.779	0.309	0.528	0.358	1.693	1.747	0.868	0.262	0.659	4.626
Age 5-14	0.632	0.240	0.227	0.300	1.331	1.465	0.513	0.275	0.738	2.909
Age 15-24	1.089	0.225	0.680	0.727	1.631	1.098	0.308	0.738	0.634	1.901
Age 25-34	1.164	0.229	0.439	0.792	1.711	1.210	0.329	0.483	0.711	2.060
Age 35-44	1.075	0.193	0.686	0.756	1.530	1.025	0.244	0.917	0.644	1.633
Age 45-54	1.048	0.143	0.730	0.802	1.370	1.006	0.252	0.980	0.616	1.643
Age 55-64	0.997	0.131	0.980	0.771	1.289	1.009	0.232	0.971	0.643	1.582
Age 65-74	1.459	0.217	0.011	1.090	1.952	1.033	0.196	0.863	0.712	1.500
Age 75-84	1.232	0.184	0.163	0.919	1.650	1.125	0.202	0.512	0.791	1.599
Female	1.126	0.073	0.069	0.991	1.279	1.198	0.054	0.000	1.097	1.308
Geographic controls										
Rural area	1.213	0.112	0.036	1.012	1.454	1.059	0.294	0.837	0.615	1.824
Local percent below poverty	1.003	0.007	0.697	0.990	1.015	0.994	0.017	0.714	0.961	1.027
Local median income	1.000	0.002	0.777	0.996	1.003	0.990	0.006	0.105	0.977	1.002
Complexity control										
Base unit (BU)	1.008	0.017	0.618	0.976	1.042	1.026	0.033	0.424	0.964	1.092
Comorbidity indicators										
Arrhythmia	1.175	0.067	0.005	1.051	1.315	1.358	0.075	0.000	1.218	1.514
Aortic stenosis	1.021	0.084	0.804	0.869	1.199	0.939	0.123	0.632	0.727	1.214
Diabetes	0.844	0.054	0.009	0.744	0.958	1.045	0.108	0.667	0.854	1.279
Cancer	1.154	0.084	0.049	1.001	1.332	1.198	0.087	0.013	1.038	1.382
Hypertension	1.195	0.094	0.024	1.024	1.395	1.044	0.053	0.395	0.945	1.153
COPD	1.058	0.078	0.448	0.915	1.222	1.107	0.069	0.103	0.980	1.250
Top 60 procedure indicators (yes)										
Intercept	0.001	0.000	0.000	0.000	0.002	0.001	0.001	0.000	0.000	0.005
P-values for joint significance tests										
$\chi^2$ test P-values										
SOP indicators	0.700					0.472				
Delivery model indicators	0.518					0.493				
Patient characteristics	0.000					0.000				
Comorbidity indicators	0.000					0.000				
Procedure indicators	0.000					0.000				

CI indicates confidence interval; CRNA, Certified Registered Nurse Anesthetists; SOP, scope of practice.

parameters being tested. The bottom panel of Table 4 contains P-values for groups of coefficients. In each case the joint hypothesis being tested is that the coefficients relating to the variables contained in that group all equal 0. ORs for 60 procedures included in the models are available in the Supplemental Digital Content 2 (see Supplementary Table 7, Supplemental Digital Content 2, <http://links.lww.com/MLR/B182>).

### RESULTS

In both settings, the P-value for the joint hypothesis that the odds of an anesthesia-related complication do not vary with the 6 patient comorbidities included in the model is

0, indicating that the hypothesis can be rejected with a high degree of confidence. Examining the individual ORs, patients with arrhythmia are estimated to be 1.175 times more likely to have a complication than patients who do not exhibit any of the 6 comorbidities. The risk in the outpatient setting for such a patient is even higher (OR=1.358). ORs associated with cancer are also significantly above 1.0.

In both settings, the P-value for the joint hypothesis of no variation in the odds of a complication by procedure is also equal to 0. In fact, the risk of a complication varies dramatically by procedure. The top 3 highest risk procedures are related to childbirth. Cesarean delivery has an OR of 4.357, normal delivery has an OR of 3.311, and cesarean

delivery add-on has an OR of 3.219. Lower intestine scope is relatively safe—its OR estimate equals 0.445 in the inpatient setting and 0.576 in the outpatient setting; both estimates are statistically significant at the 0.05 level.

Another potential control for the risk of an anesthesia-related complication is the BUs for the procedure, which measure procedure complexity. The estimates in Table 4 do not indicate any relationship of BUs with risk of an anesthesia-related complication in either setting. The BU control is highly insignificant in both the inpatient setting where on average we see relatively higher BU procedures and the outpatient setting. The results indicate that the procedure controls are much better predictors of procedure risk than the BUs associated with the procedure.

The hypothesis that anesthesia-related complications do not differ with patient characteristics can be rejected for both settings ( $\chi^2$   $P$ -value=0). Examining the individual coefficients related to age, all but one of the inpatient model ORs associated with age are insignificant and none of the outpatient model age effects are individually significant. In the outpatient model, females are estimated to be 20% more likely than males to experience a complication in that setting (OR=1.198,  $P$ -value=0). The inpatient model difference due to sex is less, 13% (significant at the 0.1 level). Generally speaking, the evidence indicates that once other factors are controlled for, there is some variation in the risk of an anesthesia-related complication by patient age group and sex. However, measured by ORs, the variation does not seem to be large.

Although there is strong evidence of differences in anesthesia complications by patient comorbidities and the undergone procedure, and some evidence of variation with patient characteristics, the results in Table 4 provide virtually no evidence that complications differ by either SOP classification or by delivery model. The joint hypothesis tests involving the SOP coefficients and the delivery models are highly insignificant.

Considering first the SOP estimates found in Table 4, most of the ORs are <1.0 when compared with the reference indicator (no supervision). However, none of the estimated ORs is individually statistically significant at the  $P$ -value <0.1 level in any of the settings. Specifically, results did not indicate statistical significance in any setting for the supervision categories (OR<sub>inpatient</sub>=1.046, OR<sub>outpatient</sub>=0.864) and direction/collaboration categories (OR<sub>inpatient</sub>=0.972, OR<sub>outpatient</sub>=0.753). Finally, the  $P$ -values for the joint tests involving the SOP indicators are both quite high. Therefore, we fail to reject the hypothesis that anesthesia-related complications are unrelated to SOP classification.

Similarly, none of the delivery model ORs is individually statistically significant at  $P$ -value <0.05. The OR estimates for CRNA-only are 1.149 and 1.009 for the inpatient and outpatient settings, respectively. However, neither estimate is significant at the  $P$ -value <0.10. These results indicate that the hypothesis that the risk of anesthesia-related complications is the same whether anesthesia is delivered by a CRNA acting alone or by an anesthesiologist acting alone cannot be rejected. Furthermore, the joint test  $P$ -values of 0.700 (inpatient) and 0.472 (outpatient) indicate that the joint

hypothesis that anesthesia-related complications do not vary by delivery model cannot be rejected for either setting.

Of the geographic controls included in our models, only the rural indicator is statistically significant for the inpatient setting; however, only approximately 6% of procedures were in rural areas. Inpatient procedures performed in rural areas have about 1.213 times higher ( $P$ -value=0.04) likelihood of complications than procedures performed in urban areas. No difference was found in the outpatient setting. We find no evidence that complications vary with the poverty rate (OR<sub>inpatient</sub>=1.003, OR<sub>outpatient</sub>=0.994). Local area median family income was associated with a significantly lower likelihood of anesthesia complications for the outpatient setting (OR=0.990,  $P$ -value=0.10), but no difference was found for the inpatient setting.

## DISCUSSION

The primary finding of this study is that there is no statistically significant difference in the risk of anesthesia complications based on the degree of restrictions placed on CRNAs by state SOP laws. Nor is there evidence that the risk of complications varies by delivery model. This evidence suggests that there is no empirical evidence for SOP laws that restrict CRNAs from practicing at levels that are below their education and training based on differences in anesthesia complication risk.

There is strong evidence of differences in anesthesia complications by patient characteristics, patient comorbidities, and the procedures for which anesthesia was administered. Depending on setting, we also find some evidence of variation with geographic factors.

In addition to being consistent with the previous literature, our findings are based on a very large commercial payor database that encompasses a wider patient population and includes data from both the inpatient and ambulatory settings. The larger sample sizes associated with this database provide a greater probability of detecting differences in complications across delivery models and state SOP categories, if differences exist.

An unavoidable limitation of this study is the possibility that small differences in risk may exist but cannot be detected even with the relatively large sample sizes of this study. Moreover, these findings are based on a privately insured population. We have no reason to believe the results would differ for other populations, but publicly insured and uninsured populations are underrepresented here. Finally, though we have controlled for a large number of factors affecting the underlying risk of anesthesia, including the procedure; the age, sex, and comorbidities of the patient; and whether the hospital or outpatient setting was in an urban or rural location, there remains a possibility that selectivity based on factors for which we do not control could have affected the results.

To the extent that state SOP limitations on CRNAs are based on the assumption that anesthesia provided by CRNAs acting alone is riskier than other delivery models, the evidence presented in this study should be considered. Potentially unnecessary restrictions can reduce patient access to

high-quality anesthesia services, particularly in underserved areas, and raise the cost of providing quality care.<sup>13,14</sup>

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# **CALIFORNIA DENTAL ASSOCIATION (CDA)**

1. June 30, 2016 Letter from Brianna Pittman, Legislative Director
2. October 14, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016
3. October 28, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016



June 30, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Dear Dr. Morrow:

The California Dental Association is deeply saddened by [redacted] death and is committed to taking actions that support the safe provision of dental care to every person, every day. We also understand the desire for action to prevent tragedies such as this from ever occurring again. We are concerned, however, that the bill proposal that has arisen from this heartbreaking event, AB 2235 (Thurmond), has brought forward unsubstantiated claims about the risks associated with pediatric dental sedation, alarming the public and generating fear. This is especially troubling for parents whose children may require sedation to receive the dental care they require for their health and wellbeing. We know that the Dental Board of California (board) shares our concerns and our commitment to safety.

CDA appreciates that the board responded immediately to Senator Hill's request that it evaluate whether the state's policies are sufficient to provide the safest and most appropriate administration of anesthesia to pediatric patients and understand that the board is undergoing a comprehensive review at this time. CDA believes that an evidenced-based approach is essential to properly identifying effective solutions and to adopting sound state policy. We have steadfastly supported this in our testimony and public comments throughout this process.

We write to you now, though, to express our concern and dismay that it has taken the board more than three months to report on the number of pediatric sedation deaths that have occurred in California over the last five years. As CDA meets with legislators and legislative staff, all are wondering just how significant a problem the legislature is trying to address. This unknown has left CDA and other advocates unable to rebut claims that children are unsafe if dentists are permitted to continue with current sedation practices and has left legislators who believe that dentistry is safe without data to support that position.

We strongly urge that the board direct all available resources to completing its assessment of deaths related to dental care and release this data as soon as possible. This information is critical to providing context to the legislature's informed consideration of AB 2235 and essential to parents' understanding of this issue as they consider care options

for their child. This data, while not the entire picture, is essential to informed problem solving.

Further, CDA urges the board to include in its report its plans to ensure that data on deaths related to dental care will be available in the future in a timely and accurate manner, including its recommendations for collecting data utilizing a standardized and comprehensive methodology.

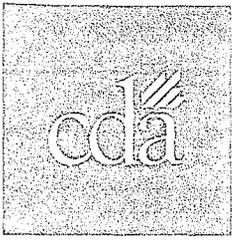
These matters are of great concern to the public and the profession. CDA appreciates the opportunity to work with the board to support the public's understanding and confidence in the care they receive and to ensure this care is provided safely every day to every person.

Sincerely,

A handwritten signature in black ink, appearing to read "Brianna Pittman", written in a cursive style.

Brianna Pittman  
Legislative Director

c: Karen Fischer, Executive Office  
Dental Board of California Board Members



*Submitted via email*

October 14, 2016

Dr. Steven G. Morrow, DDS, MS  
Dental Board of California  
Department of Consumer Affairs  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Re: Pediatric Dental Anesthesia Subcommittee Recommendations

Dear Dr. Morrow:

The California Dental Association (CDA), representing 26,000 general and specialist member dentists throughout California, sincerely appreciates the Dental Board's work on pediatric dental anesthesia. The Board's report was thorough in its review of dental anesthesia literature, comparison of California laws and regulations with other states and professional guidelines, and describing California specific morbidity and mortality related to pediatric dental anesthesia. CDA appreciates the Board's comprehensive and evidence-based process and commends the Board for fulfilling the charge given by the Senate Business, Professions and Economic Development Committee earlier this year. The report establishes a solid basis for the Board and legislature's analysis and recommendations.

After the release of the Board's draft report, CDA convened a pediatric dental anesthesia workgroup comprised of general and specialist dentists, including pediatric, oral and maxillofacial surgery, dentist anesthesiologist, and periodontist specialists. The group spent many hours discussing pediatric dental anesthesia, including levels of sedation, permit stratification based on patient age, monitoring equipment and requirements, and the personnel and training of the dental team members engaged in providing anesthesia services.

CDA agrees with the Board that patient safety should be our foremost concern, and sees the greatest opportunity in directing our efforts toward making evidence-based changes that build upon best practices and reduce the likelihood of adverse events. These principles formed the basis for our workgroup's process, and we are pleased to see that

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the recommendations released by the Board are well aligned with much of the thinking, concerns, and discussion of the workgroup.

While the current laws and regulations for anesthesia by route of administration have been a workable framework, the recommendations in the report for defining in law anesthesia by levels of sedation would better align with national guidelines to which providers adhere, ensuring that providers of anesthesia for pediatric patients receive training and maintain competency specific to that population, ensuring that training for each level of sedation should include training to recognize and rescue from a deeper level of sedation, and codifying the number of trained staff that should be present for each level of sedation.

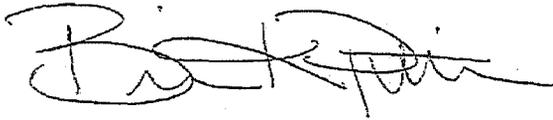
One area worth noting for further discussion is the report's recommendation for age designation for pediatric general anesthesia practice: the report recommends different permit requirements for providers treating children under 13 and children under 7. While there is some data showing children under the age of seven are the most vulnerable to the effects of anesthesia, the workgroup we convened discussed that the physiologic development of children differs from adults most notably at age 12. This recommendation for permit stratification by age, including additional training and experience warrants further discussion.

CDA is also pleased about the report's recommendation for improved data collection and reporting, standardizing the format for 1680(z) reporting, and the permit renewal process. This will provide information that regulators and the profession have heretofore been unable to access. If also collected by the Medical Board and the Department of Public Health for anesthesia providers in other medical settings, this will provide data for a more complete understanding of pediatric sedation and anesthesia across disciplines in California.

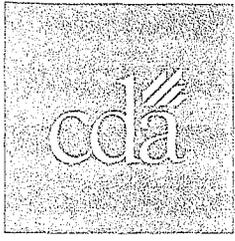
CDA believes we have an opportunity to update and improve the regulatory structure for anesthesia in California, and to advance the best and safest practices for pediatric dental anesthesia. The report showed that pediatric anesthesia deaths in recent years were rare, and occurred in a variety of settings and under the care of different anesthesia professionals. There was no one pattern, which means there can be no one simple solution. These recommendations provide a solid starting point and we look forward to working with the legislature, the Board, and stakeholders through the legislative and regulatory processes to establish the details of a permitting structure that will support these recommendations.

Finally, this report confirms for us that anesthesia always carries a risk, no matter the setting, situation, or provider. We cannot create a "never" situation that eliminates all risk. Unfortunately, no model of care ensures nothing tragic will ever happen. While we must do everything we can do reduce the potential for adverse events when anesthesia is required, we should also be doing everything we can to reduce the number of children whose dental disease is so severe as to require anesthesia. Dental disease is preventable. We look forward to working together, collectively doing all we can to be more effective in preventing dental disease.

Sincerely,

A handwritten signature in black ink, appearing to read 'Brianna Pittman', with a stylized, cursive script.

Brianna Pittman  
CDA Board Liaison



*Submitted via email*

October 28, 2016

Dr. Steven G. Morrow, DDS, MS  
Dental Board of California  
Department of Consumer Affairs  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Re: Pediatric Dental Anesthesia Subcommittee Recommendations

Dear Dr. Morrow:

The California Dental Association (CDA), representing 26,000 general and specialist member dentists throughout California, would like to applaud the Dental Board's thoughtful and systematic approach to its pediatric dental anesthesia permitting recommendations. The recommended framework provides a clear, appropriate approach that reflects the profession's best safety anesthesia and sedation practices, while modernizing the regulatory framework to better reflect the current structure of these guidelines and protocols

As mentioned in our previous letter, after the release of the Board's draft report, CDA convened a pediatric dental anesthesia workgroup comprised of general and specialist dentists, including pediatric, oral and maxillofacial surgery, dentist anesthesiologist, and periodontist specialists. While CDA and the workgroup are pleased to see much of our initial discussions align with the Dental Board's preliminary recommendations, we would like to reiterate that patient safety should be our foremost concern, focusing on evidence-based changes, rather than opinion, that build upon best practices and reduce the likelihood of adverse events in a clear and systematic framework.

CDA agrees with the recommendations made by the subcommittee to pursue better collection of high quality pediatric sedation outcomes data and update definitions of sedation and anesthesia, which will require the dental sedation and anesthesia permit system to be restructured. We submit the following comments:

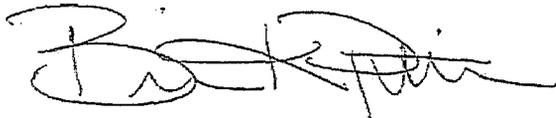
As mentioned in our previous letter, CDA believes that the collection of data regarding anesthesia in dental and other medical settings will provide a more complete understanding of the safety of pediatric sedation and anesthesia across disciplines.

The Dental Board was tasked by the legislature to submit recommendations related to pediatric dental anesthesia, and not the entire permitting structure. While CDA agrees that anesthesia definitions and permit system should be updated to better align with national guidelines, the significant implications for adult dental sedation could be much broader than what was contemplated by the legislature. It would be in line with legislative intent to limit the restructuring of the definitions and permit groups to pediatric patients only. Taking an incremental approach to revising the permitting requirements is prudent and a restructuring of adult permits could be undertaken in the future.

Restructuring the permit structure for pediatric patients to move from route of administration to level of sedation provides many advantages. However, it will be important as the permit structure is created to reflect that the age selected and required training represent the highest level of safety for that age group without being overly restrictive or defying reasonable evidence.

Lastly, CDA would like to reiterate that the study confirms that the use of anesthesia, especially in pediatric patients will always carry a risk regardless of the setting, situation, or provider. We urge the Dental Board to revise its recommendations with the same prudent and evidence-based approach found in its preliminary recommendations. As these recommendations move to the legislative process, we look forward to continuing to work with the Dental Board and other stakeholders to further refine and implement these recommendations. Our goal is to reduce the risk of complications in pediatric dental anesthesia settings and the epidemic of dental disease that often leads to the need for dental anesthesia.

Sincerely,

A handwritten signature in black ink, appearing to read 'Brianna Pittman', written in a cursive style.

Brianna Pittman  
CDA Board Liaison

# CALIFORNIA SOCIETY OF ANESTHESIOLOGISTS (CSA)

1. June 30, 2016 Cover Letter and Attachments Submitted by Mark Zakowski, MD, President

- 42 C.F.R. § 482.52 Condition of Participation: Anesthesia Services: *Please note the five classes of healthcare practitioners who may provide anesthesia services. The five classes are: physician anesthesiologists; other doctors of medicine or osteopathy; certain dentists, oral surgeons and podiatrists; nurse anesthetists; and anesthesiologist assistants.*
- ASA Policy on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (October 15, 2014)
- ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (October 17, 2012)
- ASA Statement on the Anesthesia Care Team (October 16, 2013)
- ASA Standards for Basic Anesthetic Monitoring (October 28, 2015)
- 42 C.F.R. § 482.13 Condition of Participation: Patient's Rights
- *"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists"* Anesthesiology 2002; 96:1004–17
- *"Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures"* developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (adopted 2006; reaffirmed 2011)
- CSA Patient Safety Bill of Rights: Patient Safety Across the Continuum for Deep Sedation/General Anesthesia (adopted June 5, 2016)
- AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016 (***Did not reprint – Refer to AAP for Document***)

2. July 28, 2016 Comments Delivered at Dental Board Workshop and submitted via fax by Dr. Mark Singleton

3. August 17, 2016 Letter from Mark Zakowski, MD, President

4. October 26, 2016 Letter from Mark Zakowski, MD, President



California Society of  
**ANESTHESIOLOGISTS**  
*Physicians for Vital Times*

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June 30, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: CSA Response to Dental Board of California Anesthesia Project Invitation**

Dear Dr. Morrow:

The California Society of Anesthesiologists (*hereafter*; CSA) greatly appreciates your invitation to provide you and the Dental Board of California (*hereafter*; DBC) with input into the safe administration and monitoring of sedation and general anesthesia, and assessment of whether or not California law provides sufficient protection to pediatric patients during dental anesthesia procedures.

CSA has been on record several times this year by way of AB 2235 (Thurmond), stating that we collectively must do everything in our power to prevent the inappropriate use of anesthesia and the adverse events that can result. To that end, we applaud the DBC in taking a leadership role in addressing those issues raised by State Senator Jerry Hill (D-San Mateo) in his letter to the DBC on February 8, 2016.

We await your draft report prior to the full DBC meeting in Sacramento on August 18-19, 2016, and the opportunity to provide additional comments at that time. To that end, you will find attached documents that we hope will suggest further ways for California law, regulations, and/or policies to protect pediatric patients during dental anesthesia procedures:

- **42 C.F.R. § 482.52 Condition of Participation: Anesthesia Services:** *Please note the five classes of healthcare practitioners who may provide anesthesia services. The five classes are: physician anesthesiologists; other doctors of medicine or osteopathy; certain dentists, oral surgeons and podiatrists; nurse anesthetists; and anesthesiologist assistants.*
- **ASA Policy on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (October 15, 2014)**
- **ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (October 17, 2012)**
- **ASA Statement on the Anesthesia Care Team (October 16, 2013)**
- **ASA Standards for Basic Anesthetic Monitoring (October 28, 2015)**
- **42 C.F.R. § 482.13 Condition of Participation: Patient's Rights**
- **"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" Anesthesiology 2002; 96:1004-17**
- **"Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (adopted 2006; reaffirmed 2011)**
- **CSA Patient Safety Bill of Rights: Patient Safety Across the Continuum for Deep Sedation/General Anesthesia (adopted June 5, 2016)**
- **AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016**

Although we at the CSA are not experts in the practice of dentistry, it is important to note that physician anesthesiologists are the only medical professionals recognized by the Institutes of Medicine for implementing patient safety measures and protocols that have resulted in a 50-fold decrease in deaths.<sup>1</sup> Therefore, we strongly believe that the standard of care regarding the administration and monitoring of anesthesia services must be consistent, whether the patient is six years of age or 60, and whether anesthesia care is delivered in a dental office, ambulatory surgery center or acute care hospital.

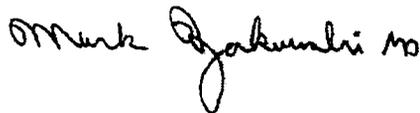
To ensure patient safety, many states require cardiac monitoring for deep sedation. Because sedation is a continuum, moderate sedation can easily progress to deep sedation. As a result, the monitors required for deep sedation should be applied equally to cases under moderate sedation. These include pulse oximetry, ECG and capnography. Otherwise, each time a patient slips into deep sedation (which can happen frequently), the facility runs the risk of non-compliance.

As reported in a national audit in the United Kingdom, "Emergency airway management outside the operating theater is known to be associated with more frequent problems than routine anaesthesia."<sup>2</sup> They found the second most common factor in avoidable airway events/deaths was education and training. These facts support limiting deep sedation and general anesthesia to the most qualified providers, as these techniques may lead to avoidable patient deaths in the hands of personnel with less training. It is critical for the facility and staff at all times to maintain the ability to manage emergency airway complications, including laryngospasm, with appropriate drugs and equipment. The definitive treatment for life-threatening laryngospasm is the administration of succinylcholine, a fast acting muscle relaxant (i.e. paralytic), (listed in Appendix 3, AAP/AAPD guideline). Please note that facilities which stock or use succinylcholine are also required to have a Malignant Hyperthermia kit immediately available on site to treat this life-threatening side effect of succinylcholine in genetically susceptible individuals.

Again, the CSA appreciates the opportunity to provide our insights. We also reaffirm our commitment and unconditional willingness to continue working with you, the Dental Board of California and all other stakeholders to ensure we are doing everything in our power to protect all patients.

Please feel free to contact CSA Legislative Advocate Bryce Docherty, at 916-448-2162 or via e-mail at [bdocherty@ka-pow.com](mailto:bdocherty@ka-pow.com) should you have any further questions or need additional information.

Sincerely,



Mark Zakowski, MD  
President

cc: Karen Fischer, Executive Director, Dental Board of California  
Honorable Jerry Hill (D-San Mateo)  
Honorable Tony Thurmond (D-Richmond)  
Bryce Docherty, KP Public Affairs

<sup>1</sup> *To Err is Human*, Institute of Medicine, 1999

<sup>2</sup> Cook TM, Woodall N, Frerk C; Fourth National Audit Project. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society.  
<http://www.rcoa.ac.uk/nap4>

Code of Federal Regulations

Title 42. Public Health

Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)

Subchapter G. Standards and Certification (Refs & Annos)

Part 482. Conditions of Participation for Hospitals (Refs & Annos)

Subpart D. Optional Hospital Services

42 C.F.R. § 482.52

§ 482.52 Condition of participation: Anesthesia services.

Effective: January 1, 2008

Currentness

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

- (1) A qualified anesthesiologist;
- (2) A doctor of medicine or osteopathy (other than an anesthesiologist);
- (3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- (4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or
- (5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

- (1) A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

(2) An intraoperative anesthesia record.

(3) A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

(4) [Reserved by 72 FR 66934]

(c) Standard: State exemption.

(1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a) (4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

#### Credits

[57 FR 33900, July 31, 1992; 66 FR 4686, Jan. 18, 2001; 66 FR 15352, March 19, 2001; 66 FR 27598, May 18, 2001; 66 FR 56768, 56769, Nov. 13, 2001; 71 FR 68694, Nov. 27, 2006; 72 FR 66934, Nov. 27, 2007]

SOURCE: 51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 41338, Nov. 14, 1986; 53 FR 6549, March 1, 1988; 57 FR 7136, Feb. 28, 1992; 57 FR 33899, July 31, 1992, unless otherwise noted; 59 FR 46514, Sept. 8, 1994; 60 FR 50442, Sept. 29, 1995; 64 FR 66279, Nov. 24, 1999; 71 FR 71334, Dec. 8, 2006; 72 FR 15273, March 30, 2007; 77 FR 29028, May 16, 2012, unless otherwise noted.

AUTHORITY: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Current through April 21, 2016; 81 FR 23441.

**CONTINUUM OF DEPTH OF SEDATION:  
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA\***

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 13, 1999, and last amended on  
October 15, 2014)

	<i>Minimal Sedation Anxiolysis</i>	<i>Moderate Sedation/ Analgesia ("Conscious Sedation")</i>	<i>Deep Sedation/ Analgesia</i>	<i>General Anesthesia</i>
<i>Responsiveness</i>	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
<i>Airway</i>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<i>Spontaneous Ventilation</i>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<i>Cardiovascular Function</i>	Unaffected	Usually maintained	Usually maintained	May be impaired

**Minimal Sedation (Anxiolysis)** is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

**Moderate Sedation/Analgesia ("Conscious Sedation")** is 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.

\* Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

\*\* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

**Deep Sedation/Analgesia** is 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.

**General Anesthesia** is 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.

Because sedation is 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 rescue\*\*\* patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue\*\*\* patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue\*\*\* patients who enter a state of General Anesthesia.

\*\* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

\*\*\* Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

**STATEMENT ON GRANTING PRIVILEGES TO NONANESTHESIOLOGIST PHYSICIANS  
FOR PERSONALLY ADMINISTERING OR SUPERVISING DEEP SEDATION**

**(Approved by the ASA House of Delegates on October 18, 2006, and amended on October 17, 2012)**

Because of the significant risk that patients who receive deep sedation may enter a state of general anesthesia, privileges for deep sedation should be granted only to nonanesthesiologist physicians who are qualified and trained in the medical practice of deep sedation and the recognition of and rescue from general anesthesia.

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.

## STATEMENT ON THE ANESTHESIA CARE TEAM

Committee of Origin: Anesthesia Care Team

(Approved by the ASA House of Delegates on October 26, 1982, and last amended on October 16, 2013)

Anesthesiology is the practice of medicine including, but not limited to, preoperative patient evaluation, anesthetic planning, intraoperative and postoperative care and the management of systems and personnel that support these activities. In addition, anesthesiology includes perioperative consultation, the management of coexisting disease, the prevention and management of untoward perioperative patient conditions, the treatment of acute and chronic pain, and the practice of critical care medicine. This care is personally provided by or directed by the anesthesiologist.

In the interests of patient safety and quality of care, the American Society of Anesthesiologists believes that the involvement of an anesthesiologist in the perioperative care of every patient is necessary. Almost all anesthesia care is either provided personally by an anesthesiologist or is provided by a non-physician anesthesia practitioner directed by an anesthesiologist. The latter mode of anesthesia delivery is called the Anesthesia Care Team and involves the delegation of monitoring and appropriate tasks by the physician to non-physicians. Such delegation should be specifically defined by the anesthesiologist and should also be consistent with state law or regulations and medical staff policy. Although selected tasks of overall anesthesia care may be delegated to qualified members of the Anesthesia Care Team, overall responsibility for the Anesthesia Care Team and patients' safety ultimately rests with the anesthesiologist.

### Definitions

#### 1. Core Members of the Anesthesia Care Team

The Anesthesia Care Team includes both physicians and non-physicians. All members of the team have an obligation to accurately identify themselves and other team members to patients and families. Anesthesiologists should not permit the misrepresentation of non-physician personnel as resident physicians or practicing physicians. The nomenclature below is appropriate terminology for this purpose.

##### a. Physicians

**ANESTHESIOLOGIST:** Director of the Anesthesia Care Team; a physician licensed to practice medicine who has successfully completed a training program in anesthesiology accredited by the ACGME, the American Osteopathic Association or equivalent organizations.

**ANESTHESIOLOGY FELLOW:** An anesthesiologist enrolled in a training program to obtain additional education in one of the subspecialties of anesthesiology.

**ANESTHESIOLOGY RESIDENT:** A **physician** enrolled in an accredited anesthesiology residency program.

**b. Non-physicians**

**ANESTHETIST:** A **nurse anesthetist** or **anesthesiologist assistant**, as each is defined below. (Note: In some countries where non-physicians do not participate in the administration of anesthesia, a physician who practices anesthesiology is known as an “anaesthetist” or “anesthetist”).

**NURSE ANESTHETIST:** A **registered nurse** who has satisfactorily completed an accredited nurse anesthesia training program and certifying examination (also, “CRNA”).

**ANESTHESIOLOGIST ASSISTANT:** A **health professional** who has satisfactorily completed an accredited anesthesiologist assistant training program and certifying examination (also, “AA”).

**STUDENT NURSE ANESTHETIST:** A **registered nurse** who is enrolled in an accredited nurse anesthesia training program.

**ANESTHESIOLOGIST ASSISTANT STUDENT:** A **health profession graduate student** who has satisfied all prerequisite coursework typical of an accredited school of medicine and is enrolled in an accredited anesthesiologist assistant training program.

**NON-PHYSICIAN ANESTHESIA STUDENT:** Student nurse anesthetists, anesthesiologist assistant students, dental anesthesia students and others who are enrolled in accredited anesthesia training programs.

**OTHERS:** Although not considered core members of the Anesthesia Care Team, other health care professionals make important contributions to the perianesthetic care of the patient (see Addendum A).

**2. Additional Terms**

**ANESTHESIA CARE TEAM:** Anesthesiologists supervising resident physicians and/or directing qualified non-physician anesthesia practitioners in the provision of anesthesia care, wherein the physician may delegate monitoring and appropriate tasks while retaining overall responsibility for the patient.

**QUALIFIED ANESTHESIA PERSONNEL OR PRACTITIONERS:** Anesthesiologists, anesthesiology fellows, anesthesiology residents, oral surgery residents, anesthesiologist assistants, and nurse anesthetists.

**MEDICAL SUPERVISION AND MEDICAL DIRECTION:** Terms used to describe the physician work required to oversee, manage and guide both residents and non-physician members of the Anesthesia Care Team. For the purposes of this statement, supervision

and direction are interchangeable and have no relation to the billing, payment or regulatory definitions that provide distinctions between these two terms (see Addendum B).

**SEDATION NURSE AND SEDATION PHYSICIAN ASSISTANT:** A licensed registered nurse, advanced practice nurse or physician assistant who is trained in compliance with all relevant local, institutional, state and/or national standards, policies or guidelines to administer prescribed sedating and analgesic medications and monitor patients during minimal sedation ("anxiolysis") or moderate sedation ("conscious sedation"), but not deeper levels of sedation or general anesthesia. Sedation nurses and sedation physician assistants may only work under the direct supervision of a properly trained and privileged physician (MD or DO).

**PROCEDURE ROOM:** An operating room or other location where an operation or procedure is performed under anesthesia care.

**IMMEDIATELY AVAILABLE:** Wherever it appears in this document, the phrase "immediately available" is used as defined in the ASA policy statement "Definition of 'Immediately Available' When Medically Directing" (see Addendum C).

#### **Safe Conduct of the Anesthesia Care Team**

In order to achieve optimum patient safety, the anesthesiologist who directs the Anesthesia Care Team is responsible for the following:

1. **Management of personnel:** Anesthesiologists should assure the assignment of appropriately skilled physician and/or non-physician personnel for each patient and procedure.
2. **Preanesthetic evaluation of the patient:** A preanesthetic evaluation allows for the development of an anesthetic plan that considers all conditions and diseases of the patient that may influence the safe outcome of the anesthetic. Although non-physicians may contribute to the preoperative collection and documentation of patient data, the anesthesiologist is responsible for the overall evaluation of each patient.
3. **Prescribing the anesthetic plan:** The anesthesiologist is responsible for prescribing an anesthesia plan aimed at the greatest safety and highest quality for each patient. The anesthesiologist discusses with the patient or guardian, as appropriate, the anesthetic risks, benefits and alternatives, and obtains informed consent. When part of the anesthetic care will be performed by another qualified anesthesia practitioner, the anesthesiologist should inform the patient that delegation of anesthetic duties is included in care provided by the Anesthesia Care Team.
4. **Management of the anesthetic:** The management of an anesthetic is dependent on many factors including the unique medical conditions of individual patients and the procedures being performed. Anesthesiologists will determine which perioperative tasks, if any, may be delegated. The anesthesiologist may delegate specific tasks to qualified

non-anesthesiologist members of the Anesthesia Care Team providing that quality of care and patient safety are not compromised, will participate in critical parts of the anesthetic, and will remain immediately available for management of emergencies regardless of the type of anesthetic (see Addendum C).

5. **Postanesthesia care:** Routine postanesthesia care is delegated to postanesthesia nurses. The evaluation and treatment of postanesthetic complications are the responsibility of the anesthesiologist.
6. **Anesthesia consultation:** Like other forms of medical consultation, this is the practice of medicine and should not be delegated to non-physicians.

#### **Safe Conduct of Minimal and Moderate Sedation Utilizing Sedation Nurses and Physician Assistants**

The supervising physician is responsible for all aspects of the continuum of care: pre-, intra-, and post-procedure. While a patient is sedated, the responsible physician must be physically present and immediately available in the procedure suite. Although the supervising physician is primarily responsible for pre-procedure patient evaluation, sedation practitioners must be trained adequately in pre-procedure patient evaluation to recognize when risk may be increased, and related policies and procedures must allow sedation practitioners to refuse to participate in specific cases if they perceive a threat to quality of care or patient safety.

The supervising physician is responsible for leading any acute resuscitation needs, including emergency airway management. Therefore, ACLS (PALS or NALS where appropriate) certification must be a standard requirement for sedation practitioners and for credentialing and privileging the non-anesthesiologist physicians who supervise them. However, because non-anesthesia professionals seldom perform controlled mask ventilation or tracheal intubation often enough to remain proficient, their training should emphasize avoidance of excessive sedation over rescue techniques.

#### **Medical Supervision of Nurse Anesthetists by Non-Anesthesiologist Physicians**

*Note: In this section, the term "surgeon" may refer to any appropriately trained, licensed and credentialed non-anesthesiologist physician who may supervise nurse anesthetists when consistent with applicable law.*

General anesthesia, regional anesthesia, and monitored anesthesia care expose patients to risks. Non-anesthesiologist physicians may not possess the expertise that uniquely qualifies and enables anesthesiologists to manage the most clinically challenging medical situations that arise during the perioperative period. While a few surgical training programs (such as oral surgery and maxillofacial surgery) provide some anesthesia-specific education, no non-anesthesiology programs prepare their graduates to provide an anesthesiologist's level of medical supervision and perioperative clinical expertise. However, surgeons and other physicians significantly add to patient safety and quality of care by assuming medical responsibility for perioperative care when an anesthesiologist is not present.

Anesthetic and surgical complications often arise unexpectedly and require immediate medical diagnosis and treatment, even if state law or regulation says a physician is not required to supervise non-physician anesthesia practitioners. The surgeon may be the only physician on site. Whether the need is preoperative medical assessment or intraoperative resuscitation from an unexpected complication, the surgeon may be called upon, as the most highly trained professional present, to provide medical direction of perioperative health care, including nurse anesthesia care. To optimize patient safety, careful consideration is required when a surgeon will be the only physician available, as in some small hospitals, freestanding surgery centers, and surgeons' offices. In the event of an emergency, lack of immediate support from other physicians trained in critical medical management may reduce the likelihood of successful resuscitation. This should be taken into account when deciding which procedures should be performed in settings without an anesthesiologist, and which patients are appropriate candidates.

#### **Medical Supervision of Non-Physician Anesthesia Students**

Anesthesiologists who teach non-physician anesthesia students are dedicated to their education and to providing optimal safety and quality of care to every patient. The ASA Standards for Basic Anesthetic Monitoring define the minimum conditions necessary for the safe conduct of anesthesia. The first standard states, "Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care." This statement does not completely address the issue of safe patient care during the training of non-physician student anesthetists. Further clarification of the issues involved is in the best interests of patients, students, and anesthesia practitioners.

During 1:1 supervision of non-physician anesthesia students, it may become necessary for the supervising anesthesiologist or nurse anesthetist to leave briefly to attend to other urgent needs or duties. This should only occur in circumstances judged to cause no significant increased risk to the patient.

This practice is to be distinguished from that of scheduling a non-physician student as the primary anesthetist, meaning that no fully-trained anesthesia practitioner is also continuously present to monitor the anesthetized patient. Though the brief interruption of 1:1 student supervision may be unavoidable for the efficient and safe functioning of a department of anesthesiology, the use of non-physician students as primary anesthetists in place of fully trained and credentialed anesthesia personnel is not endorsed as a best practice by the ASA. While the education of non-physician anesthesia students is an important goal, patient safety remains paramount. Therefore, the supervision of students at a ratio other than 1:1 must meet criteria designed to protect the safety and rights of patients and students, as well as the best interests of all other parties directly or indirectly involved: anesthesia practitioners, families, and health care institutions.

1. **Delegation:** All delegating anesthesiologists and the department chairperson must deem non-physician student anesthetists fully capable of performing all duties delegated to them, and all students must express agreement with accepting responsibility delegated to them.

2. **Privileging:** An official privileging process must individually deem each student as qualified to be supervised 1:2 by an anesthesiologist who remains immediately available (see Addendum C). Students must not be so privileged until they have completed a significant portion of their didactic and clinical training and have achieved expected levels of safety and quality (if at all, no earlier than the last 3-4 months of training). Privileging must be done under the authority of the chair of anesthesiology and in compliance with all federal, state, and professional organization and institutional requirements.
3. **Case Assignment and Supervision:** Students must be supervised at a 1:1 or 1:2 anesthesiologist to student ratio. Assignment of cases to students must be done in a manner that assures the best possible outcome for patients and the best education of students, and must be commensurate with the skills, training, experience, knowledge and willingness of each individual non-physician student. Care should be taken to avoid placing students in situations beyond their level of skill. It is expected that most students will gain experience caring for high-risk patients under the continuous supervision of qualified anesthesia practitioners. This is in the best interest of education and patient safety. The degree of continuous supervision must be at a higher level than that required for fully credentialed anesthesiologist assistants and nurse anesthetists. If an anesthesiologist is engaged in the supervision of non-physician students, he/she must remain immediately available. This means not leaving the procedure suite to provide other concurrent services or clinical duties that would be considered appropriate if directing fully credentialed anesthesiologist assistants or nurse anesthetists.
4. **Back-up Support:** If an anesthesiologist is concurrently supervising two non-physician students assigned as primary anesthetists (meaning the only anesthesia personnel continuously present with a patient), the anesthesiologist could be needed simultaneously in both rooms. To mitigate this potential risk, one other qualified anesthesia practitioner must also be designated to provide back-up support and must remain immediately available.
5. **Informed Consent:** The chair of anesthesiology is responsible for assuring that every patient (or the patient's guardian) understands through a standardized departmental informed consent process that the patient may be in the procedure room with only a non-physician student physically present, although still directed by the responsible anesthesiologist. In the best interest of all involved parties, documentation of this aspect of informed consent must be included in the informed consent statement.
6. **Disclosure to Professional Liability Carrier:** To be assured of reliable professional liability insurance coverage for all involved (qualified anesthesia practitioners, their employers and the institution), the chair of anesthesiology must notify the responsible professional liability carrier(s) of the practice of allowing non-physician anesthesia students to provide care without continuous direct supervision by a fully trained, credentialed and qualified anesthesia practitioner.

## ADDENDUM A

### 1. Other personnel involved in perianesthetic care:

POSTANESTHESIA NURSE: A **registered nurse** who cares for patients recovering from anesthesia.

PERIOPERATIVE NURSE: A **registered nurse** who cares for the patient in the procedure room.

CRITICAL CARE NURSE: A **registered nurse** who cares for patients in a special care area such as an intensive care unit.

OBSTETRIC NURSE: A **registered nurse** who provides care to patients during labor and delivery.

NEONATAL NURSE: A **registered nurse** who provides cares to neonates in special care units.

RESPIRATORY THERAPIST: An **allied health professional** who provides respiratory care to patients.

CARDIOVASCULAR PERFUSIONIST: An **allied health professional** who operates cardiopulmonary bypass machines.

### 2. Support personnel for technical procedures, equipment, supply and maintenance:

ANESTHESIA TECHNOLOGISTS AND TECHNICIANS  
ANESTHESIA AIDES  
BLOOD GAS TECHNICIANS  
RESPIRATORY TECHNICIANS  
MONITORING TECHNICIANS

## ADDENDUM B

### Commonly Used Payment Rules and Definitions

ASA recognizes the existence of commercial and governmental payer rules applicable to payment for anesthesia services and encourages its members to comply with them. Commonly prescribed duties include:

- Performing a preanesthetic history and physical examination of the patient;
- Prescribing the anesthetic plan;
- Personal participation in the most demanding portions of the anesthetic, including induction and emergence, where applicable;
- Delegation of anesthesia care only to qualified anesthesia practitioners;

- Monitoring the course of anesthesia at frequent intervals;
- Remaining immediately available for diagnosis and treatment while medically responsible;
- Providing indicated postanesthesia care;
- Performing and documenting a post-anesthesia evaluation.

ASA also recognizes the lack of total predictability in anesthesia care and the variability in patient needs. In certain rare circumstances, it may be inappropriate from the viewpoint of overall patient safety and quality to comply with all payment rules at every moment in time. Reporting of services for payment must accurately reflect the services provided. The ability to prioritize duties and patient care needs, moment to moment, is a crucial skill of the anesthesiologist functioning safely within the Anesthesia Care Team. Anesthesiologists must strive to provide the highest quality of care and greatest degree of patient safety to all patients in the perioperative environment at all times.

**MEDICAL “DIRECTION”** by anesthesiologists: A payment term describing the specific anesthesiologist work required and restrictions involved in billing payers for the management and oversight of non-physician anesthesia practitioners. This pertains to situations where anesthesiologists are involved in not more than four concurrent anesthetics.

**MEDICAL “SUPERVISION”** by anesthesiologists: Medicare payment policy contains a special payment formula for “medical supervision” which applies “when the anesthesiologist is involved in furnishing more than four procedures concurrently or is performing other services while directing the concurrent procedures.” [Note: The word “supervision” may also be used outside of the Anesthesia Care Team to describe the perioperative medical oversight of non-physician anesthesia practitioners by the operating practitioner/surgeon. Surgeon-provided supervision pertains to general medical management and to the components of anesthesia care that are physician and not nursing functions (e.g., determining medical readiness of patients for anesthesia and surgery, and providing critical medical management of unexpected emergencies).]

See the Medicare Claims Processing Manual (Chapter 12, Section 50.C-D) and individual payer manuals for additional information.

## **ADDENDUM C**

### **Definition of “Immediately Available” When Medically Directing (HOD 2012)**

A medically directing anesthesiologist is immediately available if s/he is in physical proximity that allows the anesthesiologist to return to re-establish direct contact with the patient to meet medical needs and address any urgent or emergent clinical problems. These responsibilities may also be met through coordination among anesthesiologists of the same group or department.

Differences in the design and size of various facilities and demands of the particular surgical procedures make it impossible to define a specific time or distance for physical proximity.

## **STANDARDS FOR BASIC ANESTHETIC MONITORING**

**Committee of Origin: Standards and Practice Parameters**

**(Approved by the ASA House of Delegates on October 21, 1986, last amended on  
October 20, 2010, and last affirmed on October 28, 2015)**

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual† monitoring may be unavoidable. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

### **1. STANDARD I**

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

#### **1.1 Objective –**

Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

### **2. STANDARD II**

During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

## **2.1 Oxygenation –**

### **2.1.1 Objective –**

To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

## **2.2 Methods –**

2.2.1 Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.\*

2.2.2 Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.\* When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the anesthesiologist or the anesthesia care team personnel.\* Adequate illumination and exposure of the patient are necessary to assess color.\*

## **3. VENTILATION**

### **3.1 Objective –**

To ensure adequate ventilation of the patient during all anesthetics.

### **3.2 Methods –**

3.2.1 Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.\*

3.2.2 When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.\* When capnography or capnometry is utilized, the end tidal CO<sub>2</sub> alarm shall be audible to the anesthesiologist or the anesthesia care team personnel.\*

3.2.3 When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

3.2.4 During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.

#### **4. CIRCULATION**

##### **4.1 Objective –**

To ensure the adequacy of the patient's circulatory function during all anesthetics.

##### **4.2 Methods –**

4.2.1 Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.\*

4.2.2 Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.\*

4.2.3 Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

#### **5. BODY TEMPERATURE**

##### **5.1 Objective –**

To aid in the maintenance of appropriate body temperature during all anesthetics.

##### **5.2 Methods –**

Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

† Note that “continual” is defined as “repeated regularly and frequently in steady rapid succession” whereas “continuous” means “prolonged without any interruption at any time.”

\* Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (\*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient’s medical record.

Code of Federal Regulations

Title 42. Public Health

Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)

Subchapter G. Standards and Certification (Refs & Annos)

Part 482. Conditions of Participation for Hospitals (Refs & Annos)

Subpart B. Administration

42 C.F.R. § 482.13

§ 482.13 Condition of participation: Patient's rights.

Effective: July 16, 2012

Currentness

A hospital must protect and promote each patient's rights.

(a) Standard: Notice of rights—

(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) Standard: Exercise of rights.

(1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) Standard: Privacy and safety.

(1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) Standard: Confidentiality of patient records.

(1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) Standard: Restraint or seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Definitions.

(i) A restraint is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(8) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

(iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

(11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician or other licensed independent practitioner; or

(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

(ii) To evaluate—

- (A) The patient's immediate situation;
- (B) The patient's reaction to the intervention;
- (C) The patient's medical and behavioral condition; and
- (D) The need to continue or terminate the restraint or seclusion.

(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.

(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

- (i) Face-to-face by an assigned, trained staff member; or
- (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

- (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
- (ii) A description of the patient's behavior and the intervention used;
- (iii) Alternatives or other less restrictive interventions attempted (as applicable);
- (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
- (v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(f) Standard: Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospital policy.

(2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c), medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) Standard: Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

#### Credits

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Notes of Decisions (9)

Current through May 12, 2016; 81 FR 29694.

# Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

*An Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists*

ANESTHESIOLOGISTS possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason, they are frequently called on to participate in the development of institutional policies and procedures for sedation and analgesia for diagnostic and therapeutic procedures. To assist in this process, the American Society of Anesthesiologists (ASA) has developed these "Guidelines for Sedation and Analgesia by Non-Anesthesiologists."

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

This revision includes data published since the Guidelines for Sedation and Analgesia by Non-Anesthesiologists were adopted by the ASA in 1995; it also includes

data and recommendations for a wider range of sedation levels than was previously addressed.

## Definitions

"Sedation and analgesia" comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation-analgesia, as developed and adopted by the ASA, are given in table 1. These Guidelines specifically apply to levels of sedation corresponding to moderate sedation (frequently called conscious sedation) and deep sedation, as defined in table 1.

## Focus

These Guidelines are designed to be applicable to procedures performed in a variety of settings (e.g., hospitals, freestanding clinics, physician, dental, and other offices) by practitioners who are not specialists in anesthesiology. Because minimal sedation (anxiolysis) entails minimal risk, the Guidelines specifically exclude it. Examples of minimal sedation include peripheral nerve blocks, local or topical anesthesia, and either (1) less than 50% nitrous oxide (N<sub>2</sub>O) in oxygen with no other sedative or analgesic medications by any route, or (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The Guidelines also exclude patients who are not undergoing a diagnostic or therapeutic procedure (e.g., postoperative analgesia, sedation for treatment of insomnia). Finally, the Guidelines do not apply to patients receiving general or major conduction anesthesia (e.g., spinal or epidural/caudal block), whose care should be provided, medically directed, or supervised by an anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and rescue techniques appropriate to the type of sedation or anesthesia being provided.

## Purpose

The purpose of these Guidelines is to allow clinicians to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. Se-

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The accompanying Web site enhancement is a bibliography.

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Anesthesiologists.”<sup>1</sup> The Task Force revised and updated the Guidelines by means of a five-step process. First, original published research studies relevant to the revision and update were reviewed and analyzed; only articles relevant to the administration of sedation by non-anesthesiologists were evaluated. Second, the panel of expert consultants was asked to (1) participate in a survey related to the effectiveness and safety of various methods and interventions that might be used during sedation-analgesia, and (2) review and comment on the initial draft report of the Task Force. Third, the Task Force held open forums at two major national meetings to solicit input on its draft recommendations. National organizations representing most of the specialties whose members typically administer sedation-analgesia were invited to send representatives. Fourth, the consultants were surveyed to assess their opinions on the feasibility and financial implications of implementing the revised and updated Guidelines. Finally, all of the available information was used by the Task Force to finalize the Guidelines.

### Availability and Strength of Evidence

Evidence-based Guidelines are developed by a rigorous analytic process. To assist the reader, the Guidelines make use of several descriptive terms that are easier to understand than the technical terms and data that are used in the actual analyses. These descriptive terms are defined below.

The following terms describe the strength of scientific data obtained from the scientific literature:

**Supportive:** There is sufficient quantitative information from adequately designed studies to describe a statistically significant relationship ( $P < 0.01$ ) between a clinical intervention and a clinical outcome, using metaanalysis.

**Suggestive:** There is enough information from case reports and descriptive studies to provide a directional assessment of the relationship between a clinical intervention and a clinical outcome. This type of qualitative information does not permit a statistical assessment of significance.

**Equivocal:** Qualitative data have not provided a clear direction for clinical outcomes related to a clinical intervention, and (1) there is insufficient quantitative information or (2) aggregated comparative studies have found no quantitatively significant differences among groups or conditions.

The following terms describe the *lack* of available scientific evidence in the literature:

**Inconclusive:** Published studies are available, but they cannot be used to assess the relation between a clinical intervention and a clinical outcome because the

studies either do not meet predefined criteria for content as defined in the “Focus” of these Guidelines, or do not provide a clear causal interpretation of findings because of research design or analytic concerns.

**Insufficient:** There are too few published studies to investigate a relationship between a clinical intervention and clinical outcome.

**Silent:** No studies that address a relationship of interest were found in the available published literature.

The following terms describe survey responses from the consultants for any specified issue. Responses were solicited on a five-point scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with a score of 3 being neutral.

**Strongly Agree:** median score of 5

**Agree:** median score of 4

**Equivocal:** median score of 3

**Disagree:** median score of 2

**Strongly Disagree:** median score of 1

### Guidelines

#### *Patient Evaluation*

There is insufficient published evidence to evaluate the relationship between sedation-analgesia outcomes and the performance of a preprocedure patient evaluation. There is suggestive evidence that some preexisting medical conditions may be related to adverse outcomes in patients receiving either moderate or deep sedation/analgesia. The consultants strongly agree that appropriate preprocedure evaluation (history, physical examination) increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes for both moderate and deep sedation.

**Recommendations.** Clinicians administering sedation/analgesia should be familiar with sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia. These include: (1) abnormalities of the major organ systems; (2) previous adverse experience with sedation/analgesia as well as regional and general anesthesia; (3) drug allergies, current medications, and potential drug interactions; (4) time and nature of last oral intake; and (5) history of tobacco, alcohol, or substance use or abuse. Patients presenting for sedation/analgesia should undergo a focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway. (Example D). Preprocedure laboratory testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia. These evaluations should be confirmed immediately before sedation is initiated.

### Example I. Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during sedation-analgesia. This may be more difficult in patients with atypical airway anatomy. In addition, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors that may be associated with difficulty in airway management are:

#### History

Previous problems with anesthesia or sedation  
Stridor, snoring, or sleep apnea  
Advanced rheumatoid arthritis  
Chromosomal abnormality (e.g., trisomy 21)

#### Physical Examination

##### Habitus

Significant obesity (especially involving the neck and facial structures)

##### Head and Neck

Short neck, limited neck extension, decreased hyoid-mental distance (< 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (e.g., Pierre-Robin syndrome)

##### Mouth

Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula

##### Jaw

Micrognathia, retrognathia, trismus, significant malocclusion

#### Preprocedure Preparation

The literature is insufficient regarding the benefits of providing the patient (or legal guardian, in the case of a child or impaired adult) with preprocedure information about sedation and analgesia. For moderate sedation the consultants agree, and for deep sedation the consultants strongly agree that appropriate preprocedure counseling of patients regarding risks, benefits, and alternatives to sedation and analgesia increases patient satisfaction.

Sedatives and analgesics tend to impair airway reflexes in proportion to the degree of sedation-analgesia achieved. This dependence on level of sedation is reflected in the consultants opinion: They agree that preprocedure fasting decreases risks during moderate sedation, while strongly agreeing that it decreases risks during deep sedation. In emergency situations, when preprocedure fasting is not practical, the consultants agree that the target level of sedation should be modified (*i.e.*, less sedation should be administered) for moderate sedation, while strongly agreeing that it should be modified for deep sedation. The literature does not provide sufficient evidence to test the hypothesis that preprocedure fasting results in a decreased incidence of adverse outcomes in patients undergoing either moderate or deep sedation.

**Recommendations.** Patients (or their legal guardians in the case of minors or legally incompetent adults) should be informed of and agree to the administration of

sedation/analgesia, including its benefits, risks, and limitations associated with this therapy, as well as possible alternatives. Patients undergoing sedation/analgesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before their procedure, as recommended by the ASA "Guidelines for Preoperative Fasting"<sup>2</sup> (Example II). In urgent, emergent, or other situations in which gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed, or (3) whether the trachea should be protected by intubation.

#### Monitoring

**Level of Consciousness.** The response of patients to commands during procedures performed with sedation/analgesia serves as a guide to their level of consciousness. Spoken responses also provide an indication that the patients are breathing. Patients whose only response is reflex withdrawal from painful stimuli are deeply sedated, approaching a state of general anesthesia, and should be treated accordingly. The literature is silent regarding whether monitoring patients' level of consciousness improves patient outcomes or decreases risks. The consultants strongly agree that monitoring level of consciousness reduces risks for both moderate and deep sedation. The members of the Task Force believe that many of the complications associated with sedation and analgesia can be avoided if adverse drug responses are detected and treated in a timely manner (*i.e.*, before the development of cardiovascular decompensation or cerebral hypoxia). Patients given sedatives or analgesics in unmonitored settings in anticipation of a subsequent procedure may be at increased risk of these complications.

### Example II. Summary of American Society of Anesthesiologists Preprocedure Fasting Guidelines<sup>2\*</sup>

Ingested Material	Minimum Fasting Period†
Clear liquids‡	2 h
Breast milk	4 h
Infant formula	6 h
Nonhuman milk§	6 h
Light meal	6 h

\* These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee a complete gastric emptying has occurred.

† The fasting periods apply to all ages.

‡ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

§ Since nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

|| A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

**Pulmonary Ventilation.** It is the opinion of the Task Force that the primary causes of morbidity associated with sedation/analgesia are drug-induced respiratory depression and airway obstruction. For both moderate and deep sedation, the literature is insufficient to evaluate the benefit of monitoring ventilatory function by observation or auscultation. However, the consultants strongly agree that monitoring of ventilatory function by observation or auscultation reduces the risk of adverse outcomes associated with sedation/analgesia. The consultants were equivocal regarding the ability of capnography to decrease risks during moderate sedation, while agreeing that it may decrease risks during deep sedation. In circumstances in which patients are physically separated from the caregiver, the Task Force believes that automated apnea monitoring (by detection of exhaled carbon dioxide or other means) may decrease risks during both moderate and deep sedation, while cautioning practitioners that impedance plethysmography may fail to detect airway obstruction. The Task Force emphasizes that because ventilation and oxygenation are separate though related physiologic processes, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function.

**Oxygenation.** Published data suggest that oximetry effectively detects oxygen desaturation and hypoxemia in patients who are administered sedatives/analgesics. The consultants strongly agree that early detection of hypoxemia through the use of oximetry during sedation-analgesia decreases the likelihood of adverse outcomes such as cardiac arrest and death. The Task Force agrees that hypoxemia during sedation and analgesia is more likely to be detected by oximetry than by clinical assessment alone.

**Hemodynamics.** Although there are insufficient published data to reach a conclusion, it is the opinion of the Task Force that sedative and analgesic agents may blunt the appropriate autonomic compensation for hypovolemia and procedure-related stresses. On the other hand, if sedation and analgesia are inadequate, patients may develop potentially harmful autonomic stress responses (e.g., hypertension, tachycardia). Early detection of changes in patients' heart rate and blood pressure may enable practitioners to detect problems and intervene in a timely fashion, reducing the risk of these complications. The consultants strongly agree that regular monitoring of vital signs reduces the likelihood of adverse outcomes during both moderate and deep sedation. For both moderate and deep sedation, a majority of the consultants indicated that vital signs should be monitored at 5-min intervals once a stable level of sedation is established. The consultants strongly agree that continuous electrocardiography reduces risks during deep sedation, while they were equivocal regarding its effect during moderate sedation. However, the Task Force believes that electrocardiographic monitoring of selected

patients (e.g., with significant cardiovascular disease or dysrhythmias) may decrease risks during moderate sedation.

**Recommendations.** Monitoring of patient response to verbal commands should be routine during moderate sedation, except in patients who are unable to respond appropriately (e.g., young children, mentally impaired or uncooperative patients), or during procedures where movement could be detrimental. During deep sedation, patient responsiveness to a more profound stimulus should be sought, unless contraindicated, to ensure that the patient has not drifted into a state of general anesthesia. During procedures where a verbal response is not possible (e.g., oral surgery, upper endoscopy), the ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation suggests that the patient will be able to control his airway and take deep breaths if necessary, corresponding to a state of moderate sedation. Note that a response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

All patients undergoing sedation/analgesia should be monitored by pulse oximetry with appropriate alarms. If available, the variable pitch "beep," which gives a continuous audible indication of the oxygen saturation reading, may be helpful. In addition, ventilatory function should be continually monitored by observation or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation. When possible, blood pressure should be determined before sedation/analgesia is initiated. Once sedation-analgesia is established, blood pressure should be measured at 5-min intervals during the procedure, unless such monitoring interferes with the procedure (e.g., pediatric magnetic resonance imaging, where stimulation from the blood pressure cuff could arouse an appropriately sedated patient). Electrocardiographic monitoring should be used in all patients undergoing deep sedation. It should also be used during moderate sedation in patients with significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

#### *Recording of Monitored Parameters*

The literature is silent regarding the benefits of contemporaneous recording of patients' level of consciousness, respiratory function, or hemodynamics. Consultant opinion agrees with the use of contemporaneous recording for moderate sedation and strongly agrees with its use for patients undergoing deep sedation. It is the consensus of the Task Force that, unless technically precluded (e.g., uncooperative or combative patient), vital signs and respiratory variables should be recorded before initiating sedation/analgesia, after administration

of sedative-analgesic medications, at regular intervals during the procedure, on initiation of recovery, and immediately before discharge. It is the opinion of the Task Force that contemporaneous recording (either automatic or manual) of patient data may disclose trends that could prove critical in determining the development or cause of adverse events. In addition, manual recording ensures that an individual caring for the patient is aware of changes in patient status in a timely fashion.

**Recommendations.** For both moderate and deep sedation, patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables should be assessed and recorded at a frequency that depends on the type and amount of medication administered, the length of the procedure, and the general condition of the patient. At a minimum, this should be: (1) before the beginning of the procedure; (2) after administration of sedative-analgesic agents; (3) at regular intervals during the procedure, (4) during initial recovery; and (5) just before discharge. If recording is performed automatically, device alarms should be set to alert the care team to critical changes in patient status.

#### *Availability of an Individual Responsible for Patient Monitoring*

Although the literature is silent on this issue, the Task Force recognizes that it may not be possible for the individual performing a procedure to be fully cognizant of the patient's condition during sedation/analgesia. For moderate sedation, the consultants agree that the availability of an individual other than the person performing the procedure to monitor the patient's status improves patient comfort and satisfaction and that risks are reduced. For deep sedation, the consultants strongly agree with these contentions. During moderate sedation, the consultants strongly agree that the individual monitoring the patient may assist the practitioner with interruptible ancillary tasks of short duration; during deep sedation, the consultants agree that this individual should have no other responsibilities.

**Recommendation.** A designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation/analgesia. During deep sedation, this individual should have no other responsibilities. However, during moderate sedation, this individual may assist with minor, interruptible tasks once the patient's level of sedation/analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.

#### *Training of Personnel*

Although the literature is silent regarding the effectiveness of training on patient outcomes, the consultants strongly agree that education and training in the pharmacology of agents commonly used during sedation-

analgesia improves the likelihood of satisfactory sedation and reduces the risk of adverse outcomes from either moderate or deep sedation. Specific concerns may include: (1) potentiation of sedative-induced respiratory depression by concomitantly administered opioids; (2) inadequate time intervals between doses of sedative or analgesic agents, resulting in a cumulative overdose; and (3) inadequate familiarity with the role of pharmacologic antagonists for sedative and analgesic agents.

Because the primary complications of sedation/analgesia are related to respiratory or cardiovascular depression, it is the consensus of the Task Force that the individual responsible for monitoring the patient should be trained in the recognition of complications associated with sedation/analgesia. Because sedation/analgesia constitutes a continuum, practitioners administering moderate sedation should be able to rescue patients who enter a state of deep sedation, whereas those intending to administer deep sedation should be able to rescue patients who enter a state of general anesthesia. Therefore, the consultants strongly agree that at least one qualified individual trained in basic life support skills (cardiopulmonary resuscitation, bag-valve-mask ventilation) should be present in the procedure room during both moderate and deep sedation. In addition, the consultants strongly agree with the immediate availability (1-5 min away) of an individual with advanced life support skills (e.g., tracheal intubation, defibrillation, use of resuscitation medications) for moderate sedation and in the procedure room itself for deep sedation.

**Recommendations.** Individuals responsible for patients receiving sedation/analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complications. At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means for summoning additional assistance, should be present whenever sedation/analgesia is administered. It is recommended that an individual with advanced life support skills be immediately available (within 5 min) for moderate sedation and within the procedure room for deep sedation.

#### *Availability of Emergency Equipment*

Although the literature is silent, the consultants strongly agree that the ready availability of appropriately sized emergency equipment reduces risks associated with both moderate and deep sedation. The literature is also silent regarding the need for cardiac defibrillators during sedation/analgesia. During moderate sedation, the consultants agree that a defibrillator should be immediately available for patients with both mild (e.g., hypertension) and severe (e.g., ischemia, congestive failure) cardiovascular disease. During deep sedation, the

consultants agree that a defibrillator should be immediately available for all patients.

**Recommendations.** Pharmacologic antagonists as well as appropriately sized equipment for establishing a patent airway and providing positive pressure ventilation with supplemental oxygen should be present whenever sedation-analgesia is administered. Suction, advanced airway equipment, and resuscitation medications

### Example III. Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The lists below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated.

#### Intravenous equipment

Gloves  
Tourniquets  
Alcohol wipes  
Sterile gauze pads  
Intravenous catheters [24-22-gauge]  
Intravenous tubing [pediatric "microdrip" (60 drops/ml)]  
Intravenous fluid  
Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]  
Appropriately sized syringes [1-ml syringes]  
Tape

#### Basic airway management equipment

Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)  
Source of suction  
Suction catheters [pediatric suction catheters]  
Yankauer-type suction  
Face masks [infant/child]  
Self-inflating breathing bag-valve set [pediatric]  
Oral and nasal airways [infant/child-sized]  
Lubricant

#### Advanced airway management equipment (for practitioners with intubation skills)

Laryngeal mask airways [pediatric]  
Laryngoscope handles (tested)  
Laryngoscope blades [pediatric]  
Endotracheal tubes  
Cuffed 6.0, 7.0, 8.0 mm ID  
[Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm ID]  
Stylet (appropriately sized for endotracheal tubes)

#### Pharmacologic Antagonists

Naloxone  
Flumazenil

#### Emergency medications

Epinephrine  
Ephedrine  
Vasopressin  
Atropine  
Nitroglycerin (tablets or spray)  
Amiodarone  
Lidocaine  
Glucose, 50% [10 or 25%]  
Diphenhydramine  
Hydrocortisone, methylprednisolone, or dexamethasone  
Diazepam or midazolam

should be immediately available and in good working order (Example III). A functional defibrillator should be immediately available whenever deep sedation is administered and when moderate sedation is administered to patients with mild or severe cardiovascular disease.

#### Use of Supplemental Oxygen

The literature supports the use of supplemental oxygen during moderate sedation and suggests that supplemental oxygen be used during deep sedation to reduce the frequency of hypoxemia. The consultants agree that supplemental oxygen decreases patient risk during moderate sedation, while strongly agreeing with this view for deep sedation.

**Recommendations.** Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered. Supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure. If hypoxemia is anticipated or develops during sedation/analgesia, supplemental oxygen should be administered.

#### Combinations of Sedative-Analgesic Agents

The literature suggests that combining a sedative with an opioid provides effective moderate sedation; it is equivocal regarding whether the combination of a sedative and an opioid may be more effective than a sedative or an opioid alone in providing adequate moderate sedation. For deep sedation, the literature is insufficient to compare the efficacy of sedative-opioid combinations with that of a sedative alone. The consultants agree that combinations of sedatives and opioids provide satisfactory moderate and deep sedation. However, the published data also suggest that combinations of sedatives and opioids may increase the likelihood of adverse outcomes, including ventilatory depression and hypoxemia; the consultants were equivocal on this issue for both moderate and deep sedation. It is the consensus of the Task Force that fixed combinations of sedative and analgesic agents may not allow the individual components of sedation/analgesia to be appropriately titrated to meet the individual requirements of the patient and procedure while reducing the associated risks.

**Recommendations.** Combinations of sedative and analgesic agents may be administered as appropriate for the procedure being performed and the condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (e.g., additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety). The propensity for combinations of sedative and analgesic agents to cause respiratory depression and airway obstruction emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.

### *Titration of Intravenous Sedative-Analgesic Medications*

The literature is insufficient to determine whether administration of small, incremental doses of intravenous sedative/analgesic drugs until the desired level of sedation or analgesia is achieved is preferable to a single dose based on patient size, weight, or age. The consultants strongly agree that incremental drug administration improves patient comfort and decreases risks for both moderate and deep sedation.

**Recommendations.** Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired end points of analgesia and sedation. Sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (e.g., oral, rectal, intramuscular, transmucosal), allowance should be made for the time required for drug absorption before supplementation is considered. Because absorption may be unpredictable, administration of repeat doses of oral medications to supplement sedation/analgesia is not recommended.

### *Anesthetic Induction Agents Used for Sedation/Analgesia (Propofol, Methohexital, Ketamine)*

The literature suggests that when administered by non-anesthesiologists, propofol and ketamine can provide satisfactory moderate sedation, and suggests that methohexital can provide satisfactory deep sedation. The literature is insufficient to evaluate the efficacy of propofol or ketamine administered by non-anesthesiologists for deep sedation. There is insufficient literature to determine whether moderate or deep sedation with propofol is associated with a different incidence of adverse outcomes than similar levels of sedation with midazolam. The consultants are equivocal regarding whether use of these medications affects the likelihood of producing satisfactory moderate sedation, while agreeing that using them increases the likelihood of satisfactory deep sedation. However, the consultants agree that avoiding these medications decreases the likelihood of adverse outcomes during moderate sedation and are equivocal regarding their effect on adverse outcomes during deep sedation.

The Task Force cautions practitioners that methohexital and propofol can produce rapid, profound decreases in level of consciousness and cardiorespiratory function, potentially culminating in a state of general anesthesia. The Task Force notes that ketamine also produces dose-related decreases in level of consciousness, culminating in general anesthesia. Although it may be associated with less cardiorespiratory depression than other sedatives, airway obstruction, laryngospasm, and pulmonary aspiration may still occur with ketamine. Furthermore, because of its dissociative properties, some of the usual

signs of depth of sedation may not apply (e.g., the patient's eyes may be open while in a state of deep sedation or general anesthesia). The Task Force also notes that there are no specific pharmacologic antagonists for any of these medications.

**Recommendations.** Even if moderate sedation is intended, patients receiving propofol or methohexital by any route should receive care consistent with that required for deep sedation. Accordingly, practitioners administering these drugs should be qualified to rescue patients from any level of sedation, including general anesthesia. Patients receiving ketamine should be cared for in a manner consistent with the level of sedation that is achieved.

### *Intravenous Access*

Published literature is equivocal regarding the relative efficacy of sedative-analgesic agents administered intravenously as compared with those administered by nonintravenous routes to achieve moderate sedation; the literature is insufficient on this issue for deep sedation. The literature is equivocal regarding the comparative safety of these routes of administration for moderate sedation and is insufficient for deep sedation. The consultants strongly agree that intravenous administration of sedative and analgesic medications increases the likelihood of satisfactory sedation for both moderate and deep sedation. They also agree that it decreases the likelihood of adverse outcomes. For both moderate and deep sedation, when sedative-analgesic medications are administered intravenously, the consultants strongly agree with maintaining intravenous access until patients are no longer at risk for cardiovascular or respiratory depression, because it increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes. In situations where sedation is initiated by nonintravenous routes (e.g., oral, rectal, intramuscular), the need for intravenous access is not sufficiently addressed in the literature. However, initiation of intravenous access after the initial sedation takes effect allows additional sedative-analgesic and resuscitation drugs to be administered if necessary.

**Recommendations.** In patients receiving intravenous medications for sedation/analgesia, vascular access should be maintained throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression. In patients who have received sedation/analgesia by nonintravenous routes, or whose intravenous line has become dislodged or blocked, practitioners should determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis. In all instances, an individual with the skills to establish intravenous access should be immediately available.

### Reversal Agents

Specific antagonist agents are available for the opioids (e.g., naloxone) and benzodiazepines (e.g., flumazenil). The literature supports the ability of naloxone to reverse opioid-induced sedation and respiratory depression. Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema. The literature supports the ability of flumazenil to antagonize benzodiazepine-induced sedation and ventilatory depression in patients who have received benzodiazepines alone or in combination with an opioid. The consultants strongly agree that the immediate availability of reversal agents during both moderate and deep sedation is associated with decreased risk of adverse outcomes. It is the consensus of the Task Force that respiratory depression should be initially treated with supplemental oxygen and, if necessary, positive pressure ventilation by mask. The consultants disagree that the use of sedation regimens that are likely to require routine reversal with flumazenil or naloxone improves the quality of sedation or reduces the risk of adverse outcomes.

**Recommendations.** Specific antagonists should be available whenever opioid analgesics or benzodiazepines are administered for sedation/analgesia. Naloxone or flumazenil may be administered to improve spontaneous ventilatory efforts in patients who have received opioids or benzodiazepines, respectively. This may be especially helpful in cases where airway control and positive pressure ventilation are difficult. Before or concomitantly with pharmacologic reversal, patients who become hypoxic or apneic during sedation/analgesia should: (1) be encouraged or stimulated to breathe deeply; (2) receive supplemental oxygen; and (3) receive positive pressure ventilation if spontaneous ventilation is inadequate. After pharmacologic reversal, patients should be observed long enough to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates. The use of sedation regimens that include routine reversal of sedative or analgesic agents is discouraged.

### Recovery Care

Patients may continue to be at significant risk for developing complications after their procedure is completed. Decreased procedural stimulation, delayed drug absorption following nonintravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period. Examples include intramuscular meperidine-promethazine-chlorpromazine mixtures and oral or rectal chloral hydrate. When sedation-analgesia is administered to outpatients, it is likely that there will be no medical supervision once the patient leaves the medical facility. Although there is not sufficient literature to examine the effects of postprocedure monitoring on

patient outcomes, the consultants strongly agree that continued observation, monitoring, and predetermined discharge criteria decrease the likelihood of adverse outcomes for both moderate and deep sedation. It is the consensus of the Task Force that discharge criteria should be designed to minimize the risk for cardiorespiratory depression after patients are released from observation by trained personnel.

**Recommendations.** Following sedation/analgesia, patients should be observed in an appropriately staffed

### Example IV. Recovery and Discharge Criteria after Sedation and Analgesia

Each patient-care facility in which sedation-analgesia is administered should develop recovery and discharge criteria that are suitable for its specific patients and procedures. Some of the basic principles that might be incorporated in these criteria are enumerated below.

#### General principles

Medical supervision of recovery and discharge after moderate or deep sedation is the responsibility of the operating practitioner, or a licensed physician.

- The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
- Patients receiving moderate or deep sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
- Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
- A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
- An individual capable of managing complications (e.g., establishing a patent airway and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

#### Guidelines for discharge

- Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should have returned to their baseline status. Practitioners and parents must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat.
- Vital signs should be stable and within acceptable limits.
- Use of scoring systems may assist in documentation of fitness for discharge.
- Sufficient time (up to 2 h) should have elapsed after the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.
- Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications.
- Outpatients and their escorts should be provided with written instructions regarding postprocedure diet, medications, activities, and a phone number to be called in case of emergency.

and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression. Oxygenation should be monitored periodically until patients are no longer at risk for hypoxemia. Ventilation and circulation should be monitored at regular intervals until patients are suitable for discharge. Discharge criteria should be designed to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel (Example IV).

### Special Situations

The literature suggests and the Task Force members concur that certain types of patients are at increased risk for developing complications related to sedation/analgesia unless special precautions are taken. In patients with significant underlying medical conditions (e.g., extremes of age; severe cardiac, pulmonary, hepatic, or renal disease; pregnancy; drug or alcohol abuse) the consultants agree that preprocedure consultation with an appropriate medical specialist (e.g., cardiologist, pulmonologist) decreases the risks associated with moderate sedation and strongly agree that it decreases the risks associated with deep sedation. In patients with significant sedation-related risk factors (e.g., uncooperative patients, morbid obesity, potentially difficult airway, sleep apnea), the consultants are equivocal regarding whether preprocedure consultation with an anesthesiologist increases the likelihood of satisfactory moderate sedation, while agreeing that it decreases adverse outcomes. The consultants strongly agree that preprocedure consultation increases the likelihood of satisfactory outcomes while decreasing risks associated with deep sedation. The Task Force notes that in emergency situations, the benefits of awaiting preprocedure consultations must be weighed against the risk of delaying the procedure.

For moderate sedation, the consultants are equivocal regarding whether the immediate availability of an individual with postgraduate training in anesthesiology increases the likelihood of a satisfactory outcome or decreases the associated risks. For deep sedation, the consultants agree that the immediate availability of such an individual improves the likelihood of satisfactory sedation and that it will decrease the likelihood of adverse outcomes.

**Recommendations.** Whenever possible, appropriate medical specialists should be consulted before administration of sedation to patients with significant underlying conditions. The choice of specialists depends on the nature of the underlying condition and the urgency of the situation. For severely compromised or medically unstable patients (e.g., anticipated difficult airway, se-

vere obstructive pulmonary disease, coronary artery disease, or congestive heart failure), or if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, practitioners who are not trained in the administration of general anesthesia should consult an anesthesiologist.

### References

1. Practice Guidelines for sedation and analgesia by non-anesthesiologists: A report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *ANESTHESIOLOGY* 1996; 84:459-71
2. 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: A report by the American Society of Anesthesiologist Task Force on Preoperative Fasting. *ANESTHESIOLOGY* 1999; 90:896-905

### Appendix I: Methods and Analyses†

The scientific assessment of these Guidelines was based on the following statements or evidence linkages. These linkages represent directional statements about relationships between sedation/analgesia interventions by non-anesthesiologists and clinical outcomes.

1. A preprocedure patient evaluation, (i.e., history, physical examination, laboratory evaluation, consultation)
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
2. Preprocedure preparation of the patient (e.g., counseling, fasting)
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
3. Patient monitoring (i.e., level of consciousness, pulmonary ventilation [observation, auscultation], oxygenation [pulse oximetry], automated apnea monitoring [capnography], hemodynamics [electrocardiogram, blood pressure, heart rate])
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
4. Contemporaneous recording of monitored parameters (e.g., level of consciousness, respiratory function, hemodynamics) at regular intervals in patients receiving sedation or analgesia
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
5. Availability of an individual who is dedicated solely to patient monitoring and safety
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
- 6a. Education and training of sedation and analgesia providers in the pharmacology of sedation-analgesia agents
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
- 6b. The presence of an individual(s) capable of establishing a patent airway, positive pressure ventilation, and resuscitation (i.e., advanced life-support skills) during a procedure
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
7. Availability of appropriately sized emergency and airway equipment (e.g., laryngeal mask airway, defibrillators)
  - a. Improves clinical efficacy (i.e., satisfactory sedation and analgesia)

†Readers with special interest in the statistical analysis used in establishing these Guidelines can receive further information by writing to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

- b. Reduces adverse outcomes
8. The use of supplemental oxygen during procedures performed with sedation or analgesia
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
9. Use of sedative agents combined with analgesic agents (*e.g.*, sedative-analgesic cocktails, fixed combinations of sedatives and analgesics, titrated combinations of sedatives and analgesics)
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
10. Titration of intravenous sedative-analgesic medications to achieve the desired effect
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
11. Intravenous sedation-analgesic medications specifically designed to be used for general anesthesia (*i.e.*, methohexital, propofol, and ketamine)
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
- 12a. Administration of sedative-analgesic agents by the intravenous route
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
- 12b. Maintaining or establishing intravenous access during sedation or analgesia until the patient is no longer at risk for cardiorespiratory depression
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
13. Availability of reversal agents (naloxone and flumazenil only) for the sedative or analgesic agents being administered
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes
14. Postprocedural recovery observation, monitoring, and predetermined discharge criteria reduce adverse outcomes
15. Special regimens (*e.g.*, preprocedure consultation, specialized monitoring, special sedatives-techniques) for patients with special problems (*e.g.*, uncooperative patients; extremes of age; severe cardiac, pulmonary, hepatic, renal, or central nervous system disease; morbid obesity; sleep apnea; pregnancy; drug or alcohol abuse; emergency-unprepared patients; metabolic and airway difficulties)
  - a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
  - b. Reduces adverse outcomes

Scientific evidence was derived from aggregated research literature and from surveys, open presentations, and other consensus-oriented activities. For purposes of literature aggregation, potentially relevant clinical studies were identified *via* electronic and manual searches of the literature. The electronic search covered a 36-yr period from 1966 through 2001. The manual search covered a 44-yr period from 1958 through 2001. More than 3,000 citations were initially identified, yielding a total of 1,876 nonoverlapping articles that addressed topics related to the 15 evidence linkages. After review of the articles, 1,519 studies did not provide direct evidence and were subsequently eliminated. A total of 357 articles contained direct linkage-related evidence.

A directional result for each study was initially determined by a literature count, classifying each outcome as either supporting a linkage, refuting a linkage, or neutral. The results were then summarized to obtain a directional assessment of support for each linkage. Literature pertaining to three evidence linkages contained enough studies with

well-defined experimental designs and statistical information to conduct formal metaanalyses. These three linkages were: linkage 8 [supplemental oxygen], linkage 9 [benzodiazepines combined with opioids *vs.* benzodiazepines alone], and linkage 13 [naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations].

Combined probability tests were applied to continuous data, and an odds-ratio procedure was applied to dichotomous study results. Two combined probability tests were employed as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported *P* values from the independent studies; and (2) the Stouffer combined test, providing weighted representation of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel-Haenszel method for combining study results using  $2 \times 2$  tables was used with outcome frequency information. An acceptable significance level was set at  $P < 0.01$  (one-tailed), and effect size estimates were calculated. Tests for heterogeneity of the independent studies were conducted to assure consistency among the study results. Der Simonian-Laird random-effects odds ratios were calculated when significant heterogeneity was found. To assess potential publishing bias, a "fail-safe, *N*" value was calculated for each combined probability test. No search for unpublished studies was conducted, and no reliability tests for locating research results were performed.

Metaanalytic results are reported in table 2. The following outcomes were found to be significant for combined probability tests: (1) *oxygen saturation*, linkage 8 (supplemental oxygen); (2) *sedation recovery*, linkage 13 (naloxone for antagonism of opioids and flumazenil for antagonism of benzodiazepine-opioid combinations); (3) *psychomotor recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (4) *respiratory-ventilatory recovery*, linkage 13 (naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations). To be considered acceptable findings of significance, both the Fisher and weighted Stouffer combined test results must agree. Weighted effect size values for these linkages ranged from  $r = 0.19$  to 0.80, representing moderate to high effect size estimates.

Mantel-Haenszel odds ratios were significant for the following outcomes: (1) *hypoxemia*, linkage 8 (supplemental oxygen) and linkage 9 (benzodiazepine-opioid combinations *vs.* benzodiazepines alone); (2) *sedation recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (3) *recall of procedure*, linkage 9 (benzodiazepine-opioid combinations). To be considered acceptable findings of significance, Mantel-Haenszel odds ratios must agree with combined test results when both types of data are assessed.

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a Kappa ( $\kappa$ ) statistic for two-rater agreement pairs were as follows: (1) type of study design,  $\kappa = 0.25$ -0.64; (2) type of analysis,  $\kappa = 0.36$ -0.83; (3) evidence linkage assignment,  $\kappa = 0.78$ -0.89; and (4) literature inclusion for database,  $\kappa = 0.71$ -1.00. Three-rater chance-corrected agreement values were: (1) study design,  $Sav = 0.45$ ,  $Var(Sav) = 0.012$ ; (2) type of analysis,  $Sav = 0.51$ ,  $Var(Sav) = 0.015$ ; (3) linkage assignment,  $Sav = 0.81$ ,  $Var(Sav) = 0.006$ ; (4) literature database inclusion,  $Sav = 0.84$ ,  $Var(Sav) = 0.046$ . These values represent moderate to high levels of agreement.

The findings of the literature analyses were supplemented by the opinions of Task Force members as well as by surveys of the opinions of a panel of consultants drawn from the following specialties where sedation and analgesia are commonly administered: Anesthesiology, 8; Cardiology, 2; Dental Anesthesiology, 3; Dermatology, 2; Emergency Medicine, 5; Gastroenterology, 9; Intensive Care, 1; Oral and Maxillofacial Surgery, 5; Pediatrics, 1; Pediatric Dentistry, 3; Pharmacology, 1; Pulmonary Medicine, 3; Radiology, 3; Surgery, 3; and Urology, 2. The rate of return for this Consultant survey was 78% ( $n = 51/65$ ). Median agreement scores from the Consultants regarding each linkage are reported in table 3.

Table 2. Meta-analysis Summary

Linkages	No. Studies	Fisher Chi-square	P	Weighted Stouffer Zc	P	Effect Size	Mantel-Haenszel Chi-square	P	Odds Ratio	Heterogeneity	
										Significance	Effect Size
Supplemental oxygen											
Oxygen saturation*	5	71.40	<0.001	5.44	<0.001	0.40	—	—	—	>0.90 (NS)	>0.50 (NS)
Hypoxemia*	7	—	—	—	—	—	44.15	<0.001	0.20	—	>0.50 (NS)
Sedatives/Opioids combined:											
Benzodiazepines + opioids											
Sedation efficacy	7	—	—	—	—	—	3.79	>0.05 (NS)	1.87§	—	<0.01
Recall of procedure	6	—	—	—	—	—	18.47	<0.001	2.18§	—	<0.01
Hypoxemia	5	—	—	—	—	—	11.78	<0.001	2.37	—	>0.05 (NS)
Naloxone for opioids											
Sedation recovery at 5 min*,†,‡	5	38.36	<0.001	3.13	<0.001	0.23	—	—	—	>0.30 (NS)	>0.02 (NS)
Respiration/ventilation†,‡	5	38.72	<0.001	3.97	<0.001	0.33	—	—	—	>0.10 (NS)	<0.001
Flumazenil for benzodiazepines											
Sedation recovery at 5 min	6	—	—	—	—	—	104.76	<0.001	8.15	—	>0.10 (NS)
Psychomotor recovery											
at 15 min	5	41.80	<0.001	1.69	0.046 (NS)	0.20	—	—	—	>0.70 (NS)	>0.50 (NS)
at 30 min	5	43.02	<0.001	3.36	<0.001	0.19	—	—	—	>0.90 (NS)	>0.50 (NS)
Respiration/ventilation†,‡	6	53.25	<0.001	5.03	<0.001	0.80	—	—	—	<0.01	<0.001
Flumazenil for benzodiazepine-opioid combinations											
Sedation recovery at 5 min	5	72.12	<0.001	6.76	<0.001	0.37	—	—	—	<0.001	<0.001
Respiration/ventilation†,‡	6	55.06	<0.001	5.13	<0.001	0.25	—	—	—	>0.10 (NS)	<0.001
Nausea/vomiting	5	—	—	—	—	—	0.28	>0.80 (NS)	1.22	—	>0.70 (NS)

\* Nonrandomized comparative studies are included; † Studies in which anesthesiologist administered benzodiazepines, opioids, or reversal agents are included; ‡ Studies in which subjects consist of intensive care unit patients, postoperative patients, or volunteers, with no procedures are included. § Der Simonian-Laird random-effects odds ratio.

For moderate sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 3 (electrocardiogram monitoring and capnography), linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives for improving satisfactory sedation), linkage 13b (routine administration of naloxone), linkage 13c (routine administration of flumazenil), and linkage 15b (anesthesiologist consultation for patients with medical conditions to provide satisfactory moderate sedation). In addition, Consultants were equivocal regarding whether postgraduate training in anesthesiology improves moderate sedation or reduces adverse outcomes.

For deep sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives), linkage 13b (routine administration of naloxone), and linkage 13c (routine administration of flumazenil).

The Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the updated Guidelines were instituted. The rate of return was 57% (n = 37/65). The percent of responding Consultants expecting no change associated with each linkage were as follows: preprocedure patient evaluation, 94%;

preprocedure patient preparation, 91%; patient monitoring, 80%; contemporaneous recording of monitored parameters, 91%; availability of individual dedicated solely to patient monitoring and safety, 91%; education and training of sedation-analgesia providers in pharmacology, 89%; presence of an individual(s) capable of establishing a patent airway, 91%; availability of appropriately sized emergency and airway equipment, 94%; use of supplemental oxygen during procedures, 100%; use of sedative agents combined with analgesic agents, 91%; titration of sedatives-analgesics, 97%; intravenous sedation-analgesia with agents designed for general anesthesia, 77%; administration of sedative-analgesic agents by the intravenous route, 94%; maintaining or establishing intravenous access, 97%; availability-use of flumazenil, 94%; availability-use of naloxone, 94%; observation and monitoring during recovery, 89%; special care for patients with underlying medical problems, 91%; and special care for uncooperative patients, 94%. Seventy-four percent of the respondents indicated that the Guidelines would have no effect on the amount of time spent on a typical case. Nine respondents (26%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of these Guidelines. The amount of increased time anticipated by these respondents ranged from 1 to 60 min.

Table 3. Consultant Survey Summary

Intervention or Linkage	Outcome	Moderate Sedation		Deep Sedation	
		N	Median* or Percent	N	Median* or Percent
1. Preprocedure patient evaluation	Satisfactory sedation	51	5	51	5
	Adverse outcomes	51	5	51	5
2. Preprocedure fasting	Satisfactory sedation	51	4	51	5
	Adverse outcomes	51	4	51	5
3. Monitoring					
	a. Level of consciousness				
	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
	b. Breathing (observation/auscultation)				
	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
	c. Pulse oximetry				
	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
	d. Blood pressure/heart rate				
	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
	e. Electrocardiogram				
	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	49	5
	f. Capnography				
	Satisfactory sedation	50	3	48	4
	Adverse outcomes	50	3	49	4
4. Contemporaneous recording	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
5. Individual for patient monitoring	Satisfactory sedation	49	4	48	5
	Adverse outcomes	49	4	48	5
6a. Education and training	Satisfactory sedation	50	5	49	5
	Adverse outcomes	50	5	49	5
6b. Individual with basic life support skills present in room	Satisfactory sedation	50	5	49	5
6c. Availability of advanced life support skills					
	In the procedure room	2	4.2%	39	79.6%
	Immediate vicinity (1-5 min)	27	56.2%	8	16.3%
	Same building (5-10 min)	14	29.2%	2	4.1%
	Outside provider	5	10.4%	0	0.0%
7. Emergency intravenous and airway equipment	Adverse outcomes	51	5	49	5
8. Supplemental oxygen	Adverse outcomes	50	4	49	5
9. Sedatives combined with analgesics	Satisfactory sedation	50	4	49	4
	Adverse outcomes	50	3	49	3
10. Titration	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
11. Avoiding general anesthetic sedatives	Satisfactory sedation	50	3	49	2
	Adverse outcomes	50	4	49	3
12a. Intravenous sedatives	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	4	50	4
12b. Intravenous access	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
13a. Immediate availability of naloxone or flumazenil	Adverse outcomes	51	5	51	5
13b. Routine administration of naloxone	Satisfactory sedation	37	2	37	2
	Adverse outcomes	37	2	37	2
13c. Routine administration of flumazenil	Satisfactory sedation	37	1	37	2
	Adverse outcomes	37	2	37	2
14. Observation, monitoring, and discharge criteria	Adverse outcomes	50	5	49	5
15a. Medical specialist consultation, patients with underlying medical conditions	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	4	49	5
15b. Anesthesiologist consultation, patients with underlying medical conditions	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	4	50	5
15c. Anesthesiologist consultation, patients with significant sedation risk factors	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
16. Postgraduate training in anesthesiology	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	50	4
17. In emergency situations, sedate patients less deeply		51	4	51	5

\* Strongly agree: Median score of 5; Agree: Median score of 4; Equivocal: Median score of 3; Disagree: Median score of 2; Strongly disagree: Median score of 1.

## Appendix II: Summary of Guidelines†

Except as noted, recommendations apply to both moderate and deep sedation.

1. Preprocedure evaluation
  - Relevant history (major organ systems, sedation-anesthesia history, medications, allergies, last oral intake)
  - Focused physical examination (to include heart, lungs, airway)
  - Laboratory testing guided by underlying conditions and possible effect on patient management
  - Findings confirmed immediately before sedation
2. Patient counseling
  - Risks, benefits, limitations, and alternatives
3. Preprocedure fasting
  - Elective procedures—sufficient time for gastric emptying
  - Urgent or emergent situations—potential for pulmonary aspiration considered in determining target level of sedation, delay of procedure, protection of trachea by intubation
  - See ASA Guidelines for Preoperative Fasting<sup>2</sup>
4. Monitoring
 

(Data to be recorded at appropriate intervals before, during, and after procedure)

  - Pulse oximetry
  - Response to verbal commands when practical
  - Pulmonary ventilation (observation, auscultation)
  - Exhaled carbon dioxide monitoring considered when patients separated from caregiver
  - Blood pressure and heart rate at 5-min intervals unless contraindicated
  - Electrocardiograph for patients with significant cardiovascular disease

*For deep sedation:*

  - Response to verbal commands or more profound stimuli unless contraindicated
  - Exhaled CO<sub>2</sub> monitoring considered for all patients
  - Electrocardiograph for all patients
5. Personnel
  - Designated individual, other than the practitioner performing the procedure, present to monitor the patient throughout the procedure
  - This individual may assist with minor interruptible tasks once patient is stable

*For deep sedation:*

  - The monitoring individual may not assist with other tasks
6. Training
  - Pharmacology of sedative and analgesic agents
  - Pharmacology of available antagonists
- Basic life support skills—present
- Advanced life support skills—within 5 min
- For deep sedation:*
- Advanced life support skills in the procedure room
7. Emergency Equipment
  - Suction, appropriately sized airway equipment, means of positive-pressure ventilation
  - Intravenous equipment, pharmacologic antagonists, and basic resuscitative medications
  - Defibrillator immediately available for patients with cardiovascular disease

*For deep sedation:*

  - Defibrillator immediately available for all patients
8. Supplemental Oxygen
  - Oxygen delivery equipment available
  - Oxygen administered if hypoxemia occurs

*For deep sedation:*

  - Oxygen administered to all patients unless contraindicated
9. Choice of Agents
  - Sedatives to decrease anxiety, promote somnolence
  - Analgesics to relieve pain
10. Dose Titration
  - Medications given incrementally with sufficient time between doses to assess effects
  - Appropriate dose reduction if both sedatives and analgesics used
  - Repeat doses of oral medications not recommended
11. Use of anesthetic induction agents (methohexital, propofol)
  - Regardless of route of administration and intended level of sedation, patients should receive care consistent with deep sedation, including ability to rescue from unintended general anesthesia
12. Intravenous Access
  - Sedatives administered intravenously—maintain intravenous access
  - Sedatives administered by other routes—case-by-case decision
  - Individual with intravenous skills immediately available
13. Reversal Agents
  - Naloxone and flumazenil available whenever opioids or benzodiazepines administered
14. Recovery
  - Observation until patients no longer at risk for cardiorespiratory depression
  - Appropriate discharge criteria to minimize risk of respiratory or cardiovascular depression after discharge
15. Special Situations
  - Severe underlying medical problems—consult with appropriate specialist if possible
  - Risk of severe cardiovascular or respiratory compromise or need for complete unresponsiveness to obtain adequate operating conditions—consult anesthesiologist

†This is a summary of the Guidelines. The body of the document should be consulted for complete details.

Comments to DBC July 28, 2016

Draft

Good afternoon and thank you for the opportunity to address this group on behalf of the California Society of Anesthesiologists as a past president of that organization from 2006-2007. I am Dr. Mark Singleton and I am currently a professor of pediatric anesthesiology, at both Stanford University and the University of California, San Francisco where I teach and supervise residents and fellows; and I am also an active medical staff member of the UCSF Benioff Children's Hospital Oakland. For 30 years I was a partner in a large private anesthesiology practice in San Jose, and have, throughout my career, administered anesthesia and sedation to countless numbers of children undergoing dental procedures in hospital, outpatient as well as dental and oral/maxillofacial surgical office settings.

We are gathered here today, representing multiple medical and dental specialties, as well as agencies entrusted with ensuring patient safety and advancing public policies, in an effort to prevent the tragic deaths and serious injuries that continue to occur in association with sedation and anesthesia during pediatric dental procedures. The motto of the American Society of Anesthesiologists displays the word "vigilance", and that single word summarizes the message I wish to convey today. We who specialize in the administration of anesthesia and sedation are in effect, poison managers, who carefully manipulate the unconscious state, breathe for patients whose ability to do so we have intentionally obliterated, and continuously measure and monitor a multitude of vital signs that allow us to keep our patients within the balance between life and death. Although we have learned to do this with ease and skill, it is in fact inherently fraught with inevitable and unforeseeable hazards, coupled with sudden, unexpected demands for split second and near perfect responses. These skills and knowledge are acquired through years of daily experience accruing far beyond residency training, and require continual practice to maintain proficiency, as is so with all specialized disciplines. It is not reasonable, nor rational to expect health practitioners, even those who have received advanced training in patient rescue and resuscitation, airway management, laryngoscopy and tracheal intubation and other life saving measures, to reliability and successfully perform those actions in the chaos of an unexpected crisis, when they almost never do so in their usual practice. This is why, when these situations do rarely occur, as we continue to witness across this country, the outcome is so often a shattering nightmare that forever mares the lives of all involved.

Therefore, I believe firmly that if we are to save the lives of future pediatric dental patients undergoing sedation or anesthesia, from that extraordinarily rare, unimaginably horrible, and too often irreversible spiral into the dark domain that we have named the "code blue", it will be through the principle of prevention. Whatever measures are debated and adopted, they should be aimed at keeping patients as far from that event horizon as possible. This requires vigilance and most importantly the specific requirements that enable and guarantee it. First and foremost in my opinion, is the absolute requirement for the assurance of the continuous adequacy of breath-to-breath

ventilation. This means that a qualified member of the procedural team, whose qualifications are determined by the needs of the patient and nature of the procedures, will be responsible **solely** to monitor every single breath the patient takes along with measuring other vital signs, as their **primary duty**. The use of a capnographic device, which measures exhaled carbon dioxide and has for decades been a ubiquitous monitor for general anesthesia in ORs across the nation, is now mandated as a standard by the ASA in all settings where patients receive procedural sedation, in an effort to ensure this necessary level of vigilance. An overarching principle being that for any intended levels of sedation, regardless of the drugs used or the route of administration or the setting in which they are given, the level of care and monitoring for adequacy of ventilation should be the same, because the risk that a patient may stop breathing is the same in a dental or oral surgeon's office as it is in the hospital OR.

This meeting today is evidence that the dental and oral surgery professions are coming to recognize what the anesthesiologists and other surgical specialties have been adapting to for several decades; that our youngest and most fragile patients require care from practitioners with specialized training, experience and skill provided in facilities with resources optimal for their needs. The American Academy of Pediatrics Section on Anesthesia and Pain Medicine, the Society for Pediatric Anesthesia, the American and California Societies of Anesthesiologists, and recently the American College of Surgeons all recommend and promote requirements of specialized qualifications for providers of anesthetic and surgical care for pediatric patients in stratified risk categories based on age, co-existing disease, and complexity of procedures. The Dental Board of California should adopt the same approach. Additional, separate requirements for documented ongoing experience and proficiency in the administration of deep sedation/anesthesia of the youngest patients should be established and enforced, as should requirements for monitoring standards proven to improve outcomes for this at-risk population. The DBC makes the distinction between pediatric and adult patients in issuing permits for oral conscious sedation but not for the higher risk undertaking of deep sedation/anesthesia, which leaves an unaddressed opportunity to protect children, and makes no sense. Parents are appropriately concerned, increasingly well informed and legitimately insistent that the care of their children be provided by professionals with special training and expertise in pediatric care and in a setting where that care can be optimally provided. No one benefits from cutting corners or ignoring mounting evidence of potential hazard, and certainly not the unfortunate practitioner upon whom such a career destroying disaster falls.

It has been suggested that additional requirements for qualified professionals to administer and monitor patients undergoing dental sedation and anesthesia will create a "barrier of access to care". This is an unfounded "straw man" argument, a hypothetical suggestion that serves only to continue a status quo, which has repeatedly failed the families of countless pediatric dental patients who have been harmed or lost their lives. Evidence shows us, in fact, that when we as professional societies and regulatory agencies, advance the definitions safety and protection for our most vulnerable patients, access to care is never diminished. We learn to improve our practices, we provide a higher level of care, we increase safety and protect patients, and our patients, families,

and even our insurers and third party payers appreciate the obvious benefits and seek our services with a greater sense of security and trust. This is the essence of our most essential mission as health professionals.

Thank you for the opportunity to express these comments.



California Society of  
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August 17, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: CSA Response to Dental Board of California Subcommittee "Working Document" Regarding the Progress of the Pediatric Anesthesia Study Requested by Senator Jerry Hill**

Dear Dr. Morrow:

The California Society of Anesthesiologists (CSA) appreciates the opportunity to comment on the important work that the Dental Board of California has undertaken to review current laws and regulations pertaining to pediatric dental anesthesia. Our first written response dated June 30 provided information to the Subcommittee concerning current standards of care, as delineated in practice guidelines and statements from the American Society of Anesthesiologists (ASA).

In further written response to your letter of June 1, we would like to offer the opinion to the Board that California's present laws, regulations, and policies are *not* sufficient to provide protection of pediatric patients during dental anesthesia.

Anesthesiology is the only medical profession recognized by the Institute of Medicine for implementing patient safety measures and protocols that have resulted in a 50-fold decrease in anesthesia-related deaths, due to physician anesthesiologist efforts.<sup>1</sup> We can offer assistance as the national experts in anesthesia safety, anesthesia medications, clinical monitoring, and airway management during sedation and anesthesia.

We strongly believe that the standard of care regarding sedation and anesthesia services for children must be consistent regardless of the route of administration, and regardless of the presence or absence of an airway device. Children easily pass from an intended level of moderate sedation to an unintended level of deep sedation or general anesthesia, with the potential danger of cardiorespiratory arrest. Therefore, standards of care for personnel, equipment, emergency medications, and monitoring should not differ.

**To summarize, we recommend:**

- **Revision of terminology in California laws and regulations to replace the terms "oral conscious sedation" and "conscious sedation" with the standard terminology of minimal sedation, moderate sedation, and deep sedation/general anesthesia.**
- **Elimination of the route of administration (oral vs. parenteral) as a distinction among types of sedation permit.**
- **One standard of care for children undergoing moderate sedation and deep sedation/general anesthesia, to include full respiratory monitoring, and the presence of a second anesthesia provider in addition to the operating dentist or oral surgeon.**

## 1. Terminology

The terminology used in the existing laws, regulations and permits is out of date, specifically in its use of the terms “oral conscious sedation” and “conscious sedation” to refer to all states of sedation other than general anesthesia. As a first step, we recommend revision of the Business and Professions Code, AB 2235 (Thurmond), and all applicable regulations to reflect the current classification of states of sedation and anesthesia. These have been agreed upon by the ASA and by the Centers for Medicare and Medicaid Services (CMS):

- a. **Minimal Sedation**
- b. **Moderate Sedation**
- c. **Deep Sedation**

A state of deep sedation is considered to be in most respects identical to general anesthesia by the ASA, by the Dental Board of California, and by CMS.

- d. **General Anesthesia**

The current categories are described in detail in the recently updated “Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016”, from the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD).<sup>2</sup> The full definitions are appended at the conclusion of this letter.

## 2. Distinction between oral and parenteral sedation

The distinction between oral and parenteral techniques of sedation should be abandoned, in our opinion. All levels of sedation – minimal, moderate, and deep – may be reached with oral medications in sufficient doses as well as with parenteral means. Independent of the medication given, or the presence or absence of an airway device, a patient who responds purposefully only to pain is in a state of deep sedation, and one who does not respond even to pain is in a state of general anesthesia.

Some of the patients in the cases that were reviewed by the Subcommittee suffered adverse outcomes, including death, as a result of oral medications alone. The practice of giving repeated doses of oral medications (“medication stacking”) has proved on many occasions to be hazardous, as both the onset and the duration of action may be difficult to predict. **We recommend categorization by depth of sedation, not by the route of administration.**

## 3. Revision of existing dental anesthesia regulations for office practice

We strongly recommend the definition of new permit categories to replace those currently in existence, in order to eliminate use of the term “conscious sedation” and to stratify permits by depth of sedation.

Children with significant underlying health problems may not be appropriate candidates for sedation or anesthesia in the dental office setting. This would include ASA Physical Class 3 and 4 patients. Further guidance about the classification of patients as ASA 3 or 4 may be found on the ASA’s website, under the heading of Resources (<http://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system>). In children, these conditions could include (but not be limited to) asthma, enlarged tonsils, obesity, sleep apnea, congenital heart disease, a history of prematurity, significant developmental delay, and abnormal airway anatomy. Such cases should be performed in an ambulatory surgery center or hospital.

We recommend recognition of the fact that children **under 7 years of age** are different from older children, teenagers, and adults in these respects:

- They represent the highest risk of life-threatening complications under sedation or anesthesia due to small airways and reduced physiologic reserve;<sup>3</sup>

- Those who are unable to cooperate or hold still – sometimes referred to as “pre-cooperative” in developmental age – require a deeper level of sedation/anesthesia in order to control behavior and ensure relaxation;
- California law, AB 2003 (1998), already sets the precedent of requiring health plans to pay for anesthesia and associated facility charges when anesthesia is indicated for enrollees under 7 years of age, or enrollees who are developmentally disabled, regardless of age.

Therefore, we recommend creation of **two new categories** of pediatric dental sedation/anesthesia permits for children of pre-cooperative age. This may be defined either as a chronological age under 7, or a child of 7 years or older with a developmental age that renders the child unable to tolerate a dental/oral surgery procedure with local anesthesia and distraction techniques.

#### **A. Minimal sedation for children**

The rationale for this category is to preserve access to care for children, otherwise in good health, requiring brief, limited dental procedures in the office setting. Criteria would mandate:

- Meeting all existing requirements of the current “oral conscious sedation for minors” permit;
- Adherence to AAP/AAPD guidelines for monitoring and staffing of cases under minimal sedation;<sup>2</sup>
- Medication use restricted to nitrous oxide and one dose of a single oral agent;
- No use of halogenated inhalational agents, or of medications administered by the intranasal, rectal, intravenous, or intramuscular route.

#### **B. Moderate sedation, deep sedation, general anesthesia for children**

The rationale for including moderate sedation in this category is the recognition that levels of sedation are on a spectrum, and children may progress unpredictably from a lighter to a deeper level of sedation, and into a state of general anesthesia, during the course of a procedure. Criteria would mandate:

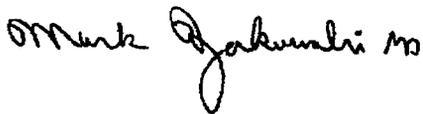
- AAP/AAPD guidelines for monitoring, including the use of respiratory monitoring (pulse oximetry, capnography) for all cases whether or not endotracheal intubation is utilized.
- The continuous presence of a second provider **in addition to** the operating dentist or oral surgeon. This individual’s sole responsibility would be “to constantly observe the patient’s vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration,” as stated in the AAP/AAPD guidelines.<sup>2</sup>
- The second provider should be a qualified, licensed, independent anesthesia provider, trained in Pediatric Advanced Life Support (PALS). Qualified providers would include a dentist with appropriate additional training in anesthesia as defined by California law, an oral surgeon, a dentist anesthesiologist, a certified registered nurse anesthetist, or a physician anesthesiologist.
- Performance of a defined minimum number of pediatric cases per year.

It is our belief that implementation of these recommendations would improve safety for pediatric patients undergoing dental procedures, but would not unduly restrict access to care. The literature strongly supports the view that advances in monitoring, continuous practice with pediatric cases, and prompt recognition of high-risk situations have reduced the incidence of cardiac arrest in anesthetized children.<sup>3</sup> Adoption of the medical model of documenting and reviewing adverse events and near-misses, as recommended in AB 2235 (Thurmond), may identify system issues. Occasional adverse outcomes tend to reflect system-wide deficiencies, rather than individual misdeeds, and are likely to be amenable to solutions that improve care system-wide.

We look forward to further productive discussion, and again appreciate the opportunity to work with you on this important issue for the health and safety of California children. Please feel free to contact CSA Legislative Advocates Bryce Docherty or Vanessa Cajina, at 916-448-2162 or via e-mail at [bdocherty@ka-pow.com](mailto:bdocherty@ka-pow.com) or [vcajina@ka-pow.com](mailto:vcajina@ka-pow.com) should you have any further questions or need additional information.

Respectfully submitted on behalf of the California Society of Anesthesiologists,

Sincerely,



Mark Zakowski, MD  
President

cc: Karen Fischer, Executive Director, Dental Board of California  
Honorable Jerry Hill (D-San Mateo)  
Honorable Tony Thurmond (D-Richmond)  
Bryce Docherty, KP Public Affairs  
Vanessa Cajina, KP Public Affairs

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References:

1. To Err is Human: Building a Safer Health System. Publication of the Institute of Medicine, National Academy Press, November, 1999.
2. Cote CJ, Wilson S. American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. Pediatrics 2016; 138(1): e20161212.
3. Morray, JP. Cardiac arrest in anesthetized children: recent advances and challenges for the future. Pediatric Anesthesia 21 (2011) 722-729.

**Definitions for levels of sedation and anesthesia:**

- a. **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.
- b. **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.
- c. **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.
- d. **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.



California Society of  
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October 26, 2016

Steven G. Morrow, DDS, MS  
President, Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: Dental Board of California, Subcommittee on Pediatric Dental Sedation, Preliminary Recommendations for Discussion, October 3, 2016**

Dear Dr. Morrow:

The California Society of Anesthesiologists (CSA) appreciates the opportunity to comment on the Subcommittee's preliminary recommendations regarding pediatric dental sedation.

We commend the Subcommittee members for their careful consideration of the complex issues involved. The CSA concurs completely with the first recommendation, to continue outcomes research, and the second recommendation, to update and standardize the definitions of sedation and general anesthesia within California law and regulations.

However, we cannot agree with the content of the Subcommittee's third recommendation where it diverges from the recommendations in our letter of August 17, 2016.

Specifically, we disagree with the Subcommittee's recommendation endorsing a lower standard of care for moderate sedation compared with deep sedation/general anesthesia in pediatric patients.

The Subcommittee has chosen to group all children under the age of 13 in one category for moderate sedation, whereas it is obvious to any parent who has taken a child for a haircut that the ability to cooperate is far different in a child of 2 or 3 compared with a child of 12.

We stand by our prior recommendation that moderate sedation, deep sedation, and general anesthesia should have the same standard of care for pre-cooperative children, defined as a chronological age under 7, or a child of 7 years or older with a developmental age that renders the child unable to tolerate a dental/oral surgery procedure with local anesthesia and distraction techniques.

Levels of sedation are on a continuum, and children may progress unpredictably from a lighter to a deeper level of sedation, and into a state of general anesthesia, during the course of the anesthetic. If life-threatening problems with breathing or heart function develop, they may not be recognized in time if an appropriate level of staffing and monitoring is not already in place.

We stand by our prior recommendations for safe provision of moderate sedation, deep sedation, and general anesthesia to pre-cooperative children:

- AAP/AAPD guidelines<sup>1</sup> for monitoring, including the use of respiratory monitoring (pulse oximetry, capnography), for all cases whether or not endotracheal intubation is utilized.
- The continuous presence of a second provider **in addition to** the operating dentist or oral surgeon. This individual's sole responsibility would be "to constantly observe the patient's vital signs, airway patency,

and adequacy of ventilation, and to either administer drugs or direct their administration," as stated in the AAP/AAPD guidelines.

- The second provider should be a qualified, licensed, independent anesthesia provider, trained in Pediatric Advanced Life Support (PALS). Qualified providers would include a dentist with appropriate additional training in anesthesia as defined by California law, an oral surgeon, a dentist anesthesiologist, a certified registered nurse anesthetist, or a physician anesthesiologist.
- Performance of a defined minimum number of pediatric cases per year.

We look forward to further productive discussion, and again appreciate the opportunity to work with you on this important issue for the health and safety of California children. Please contact CSA Legislative Advocates Bryce Docherty or Vanessa Cajina at 916-448-2162, or via email at [bdocherty@ka-pow.com](mailto:bdocherty@ka-pow.com) or [vcajina@ka-pow.com](mailto:vcajina@ka-pow.com), should you have any further questions or need additional information.

Respectfully submitted on behalf of the California Society of Anesthesiologists,

Sincerely,



Mark Zakowski, MD  
President, California Society of Anesthesiologists

cc: Karen Fischer, Executive Director, Dental Board of California  
Honorable Jerry Hill (D-San Mateo)  
Honorable Tony Thurmond (D-Richmond)  
Bryce Docherty, KP Public Affairs  
Vanessa Cajina, KP Public Affairs

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Reference:

1. Cote CJ, Wilson S. American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics* 2016; 138(1): e20161212.

# **CALIFORNIA SOCIETY OF DENTIST ANESTHESIOLOGISTS (CSDA)**

1. October 28,2016 Letter from Richard F. Stafford, DDS – President, California Society of Dentist Anesthesiologists

# CSDA

California Society of  
Dentist Anesthesiologists

321 North Larchmont Blvd. Suite 721, Los Angeles, CA 90004

October 28, 2016

Dr. Steven Morrow, DDS, MS  
Dental Board of California  
Department of Consumer Affairs  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

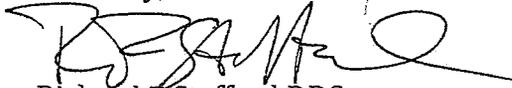
The California Society of Dentist Anesthesiologists (CSDA) appreciates the Dental Board's work on pediatric dental anesthesia. CSDA is in agreement that safety should be the paramount concern regarding pediatric anesthesia in the dental office.

CSDA would like to restate our recommendations for pediatric general anesthesia: *All children below the age of 13 years receiving general anesthesia in the dental office must have a separate dentist anesthesiologist or physician anesthesiologist providing that care.*

We join AAP, CSA, and CNA in this recommendation. All these organizations are aware that the medical pediatric anesthesia literature indicates children are at higher risk for general anesthetic complications. By administering both general anesthesia and performing pediatric procedures, the risks of general anesthesia are increased.

Waiting for evidence-based data to implement this one change ignores decades of experience by experts in the field of anesthesia, current medical anesthesia literature, and common sense.

Sincerely,



Richard F Stafford DDS

President, California Society of Dentist Anesthesiologists

# **CALIFORNIA SOCIETY OF PEDIATRIC DENTISTRY (CSPD)**

## **See American Academy of Pediatric Dentists Comment**

1. October 13, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016



## **CALIFORNIA SOCIETY OF PEDIATRIC DENTISTRY**

October 13, 2016

Dental Board of California  
2005 Evergreen St, Suite 1550  
Sacramento, CA 95815

Attn: *Subcommittee on Pediatric Dental Sedation*  
Re: Preliminary Recommendations Published October 3, 2016

The California Society of Pediatric Dentistry (CSPD) again commends the Dental Board of California and the Pediatric Dental Anesthesia Subcommittee on the quality of research and thoughtful analysis that has gone into the working documents released in July and on October 3, 2016. We support and applaud the open and transparent process by which the subcommittee is moving forward to identify any necessary statutory or other changes to the administration of office-based sedation which improve the margin of safety for pediatric patients. We recognize that while change in existing practice and delivery models can pose significant challenges to medical and dental providers, and must be supported by an evidence-based development process, every effort must be made to ensure the safest possible environment of care.

While it is too early to comment specifically on the final recommendations that will come from the Dental Board's Subcommittee on Pediatric Dental Sedation, we can provide the following observations and comments.

CSPD is in general agreement with restructuring plan for the dental sedation and general anesthesia permitting system as outlined in the draft of October 3, 2016, and with the need to establish the definitions of general anesthesia, conscious sedation, and pediatric and adult oral conscious sedation in statute and regulation so as to be consistent with the contemporary nomenclature used in training standards and in the guidelines and recommendations of professional organizations.

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The **California Society of Pediatric Dentistry** is the state's leading advocate and recognized authority on oral health issues affecting infants, children, adolescents and patients with special health care and developmental needs. The Society interacts with the state legislature, regulatory bodies, licensing bureaus, institutions of dental education, media outlets, and policy makers at all levels of public and private participation to promote and ensure optimal pediatric oral health throughout the state. CSPD is the professional membership organization of California's over 900 pediatric dental practitioners, educators and researchers.

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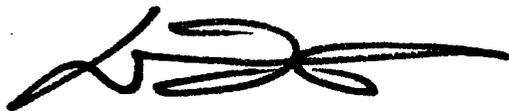
The recommendation to adopt a tripartite permit approach of **Minimal Sedation, Moderate Sedation, and Deep Sedation / General Anesthesia** is logical and practical.

We support the codification of support personnel that must be present for each sedation level and the requirement to provide evidence of continued competence in a particular sedation level, either by demonstration of performing a specific number of cases in each renewal cycle or completing a specific educational requirement, as a condition of permit renewal. We are in agreement with the concept of a pediatric minimal sedation permit, but believe the age for such permit should be required for patients twelve years of age and under and that multiple dosing under this pediatric permit should be prohibited.

CSPD believes further consideration should be given to the age of demarcation for an unrestricted general anesthesia/deep sedation permit and that that age should most likely be twelve and under instead of below the age of seven. While the data for adverse outcomes in the seven to twelve age range is not persuasive, the differences from adult physiology and time to resuscitation in this cohort suggest further deliberation before adopting the subcommittee's recommendation.

Lastly, CSPD supports all efforts contained in the recommendations to improve data collection and the reporting of sedation and anesthesia outcomes to identify any additional future improvements to the administration of office-based sedation.

The California Society of Pediatric Dentistry recognizes that the adoption of new or modified parameters of care will place additional responsibilities of training and patient monitoring on providers across the spectrum of anesthesia modalities. In this regard, our members stand ready to support and implement all measures which improve the margin of safety for our pediatric patients.



David Okawachi, DDS  
President, CSPD



Paul Reggiardo, DDS  
Public Policy Advocate, CSPD

cc: Officers and Directors, CSPD  
Andrew Soderstrom, Executive Director, CSPD

# **CALIFORNIA SOCIETY OF PERIODONTISTS (CSP)**

1. October 23, 2016 Letter from Nicholas Caplanis, DMD, MS, President Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016



# California Society of Periodontists

October 23, 2016

Dr. Steve Morrow  
President Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Re: Pediatric Dental Sedation Subcommittee Preliminary Recommendations

Dear Dr. Morrow

The California Society of Periodontists (CSP), representing a majority of conscious sedation permit holders in the state of California appreciates the opportunity to offer its input on the preliminary recommendations by the subcommittee on pediatric dental sedation. The CSP recognizes and shares the Dental Board's concerns over deep and general anesthesia. We would like to respectfully emphasize that the operator/anesthetist model for moderate (aka conscious) sedation in adults is distinct from deep and general anesthesia and has a flawless track record for safety. Therefore any new regulations affecting moderate sedation must not only consider improvement in patient outcome but also access to care and be grounded in scientific evidence.

It is apparent after reading the subcommittee's report that a far reaching evaluation of all levels of anesthesia in dentistry, and in all patient age groups, has been undertaken. Perplexingly, the preliminary report seems to focus more on moderate and minimal sedation rather than on deep sedation and general anesthesia. While we appreciate the efforts of the committee for this comprehensive undertaking, it seems that an evaluation of moderate sedation at this time, especially in adults, somewhat distracts from the significant concerns recently raised by Caleb's law which exclusively focused on pediatric general anesthesia. Further, if the intent of the subcommittee was to comprehensively address all levels of anesthesia in dentistry it would have been beneficial to include conscious and oral sedation permit holders on that committee to help draft a more inclusive report.

With this in mind, the CSP makes the following comments:

1. The CSP agrees with item 1 of the subcommittee's recommendations. In addition, we recommend that the blue ribbon committee in anesthesia be reactivated by the DBC with representatives from all stakeholders of anesthesia in dentistry to continuously collect patient data and evaluate adverse outcomes when they do occur in order to make appropriate recommendations to the DBC.
2. The CSP fully agrees with item 2 of the subcommittee's recommendations regarding the updated definitions of anesthesia reflecting depth and physiology of anesthesia rather than route of administration.
3. The CSP disagrees with the arbitrary use of 13 years of age to stratify the moderate sedation permit structure. Whereas we recognize that this may be a valid consideration for general anesthesia, there

is little scientific evidence to support an improvement in patient outcomes with moderate sedation. In addition, there have not been any significant adverse outcomes reported with moderate sedation in patients aged 7-13 to our knowledge. Further, moderate sedation in this age group is being actively taught to Residents in at least one California Periodontal Residency Program (LLU School of Dentistry). It is well recognized that patient compliance with moderate sedation in this age group is a more significant concern. We concede the requirement for a new pediatric moderate sedation permit requirement for children ages 6 and under. The CSP however, recommends that clinician discretion be respected between the ages of 7 and 13 with regards to moderate sedation considering the varied levels of compliance in this age group.

4. The CSP agrees with the need for pediatric advanced life support (PALS) for deep and general anesthesia in children of all ages, as well as for moderate sedation for children 6 and under. The CSP however disagrees with the need for PALS training for moderate sedation in patients under the age of 13. By definition, moderate sedation does not require intervention for airway maintenance and spontaneous ventilation. Further, moderate sedation permit holders are not trained in the diagnosis and management of cardiac arrhythmias or in the administration of anti-arrhythmic medications. Therefore the PALS course is not only inconsistent with the definition of moderate sedation but may even increase the risk for an adverse outcome by having untrained and inexperienced practitioners administer potent cardiac medications. The CSP instead recommends that instruction in pediatric and small adult airway management be mandated within the existing continuing education re-certification requirements.
5. The CSP recognizes the benefits of capnography for deep and general anesthesia when respiratory depression is likely and when airway assistance is commonly required. The CSP however, strongly disagrees with this requirement for moderate sedation. End tidal CO<sub>2</sub> monitoring in an open airway (non- intubated) is simply not reliable. In addition, false positives are common which increases the likelihood that alarms will be ignored. Furthermore, the use of a precordial stethoscope is far more beneficial when monitoring an airway during moderate sedation and the presence of a precordial stethoscope is currently mandated. The CSP would therefore be receptive to the requirement of either constant monitoring with a precordial stethoscope OR the use of capnography, at the clinician's discretion. The mandate for capnography in moderate sedation will only increase health care costs further reducing access to care and yet have no appreciable effect on patient outcomes.
6. The CSP recommends that the language used regarding staff member "monitoring and resuscitation of sedated patients" found in sections 3bi3, 3bii3 and 3cv "trained in the monitoring and resuscitation of sedated patients" should be eliminated. At the present time, there are no courses approved by the Dental Board readily available to the staff of moderate or minimal sedation permit holders to fulfill the requirement of "trained". Such a course when it is developed should be readily available for all staff members involved in dental sedation and designed to address the unique needs of each level of anesthesia; minimal and moderate vs. deep and general anesthesia. After such a course is developed, the issue regarding staff training can then be re-assessed. The CSP recommends that certification in Basic Life Support be required for all Registered Dental Assistants



# California Society of Periodontists

assisting with moderate sedation.

7. The CSP recommends that a moderate sedation permit be required when multiple oral doses of medications exceeding the maximum daily allowance recommendations, or when multiple medications (polypharmacy) are used to achieve a desired level of sedation. Dosages exceeding those recommendations and interactions between different types and classes of medications increase the risk of respiratory depression and airway compromise, requiring knowledge of rescue from the level of deep sedation.

Once again, thank you for allowing the California Society of Periodontists to offer its comments and recommendations on this very important issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Nicholas Caplanis".

Nicholas Caplanis DMD MS  
President California Society of Periodontists  
Assistant Professor Loma Linda University School of Dentistry  
Diplomate American Board of Periodontology

Cc: Dr. Kenneth G. Wallis  
President California Dental Association

Gayle Mathe RDH  
Community Programs Director  
California Dental Association

Karen Fischer  
Executive Officer  
Dental Board of California

# **HERMAN OSTROW SCHOOL OF DENTISTRY OF USC**

1. October 28, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

# Herman Ostrow School of Dentistry of USC

Division of Endodontics, Orthodontics,  
and General Practice Residency  
*James W. Tom, DDS, MS, FACD*  
*Clinical Associate Professor*

October 28<sup>th</sup>, 2016

Karen Fischer, Executive Director  
Dental Board of California  
Pediatric Anesthesia Subcommittee  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: October 3<sup>rd</sup>, 2016 DBC Recommendations to amend Section 1646- 1647.26  
CA B&P Code**

Dear Mrs. Fischer and Members of the Dental Board of California,

After extensive review of the proposed amendments from the Pediatric Anesthesia Subcommittee, I applaud the Board's willingness to update the and amend the current rules and regulations to ensure clarity among professionals, to promote congruence with national standards, and to ultimately secure patient safety in the area of pediatric anesthesia in dental settings. Specifically, the changes to the definition of moderate sedation from "conscious sedation" and the movement towards licensure and permitting to intended levels of sedation rather than routes of administration are prudent and sound.

Understanding that the process is dynamic and evolving, I would offer the following recommendations to the Subcommittee with the perspective of a dentist anesthesiologist educator, the ADA-appointed Task Force Member on the American Society Of Anesthesiologists' *Practice Guidelines on Sedation and Analgesia by Non-physicians*, and a subject matter consultant to the Dental Board of California for 1680(z) reports.

- Adoption of the 2005 DBC-Commissioned, Blue Ribbon Panel Report's primary recommendation of establishing a multidisciplinary standing committee to review issues related to all sedation & anesthesia issues. Knowing that various stakeholders exist within the dental and medical communities, multiple perspectives must be considered when crafting regulation that ensures patient safety. It must include oral surgeons, dentist

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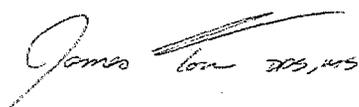


anesthesiologists, pediatric dentists, and periodontists since they are regularly providing various levels of sedation and general anesthesia to their patients. The inclusion of physician anesthesiologists and pediatricians also ensures the practices and direction of the committee align with the greater anesthesia and oral health community.

- Strict adherence to the already established parameters of care outlined by the American Academy of Pediatrics/American Academy of Pediatric Dentists (AAP/AAPD) *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* (2016). The ADA has long established in their own *Guidelines for the Use of Sedation and General Anesthesia by Dentists* (updated and approved last week on October 25<sup>th</sup>, 2016), that “For children 12 years of age or under, the ADA supports the use of AAP/AAPD Guidelines.” This includes the provisions of
  - Any patient undergoing sedation or general anesthesia ages 12 and under
  - Requiring “one person whose only responsibility is to constantly observe the patient’s vital signs, airway patency, and adequacy of ventilation and to either administer or direct their administration” not involved in the conduct of the procedure. A dental sedation assistant cannot fulfill these requirements without formal education and clinical decision-making skills pertaining to pediatric physiology, pediatric anesthesiology, pediatric pharmacology, and pediatric resuscitation.

It is without question that the actions of the Dental Board of California are under much scrutiny outside of the dental profession. The progress thus far has been encouraging for those involved, and I look forward to further opportunities to comment on patient safety issues.

Sincerely,



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**LOMA LINDA UNIVERSITY – PEDIATRIC  
DENTISTRY DEPARTMENT – SCHOOL OF  
DENTISTRY**

1. November 10, 2016 Letter from Samah Omar, BDS, DDS, MSD on behalf of the LLU Pediatric Dentistry Department with attachments



LOMA LINDA  
UNIVERSITY

**Pediatric Dentistry Department  
School of Dentistry**

November 10, 2016

To Whom It May Concern:

It was brought to our attention that the California Dental Board will vote on a new regulation that will no longer allow sedating patients under the age of 7 with more than one oral sedative in addition to nitrous oxide.

If this becomes effective, it will have a huge impact on the quality and access to care that we provide to young apprehensive children and will impact our profession. There are a few points that I would like to bring to the board's attention:

- Oral sedation is safe when carried with strict adherence to the guidelines and the recommended doses. All documented cases of adverse effects were cases when amounts higher than the recommended doses were used for either the sedatives or the local anesthetic agents or when re-dosing. These problems are related to individual practitioners behaviors not to the universal guidelines or state limitations of the number of agents used.
- All the most commonly used oral sedation medications are not as effective when used orally specially if used solely. There is no evidence that any medication that is known or widely acceptable to be as effective when used alone.
- When only one sedative is used, higher doses are required to reach the desired level of sedation. This increases the risks of toxicity and adverse effects. One advantage of multi-agent sedation is using lower doses of each to decrease the incidence of toxicity and adverse effects while taking an advantage of the different physiological actions of the different medications.
- Using one agent only will increase the chances of failure and compromise the quality of care provided. This will be reflected on the number of children that will be either treated with protective stabilization or physical restraint and will require more utilization of general anesthesia for dental treatment.
- The majority of children in CA are insured through the government aid (MediCal) under the Obama care and treatment with general anesthesia is only a covered benefit for them in hospitals and surgery centers. Patients already have access to care problems as many hospitals and centers have

long waiting lists, for example in LLU, our waiting list for the hospital is 9-12 months.

- This new regulation may lead to lower success rate and with time practitioners will direct their practice to either using physical restraint which has some indications and can be used in highly selective cases. However, the routine use of protective stabilization (Papoose board) is discouraged by AAPD for it's long-term negative impact on children socially and emotionally.
- Oral sedation is a very helpful tool to manage patients with acute situational anesthesia or too young to cooperate in a dental office set up. One of the main roles of our profession is to instill positive attitudes towards oral health care and dental treatment at an early stage of life.
- Please refer to the attached studies for more information.

The Pediatric Dentistry Department full time faculty at Loma Linda University would like to thank the board for their constant and diligent efforts to protect the pediatric patients and ensure their safety. We also affirm that we all, as individuals and as a profession, work jointly towards achieving the same goals. We hope that the committee may reconsider that decision or at the least not vote on it at this time and allow our local and national professional societies the chance to investigate and discuss with the board the long-term influence on the Pediatric Dentistry profession in California.

Sincerely,

*Samah Omar, BDS, DDS, MSD*

*Associate Professor and Diplomat of ABPD.*

On Behalf of the LLU Pediatric Dentistry Department  
Loma Linda University, Loma Linda, CA.

# Management of Child Patient Behavior: Quality of Care, Fear and Anxiety, and the Child Patient

Stephen Wilson, DMD, MA, PhD

## Abstract

Behavior management is a key component when providing dental care to children who have suffered traumatic dental injuries. This article reviews the current status of behavior management including basic communication techniques and advanced techniques used by pediatric dentists. Emphasis is given to oral and inhalation sedation when treating children at initial visits status post dental injury. Little is known about the use of pharmacologic agents in managing young but behaviorally challenging patients who have suffered dental trauma. Future care involving sedation and specialized endodontic procedures of these young patients through collaborative efforts between endodontists and pediatric dentists seems promising and should be pursued. (*J Endod* 2013;39:S73-S77)

## Key Words

Basic communication techniques, behavior management, children, sedation

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0099-2399/\$ - see front matter

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The first encounter with a trauma patient is important in terms of managing not only the immediate consequences of the dental injury but also the patient's anxiety and response to the initial and subsequent phases of treatment. The goal is multifaceted:

1. To stabilize the patient's orofacial trauma
2. To develop trust among the patient, family, and the dental provider
3. To set the stage for the discussions of potential outcomes associated with the trauma
4. To minimize the patient's fear and anxiety, thus decreasing the likelihood of significant disruptive behaviors

A patient whose anxieties and fears are not addressed and managed initially during treatment may exhibit poor compliance with instructions including failure to return for critical follow-up care.

There is evidence that the patient's level of anxiety may increase or even result in the onset of fear after treatment subsequent to dental injury or treatment (1-6). In the child population, increased anxiety and fear may manifest itself in many ways including "acting out" or disruptive behaviors at the time of initial treatment or in subsequent visits (7). Likewise, minimizing the patient's anxiety and fear should theoretically promote a smoother visit and better working conditions for the dental team. One of the possible negative consequences of anxiety and fear in patients is the development of avoidance behaviors (8). Failure to return for follow-up visits may compromise the outcome of care, resulting in early tooth loss or an abscess, all of which may ultimately compound the patient's avoidance behaviors.

Most likely, any trauma to the anterior primary teeth will be seen and managed first by the pediatric or general dentist. However, as a part of the management, both types of dentists may refer children who have suffered injury to traumatized permanent, immature incisors to the endodontists. Children who have these immature teeth usually range in age from 5½-8½ years. The behavior of a child of this age is beginning to change significantly in terms of emotional and social cognition (9) as well as developing an increasingly independent relationship with parents that will culminate in the teenage years (10, 11). They are "ready" for school and hence usually respond well to adult reasoning, expectations, and explanation. That type of behavior generally portends well for the dental provider. In fact, some evidence suggests an inverse relationship between dental fear and patient age (12).

The importance of good communication with the parent is necessary to set the stage for understanding prognostic possibilities and expectations of treatment processes their children receive, especially those who have suffered traumatic injuries. Good communication, clear concepts, and well-expressed detailing of procedures, active listening, and expectations of short- and long-term outcomes (13) are the prerequisites to gaining informed consent, parent confidence with the rendered care, and even patient assent before treatment.

Several factors are known to influence the child's behavior during a visit to the dentist. Children's developmental age and the corresponding level of cognition and emotionality play a prominent role in clinical behavior (11). Interwoven with these primal characteristics is the child's temperament, broadly embraced and defined as how a child responds to novel environments and strangers (14-16). Temperament is thought to have a genetic basis, and some aspects of the temperament domain significantly influence children's behavior in clinical settings including dental offices (12, 17-28). Shy or withdrawn, nonapproachable, and moody children generally may not be cooperative for routine dental procedures (19). In fact, some evidence

suggests that they are not good sedation candidates unless the attained depth of sedation is relatively deep (18, 27, 29–31).

Another possible consideration is the degree of procedural challenge a child will undergo during dental treatment. In general, the greater the extent of treatment, potential for multiple visits, and perceived threat of procedures, the greater the likelihood of uncooperative and disruptive behaviors (32, 33). Individuals may respond differently in threatening situations (34). Dental experiences involving the rubber dam, handpiece, and injections seem especially anxiety-provoking in many children. Also patient experiences may be associated with a medical history (eg, cancer) wherein many invasive procedures may have occurred and are recognized and potentially anticipated in a counterproductive way (35). Finally, circadian rhythms may influence basic physiological responses in children in clinical settings (36).

There are some common disruptive behaviors that are elicited in children when they are in the dental setting (10). The range of these disruptive behaviors may vary from delay tactics, defiance, kicking, gagging, and screaming.

The American Academy of Pediatric Dentistry has guidelines on the use of behavior management techniques ([www.aapd.org](http://www.aapd.org)) (37). They broadly characterize these techniques as either communicative or advanced techniques, although in reality they are rarely separated. The most frequently used communication technique is called "tell-show-do." Probably the second most frequently used technique is that of positive reinforcement. Advanced techniques are characterized as either using restraints or pharmacologic management of the patient and require pre-procedural informed consent before their use.

Pharmacologic methods of behavior management can be broken down into different levels of sedation and general anesthesia. Nitrous oxide is the most frequently used sedation procedure with the child dental patient (38). Sedative/antianxiety agents administered via the oral route of administration are the second most frequently used pharmacologic technique with children. It is imperative to understand that there are 3 recognized depths of sedation: mild, moderate, and deep (39). Most of the time practitioners aim to achieve mild or moderate sedation with their patients; however, very young children or those who are cognitively impaired may require deep sedation to accomplish some procedures. Unfortunately, deeper levels of sedation are most often associated with adverse outcomes including hypoxemia, respiratory depression, cardiovascular collapse, and death (40).

Several different drugs can be used for sedation of children, but the most frequently used drugs historically have been chloral hydrate, meperidine, hydroxyzine, and the benzodiazepines (most specifically, midazolam) (38, 41). Finally, the most effective pharmacologic method of managing children is the use of general anesthesia.

It is imperative that the practitioner knows and understands intimately the sedation guidelines for children as well as their state board rules and regulations associated with sedation. The sedation guidelines appropriate for children are endorsed and published by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (39).

In those guidelines, 3 recognized levels of sedation are defined and appropriately addressed in terms of practitioner considerations and responsibilities in performing sedations on children. The 3 levels are minimal, moderate, and deep sedation. The levels actually represent a continuum from full wakefulness to unconsciousness. Nonetheless and importantly, the minimal and moderate levels of sedation assume that the patient is interactive with the practitioner and can independently maintain their airway in a patent and appropriately functioning fashion. Thus, a loss of consciousness should not be expected for those levels of sedation. On the other hand, deep sedation can and does occur at times. During deep sedation, the patient is usually unconscious, unable to effectively maintain their own airway and its reflexes, and difficult to

arouse. This level of sedation is often indistinguishable from general anesthesia but is characterized as an unstable and potentially dangerous clinical condition during which significant life-threatening events can occur (eg, laryngospasms).

Nitrous oxide, the most frequently used inhalational sedative agent for children during dental procedures, is safe and effective if used appropriately by a well-trained clinician. It rarely causes children to become unconscious when administered in therapeutic concentrations by using dental delivery systems (ie, open system in which room air is entrained along with the gases). It also produces several effects that benefit both the child and the practitioner during their interactions (42, 43).

Let us quickly review nitrous oxide's general physical properties and characteristics (44–47). Nitrous oxide is heavier than air, and if the gas were colored, which it is not, you would tend to see the nitrous oxide descend from the patient's level in the reclined position to the floor. The gas itself does not have an odor, although the tubing and nasal hood may have some odor that the child dislikes. Hence, the practitioner would be wise to flavor the inside of the nasal hood by using fluoride foam or drops of flavored liquid to produce vapors that the child finds quite pleasant.

Nitrous oxide is relatively insoluble in the blood, and thus the onset and offset of its effects in children are fairly rapid, a definite benefit for the practitioner. It remains unchanged in the blood and is primarily excreted from the body via the respiratory tree, although a minute amount escapes via the skin. Nitrous oxide, which is stored in color-coded tanks around 750 psi, is essentially a vapor overlying a liquid in the tank compared with oxygen tanks in which the oxygen is a compressed gas at room temperature. Oxygen or nitrous oxide is not flammable, but both certainly support combustion; open flames around these tanks are definitely contraindicated.

It is important for the clinician to recognize that nitrous oxide as a gas in the body tends to displace other gases, primarily nitrogen, and thus can cause some unpleasant circumstances. A prominent circumstance the practitioner can avoid is the aggravation of otitis media, a common condition in children; therefore, nitrous oxide should be avoided in children with this condition. Other side effects that are annoying are increased likelihoods of flatulence and the perception of the need to void.

There are very few major medical concerns associated with the use of nitrous oxide, but there are several relative issues of which the clinician should be aware. Nitrous oxide, a weak gaseous anesthetic, is not associated with malignant hyperthermia as are some other gaseous anesthetics. Also, there is no known allergy to nitrous oxide. Nonetheless, it is advisable for the clinician to seek medical consultation for certain clinical conditions including recent eye surgery, otitis media, bowel obstructions, and several lung conditions. The lung conditions do not occur frequently in healthy children and thus do not interfere with its use in these children. Also, nitrous oxide has been associated with spontaneous abortions and induction of labor in women and thus should be used cautiously and never during the first and third trimesters in women during elective procedures.

There are several beneficial attributes of nitrous oxide when used in healthy children. It is an adjunct with other sedatives and is especially important in behavior management when the other sedatives are given orally, because the nitrous oxide becomes, in effect, a titrating and settling agent under those conditions (48). This is an often overlooked but important consideration for subtle behavior management effects when used by seasoned clinicians.

It also has mild anxiolytic properties that help calm a mild to moderately anxious child (47). Complementing this effect is the onset of an unusual, psychologically receptive mindset, wherein the child's imagination and their susceptibility to suggestions are amplified.

Clinically favorable effects also include physiological inhibition of the gag and swallowing reflexes (49) and the actual reduction in pain perception (ie, raises the pain perception threshold) (50). Another procedurally related and favorable effect is the tendency to increase young children's tolerance of procedures by reducing their fatigue and natural hyperactivity. These clinically beneficial effects suggest a clear rationale to the use of nitrous oxide to manage potentially behaviorally challenging children.

The administration of nitrous oxide is primarily based on patient cooperation and the practitioners' understanding of its influences and its effects. The standard technique of administering nitrous oxide is slow titration in a series of steps in which the concentration of nitrous oxide is increased by 5%–10% per step. During the steps, the clinician is constantly obtaining patient feedback on symptoms as well as monitoring patient responsiveness and subtle signs of nitrous oxide effects (43). This type of administration is used most often and is well suited for most patients who are cognitively competent.

Another administrative technique is possible but should only be used by trained pediatric dentists familiar with this technique in children. The rapid onset technique involves the immediate administration of nitrous oxide at high concentrations (ie, 50%–70%) in which the nasal hood is held just off the face and over the nose and mouth (45). Once the child is settling and becoming calm, the clinician should immediately reduce the concentration to 50% or less, depending on patient signs and symptoms. It is noteworthy that if settling and calming are not apparent within 5 minutes, nitrous oxide administration should be discontinued.

Children who exhibit defiant, hysterical behaviors and are unresponsive to distraction interventions cannot be expected to inhale nitrous oxide efficiently. Therefore, nitrous oxide administration is generally contraindicated in these children regardless of the administration technique. Other groups of patients who are less likely to benefit from nitrous oxide are those who have reported previous negative reactions to the dental staff (30), have compulsive or type A personalities, suffer from claustrophobic conditions, or have significant personality disorders (45).

Nitrous oxide is well known to have very prominent beneficial effects for cooperative children who are mildly apprehensive, including decreased likelihood of adverse behaviors either at a single visit or during multiple restorative visits. Patients under the influence of nitrous oxide are also generally appreciated to be responsive to hypnotic suggestion; thus, storytelling to young children under its influence works well.

There have been few studies investigating nitrous oxide's clinical effects on children. A relatively recent study looked at clinical signs of children sedated with nitrous oxide and showed that open, warm hands, limp legs, and a small facial smile were most frequently observed (43). These signs are clues for the clinician in determining whether the young child has reached a sedative state consistent with good behavior and pharmacologic effectiveness.

Different levels or depths of sedation can be targeted as an end point with oral sedatives. Even if one targets a certain depth of sedation, the clinician must always be aware that the patient's response may be different than expected with therapeutic doses of sedatives (51). Those who, for various reasons, respond in a less than expected level of sedation to a therapeutic dose of drug may be referred to as hyporesponders, whereas those who respond more excessively than expected to the same therapeutic dose of drug are referred to as hyperresponders. The distribution of responses tends to follow a bell-shaped curve; thus, patients who tend to respond in the extremes of the distribution are always a concern.

The clinician who uses pharmacologic methods of patient management should always be trained in recognizing and responding to emergent situations, thus rescuing the patient who reaches deeper levels of sedation than targeted. Many children can be managed with

minimal to moderate depths of sedation. Various agents, including nitrous oxide, are capable of inducing these depths of sedation.

Drugs can cause many effects in patients. Ideally, drugs used for sedation should have characteristics that influence the patient's memory, anxiety and fear, movement, and pain elicited by procedures. Unfortunately, there is no ideal sedative, and often more than 1 sedative is needed for any given patient. When 1 or more drugs are used, possible interactions may occur including increased depth of sedation and likelihood of adverse events (52).

It is important for the clinician to understand the concept of timing involved with sedatives administered orally. Intravenous sedation can cause effects in the patient within 15–30 seconds, whereas orally administered sedatives usually have a much slower onset of clinical effects. Each drug given orally has a different onset time that varies from 10 minutes to more than an hour. Working duration refers to the length of time the clinician can expect to do procedures while the patient is comfortable, and again, working duration can vary from 20 minutes to an hour or more. Finally, recovery, or the amount of time a patient must stay in the clinical facility to meet discharge criteria, is dependent on drug metabolism and elimination.

Another important concept to understand is drug reversibility or the ability of a second drug to reverse the effects of the first drug. Currently, there are 2 broad classes of sedatives that can be reversed. Opioids can be reversed with naloxone and benzodiazepines with flumazenil.

Benzodiazepines have become the most popular class of drugs used for sedating children in the United States today. There are many benzodiazepines on the market, with each usually having a singular primary effect and varying degrees of other effects often found to be characteristic of benzodiazepines. The common characteristics of benzodiazepines to varying degrees are relaxation, amnesia, anticonvulsive, hypnotic, sedative, and anxiolytic (46). For instance, midazolam (ie, Versed) causes profound amnestic effects, especially when used via the intravenous route, but can also mediate relaxation, anticonvulsive effects, and to a certain extent anxiolysis. Unfortunately, it can also cause a paradoxical excitement in children (53) that is known by many as "angry child syndrome."

Benzodiazepines mediate their effects by binding to the  $\gamma$ -aminobutyric acid receptor complex whose main effects when activated are inhibition (46). Depending on the type of benzodiazepines, the onset of clinical effects can also vary quite significantly. Midazolam has an onset of only 10 minutes when given orally compared with diazepam (ie, Valium), which takes 60 minutes to reach clinically significant blood levels, mediating its effects.

The benzodiazepines are relatively safe when used in therapeutic doses. Midazolam, the most frequently used benzodiazepine in pediatric dentistry, is used off label (41, 54). Another property of the benzodiazepines is that of reversibility. All can be reversed by an agent known as flumazenil (Romazicon).

Some patients are moderately to severely anxious or frankly fearful about dental procedures. Consequently, very mild agents such as nitrous oxide may not work well with these patients. The clinician is then faced with either increasing doses of single agents, sometimes beyond recommended therapeutic doses, or combining more than 1 agent, all in therapeutic doses, in a "cocktail." The cocktails may be more effective in aiding the clinician in treating these patients. Most often these patients are preschoolers who have fewer effective coping strategies (55).

Another reason for combining agents is to increase working time so that more dental procedures can be accomplished in a single setting (54). Also, by combining agents that have different properties, the clinician can address 2 or more patient-related challenges while undergoing

procedures. For example, one can combine an analgesic with an anxiolytic agent to address not only potentially painful procedures but also to relax the anxious patient.

The clinician always has to be cognizant of potential adverse events associated with pharmacologic agents. Recognition of the adverse events and appropriate interventions including advanced airway management can only be gained through significant training most often associated with advanced training programs (51). Most often the adverse effects involve the respiratory system in which respiratory depression or apnea may occur and require competent intervention (52, 56).

A relatively safe oral cocktail that is becoming fairly popular now that chloral hydrate is waning from the pharmacologic marketplace is that of midazolam, meperidine, and hydroxyzine (57). Again, it must be emphasized that the individual doses should be conservatively within the therapeutic dose range of each agent. This cocktail has a relatively quick onset of about 15–20 minutes, a longer working time, and the increased likelihood of amnesia.

The use of sedation in children who have suffered orofacial trauma has not been well documented. Certainly sedation has become an expected part of many protocols that occur in emergency departments across the world (54). From a theoretical standpoint, the use of sedation may be quite important in managing children who have suffered dental trauma. Nonetheless, care must be taken to ensure that the child first has been adequately and fully assessed to rule out neurologic and other life-threatening conditions. If any suspected signs or symptoms suggestive of such conditions should be present, immediate referral to medical personnel is the first and only consideration compared to any dental injury.

A review of the literature indicates that only 1 study has been completed in which the services of endodontic and pediatric dentistry specialties in an academic institution have been used to address dental caries and trauma cases with pharmacologic agents (58). In this retrospective study, the charts of 32 pediatric patients who received sedation and either had deep carious lesions or suffered traumatic dental injuries were reviewed. Four of the cases involved tooth trauma. Various sedative agents including midazolam, chloral hydrate, meperidine, and hydroxyzine were used either alone or in combination. The results indicated that midazolam combined with other sedative agents was used in the majority of cases. In fact, midazolam with either meperidine or hydroxyzine was used in 88% of the cases. Only 2 cases (6%) were categorized as “aborted” because of uncontrolled behavior, and no adverse events were noted.

The study demonstrated collaborative interactions between endodontists and pediatric dentists to address the behavioral and dental needs of children. The extent to which such collaboration occurs in the private practice community is unknown; however, such future collaboration would seem reasonable and highly beneficial in rendering quality care to the behaviorally challenging pediatric patient. The American Association of Endodontists and the American Academy of Pediatric Dentistry should endeavor to establish an organized repository that is based on such collaborative efforts for purposes of developing a significant corpus of evidence-based data to better guide quality clinical care of young dental patients.

## Acknowledgments

*The author denies any conflicts of interest related to this study.*

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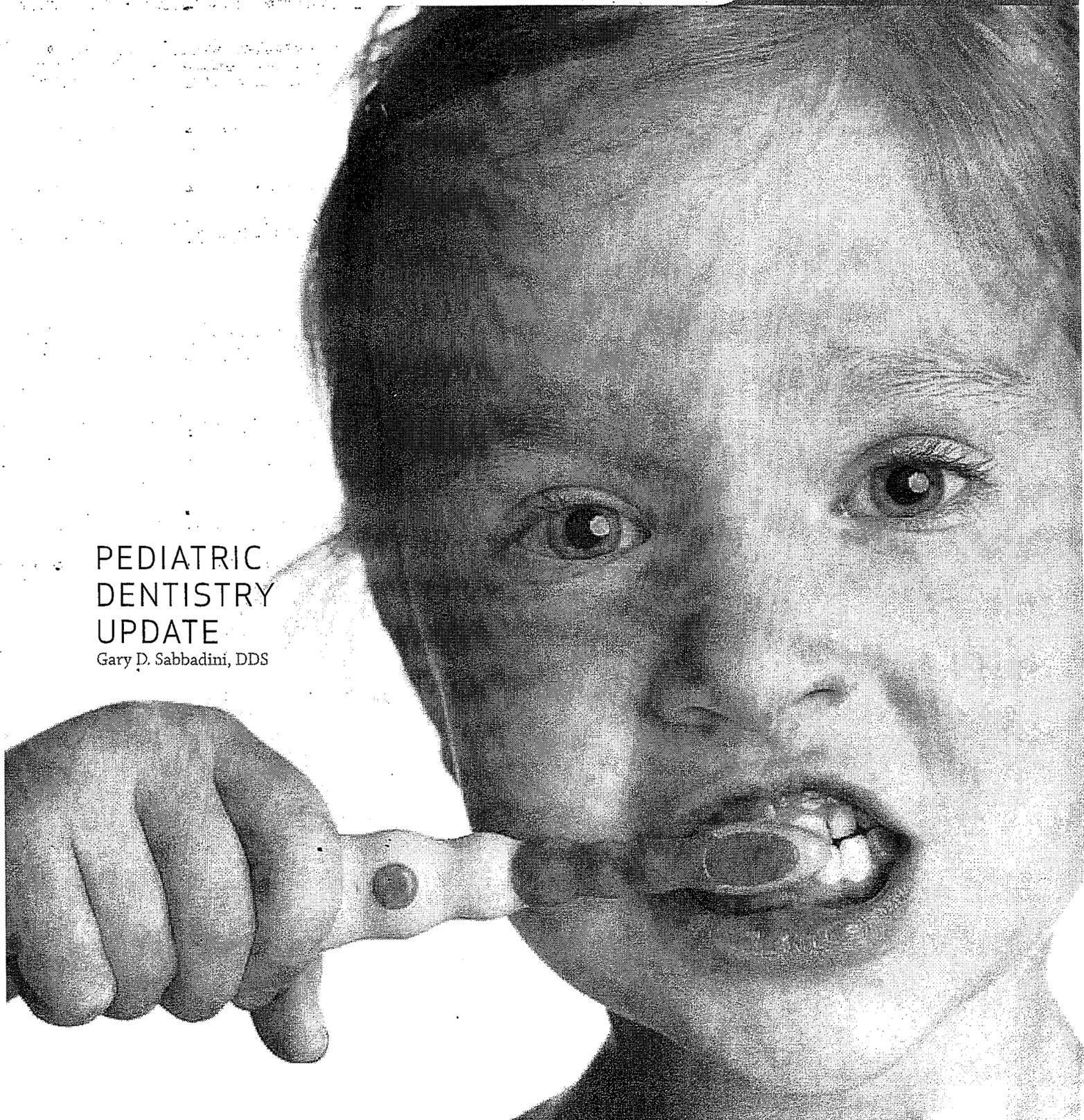
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# Journal

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Pulp Therapy for Primary and  
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Communicating With Parents  
in the Dental Office

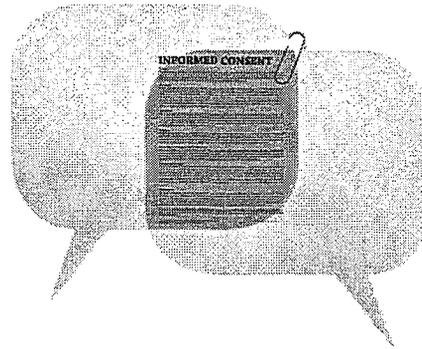
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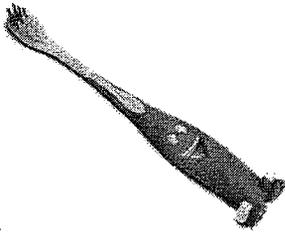
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# Sedation of the Pediatric Patient

DAVID L. ROTHMAN, DDS

**ABSTRACT** Children's behavior during dental treatment is often unpredictable. Many techniques for behavior management have been developed and include both pharmacologic and nonpharmacologic methods. Pharmacologic management with sedation has been shown to be an important adjunct in treating the fearful, uncooperative or precommunicative patient. This article reviews the definitions, levels, techniques and pharmacology of typical drugs used for sedation. The protocols for safe management of children before, during and after sedation are also discussed.

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Sedation and pain management for dental or medical procedures has roots that extend back thousands of years. As long ago as 9000 BCE, the Sumerians used fermented beverages for both sedation and religious rituals.<sup>1</sup> In 1799, Sir Humphry Davy demonstrated the use of nitrous oxide in obstetrics. A German chemist, Justus von Liebig, synthesized chloral hydrate in 1832. Chloroform was used in 1847 by Sir James Young Simpson and his colleagues for surgeries, especially amputations, which often proved fatal. In 1845, after successfully using nitrous oxide in his private practice for more than a year, Horace Wells demonstrated the use of nitrous oxide for pain control during extractions to the Massachusetts General Hospital faculty, which is considered the basis of dental procedural sedation today. The famous rivalry between Wells and his student, William T.G. Morton, who demonstrated the use of ether in 1846, is well known. "Sleeping pills," or barbiturates,

have their origins in the 1860s with the discovery of barbituric acid by Adolf von Baeyer. Derivatives of barbituric acid became the basis of sedation in the early 20<sup>th</sup> century. Their poor margin of safety, addictive nature and unpleasant side effects led to the exploration for better sedatives such as the sedative hypnotics, which includes the benzodiazepines.<sup>2</sup> The antihistamine diphenhydramine was first approved for use by the FDA in 1946 followed by promethazine in 1951, although it has since received a "black box warning" for children age 2 and under. Diazepam, the progenitor of all benzodiazepines, was introduced in 1965.

The use of sedation in combination with classical nonpharmacologic behavior management is an important adjunct in the treatment of anxious children or those who need extensive treatment. Referencing the American Academy of Pediatric Dentistry (AAPD) Clinical Guidelines — "Behavior Guidance for the Pediatric Dental Patient,"<sup>3</sup> "Use of Nitrous

TABLE 1

Levels of Sedation<sup>5,8</sup>

Intended Level	Responsiveness	Airway	Spontaneous Ventilation	Cardiovascular
Minimal Sedation	Normal response to verbal stimulation	Unaffected	Unaffected	Unaffected
Moderate Sedation	Purposeful response to verbal and tactile stimulation	No intervention required	Adequate	Maintained without intervention
Deep Sedation	Purposeful response after repeated or painful stimuli	May require assistance	May be impaired	Maintained without intervention
General Anesthesia	Cannot arouse, even with painful stimuli	Intervention often required	Frequently inadequate	Could be impaired

Oxide for Pediatric Dental Patients”<sup>4</sup> and “Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures”<sup>5</sup> — helps the doctor select a behavior management technique or combination of techniques that are appropriate for children. It is important to note that the use of any form of sedation does not supplant nor negate the concurrent use of nonpharmacologic behavior management. It is recommended that clinicians use the lightest possible level of sedation necessary to maintain the patient’s vital protective reflexes.<sup>5</sup> Though not discussed in this paper, the administration of local anesthesia to alleviate procedural pain is the most important pharmacologic adjunct in achieving a successful sedation experience. When sedating a child, it is recommended to decrease the total amount of local anesthetic because of the potential for a synergistic effect of the multiple drugs leading to increased levels of sedation.<sup>6</sup>

### Definition of Sedation

Pediatric and adult sedation is defined by a continuum of levels as recognized by the American Society of Anesthesiologists (ASA), American Academy of Pediatrics (AAP), American Dental Association (ADA) and AAPD (TABLE 1). Permitting and licensure in many states follows these levels because it is understood

that sedation level risk is a factor of the drug, depth of sedation and stimulation rather than the route by which it is administered. The Dental Board of California defines both the level and route of administration when permitting or licensing, using the term “conscious sedation,” which has appeared in prior versions of the ADA and AAPD *Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* on the use of conscious sedation. The AAPD, in conjunction with the AAP and the ASA, developed and accepted new guidelines in 2006. In 2007, the ADA deferred to the AAPD guidelines for children age 12 and under. Available permits in California ([dbc.ca.gov/licensees/dds/permits\\_index.shtml](http://dbc.ca.gov/licensees/dds/permits_index.shtml)) include:

*Oral Conscious Sedation for Minor Patients:* allows “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.” This permit applies to patients both younger than 13 and older.

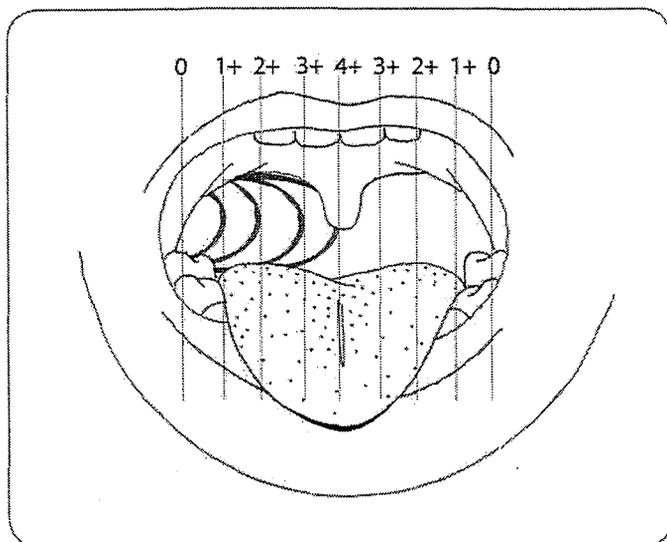
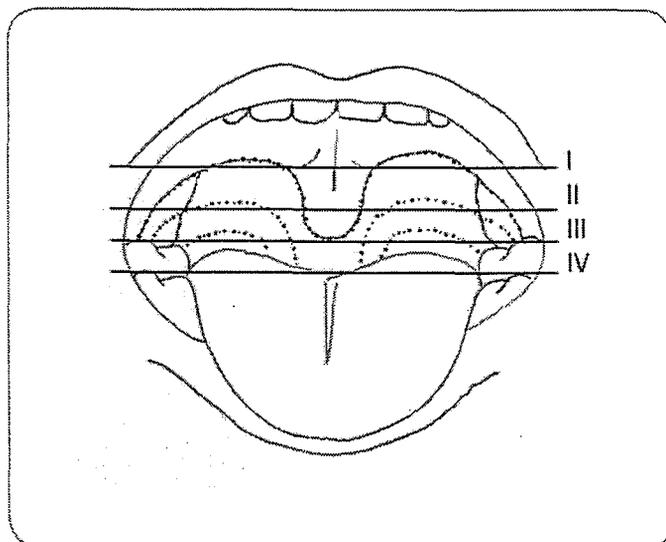
*Oral Conscious Sedation:* allows “a minimally depressed level of consciousness produced by oral medication that retains the patient’s ability to maintain independently and continuously an airway, and respond appropriately to physical stimulation

or verbal command. Oral conscious sedation does not include dosages less than or equal to the single maximum recommended dose that can be prescribed for home use.” This permit is for patients age 13 or older.

*Conscious Sedation:* allows “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 the administration of oral medications or the administration of a mixture of nitrous oxide and oxygen, whether administered alone or in combination with each other”<sup>7</sup> (see TABLE 1).

### Levels of Sedation

In determining the type and level of sedation, it is important to assess the developmental stage of the child. Developmental stages can be divided into predetermined physical, behavioral and cognitive skill sets (Piaget and others) or by the precommunicative/communicative division. Precommunicative is understood as being younger than age 3 and unable to partially or fully comprehend the procedure. This child is more likely to require deeper levels of sedation to achieve the desired results because the combination of nonpharmacologic and

FIGURE 1. Brodsky Classification.<sup>22</sup>FIGURE 2. Mallampati Classification.<sup>23</sup>

pharmacologic modalities is unlikely to result in a more cooperative patient. Communicative is defined as the ability to partially or fully comprehend what is going on and this patient would benefit from a combination of pharmacologic and nonpharmacologic intervention. Practitioners tend to use larger doses of sedative medications because of metabolism and behavioral issues in the younger patient; however, the risk rises exponentially because of the potential loss of airway and protective reflexes.<sup>9,20</sup>

Pediatric dentists report a 30–70 percent success rate using all forms of sedation, although the definition of success varies amongst clinicians. Because children react differently to medications than adults, outcome predictability is never guaranteed and children cannot be expected to demonstrate a predictable pattern of behavior. Sedated children often show the signs of sleep deprivation, which can include increased activity levels, crying and inability to respond to commands.

Dentists performing sedation must be well trained in both sedation and emergency medical care and be prepared to rescue or manage the patient in the event of respiratory distress, cardiac

failure or deeper levels of sedation until emergency care arrives. It is mandatory to have the appropriate medical equipment to deliver emergency care, and the doctor and staff members must regularly practice the skills necessary for rescue.<sup>5,20,21</sup> Factors that affect the risk of an adverse outcome include the level of training of the practitioner, the age of the patient, the choice of sedative medications, the type of monitoring, the ability to recognize deviations from normal and, for those in private practice, the distance from a primary or secondary medical care facility.<sup>20,21</sup>

Questions regarding the long-term effects of general anesthesia on the brains of developing children and potential future cognitive deficits were raised in a number of studies.<sup>12–15</sup> Rappaport et al.<sup>16</sup> reported the findings of a collaborative review effort which concluded that when a single anesthetic is administered in a healthy child, risk of cognitive deficit is minimal. Discussions with parents or caregivers are necessary about the risks and benefits of having or not having a procedure involving sedation or general anesthesia and doctors must stay informed of new developments in the discipline and recognize that anesthetics

and sedatives are necessary for infants and children who require surgery or painful and stressful procedures.

All medications given for sedation in children 12 years old and under should be administered in the office under the direct supervision of the doctor or trained individual. Vital signs and sedation levels should be monitored and recorded preoperatively, intraoperatively and postoperatively in a time-based record with specific interval entries. Monitoring is useful in assessing the levels of sedation and pain control as well as the patient's cardiovascular and respiratory systems. Monitoring includes visual cues such as chest excursions and effort, mucosal coloring and skin turgor. Electronic and mechanical monitors include pulse oximetry to measure oxygen saturation of the blood, blood pressure monitors, electrocardiography and capnography to record expired carbon dioxide. Recommended monitors for specific intended sedation levels can be found in the AAPD guidelines, but state regulations dictate which monitors must be used for specific procedures, routes of administration and sedation levels. The reader is referred to the Dental Board of California<sup>25</sup> for appropriate state regulations. In California,

TABLE 2

American Society of Anesthesiologists Patient Physical Status Classification<sup>25</sup>

ASA Status	Preoperative Health Status	Organ System Status
ASA 1	Normal, healthy patient	All organ systems intact and functioning
ASA 2	Patient with mild systemic disease	No functional limitations Has well-controlled disease of one body system <i>Update medical history and crosscheck for drug interactions</i>
ASA 3	Patient with severe systemic disease	Some functional limitation Has controlled disease of more than one body system or major organ No immediate danger of death <i>Physician consult required</i>
ASA 4	Patient with severe systemic disease that is a constant threat to life	Has at least one severe disease that is poorly controlled or at end stage <i>Physician consult required, laboratory tests</i>
ASA 5	Patient not expected to survive >24 hours without surgical intervention	Multi-organ and system failure
ASA 6	Patient declared brain dead	Maintenance for organ harvesting
E	Emergency operation of any variety (used to modify one of the above classifications)	

the use of nitrous oxide/oxygen inhalation sedation in conjunction with local anesthesia does not require the use of monitors other than visual recognition of patient status. For all sedation, it is recommended that supplemental oxygen be administered to increase the margin of safety in the event of respiratory depression. With supplemental oxygen levels above the ambient level of 21 percent, the failure of pulse oximetry to recognize a drop in oxygen saturation may be prolonged.<sup>20</sup>

Recovery must occur in a facility or area supervised by trained personnel with appropriate monitoring and rescue equipment, including positive pressure oxygen. Discharge is determined by the patient's return to baseline vital signs and the ability to maintain protective reflexes (such as keeping the head erect) and respond to commands.<sup>5,20</sup> Children must be accompanied by at least one responsible adult who will be able to observe and stimulate the child during his or her entire trip home to help prevent re-sedation.<sup>16,27</sup> Children must be secured in a protective restraining device appropriate for the age group as specified

by the California Department of Motor Vehicles<sup>18</sup> and should never be transported in an accompanying adult's lap.<sup>19</sup> The components of the discharge instructions should include the name of practitioner, a 24-hour emergency contact number, the contact number of emergency services and diet and pain control instructions. The clinician may opt to include the drugs and doses used for the procedure (including local anesthesia). These instructions must be reviewed verbally with the responsible adult and it is recommended that a follow-up phone call to check on the child be made shortly after the patient's discharge.<sup>16,27</sup>

A child's response to a specific drug and dose is often unpredictable. Children and adults may be hypo-responders who show less than an anticipated level of sedation or hyper-responders who achieve a deeper level of sedation than anticipated. The office and the practitioner must be prepared to maintain and potentially rescue the patient who slips into a deeper level of sedation. This may include stopping the dental procedure and observing/supporting the patient or administering reversal medications.

### Evaluation of the Child for Sedation

The determination of whether sedation is appropriate for a child is based upon multiple factors:

1. The clinician must evaluate the severity of the disease and the complexity of the treatment.
2. The patient's age, developmental stage and anticipated cooperation will help determine the time necessary for the procedure and the number of visits.
3. The cost of single versus multiple procedures must also be considered. However, it is debatable whether time off from work for the parents or school for the child should be a mediating factor in the decision to use pharmacologic behavior management techniques.
4. It should be decided whether the treatment can be postponed or if a less invasive procedure may be performed to allow the child to mature and be more prepared to accept treatment. These preventive interventions include the use of multiple visits to apply fluoride varnish while educating the parent on better home oral health

TABLE 3

### Fasting Guidelines for Elective Sedation<sup>5</sup>

Food	Time (hours)
Clear liquids	2
Breast milk	4
Formula, non-human milk	6
Light meal	6

care or placing glass ionomer or other similar dental materials. These intermediate therapeutic restorations are recognized by the World Health Organization as an acceptable treatment modality.<sup>24</sup>

- It is critical to thoroughly review the patient's medical history with the parents to determine if the child is suitable for sedation. Frequent or recent upper respiratory infections will mean a delay of at least six weeks while the lung parenchyma heals. If there is a history of cardiovascular problems, a medical consultation from the child's pediatrician may help sort out significant findings. A family history of adverse sedation or anesthetic incidents is important to help decide your choice of procedures and medications. No discussion of sedation is complete without a warning about sleep disordered breathing, sleep apnea and sleep hypopnea, which may lead to respiratory complications such as obstruction and CO<sub>2</sub> retention. Any history of difficult and noisy breathing at night, snoring, frequent awakening, night sweats, night terrors, enuresis and ADD/ADHD-type behaviors are a red flag and warrants a referral to an otolaryngologist for an evaluation prior to proceeding with sedation.

The physical examination should include the vital parameters of heart rate and rhythm, blood pressure, oxygen saturation and weight, in addition to a standard head and neck exam. The Brodsky<sup>25</sup> and Mallampati<sup>23</sup> classifications

of oropharyngeal and tonsillar size (FIGURES 1 AND 2) are important because they help determine the risk of obstruction during sedation.<sup>24</sup>

The American Society of Anesthesiologists has developed a risk-based scale for categorizing the medical status of patients (TABLE 2). Practitioners should only consider in-office sedation for ASA 1 and well-controlled ASA 2 patients.

The dental examination, though potentially difficult to perform if the child is uncooperative, must be done to give the practitioner an idea of the severity and complexity of treatment. A full discussion of the risks of treatment, options for treatment (including no treatment) and the benefits of completing treatment must be done and should be specific to the anticipated level of sedation. Verbal and signed confirmation must be received and recorded in the chart. Written instructions including NPO status, pre- and post-sedation instructions and 24-hour contact numbers must be provided and reviewed both at the screening and sedation visits. Forms should be customized for your office and practice and may include the drug or drugs used in case of emergency. Regardless of the level of sedation, fasting prior to the procedure is believed to be important in preventing aspiration of stomach contents in the event of regurgitation, but there are few studies that document aspiration risk in the sedated patient. Recent articles in the pediatric emergency literature show that sedated children do not have an increased risk of aspiration with a full or partially full stomach in an emergency facility,<sup>26-28</sup> but it is still recommended that the practitioner comply with the guidelines for fasting developed for the patient undergoing general anesthesia.<sup>5</sup> The recommended fasting times are outlined in TABLE 3.

### Contraindications to Sedation

The following are some contraindications to sedation:

- Sensitivity or allergy to sedation drugs or drug combinations.
- Patients who are ASA 3 and above.
- Patients with special needs who may have problems maintaining cardiovascular or respiratory systems.
- Patients who may lack understanding or the ability to respond appropriately.
- Patients with anatomic airway abnormalities, extreme tonsillar hypertrophy or obesity who may have difficulty maintaining an airway during sedation.
- Patients who pose a risk to the safety or health of staff members.
- Patients who would have difficulty recovering safely and comfortably in the facility.
- Patients for whom resuscitation and transport would be difficult in the event of an emergency.

### Drugs, Pharmacology and Metabolism

The drug categories commonly used in pediatric sedation include the benzodiazepines, the antihistamines, the opioids and nitrous oxide/oxygen inhalation. Other drugs falling out of favor because of the higher incidence of adverse effects include the sedative hypnotics chloral hydrate and promethazine. Drugs used for adult sedation may not be appropriate for pediatric sedation because of lack of clinical studies, FDA approval or inadequate dosage formulations to allow weight-based dosing in pediatric patients (TABLE 4). These include Triazolam and the nonbenzodiazepine gamma amino butyric acid (GABA) agonists Zaleplon and Zolpidem. Combinations of the drugs allow the practitioner to decrease dosages of the individual drugs and minimize adverse effects.<sup>10</sup>

TABLE 4

## Drugs Commonly Used for Pediatric Oral Sedation

Drug	Proprietary Name	Route	Class (Action)	Dose (PO) mg/kg	Onset (PO) (min)	Working Time (PO) (min)	Half Life (PO) (hr)	Comments
Hydroxyzine	Vistaril, Atarax	PO	Antihistamine (H1 blocker)	1-2	30-45	30-45	2	Antiemetic Anxiolysis
Diphenhydramine	Benadryl	PO	Antihistamine (H1 blocker)	1-2	5-30	30-45	4-7	Antimuscarinic Antihistaminic Antiemetic Anxiolysis Emergency drug for anaphylaxis
Promethazine	Phenargan	PO	Antihistamine (H1 blocker)	0.5-1	15-30	60	2-8	Antiemetic Anxiolysis Antihistaminic Phenothiazine Black box warning for children $\leq 2$ Respiratory depression Extrapyramidal effects
Midazolam	Versed	PO	Benzodiazepine	0.3-0.75	10-20	30-45	1.7-2.4+	Muscle relaxant Amnesia Anticonvulsant Best delivered in acidic base to improve uptake in ionized form Syrup or injectable form No active metabolite Inconsolable crying Dysphoria Respiratory depressant (high levels)
Diazepam	Valium	PO	Benzodiazepine	0.25-0.5	45-60	60	20-40+ (bi-phasic due to metabolite action)	CNS depression with minimal cardiovascular or respiratory effect Amnesia Muscle relaxant Anticonvulsant Active metabolites with long half lives (desmethyldiazepam, oxazepam)
Lorazepam	Ativan	PO	Benzodiazepine	0.05	30-60	60	14-16	Limited pediatric data Half life shorter than diazepam but longer sedative effect because of lower lipid solubility
Meperidine	Demerol	PO	Narcotic	1-2	30-45	30-45	2	Cardiovascular and respiratory effects Lowers seizure threshold
Chloral Hydrate	Noctec	PO	Sedative Hypnotic	25	30-60	60	4-6	No longer available as suspension Significant risk for cardiovascular event by sensitizing myocardium to circulating catecholamines (epinephrine) Active metabolite: trichloroethanol Not an FDA approved drug Gastric irritant May cause respiratory and cardiovascular depression at doses $> 25\text{mg/kg}$

Referenced to and modified from: Banks, D, Bernard, P, Cravero, J, et al. Sedation Provider Course Syllabus, The Society for Pediatric Anesthesia, 2010; Pediatric Sedation for Diagnostic and Therapeutic Procedures. University of VA Children's Hospital. 2009; Pediatric Moderate Sedation. Illinois Emergency Medical Services for Children, 2008; Primosch, R, Kosinski, R, Wilson, S. Oral Sedative Agents, Contemporary Sedation, AAPD course, 2011.

Benzodiazepines are the most commonly used oral agents for sedating children. They have a wide margin of safety that is mostly attributable to their mode of action. Benzodiazepines have the following properties: sedative/hypnotic, muscle relaxant, anxiolytic, amnesic and anticonvulsant. Flumazenil, a benzodiazepine receptor antagonist, reverses the benzodiazepines but may have a shorter half-life than the drug it is reversing (i.e., midazolam) and also lowers the seizure threshold.

Antihistamines are primarily used in the treatment of allergic reactions. However, they can be used as sedative-hypnotics because of their sedative effects. Additional benefits include anti-nausea, antisialogogue and antiemetic properties. They are not reversible.

Opioids are naturally occurring, synthetic and semisynthetic. Although their primary use is to decrease pain and anxiety, they can cause dose-related sedation. Adverse effects include depression of the respiratory and cardiovascular systems and unconsciousness. Naloxone, a competitive antagonist, reverses the opioids but may have a half-life shorter than the drug it is reversing.

For safe sedation, it is important to remember that when using multiple drugs in a combination technique, the quantity of each drug should be reduced because of the additive and synergistic effects of the drugs.<sup>6</sup>

The site of activity for most sedative agents is the reticular activating system (RAS), a cluster of cells in the cerebral cortex, basal ganglia, limbic system and cerebrum. The RAS controls the state of consciousness, cardiovascular control and respiratory and vomiting centers. In general, drugs used for sedation are in the GABA or n-methyl d-aspartate

(NMDA) categories. The GABA system drugs either increase the amount of GABA remaining at a neuron after activation of the GABA<sub>A</sub> sites or prevent its metabolic breakdown or reuptake both of which add to the concentration of GABA at the neuronal junction. GABA is an inhibitory neurotransmitter, which opens the chloride channels within the cell membrane of the neurons preventing neural excitation resulting in muscle relaxation, anxiolysis and additionally anticonvulsant effects. The drugs work at the GABA<sub>A</sub> subtype

### THE NARCOTICS DISRUPT both REM and non-REM sleep and bring about dose-dependent respiratory depression by acting on the pons and the medulla.

of the GABA receptors that activate the benzodiazepine receptor site to enhance the chloride ion channel response to GABA when it is present. Nitrous oxide and the benzodiazepines affect the GABA system. It is believed that the benzodiazepines are able to achieve their relative level of safety because they do not act directly on GABA sites, instead only potentiating and enhancing the ability of GABA to open chloride channels. Alcohols, barbiturates and propofol have specific sites on GABA<sub>A</sub>, which open the chloride channel independently of GABA.<sup>17,29</sup>

The NMDA system controls the transfer of electrical signals between neurons through Ca<sup>2+</sup> movement intracellularly and is modulated by glutamate and glycine. Ketamine, nitrous oxide and the synthetic opioids work

as either competitive antagonists or noncompetitive agonists to NMDA, glycine antagonists or as Ca<sup>2+</sup> channel blockers, thus preventing transfer of electrical impulses between neurons. This class of sedative agents causes dissociative anesthesia marked by catalepsy, amnesia and analgesia.<sup>2</sup>

Synthetic, semisynthetic and natural narcotics work on the body's opioid receptors by inhibiting the release of excitatory neurotransmitters from the primary afferents of the spinal cord and by directly inhibiting dorsal horn pain transmission neurons of the spinal cord. The opioid receptors are a component of an inherent pathway, which blocks afferent pain transmission by blocking the release of substance P factor. Because pain consists of both sensory and affective (emotional) components, narcotics can also increase the pain threshold through euphoria by relieving anxiety and bringing on sedation and amnesia. The narcotics disrupt both REM and non-REM sleep and bring about dose-dependent respiratory depression by acting on the pons and the medulla.

Nitrous oxide has multiple modes of action in the central nervous system. It exhibits action on both the GABA<sub>A</sub> and NMDA receptor<sup>30</sup> and stimulates the release of endogenous endorphins that act directly on the opioid receptor<sup>31</sup> to provide analgesia. An excellent discussion of the use of nitrous oxide/oxygen analgesia is available in the *AAPD Clinical Guidelines* on the "Use of Nitrous Oxide for Pediatric Dental Patients."<sup>4</sup>

Drugs may be initially metabolized in the intestines and then transported to the liver by the cytochrome p450 family of superenzymes, a mixed-function oxidase system responsible for the synthesis of cholesterol and lipids. It is important to note that individuals

TABLE 5

## Reversal Agents

Drug	Proprietary	Route	Class (Action)	Dose	Onset/Duration (minutes)
Flumazenil	Romazicon	IM, IV	Benzodiazepine reversal	0.01 mg/kg (First dose: 0.2 mg)	1-3 minutes/<60min Repeat doses to max 1mg
Naloxone	Narcan	IM, IV	Narcotic reversal for overdose	<5 year- 0.1 mg/kg >5 year- 2.0 mg	<2min/20-60min q 2-3 minutes to max 5mg q 2-3 minutes to max 10mg

References: [www.reference.medscape.com/drug/narcan-naloxone-343741](http://www.reference.medscape.com/drug/narcan-naloxone-343741); [www.reference.medscape.com/drug/romazicon-flumazenil-343731](http://www.reference.medscape.com/drug/romazicon-flumazenil-343731); Banks, D, Bernard, P, Cravero, J, et al. Sedation Provider Course Syllabus, The Society for Pediatric Anesthesia, 2010.

have variable enzyme expression that can lead to inconsistent drug sensitivity between patients. CYP3A4 is responsible for the metabolism of more than 50 percent of drugs, including the amide anesthetics and the benzodiazepines. Alcohol dehydrogenase, also found in the liver, breaks down alcohol-based drugs, such as chloral hydrate. Other drugs, such as ester anesthetics and synthetic opioids, may be broken down in the bloodstream by pseudocholinesterases and nonspecific tissue esterases.

Metabolized drugs can go through either deactivation or bioactivation. They either pass through the blood stream bound to plasma proteins or as a free compound in equilibrium prior to reaching the target organ. From there, they are carried to the kidneys for excretion. Impaired liver or renal function may prolong active drug metabolites (TABLE 5).

## Routes of Administration

There are multiple routes of administration in pediatric sedation, each with specific onset and duration of action, indications and contraindications. Each state's licensure or permitting process determines the route of administration and the level of sedation. Many drugs are capable of all levels of sedation and are dose, not route, dependent (TABLE 6).

## Inhalation

The inhalation route, specifically utilizing nitrous oxide/oxygen analgesia, yields the most consistent results and is the easiest to learn. It is the second most frequent type of sedation.<sup>32</sup> Dentistry uses an open nitrous oxide/oxygen system, which increases safety,<sup>33</sup> lowers the risk of hypoxia, helps block dental smells and the sight of dental instruments and requires no mechanical or electrical monitoring in California. Some negative factors include the initial cost of equipment, ongoing maintenance costs, the cost and storage of the nitrous oxide and oxygen tanks, increased risk of nausea and vomiting and environmental concerns with the exhaled and scavenged gases.<sup>34,35</sup>

## Oral (PO)

The oral route is frequently used in pediatric patients. The benefits include the low cost, ease of administration and the relative safety because the slow drug uptake and first-pass effect limits the maximum effectiveness. Problems with this route include the inability to titrate or control the length of the sedation, occasional gastric upset, lack of an oral reversal agent, extended drug half-life and slow drug uptake because of delayed gastric emptying and pH incompatibility. Additional problems include the extended office time waiting for the onset of the drug and the postsedation recovery time prior to discharge and the increased costs and training necessary for monitoring.

TABLE 6

## Absorption Rates by Route

Route of Administration	Absorption Time (minutes)
Intravenous	1
Inhalation	1 to 3
Sublingual	3 to 5
Intranasal	5 to 10
Subcutaneous	10 to 30
Intramuscular	10 to 30
Enteral (oral)	20 to 60

## Intravenous (IV)

The IV route provides the most reliable and consistent sedation. The IV line allows for a titratable and rapid sedation, which can be adjusted for the patient's level of pain and anxiety control. In the case of an emergency, the intravenous route provides a portal for rapid administration of emergency and rescue drugs. The factors that limit use are the need for advanced training, cost of supplies and equipment, advanced monitoring, potential venipuncture complications and difficulty with needle-phobic patients.

## Intramuscular (IM)

The IM route offers the benefits of speed and ease of administration, reliable outcomes and the ability to potentially titrate doses. The negatives to IM sedation are muscle pain, potential nerve damage, difficult titration, defined sedation length with reinjection for additional sedation time and needle phobia.

## Transdermal (TD)

The transdermal route is more commonly used in fields other than dental sedation and with drugs specially formulated for passage through skin either by increasing the blood flow or permeability of an area. The benefits of this route are that it is nonthreatening, easy to apply with little training, has few complications and is long acting; whereas, the negatives include inconsistent results and slow uptake.

### Submucosal (SM)

The submucosal route has been used in pediatric dentistry for the administration of narcotic sedatives, analgesics and emergency medications. All dentists are trained in this route and the drug uptake profile mirrors that of the intravenous route. When used for sedation, this route is not allowed in California without a conscious sedation permit. The contraindications include pain in the injection area, unintentional intravascular access and interference with sedative uptake if the sedative medication is administered in the same quadrant as a local anesthetic with epinephrine.

### Intranasal (IN)

The intranasal route is increasing in popularity in pediatric sedation.<sup>36</sup> It can either be used for anxiolysis to help the practitioner gain intravenous access or for very short procedures. It provides rapid onset, is inexpensive and has both oral and mucosal uptake. The negative factors are that it is an invasive and noxious technique, has variable uptake in nonpatent nares, may cause nosebleeds and can have an offensive taste. It is a parenteral technique and drug uptake mimics that of other parenteral routes.

### Conclusion

Safe and effective sedation in the uncooperative or fearful child is an important adjunct in behavior management during dental procedures in young, fearful and uncooperative children. Protocols for its use and an understanding of sedation pharmacology and pediatric physiology are important for a successful outcome. It is vital to review and respect the established sedation guidelines as well as the state laws that regulate the practice of sedation in the dental office. ■■■■

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# Comparison of Oral Midazolam With and Without Hydroxyzine in the Sedation of Pediatric Dental Patients

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## Abstract

**Purpose:** The purpose of this study was to compare the effectiveness of midazolam (MDZ) alone to a combination of MDZ and hydroxyzine (MDZH) when sedating young children for dental treatment.

**Methods:** This was a prospective, double-blinded, crossover clinical study of young uncooperative children in need of at least 2 restorative visits. Twenty-eight children, ages 21 to 56 months, with a mean age of 36.6 months, participated in this study. The subjects were assigned randomly to receive either 0.5 mg/kg of oral MDZ 20 minutes prior to the beginning of dental treatment or the combination of 0.3 mg/kg oral MDZ with 3.7 mg/kg of hydroxyzine 30 minutes before treatment. The alternative drug regimen was administered at the second appointment. All subjects also received 50% nitrous oxide and were restrained with a papoose board. The child's behavior (quiet or crying, relaxed or moving) was evaluated every 5 minutes by an experienced pediatric dentist who was unaware of the drug given to the child. At the conclusion of treatment, each session was evaluated for overall effectiveness.

**Results:** Regardless of the type of premedication, more patients exhibited quiet behavior at the beginning of treatment, with an increase in crying and movement toward the end of treatment. Regarding movement, a significant difference was observed during the first 20 minutes between the 2 regimens. MDZ showed more children exhibiting movement. During the first 30 minutes of treatment, more children cried in the MDZ group, while MDZH presented more children asleep or quiet. No significant differences were found in behavior as a function of the order the sedative regimens were given. No significant differences between the 2 regimens regarding overall behavior and success ( $t=0.655$  at 27 degrees of freedom;  $P=.518$ ) were found.

**Conclusions:** The combination of hydroxyzine (3.7 mg/kg) with MDZ (0.3 mg/kg) administered 30 minutes before treatment resulted in safe and effective sedation for the dental treatment of young children. This combination's use might be more advantageous when compared to MDZ alone, resulting in less crying and movement during the first 30 and 20 minutes, respectively. (*Pediatr Dent.* 2004;26:492-496)

**KEYWORDS:** MIDAZOLAM, HYDROXYZINE, SEDATION, PEDIATRIC DENTISTRY

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Conscious sedation is frequently employed for the management of preoperative or extremely anxious preschool dental patients. Many medications have been used to sedate children in the dental office safely and successfully. Narcotics, antihistamines, hypnotics, and benzodiazepines have all been used separately and in combination in an attempt to find an ideal sedation regimen, which may be used for most clinical

situations. Among these are 2 time-tested premedications that have each been successfully used on their own, midazolam (MDZ) and hydroxyzine. Both are remarkably safe and have no serious side effects. The ideal combination will provide: (1) safety; (2) minimum respiratory depression; (3) adequate sedation; (4) minimal patient movement; (5) early onset of drug action; and (6) adequate working time (adequate duration of action).

**Table 1. Behavior Criteria (Modified The Ohio State University Behavior Rating Scale)**

**Crying:** patient crying, noticeably annoyed, treatment difficult but possible.

**Quiet:** patient quiet, not asleep, with only slight, inconsequential movements.

**Sleeping:** patient asleep, easily aroused, no movement.

**Movement:** patient extremely defiant, strong movement, treatment extremely difficult.

MDZ is a potent, short-acting benzodiazepine sedative hypnotic, which has been regularly used by anesthesiologists as a premedication for general anesthesia and routinely used in pediatric dentistry for short dental procedures.<sup>1-3</sup> In addition to its sedative properties, MDZ has anticonvulsant,<sup>1</sup> muscle-relaxant, and amnesic effects.<sup>4</sup> It is well absorbed orally, with an absorption half-life of 13 minutes. Because of MDZ's high-lipid solubility, it is readily absorbed by the gastrointestinal tract and central nervous system. MDZ reaches a peak plasma concentration at 1.25 hours and has an elimination half-life of 2.3 hours.<sup>1</sup>

Pediatric dentists have used hydroxyzine safely as a sedative agent for many years for the sedation of young dental patients.<sup>5,6</sup> It is an antihistamine with sedative and antiemetic properties. It has been used routinely, and, when limited to the recommended doses, there is no respiratory depression or known side effects. Adverse reactions are uncommon.

Few pediatric studies have investigated the use of MDZ in combination with other sedative medications.<sup>7</sup> One of the favorable characteristics of MDZ is its rapid onset, making it ideal for use in the dental office. Its relatively short duration of action, however, may rule out its use in dental procedures of more than 20 minutes.<sup>5</sup> Hydroxyzine has a slower onset of action with a longer duration of action. It would seem appropriate to use these 2 drugs together, one complementing the other, resulting in an ideal sedative combination appropriate for use in the dental office. A study comparing intranasal MDZ with oral MDZ utilized a flavored hydroxyzine suspension as an oral vehicle to administer parenteral MDZ, since, at the time, MDZ was marketed only for parenteral use.<sup>2</sup> The study, however, did not investigate its use as a supplementary drug to MDZ.

The purpose of this prospective, double-blinded, cross-over clinical study was to compare the sedative effectiveness of MDZ alone with a combination of MDZ and hydroxyzine when sedating young children for dental treatment.

### Methods

This study's experimental protocol was approved by the Institutional Human Subjects Ethics Committee of the Hadassah University Hospital in Jerusalem, Israel. Informed consent was obtained from all parents or legal guardians of participating subjects.

**Table 2. Rating Scale to Evaluate General Behavior**

Rating	Definition
1	Quiet>90% of treatment time, 1 undesirable behavior exhibited.
2	Quiet>50% of treatment time, no violent interrupting movements.
3	Crying>50% of treatment time, interrupting movements toward end of treatment.
4	Crying throughout treatment, interrupting movements from onset of treatment.
5	Crying and extremely defiant behavior throughout session, treatment extremely difficult.

### Subjects

Twenty-eight subjects between the ages of 21 and 56 months, with a mean age of 36.6 months, participated in this study. They weighed between 10 and 18 kg, with a mean weight of 13.8 kg. All participants were in good health (ASA I) and required at least 2 restorative treatment sessions. The patients required sedation for treatment because of a "definitely negative" rating, according to the Frankl rating scale.<sup>8</sup>

### Procedure

All subjects were without solid food for at least 4 hours prior to medication administration and without clear liquids 2 hours before treatment. The subjects were assigned randomly to receive either 0.5 mg/kg of oral MDZ 20 minutes prior to the beginning of dental treatment or the combination of 0.3 mg/kg oral midazolam with 3.7 mg/kg of hydroxyzine (MDZH) 30 minutes before treatment. The alternative drug regimen was administered at the second appointment. The medication was offered in a plastic cup or syringe to the patient by a member of the research team other than the operator or the independent evaluator to ensure that both were blind to the treatment regimen. If the child refused to drink, the medication was administered via a needleless syringe to the back of the mouth.

At the appropriate time, the child was transferred to the operatory and placed in a papoose board, and a pulse oximeter was attached to the subject's great toe (Nellcor Inc, Hayward, Calif). Fifty percent nitrous oxide/oxygen was administered, and treatment was rendered by 1 of 2 operators. Vital signs were monitored continuously.

### Evaluation

Each patient was evaluated continuously by 1 of 2 independent observers for sleep/quiet/crying and body movement, with assessments recorded at 5-minute intervals. The observers were standardized by evaluating 20 assessments of behavior of children undergoing conscious sedation in a similar manner prior to the study. Nineteen of the 20 assessments were identical for an inter-rater

**Table 3. Distribution of Ratings for General Behavior\***

Rating	Midazolam alone		Midazolam and hydroxyzine	
	No.	%	No.	%
1	14	50	14	50
2	7	25	7	25
3	3	11	6	21
4	4	14	1	4
5	0	0	0	0

\*Overall success rate (ratings 1 and 2) for both regimens=75%.

reliability of 95%. A modified version of The Ohio State University behavior rating scale<sup>9</sup> was used (Table 1). In addition, an overall evaluation was made of the child's behavior at the completion of the operative procedures (Table 2) similar to Houpt's scale of overall behavior.<sup>10</sup>

#### Data analysis

This study was designed so that each patient served as his/her own control, with time of day, operator, and type of procedure being relatively constant between the 2 treatment sessions.

Findings for movement, crying, quiet and sleep, and overall behavior were analyzed for statistically significant differences between the 2 drug regimens using the McNemar test. The means for treatment time and overall behavior of both regimens were analyzed using a paired *t* test.

### Results

#### Crying/quiet/sleep

The percentages of crying behavior as a function of 8 time periods for both drug regimens are presented in Figure 1. Regardless of the type of premedication, more patients exhibited quiet behavior at the beginning of treatment, with an increase in crying towards the end of treatment. A significant difference was observed during the 30-minute time-period between the 2 regimens: MDZ showed more children crying, while MDZH presented more children asleep or quiet. During the first 7 points of measurement (0-30 minutes), the percentage of crying children was always lower in

MDZH in comparison to MDZ. This finding was statistically significant ( $P<.008$ ). No significant differences were found in behavior as a function of the order the sedative regimens were given.

#### Movement

The presence of movement pattern was similar in both MDZ and MDZH, with the incidences of movement increasing with treatment time (Figure 2). The percentage of children exhibiting movement during the first 5 points of measurement (0-20 minutes), however, was always lower in MDZH in comparison with MDZ. This difference was statistically significant ( $P=0.031$ ).

#### General behavior rating

At the conclusion of treatment, each session was evaluated for overall effectiveness. The results are presented in Table 3. The success of sedation, including ratings of 1 and 2, was 75% for both regimens. Analysis using a paired *t* test showed no significant differences between the 2 regimens regarding overall behavior and success ( $P=.518$ ). Analysis using a paired *t* test showed no significant differences between the 2 regimens regarding length of treatment visit: MDZ=37 minutes; MDZH=39.5 minutes ( $P=.275$ ).

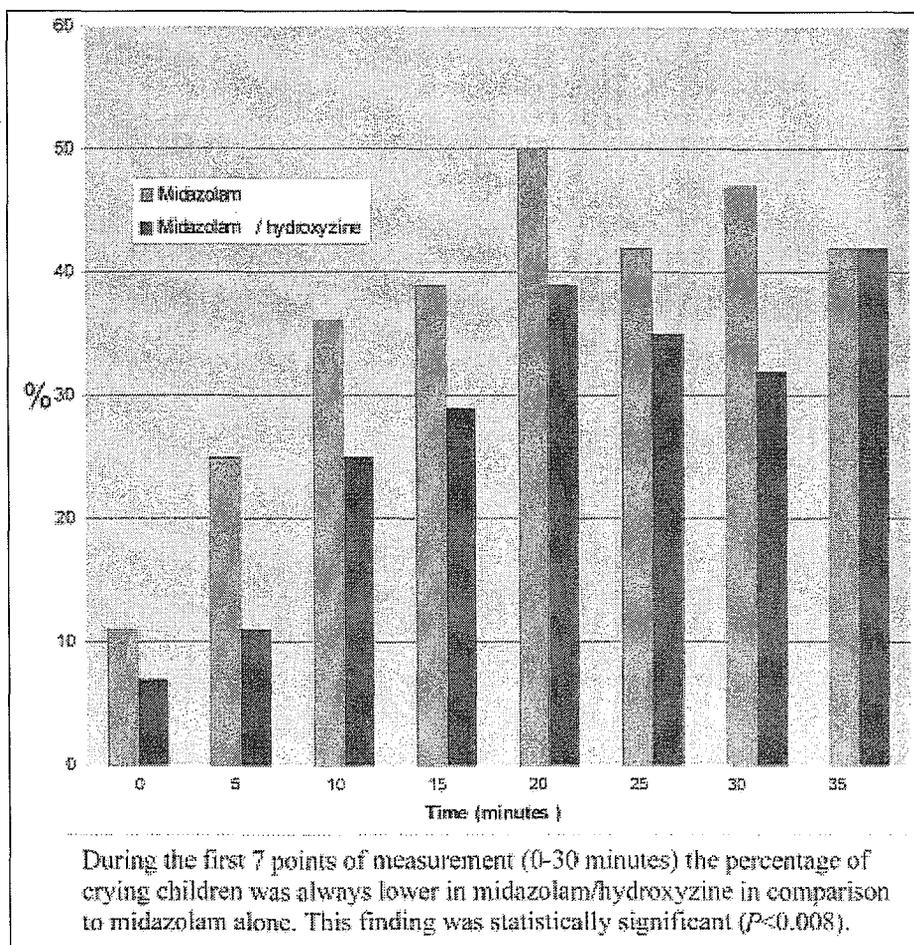


Figure 1. Percentage of children exhibiting crying behavior at 5-minute intervals.

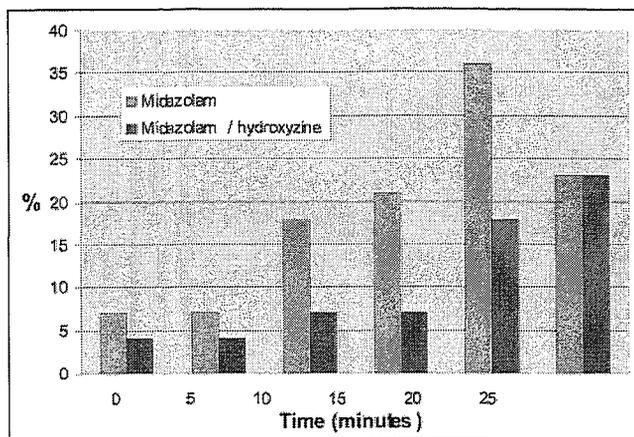


Figure 2. Percentage of children exhibiting movement at 5-minute intervals.

### Vital signs and adverse reactions

Pulse and blood oxygen saturation level were continuously monitored with a Nellcor pulse oximeter. In general, vital signs remained stable throughout treatment procedures. No adverse reactions were observed in any of the sedation visits.

### Discussion

This study's results demonstrate that the combination of oral MDZ with hydroxyzine supplemented by 50% nitrous oxide/oxygen inhalation is a safe and effective method to sedate young children for dental treatment. The combination of these drugs has advantages over their use as single agents. Hydroxyzine's onset of action is slow compared to MDZ. Yet, MDZ's duration of action is short, limiting its use to short dental procedures. As a combination, the 2 drugs facilitate early treatment time following administration and an adequate working time allowing most dental procedures. Indeed, this study's results showed that children sedated with MDZH were more likely to exhibit quiet and/or sleep behavior than with MDZ alone up to 30 minutes into treatment. This may be attributed to the combined actions of MDZ and hydroxyzine. Further into treatment, however, crying behavior was the same for both groups, due to the shorter duration of action of MDZ, the sedative effect of which dissipates after 20 minutes.

Recently, a study has been published investigating the combination of MDZ with meperidine (MPD).<sup>7</sup> Oral MDZ alone was found to be just as effective as MDZ with MPD at a dose of 0.5 mg/kg and 1 mg/kg, respectively. Higher doses of this combination, however, resulted in fewer disruptive behaviors in a current retrospective study.<sup>11</sup> MPD, a narcotic, potentiates the action of sedatives when taken in combination. Its side effects, which include nausea, vomiting, and respiratory depressions, however, make it less than desirable for sedation in a dental setting. In addition, sedation with opioids may increase the risk of local anesthesia toxicity, particularly with young children.<sup>12</sup>

On the other hand, hydroxyzine may be the more favorable drug when used in combination with MDZ, since its only frequent adverse reaction is drowsiness, which is favor-

able in sedation. One of the drawbacks of hydroxyzine is the relatively long waiting period between its administration and the start of treatment. This study's results show that addition of MDZ allows a significant reduction in the waiting time without compromising the effectiveness of the sedation. Indeed, 75% of the sedations were rated as being successful and none were aborted.

The choice of hydroxyzine dose was based on a previous study in which a dose of 3.7 mg/kg supplemented by 50% nitrous oxide/oxygen inhalation was found to be more effective than a standard dose of 50 mg, regardless of weight<sup>13</sup> and which had been subsequently used in other studies.<sup>4,5</sup> It is recommended to use MDZ alone for short dental procedures (eg, extractions or preventive resin restorations to be administered 20 minutes before). Longer procedures should use MDZH administered 30 minutes before.

A few of this study's limitations should be noted. Although significant differences were detected between the 2 groups during the first 20 to 30 minutes of treatment, other differences might exist but may not have been detected, due to the small number of subjects. Although movement was found in many subjects, the use of a papoose board only allowed observation of extreme movement. It is precisely these types of movements, however, that are of concern to the operator, and that may determine the success of the sedation. Another point is that the routine use of the papoose board may have contributed to the relatively high success rates of both regimens.

More research is needed to determine the role of medical immobilization in the success of conscious sedation. Future studies should also include the comparison of MDZH to hydroxyzine alone to elucidate the role of MDZ in shortening the waiting period before commencement of dental treatment.

### Conclusions

1. The combination of hydroxyzine (3.7 mg/kg) with MDZ (0.3 mg/kg) administered 30 minutes before treatment resulted in safe and effective sedation for the dental treatment of young children.
2. The use of this combination might be more advantageous when compared to MDZ alone, resulting in less crying and movement during the first 30 and 20 minutes, respectively.

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## ABSTRACT OF THE SCIENTIFIC LITERATURE



### PREVALENCE OF OVERWEIGHT TEXAS SCHOOLCHILDREN

The prevalence of children being overweight has more than doubled in the past 20 years. This study describes results from year 1 of a surveillance system to monitor body mass index in children at the state level. A sample of 6,630 children attending Texas public schools, representing fourth-, eighth-, and 11th-grade students within race/ethnic subpopulations, was assessed. Body mass index was calculated, and demographic information was obtained from a questionnaire. The prevalence of being overweight was 23%, 19%, and 16% for fourth-, eighth-, and 11th-grade students, respectively. Overweight prevalence was highest among Hispanic boys (30% to 33%), fourth-grade Hispanic girls (27%), and fourth- and eighth-grade African American girls (31% and 23%, respectively). Eleventh-grade white/other girls had the lowest prevalence of being overweight (6%). These data confirm the increasing prevalence of being overweight among US children, especially among Hispanic and African American students, compared to white/other students and fourth-grade students relative to eighth- and 11th-grade students.

**Comments:** The trend of children being overweight, which was highest among minority populations, is alarming because childhood obesity often persists into adolescence and adulthood. This is disturbing, in view of the fact that obesity is considered a risk factor for many chronic diseases as well as increased mortality. FSS

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Hoelscher DM, Day RS, Lee ES, Frankowski RF, Kelder SH, Ward JL, Scheurer ME. Measuring the prevalence of overweight in Texas schoolchildren. *Am J Public Health.* 2004;94:1002-1008.

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## Sedation of children undergoing dental treatment (Review)

Lourenço-Matharu L, Ashley PF, Furness S

Lourenço-Matharu L, Ashley PF, Furness S.

Sedation of children undergoing dental treatment.

*Cochrane Database of Systematic Reviews* 2012, Issue 3. Art. No.: CD003877.

DOI: 10.1002/14651858.CD003877.pub4.

[www.cochranelibrary.com](http://www.cochranelibrary.com)

[Intervention Review]

## Sedation of children undergoing dental treatment

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### ABSTRACT

#### Background

Children's fear about dental treatment may lead to behaviour management problems for the dentist, which can be a barrier to the successful dental treatment of children. Sedation can be used to relieve anxiety and manage behaviour in children undergoing dental treatment. There is a need to determine from published research which agents, dosages and regimens are effective.

#### Objectives

To evaluate the efficacy and relative efficacy of conscious sedation agents and dosages for behaviour management in paediatric dentistry.

#### Search methods

Electronic searches of MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Dissertation Abstracts, SIGLE, the World Wide Web (Google) and the Community of Science Database were conducted for relevant trials and references up to 4th August 2011. Reference lists from relevant articles were scanned and the authors contacted to identify trials and obtain additional information. There were no language restrictions. Trials pre-1966 were not searched.

#### Selection criteria

Studies were selected if they met the following criteria: randomised controlled trials of conscious sedation comparing two or more drugs/techniques/placebo undertaken by the dentist or one of the dental team in children up to 16 years of age. Crossover trials were excluded.

#### Data collection and analysis

Information regarding methods, participants, interventions, outcome measures and results were independently extracted, in duplicate, by two review authors. Where information in trial reports was unclear or incomplete authors of trials were contacted. Trials were assessed for risk of bias. The Cochrane Collaboration statistical guidelines were followed.

#### Main results

Thirty-six studies were included with a total of 2810 participants. Thirty trials (83%) were at high risk of bias and six (17%) were at unclear risk of bias. There were 28 different sedatives used with or without inhalational nitrous oxide. Dosages, mode of administration and time of administration varied widely. Trials were grouped into placebo-controlled, dosage and head-to-head comparisons. Meta-analysis of the available data was possible for studies investigating oral midazolam vs placebo only. There is weak evidence from five

small clinically heterogeneous trials at high risk of bias, that the use of oral midazolam in doses between 0.25 mg/kg to 0.75 mg/kg is associated with more co-operative behaviour compared to placebo; standardised mean difference (SMD) favoured midazolam (SMD 2.98, 95% confidence interval (CI) 1.58 to 4.37,  $P < 0.001$ ,  $I^2 = 91\%$ ), which translates to an increase of approximately 1.8 points on the six-point Houpt behaviour scale. There is very weak evidence from two trials which could not be pooled that inhalational nitrous oxide is more effective than placebo.

#### **Authors' conclusions**

There is some weak evidence that oral midazolam is an effective sedative agent for children undergoing dental treatment. There is very weak evidence that nitrous oxide inhalation may also be effective. There is a need for further well designed and well reported clinical trials to evaluate other potential sedation agents. Further recommendations for future research are described and it is suggested that future trials evaluate experimental regimens in comparison with oral midazolam or inhaled nitrous oxide.

## **PLAIN LANGUAGE SUMMARY**

### **Sedation of children undergoing dental treatment**

Fear of the dentist may be expressed as unco-operative behaviour in children requiring dental treatment. Behaviour management problems can result in a child's tooth decay going untreated. While behavioural techniques play an important role in managing children, some children still find it difficult to co-operate with dental treatment and may require sedation. This review examined the effectiveness of drugs to sedate a child whilst keeping them conscious. There is some weak evidence that midazolam administered in a drink of juice is effective, and nitrous oxide (laughing gas) may also be effective.

# ORAL AND FACIAL SURGEONS OF CALIFORNIA

1. August 11, 2016 Letter from Leonard M. Tyko II, DDS, MD, FACS, President with Attachment
  - Report, References, and Appendix A
2. October 13, 2016 Letter Regarding Response to DBC Subcommittee Preliminary Recommendations Published 10/3/2016

11 August 2016

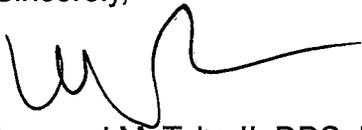
RE: Invitation to Participate in the Dental Board of California's Anesthesia Project

Ms. Karen Fischer  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Dear Ms. Fischer,

In response to the Dental Board of California's invitation to participate in the Anesthesia Project, the Oral & Facial Surgeons of California submit the attached report. If the Board has any questions about this report, we are happy to elaborate. OFSOC plans to attend all of the upcoming DBC's Anesthesia Projects meetings.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Tyko II', with a long horizontal flourish extending to the right.

Leonard M. Tyko II, DDS, MD, FACS  
President, Oral & Facial Surgeons of California  
950 Reserve Drive, Suite 120  
Roseville, CA 95678

# **Oral & Facial Surgeons of California**

## **Introduction**

In response to the Dental Board of California's (DBC) 1 June 2016, invitation to participate in the Dental Board of California's Anesthesia Project, the Oral & Facial Surgeons of California (OFSOC) respectfully submit this report that describes the Oral & Maxillofacial Surgery Team Model of out-patient anesthesia delivery.

For more than 60 years, California Oral & Maxillofacial Surgeons (OMS's) have held the practice authority to provide deep sedation/general anesthesia in an out of hospital setting. During short, potentially painful, and anxiety provoking procedures, it is common for OMS's to provide deep sedation and general anesthesia for in-office surgery via the Oral & Maxillofacial Surgery Team Model. Professional outcomes data show that the OMS anesthesia model delivers care that is safe and cost-effective. This model increases access to necessary oral health care for individuals who otherwise are unable to afford hospital-based surgical care.

## **What is an Oral & Maxillofacial Surgeon?**

Oral & maxillofacial surgeons are the surgical specialists of dentistry. There are two paths to becoming an OMS. The first route requires the completion of 4 years of dental school and a 4-year, hospital-based residency program. The second route includes the completion of both dental school and medical school and a 4-year residency program. Oral Maxillofacial surgeons have between 8-12 years of post-graduate clinical training.

Procedures within the OMS's scope of practice include: surgery to correct maxillofacial trauma (e.g. motor vehicle accidents, gunshot wounds, industrial accidents, interpersonal violence); corrective jaw surgery for developmental deformities of the face and jaws; surgical treatment of head, neck and oral pathology, including benign lesions and cancer; cosmetic surgery; reconstructive surgery, including bone and skin grafts and dental implants; jaw joint surgery; and dental extractions. OMS's operate in both hospital and outpatient settings. While major and lengthy surgeries are carried out in a hospital setting, minor surgeries, on otherwise healthy individuals, are typically performed in an office setting. To facilitate office-based surgery, OMS's are trained to administer all forms of anesthesia.

## **OMS Team Model of Anesthesia**

The OMS Team Model of anesthesia delivery is a core clinical competency taught throughout the residency program and requires post residency specialty licensure. This

specialized training during residency includes a 5-month medical anesthesiology rotation. While in this rotation, the OMS functions as an anesthesiology resident, alongside the other medical anesthesiology residents. The OMS Resident is supervised by medical anesthesiologists and performs a minimum of 300 general anesthetics. This anesthesia training includes: evaluation of patients for anesthesia, risk assessment, diagnosis and treatment of complications, appropriate patient monitoring and post-anesthesia care, and techniques to administer of all levels of anesthesia. As the anesthesiology resident, the OMS trainee performs local anesthetic techniques as well as general anesthesia for all types of major, hospital based surgical procedures.

In addition to their anesthesiology rotation, OMS residents continue their anesthetic training in the OMS outpatient clinic under faculty supervision in their clinical specialty. Throughout training, the OMS performs hundreds of office-based surgeries delivered under all forms of anesthesia while directing the anesthesia team.<sup>1</sup> In addition, OMS residents must complete Pediatric Advanced Life Support (PALS) and Advanced Cardiac Life Support (ACLS) training.

In order to provide deep sedation and general anesthesia, the practicing OMS must secure and maintain a separate General Anesthesia Permit issued by the Dental Board of California. California regulations require this General Anesthesia Permit in addition to (and separate from) their medical and/or dental license. As part of the anesthetic permit maintenance, the Dental Practice Act requires the OMS to obtain on-going anesthesia-related continuing education as well as completing Basic Life Support and Advanced Cardiac Life Support every two years. California regulations also require anesthesia permit holders to undergo regular, in-office evaluations by the Dental Board of California. These evaluations include a site inspection, observation of the OMS and his/her team during a surgery with general anesthesia delivery, and the successful completion drills of 13 medical emergency scenarios.

## **OMS Team Members**

The Oral & Maxillofacial Surgery Anesthesia Team consists of the surgeon and at least two, trained assistants. The first assistant monitors the patient and maintains the airway as his/her only duties during the procedure. The second assistant assists the OMS in performing the surgery. Assistants achieve certification via completion of the California's Oral & Maxillofacial Surgery Assistants (OMSA) Program or the Dental Anesthesia Assistant National Certification Examination (DAANCE). Assistants are trained in the use of anesthesia monitoring equipment equivalent to the monitors found in many hospital surgical suites and are trained in the latest medical anesthesia protocols. Monitoring patients' vital signs, anticipating, and if needed, reacting to emergency situations are a major focus of the assistants' training and on-going performance evaluation.

## Growing Role of Sedation out of the Operating Room

OMS's have a long history of administering anesthetics to patients undergoing short, interruptible, minor surgeries. However, OMS are not the only practitioners who provide out-of-operating-room anesthesia without an anesthesiologist.<sup>2-3</sup> The delivery of sedation has become common, and as many providers argue, is the standard of care for uncomfortable or painful diagnostic and treatment procedures. Sedation helps patients tolerate lengthy MRI or nuclear medicine scans. Cardiologists and emergency department physicians provide procedural sedation and analgesia. Gastroenterologists routinely provide sedation for endoscopy. In fact, a survey by the American College of Gastroenterology found more than 98% of providers in the United States routinely administer sedation.<sup>4</sup> Providers cite difficulty obtaining operating room time, excessive costs for in-patient care, and reimbursement challenges as reasons for providing more outpatient anesthetics. Multiple studies have demonstrated the safety of anesthesia in the above situations when administered to *appropriate patients* by *well-trained providers*. Furthermore, many studies report decreased patient anxiety and increased patient satisfaction with procedures performed under outpatient anesthesia. Together, these factors provide the basis for a multi-specialty practice of providing safe and affordable single-provider, outpatient anesthesia.

## OMS Safety Record

All surgical procedures and all forms of anesthesia in every healthcare setting carry risks. The overall estimated mortality rate from hospital-based anesthesia in the United States is approximately 1 in 100,000.<sup>5-6</sup> In comparison, the overall estimated mortality rate from office-based OMS anesthetics is 1 in 648,794.<sup>7-22</sup> This difference is striking, but not surprising. One would expect a lower mortality rate with the OMS Team Model. Unlike other operating room surgeries, the typical, office-based anesthetic is less deep, the surgeries are minor, short and interruptible, and the patients are relatively healthy individuals. Multiple academic papers published in peer-reviewed, scientific journals attest to this safety record.

Repeatedly, retrospective and prospective studies, individual case studies, surveys, and closed claims reports report very low morbidity and mortality rates for OMS anesthesia delivery.<sup>7-22</sup> In a 2003, prospective, cohort study of more than 34,000 patients, Perrott et al., reported an overall complication rate of 1.3% for office-based ambulatory anesthesia by the OMS Anesthesia Team Model.<sup>20</sup> Most complications were minor and self-limiting, and no complication resulted in long-term adverse sequelae. There were no deaths reported in this study of more than 34,000 patients.

Most recently, Inverso et al., 2016, published a multi-center, prospective study of 29,548 adolescent patients undergoing moderate sedation or deep sedation/general anesthesia in an outpatient setting.<sup>22</sup> They reported overall complication rates for moderate sedation of 0.5% and 0.9% for deep sedation/general anesthesia. The most common

complications were vomiting and prolonged emergence from anesthesia. Multivariable logistic regression analysis showed no increase in risk between deep sedation/general anesthesia and moderate sedation in an out patient setting. As in earlier studies, Inverso reported no deaths in this large, multi-center trial. Inverso's findings are particularly relevant to discussions surrounding AB 2235, as all of the 29,548 subjects were pediatric patients less than 21 years old.

Large, randomized, cohort studies are expensive and difficult to conduct. As such, closed case claims reviews are an established method to look for low incident events. The American Society of Anesthesia used closed case reviews to help lower complication rates by identifying scenarios that led to poor outcomes.<sup>22-23</sup>

In a similar fashion, the OMS National Insurance Company (OMSNIC) recently completed its own closed case claims review of pediatric, anesthesia claims. OMSNIC is the largest OMS malpractice insurance company in the country, insuring approximately 80% of the United States 9,500 OMS's. They evaluated California claims from 2005 through 2015 for patients less than 21 years old and found 5 claims related to the delivery of anesthesia. Four claims were related to anesthesia care in an office setting and one claim involved a patient treated in a hospital. During the period of review, 2005 through 2015, there were no claims of a pediatric patient anesthetic death (see Appendix A).

It is important to note that in a detailed review of the OMS literature, no study demonstrates an increase in anesthetic complication rates in appropriately screened individuals, including pediatric patients, with the OMS Team Model of Anesthesia. As multiple researchers explain, office-based oral surgeries are minor procedures, performed on carefully screened, low risk individuals in an area that allows for direct monitoring of the airway. Given these findings, it is reasonable to conclude that for relatively healthy patients undergoing brief, interruptible surgeries in the head and neck region, the OMS Anesthesia Model provides a safe and effective standard for out patient anesthesia.

## **Efforts to Establish California Complication Rates**

Currently, the DBA is compiling a report of adverse clinical events in pediatric patient between 2011 and 2016. In order to calculate complication rates for California OMS practicing under the current OMS Anesthesia Team Model, investigators need to know the number of anesthetics given by a practicing provider. There have been a number of past surveys in the United States and Canada attempting to estimate this denominator.

6-19

In order to obtain the most current number of deep sedations/general anesthetics provided by an average California OMS, OFSOC is conducting a survey of its active membership. Including residents, candidates, affiliates, and active members, OFSOC has a total membership 953 OMS's. Out of the total membership, there are 725 active

members. We assume that the vast majority of active members have general anesthesia permits. As of this report's submission date, 284 active members of OFSOC responded to the survey, for an overall response rate of 39%. OFSOC members were asked to provide the number of pediatric (less than 21 years old) and adult (21 years old and older) anesthetics. Members were requested to obtain the data from their practice management software by searching for anesthesia codes CDT 9220 and CDT 9223. Tables 1-5 summarize this data.

**Table 1: Number of Deep Sedation/General Anesthetics Per Year**

Year	Pediatric Patients Deep Sedation/General Anesthetics	Adult Patients Deep Sedation/General Anesthetics	Total Deep Sedation/General Anesthetics
2011	68,290	77,398	145,688
2012	71,070	82,445	153,515
2013	76,606	85,561	162,167
2014	78,639	86,613	165,252
2015	83,737	88,694	172,431
2016 (partial year)	53,003	56,210	109,213

**Table 2: Number Of OMS Reporting By Year**

Year	Number of Responders
2011	234
2012	244
2013	258
2014	268
2015	279
2016 (partial year)	270

**Table 3: Average Number of Pediatric Deep Sedation/  
General Anesthetics Per OMS Per Year**

Year	Average
2011	292
2012	291
2013	297
2014	293
2015	300
2016 (partial year)	196

**Table 4: Average Number of Adult Deep Sedation/  
General Anesthetics Per OMS Per Year**

Year	Average
2011	331
2012	338
2013	332
2014	323
2015	318
2016 (partial year)	208

**Table 5: Average Number of Deep Sedation/  
General Anesthetics Per OMS Per Year**

Year	Average
2011	623
2012	629
2013	629
2014	617
2015	618
2016 (partial year)	404

Data collection is on-going, but thus far, OFSOC survey results correlate closely with previously published papers.<sup>6-19</sup> OFSOC anticipates that the results of this survey will be combined with the DBC's data to generate OMS anesthesia morbidity and mortality rates during the period of 2011-2016.

## **Legal & Professional Standards to Ensure Patient Safety**

The California Dental Practice Act defines the legal standards of practice for dentists in California. The requirements for obtaining and maintaining an anesthesia permit are contained within the Act. Permit holders are required to undergo office anesthesia evaluations (OAE) by the Dental Board of California as previously discussed. These evaluations of the OMS and his/her team include a site inspection, observation of a surgery with anesthetic delivery, and medical emergency scenario drills. The purpose of the OAE is to assess the OMS's ability to gauge a patient's anesthetic risk and to ensure the facility is prepared for emergencies associated with the administration of anesthesia in all types of patients, including pediatric individuals.

In order to give clear direction to the practicing OMS beyond the legal dictates of the Dental Practice Act, state and national professional societies define the standards of care for OMS. Beyond a general ethic of "do no harm," oral and maxillofacial surgeons are professionally bound to the specific principles outlined by the mission, actions, and publications of the OFSOC and AAOMS. Of the nearly 1,000 California OMS's, 953 are members of OFSOC and AAOMS.

The purpose of OFSOC is to contribute to the public welfare by advancement of the profession of dentistry and in particular the specialty of oral and maxillofacial surgery; to foster programs of education, research, standards of practice and scientific investigation in the specialty of oral and maxillofacial surgery; to provide a means of self-government relating to professional standards, ethical behavior and responsibilities of its fellows and members; to provide opportunities for social and professional development.<sup>25</sup> In order to qualify for membership in OFSOC and AAOMS, OMS's must undergo a professional evaluation. Once a member, the OMS is required to adhere to a code of professional conduct and a code of ethics; and to submit to peer review and to an ongoing evaluation of their office, staff and office procedures related to the anesthesia team model. Through their membership in the professional organization, OMS commit to following evidence-based standards of practice to insure safe anesthesia delivery.

Two AAOMS publications set the standards for OMS office-based anesthesia: *AAOMS Parameters of Care for Anesthesia in Outpatient Facilities* and the *Office Anesthesia Evaluation (OAE)* program.<sup>26-27</sup> More rigorous than the California Dental Practice Act, the *AAOMS Parameters of Care* describes criteria and parameters for pain and anxiety control in the ambulatory surgery setting. Subjects covered within this document include: informed consent, proper documentation, facility attributes and required equipment, pre-anesthetic physical and laboratory assessment, perioperative

complications and emergencies, general therapeutic goals, general risk factors that may exclude a patient from office-based surgery, desired outcomes, and risks and complications of anesthesia. This publication also outlines special considerations for pediatric, pregnant, and obese patients.

Each subject within the *AAOMS Parameters of Care* outlines what is expected of the OMS. For example, the operating theater must be large enough and equipped to allow for ACLS. Readily available mobile auxiliary sources of light and suction that can be used in a power failure must be present. Back up oxygen that can be delivered under positive pressure is required. Further, during deep sedation and general anesthesia, the *Parameters* call for the use of anesthesia monitoring equipment that is similar to those used in the operating room: blood pressure readings every 5 minutes, evaluation of the heart rate and rhythm by ECG, continuous evaluation of the patient by observation, pulse oximetry, and end-tidal CO<sub>2</sub> by capnography. Of note, OFSOC and AAOMS require monitoring devices that exceed those mandated in the California Dental Practice Act. The *Parameters of Care for Anesthesia in Outpatient Facilities* is regularly updated (at more frequent intervals than that of the Dental Practice Act) to ensure that the document reflects current, evidenced-based standards of care.

Both OFSOC and AAOMS require continuing education courses specific to anesthesia. OFSOC offers to its members and allied staff six to seven educational opportunities per year, with subjects ranging from medical emergencies, to anesthesia, to ACLS, to surgical updates, to the Oral & Maxillofacial Surgery Assistance (OMSA) program.

Finally, the AAOMS promotes many practices originally promulgated by the aviation industry to foster a culture of safety. The AAOMS publication *Culture of Safety in the OMS Office* defines policies and actions to ensure patient safety. Adopted by JCAHO and numerous healthcare entities, the pre-surgical “time out,” promotion of the team concept, cross training, collaboration, transparency, accountability, and systematic evaluation are all tools endorsed by AAOMS to help prevent potential errors. A full description of the *Culture of Safety in the OMS Office* is available on the AAOMS website. In March 2017, AAOMS will host a Patient Safety Summit to highlight their efforts in this arena.

## **Future Pathways to Increase Patient Safety**

Despite outcomes data demonstrating extremely low complication rates, OFSOC and AAOMS strive to increase safety in the delivery of anesthesia. To that end, OFSOC and AAOMS continuously review, revise, and develop standards, policies, and educational opportunities for their members. Though rare in their occurrence, research points to airway problems as a major component of poor anesthesia outcomes. To further improve outcomes and to help its members better manage rare airway emergencies, AAOMS developed an emergency airway management simulation program, BEAM (Basic Emergency Airway Management), to be implemented in 2017.

Also, AAOMS is in the final stages of  $\beta$ -testing a national registry to prospectively track rare anesthetic adverse events. This anesthesia registry will interface directly with OMSs' practice management systems to provide needed prospective data. Commonalities gleaned from the registry will be helpful in further reducing anesthesia morbidity and mortality.

## **Access to Care**

According to the statistics above, requiring patients to receive care in the hospital would transfer approximately 452,000 patients (average number of 623 deep sedation/general anesthetic per OMS per year (Table 5) X 725 active OMS's) per year to hospital operating rooms. California's hospitals are ill-prepared to absorb this increase in patient utilization. California lacks a sufficient number of anesthesiologists, dental anesthesiologists, and nurse anesthetists to accept this load. Already, providers cite problems with obtaining OR time and the subsequent delay in care as a reason for needing alternatives to inpatient procedures.

Additionally, moving these cases to the hospital will increase the cost of basic oral health care dramatically. Insurance coverage for dental care is already a challenge, and patients who risk out of office-based procedures struggle to obtain adequate coverage for hospital surgeries. It is unclear if insurance companies will cover the cost of hospital care simply because of the patient's age. Of note, Denti-Cal currently requires pre-authorization for office-based anesthesia; this authorization is not guaranteed and already delays services. Furthermore, one 2015 (post Affordable Care Act) study estimates 31% of Californians delay or decline care due to cost-concerns. The same study reports that 9% of Californians have deductibles that are  $\geq 5\%$  of their annual income.<sup>28</sup> More expensive treatment plans will force Californians to delay or decline more care. Currently, untreated dental patients seeking care comprise 1% of all emergency department visits in the United States.<sup>29</sup> This number certainly will increase if dental care becomes more expensive, causing further negative effects on already understaffed and over-taxed hospital systems.

It is evident that the ability to provide out-of-hospital deep sedation/general anesthesia, reduces the volume of patients treated in operating and emergency rooms. This, in turn, decreases cost, increases access to care and improves oral health of Californians.<sup>30</sup>

## **Summary & Recommendations**

Oral & Maxillofacial Surgeons provide deep sedation/general anesthesia because head and neck surgery is painful, and because there is a societal wide fear of surgery in the mouth, on the face, and in the neck. The alternatives to anesthesia are limited. Physically restraining a child is unacceptable and would cause both physical and emotional suffering. Lighter levels of sedation are inadequate for sensitive patients and

painful surgeries. Lightly sedated patients often lose inhibitions and, correspondingly, their ability to tolerate the noises, pressures, and pain that accompany surgery. This typically results in a combative patient, which increases overall risk both to him/herself and to their providers. Appropriate level anesthesia is critical to the delivery of safe oral and maxillofacial surgical care.

According to the Dental Board of California's working document, there were nine pediatric death during the study period of 2011-2016; only one of these was attributed to an OMS. During this period of study, it is estimated that 1,069,375 (average of 295 pediatric anesthetics (Table 3) multiplied by 725 active California OMSs times 5 years) pediatric anesthetics were administered. These data establish an office-based, mortality rate of less than 1 in a million for the OMS Anesthesia Team Model when applied to pediatric patients.

When properly performed, the OMS Anesthesia Team Model is a proven safe and effective method to provide care for patients who meet the specific risk criteria for office sedation and surgical procedures. OMS education, professional standards, and staff preparation establish an environment of safety. Multiple studies demonstrate safety of the OMS Anesthesia Model, and legal and professional systems exist to ensure individual providers are practicing within these safety standards. Current outcomes data validate the effectiveness of the current method.

Despite the proven safety record, every system can be improved. Patient safety is our paramount concern. To that end, OFSOC recommends the following enhancements to the Dental Practice Act's section on deep sedation & general anesthesia.

**1. Adopt the standards outlined in *AAOMS Parameters of Care for Anesthesia in Outpatient Facilities***

OFSOC feels strongly that no professional organization's name should be codified into the California Dental Practice Act. However, OFSOC suggests changing the California Dental Practice Act's section on deep sedation/general anesthesia to parallel the *AAOMS Parameters of Care*. These standards are the most complete and most rigorous, in all of dentistry. This change would update California law to the current standards of outpatient anesthesiology, and require all dentists who provide sedation or general anesthesia to abide by the same rigorous standards.

**2. Require the presence of 2 trained assistants during moderate sedation and deep sedation/general anesthesia**

OFSOC recommends the presence of two, certified assistants where one assistant is tasked solely with providing continuous, direct observation and monitoring of the patient's status.

**3. Add Capnography to the required monitoring equipment during moderate sedation and deep sedation/general anesthesia.**

In dentistry, airway complications are the most common pathway to an anesthetic complication. As such, OFSOC advocates for the use of operating room level patient monitors during all moderate and deep sedation/general anesthesia procedures. The currently required monitors include an ECG, blood pressure, and pulse oximetry. OFSOC and AAOMS suggest the addition of monitoring exhaled carbon dioxide via capnography. Capnography provides immediate and constant data on an anesthetized patient's respiratory status. Monitoring exhaled carbon dioxide is the standard of care in the hospital operating room. The American Society of Anesthesiologists and American Heart Association include this level of monitoring in their parameters of care. OFSOC understands that the use of capnography is somewhat limited in patients who are not intubated. However, implementation of capnography would provide another layer of patient safety.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'L. Tyko II', with a long horizontal flourish extending to the right.

Leonard M Tyko II, DDS, MD, FACS  
President, Oral & Facial Surgeons of California

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## Appendix A



OMS NATIONAL  
INSURANCE COMPANY, RRG

6133 N. River Road, Suite 650  
Rosemont, IL 60018-5173  
(800) 522-6670  
Fax: (847) 384-0070  
www.omsnic.com

August 6, 2016

Dr. Leonard Tyko II  
President  
Oral and Facial Surgeons of California  
950 Reserve Drive, Suite 120  
Roseville, CA 95676-1351

Dear Dr. Tyko:

The following outlines the results of a review performed by OMSNIC earlier this year on its closed claim data on pediatric anesthesia related claims in California. This information is provided per the request of Ms. Pamela Congdon, Executive Director of OFSoC.

We reviewed OMSNIC's claim statistics based on the following criteria:

- Claims closed from 2005-2015
- Patient age range: 21 years or younger

A query of the Company's database of all closed claims of individuals under 21 years of age in California for the period from 2005 to 2015 was made. This query revealed a total of fifty four (54) claims involving patients age 21 or under. These claims were reviewed by experienced risk management personnel overseen by the Company's Chief Operating Officer, who herself has thirty years of insurance experience, to determine which claims were due to the administration of anesthesia. Five (5) of the fifty four claims identified were found to be related to the administration of anesthesia. Of these five, four (4) claims involved patients treated in an office setting and one (1) claim involved a patient treated in a hospital. We note that none of the claims resulted in a patient's death.

The time period reviewed covers an estimated 2,682 mature equivalent exposures (MEEs). The MEE is calculated as follows. A full-time OMS who is mature for purposes of claims-made liability coverage (i.e., practicing for five years or more) is equal to 1.00 for each year and cumulatively as 11.00 over the full period under review. Part-time or new-to-practice OMS are included at a fraction of 1.00 based on OMSNIC's claims-made factors. For example, an OMS practicing part-time would be included as .50 MEE for each year and 5.50 cumulatively. Put differently, each MEE approximates a full year of an OMS's practice.

On this basis, the incidence of closed pediatric anesthesia related claims for the period under review was 5 claims divided by 2,682 MEEs, or 0.2%. The incidence of pediatric anesthesia related death claims was Nil as there were no closed claims of this nature during the period under review.

Information regarding Mature Equivalent Exposures ("MEE") was prepared by me from proprietary Company actuarial data. I am a certified public accountant with twenty-four years of experience with OMSNIC and over thirteen years of public accounting experience. The MEE represents a more refined calculation of the risks insureds for the time period the claims were reviewed.

OMSNIC insured an average of 316 OMS in California for the time period between 2011 and 2015 based on the year-end policyholder counts for those years. The number can fluctuate during any given year but this average is a reasonable approximation.

## Appendix A



Dr. Leonard Tyko II  
August 6, 2016  
Page 2 of 2

Finally, the findings outlined above were reviewed by the five OMS directors of OMSNIC. Each of these directors is a practicing OMS with twenty or more years in practice and related activities.

In summary, the information was accumulated by very experienced Company personnel and was overseen and reviewed by individuals at the highest levels of our organization.

We understand this information will be used for the purpose of study and potential advocacy efforts by the California Dental Board. The data outlined above is provided solely for this purpose. Also, please note OMSNIC is providing this information without any position for or against any current or pending California legislation.

Sincerely,

William C. Passolt  
President and CEO

cc: Ms. Pamela Congdon, CAE, IOM – Executive Director, Oral and Facial Surgeons of California



CALIFORNIA ASSOCIATION of  
ORAL & MAXILLOFACIAL SURGEONS

Advancing our  
specialty through  
ethics, education,  
public service and  
advocacy

13 October 2016

Steven G. Morrow, DDS, MS  
Dental Board of California  
Department of Consumer Affairs  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

**RE: Pediatric Dental Anesthesia Subcommittee Preliminary Recommendations**

Dear Dr. Morrow,

The California Association of Oral & Maxillofacial Surgeons (CALAOMS) recognizes the Dental Board subcommittee's efforts in the development of the working document and appreciates the scope and complexities of these, preliminary recommendations. CALAOMS is committed to ever-improving patient safety and to the process of finalizing pediatric anesthesia recommendations. CALAOMS applauds the DBC's preliminary recommendations, published on 3 October 2016, as an effective and meaningful step toward insuring greater safety for pediatric anesthesia delivery.

In regards to the specific recommendations, CALAOMS embraces the following changes:

- Adoption of updated anesthesia definitions to include minimal sedation, moderate sedation, deep sedation, and general anesthesia regardless of route of administration.
- Addition of capnography to accompany ECG, blood pressure and pulse oximetry for deep sedation, general anesthesia, and, when possible, moderate sedation.
- Requirement of at least two assistants, with one trained assistant tasked only with monitoring the patient undergoing a deep sedation or general anesthetic.
- Expansion of outcomes reporting. In addition, CALAOMS believes this expanded reporting should include our medical colleagues. Some dental patients undergo anesthetics under medical model. Ensuring out-patient anesthetic safety requires a multi-discipline approach. Physician data is an important component of this outcome picture.
- Requirement of permit holders to report number of anesthetics.

CALAOMS encourages further discussion regarding to following matter:

- Age stratification: The majority of anesthetic deaths were among the very young. The greatest impact to improved outcomes could come from addressing children less than 7-years old, not 13-year olds.
- Pediatric Permit Parameters: Even the smallest change in the delivery of anesthesia will have a large impact on providers and patients alike. CALAOMS is concerned that restructuring deep sedation/general anesthesia permits may lead to a significant decrease in pediatric anesthetic providers and will adversely impact access to care for vulnerable populations.

Respectfully submitted,

Leonard M. Tyko II, DDS, MD, FACS  
CALAOMS President



# INDIVIDUALS

1. Diana Belli, DDS (Dental Anesthesiologist) – Emails dated July 21, 2016 and July 22, 2016
2. David Crippen, DDS (Pediatric Dentist) – Email dated July 26, 2016
3. Skip Harris, DDS (Oral and Maxillofacial Surgeon in Arizona) – Email dated July 22, 2016
4. Annie Kaplan, MD – Emails dated June 15, 2016 and July 18, 2016 – Attachments
  - August 11, 2010, 12 page letter signed by Janet Woodcock, MD Center for Drug Evaluation and Research.
  - Caleb's Law – White Paper, March 29, 2016 (Author Unknown)

## EMAILS RECEIVED IN RESPONSE TO NBC BAY AREA MEDIA REPORT ON OCTOBER 24, 2016

Alahwal, Jennifer  
Anonymous  
Belcher, Naomi  
Bentley, John and Ann  
Berlet, John  
Blucher, Debbie  
Brereton Mondanlou, Karen  
Brown, B.  
Butwick, Dr. Alex  
Chan, Nancy  
Chiba, Michelle  
Civitello, Linda  
Collins, Lorraine  
Cruciani, Michelle  
DeRooy, Jessica  
DeSimone, Joseph  
Dolan, Patricia  
Elder, Desmond  
Elder, Pamela  
Fernandez, Lissette  
Fernandes, Ross  
Fontes, David  
Friedman, Dr. Laura  
GG  
Gagne, Dr. Richard  
Geraghy, Grace

Giraud, Judy  
Hancock, Valerie  
Haynes, Charlotte  
Herrera, Daisy  
Jensky, Britt  
Jolivette, Robin  
Kaloyanova, Elena  
Kantor, Cathy  
Kaplan, Dr. Anna  
Kaplan, Laurence  
Kaplan, Noa  
Leibowitz, Dr. Howard  
Lilly, Laura  
Lund, Stephanie  
Mashni, Dr. Michael  
McCarthy, Linda  
McCormick, Gail  
McLean, Barbara  
McLean, Jennifer  
McLean, Alex & Jennifer  
Miller, Megan  
Molloy, John  
Moretti, Carolina  
Munro, Katy  
Munro, Kristine  
Myers, Sara  
Nino-Murcia, Anamaria

Nino-Murcia, Dr. Matilde  
Packer, Dr. Leslie  
Palacios, Diane  
Paluska, Karen  
Phelan, Shirley  
Pine, Bruce  
Pine, Wendy  
Ptaszynski, Andre  
Rodriguez, Jesus  
Rudolf, Sally  
Sanghi, Vivek & Rashi  
Schneider, Karen  
Scholnick, Nadia  
Selchau-Hansen, Lou  
Sunzeri, Debbie  
Sykes, Joy  
Tan, Corrine  
Tang, Lien  
Thomas, Ajit  
Tong, J  
Turner, Susan  
Walke, B. Blaine  
Welcome, Jessica  
Wong, Sheri Glucoft

## Fischer, Karen@DCA

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**From:** DrDianaBelli.com <email@drdianabelli.com>  
**Sent:** Thursday, July 21, 2016 7:55 PM  
**To:** Fischer, Karen@DCA  
**Cc:** Wallace, Sarah@DCA  
**Subject:** Feedback to AB2355 Pediatric Anesthesia Study

Dear Karen,

I am writing you this letter regarding AB2235 for which a subcommittee is writing a Pediatric Anesthesia Study. I had the opportunity to review the draft and would like to offer my professional feedback on what I read.

First of all, I am a DDS Anesthesiologist and I completed a 2 year CODA approved anesthesiology residency at Lutheran Medical Center in Brooklyn, NY. I hold both a California DDS license as well as a California General Anesthesia permit, however, I do not practice dentistry. I only provide anesthesia services at various dental practices.

My first concern affects public knowledge about pediatric sedation for dentistry. The second concern affects how dentists practice. Here are the items I noted in the draft that the public, the media and practitioners need to be on the same page on.

- 1) Are the studies on patient deaths including the distinction of whether there was a separate anesthesia provider from the dental provider? I believe this is a critical question and is a distinction that must be made in the research.
- 2) The report does not make the distinction between adjunct training in various forms of anesthesia and the highly specialized training residencies in dental anesthesiology. Although the draft report mentions the ADSA in the discussion on the history of anesthesia in dentistry (Par1 Pg3), it does not “highlight” the specialized training programs in dental anesthesiology in the history, that they parallel the medical anesthesia residency training programs. The mention of dental anesthesiology residencies in General Anesthesia Training (P13) doesn't really point this matter out either.
- 3) Nowhere in the report does it mention that there are licensed dentists in California who attended these programs and that they are called “dental anesthesiologists”. Regardless of whether the ADA wants to recognize us as a specialty, it is an accepted title (by ADSA and ASDA) and we are still highly specialty trained in our field. Many of us if not the majority practice ONLY anesthesia.
- 4) Under Permit Types on page 11, it might be helpful if there were a second column that identifies the *type* of *dental* practitioner eligible for each type of permit.(apart from the training requirements) to make the distinctions even clearer:

Minimal Sedation – Any licensed dentist

Moderate Enteral Sedation – Any licensed dentist

Moderate Parenteral Sedation – Any licensed dentist

Deep Sedation / General Anesthesia – Oral Surgeons, Dental Anesthesiologists

- 5) There is no mention that there are 2 practice models; single-practitioner doing the anesthesia, monitoring and the surgery, and the dual-practitioner model where there is a separate anesthesiologist dedicated to the anesthesia and monitoring, and the dental practitioner who is dedicated to the dentistry. This is not public knowledge and it is not currently a requirement that patients or parents be given that information or an opportunity to choose.

Unfortunately neither the media or the general public currently understands these distinctions and when these tragedies occur, the result is an assumption that general anesthesia or sedation in and of itself, is unsafe for pediatric dentistry, when in fact it is beneficial. If we want to provide laws and guidelines that optimize the safety of all patients, and justify them, then patients must be properly informed and everyone needs to be on the same page.

I hope you will pass this information on to the subcommittee for review and thank you so much for your time.

Sincerely,  
Dr. Diana Belli  
DDS Anesthesiologist  
855-773-7363  
[www.dradianabelli.com](http://www.dradianabelli.com)

## Fischer, Karen@DCA

---

**From:** DrDianaBelli.com <email@drdianabelli.com>  
**Sent:** Friday, July 22, 2016 1:41 PM  
**To:** Fischer, Karen@DCA  
**Cc:** Wallace, Sarah@DCA  
**Subject:** Additional feedback on the Pediatric Anesthesia Study

To whom it may concern,

There are a few more points I think are important in this matter.

California's current definition of General Anesthesia is "an induced state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command".

- 1) If a pediatric dentist administers oral sedation to a child who becomes unconscious and unresponsive to verbal command, they are considered to be under general anesthesia and are practicing outside of the law. Pediatric dentists who have NOT also completed an anesthesiology residency, are not qualified or trained in advanced airway management when a patient loses their airway reflexes. Many pediatric dentists use oral medications that can often cause loss of consciousness and patient response is unpredictable. When a patient is unconscious, there is no way to accurately assess whether the airway reflexes are intact.
  
- 2) If the majority of these deaths are occurring in pediatric dental offices or offices under the operator/anesthetist model (single practitioner model where one party does the surgery, anesthesia and monitoring), then the issue is about practitioner judgement as to when it is more responsible to call in an anesthesiologist.

In order to determine what the underlying patterns are, any beneficial study must ask the following minimal set of questions:

- a) was the case performed under the single-practitioner, or two-practitioner model
- b) what was the training of the practitioner(s) involved in the incident
- c) who was monitoring the patient and what was being monitored
- d) what medications were given, what doses and by what route (oral, I.V., I.M....)
- e) was an IV in place
- f) what were the events that lead up to the outcome
- g) how was the airway managed and by whom (open airway, nasal hood, LMA, Nasal/Endotracheal intubation)
- h) what were the dental procedures being done
- i) was proper medical history obtained and by whom
- j) what were the preoperative steps taken
- k) who recovered the patient and in what setting

Just to name a few.....

If it turns out that there is a common thread such that for instance, the majority of these cases are occurring in the single-practitioner model, with an unprotected airway (no LMA and not intubated) and no separate

anesthesiologist, then bringing in a qualified anesthesia provider for all pediatric sedation cases, may be a decision some practitioners decide to make.

Thank you again for your time.

Sincerely,

Dr. Diana Belli, DDS Anesthesiologist 855-773-7363

**From:** Dr. David Crippen [mailto:drcrippen@capitalpd.com]  
**Sent:** Tuesday, July 26, 2016 9:49 AM  
**To:** Fischer, Karen@DCA  
**Subject:** 2016 anesthesia study

Hello Ms. Fischer,

My name is David Crippen and I am a board certified, practicing pediatric dentist in Sacramento. I maintain both an oral conscious sedation for minors certificate as well as a conscious sedation permit. I am also a current subject matter expert in the field of pediatric dentistry for the Dental Board of California.

This email is regarding the DBC 2016 Anesthesia Study. I understand there is a meeting this Thursday with the subcommittee to discuss the recently released working document. I have emailed Ms. Linda Byers to set up a call-in line because I am unable to reschedule patients on that day and thus cannot attend the meeting in person. In addition to being involved in the working document discussion, I am very interested in participating in any additional meetings or committees that the board deems appropriate. I believe my experience and expertise in the field of Pediatric Dentistry and sedation would prove valuable to the board and the public and I would welcome the opportunity to serve in this capacity.

Thank you in advance for your consideration.

David

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David J. Crippen, DDS  
920 29th Street  
Sacramento, CA 95816  
916.476.3972

**From:** Dr. Skip Harris [mailto:[dr.harris@HighDesertOralSurgery.com](mailto:dr.harris@HighDesertOralSurgery.com)]

**Sent:** Friday, July 22, 2016 10:14 AM

**To:** Wallace, Sarah@DCA

**Subject:** Pediatric Anesthesia Study and Arizona

Hello,

My name is Brown "Skip" Harris. I am a private practice Oral and Maxillofacial Surgeon in AZ.

I am also an official consultant to the Dental Board and an unofficial subject matter expert and tracker of anesthesia related adverse events and fatalities in the state of Arizona.

I would very much like to offer the data I have collected to your panel creating this study and as you might imagine, I have some things I would like to discuss with your panel.

Would it be possible for you to give them my email address so that I could correspond with the authors and aid them in adding data they don't appear to have. I would also be willing to contact them directly if they are willing and you would provide me with their contact information.

Of course this is all unofficial and I am not speaking on behalf the Arizona Board or any of it staff.

I just want to be helpful and I am interested.

Thank you

Skip Harris, DDS, OMFS  
[dr.harris@highdesertoralsurgery.com](mailto:dr.harris@highdesertoralsurgery.com)  
[480-575-0844](tel:480-575-0844)(o)  
[602-509-5356](tel:602-509-5356)(c)

**Fischer, Karen@DCA**

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**From:** Annie Kaplan <anna987@gmail.com>  
**Sent:** Wednesday, June 15, 2016 12:05 PM  
**To:** Fischer, Karen@DCA  
**Cc:** Kolakosky, Bridget  
**Subject:** Fwd: propofol safety  
**Attachments:** Response to Citizen Petition.pdf

Dear Ms. Fischer,

I'd like to formally submit this email from the FDA to the Dental Board's subcommittee for use in their evaluation. Their explanation/ summary in the body of the email, as well as the attached letter with references is very pertinent to their investigation. Can you make sure they get it?

Thank you so much,

Annie

----- Forwarded message -----

**From:** CDER DRUG INFO <DRUGINFO@fda.hhs.gov>  
**Date:** Tue, Jun 14, 2016 at 1:52 PM  
**Subject:** RE: propofol safety  
**To:** Annie Kaplan <anna987@gmail.com>

Dear Dr. Annie Kaplan,

Thank you for your inquiry. Please accept our deepest condolences on the loss of your nephew Caleb. FDA has no comment on California bill AB2235. Regarding the need for a separate anesthesia provider to monitor propofol administration, however, we evaluated this issue in connection with a 2005 citizen petition from the American College of Gastroenterology. The petition asked FDA to remove the warning from the labeling of Diprivan (propofol) stating that “[F]or general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.” We denied this petition in 2010, explaining as follows:

In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary. This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure. [...]

Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur. Others not so trained, or whose attention is

divided between administering propofol and conducting other tasks associated with the procedure, may not be.

A copy of our response to the 2005 petition is attached.

Best Regards,

HT | Pharmacist  
Drug Information Specialist

Division of Drug Information | Center for Drug Evaluation and Research  
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter at [http://twitter.com/fda\\_drug\\_info](http://twitter.com/fda_drug_info)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 11 2010

Richard M. Cooper, Esq.  
Williams & Connolly LLP  
725 Twelfth Street, N.W.  
Washington, D.C. 20005

*Rec'd 8/11/2010*

Re: Docket No. FDA-2005-P-0059

Dear Mr. Cooper:

This responds to your citizen petition dated June 27, 2005 (Petition), submitted on behalf of the American College of Gastroenterology.<sup>1</sup> You ask the Food and Drug Administration (FDA or Agency) to remove the following warning from the labeling for Diprivan (propofol) (Petition at 1-2).<sup>2</sup>

For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.

After carefully considering your request, we deny it for the reasons given below. This decision is based on a review of the Petition including the scientific and medical literature accompanying the Petition, the comments submitted on the petition,<sup>3</sup> and the experience and judgment of the Agency.

<sup>1</sup> This citizen petition was originally assigned docket number 2005P-0267/CP1. The number was changed to FDA-2005-P-0059 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

<sup>2</sup> The labeling for a generic drug product approved under an abbreviated new drug application (ANDA) is required to be the same as the labeling for the reference listed drug, with certain permissible differences not relevant here. See 21 U.S.C. 355(j)(2)(A)(v), 21 CFR 314.94(a)(8)(iv); see also 21 CFR 314.127(a)(7). Therefore, removal of the warning quoted above from the labeling for Diprivan would require removal of the warning from the labeling for all generic versions of the drug approved under an ANDA as well.

<sup>3</sup> More than 300 comments were submitted on this Petition. A majority of the comments came from members of the anesthesiology community asking that we maintain the warning as it is currently written. However, we received a few comments from gastroenterologists, anesthesiologists, and other health care practitioners who believe that the warning should be removed.

FDA-2005-P-0059

PDN

## I. BACKGROUND

### A. Diprivan

FDA approved a new drug application (NDA) for Diprivan (propofol) injectable emulsion submitted by Zeneca Inc., now AstraZeneca Pharmaceuticals LP (AstraZeneca), on October 2, 1989.<sup>4</sup> Diprivan is a sterile, nonpyrogenic emulsion containing 10 milligrams (mg)/milliliter (mL) of propofol suitable for intravenous administration.

Diprivan is a sedative-hypnotic agent for use in the induction and maintenance of anesthesia or sedation. Intravenous injection of a therapeutic dose of propofol induces hypnosis, with minimal excitation, usually within 40 seconds from the start of injection. Diprivan is indicated for use in initiation and maintenance of monitored anesthesia care sedation, combined sedation and regional anesthesia, induction and maintenance of general anesthesia, and intensive care unit sedation of intubated, mechanically ventilated patients.<sup>5</sup> Diprivan is often used to sedate patients undergoing endoscopic procedures, such as colonoscopy and esophagogastroduodenoscopy procedures.

FDA has also approved a number of ANDAs for generic versions of Diprivan. The labeling for both Diprivan and the generic propofol products includes the warning at issue in the Petition (see footnote 2).

### B. Levels of Sedation and Anesthesia

The Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Comprehensive Accreditation Manual for Ambulatory Care defines the four levels of sedation and anesthesia as follows:

- *Minimal sedation (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.
- *Moderate sedation/analgesia (conscious sedation)*—A drug-induced depression of consciousness during which patients respond purposefully to

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<sup>4</sup> APP Pharmaceuticals, LLC is the current holder of the approved NDA (19-627) for Diprivan.

<sup>5</sup> Diprivan is indicated for use in adults only, except for the induction of general anesthesia (indicated for use in patients three years of age and older only) and maintenance of general anesthesia (indicated for use in patients two months of age and older only).

verbal commands,<sup>6</sup> 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.

- *Deep sedation/analgesia*—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 impaired.
- *Anesthesia*—Consists of general anesthesia and spinal or major regional anesthesia. It does *not* include local anesthesia. General anesthesia is a drug-induced 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.

Based on these definitions, patients undergoing endoscopic procedures, particularly colonoscopies, generally require light to moderate sedation, although deep sedation may be required during certain stages of these procedures. It is possible that doses of sedative medications required to induce or maintain a state of deep sedation could inadvertently result in the induction of general anesthesia. Also, studies submitted with your Petition show that the dosing range of propofol required to achieve and maintain sedation during endoscopic procedures overlaps with the range required to achieve and maintain general anesthesia.

### **C. Relevant Regulations on Warnings and Precautions in Prescription Drug Product Labeling**

FDA regulations state that the WARNINGS AND PRECAUTIONS section of prescription drug product labeling must describe clinically significant adverse reactions, other potential safety hazards, limitations in use imposed by them, and steps that should be taken if these situations occur (21 CFR 201.57(c)(6)(i); 21 CFR 201.80(e)). This section must also contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (21 CFR 201.57(c)(6)(ii); 21 CFR 201.80(f)(1)).

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<sup>6</sup> A reflex withdrawal from a painful stimulus is not considered a purposeful response.

## II. DISCUSSION

You request that FDA remove the warning from the propofol labeling stating that propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.<sup>7</sup> You state that propofol has several advantages over alternative sedation agents for endoscopic procedures but has a similar "risk profile" (Petition at 2). You claim the warning is no longer warranted because studies have established that propofol can be administered safely and effectively by medical professionals other than anesthesiologists and nurse anesthetists (Petition at 3-8). You believe that the requested labeling change will promote efficiency and reduce costs to payors by eliminating the need for an anesthesiologist or nurse anesthetist to be present to administer propofol during an endoscopic procedure (Petition at 1). You also suggest that the current warning places an unwarranted restriction on the ability of gastroenterologists to practice medicine (Petition at 1).

After considering your claims and the literature you provided for our review, we conclude that you have not shown that the warning is no longer warranted or appropriate. In fact, we conclude that the warning is warranted and appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. Accordingly, we will not seek to have the warning removed, reduced, or otherwise amended.

### A. The Warning Is Warranted and Appropriate in Light of the Risks Associated with the Use of Propofol as a Sedation Agent for Endoscopic Procedures

You state that while propofol has several advantages over alternative sedation agents for endoscopic procedures, "the risk profile of propofol appears to be no worse than" these alternative agents. (Petition at 3). We disagree. As explained below, we believe the risks associated with propofol are significantly different from — and, in some critical respects, greater than — the risks associated with the alternative sedation agents you

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<sup>7</sup> The warning at issue has two components: that propofol should be administered only by persons trained in the administration of general anesthesia and that the person administering propofol should not be otherwise engaged in the conduct of the procedure. While you request that the entire warning be removed (Petition at 2, *passim*), your petition only addresses the first component of the warning. Specifically, while you contend that "[a] number of controlled and uncontrolled clinical studies have established that propofol can be administered safely and effectively by medical professionals other than anesthesiologists or nurse anesthetists" (Petition at 2), you do not appear to contend that any studies support the position that propofol could be administered safely and effectively by medical professionals — whatever their training — whose attention is divided between administering propofol and conducting the procedure itself. Nevertheless, we discuss both components of the warning in this response.

mention. We further conclude that the warning you seek to have removed is warranted and appropriate in light of the unique risks posed by propofol.

You claim that propofol is superior to alternative agents such as Versed (midazolam) and Demerol (meperidine) because it induces sedation more rapidly than a midazolam-meperidine or midazolam-fentanyl combination, results in faster recovery times than midazolam with meperidine or midazolam with fentanyl, and is associated with better post-procedure functioning than alternative sedation drugs (Petition at 2).<sup>8</sup> We agree that because of the quick onset and offset of sedation associated with propofol, along with a clear sensorium following its use, practitioners might choose propofol over the routinely used alternative sedation agents for short endoscopic procedures. The issue, however, is not propofol's therapeutic advantages over alternative agents, but the safety of propofol as a sedation agent relative to the administrator's level of training in the administration of general anesthesia and relative to whether the administrator is taking part in the procedure apart from administering propofol.

You acknowledge that propofol has risks that make it unique and uniquely demanding to administer among agents used for procedural sedation (Petition at 2).<sup>9</sup> We agree. Propofol has a narrow therapeutic window, that is, a narrow dosage range that produces the desired effect while staying within the safety range. The additional dosing required to deepen sedation from one level to the next is small. This means that propofol poses a significant risk that a level of sedation greater (or lesser) than that intended may be induced.

Over-sedation with propofol poses especially serious risks. Propofol is a cardiovascular depressant that causes a drop in blood pressure as well as a respiratory depressant that can cause partial airway obstruction. In particular, the possibility of apnea with arterial oxygen desaturation and hemodynamic changes, most notably hypotension, increases

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<sup>8</sup> We note that propofol and the alternative sedation agents you mention are in different drug classes. Fentanyl and meperidine are narcotics and not indicated for sedation. Their analgesic properties and sedative side effects allow for a significant reduction in the amount of other medications required to produce a desired level of sedation. The side effects of narcotics, particularly their respiratory depressive effects, may be enhanced when they are co-administered with benzodiazepines, like midazolam, or sedative-hypnotics, such as propofol.

Midazolam is a short-acting benzodiazepine that is indicated for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic, or endoscopic procedures, such as bronchoscopy, gastroscopy, and cystoscopy, among others. Midazolam, which was approved after meperidine and fentanyl, contains both a boxed warning and a partially bold warning providing detailed information on the risks involved with its use, the equipment and drugs that should be readily available when it is used, and the types of monitoring that should be used.

<sup>9</sup> While the risks associated with propofol use are dose dependent, the risks pertain to patients receiving propofol for sedation as well as for general anesthesia. As the studies you submit in support of your Petition show, the propofol dose ranging used to sedate patients for endoscopic procedures, particularly colonoscopies, overlaps with propofol dose ranging used to achieve and maintain general anesthesia.

with deepening levels of sedation. These side effects tend to occur suddenly and can be of life-threatening magnitude if appropriate intervention is not instituted immediately. Furthermore, as you acknowledge, there is no reversal agent for propofol (Petition at 2), whereas there are reversal agents for the other routinely used sedation agents. A propofol dose which exceeds that needed to maintain moderate-to-deep sedation may require treatment including assisted ventilation and hemodynamic support until the patient's own spontaneous ventilation resumes.

For endoscopic procedures, particularly colonoscopies, a light-to-moderate level of sedation is needed for less stimulating parts of the procedure. However, the anesthetic requirements often increase substantially during the more painful portions of the procedure (for example, when negotiating the colonoscope through the splenic and hepatic flexures). Hence, a state of deep sedation is likely to be induced during the more painful parts of the procedure to manage pain and minimize patient movement and the concomitant risk of bowel perforation. Dosing of propofol to achieve such states of sedation has been associated with unintended induction of general anesthesia and the attendant respiratory and hemodynamic risks just described.

Under-sedation also poses risks. For example, as just noted, the risk of unnecessary patient pain or even bowel perforation during a colonoscopy may increase if an insufficient amount of propofol is administered. An inexperienced or insufficiently trained medical professional not confident in his or her ability to intervene in response to over-sedation may err on the side of administering an insufficient dose of propofol, increasing the risk of adverse events associated with under-sedation.

Furthermore, many patients presenting for endoscopic procedures are older, frequently have multiple co-morbidities, and are generally on multiple medications. Each of these factors increases the risks associated with using propofol as a sedation agent, particularly the risks of oxygen desaturation and wide swings in blood pressure.

In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary.<sup>10</sup> This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure.

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<sup>10</sup> This is especially true for endoscopic procedures, where the level of stimulation varies greatly and frequently.

Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur.<sup>11</sup> Others not so trained, or whose attention is divided between administering propofol and conducting other tasks associated with the procedure, may not be.

We note that the warning is consistent with the findings and policies of JCAHO, the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, Inc., and the American Society of Anesthesiologists. According to the JCAHO's revised standard, *Moderate and Deep Sedation and Anesthesia Standards*, individuals administering moderate or deep sedation and anesthesia must be qualified and have the appropriate credentials to manage patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. Those practitioners must be qualified to rescue patients from general anesthesia and be competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation. A sufficient number of qualified personnel (in addition to the licensed independent practitioner performing the procedure) must also be present during the procedure to provide moderate or deep sedation.

Accordingly, we disagree with your assertion that the risk profile of propofol when used in endoscopic procedures appears to be comparable to that of alternative sedation agents. More importantly, we believe both components of the warning you seek to have removed are, in fact, appropriate and well warranted in light of the risks posed by the use of propofol — which you seem to acknowledge are both significant and materially different from those posed by the routinely used alternative sedation agents (Petition at 2). Thus, we believe that the warning should help ensure that propofol is used safely.

**B. The Studies Submitted Fail to Show that the Warning is Unwarranted**

You submitted 31 publications with your Petition. You assert that studies reported in these publications show that gastroenterologists and nurses supervised by them can safely and effectively administer propofol to patients for endoscopic procedures even without training in the administration of general anesthesia (Petition at 3). As previously noted (see footnote 7), your contentions concerning these studies appear to be limited to the first component of the warning (training in general anesthesia), but you seek to have the second component of the warning (involvement in the conduct of the procedure) removed as well. We address both components below.

Among the publications you submitted were 13 papers reporting on studies involving propofol administration by non-anesthesia trained personnel, 10 abstracts, a review

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<sup>11</sup> The warning does not specify what constitutes sufficient training.

article, 4 opinion papers, a historical review, a case report, and a paper discussing cardiovascular complications occurring in the gastrointestinal clinic setting. While the Agency respectfully considers the opinions proffered by experts, it places greater weight on the findings of studies that are prospective, randomized, and controlled by design, adequately powered to discern outcome differences between study arms for the primary endpoint(s), and appropriately executed according to the protocol. Because the opinion papers indicate there are proponents on both sides of this issue, and the historical perspective and review articles provide no substantial data for consideration, we only evaluated the abstracts, study reports, and safety information from the case report and cardiovascular complications report.

We have reached the following conclusions based on our analysis of the articles you submitted in connection with your Petition:

- There is a significant risk of adverse events due to over-sedation when using propofol for procedural sedation, including oxygen desaturation, hypoxemia, hypotension, and bradycardia. These events can result in serious injury or death if appropriate intervention is not instituted immediately.
- Vulnerable populations, like the elderly, who often require endoscopic procedures for diagnostic and therapeutic purposes, are especially at risk of adverse events associated with propofol sedation.
- The only study comparing the safety of administration of propofol by anesthesiologists with administration of propofol by a GI (gastrointestinal) provider (i.e., a gastroenterologist or a nurse supervised by a gastroenterologist) suggests that the risk of cardiopulmonary complications is significantly reduced when propofol is administered by anesthesiologists.<sup>12</sup>
- In several studies assessing the relative safety of propofol versus other sedation agents administered by a GI provider, the frequency and extent of adverse events were quite significant for *both* sedation methods.<sup>13</sup>
- In several studies assessing the safety of administration of propofol by a GI provider with no comparator arm (i.e., no alternative sedation agent), the frequency and extent of adverse events were quite significant.<sup>14</sup>

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<sup>12</sup> Vargo JJ et al. Cardiopulmonary complications with non-anesthesiologist-administered propofol vs. standard sedation: the CORI experience. *Gastrointest. Endosc.* 2004;59:AB132.

<sup>13</sup> Vargo JJ et al. Gastroenterologist-administered propofol versus meperidine and midazolam for advanced upper endoscopy: a prospective, randomized trial. *Gastroenterology* 2002;123(1):8-16. Koshy G et al. Propofol versus midazolam and meperidine for conscious sedation in GI endoscopy. *Am. J. Gastroenterol.* 2000;95:1476-79. Carlsson U, Grattidge P. Sedation for upper gastrointestinal endoscopy: a comparative study of propofol and midazolam. *Endoscopy* 1995;27:240-43.

<sup>14</sup> Cohen LB et al. Moderate level sedation during endoscopy: a prospective study using low-dose propofol, meperidine/fentanyl, and midazolam. *Gastrointest. Endosc.* 2004;59:795-803. Cohen LB et al. Propofol for endoscopic sedation: a protocol for safe and effective administration by the gastroenterologist. *Gastrointest. Endosc.* 2003;58:725-32. Walker JA et al. Nurse-administered propofol sedation without anesthesia

- In several studies assessing the safety of administration of propofol by non-anesthesiologists, the GI providers received training — sometimes several months of training — from anesthesiologists.<sup>15</sup> This included elements of training associated with the administration of general anesthesia (e.g., airway management techniques, advanced respiratory monitoring). Furthermore, several authors emphasized the need for adequate training before GI providers could administer propofol safely and effectively.<sup>16</sup>
- Several authors concluded that administration of propofol by GI providers was sufficiently safe despite the occurrence of significant sedation-related adverse events and despite the lack of any comparator arm in the studies on which they based their conclusions.<sup>17</sup>

Having carefully reviewed the studies you submitted, we first conclude that there are no data from prospective, randomized, adequately-powered,<sup>18</sup> well-controlled clinical trials that demonstrate that gastroenterologists or nurses supervised by them who are not trained in the administration of general anesthesia can administer propofol safely and effectively. Furthermore, we conclude that the studies you submitted do not support your contention that the first component of the warning is unwarranted or inappropriate. In fact, we believe the studies, taken as a whole, support the opposite conclusion. Specifically, the studies tend to show that the risks posed by the use of propofol to sedate patients for endoscopic procedures are significant, and that substantial training, experience, and professional judgment are necessary to sufficiently mitigate those risks. Accordingly, we consider the first component of the warning wholly appropriate and warranted.

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specialists in 9152 endoscopic cases in an ambulatory surgery center. *Am J. Gastroenterol.* 2003;98: 1744-50.

<sup>15</sup> Yusoff IF et al. Endoscopist administered propofol for upper-GI EUS is safe and effective: a prospective study in 500 patients. *Gastrointest. Endosc.* 2004;60:356-60. Walker JA et al. 2003 (see supra footnote 14). Heuss LT et al. Conscious sedation with propofol in elderly patients: a prospective evaluation. *Aliment. Pharmacol. Ther.* 2003;17:1493-1501. Heuss et al. Risk stratification and safe administration of propofol by registered nurses supervised by the gastroenterologist: a prospective observational study of more than 2000 cases. *Gastrointest. Endosc.* 2003;57:664-71. Heuss LT et al. Safety of propofol for conscious sedation during endoscopic procedures in high-risk patients: a prospective, controlled study. *Am. J. Gastroenterol.* 2003;98:1751-57.

<sup>16</sup> Yusoff IF et al. 2004 (see supra footnote 15). Kulling et al. Anesthetist sedation with propofol for outpatient colonoscopy and esophagogastroduodenoscopy. *Endoscopy* 2003;35:679-682.

<sup>17</sup> Walker JA et al 2003 (see supra footnote 14). Heuss LT et al. Risk stratification and safe administration of propofol by registered nurses supervised by the gastroenterologist: a prospective observational study of more than 2000 cases. *Gastrointest. Endosc.* 2003b;57:664-71. Rex DK et al. Safety of propofol administered by registered nurses with gastroenterologist supervision in 2000 endoscopic cases. *Am. J. Gastroenterol.* 2002;97:1159-63.

<sup>18</sup> We note that, as there are low rates of morbidity and mortality associated with sedation, adequately powering a study purporting to show that GI providers can safely and effectively administer propofol for endoscopic procedures is likely to require enrollment of large numbers of patients.

Furthermore, we believe your specific contention that GI providers administering propofol for sedation for endoscopic procedures poses no greater risks than GI providers administering benzodiazepine (together with a narcotic) is not sufficiently supported by the literature you submitted. Shortcomings in the relevant studies include differing findings for the cardiovascular versus respiratory outcomes, evaluation of oxygen saturation but not the hemodynamic changes during sedation, and reporting of findings in a manner that precluded further analysis or interpretation of the data. Also, as noted above, we are concerned with the frequency and extent of adverse events reported for *both* treatment arms in several of those comparison studies.

Accordingly, the contention that the incidence of adverse events was similar gives us no comfort.<sup>19</sup> Finally, we are skeptical that the studies in question — even if the flaws just discussed were not present — could reliably predict real-world outcomes. GI providers participating in the studies you submitted may well have greater levels of training, experience, or proficiency administering propofol than the average GI provider.

We also conclude that none of the studies you have presented support your position that the second component of the warning is unwarranted and should be removed. As discussed in the previous section, we believe the warning's admonition that the person administering propofol should not be otherwise involved in the conduct of the procedure is appropriate and warranted because adverse events associated with propofol can occur suddenly and must be addressed immediately.

Accordingly, we do not find the studies you submitted persuasive, and we continue to believe, for the reasons expressed here and in the previous section, that the warning that propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure is appropriate and warranted in light of the risks associated with the administration of the drug.

### **C. Increased Procedural Costs Do Not Support Removal of the Warning**

You assert that, in accordance with the warning you seek to have removed, as many as 12 states and many hospitals require that propofol be administered only by anesthesiologists or nurse anesthetists (Petition at 2). This increases the costs of using propofol for

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<sup>19</sup> We further note that it appears that the amount of the alternative sedation agent administered in several of these studies was higher than may be indicated on the relevant drug labeling for the procedures studied. Vargo JJ et al 2002 (see supra footnote 13); Ulmer BJ, et al. Propofol versus midazolam/fentanyl for outpatient colonoscopy: administration by nurses supervised by endoscopists. Clin. Gastroenterol. Hepatol. 2003;1:425-32. To the extent the risks associated with these alternative agents are dose dependent, higher-than-normal dosing would tend to increase the incidence of complications associated with the alternative sedation agent, making propofol look safer by comparison.

endoscopic procedures because an anesthesiologist or nurse anesthetist must be present to administer propofol during an endoscopy, resulting in higher costs than if the drug were administered by the gastroenterologist or nurse working under his or her direction. (Petition at 2-3).

We first note that the warning does not state that only anesthesiologists or registered nurse anesthetists may administer propofol – it simply warns that only those “trained in the administration of general anesthesia” should administer the drug.

Hospitals and state credentialing authorities set their own rules and policies regarding the administration of drugs; FDA is not involved in that process.<sup>20</sup>

You represent that the services of an anesthesiologist add about \$100 to \$400 to the cost of an endoscopic procedure (Petition at 3).<sup>21</sup> But as discussed in Part II, the risks associated with propofol are significant and may result in serious injury or death. Accordingly, we continue to think the warning at issue is warranted and appropriate in light of the significant risks posed by propofol, despite any increased costs that may be associated with this warning.

**D. The Warning Does Not Unduly Restrict the Practice of Gastroenterologists**

You state that the requested labeling change would eliminate an unwarranted restriction on the practice of gastroenterologists (Petition at 1, 8). We disagree.

We first note that the warning simply provides guidance as to the nature of the clinical skills that allow for the safe use of propofol, and neither prohibits the use of propofol by any group of health care providers nor limits its use to a particular medical specialty.

Next, to the extent that some hospitals and state credentialing authorities have determined that only anesthesiologists or registered nurse anesthetists may administer propofol, we note again that these institutions set their own rules regarding the administration of drugs, and, in the case of propofol, they may have done so for reasons other than (or in addition to) the warning on the approved labeling (see footnote 20).

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<sup>20</sup> As previously noted (see section II.A), the warning is consistent with the findings and policies of JCAHO, the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, Inc., and the American Society of Anesthesiologists. Hospitals and states that restrict those who may administer propofol may be influenced by these institutions' positions quite apart from (or in addition to) the warning in the approved labeling. For that matter, they may simply be following their own judgments about the risks attending propofol use.

<sup>21</sup> You make no representations concerning the costs associated with using a registered nurse anesthetist to administer propofol for an endoscopic procedure.

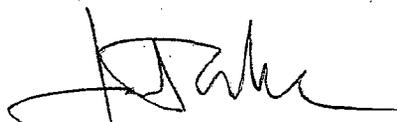
Finally, regardless of whether the warning can be said to restrict the practice of gastroenterologists, we continue to believe it is appropriate and warranted in light of the significant risks associated with propofol.

### III. CONCLUSION

For the reasons described, we conclude that you have not demonstrated that the warning is inappropriate or unwarranted. In fact, we conclude that both components of the warning are appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. We therefore will not seek to have the warning removed, reduced, or otherwise amended.

For the reasons stated above, your Petition is denied.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet Woodcock", with a large, sweeping flourish extending to the right.

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research

## **Fischer, Karen@DCA**

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**From:** Annie Kaplan <anna987@gmail.com>  
**Sent:** Monday, July 18, 2016 1:46 PM  
**To:** Fischer, Karen@DCA  
**Cc:** Kolakosky, Bridget  
**Subject:** Re: propofol safety  
**Attachments:** Caleb'sLawWhitePaper2016.pdf

Hi Ms. Fischer,

In addition to the FDA information, I would love to formally submit the research and references we have put together regarding AB2235 for use by the Sub-committee to evaluate dental anesthesia safety. Can you make sure they get this information?

Thank you!

Annie Kaplan, MD

On Wed, Jun 15, 2016 at 12:04 PM, Annie Kaplan <anna987@gmail.com> wrote:  
Dear Ms. Fischer,

I'd like to formally submit this email from the FDA to the Dental Board's subcommittee for use in their evaluation. Their explanation/ summary in the body of the email, as well as the attached letter with references is very pertinent to their investigation. Can you make sure they get it?

Thank you so much,

Annie

----- Forwarded message -----

**From:** CDER DRUG INFO <DRUGINFO@fda.hhs.gov>  
**Date:** Tue, Jun 14, 2016 at 1:52 PM  
**Subject:** RE: propofol safety  
**To:** Annie Kaplan <anna987@gmail.com>

Dear Dr. Annie Kaplan,

Thank you for your inquiry. Please accept our deepest condolences on the loss of your nephew Caleb. FDA has no comment on California bill AB2235. Regarding the need for a separate anesthesia provider to monitor propofol administration, however, we evaluated this issue in connection with a 2005 citizen petition from the American College of Gastroenterology. The petition asked FDA to remove the warning from the labeling of Diprivan (propofol) stating that "[F]or general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." We denied this petition in 2010, explaining as follows:

In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for

the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary. This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure. [...]

Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur. Others not so trained, or whose attention is divided between administering propofol and conducting other tasks associated with the procedure, may not be.

A copy of our response to the 2005 petition is attached.

Best Regards,

HT | Pharmacist  
Drug Information Specialist

Division of Drug Information | Center for Drug Evaluation and Research  
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter at [http://twitter.com/fda\\_drug\\_info](http://twitter.com/fda_drug_info)

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Annie Kaplan  
[anna987@gmail.com](mailto:anna987@gmail.com)  
(510) 846-7847

## CALEB'S LAW - WHITE PAPER A.B. 2235

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*A.B.2235 seeks to increase the safety of administering general anesthesia to children during dental procedures.*

### SUMMARY

Following the death last year of Caleb Sears, a healthy six year-old child, a team of family and friends made up of medical, legal and policy professionals were motivated to find out why it happened and could it have been prevented. The findings were alarming. The most disconcerting discovery was that some oral surgeons are the only healthcare professionals who operate and administer anesthesia on children simultaneously, without a separate anesthesia provider,<sup>12</sup> and many do not use modern monitoring technologies. Additionally, data collection regarding adverse events during dental anesthesia has been unscientific, unreliable, and inaccessible.<sup>3 4 5 6</sup> A.B. 2235, authored by Assemblymember Tony Thurmond (D15), seeks to address these issues and close any gaps in dental anesthesia safety measures.

### BACKGROUND

The question sometimes arises, 'Why now?' The short answer is that the proposed legislation is long overdue. Guidelines and warnings have been in place for decades advising against the operator-anesthetist model outlined above, as there are high risks associated with general anesthesia and deep sedation that can lead to death or injury.<sup>7 8 9 10</sup>

The model in which the surgical operator is different from the person administering and monitoring anesthesia is supported by the American Society of Anesthesiologists (ASA) and the American Association of Nurse Anesthetists (AANA). The American Academy of Pediatric Dentists (AAPD) also supports having a separate anesthesia provider/monitor in addition to the operating dentist and support staff trained in emergency procedures.<sup>11</sup> To be clear, many dentists and oral surgeons choose to adhere to the model put forth by the ASA but in all the cases where they are not, there are additional risks to undergoing dental anesthesia, particularly for children.

In fact, in 2005, gastroenterologists unsuccessfully petitioned the FDA to remove the warning language from the Propofol label, the most commonly used drug for anesthesia/deep sedation.<sup>12</sup> The warning states that it "should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." The FDA argued that the safety of the drug is only relative to the administrator's level of training in general anesthesia administration and if someone else is conducting the procedure. As there is a narrow window to achieve the desired effect of the anesthetic within a safe range, the FDA clarified that along with experience, training and judgment, *undivided focus* is critical in safely maintaining sedation.

Undivided focus is vital in a surgical setting and neuroscience studies show that performing more than one task at the same time drastically interferes with the other task, no matter how simple they may be.<sup>13</sup> A complement to focus, vigilance is also an essential component of performing efficiently in medical settings (i.e., monitoring anesthesia levels and an EKG during surgical procedures).<sup>14</sup> A high level task, such as a dental procedure, requires a high level of mental effort, which in turn leads to high stress and a faster decline in vigilance, no matter someone's training or experience.<sup>15</sup>

Training in general anesthesia administration varies greatly across professional specialties.<sup>16</sup> Lower levels of training combined with the dual role of anesthesia administration and surgical practitioner lead to an increased likelihood of adverse events given the small window to recognize danger and respond.

- o Anesthesiologist: 4 years anesthesia residency, 2 months pediatrics<sup>17</sup>
- o Pediatric Anesthesiologist: 4 years anesthesia residency, 1 year pediatrics<sup>18 19</sup>
- o CRNA: 2-3 years of anesthesia training<sup>20</sup>
- o Dentist Anesthesiologist: 3 years anesthesia residency<sup>21</sup>

- o Oral Surgeons: 5 months, 1 month pediatrics<sup>22</sup>
- o Pediatric dentists: 2 months of training<sup>23</sup>
- o Veterinarian: 3 years anesthesia residency<sup>24</sup>

Studies show that there are a disproportionate number of recent deaths stemming from anesthesia or sedation given by a dentist, which is echoed by multiple media reports.<sup>25 26 27 28 29 30</sup> There is also a rise in office-based anesthesia administration in the dental field, despite a lack of reliable data collected in a scientific manner that indicates that this is a safe model of operation.<sup>31</sup> There were 55 deaths in California (2008-2011),<sup>32</sup> including at least 20 deaths of children reported by the media since 2005. In contrast, there have been very low numbers and, a large multi-center study of outpatient medical anesthesia care had 0 deaths in the parallel setting with a separate anesthesia provider.<sup>33</sup>

Adverse events during anesthesia are more common in children and seniors. Serious sedation risks of pediatric patients include hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment,<sup>34</sup> which can lead to long-term injury and death. Given the higher doses of medication that are often required to sedate children,<sup>35</sup> it is not uncommon for children to reach a higher level of sedation than is intended, which can lead to the aforementioned risks.<sup>36 37</sup>

Despite sufficient data showing a higher level of risk by having the same person administer general anesthesia/deep sedation and perform the surgical procedure, to date, evidence-based data regarding safety in the administration of anesthesia while performing dental operations is lacking.<sup>38 39 40 41</sup>

Upon review of the references used in the 2013 American Association of Oral and Maxillofacial Surgeons' white paper (AAOMS) about office-based anesthesia provided by oral surgeons, they were determined to be out of date, even 'historical' (i.e., 1947), and used a skewed volunteer survey model. The major study referenced was never actually published by the insurance company, OMSNIC (which is part of AAOMS)<sup>42</sup>, and the company has refused to issue the report externally.<sup>43</sup>

Hard data is also unavailable from the CA Dental Board. For example, in 2011 the President of American Society of Dentist Anesthesiologists (ASDA) formally requested hard data from the CA Dental Board multiple times so that he could perform a scientific study to evaluate what he saw as an alarming number of patient deaths. His requests were denied and he was never provided any data.<sup>44</sup> Recent requests for data from the Dental Board have also indicated that there is a lack of consistent, available data.<sup>45</sup>

## SOLUTIONS

A.B.2235 outlines the first steps toward increasing the safety of administering and monitoring general anesthesia, and deep sedation to children during dental procedures. Notably, it encourages dentists to contribute sedation data to a national pediatric sedation database. There is already the Pediatric Sedation Research Consortium Database that logs data from each sedation encounter that could be set up to incorporate California dental sedation data for almost no cost since it is already set up and running and used by the outpatient medical community for the past 16 years.

Another extremely important part of the bill increases the data found within adverse event reports and sets up an enforceable time frame for dentists to report to the board after an adverse event happens. These adverse event reports are both the starting points of investigations and are the only transparent part of the investigatory file available for outside study. The bill also lays forth language to be included in the consent to be given to parents regarding the existence of these different anesthesia practices. The bill requires dental sedation providers to give parents more information with regard to the existence of differences in anesthesia practices within different settings and providers. Finally, the law will also require that the California Dental Board establish a committee to study the safety of pediatric anesthesia in dental offices and whether additional safety measures would reduce the potential for injury or death in minors. This committee will act in addition to the important primary steps that the law is immediately taking to improve both data collection and distribution of information to parents of minors undergoing dental anesthesia.

The proposed collection, study, and dissemination of epidemiological data on adverse dental anesthesia events is critical to ensure that there are no gaps in the safety measures.

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**Fischer, Karen@DCA**

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**From:** Jenn [REDACTED]  
**Sent:** Tuesday, October 25, 2016 11:57 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental anesthesia

Hello Karen,

I'm a registered nurse and I believe that any dental procedure that requires anesthesia should have an anesthesiologist present. The dentist performing the procedure shouldn't have to monitor the patient for anesthesia as well. No where else do we practice like this and now should be the time for change. Thanks for hearing us out.

Best,  
Jennifer Alahwal

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Monday, October 24, 2016 8:27 PM  
**To:** Fischer, Karen@DCA  
**Subject:** TOO MUCH ANESTHESIA DURING MOLAR EXTRACTIONS

Dear Ms. Fischer:

**I do not want my name posted on any social media, public reading board, or website at all. I would like to remain anonymous. THANK YOU**

When I was 25 years old and just out of college, I had 4 molars that were not impacted (and completely all the way out with plenty of room) and I am sure my dentist at the time (1985 or 1986) let at least one of them decay to the point of complete blackness, because he wanted me to have them all removed. I went to the dentist every 6 months for cleanings and do not think the tooth would have decayed that much had he taken care, or even let me know what was going on. My breath was so bad my boss at the time even asked me if I had a dental issue. I was shocked when the dentist very nonchalantly handed me a mirror and I gasped as I saw that the tooth was completely pitch black. That was Dr. Zarganis in South San Francisco, California. I'm sure he must be retired by now. I had plenty of room but he wanted them out because they were hard to work on and talked me into having all 4 out. He never pointed it out before and it was so far back that I could not see it when I brushed my teeth and looked in the mirror. However, he had mentioned

a couple of times that I should have the molars removed - that was it.

Dr. Zarganis suggested I go to a nearby oral surgeon named Dr. Roberts. I went there and they told me on the day of surgery that they were going to give me laughing gas and anesthesia. I was surprised and asked why I was getting both. They said it was normal practice. All I remember was the mask going on and the next thing I knew someone was shaking me to try to wake me up. They said I had to get out of the chair and my dad was there to pick me up. I could not wake up. They said I had to wait in another room - I think I crawled to the other room and the next thing I knew, my dad was shaking me and said he needed to go back to work and I he had been waiting a very long time for me to wake up. I could not wake up, I don't remember how I made it to the car, but I know I barely made it into the house. That was a Friday morning. I slept the entire weekend and had to call in sick on Monday, because I still could not wake up. I was never the type of person that called in sick or overslept. I was telling my boss and her brother-in-law is a dentist. She talked to him about it and was told that I was over anesthetized. I had absolutely no pain, and I know they only took a short time to get the teeth out and all of that laughing gas and anesthesia was unnecessary. I was only about 125 lbs. and 5'5" tall. I called the dentist office as soon as I was able and complained about it but got no answers. I also told my regular dentist who

could really care less. I immediately switched dentists.

The biggest problem that I noticed immediately was that my short term memory was not the same. I could not remember things that I had no problem remembering prior to the surgery, and it has remained that way till this day. There are many things that I have absolutely no recollection of. I went all through college and majored in Business and had no problem at all with my memory, but it was quite obvious after the surgery. My boss was really surprised with the change and it was embarrassing. I could not trust myself after that and had to start making notes. I'm still really angry over what happened by a careless dentist office.

The surgeon tried to bill me for anesthesia and I refused to pay for it. I called them and told them I would not pay for it because they over medicated me unnecessarily. They did not say a word, but I did not have to pay for it. Of course, the insurance paid for most of it - there was an extra \$80 they claimed was my part.

I would also like to complain about dentist x-rays. I now have a disease called SJOGREN'S SYNDROME, which I absolutely did not have when I was 25. I had lots of saliva at that time. I got Sjogren's in my 40s. When I have x-rays where they are probably giving too much radiation, more salivary glands die. I believe it is the people and possibly the equipment. It

is devastating. I have very little saliva and only with the help of EVOXAC and PREDNISON. I know the prednisone is only a mask and when I go down on it I have no saliva at all. I cannot get food out of my teeth and have lost two teeth because I could not have all the x-rays required for a root canal. I don't know what to do and the Dentists could care less. They are only concerned with getting their x-rays. I don't have dental insurance anymore and pay for it myself so they cannot say it is for the insurance. I only mention this to you INCASE YOU KNOW OF SOMETHING THAT CAN BE DONE. I AM VERY SCARED.

Just to add, when my son had his molars out about 7 years ago, I was careful to discuss with the Surgeon that my son have as little medication as possible to have the teeth removed. He was in and out very quickly and was awake. Thank God!

So here are two complaints. Thanks for reading. **I do not want my name posted on any social media, public reading board, or website at all. I would like to remain anonymous. But if you have any suggestions about avoiding x-rays for dental work, I would greatly appreciate it. Thank You**

**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Tuesday, October 25, 2016 7:42 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Opinion

Good Evening,

I am a mother of a 4year old that will be required to be sedated under anesthesia for a upcoming dental surgery. As a mom I believed that we are being directed and informed that the dentist does have a anesthesiologist present. Unfortunately, I just found out that this is not so. I do hope that the Board of Dentistry do ban dentist from administrating the medication with out a licensed anesthesiologist.

I am now going to be questioning the dental surgery center if there will be a licensed anesthesiologist present to monitor my sons health as he goes under. Otherwise, I will be taking my son and finding a dental center that will have a licensed anesthesiologist present.

I am surprised that all this time, they aren't present.

Thank you for your time and consideration,

Naomi Belcher  
Mother of two beautiful toddlers and  
California Central Valley Resident.

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Tuesday, October 25, 2016 4:16 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Not one more healthy child should suffer a preventable death from anesthesia in a dental office. Please change the law to prevent dentists and oral surgeons from administering anesthesia to children whom they are simultaneously treating. There should be at least three people present in these situations and at least one of the dental staff should have special training in pediatric dentistry/anesthesiology.

John and Ann Bentley

**Fischer, Karen@DCA**

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**From:** John Berlet  
**Sent:** Monday, October 24, 2016 11:31 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Pediatric Anesthesia Update

Hello,

I am a father of a 5 year old and cannot understand how/why pediatric dentists can continue to administer anesthesia to children without the expertise of anesthesiologists in their dentist office.

Dentists are not skilled in the delicate art/science of anesthesia and there is insufficient oversight of this practice. I will not consent to ANY oral surgery without a licensed anesthesiologist present in my pediatric dentist's operating room. Please do not allow unnecessary harm to our children so dentists can save money and time by administering anesthesia themselves.

John Berlet

**Fischer, Karen@DCA**

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**From:** Debbie Blucher  
**Sent:** Friday, October 28, 2016 9:31 PM  
**To:** Fischer, Karen@DCA  
**Subject:** A call for safer dental procedures

Hello,

I'm writing to help keep kids safe during dental procedures. Please help prevent another California family from losing a loved one to unsafe dental practices. I want to see an end to the single operator anesthetist model for anesthesia. All California children should have the safety of a separate trained anesthesia provider.

Thank you for your time with this very important issue.

Debbie Blucher  
San Carlos, CA

**Fischer, Karen@DCA**

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**From:** Karen Brereton Modanlou  
**Sent:** Tuesday, October 25, 2016 7:14 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Re: Caleb's Law

Specifically, I would like to see an end to the single operator anesthetist model for anesthesia and see that all California children have the safety of a separate trained anesthesia provider.

> On Oct 25, 2016, at 4:45 PM, Fischer, Karen@DCA <[Karen.Fischer@dca.ca.gov](mailto:Karen.Fischer@dca.ca.gov)> wrote:

>

> Thank you for your email regarding the Board's study of Pediatric Anesthesia. The Board appreciates you taking the time to submit your opinion on this very important issue. Your comments will be considered by the Board and will become part of the public record that will be available on the Board's website, when the final report to the Legislature is submitted.

>

> Karen M. Fischer, MPA  
> Executive Officer  
> Dental Board of California

>

> Privilege and Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, or distribution is prohibited. The forgoing applies even if this notice is embedded in a message that is forwarded or attached. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

>

> -----Original Message-----

> From: Karen Brereton Modanlou [<mailto:karen.brereton@gmail.com>]  
> Sent: Tuesday, October 25, 2016 3:48 PM  
> To: Fischer, Karen@DCA  
> Subject: Caleb's Law

>

> Not one more healthy California child should suffer a potentially preventable death in a dental chair. This seems so obvious. Please help us! Support Caleb's Law!

>

**Fischer, Karen@DCA**

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**From:** Karen Brereton Modanlou  
**Sent:** Tuesday, October 25, 2016 3:48 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Not one more healthy California child should suffer a potentially preventable death in a dental chair. This seems so obvious. Please help us! Support Caleb's Law!

**Fischer, Karen@DCA**

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**From:** Binkey Brown  
**Sent:** Monday, October 24, 2016 11:41 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Sedation

Dear Ms. Fischer, It is not clear what types of dental sedation are being discussed in the extremely short NBC Bay Area news item of October 24, 2016. -- Are children dying from shots of novocaine or nitrous oxide? Details are lacking here.

If dentistry for children is a problem than please confine decisions made to dentistry for children. End of story.

Regardless, I sincerely hope that CA dentists administering nitrous oxide for anxious ridden ADULT patients are allowed to continue this form of dental "sedation." -- I feel quite strongly about this.

Please do NOT regulate the availability of nitrous oxide away from adult CA dental patients. -- I don't particularly wish to travel or move to a different state for dental procedures.

Thank you in advance for your consideration.

Sincerely,  
B. Brown

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Alex James Butwick  
**Sent:** Wednesday, October 26, 2016 4:00 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Public input re dental sedation and child deaths

As an anesthesiologist, I am appalled about there is a lack of inhouse supervised anesthesia care and no immediately accessible equipment for monitoring respiratory function or resuscitation equipment at dental surgeries that provide sedation to children.

This practice must stop to avoid further preventable child deaths.

If or when the time comes for my son to require a dental procedure under sedation, I will ensure that this is done in a safe environment, in the presence of an anesthesiologist who is (a) delivering the sedation (b) monitoring my son's breathing and airway patency and (c) is qualified and experienced to deliver emergency care (if needed) using immediately available resources for resuscitation.

The lack of data on severe morbidity and mortality that results from major respiratory morbidity from these procedures is also appalling. Without these data, we likely only hear about sentinel cases that parents are motivated to bring to the attention of the media.

We should and must do better for our children and their parents who blindly assume that dentists can manage these situations. Until we have data to prove this, they should no longer be allowed to administer sedation to kids in their dental surgeries.

Sincerely,

Dr. Alexander Butwick

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**Dr. Alexander Butwick MBBS, FRCA, MS**  
Associate Professor in Anesthesia,  
Department of Anesthesiology, Perioperative and Pain Medicine (MC:5640),  
**Stanford University School of Medicine,**  
300 Pasteur Drive,  
Stanford,  
CA 94305  
Email: [ajbut@stanford.edu](mailto:ajbut@stanford.edu)

**Fischer, Karen@DCA**

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**From:** Nancy Chan  
**Sent:** Monday, October 24, 2016 11:35 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Opinion on topic - Parents, Doctors Question Safety of Sedation

The regulation should establish to require dentist to hire anesthesiologist to handle complete sedation. It will avoid untrained dentist administer sedation to patient especially sedation is meant to put the patient completely out.

Thanks for listening!

Nancy Chan

Sent from my iPad

**Fischer, Karen@DCA**

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**From:** Michelle Chib-  
**Sent:** Tuesday, October 25, 2016 2:38 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentistry

Karen,

I am casting my opinion that dentistry should be far more regulated. My daughter has had a reaction to the novacaine twice and the dentist did not recognize the symptoms. My heart reacjes.

is

Michelle Chiba, CFM

[Redacted signature block]

**Fischer, Karen@DCA**

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**From:** Linda Civitello  
**Sent:** Tuesday, October 25, 2016 1:17 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Fw: Anesthetic pediatric procedures

Dear Ms. Fisher:

As a child I had multiple fillings. My kindergarten photo shows a silver smile - almost every tooth filled. I only had anesthesia once in the primary grades when several adult teeth were pulled before they erupted as there was no room. Only that procedure - done at a special dental surgeon's office was done with anesthesia. Children should not be put under for fillings or pulling a tooth.

As an adult I ran a group home and oversaw the dental care of dozens of children. None ever needed to be put to sleep.

Perhaps dentists who do this do not know how to relate to children.  
Only qualified anesthesiologists should use this procedure and only for surgery. Not basic dental procedures.

Please ban use of anesthesia in these dental office procedures. Parents have enough to worry about. Fear that their child will die from a filling should not be one of them!

Linda Civitello, MA



Sent from Yahoo Mail on Android

**Fischer, Karen@DCA**

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**From:** Lorraine Collins  
**Sent:** Tuesday, October 25, 2016 7:49 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's law

I've been following this case with much interest and saw the info on tv again last night. We must make these changes in the dental office. We have it mandatory for medical children and need the same for all children??  
Why the difference? Aren't all kids equal?

Lorraine Collins  
Santa Rosa Ca

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Michelle Cruciani  
**Sent:** Tuesday, October 25, 2016 9:47 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law AB2235

Hello Ms. Fischer,

California children are dying in dental offices from poorly managed appointments from dentists during routine and surgical care.

Children like Caleb Sears should not have to die. I knew this family well from our preschool.

I am this mother. A young parent that takes my 2 children to dentist appointments. We have not needed anesthetics yet but we will refuse treatments that suggest the use of anesthetics.

Put yourself in our shoes. Would you take children to the dentist for treatments with anesthetics that have 1 dentist performing the operation while simultaneously monitoring vitals on the patient? No. Not anymore. California dentistry must change.

Thank you,  
Michelle Cruciani

[Redacted signature block containing a name, phone number, and email address]

**Fischer, Karen@DCA**

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**From:** Jesse Rose  
**Sent:** Monday, October 24, 2016 9:14 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Ensure children's safety

Dear Ms. Fischer,

I am writing to express my concern over the current safety regulations around sedation dentistry, for children.

As a mother of two and a public school teacher in a low-income district, I feel it is very important to have the most protections possible for the care of children, especially those living in poverty and without dental insurance. For example, a concern that strikes me is that many of my students have poor dental hygiene and their parents do not speak English. These families are at increased risk.

Also, since parents TRUST their dentist to be qualified to perform the necessary treatments, we must insist that we be able to TRUST our public representatives to set and enforce safety regulations for the health care industry. Thank for pushing for the highest standards in your role in this matter. Thank you also for your work as a civil servant.

Sincerely,  
Jessica DeRooy

**Fischer, Karen@DCA**

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**From:** DeSimone, Joseph M.  
**Sent:** Monday, October 24, 2016 11:30 PM  
**To:** Fischer, Karen@DCA  
**Cc:** joe@carbon3D.com  
**Subject:** Patient input for guidance on anesthesia at dentist offices

Hello Karen,

I just saw this report about potentially requiring an anesthesiologist in dentist offices. I think this IS needed. I say this because I had a horrific incident about 15 years ago at my dentist in NC where I got too much anesthesia in the dentist office: my wife found me at home in bed afterwards when I went missing. I don't recall the full incident. I apparently got nauseous extensively, I was hallucinating and they let me drive away on my own. I firmly believe I lost some memory as a result of this incident.

As an FYI, I am an elected member of all three national academies (Science, Engineering and Medicine) and a recipient of the National Medal of Technology and Innovation from President Obama. I am in leave from UNC while I lead a start up for the last two years in Silicon Valley called Carbon.

Joseph M. DeSimone

Chancellor's Eminent Professor of Chemistry at UNC  
William R. Kenan Jr. Distinguished Professor of Chemical Engineering at NC State University and of  
Chemistry at UNC  
Co-founder of Carbon3D, Liquidia Technologies, Bioabsorbable Vascular Solutions, and Micell

<http://www.chem.unc.edu/people/faculty/desimone/>

Tel: [919-962-2166](tel:919-962-2166)  
Fax: [919-962-5467](tel:919-962-5467)

"La vita è bella"

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Patricia Dolan  
**Sent:** Monday, October 24, 2016 11:44 PM  
**To:** Fischer, Karen@DCA  
**Subject:** anesthesia

I am glad the Ca Dental Board is open to improving public safety regarding dental anesthesia , and policing it's own. I think dentists should not be allowed to administer anesthesia, especially to pediatric patients. There is too much risk of harm since this is not their area of specialization. Even one death is too many. In reality, there have been several deaths of young children around the country as a result of dental anesthesia going terribly wrong. For that reason, I have always believed that any parent who would allow their child to be sedated in a dental office is very foolish. This option should not be available. There needs to be a state law banning this practice , and, the Ca. Dental Board should strictly enforce it. Only state licensed RN nurse anesthetists, or MD's who are board certified in anesthesia, should be allowed to administer the anesthesia, and, they should be required to stay with the dental patient at all times while the dental procedure is being performed to monitor the patient's status. It's more costly for dentists to employ such persons than to sedate the child on their own. But, what is profit compared to a human life? Maria Giordano

**Fischer, Karen@DCA**

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**From:** Desmond Elder  
**Sent:** Tuesday, October 25, 2016 10:36 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Ms. Fischer

It is really imperative that when pediatric dental procedures are undertaken that an anesthesiologist be present to assist the dentist to safeguard the health and welfare of the child. We have recently seen instances where the absence of an anesthesiologist has led to the death of a child during or following a dental procedure.

Please use all influence and whatever strategies are necessary to have Caleb's law strengthened/ rewritten to mandate the presence of an anesthesiologist when a pediatric dental procedure is performed. It will protect the child, the parents and the dentist from unintended consequences.

Thank you.

Desmond Elder

**Fischer, Karen@DCA**

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**From:** Pam Elder  
**Sent:** Tuesday, October 25, 2016 11:10 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law and Your Committee's Studies

Karen Fischer  
Executive Officer  
Dental Board of California

Dear Ms. Fischer,

According to the website Calebslaw.org, the provisions of Caleb's Law, which will be enacted in January, are as listed below.

Grateful as I am that the law was passed and signed, it is inadequate. In recent years, too many children have died because there was inadequate professional supervision of anesthetics during their dental procedures.

I believe that it is impossible for any dentist or oral surgeon to adequately attend to careful monitoring of a child's vitals while he or she is doing dental procedures that require close, complete attention.

As required by Caleb's Law, you and an appointed committee will be studying this matter shortly. I urge you and the assigned Dental Board members to strengthen your recommendations to require a professional anesthetist or nurse anesthetist to perform the administration and monitoring of anesthesia that may be required for any child's oral surgery.

Even if you may find statistical data low for mortalities, the loss of even one healthy child because of inadequate professional attention is utterly unconscionable. You cannot permit the continuing heartbreak of the loss of more precious children through what amounts to professional hubris.

I look forward to hearing that your study will conclude, as many of us in the public have, that professional anesthesiologist oversight is necessary to assure safe pediatric oral surgery in dental offices.

Thank you for your consideration.

Pamela Elder

**Caleb's Law was signed into law by Governor Brown on September 23, 2016 and it goes into effect on January 1, 2017.**

*It requires that the Dental Board of California establish a committee to study the safety of pediatric anesthesia in dental offices and whether additional safety measures would reduce the potential for injury or death in minors. These findings will be reported to the Board and be made publicly available.*

· *It requires that people licensed by the Dental Board to administer general anesthesia inform a child's parent or guardian of the differing practice models and safety precautions currently in place.*

· *It facilitates the epidemiological study of pediatric anesthesia and sedation by requiring the Dental Board to collect more information regarding adverse events.*

**Fischer, Karen@DCA**

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**From:** Lissette Fernandez  
**Sent:** Monday, October 24, 2016 11:27 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentists administering anesthesia

I just saw a report on NBC's 11 o'clock news in which they discussed dentists administering anesthesia to children. As a resident of CA and the mother of a 5 year old, I wanted to voice my opinion: dentists should not be allowed to administer anesthesia to children. Only anesthesiologists should be allowed to administer anesthesia to children.

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Ross Fernandes  
**Sent:** Monday, October 24, 2016 11:28 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Sedation of children by dentists

Hi Karen:

I watched the report of NBC Bay Area on children dying or suffering brain damage from dentists administering anesthesia. As a father of two children, I feel that even one death is way too much. If you gave any parent the choice of paying extra to ensure their children live through simple dental surgery versus taking a risk with the Dentist going solo, no one would say no. Unfortunately none of the affected parents knew any better. So why is there even a question on this topic. We are talking lives here which are invaluable. Please make it illegal for nay Dentist to administer anesthesia on their own and save another child.

Regards  
Ross

Ross Fernandes | [\[Redacted\]](#)

**Disclaimer**

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**Fischer, Karen@DCA**

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**From:** david fontes [mailto:davidfontes@comcast.net]  
**Sent:** Monday, October 24, 2016 11:30 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Parents, Doctors Question Safety of Sedation Dentistry

As a parent who has recently taken his children to dental appointments, I definitely feel that a separate anesthesiologist should be present to sedate minors to provide a safe procedure. Death should never be a possibility in a dental procedure!

Thank you for your time,  
David Fontes

**Fischer, Karen@DCA**

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**From:** Laura Friedman  
**Sent:** Wednesday, October 26, 2016 12:20 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Don't put pediatric patients at risk!

Dear Ms. Fischer:

I am writing to voice my opinion on the current topic of dentists providing anesthesia to children and other patients alone without the supervision of a trained and qualified anesthetic provider. It is no surprise this is a topic of concern given the high number of recent close calls and deaths especially in children. There is no reason this day in age that this is occurring! As a trained and board certified anesthesiologist, I believe you need to address the reasons why this is occurring at such high numbers and pass legislation that DOES NOT allow dentists to take on the role of anesthesiologist and administer their own anesthesia. Dentists are not medical doctors and they are also not trained in airway issues especially when a patient becomes apneic or an emergency arises. We need to protect our children from bad decisions of others. Please, seriously consider the bad outcomes and the parents who no longer have their children to hug, hold, or kiss.

Thank you,

Laura Friedman, MD

**Fischer, Karen@DCA**

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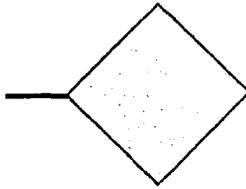
**From:** g g  
**Sent:** Tuesday, October 25, 2016 10:53 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Anesthesia Safety Comment

As a parent I would like to voice my support for disallowing dentists to perform anesthesia on patients, especially children. Steps to change the current procedure:

- Requiring three people during complex anesthesia
- Requiring dentists to get a special permit to sedate children
- Requiring more expertise for dental assistants.

is not enough. Dentists can't perform dental procedures and monitor anesthesia to an acceptable degree. Not one more healthy child should die from anesthesia at the dentist. Trained anesthetists, just like in hospitals, should be present for these procedures to monitor and improve patient safety.

Thank you



## Richard A. Gagne, D.D.S., Inc.

- General Dentistry
- Intravenous Sedation
- Dental Implant Surgery

1350 W. Gonzales Rd. Suite B • Oxnard, California 93036 • (805) 485-2777 • Fax (805) 485-0517

October 26, 2016

Dental Board of California  
2005 Evergreen St, Suite 1550  
Sacramento, California 95815

Re: Proposed changes to the anesthesia provisions of the Dental Practice Act.

My background: I have held a CS permit since 1991. When I made my original application I was told by a Board employee that my permit (#26) was the first permit issued under the new law that started in July, 1991 where I took a course that followed the ADA Guidelines and was not "grandfathered in". My practice does a significant amount of IV Sedation. I have been a CS On-site evaluator since 2000. I attended yearly the CDSA meeting in Costa Mesa, and I am well aware of sedation issues in California and nationally.

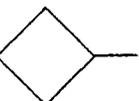
***In regard to educational requirements for pediatric moderate sedation:***

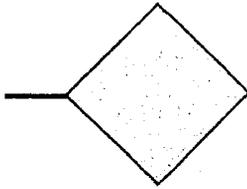
The wording in the proposed changes calls for "completion of a course of instruction plus a sufficient number of clinical cases for pediatric patients under age 13." While I can support such a change, the question to the board is how to implement this proposal. Who is going to offer a course on a Continuing Education (CE) basis? Presently the only IV Moderate Sedation course given on a CE basis in California is at the University of Southern California. I would not anticipate that this course would contain ANY pediatric training. Developing a course that is SOLEY related to getting the requirements for pediatric sedation is going to be very difficult and very expensive. The course will have to entail live patient care for pediatric patients, some of which will have to be seven (7) or younger. This is going to be a very difficult task. This proposal needs to be thought out carefully before adoption.

***In regard to the onsite inspection program:***

I support the change that would only require a single evaluator. As an evaluator for sixteen years, I can attest to the fact that a single evaluator can make a decision on the competence of a permit holder. When the law was originally written in 1990 there were few CS permit holders. Even then, there was a dearth of dentists that volunteered to do these exams. Now there are significantly more CS permits, but probably not a corresponding increase in evaluators. I'm sure the Board will be able to schedule exams much more easily with a single evaluator.

I would like to offer the following comment for the Board to consider. This is probably not something that is being discussed, but is very relevant: Five times I have had the unfortunate responsibility to fail a **temporary** permit holder. I have never failed an existing permit holder that was doing a re-certification evaluation. Failing an examinee was a decision that I did not take lightly! I have found that the quality of the emergency training of those temporary permit holders was POOR, to say the least. This is something that I have discussed in person with several members of the Board over the past ten years trying to bring this issue to their attention. Therefore, I would like the Board to consider





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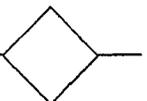
the following: “Two evaluators are required when a temporary permit holder is to be evaluated. In the case of a existing permit holder, only one evaluator is required.” The requirement of two evaluators for the evaluation of a temporary permit holder will make the evaluation more equitable when the possibility of failure is being considered by the evaluation team.

***In regard to the authority to require completion of a specific remedial educational program after an evaluation failure:***

To require a permit holder that has failed an evaluation to get remedial education is long, long overdue. As I mentioned, I have failed permit holders. In one such case, I called the Board to make them aware that this permit holder should have that permit IMMEDIATELY suspended. The Board did take this action. Present law only requires that the permit holder retake the exam. We need to implement this change to protect the people of California moving forward. This one change is well worth all the time the subcommittee has put into the review effort.

*Richard Gagne, DDS.*

Richard Gagne, DDS



**Fischer, Karen@DCA**

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**From:** Grace Geraghty  
**Sent:** Monday, October 24, 2016 11:26 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentist and kids

I want to voice my opinion that dentist should not be allowed to administer anesthetics to children. This is extremely dangerous and we owe it to the many kids who've already died and most importantly those young deaths in the future if we keep up the status quo.

Thanks,  
Grace

Sent from my iPad

**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Tuesday, October 25, 2016 9:33 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Sedation in Dentistry

I am responding to the safety of sedation in dentistry.

I feel strongly that the dental board should make changes and require anesthesiologists to do their job and a dentist should do their job.

A dentist is not an anesthesiologist, and visa versa!

With my children, we have had some situations that did not go well and we had to follow up and put a claim against our dentist. I found that a lot more mistakes happen without the general public knowledge. I am pleased that eyes are opening up towards the practice of dentistry.

I am hoping for my stringent guidelines and oversight.

Judy Giraudo

[REDACTED]

**Fischer, Karen@DCA**

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**From:** [Redacted]  
**Sent:** Wednesday, October 26, 2016 10:02 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Dear Ms. Fischer,

Please support having anesthesiologists present when dentists are operating on kids and prohibiting dentists from simultaneously doing surgery and giving anesthesia. Caleb's Law is so important and will save the lives of children undergoing dental surgery. Too many have died because of being overdosed during anesthesia.

Thank you for your support.

Valerie Hancock



**Fischer, Karen@DCA**

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**From:** Charlotte Haynes <[redacted]>  
**Sent:** Monday, October 24, 2016 11:27 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Child dentistry

I have 4 daughters and one that has had teeth extracted with anesthesia. I would be devastated if my daughter died due to something preventable.

There should be an anesthetist administering the medicine as well as an assistant that is properly trained. There should also be a specified amount of medicine administered based on age, body weight, past and present illness and any other specifics needed to ensure each child leaves the dentist alive.

Please change the way procedures are done now. May each of the children lost rest in peace. It could be your child next.

--

*Charlotte Haynes*  
Founder, Abstract Potential  
Certified Life Coach

**Reinvent yourself**

**Fischer, Karen@DCA**

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**From:** Daisy Mae Magana  
**Sent:** Wednesday, October 26, 2016 3:04 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Public input on Dental Anesthesia

Dear Karen Fischer,

My name is Daisy Herrera. I am a mother to a wonderful 18 month old boy. I've been afraid to take him to the dentist because of these sad incidents that have happened to children. Unfortunately, it has happened in other States as well.

Please make it safer for my son and all the children in California by having a law stating that every dental office that works with children have a Pediatric Anesthesiologist.

Thank you,

Daisy Herrera

**Fischer, Karen@DCA**

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**From:** Britt Jensky  
**Sent:** Tuesday, October 25, 2016 6:43 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentists doing surgery

I believe dentists should have to use a licensed anesthesiologist when administrating anesthesia on both children and adults.

Thank you,  
Britt Jensky

Sent from my iPad .

**Fischer, Karen@DCA**

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**From:** Robin Dan  
**Sent:** Saturday, October 29, 2016 12:00 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental anesthesia

Dear Ms.Fischer,

After watching the NBC Bay Area news investigative report, I needed to add my opinion in the discussion regarding the administering of anesthesia by dentists.

These families, as we all do, entrusted the dentist with their child's care. We cannot accept the excuse that the dentist makes an anesthesia error because they are working alone.

There cannot be another preventable death from this practice. To hear about these young children dying because of anesthesia errors screams that the equation doesn't work. Hospitals have specialists in this area for a reason, dentists should have an anesthesiologist on site for the procedures that call for it. It's a careful science, a specialist should be present.

My hope is that other families vocalized their opinions and we can see change happen. I'm afraid that with all the election noise of late that this issue wasn't heard in time to say something.

Thank you,  
Robin Jolivette

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Elena Kaloyanova  
**Sent:** Monday, October 24, 2016 11:43 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Response to Caleb's Law

Please have an anesthesiologist present when a child is put under during a procedure. Have at least two people while a child is under during a procedure and require dentists to get additional license/ education if they will be administering anesthesia during treatment of children under full anesthesia.

Thanks Elena Kaloyanova  
Sent From my iPhone

**Fischer, Karen@DCA**

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**From:** Cathy Kantor  
**Sent:** Monday, October 24, 2016 11:28 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Anesthesia

Hi Ms Fischer,

My comment is regarding nitrous oxide, is the equipment run through checks?  
I had two separate visits a couple of weeks apart and both times asked for nitrous oxide before numbing shot for cracked tooth and cap. Both times I sat in the same chair and at one point in the procedure the gas increased on it's own and started feeling too strong. I mentioned it both times and they turned it down but don't think the dentist pursued checking the equipment for malfunction.

Cathy Kantor

**Fischer, Karen@DCA**

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**From:** Annie Kaplan <[REDACTED]>  
**Sent:** Thursday, October 27, 2016 2:06 PM  
**To:** Fischer, Karen@DCA; Huchel, Sarah; Lucien, Michael; Kolakosky, Bridget  
**Subject:** Comments on the Ped Anesthesia Subcommittee preliminary recs  
**Attachments:** Kaplanresponse to Dental Board recs.pdf

Dear Ms. Fischer,

Attached are my written comments in response to the Pediatric Anesthesia Sub Committee preliminary recommendations. Please let me know if you have any questions or need additional information.

Thank You!

Anna Kaplan, MD

October 27, 2016

VIA EMAIL

Karen Fischer, Executive Officer  
Dental Board of California  
2005 Evergreen Street, Suite 1550  
Sacramento, CA 95815

Re: Subcommittee on Pediatric Dental Sedation Preliminary Recommendations

Dear Ms. Fischer and Members of the Dental Board of California:

I have closely reviewed the Preliminary Recommendations of the Dental Board's Subcommittee on Pediatric Dental Sedation dated October 3, 2016. I am writing to submit my comments on the preliminary recommendations and respond to certain assertions made during discussion of the preliminary recommendations at the Dental Board's October 13, 2016 meeting.

1) There was an assertion that there is "not enough data" to make a decision about the operator anesthetist model of care. To the contrary, there is clearly "not any data" to show that this model of care is safe.

- **The "not enough data" conclusion is at odds with expert opinion in the anesthesia community.** Here is a short list of consumer safety organizations and expert organizations that practice pediatric sedation that have concluded that the operator-anesthetist model is indeed unsafe.

- FDA (see footnote from FDA included in public comments<sup>1</sup> and their written statement concluding that the operator anesthetist

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<sup>1</sup> In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary. This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure. [...]

Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur. Others not so trained, or whose attention is divided between

model is risky warranting their WARNING labels on the most commonly used drugs. FYI the FDA is completely evidence based.)

- The California Society of Anesthesiologists (“CSA”)<sup>2</sup>
  - American Academy of Pediatrics (“AAP”)/ American Academy of Pediatric Dentistry (“AAPD”)<sup>3</sup>
  - American College of Emergency Physicians (“ACEP”)<sup>4</sup>
- **The assertion that “there is no clear pattern leading to the adverse events” is unfounded** in that the Dental Board report only looked at 1680(z) adverse event reports. These were incredibly vague, ambiguous and not descriptive of the events leading to the adverse event. If the Board members (or any expert in the field) would have looked at medical records from these adverse events, or even the investigatory reports then there would undoubtedly be clear patterns. This is how the medical field runs morbidity and mortality conferences in that they explore the events leading up to the adverse event to see the pattern. That information is not contained in the 1680(z) reports, nor is it in the Dental Board report.
  - **If only looking at numbers, can the Dental Board define what constitutes proof of unsafe practice?** Will the board restrict operator-anesthetist practice if the mortality rate is less than 1 in 100,000? 1 in 10,000? The stakeholders know that kind of data will take years to obtain, which effectively means continuing the status quo regardless of patient risk. I’d like to point out that it’s easy to perpetually resist change on basis of insufficient evidence unless you define what you are looking for.
  - **How many more patients need to die or be seriously injured while more data is collected?** Shouldn’t the Dental Board err on the side of caution and highest quality of care to protect the public?
    - Proponents of the operator-anesthetist model have had decades to study patient safety, but failed to do so. According to the dental board, much of the data necessary for a retrospective study has been destroyed under the board’s retention policy. Collecting data

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administering propofol and conducting other tasks associated with the procedure, may not be.

<sup>2</sup> Reference Letter sent to Dental Board on August 17, 2016 from the CSA, included again for emphasis.

<sup>3</sup> Reference: Cote, C et al.. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics*. Volume 138 , number 1 , July 2016.

<sup>4</sup> Godwin, S. et al.. Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department. *Ann Emerg Med*. 2014;63:247-258.

going forward will take years. The proponents of the model should not be permitted to delay regulations (at the cost of patient injury and death) especially when they were uniquely situated to avoid the problem by adequately studying patient safety.

- Car seats for children were mandated long before there was evidence to prove the efficacy of this practice, because lives were at stake. A prudent action by the DBC would be to rapidly develop an outcomes registry to gain the proof they seek while proactively requiring the use of a two person model for the same reason that child car seats were required long before studies of car seat outcomes were available.
- The precautionary principle demands that where there is risk of catastrophic outcome from a practice, and there already is prima facie evidence of such outcomes occurring and medical experts conclude the practice is unsafe, then regulatory bodies must act to reduce or eliminate that risk by changing the practice. The operator anesthetist model should be prohibited until it has been proven to be safe.

## **1. Specific opinions about preliminary recommendations**

### **a. Proposal 1**

I appreciate the board's commitment to continue to research patient safety during sedation in dentistry. Nevertheless, how is the board going to research high quality outcomes data without dentists contributing the data? AB2235 encourages the dental community to contribute data to already in existence databases (SCOR, or PSRC.) But this is not currently being done.

I recommend: At the bare minimum, licentiates holding general anesthesia permits should be mandated to contribute to the SCOR database or the PSRC database. Creating yet another database would be unnecessarily costly and counterproductive, since both of these outcomes databases are in existence, easily accessible, and already offered to be adopted for use by the California dental community and used for the dental board's stated purpose.

### **b. Proposal 2**

Thank you for updating the definitions to the modern definitions.

### **c. Proposal 3(a)(2)**

This recommendation effectively codifies the operator-anesthetist model because the recommendation does not specify that the person dedicated to monitoring the patient be competent to administer anesthesia. Codifying the operator anesthetist model in this way without any evidence to show that this unique practice is safe would do more harm to the protection of consumers.

Further, the words "at least one trained in monitoring and resuscitation of sedated patients" are at best ambiguous and misleading. The qualifications of the second person (trained anesthesia provider) should be spelled out as it is in the August 17, 2016 letter addressed to the Dental Board from the California Society of Anesthesiologists. A Dental Assistant should NOT qualify as this second person.

At every Dental Board meeting there is clear agreement between the Dentist Anesthesiologists, the Physician Anesthesiologists, and the Pediatricians that there needs to be a separate qualified anesthesia provider for any child undergoing moderate and deep sedation, or general anesthesia.

The oral surgeons have stood alone in their claim that this practice should remain without change. The subcommittee appears to be swayed by this lone professional group with the most financial self-interest in maintaining the status quo.

**d. Proposal 3(b)(ii)(3)**

This recommendation is again not consistent with the recommendations of the anesthesiologists and would do nothing to protect the public.

\* \* \*

In conclusion, I would like to say that the coalition advocating on behalf of California patients and consumers strongly recommends to the board a complete adoption of recommendations set forth clearly in the August 17, 2016 letter from the California Society of Anesthesiologists sent to the Dental Board. These recommendations do NOT represent an unreasonable high bar, but instead, are a standard bearing low bar for the minimum that can be done to protect consumers while taking into consideration how dentistry is practiced in an office-based setting.

The Dental Board's stated mission is to protect and promote the health and safety of consumers of the State of California. You have the opportunity to take common-sense steps that will immediately and significantly improve the safety of children undergoing sedation in dental offices across California and avoid preventable tragedies. I urge you to develop final recommendations that will actually decrease risk by changing practice, and not just updating definitions and the structure of permits.

Thank you for using your positions to protect the public and improve the safety of children undergoing sedation in dental offices throughout California.

Sincerely,

Anna Kaplan, MD

Cc: Assemblymember Tony Thurmond  
Senator Jerry Hill

## Fischer, Karen@DCA

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**From:** Laurence Kaplan  
**Sent:** Tuesday, October 25, 2016 12:52 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental anesthesia

Dear Ms. Fischer,

I am writing as a concerned professional and as the grandmother of 8 children, one of whom will never grow up to be the extraordinary person he was meant to become. My entire family has been gravely affected by my little grandson's death. We miss him every day. I imagine that the well respected oral surgeon who was responsible for my grandson's death is also deeply affected by my grandson's death, perhaps he cringes every time he hears a news report about the death of another child, perhaps he is traumatized by recurring visions of a child limp in his office chair, or covered in blood from a failed tracheotomy. As a psychologist I have treated physicians who suffer from the mistakes they have made, failures in judgement or missed diagnosis, heartbreaking decisions that can never be undone. I have been in practice long enough to have the laws of my own profession change to guarantee the safety of my patients with the Tarasoff decision and the laws on reporting. I know that changing the habits of clinical practice is challenging but I can guarantee that the inconvenience of hiring a separate anesthesiologist for the surgical treatment of children's oral surgery procedures does not compare to the nightmare of losing a child or of being clinically responsible for that loss.

Sincerely,

Laurence Kaplan

Sent from my iPad

**Fischer, Karen@DCA**

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**From:** Noa P. Kaplan  
**Sent:** Tuesday, October 25, 2016 6:41 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Its important that the Dental Board of California hear our message loud and clear. We want to see an end to the single operator anesthetist model for anesthesia and that all California children should have the safety of a separate trained anesthesia provider. "Not one more healthy California child should suffer a potentially preventable death in a dental chair," - Pediatrician Dr. Paula Whiteman, American Academy of Pediatrics

My darling nephew and many other children would still be with us if dentists had the same regulations and oversight as medical doctors. Please help protect children from unnecessary risk.

Sincerely,  
Noa Kaplan

Noa P. Kaplan  
w: noa.kaplan@ucsf.edu  
t: 415.734.1111

**Fischer, Karen@DCA**

---

**From:** [REDACTED]  
**Sent:** Tuesday, October 25, 2016 6:17 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentist and Anesthesia

Dear Ms. Fischer,

I don't have a dog in this fight, seeing that I live in Florida, however as a board certified anesthesiologist for over 25 years I can tell you that allowing one provider do both a procedure and administer anesthesia is a catastrophe waiting to happen, as the citizens of your state know so well.

I am the medical director and chief of the department of anesthesiology for a free-standing ambulatory surgical center in Broward County, Florida. Myself and my staff administer anesthesia while the surgeon does his procedure. Allowing one provider to do both the procedure and the anesthesia just means that they are unable to concentrate on either procedure fully. To allow this in pediatric patients, where things can go very badly, very quickly, can be deadly.

In this day and age, where safety is paramount, justifying this policy in the name of either efficiency or cost is unconscionable.

For the sake of the children, please prohibit dentists from giving anything more than minimal sedation to the patients they are working on.

Sincerely,

Howard Leibowitz, MD

**Fischer, Karen@DCA**

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**From:** Laura Lilly  
**Sent:** Tuesday, October 25, 2016 7:03 PM  
**To:** Fischer, Karen@DCA  
**Subject:** PEDIATRIC ANESTHESIA STUDY

I'm writing to share my thoughts and concerns about pediatric anesthesia procedures. My heart goes out to the parents who've lost their children.

I am concerned if it is required that an anesthesiologist be present at all pediatric dental procedures requiring anesthesia, those procedures are going to be extremely expensive. Who is going to be able to afford them? Will insurance companies cover those costs? I have my doubts. And if they do, will dental insurance prices increase? I would say YES.

Also, most anesthesiologist don't accept any medical health insurance, so they probably won't accept any dental insurance either, so the patient, or patient's parents will have to pay the full price for the anesthesiology procedures, and they aren't cheap!

I don't have children, so I have no idea what-so-ever what it feels like to have my child die. I also don't feel any law(s) can prevent accidents from happening.

Special licensing, and continued training, for dentists who work with/on children, I feel are all wanted and needed, but requiring an anesthesiologist to be present on all cases where children require anesthesia, I feel will sadly, result in costs so high, it will actually prevent people from being able to afford dental work.

It is a tough situation. No one wants to see anyone die from a trip to the dentist, and especially when it's a child and, I feel it's important to look at the big picture. Again, it's a tough one.

Thank you for your time,  
Laura Lilly

**Fischer, Karen@DCA**

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**From:** Stef [redacted]  
**Sent:** Monday, October 24, 2016 11:49 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentist administering anesthesia

Good Evening Karen,

I recently saw the story on NBC news regarding children dying as a result of improper administration of anesthesia at dental office's. My heart sank! Such tragedies are absolutely avoidable.

Why is it required for a physician to have an anesthesiologist but not a dentist? There are many medical issues that are compromised by anesthesia. Only someone who specializes in administering anesthesia would have the expertise to be able to safely proceed while keeping the patients well being as their highest priority during a procedure.

I ask you, would you allow a plastic surgeon to perform heart surgery on a loved one? No you wouldn't, its not their expertise. So why are we allowing dentists to administer something that is so delicate the slightest miss calculation results in death. It is not their expertise!

Please I beg of you, put an end to this. Protect the well being of patients. Be an advocate for children. Require anesthesiologist in dental offices!

Thank you for your time!  
Stefanie Lund  
San Jose, CA

Sent from my iPhone

Via Email

October 28, 2016

To: Dental Board of California Members

I would like to submit my comments on the pediatric anesthesia subcommittee recommendations.

I believe we should comply with the AAP/AAPD Guidelines for deep sedation and general anesthesia for pediatric patients. The ADA has guidelines for anesthesia yet defers to the AAP/AAPD guidelines for patients 12 years old and younger. Consistent with these guidelines I believe there should be a separate independent anesthesia provider, such as a physician anesthesiologist or dentist anesthesiologist. The Dental Sedation Assistant currently recognized by the Dental Board does not qualify and in fact should be abolished. The 110 hour requirement for a Dental Sedation Assistant to monitor a patient and push medication that will render a patient unconscious is woefully inadequate compared to a registered nurse who has to take 2-3 years additional years of training as a certified nurse anesthetist.

My previous email detailing the increase in malpractice premiums to practice as an operator anesthetist is evidence of the increase risk in this practice model. I am insured to do any and all procedures for which I am licensed. The only restriction is I cannot perform the dentistry while I provide anesthesia. IF I want to do both at the same time, my rates would go up "significantly". This includes adults, the risk is even higher in children. This increase in premium is evidence of the increase in risk of doing both the dentistry and the anesthesia simultaneously. This cannot be ignored.

I support activating the Blue Ribbon Committee consisting of all stakeholders to evaluate all bad outcomes and reports to the dental board.

I agree with updating the terminology consistent with current medical terminology for levels of anesthesia.

Dr. Whitcher in his committee presentation to the Dental Board on October 13, 2016 classified children age 6 and under as higher risk, children ages 7-12 as moderate risk and children above the age of 12 as lower risk. It is inconceivable to admit children are at moderate or higher risk and not change things to protect them.

Respectfully,

Michael Mashni, DDS  
Dentist Anesthesiologist

**Fischer, Karen@DCA**

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**From:** Lynn McCarthy  
**Sent:** Tuesday, October 25, 2016 4:30 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Calebs Law

I agree that not one more healthy, potentially preventable child should die in a dental chair.

Signed:  
Linda McCARTHY



Sent from my iPad

**Fischer, Karen@DCA**

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**From:** Gail McCormick  
**Sent:** Tuesday, October 25, 2016 5:23 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's law

I am in support of Caleb's law that will help protect our children from the risk of dental accidents. All children must be monitored when going under any anesthesia.

Gail McCormick  
Sent from my iPad

## Fischer, Karen@DCA

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**From:** Barbara McLean  
**Sent:** Tuesday, October 25, 2016 9:35 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Anesthesia for minors  
**Attachments:** maggie.jpg

I understand that you are investigating the practice of anesthesia for minors during dental procedures. I'm sure you have read some heartbreaking stories and I hope that no one in your family ever has to be in a photo like I've attached of people praying for my granddaughter, Maggie, as she lay in a coma near death.

Two years ago I got that call no grandma ever wants to get. My son was on his way to the hospital as their 4-year old daughter had a "bad reaction" to anesthesia while undergoing fillings. She was transported via life-flight helicopter to Loma Linda Children's Hospital and we arrived just as her helicopter was landing. We saw her little body as the elevator doors opened and she was rushed into the intensive care unit. My son and his wife arrived shortly after that. Since there was no place to stay we went home around 10 p.m. but at 4 a.m. my son called and said "If you want to see Maggie again you need to get here." We rushed back to the hospital to find she was not doing well. The hospital staff allowed us to pray around her bed as they attempted to stabilize her.

Fortunately Maggie survived this ordeal after 10 days in the hospital, most of those in a coma on life support. And why did this happen? Because she was "feisty" as the dentist explained to my daughter-in-law and it would be "easier" if she were fully sedated. No one bothered to explain that the person administering the sedation was not a qualified M.D. but merely a dentist who had taken a 12-hour seminar! As Maggie's doctors explained to my son she did not have an allergy to the medication as the dentist tried to convince them – she was over-sedated because the dentist felt she was not reacting fast enough to the anesthesia so they gave her more....and then more again.

We are blessed that she is recovered and back to her active self but can you imagine what her family went through? In addition to her hospital stay she has had to return for testing on her heart for the last two years. Financially it's been very difficult for the family who have three other children. All this because dentists don't want to lose money having to pay for a real anesthesiologist? Parents put great faith in the medical/dental professionals but in this case I believe they have failed.

I'm sure you've received stories that did not have happy endings. For the sake of these damaged lives I urge you....no, implore you, to do what you can to stop this practice and make the dental profession accountable.

Regards,  
Maggie's Grandma  
Barbara McLean

**Fischer, Karen@DCA**

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**From:** Jennifer McLean  
**Sent:** Tuesday, October 25, 2016 1:00 PM  
**To:** Fischer, Karen@DCA  
**Cc:** Alex McLean  
**Subject:** Our Story

Dear Ms. Fischer,

I have attached our story for your review, as I understand you are investigating the practice of child sedation dentistry. If you have any questions please feel free to contact us. It is my hope that the Dental Board will begin to hold dentist to a higher standard of care, and that the risks of child sedation dentistry will be thoroughly investigated.

Jennifer McLean



Maggie Story 1

On August 28th, 2014, our then four year old daughter was scheduled to have four minor fillings filled at the Indio Surgery Center, in Indio California. During the procedure there were complications and our daughter was transported by ambulance to a local hospital. Once she arrived at the hospital we were told she was in critical condition and would need to be transported to Loma Linda Children's hospital via Mercy Air.

How could this happen? She was just getting four fillings. Our daughter was transported to Loma Linda Children's Hospital, and remained on life support in the PICU for 2 weeks. Miraculously she survived. She sustained respiratory and heart failure. She now lives with Left ventricular heart dysfunction from the trauma of the accident. We still have so many unanswered questions, and two years later we are still searching for those answers. We are certain that grave mistakes were made in that dental office that day. Mistakes that left our perfectly healthy four year old daughter fighting for her life.

We must protect our children. It is our job as parents and members of society to call for tougher stricter laws for children sedation dentistry. We were misled in so many ways during our journey and I never want another parent or child to go through what we endured. In saying this I know that we are one of the lucky ones that still gets to hug our daughter every day, where so many other families will never get that opportunity again.

We ask the Dental Board to please consider these stories you hear, and our story when reviewing these laws. Please feel free to contact us with any questions.

Alex & Jennifer McLean

  
#prayformaggieruth

**Fischer, Karen@DCA**

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**From:** meganmil  
**Sent:** Tuesday, October 25, 2016 3:23 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Not one more healthy California child should suffer a potentially preventable death in a dental chair. We support Caleb's Law.

Thank you.  
Megan

**Fischer, Karen@DCA**

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**From:** Molloy John;  
**Sent:** Thursday, October 27, 2016 2:34 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Anesthesia Safety

Karen Fischer, executive director of the Dental Board of California:

Please implement the safety steps you are considering for the administration of anesthesia:

- 1) Requiring three people during complex anesthesia
- 2) Requiring dentists to get a special permit to sedate children
- 3) Requiring more expertise for dental assistants.

Thank you,

John Molloy

**Fischer, Karen@DCA**

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**From:** Carolina Moretti  
**Sent:** Wednesday, October 26, 2016 7:00 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Please put an end to the single operator anesthetist model

Dear Mrs. Fischer,

I want to see an end to the single operator anesthetist model for anesthesia. All California children should have the safety of a separate trained anesthesia provider. "Not one more healthy California child should suffer a potentially preventable death in a dental chair," - Pediatrician Dr. Paula Whiteman, American Academy of Pediatrics

Thank you,  
Carolina Moretti

**Fischer, Karen@DCA**

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**From:** Katy Munro-Hampton  
**Sent:** Wednesday, October 26, 2016 7:11 PM  
**To:** Fischer, Karen@DCA  
**Subject:** NBC Story - Sedation Dentistry

Dear Ms Fischer,

I would like you to consider my opinion regarding sedation dentistry.

Any patient that requires sedation for a procedure should have an anesthesiologist present, preferably in a hospital for vital monitoring. This should apply to all patients, adults and children.

I was truly shocked to hear that a child had died recently and that this is one of a number of documented instances resulting in either death or brain damage.

Yours sincerely,

Katy Munro

**Fischer, Karen@DCA**

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**From:** Kristinemunro <[redacted]>  
**Sent:** Wednesday, October 26, 2016 8:11 PM  
**To:** Fischer, Karen@DCA

Hello,

In response to the recent exposé on NBC news about a child's death following sedation at the dentist I think it's imperative that anesthesiologists are present in all dentist offices. I know the state is working on making changes with the requirements and it's very important that children get the highest quality treatment. Please consider my plea as one of many who seek to see changes within the dental community.

Sincerely,

Kristine Munro

—  
Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Sara Myers  
**Sent:** Tuesday, October 25, 2016 9:25 PM  
**To:** Fischer, Karen@DCA  
**Subject:** single operator anesthetist model for anesthesia

I'm writing on behalf of Caleb's Law. I feel it is import that an anesthesiologist and a surgeon assigned to each case of dental surgery so that the dentist can focus on their area of expertise and the anesthesiologist can handle the drug dosing and monitoring. How can we expect dentists or dental assistants to perform both tasks, especially without specialized training?

Thank you,  
Sara Myers

**Fischer, Karen@DCA**

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**From:** Anamaria Nino Murcia  
**Sent:** Tuesday, October 25, 2016 5:29 PM  
**To:** Fischer, Karen@DCA  
**Subject:** dental anethesia

Dear Dental Board of CA:

I'm writing to support the passage of Caleb's Law and ask that the Dental Board take steps to stop the practice of dentists using general anesthesia while performing dental procedures. I think for the safety and health of patients---general anesthesia should be performed and monitored by trained anesthesiologists.

Sincerely,

Anamaria Nino-Murcia

**Fischer, Karen@DCA**

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**From:** Matilde Nino-Murcia  
**Sent:** Tuesday, October 25, 2016 3:12 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Anesthesia in Pediatric Dental Procedures

I am writing to you in support of a change in policy and procedures for Anesthesia given during Pediatric Dental Procedures.

Administration of anesthesia during pediatric dental procedures should be given and the patient monitored by a another person different from the dentist performing such a procedure. We should not see one more case of a child death or brain damage due to this unsafe practice!

Thanks,

Matilde Nino-Murcia, M.D.

**Fischer, Karen@DCA**

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**From:** Leslie S. Packer  
**Sent:** Saturday, October 29, 2016 9:17 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Board Requiring Anesthesiologists for Children

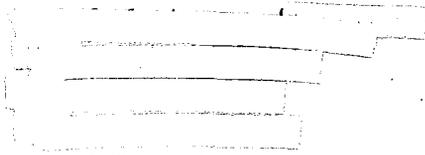
Dear Ms. Fisher,

I would like to go on record in support of a policy to prevent unnecessary and tragic deaths of children undergoing dental procedures requiring anesthesia.

I am urging the Dental Board to adopt a policy of requiring an anesthesiologist to be present when children are undergoing dental procedures requiring anesthesia.

Thank you for registering my concerns and my urging of the Dental Board to do the right thing.

Leslie S. Packer, Ph.D.



[kidwrk@gmail.com](mailto:kidwrk@gmail.com)

**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Monday, October 24, 2016 11:26 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Children's dentist

They need anesthesiologist and surgeon present.

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** Karen Paluska  
**Sent:** Thursday, October 27, 2016 12:28 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Please support Caleb's Law

Dear Executive Director Fischer,

I am writing you to voice my support for Caleb's Law.

My 9 year old daughter needs to have teeth extracted, and the thought of her being put under anesthesia without the safety of a separate, trained anesthesia provider is terrifying. She has many allergies, (some of which we have not identified yet), and her body can react very unpredictably to any chemicals introduced into her system. She is going to have back surgery next year, and we have already begun multiple, extensive conversations with the anesthesiologists about how we can possibly make her anesthesia as safe as possible. The idea of putting her under anesthesia even with a designated, trained provider (even for something as critical as back surgery) is terrifying to me because when things go wrong, they can go seriously wrong. Because of the severity of the back surgery my daughter is facing, we are taking the time to do extensive research to prepare for the anesthesia. In the case of a tooth extraction, I know that parents think it's a much less severe procedure, so they are not doing the same kind of agonizing research about the anesthesia. However, being "put under" is always a serious decision. It would be very easy for a child to have a bad reaction to anesthesia, and without the attention of a separate, trained anesthesia provider, this could easily be lethal, as in the case of Caleb and other children who have died during dental procedures.

Please, help make sure that no more children are put at risk this way.  
Thank you for helping support Caleb's Law.

Sincerely,  
Karen Paluska

**Fischer, Karen@DCA**

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**From:** Shirley Phelan  
**Sent:** Friday, October 28, 2016 11:31 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Dear Karen,

I support Caleb's Law and hope that you will also. I'd like to see an end to the single operator anesthetist model for anesthesia and would like all California children to have the safety of a separate trained anesthesia provider. A few death seems little but each death hurts many lives and the pain of a losing a child is endless. There are also children who have been disabled from these improperly administered procedures that are not accounted for; I implore you to support Caleb's Law before another avoidable injury or death occurs again.

Shirley Phelan  
San Francisco CA

**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Tuesday, October 25, 2016 4:23 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Children Dental deaths must be prevented

Dear Ms Fischer:

**Subject: Children Dental deaths must be prevented**

I agree that not one more healthy California child should suffer a potentially preventable death in a dental chair.

Bruce Pine

[REDACTED]

**Fischer, Karen@DCA**

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**From:** Wendy Pine  
**Sent:** Tuesday, October 25, 2016 4:21 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Children Dental deaths must be prevented

I agree that not one more healthy California child should suffer a potentially preventable death in a dental chair.  
Wendy Pine



**Fischer, Karen@DCA**

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**From:** Andre Ptaszynski  
**Sent:** Friday, October 28, 2016 6:34 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

To: Karen Fischer, The Executive DirectorThe Dental Board of California

As the step-Grandfather of Caleb Sears, I wish to see an end to the single operator anesthetist model for dental anesthesia, and I want all California children to have the safety of a separate, trained anesthesia provider during oral surgery procedures.

Sincerely,

Andre Ptaszynski

**Fischer, Karen@DCA**

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**From:** Jesus Rodriguez  
**Sent:** Monday, October 24, 2016 11:30 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Anesthesia with dentistry

I am a registered ER nurse with 43 yrs experience and absolutely believe that you need a designated experienced person to administer pediatric anesthesia. Another individual free to monitor airway and vital signs and a separate individual doing the procedure. One or two individuals can not do this safely. If something goes wrong you have seconds to a minute or two to prevent tragic outcomes.

**Fischer, Karen@DCA**

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**From:** Sally Rudolf  
**Sent:** Tuesday, October 25, 2016 7:36 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Calebs Law

Please support this very important legislation to save other young children from unnecessary death and tragedy.

Sally

Sent from my iPhone

**Fischer, Karen@DCA**

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**From:** VIVEK SANGHI  
**Sent:** Monday, October 24, 2016 11:35 PM  
**To:** Fischer, Karen@DCA  
**Cc:** Rashi Sanghi  
**Subject:** We need enhanced safety standards for sedation dentistry

Hi,  
We are the parents of a pre-teen, who will likely need to undergo dental treatment.  
It was heart wrenching to see stories of little kids being harmed, and even losing their lives, during sedation dentistry procedures gone wrong! These avoidable tragedies clearly call for enhanced safety during such procedures, including supervision by anaesthetists.

Vivek & Rashi

**Fischer, Karen@DCA**

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**From:** Karen Schneider  
**Sent:** Tuesday, October 25, 2016 2:51 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Stop Sedation Dentistry for Children  
**Attachments:** Maggie's story-dental board.doc

My letter and request to stop sedation dentistry is attached

When you hear the word: Anesthesiologist, most people immediately think of a medical doctor-someone with medical experience and training. This is not the case for a dentist holding the title of anesthesiologist. A dentist holding this title has only hours of training to use sedative drugs, and they are killing our children.

Two years ago, my then 4 year old granddaughter Maggie McLean went to Indio Surgery Center in Indio, CA, for what was "sold" to the parents, as a routine sedation type dentistry for filling children's teeth who were not cooperative in holding their mouth open. My daughter all along was apprehensive, but knowing there was a dentist and what she thought was a medical doctor "anesthesiologist" swayed her to allow the procedure.

Maggie was a very determined, feisty 4 year old-she wanted no part in getting her teeth filled. In retrospect, many believe it was her determination, feisty character, and Grace of God that saved her. Maggie was given many doses of sedation-another child who is more complacent may have "gone under" with one dose, however, many, many doses were given to Maggie. She was **heavily** sedated, and the dentist proceeded by placing some sort of pack down her throat, to catch debris (probably the source of her suffocation). Sometime during this procedure Maggie started suffocating and unable to breathe, however, NO ONE NOTICED-not the dentist who was 1 foot away from Maggie's face, or the so called anesthesiologist who either: 1) didn't have her on an oxygen monitor, or 2) he wasn't looking at the monitor, or 3) because of his lack of MEDICAL training didn't notice her struggling to breathe. Maggie struggled so hard to breathe, that all her blood vessels in her lungs punctured and her lungs filled with blood. It wasn't until the dentist saw "pink froth" coming of her nose that he was even aware there was a problem-and then he says he thought it was just a routing nose bleed.

Maggie was air transported to Loma Linda Children's Hospital and remained in critical condition, in a coma for 12 days. It seemed to us the dentists involved in this tried to persuade Loma Linda staff that Maggie had an allergic reaction to the sedation-but the trained medical professionals found this rather perplexing. A 20 year experienced PICU nurse showed me the suction tank and blood they got from Maggie's lungs and went on to say-"something is not right here-the dentist screwed up".

Maggie lived-with the potential of lifelong damage to her heart and lungs. And the dentist and so called anesthesiologist continue to sedate and drill children's teeth, with the potential of maiming or killing another child.

The title anesthesiologist for a dentist is misleading to the laymen public. They should be called what they are: dentist with a few hours of sedative drug training. The definition for an anesthesiologist is: a highly skilled **medical doctor**-how in the world is a dentist with a few hours of training using this title!

Maggie's incident was horrifying, tragic, and heartbreaking for our entire family and friend community. To think that she almost died still is unbelievable to me. There are other families with similar stories, with much worse endings-of total loss.

Sedation dentistry to children in this manner needs to stop.

For more information, I can be contacted:

Karen Schneider (Maggie's grandmother)

[Redacted contact information]

**Fischer, Karen@DCA**

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**From:** Nadia Scholnick  
**Sent:** Tuesday, October 25, 2016 7:21 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law: Please Protect Our Kids!

Dear Dr. Fischer,

I'm writing to ask that the dental board change its procedures regarding dental surgery for children. Specifically, the single operator anesthetist model is NOT working. To ask a dentist to function as both anesthesiologist and surgeon results in accidents. Caleb Sears and other children are proof of a failed model. Children need to be protected, and requiring a separate trained anesthesia provider be present during surgery will go a long way to guarantee that other families do not have to suffer the loss that the Sears family did.

It is my fervent hope that the CA dental board follows the lead of many other states and ends the single operator anesthetist model.

With sincere thanks for your efforts,

Nadia Scholnick

## Fischer, Karen@DCA

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**From:** Louise Selchau-Hansen  
**Sent:** Wednesday, October 26, 2016 11:50 PM  
**To:** Fischer, Karen@DCA  
**Subject:** In support of ending the single operator anesthetist model

Hello Karen,

My name is Lou(ise) Selchau-Hansen, and I am a close friend - and almost relative of the Sears family. My brother's brother-in-law's brother is Tim Sears, Caleb's father - so I am undeniably biased in my plea to change the system so that there is always a dedicated person in the room monitoring a dental patient's anesthesia during any kind of procedure.

My husband, Christian Selchau-Hansen, and I--along with the rest of the Sears family and friend network--urge you to change the system as quickly as possible.

Over this past weekend, I went camping with my husband and two children, ages 6.5 and 4.5. I was tickling my 6.5 year old daughter, and she ended up fully upside down, so I happened to get a glance into her mouth at an angle I never do when brushing the kids' teeth. The light must have been weird in the tent, because I swore that I saw two permanent teeth trying to erupt into the roof of her mouth about a centimeter (waaay too far) behind her two front baby teeth. My daughter is very self-conscious about being the only child in her class who still has yet to lose a tooth. And my husband's sister had issues related to her teeth coming in when she was a child, so I saw these two apparently white bumpy spots on the roof my girl's mouth well behind where permanent teeth should grow in, and I literally started shaking.

"Oh my God," I thought. "I cannot take her in. I cannot sit in the waiting room like Tim and Eliza did and not know what is going on behind those closed doors, not knowing what combination drugs was being given to her to suppress her consciousness and her bodily systems, imagining this oral surgeon starting in on what I'm sure is quite difficult work cutting into bone and tissue and also keeping an eye on her blood oxygen levels...and if something were to go wrong, this would be the sole person to try to save her." My mind was spinning. I practically threw up. I got out of the tent and paced around the campsite with my head in my hands. >>I should say at this point that I am NOT a dramatic person, so my husband got extremely worried and ran over to see what was wrong.

Together, we reasoned that no matter what, we would find a provider who had a second person whose sole job was to watch my Inga's vital signs. We would find a dentist who would allow or even welcome this. We would do it no matter what.....because we knew.

Now, about five minutes later, my husband and I got our son to come lie down in the tent next to his sister, and we looked in both of their mouths with a flashlight, and I guess that all I was seeing was normal bumpiness...not tips of serrated-ended teeth trying to poke through. I cried in relief.

But I also cried for Tim and Eliza Sears, and the mother of the little girl who passed away in a California dentist's office more recently named Daisy. If one of my children needed treatment, I would sell every possession I own to ensure that they did not have a Single Operator Anesthetist providing their care. Pay out of pocket - do anything it took. What about all the people who don't even know that there's a difference between what is going to happen to their child in an oral surgery vs. a surgery on any other part of their body? What

about the people who have not stumbled across the investigative reports and just have no clue...like Tim and Eliza did not?

One of Caleb's aunts (the wife of one of Caleb's father's brother) is a physician. She wrote a beautiful, heartbreaking article for a medical magazine earlier this week. She describes rushing to join her sister-in-law at the hospital:

"What felt like moments later, the EM attending pulled me into the hallway and recited his condition: 'He was possibly without an airway for 45 minutes but we don't know.' Then: 'All his teeth were broken. A surgical airway had been attempted and failed. He coded 3 times in the ambulance.' . . .

"Grief takes many forms. For me, I needed to find out what had happened. I already knew my nephew did not have an allergic reaction or some latent heart defect. He was not a high-risk patient. He should not have died. I analyzed Caleb's medical records and learned the oral surgeon had both operated on Caleb and administered his anesthesia in a private office. There was no separate anesthesia provider, not even a nurse. And this is normal; oral surgeons call it the 'operator-anesthetist model' of sedation. Caleb's oral surgeon pushed propofol, ketamine, fentanyl, and versed, then went to work on Caleb's teeth. The manual notations showed no one noticed Caleb's oxygen saturation drop until it hit 60%. I could picture the oral surgeon's desperation as he failed to intubate and his panic that led him to futilely cut into Caleb's throat looking for an airway. An anesthesia provider would have noticed immediately and deployed any number of interventions to maintain airflow until Caleb could maintain his own airway. How could an oral surgeon operating alone be the standard of practice?"

(article: <https://feminem.org/.../turning-tragedy-advocacy-calebs-law/>)

Indeed, HOW COULD AN ORAL SURGEON OPERATING ALONE BE THE STANDARD OF PRACTICE?

You know, I feel like our country is falling apart around us right now. So many people feel this way...no matter which side we see things from. And I realize that thousands of children aren't dying in the dentist's chair. But, my gosh...it just feels like this is such a correctable problem. Just change! I honestly feel so sad at the effort my extended family had to put forth to get the legislation through. I don't understand why your board didn't hear of Caleb's case--even if it was the only one that ever happened--which is isn't--and didn't spring into action straight away to start fixing the issue yourself. Instead, I don't know exactly which entities the lobby that my extended family was up against - but I know they faced a lot of opposition, and I frankly just can.not.understand.it.

I can't imagine being a dentist and \*wanting\* to do the anesthesia myself. How does the provider feel right now who looked up and saw Caleb's blood oxygen at 60 and then tried so hard to save him that he broke all Caleb's teeth, but Caleb was without oxygen so long the dentist effectively killed him? How does a person live with that on their conscience? I would have nightmares. I would see that number "60" and think, Holy You Know What, how did I not notice until this child was at \*60\*?

(My son has asthma, and he's had the pulse ox so many times late at night I've lost count, but I know that even getting into the low 90's makes the hospital and urgent care staff start to freak out.)

I urge you to see that having a dedicated anesthesia specialist is better not only for us parents out here but really for dentists, too. It must be so horrible for a procedure to go very wrong. I'm sure it will still happen at times, but how much better would you all feel if you knew that you did everything you could and that the system was in place to protect EVERYONE, both you and the patient?

Sincerely yours,

Lou Selchau-Hansen

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**Fischer, Karen@DCA**

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**From:** [REDACTED]  
**Sent:** Monday, October 24, 2016 11:51 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental anesthesia

*By all means a Dentist CANNOT do both *anesthesia and pull or fix a tooth!! I can't believe it's been acceptable this whole time! It's horrible, you trust your Dentist to fix your child's tooth/teeth and to have your child die!! That's NOT okay!!!! Ever!!**

*Sincerely Debbie Sunzeri*

**Fischer, Karen@DCA**

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**From:** [Redacted]  
**Sent:** Monday, October 24, 2016 11:34 PM  
**To:** Fischer, Karen@DCA  
**Subject:** public input on dental anesthesia

Dear Karen,

I am writing to you as a parent who recently moved to CA from CO.

I strongly support the board adopting policies and procedures that do not allow dentists to do ANY procedure requiring anesthesia without a separate anesthesiologist administering the medication as well as further education for dentists.

Do no harm.

Thank you,  
Joy Sykes  
San Carlos, CA

**Fischer, Karen@DCA**

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**From:** Corrine Tan  
**Sent:** Friday, October 28, 2016 11:11 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Dear Karen,

I support Caleb's Law and hope that you will also. I'd like to see an end to the single operator anesthetist model for anesthesia and would like all California children to have the safety of a separate trained anesthesia provider. A few death seems little but each death hurts many lives and the pain of a losing a child is endless. There are also children who have been disabled from these improperly administered procedures that are not accounted for; I implore you to support Caleb's Law before another avoidable injury or death occurs again.

Thanks

Corrine

**Fischer, Karen@DCA**

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**From:** Lien Tang  
**Sent:** Friday, October 28, 2016 10:53 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Hi Karen,

I support Caleb's Law and hope that you will also. I'd like to see an end to the single operator anesthetist model for anesthesia in dental offices and would like all California children to have the safety of a separate trained anesthesia provider. A few death seems little but each death hurts many lives and the pain of a losing a child is endless. There are also children who have been disabled from these improperly administered procedures that are not accounted for; I implore you to support Caleb's Law before another avoidable injury or death occurs again.

Regards,

Lien Tang

**Fischer, Karen@DCA**

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**From:** Ajit Thomas  
**Sent:** Tuesday, October 25, 2016 8:30 AM  
**To:** Fischer, Karen@DCA  
**Subject:** Dental Anesthesia - We need change!

Dear Dental Board,

I'd like to add my voice to the many others that have heard the story of Caleb Sears and children like him who have suffered under the poor policy and regulations overseeing this area of practice.

Do not allow dentists to perform anesthesia and surgery during a single procedure. This is virtually unheard of outside dental surgery. Why would we hold dentists to a lower standard operating procedure than we do other medical practitioners?

I hope to see real change in the near future in California based on your leadership.

Regards,  
Ajit

Sent from Windows Mail

## Fischer, Karen@DCA

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**From:** Jane Tong  
**Sent:** Tuesday, October 25, 2016 2:20 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Dentistry sedation

Dear Ms. Fischer,

I'm contacting you to provide my input regarding dentists providing anesthesia due to my family's personal experience.

Two years ago, my son's orthodontist recommended a DDS in Hayward, California to extract two teeth. My son was 9 years old at the time. We went in for the consultation and decided to schedule the extraction appointment.

We were aware that my son would be put under general anesthesia and my husband and I waited in the waiting room. After the surgery was completed, the doctor told us that our son was coming out of anesthesia and we could see him. We walked into the recovery room and I immediately knew that something wasn't right. My son was laying in a recliner and crying with both arms extended and supine. I saw several cotton balls taped to his arms. I asked the doctor, "what happened? Something isn't right". He said, "everything went well and he's coming out of sedation". I again said, "No, something is NOT right. I know my son and something happened. Why is he crying like this? What happened with his arms?" The doctor, knowing that I was not buying into the "he's just responding this way coming out of sedation" explanation, finally told me that he wasn't able to find a vein and had to poke my son 8 times with a needle in order to put him under anesthesia.

I could not believe it — Eight times!! What kind of doctor does this to a child? Instead of being ethical and coming out to the waiting room to tell us that he could not safely put my son under anesthesia, he took it upon himself to stick him eight different times.

I saw the news story on NBC News last night about other families who have tragically lost their child due to dentistry sedation. It just broke my heart to hear what these families are going through. To this day, it is terribly upsetting to me what the dentist did to my son. My husband & I were right there in the other room at the dentist's office and my son was all alone and scared, being poked over and over with a needle. I asked my son this morning if he remembers the incident and he said that he tried to be brave and not cry when the doctor kept using the needle over and over, but he said that he was scared and tears were rolling down his face during the procedure. I trusted that dentist because he said he has two sons that were around the same age as my son. I'm sure he would not have allowed someone else to do to his sons what he did to mine.

I am imploring you to please overhaul how these dentists can use anesthesia in an unsafe manner. We feel so fortunate that my son was able to recover, but the dentist was unethical by putting my son through unnecessary pain and trauma. There needs to be more oversight and regulations put into place. Whether that is allowing the parents to be in the room while the child is being sedated, performing the procedures in a hospital setting, using only an anesthesiologist, etc. One more child who is killed or suffering because of a dental procedure is one too many.

Thank you.

J. Tong

**Fischer, Karen@DCA**

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**From:** susan turner  
**Sent:** Tuesday, October 25, 2016 6:59 PM  
**To:** Fischer, Karen@DCA  
**Subject:** dental anesthesia

I think that when a dentist has to administer anesthesia to any patient especially a child there should be a licensed anesthesiologist there Not the dentist or the dentist assistant ( or anyone else in the office) should be able to administer the anesthesia Would a surgeon do his or her own anesthesia NO THEY WOULDN'T AND A DENTIST SHOULD NOT BE ALLOWED TO DO THIS EITHER PLEASE PASS A LAW THAT STATES NO ONE BUT AN ANESTHESIOLOGIST CAN ADMINISTER ANESTHESIA IN ANY DENTAL OFFICE (ORAL SURGERY OR A GENERAL DENTAL OFFICE) SO THAT NO OTHER CHILDREN OR ANY ONE DIES AGAIN!!!!!! susan turner

**Fischer, Karen@DCA**

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**From:** Blaine Walke  
**Sent:** Tuesday, October 25, 2016 7:38 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Sedation

I am an RN who specializes in giving sedation medications to patients during procedures under the direction of an MD. I have also worked in an Emergency Department as well so I feel I can speak to this matter. I personally have had a tooth removed by a dentist. My medical history was not evaluated for sedation. My condition of sleep apnea should have warranted special consideration yet none was given. No where in the room was there any equipment to assist in mechanical ventilation if I had stopped breathing. I did not feel safe.

As a RN I have to evaluate the medical history and medications of all my patients. Patients with certain medical conditions and especially pediatric patients should be done by an anesthesiologist or certified nurse anesthetist. Don't place patients lives over doctor preference. I have also seen over sedated patients come into my ER. Emergency rooms should not be the first line of defense against oversedation. Please do the right thing and develop mandatory standards to protect patients especially the children.

B. Blaine Walke, RN  
[Get Outlook for iOS](#)

**Fischer, Karen@DCA**

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**From:** Jessika Welcome  
**Sent:** Tuesday, October 25, 2016 6:37 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Children and dental-related anesthesia

Dear Ms. Fischer:

I want to see an end to the single-operator anesthetist model for anesthesia. All California children should have the safety of a separate, trained anesthesia provider.

“Not one more healthy California child should suffer a potentially preventable death in a dental chair,” - Pediatrician Dr. Paula Whiteman, American Academy of Pediatrics

Sincerely,  
Jessika Welcome

**Fischer, Karen@DCA**

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**From:** Sheri Glucoft Wong  
**Sent:** Tuesday, October 25, 2016 9:12 PM  
**To:** Fischer, Karen@DCA  
**Subject:** Caleb's Law

Dear Ms Fischer,

I am writing to ask you to please support an end to the single operator anesthetist model for anesthesia. I am a close friend of the Sears family and loved Caleb very much. Please don't let one more family suffer this most horrible of loses. All California children should have the safety of a separate trained anesthesia provider. There is nothing more tragic than the preventable death of a child. Please keep the rest of our kids safe from what happened to Caleb.

Sheri Glucoft Wong  
[Redacted]

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Sheri Glucoft Wong, LCSW  
[Redacted]

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