This PDF document includes written comments received during June and July 2016 in response to a request from the Council inviting input on June 2016 proposed revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.
I would like to enter these remarks on behalf of the University of Oklahoma College of Dentistry Department of Oral and Maxillofacial Surgery who is responsible for the teaching of local anesthesia and pain/anxiety control, including IV sedation and general anesthesia for oral and maxillofacial surgery residents.

I strongly support the use of end tidal CO2 monitoring during the course of moderate sedation as we all know well this is the standard of care with our anesthesia colleagues, and there is no reason to set ourselves apart by dumbing down this particular recommendation. It is clear that this is being promulgated by those who are too cheap to spend the money in the name of good patient care to get monitors that provide important information during the process of an anesthesia.

Additionally, I believe that moderate sedation can occur, as well as general anesthesia, regardless of the route of administration and can be drug-dependent as well as dose-dependent. With that in mind, I think that everyone should have a maximal number of hours of course content as well as hands-on exposure and experience before being permitted to treat patients. Keep in mind this is about patients and not about providers.

Furthermore, it is important that all patients have an appropriate updated medical history prior to any type of sedation or anesthetic and that all ASA 3 and 4 patients realistically should not be done in a dental office but taken to a hospital where potential complications due to their comorbidities can be managed. Additionally, it is important to realize patients with an elevated BMI pose additional risks that a poorly trained dentist may have difficulty dealing with.

I appreciate the opportunity to enter these remarks on behalf of the University of Oklahoma.

Steven M. Sullivan, DDS
Professor and Chairman
Department of Oral and Maxillofacial Surgery
University of Oklahoma
405-271-4955
www.oralfacialsurgeons.com

Sent from my iPhone please excuse typographical errors
June 24, 2016

Dr. Daniel J. Gesek, Jr., Chair
Council on Dental Education and Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

Dear Dr. Gesek:

The American Academy of Periodontology is pleased to provide comments on the proposed changes to the American Dental Association (ADA) Guidelines for the Use of Sedation and General Anesthesia by Dentists and the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.

Lines 468-472 and 595-598: Elimination of the mandate for monitoring end tidal CO₂ for moderate sedation to allow for the choice of options such as continuous use of a precordial or pretracheal stethoscope, continuous monitoring of end tidal carbon dioxide, and continual verbal communication with the patient.

The Academy supports the mandate for end-tidal CO₂ monitoring.

Lines 1362-1365 and 1366-1372: Reconsideration of the section “Moderate Sedation Course Duration” (hours and content), as proposed by level of sedation, or a possible option of separate course requirements for enteral and parenteral routes of sedation.

The Academy does not support two separate training requirements, one for parenteral and a lesser one for enteral, if the level of sedation is the same. Training should prepare dentists to competency in intravenous moderate sedation, titration of drugs, and rescuing the patient from the next level of sedation. The Academy recommends lines 1364-1365 be modified as follows, with additions noted in red:

- A minimum of 60 hours of instruction plus administration of sedation for at least 20 individually managed patients by intravenous route.
Lines 302-322; 397-409; and 518-550: Making patient evaluation provisions consistent throughout the document, including but not limited to, rationale and guidelines for the use of Body Mass Index (BMI) and the timing of medical history review.

The Academy believes the Guidelines should state the necessity for a recent medical history (without specific time frame) and prior to administration of sedation an assessment of changes with a pre-operative assessment. In regard to BMI, the Academy does not believe a specific BMI number is an appropriate way to assess if a patient is a candidate for sedation. Each patient must be assessed on their entire medical history including condition of airway. The Academy recommends that lines 404-409 be deleted.

Lines 107-112; 389-393; 510-514; 549-550; 627; 637; and 1097: Because of reference to and support of the American Academy of Pediatrics and American Association of Pediatric Dentist’s Guidelines for management of pediatric patients undergoing sedation, the CDEL is recommending that the ADA Guidelines apply to the adult patient population only.

The Academy supports that the ADA Guidelines apply to patients who are 18 and over.

If you have any questions or need additional information, please contact Cheryl Parker at 312-573-3231 or cheryl@perio.org.

Sincerely,

Wayne Aldredge, DMD
President

c: Board of Trustees
June 28, 2016

Dr. David Sarrett  
Chair, Council on Dental Education and Licensure  
American Dental Association  
211 E. Chicago Ave.  
Chicago, IL  60611

Dear Dr. Sarrett:

Thank you for the opportunity to provide comments to the proposed ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists.

These comments are predicated on the differences between the proposed ADA guidelines and the American Academy of Pediatrics and 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 (AAP/AAPD Guidelines) with regards to the role of capnography during moderate sedation.

The AAP/AAPD Guidelines states that moderate sedation 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...’

Assessment of ventilation is understood to be key to prevent respiratory compromise / distress. The AAP/AAPD Guidelines outline monitoring based on bidirectional verbal communication with the patient.

1. When bidirectional verbal communication is appropriate monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (e.g., Bluetooth technology) or precordial stethoscope is strongly recommended.

It is the intent of this statement is to reinforce to the provider the critical nature of assessing ventilation, while at the same time providing multiple avenues when bidirectional verbal communication is appropriate.


2 Ibid., e10
2. When bidirectional verbal communication is not appropriate or possible, then ventilation is to be assessed as a requirement by capnography (preferred), amplified, audible pretracheal stethoscope, or precordial stethoscope.3

The AAPD understands that sedation exists on a continuum; and a patient intended for moderate sedation may proceed into deep sedation. Deep sedation is defined as “drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation.” These patients are required by the AAPD/AAP to be assessed by capnography/end-tidal carbon dioxide assessment until they return to a state defined by moderate sedation.4

The AAPD respectfully requests the ADA to consider making an option for ventilation assessment when bidirectional verbal communication is appropriate.

Should you have any questions, please direct them to Dr. John S. Rutkauskas, CEO of the AAPD at jrutkauskas@aapd.org.

Sincerely,

Jade A. Miller, DDS
President

cc: AAPD Board of Trustees
John R. Liu, Chair, AAPD Committee on Sedation and Anesthesia
Sarat A. Thikkurissy
Karen Hart

3 Ibid., e11
4 Ibid., e11
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.
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.1–5 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.53–58 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.56,57,59–61

This revised statement reflects the current understanding of appropriate monitoring needs of pediatric patients both during and after sedation for a procedure.1,4,11,18,20,21,23,24,33,39,41,44,47,51,62–73,175–181 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.11,23,24,27,30–33,35,39,41,44,47,51,74–84 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.38,43,47,48,59,62,63,85–112

Procedural sedation of pediatric patients has serious associated risks.2,5,38,43,45,47,48,62,63,71,83,85,88–105,107–138 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.74,78,103 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.42,48,62,63,92,97,99,125–127,132,133,139–158 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.44,63,64,67,68,74,90,96,110,159–174

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.45,83,95,128–138 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.129 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.175–181 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.86,87,103 Children younger than 6 years (particularly those younger than 6 months) may be at greatest risk of an adverse event.129 Children in this age group are particularly vulnerable.
to the sedating medication’s effects on respiratory drive, airway patency, and protective airway reflexes. 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. Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation, 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. Rescue techniques require specific training and skills. The maintenance of the skills needed to rescue a child with apnea, laryngospasm, and/or airway obstruction include the ability to open the airway, suction secretions, provide continuous positive airway pressure (CPAP), perform successful bag-valve-mask ventilation, insert an oral airway, a nasopharyngeal airway, or a laryngeal mask airway (LMA), and, rarely, perform tracheal intubation. These skills are likely best maintained with frequent simulation and team training for the management of rare events. Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue (see Figs 1, 2, and 3).

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. 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. 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.
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.62, 127, 136, 173, 235 Recently, there has been renewed interest in noninvasive routes of medication administration, including intranasal and inhaled routes (eg, nitrous oxide; see below).236

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 minutes237–239). Titration of drug to effect is an important concept;
one must know whether the previous dose has taken full effect before administering additional drugs. Drugs that have a long duration of action (e.g., 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. In particular, promethazine (Phenergan; Wyeth Pharmaceuticals, Philadelphia, PA) has a “black box warning” regarding fatal respiratory depression in children younger than 2 years. 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. Pracitioners 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.

**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. 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. 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, LMA 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.

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.\textsuperscript{163,253-255} 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.\textsuperscript{62,63,238,242,256,257}

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.\textsuperscript{95,127,258}

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.\textsuperscript{259,260}

However, the absolute risk of aspiration during elective procedural sedation is not yet known; the reported incidence varies from \( \sim 1 \) in 825 to \( \sim 1 \) in 30,037.\textsuperscript{95,127,129,173,244,261} 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.\textsuperscript{262,263}

For emergency procedures in children undergoing general anesthesia, the reported incidence of pulmonary aspiration of gastric contents from 1 institution is \( \sim 1 \) in 373 compared with \( \sim 1 \) in 4544 for elective anesthetics.\textsuperscript{262} 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,\textsuperscript{95,127,129,173,244,259-261,264-268} 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\textsuperscript{260,264,268}; 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.\textsuperscript{268,269}

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.\textsuperscript{262-270}

**Before Elective Sedation**

Children undergoing sedation for elective procedures generally should follow the same fasting guidelines as those for general anesthesia (Table 1).\textsuperscript{271} 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, hemotoma block or nerve blocks, and other techniques advised by child life specialists, are particularly helpful and should be considered.294,49,182–201, 274,275

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.276 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.277–281 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.282 The purpose of this evaluation is not only to document baseline status 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).283–292 Kava may increase the effects of sedatives by potentiating γ-aminobutyric acid inhibitory neurotransmission and may increase acetaminophen-induced liver toxicity.293–295 Valerian may itself produce sedation that apparently is mediated through the modulation of γ-aminobutyric acid neurotransmission and receptor function.291,296–299 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.300–304 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.305–314 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.315–319 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.320–324

The health evaluation should include the following:

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

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

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period, h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids: water, fruit juices without pulp, carbonated beverages, clear tea, black coffee</td>
<td>2</td>
</tr>
<tr>
<td>Human milk</td>
<td>4</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6</td>
</tr>
<tr>
<td>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.</td>
<td>6</td>
</tr>
<tr>
<td>Light meal: a light meal typically consists of toast and clear liquids.</td>
<td>6</td>
</tr>
<tr>
<td>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.</td>
<td>6</td>
</tr>
</tbody>
</table>

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 al272 and Green et al.273
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, 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) because of concerns for the potential adverse effects of most sedating and anesthetic drugs on the fetus; (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; 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; and

- 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 presedation 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.

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. 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.

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.353–359 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-sedation62, 104, 256, 349, 350 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.239 Several scales to evaluate recovery have been devised and validated.212, 346–348, 351, 352 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.238

**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.353–359 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.360 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,361, 362 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.85, 363

**Moderate Sedation**

Moderate sedation (old terminology, “conscious sedation” or “sedation/analgnesia”) 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.85

**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.79,80,128,130,217–220, 364

**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.60 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.133,365–367

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)368–371 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). 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. 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).

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.
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, resulting in prolonged sedation and the need for extended postsedation monitoring. Former preterm infants have an increased risk of postanesthesia apnea, but it is unclear whether a similar risk is associated with sedation, because this possibility has not been systematically investigated.

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).

**Local Anesthetic Agents**

All local anesthetic agents are cardiac depressants and may cause central nervous system excitation or depression. Particular weight-based attention should be paid to cumulative dosage in all children. 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). In general, when administering local

| 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                | Capnography required        |
|                             | ECG recommended               | Suction equipment, adequate oxygen source/supply |
|                             | Heart rate                    | Respiration                 |
|                             | Blood pressure                | 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 | 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                 |
|                             | Required                     | Required                    |
| Discharge criteria           | See Appendix 1               | See Appendix 1              |

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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.\textsuperscript{401} 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).\textsuperscript{402–409} 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.\textsuperscript{410–415}

**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.\textsuperscript{416–420} 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 artificial data (under- or overestimation of oxygen saturation).\textsuperscript{361,362}

**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.\textsuperscript{64,66,67,72,90,96,110,159–162,164–170,372–375,421–427} 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.\textsuperscript{161} One study in children sedated in the emergency department found that the use of capnography reduced the incidence of hypoventilation and desaturation.

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

<table>
<thead>
<tr>
<th>Local Anesthetic</th>
<th>Maximum Dose With Epinephrine, \textsuperscript{a} mg/kg</th>
<th>Maximum Dose Without Epinephrine, \textsuperscript{a} mg/kg</th>
<th>Duration of Action, \textsuperscript{b} min</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical</td>
<td>Dental</td>
<td>Medical</td>
</tr>
<tr>
<td><strong>Esters</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procaine</td>
<td>10.0</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Chloroprocaine</td>
<td>20.0</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Tetracaine</td>
<td>1.5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Amides</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lidocaine</td>
<td>7.0</td>
<td>4.4</td>
<td>4</td>
</tr>
<tr>
<td>Mepivacaine</td>
<td>7.0</td>
<td>4.4</td>
<td>5</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>3.0</td>
<td>1.3</td>
<td>2.5</td>
</tr>
<tr>
<td>Levobupivacaine\textsuperscript{c}</td>
<td>3.0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ropivacaine</td>
<td>3.0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Articaine\textsuperscript{d}</td>
<td>—</td>
<td>7</td>
<td>—</td>
</tr>
</tbody>
</table>

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

\textsuperscript{a} 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.

\textsuperscript{b} Duration of action is dependent on concentration, total dose, and site of administration; use of epinephrine; and the patient’s age.

\textsuperscript{c} Levobupivacaine is not available in the United States.

\textsuperscript{d} Use in pediatric patients under 4 years of age is not recommended.

### TABLE 4 Local Anesthetic Conversion Chart

<table>
<thead>
<tr>
<th>Concentration, %</th>
<th>mg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>40</td>
</tr>
<tr>
<td>3.0</td>
<td>30</td>
</tr>
<tr>
<td>2.5</td>
<td>25</td>
</tr>
<tr>
<td>2.0</td>
<td>20</td>
</tr>
<tr>
<td>1.0</td>
<td>10</td>
</tr>
<tr>
<td>0.5</td>
<td>5</td>
</tr>
<tr>
<td>0.25</td>
<td>2.5</td>
</tr>
<tr>
<td>0.125</td>
<td>1.25</td>
</tr>
</tbody>
</table>

(7% to 1%). 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. 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. 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. 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. Opioids and benzodiazepines have minimal and variable effects on the BIS. Dexmedetomidine has minimal effect with EEG patterns, consistent with stage 2 sleep. Several sedation studies have examined the utility of this device and degree of correlation with standard sedation scales. 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. Presently, it would appear that BIS monitoring might provide useful information only when used for sedation with propofol; 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 tracheotomy. 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. The LMA can also serve as a bridge to secure airway management in children with anatomic airway abnormalities. 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 intraosseous adapter. 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. The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events. One study that simulated the quality of cardiopulmonary resuscitation compared standard management of ventricular fibrillation versus rescue with the EZ-IO for the rapid establishment of intravenous access and placement of an LMA for establishing a patent airway in adults; the use of these devices resulted in more rapid establishment of vascular access and securing of the airway.

**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. 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. 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. 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. The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide of ≤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. In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient’s response.

ACKNOWLEDGMENTS

The lead authors thank Dr Corrie Chumpitazi and Dr Mary Hegenbarth for their contributions to this document.

LEAD AUTHORS

Charles J. Coté, MD, FAAP
Stephen Wilson, DMD, MA, PhD

AMERICAN ACADEMY OF PEDIATRICS

AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

STAFF

Jennifer Riefe, MEd
Raymond J. Koteras, MHA

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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/content/early/2016/06/24/peds.2016-1212.full.html

Supplementary Material
Supplementary material can be found at:
/content/suppl/2016/06/22/peds.2016-1212.DCSupplemental.html

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30 June 2016

Dr. Daniel J. Gesek, Jr., Chair  
Council on Dental Education and Licensure  
American Dental Association  
211 East Chicago Ave.  
Chicago, IL 60611

Sir:
I have read the revised Call for Comments on the "ADA Guidelines for... Sedation..." again this year with the same interest and professional curiosity.

I can only hope that you perhaps are in possession of my letter to your predecessor, Dr. James M. Boyle, III dated from 25 June 2015.

Let me tell you a bit about myself:
1) I am a general dentist.
2) I possess a Comprehensive Conscious Sedation Permit here in Tennessee since 2007.
3) I am still currently on the TDA Committee for Anesthesia, Sedation and Scope of Practice.
4) I have taught nitrous oxide-oxygen monitoring courses to assistants and administration to hygienists since 2010.
5) I now speak nationally on nitrous oxide (and other topics) having spoken last year at the ADA and will speak again on 15 July 2016 in Boston to the Academy of General Dentistry. My courses are peer reviewed by an author of "The Handbook of Nitrous Oxide and Oxygen
Sedation," not because I need to do such, but because I choose to do just that to give the best presentations possible.

I will write freely as I do not have a dog in the fight so to speak as the proposals do not affect me or my practice. The areas of concern are often repeated through the document so only one example of each is given.

Concerns:
Line 130. Why is titration defined here when the topic of nitrous oxide was introduced in the earlier minimal sedation category? Nitrous oxide is an inhalant that can be titrated to effect. I think there should be reconsideration to insert the concept right after it is first introduced then it can be reinforced again or restated in the moderate section when discussing the parenteral route.

Line 337. Nitrous oxide fail safes have been in place since 1962. It is not possible to purchase such a unit that has none. Sadly, mistakes do happen like the crossed lines at a University of Iowa pediatric dentistry clinic in Iowa City this past spring. Is this line necessary considering what Porter, Belmont, Accutron and Mada offer in the United States?

Line 340. Other gases is ambiguous for this section. A dentist of a certain disposition may wish to look at halogen based inhalants with this lack of clarity. With Criticare's Poet IQ (1 or 2) ways to monitor these gases exist. This must be changed to limit to nitrous oxide.

Line 404. BMI. BMI varies by sex and age. I feel this point cannot be made strenuously enough. When I was active duty in the U.S. Army, even the standards for physical fitness testing were different based upon these biological and chronological issues. The BMI of an 21 years old male will be quite different than that of a 53 years old female if we keep their height the same. I believe further emphasis is required.

Line 468. This makes no sense. Which patients would be precluded from capnography? Which procedures would be declared ineligible for capnography? What equipment invalidates the usage of capnography? Asking yourself those questions as you reflect on the passage, you will see it from another point of view. Without points of reference, examples, case studies, etc. the phrase is quite open to individual (mis)interpretation instead of creating one standard of care. It still needs clarification and/or revision, just like last year's version.

Line 1170. 14 hours plus cases for a nitrous oxide course is a historical benchmark. It is one that requires reconsideration. I'd suggest a simple survey to each dental school to see if this is taught for two days. If you are honest with yourself, the answer is not many, if any at all. As the top national lecturer on the topic, I can do it, but can others? I have not seen a national course that offers 14 hours plus experiences.
Most courses on sedation whether they are parenteral, review or enteral only spend about one hour on the topic. With 13 safety features that didn't exist in the 1800's and its wide safety index, are we being too harsh?

Kudos:
I applaud you for taking things from my earlier letter under consideration.
1) Elimination of post-operative equipment checks
2) I still love the ASA fasting guidelines
3) I love the elimination of route as a hang up that some have to level!

Sincerely Yours in Dentistry,

Anthony S. Carroccia, DDS, MAGD, ABGD
Laura Williams, DMD
Caucus Chair, ADA District XI

Anesthesia Committee
Council on Dental Education and Licensure
211 East Chicago Ave.
Chicago, IL 60611
July 1, 2016

Dear Committee Members,

As Chair of the District XI Caucus I am responding on behalf of District XI to your recent Call for Comment to the Proposed Revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.

After reading the committee's very brief explanation of their recommendations for the revisions it is difficult to follow the reasoning used in evaluating data and information when substantiating their decisions. There is confusion regarding which documents and data the committee members are using to document their decisions, especially with regard to the Capnography recommendations. There are 2 ADA Scientific Institute systematic reviews mentioned but no citations given. Additionally, there is no data support given for the recommendations regarding educational requirements or BMI assessments. Without a thorough explanation of the committee's data interpretations and references to that data it will be very difficult for delegates to responsibly vote on a resolution. Undoubtedly these questions will be raised at the House of Delegates and discussion will consume a significant amount of time.

The testimony received at the Open Hearing was not addressed by the committee members in the proposed amendments background giving the impression that it was not found to be useful. Response to that testimony would also allow delegates to more fully understand the committee's evaluation process and streamline the discussion at the House of Delegates.
The 11th District has asked for a copy of the CSA report and has yet to receive it. The *Report on the Risks and Benefits of Using Capnography in Dental Patients Undergoing Moderate Sedation* that is included in the background and resources released may well be the CSA report but it does not indicate that in the article or in the title. Again, this creates confusion for the delegates trying to follow the committee's process.

Thank you for the opportunity to comment on this very important issue.

Sincerely,

Laura Williams, DMD
Chair, 11th District Caucus
June 30, 2016

Dr. Daniel J. Gesek, Jr., Chair
Council on Dental Education and Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611
Via email, care of: JasekJ@ada.org

Dear Dr. Gesek:

The Virginia Board of Dentistry (the Board) appreciates this opportunity to comment on the Council’s proposed revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. These guidelines are an invaluable resource for the Board. In addition, the Guidelines for Teaching are incorporated by reference in the Board’s Regulations Governing the Practice of Dentistry as Virginia’s education standard for issuance of conscious/moderate sedation permits and deep sedation and general anesthesia permits.

We support, and are especially appreciative of, the Council’s proposed language in:

- Lines 468 – 472 and 595 - 598 to require monitoring end-tidal CO2 for moderate sedation and for deep sedation and general anesthesia.
- Lines 1362 - 1365 to require 60 hours of instruction plus 20 patient experiences for moderate sedation courses regardless of the route of administration.
- Lines 1366 – 1372 to require certification of the competence of each participant, additional experience to achieve competence, and the maintenance of records of instruction and clinical experiences to capture the number of patients managed by each participant.
- Lines 402 – 409 and 523 – 530 to include an assessment of Body Mass Index (BMI) as a part of a pre-procedural workup.

The Board also wants to inform the Council of three changes it has advanced in our sedation and anesthesia regulations which are germane to the Council’s proposed amendments. The first one is to separate the administration of only nitrous oxide from the provisions for minimal sedation
into a new section on the administration of inhalation analgesia. This action will facilitate having a clear delineation in equipment and monitoring requirements between inhalation analgesia alone, and minimal sedation with or without nitrous oxide. The second change is to limit intraoperative monitoring to continuous visual observation of responsiveness, color, and respiration for both inhalation analgesia and minimal sedation with or without nitrous oxide. The third change is to require the recording of patients’ height and weight and, if appropriate, Body Mass Index (BMI).

The Board commends the Council’s commitment to patient safety and its thoughtful and well-reasoned development of both guidelines. The proposed changes are needed to foster a common understanding of the steps needed to promote both the well-being of patients, and the competence of dentists.

The Board looks forward to learning of the Council’s success in advancing its proposals. Please contact me at sandra.reen@dhp.virginia.gov if you have any questions about these comments.

Sincerely,

Sandra K. Reen
Executive Director
Virginia Board of Dentistry
July 1, 2016

Dr. Daniel J Gesek, Jr., Chair
Council on Dental Education and Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

Dear Dr. Gesek:

The California Dental Association (CDA) has worked with a group of representatives from California dental specialty groups since 2013 to provide comments on proposed revisions to ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. CDA appreciates the Council on Dental Education and Licensure’s work on the guidelines and supports revisions that reflect evidence and contemporary practice.

Regarding the current proposal, CDA’s concern relates to the document’s handling of pediatric sedation. The current proposal recommends removing references to pediatric sedation and focusing its guidance on adults, citing ADA’s reliance on the AAP-AAPD Guidelines for Sedation of Children Undergoing Sedation for Diagnostic and Therapeutic Procedures. However, the deletion of “12 years of age and under,” in the guideline introduction (Lines 23-25), creates ambiguity with regard to the age ADA considers the onset of adulthood and for which ADA guidelines apply. As the AAP-AAPD Guidelines state that they apply to pediatric patients age 21 and under, absent a statement to the contrary, many may interpret that age 21 would apply here. Further, as there is no discussion of the physiologic changes that are used to stratify risk related to pediatric sedation or other evidence in support of a policy change with regard to the age for the onset of adulthood, CDA believes clarification is essential.

Given these concerns, CDA recommends the following for lines 15-18:

The administration of local anesthesia, sedation, and general anesthesia is an integral part of dental practice. The American Dental Association is committed to the safe and effective use of these modalities by appropriately educated and trained dentists. The purpose of these guidelines is to assist dentists in the delivery of safe and effective sedation and anesthesia to persons 13 years of age and older.

This recommendation is consistent with current California law, recognizes that different states specify different ages as the age of majority, and acknowledges the physiologic considerations that are a basis for age stratification related to sedation.
CDA respects the work of the council and appreciates the opportunity to contribute our concerns and recommendations. If you have questions, please do not hesitate to contact Gayle Mathe, CDA staff, at Gayle.Mathe@cda.org or 916.554.4995.

Sincerely,

[Signature]

Gayle Mathe
Public Affairs
Dr. Daniel Gesek, Jr., Chair
Council on Dental Education and Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

June 30, 2016

Dear Dr. Gesek,

As an Oral and Maxillofacial Surgeon practicing in Rhode Island, we would like to take this opportunity to share with the committee some of the issues that have presented themselves as the Rhode Island Board of Examiners in Dentistry attempts to formulate regulations regarding ambulatory anesthesia in the dental office. The Board utilized the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students for direction in drafting, particularly with respect to moderate sedation. There is significant ambiguity in the educational recommendations provided by these documents for practitioners seeking permits/privileges to administer anesthesia under their dental licenses, which makes state board assessment and evaluation for moderate sedation permits especially difficult.

The Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students line 637-643 state the pre-doctoral education, which are CODA accredited programs, should provide instruction exposure and/or experience. Proficiency training in moderate sedation is obtained on a graduate level. The guidelines on a post doctorate level education do not distinguish between CODA accredited programs and education obtained through continuing education ("CE") courses. Line 829 defines competency and Lines 831-832 define proficiency as well as the
requirement for assessment and documentation of a dentist’s competency. Lines 856-877 define education courses.

The issue of applicants requesting Moderate Sedation permits with CE courses, which at best will offer competency, needs to be addressed to avoid dentists spending time and money on courses that may not lead to fulfilling the competency requirement in moderate sedation. The ADA needs to decide if continuing education courses have a place in qualifying doctors in Moderate Sedation, and if they do, identify the programs that meet the requirements.

The bottom-line is the education requirement must be better defined. Simply stating 60 hours on instruction is not specific enough. Continuing education alone does not offer the same structure and training of a CODA approved advanced education program. Although CE's are beneficial, they can't replace the composition of an advanced education program where required proficiency of the participant can be assessed.

While the definition of moderate sedation is well defined; the reality of administering sedation is a variable. With multiple sedation techniques, medications, pediatric and ASA statuses, staffing and faculty requirements, we need to ensure education and training of our doctors in sedation to meet all these demands to guarantee patient safety.

Not all advanced education programs offer training in sedation. Furthermore not all programs offer hands-on experience or actual IV training. Graduates must be proficient in actual clinical cases and the handling of emergencies. The programs that offer sedation competency/proficiency must be recognized by the ADA. These programs then can offer a certificate in Moderate Sedation to each graduate that has met the requirements.
The certificate obtained from an accredited program certified by the ADA in Moderate Sedation can then be submitted to the applicable state licensing board to support an individual's application for a moderate sedation permit. An ADA certification would allow licensing boards to assess the competency and education qualifications of an applicant and offer guidance in course selection to those dentists seeking to obtain proficiency in Moderate Sedation.

Another area that requires an immediate decision by the ADA is capnography. Recommendations from the American Society of Anesthesiologists, the American Association of Oral and Maxillofacial Surgeons and most recently, the American Academy of Pediatrics and American Academy of Pediatric Dentistry are all fairly in sync with respect to the use of capnography in anesthesia. You also see these groups speaking out in similar fashion on the need for certain emergency reversal agents to be present in every facility where Moderate Sedation is being administered. This is also true with the need to have staff with appropriate advanced life support training as well as necessary airway recovery equipment. It is time for the American Dental Association to recognize its responsibility. For as long as the American Dental Association fails to take a leadership role, establish guidelines, and stand as equals with other healthcare specialties, our profession is going to remain under attack through both public scrutiny and those medical providers that don’t believe anesthesia should be administered in a dental office. With each and every adverse event that occurs in this country while these guidelines are not written it is all dental providers of anesthesia that are going to be in the spotlight not just the one involved. It is better to be proactive than reactive.
We fully support the efforts of your council to provide safe and effective sedation guidelines and recognize that other states are waiting on the sidelines, just as Rhode Island is, for further guidance from our national association on this very important topic.

In summary, we not only believe capnography should be required for moderate sedation, that it is time for the ADA to set forth an specific certified education requirements in Moderate Sedation that each provider shall be required to have in order to administer moderate sedation in their offices.

Thank you for your time and consideration of these comments. Should you have any questions please do not hesitate to contact me.

Sincerely,

Martin Elson, DDS
Immediate Past President
RI Association Oral and Maxillofacial Surgeons

Christy D. Durant Esq.
Legal Counsel for RI Association Oral and Maxillofacial Surgeons
July 1, 2016

Dr. Daniel J Gesek, Chair
Council on Dental Education and Licensure (CDEL)
American Dental Association (ADA)
211 East Chicago Avenue
Chicago, IL 60611

RE: Review of the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists ("Use Guidelines") and Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students ("Teaching Guidelines")

Dear Dr. Gesek,

On behalf of the Texas Academy of General Dentistry (TAGD), I thank you for the opportunity to provide comments on the proposed amendments to the ADA Sedation "Use Guidelines" and "Teaching Guidelines." TAGD facilitated this review through its Advocacy Council.

The TAGD Advocacy Council expressed some specific and important concerns with the proposed revisions provided in the documents. I would like to share them with you:

1. "The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO2 unless precluded or invalidated by the nature of the patient, procedure or equipment. In addition, ventilation should be monitored by continual observation of qualitative signs, including chest excursion and auscultation of breath sounds with a precordial or pretracheal stethoscope." (P. 10, Lines 468-471)

**TAGD Comment/Recommendation:**
The mandate for capnography remains for moderate sedation even after Resolution 77H-15 from ADA House of Delegates called for "elimination." Now, the proposed guidelines not only include capnography but the addition of auscultation as well. The ADA Scientific Committee conducted a literature review to determine if scientific literature substantiated use of capnography during moderate sedation. The Scientific Committee returned an analysis showing improved outcomes during moderate sedation when end-tidal CO2 was monitored. However, the majority of the studies cited utilized patient populations, drugs and techniques which do not represent moderate sedation as it is practiced in dentistry. For example, many of these studies utilized propofol and ketamine. These drugs specifically do not meet the ADA definition of appropriate moderate sedation agents and are prohibited by more than 40 state boards of dentistry for dentists administering moderate sedation. In addition, CDEL's guideline draft states, "nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia". Yet there is no mandate for monitoring end-tidal CO2 during minimal sedation.
2. “Moderate Sedation (enteral and parenteral) Course Duration and Documentation: The Course must include: A minimum of 60 hours of instruction plus administration of sedation for at least 20 individually managed patients.” (P. 28, Lines 1363-1366)

TAGD Comment/Recommendation:
The previous guidelines for enteral moderate sedation courses included “A minimum of 24 hours of instruction, plus management of at least 10 adult case experiences” (P. 28, Lines 1348-1353). Now, enteral and parenteral both require the same training of 60 hours and 20 managed cases. There is no scientific evidence to conclude enteral sedation didactic hours should be more than doubled to 60 hours and 20 managed patient cases.

3. Patient pre-operative evaluations are not consistent throughout the document as recommended in resolution 77H-15. (Lines P. 7, 312-322, P. 9, 414-426, P. 8, 397-409, P. 11, 518-550)

TAGD Comment/Recommendation:
There are no risk assessment guidelines in place for minimal sedation patients. While we feel the guidelines should reflect the appropriate patient evaluation for the proposed level of sedation, if a BMI is considered a pertinent medical evaluation consideration, it should also be evaluated for minimal sedation.

4. All references to guidelines for the sedation of children have been deleted. (Lines P. 3, 107-112, P. 8, 389-393, P. 11, 510-514, P. 11, 549-550, P. 13, 627-638, P. 23, 1097)

TAGD Comment/Recommendation:
The proposed revisions contain no ADA guidance on pediatric sedation for the general dentist. All pediatric sedation references have been removed and dentists are referred to AAP/AAPD guidelines. New AAP/AAPD guidelines are yet to be released and public comment on ADA guidelines will end prior to release of the AAPD guidelines. It is the ADA’s responsibility and duty to provide guidance to its members regarding both children and adult patients requiring sedation.

We also strongly feel it is the ADA’s responsibility to define the age of the pediatric patient. In the current AAPD guidelines, the “pediatric” dental patient is up to 21 years of age. As general dentists, we assume it is 12 years of age and under, but feel it should be clarified by the ADA. TAGD would recommend 13 years of age and older as the adult patient when administering enteral and parenteral sedation.

Numerous places in these two documents reference the fact that ADA supports the joint AAP/AAPD Guidelines for sedation of children. Unfortunately, the current AAP/AAPD document does not address recommended CE training for the general dentist. Due to the fact that there are not enough residency trained pediatric dentists to manage all of the children in the US requiring sedation, general practitioners are put into this role. Since there are no guidelines for non-pediatric dentist training in pediatric sedation, states are left to come up with their own requirements. This ranges nationally from full moderate sedation training (60 hours/20 cases) to a two-day weekend course with no clinical experiences to no requirement of training at all. Consequently, we continue to see tragedies in dental offices involving children.
We feel the ADA should specify the course content and clinical learning experience that are adequate for dentists to provide minimal and moderate sedation to pediatric patients in order to set the standard for the profession.

5. “A log of equipment maintenance, including monitors and anesthesia delivery system, must be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.” (P. 7, Lines 334-35, P. 9, Lines 438-39, P. 12, Lines 568-569)

**TAGD Comment/Recommendation:**
There are no established guidelines for frequency of monitor and anesthesia delivery system maintenance, ranging from minimal sedation with nitrous oxide to general anesthesia inhalational equipment. Modern vital signs monitor do not require maintenance. In addition, there needs to be clear guidelines for what would constitute a pre-procedural check.

Thank you again for the opportunity to provide these comments.

Sincerely,

[Signature]

Brooke Elmore, DDS, FAGD
Texas Academy of General Dentistry
Advocacy Council Chair

Cc: TAGD Executive Committee
July 1, 2016

Dr. Daniel J. Gesek, Jr., Chair  
Council on Dental Education and Licensure  
American Dental Association  
211 East Chicago Avenue  
Chicago, IL 60611

Dear Doctor Gesek:

As a member of the community of interest, the American Dental Society of Anesthesiology (ADSA) appreciates the opportunity to respond to the Call for Comments requested by the American Dental Association’s Council on Dental Education and Licensure (CDEL) regarding the ADA’s Guidelines for the Use of Sedation and General Anesthesia by Dentists and the ADA’s Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. The ADSA feels overall, that the proposed revisions of both documents are sensible, clear, and the framework is sound. We are especially appreciative of the committee’s efforts to clarify the topics concerning moderate sedation education and strongly support the revisions relative to training requirements for moderate sedation. Furthermore, while we believe the evidence presented by CDEL for requiring capnography during moderate sedation as practiced in dentistry is only marginally supportive, we believe it is prudent to monitor end-tidal CO₂, particularly when verbal communication with the patient is not possible, to help ensure patient safety.

The ADSA has concerns with a few of the suggested revisions. In the interests of time and space we have not addressed all of our concerns in this document, but instead have focused on several specific recommendations the ADSA believes are the most critical for your consideration. They are as follows:

1. Lines 23-25: The ADSA continues to be concerned with the absence of appropriate training guidelines for the sedation of children 12 years and younger by dentists not residency trained in pediatric dentistry or deep sedation/general anesthesia. The absence of these guidelines in both this document as well as the AAP/AAPD document, which the ADA Guidelines reference for pediatric sedation, leaves regulatory agencies with little guidance in formulating regulations which protect children in this age bracket while still allowing adequate access to care. We respectively request that CDEL revisit this issue to establish sedation training criteria for sedation of children with the full participation of the communities of interest in dentistry, particularly the pediatric dental community.

2. Lines 468-479, 595-597, 614-615: The ADSA is also very concerned regarding differing standards of ventilation monitoring present between the proposed ADA Guidelines and the recently released Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Diagnostic and Therapeutic Procedures: Update 2016 produced jointly by the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry.
(AAPD). The proposed ADA guidelines for monitoring ventilation during moderate sedation, which require capnography, are at odds with the just published AAP/AAPD guidelines which require ventilation monitoring only when bidirectional verbal communication is not possible. In this circumstance, capnography is preferred but monitoring of breath sounds is also acceptable. The differences in the two standards can only lead to confusion for patients, regulatory agencies and practitioners. There must be only one unified guideline for sedation and anesthesia care for all of dentistry. An effort at consensus must be undertaken by CDEL and AAPD to ensure consistency between both guidelines and help ensure patient safety.

3. Lines 334, 438, and 568: The ADSA believes these lines requiring maintenance logs and calibration are too prescriptive. We suggest the following language be substituted: "Documentation of compliance with manufacturer's recommended maintenance of monitors, anesthesia delivery systems and other anesthesia related equipment should be maintained."

4. Lines 448-449: The ADSA believes that requiring a secure intravenous access site is neither necessary nor practical during parenteral sedation involving solely intramuscular or intranasal drug administration. We also recognize that not all dentists trained in intramuscular and intranasal parenteral sedation are fully adept at intravenous access. Therefore, we recommend this line be re-written to read: "When parenteral sedation is administered, intravascular/intraosseous access should be available until the patient meets discharge criteria."

5. Lines 397-409 and 518-530: The ADSA continues to believe that consistency and clarity help ensure patient safety. For this reason, we believe the sections discussing patient evaluations for moderate sedation and deep sedation/general anesthesia should read the same for consistency. This would require language concerning review of NPO status be placed into the section on moderate sedation.

The ADSA is grateful for the opportunity to comment and recommend possible changes to the ADA’s Anesthesia Guidelines documents and would be happy to discuss any questions with the Council at their convenience.

Sincerely,

Kenneth L. Reed, DMD
Kenneth L. Reed, DMD
President, ADSA
Dr. Sarrett,

First of all, let me thank the Anesthesia Committee for taking the time to review and propose updates to the 2012 ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. The safe and effective use of sedation and anesthesia is an important part of dental care, and patient safety is paramount in the provision of that care. Guidelines supported by sound science are a useful aid in protecting our patients.

I am writing these comments with the intent of asking questions about the proposed changes to the anesthesia guidelines. My purpose is to help clarify the intent and language of the update to the current 2012 guidelines so that discussion in Reference Committees and on the floor of the HOD is kept to a reasonable minimum. By providing these comments now, it is hope that this will help to address that purpose. I am not making any judgement, but only trying to clarify to the reader of these documents what the statement is intended to mean. Thank you for this opportunity to comment.

First of all there appears to be two different deadlines for comment. These do not have line numbers, but appear on pages 2, 3 and 17 listing July 4, 2016 and July 15, 2016. This may lead to confusion as to just when the guidelines are actually due.

I believe a written explanation of why the 2012 Guidelines are being used rather than the 2015 Resolution language would help in answering a number of questions between now and the HOD. While the anesthesia committee has shared this with me on our conference call June 26, 2016, other communities of interest may not be aware. Communication from the committee in my opinion can not be overdone.
1. It appears that there is an acceptable option to NOT utilize capnography in certain situations. ("The dentist must observe chest excursions continually. 467 • The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO2 unless precluded or 468 invalidated by the nature of the patient, procedure or equipment. In addition: ventilation should be 469 monitored by continual observation of qualitative signs, including chest excursion and auscultation of 470 breath sounds with a precordial or pretracheal stethoscope. This can be accomplished by auscultation of 471 breath sounds, monitoring end-tidal CO2 or by verbal communication with the patient.") And later: ("Intubated patient: End-tidal CO2 must be continuously monitored and evaluated. 594 • Non-intubated patient: Breath sounds via auscultation and/or end-tidal CO2 must be continually monitored and evaluated unless precluded or invalidated by the nature of the patient, procedure, or equipment. In addition, ventilation should be monitored and evaluated by continual observation of 597 qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.") To me, this is not a mandate as much as a strong recommendation. In my opinion, at least one example of what sort of circumstance would allow for not using the capnography would be helpful to the reader. A similar situation exists for BP monitoring in lines 476-478.

2. Also on the opening page: To state that there should be no difference in training requirements for oral or IV moderate sedation, and then to allow different training methods does not seem to be an accurate statement. I think what is meant is that the training should assure the ability of the provider to recover a patient who has an airway issue or goes into a deeper level of sedation than intended. If a dentist who chooses to only provide oral sedation never does an IV case during training, and a dentist who chooses to provide IV cases does no enteral cases during training, they will not have had the same training. Confusion may result in using the proposed statements. Lines 1362-1372: ("Moderate Parenteral Sedation Course Duration and Documentation: 1362 The Course must include: 1363 • A minimum of 60 hours of instruction plus administration of sedation for at least 20 individually managed patients. 1364 • Certification of competence in moderate sedation technique(s). 1365 • Certification of competence in rescuing patients from a deeper level of sedation than intended including 1367 managing the airway, vascular access and reversal medications. 1368 • Provision by course director or faculty of additional clinical experience if participant
competency has not been achieved in time allotted. Records of instruction and clinical experiences (i.e., number of patients managed by each participant in each modality/route) that are maintained and available for participant review.

4. Personal communication on the conference call June 26, 2016, Dr. Gesek stated that there was no directive on whether the cases were enteral or IV, or in other words all cases could be one or the other, or a combination—that it was up to the individual dentist to determine. I infer that it could also include enteral/inhalation, IV/inhalation as well, and the committee may choose to clarify this distinction too. A detailed clarification of what is allowed and what is mandated would in my opinion be helpful to the reader of these documents. I think the informed reader might also question whether or not the same number of hours would be required to become educated and competent on enteral only moderate sedation techniques versus IV moderate sedation techniques. In my opinion an equal amount of instruction to become competent in rescue methods whether enteral or IV is reasonable and a separate competency.

3. While I understand that sedation is a continuum, lines 64-67 when compared to lines 118-120, do not appear to be clinically different by these descriptions. There seems to be no descriptive differentiation between minimal sedation and moderate sedation. Clarification of the difference would be helpful to the readers and instructors of these documents.

4. What about medical emergencies that may arise that are not the consequence of treatment but occur during anesthesia/sedation administration? Perhaps "during the course" instead of consequence should be considered. (Lines 734-735)

5. Additional sources of information should be listed as to location for the convenience of the reader and completeness of the document. (Lines 485, 647-648, 1414-1415)

6. In my pharmacology classes, dose is individually dependent upon many factors, including body size and liver and kidney function among others. Arbitrary definition of moderate sedation based on exceeding the MRD only does not seem pharmacologically reasonable in all circumstances. Can you explain? At the face of it, this seems appropriate for the 70 Kg Goodman and Gilman patient, but somewhat arbitrary to not allow for patient variability. (Lines 816-817)

7. So from the October 2014 ASA Definitions and Examples—Moderate disease is not in this list. Moderate disease that is well controlled would be considered ASA II? (Lines
951-959). For example, hypertension is classified as pre, stage 1, & stage 2. Higher than stage 2 I would consider severe. If a patient without medication is stage 2, and controlled to stage 1, then they would be ASA II?

8. This update course definition would seem to not allow those "grandfathered" in by previous training and experience to update their skills, since they have not all had the stated training described in these proposed guidelines. (Lines 986-990)

9. It seems reasonable to expect that the level of certification and training of the instructor or director of a training program be at least equal to the level of training of being taught. This is not the same for minimal sedation training course directors (trained at moderate level or higher) as it is for moderate sedation training course directors (trained at moderate level or higher). (Lines 1182-1186, 1394-1399). Why the difference required?

In summary, let me thank you again for taking on the task of updating the anesthesia guidelines. It is a necessary and significant undertaking. I hope that you will find these comments and questions helpful in finalizing the recommendations of the committee.

Sincerely,

Rickland G. Asai
Michael J. Hoffmann, DDS  
The Dental Anesthesia Center  
950 Francis Place Suite 305  
St. Louis, MO  63105

Dr. Daniel J Gesek, Jr. Chair  
Council on Dental Education and Licensure  
American Dental Association  
211 East Chicago Avenue  
Chicago, IL  60611

Re: Propose revisions to Sedation Guidelines

Dear Council;

I strongly support the proposed changes in the Sedation Guidelines for Use and Teaching. They are long overdue.

There has never been, to my research, an adult oral sedation death in a dental office until someone proposed a multiple oral dosing technique and began teaching it nation wide. Since approximately 2005, there have multiple oral sedation deaths in the United States. In the St Louis area there has been two deaths that I have provided expert opinion. Currently, I am involved in two enteral sedation death cases outside my state. One is a a 20 year old male in the Atlanta area and the other is an elderly male in Alabama. Both deaths were very preventable. Both patients that died in St Louis and the patient that died in Atlanta received flumazenil. Very few deaths and accidents make the news or are disclosed to the public.

These deaths were due to several factors

1. An unpredictable sedation technique
2. Education and certification by dentists with no formal training in sedation.
3. Providing a sedation technique that has been poorly researched. However, one study on the technique points out that the patients are being sedated to levels deeper than intended.
4. Use of and dependence on reversal agents in a manor which has been shown to produce poor outcomes. Too much emphasis has been placed on reversal agents by many of these instructors. The entire emphasis should be on prevention and keeping patients verbal. If a patient becomes unresponsive, airway management should be key and not reversal agents.

Most of the deaths that occurred in these states were already in violation of state laws. The problem begins with the training and the misinformation that is being presented.

The use of Capnography is a “no brainer”. I have been using Capnography for all level of sedation and anesthesia for years. Capnographs are now available for as little as $600.00. The
cost of disposable is negligible. When considering the capnograph vs the pretracheal stethoscope, the stethoscopes use is limited during dentistry due to background noise of the dental handpiece and ultrasonic scaler. Data is easily captured using the disposable tip for a flowable syringe place through the side of a nasal hood connected to the capnograph tubing. Assistants can be easily taught how to read the capnograph in less than an hour.

I strongly support the amendments to the Sedation Guidelines. Thank you for reaching out to the membership for input.

Sincerely,

Michael J. Hoffmann, DDS, FAGD, FICD, FACD
Diplomat, American Dental Board of Anesthesiology
Diplomat, National Dental Board of Anesthesiology
July 4, 2016

Dr. Daniel J. Gesek, Jr., Chair
Council on Dental Education and Licensure (CDEL)
American Dental Association (ADA)
211 East Chicago Avenue
Chicago, IL 60611

RE: Comment of the Academy of General Dentistry (AGD) on Proposed Revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (the “Sedation Guidelines”)

Dear Dr. Gesek,

On behalf of the AGD, I am pleased to present the following written comments in response to CDEL’s Proposed Revisions to the ADA Sedation Guidelines. All page and line numbers referenced herein refer to the page and line numbers of the Proposed Revisions.

In this letter, we address those proposed revisions that will likely be of the greatest adverse impact to general dentists and their patients. Our decision not to address some of the other proposed changes at this time does not necessarily constitute AGD’s acceptance of those changes.

_____________________________________________________________________________________

The mandate for monitoring end tidal CO2 for moderate sedation
Page 9, Lines 444-445; and Page 10, Lines 468-472

_____________________________________________________________________________________

NOTE: Per 2015 Resolution 77H-2015, the ADA HOD had requested CDEL, in collaboration with the Council on Scientific Affairs, to consider:

Elimination of the mandate for monitoring end tidal CO2 for moderate sedation to allow for the choice of options such as: continuous use of a precordial or pretracheal stethoscope, continuous monitoring of end tidal carbon dioxide, and continual verbal communication with the patient.

In its response to the ADA’s request, CDEL states:

Per a detailed report by the ADA Science Institute on two systematic reviews, the Council continues to support its proposed mandate for monitoring end-tidal CO2 during moderate sedation. [Lines 468-472 and 595-598].

CDEL cited lines 595-598 in error, as lines 595-598 are in the Deep Sedation and General Anesthesia section, not the Moderate Sedation section.

**AGD Recommendations:**

1. Revise Page 9, Lines 444-445 as follows: “The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available;”
2. Continue to retain Page 10, Line 465 (“Oxygen saturation must be evaluated by pulse oximetry continuously”); and
3. Revise Page 10, Lines 468-472 as follows: “The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment. In addition, should monitor ventilation should be monitored by continual observation of qualitative signs, including chest excursion and auscultation of breath sounds with a precordial or pretracheal stethoscope. In addition, the dentist may monitor ventilation and/or breathing by monitoring end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment.

**Rationale:**

I. Systematic reviews fail to support an end-tidal CO₂ requirement for moderate sedation

The two systematic reviews referenced by CDEL, CSA, and the ADA Science Institute, do not support a mandate for end-tidal CO₂ during moderate sedation in an open airway system.

The ADA Science Institute produced additional meta-analyses with the stated intent of “updating” the two reviews with its own findings, in an effort to manufacture supporting data that did not exist in the reviews themselves. However, these new meta-analyses fail to cure the shortfalls of the original systematic reviews, Waugh et al. (2011) and Conway et al. (2016).

**Waugh et al. (2011)**

Waugh et al. (2011) was authored by Drs. Epps and Waugh, consultants for Oridian Capnography, Inc., “a manufacturer of capnography devices.”

The most important point to note about Waugh et al. (2011) is that it only assessed whether capnography added value to pulse oximetry and/or visual inspection alone. It does not compare capnography to precordial or pretracheal stethoscopes or other modalities of monitoring ventilation or depressed respiration.

Note that Waugh et al. (2011) stated as follows as its conclusion:

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2 Id. at 189.
Capnography is an important addition to pulse oximetry in detecting respiratory depression during procedural sedation. There is no support for substituting pulse oximetry for traditional monitoring of respiratory depression such as capnography, and doing so could be dangerous, especially when supplemental oxygen is used.\(^3\) [Emphases added]

**Waugh did not purport to include, explore or render any finding with respect to whether capnography provided any benefit in comparison to use of a precordial or pretracheal stethoscope.**

Stated more broadly, the purpose of Waugh was really to assess whether monitoring oxygen saturation was enough, or whether it needed to be supplemented with monitoring of respiratory depression (“such as” capnography).

**This is not the issue that the ADA House of Delegates had asked CDEL to evaluate, per Resolution 77H-2015, when it asked CDEL, along with CSA, to explore a choice of options including the use of a precordial or pretracheal stethoscope or a capnograph, among other choices, to monitor respiratory depression. Comparison to oxygen saturation (pulse oximetry) alone was never at issue per Resolution 77H-2015, as pulse oximetry was already an independent requirement in a different section (Page 10, Line 465) of the Sedation Guidelines, and was not at issue here.**

The ADA’s Science Institute’s “Update of Waugh et al. (2011)” also fails to compare capnography with other ventilation or respiratory depression monitoring techniques. CDEL conveniently glosses over the glaring failure by simply stating that, as in Waugh, the ADA’s “update” compares use of capnography in addition to “standard monitoring” versus “standard monitoring” alone. It fails to mention that, by “standard monitoring,” it means pulse oximetry and visual inspection, not methodologies of monitoring ventilation and respiratory depression such as a precordial or pretracheal stethoscope.

While neither Waugh nor its “update” addresses precordial or pretracheal stethoscopes as an alternative to capnography, the American Dental Society of Anesthesia (ADSA) did! ADSA stated in a letter to CDEL, dated January 6, 2015:

> Because moderate sedation does not require the presence of a second assistant, visual changes in an end tidal CO2 waveform might escape detection in the absence of such an individual dedicated to continuously observing the monitors. Conversely, the ADSA believes that for moderate sedation, a precordial/pretracheal stethoscope can be a highly useful and reliable monitor, because it provides instantaneous feedback regarding the presence or absence of breath sounds, which in many instances may make it more practical than end tidal CO2 (capnography). Therefore it is our recommendation that either a precordial/pretracheal stethoscope or capnography should be acceptable options to monitor ventilation on patients undergoing moderate sedation.

A precordial or pretracheal stethoscope remains an equal if not better option to a capnography for moderate sedation.

\(^3\) Id. at 194.
Conway et al. (2016)⁴

Conway is a current 2016 systematic review and meta-analysis that recommends AGAINST mandating capnography at this time. Specifically, Conway found as follows:

Future research might confirm whether or not a benefit of capnography applies more generally to sedated patients and what mechanisms mediate any [adverse] effects. Such research should precede recommendations that capnography becomes mandatory for sedated patients.⁵ [Emphasis added]

The adverse effects of capnography noted by Conway include “premature stimulation of the patient in response to hypoventilation [which] may be counterproductive and result in inadequate sedation” and “numerous clinical irrelevant physiological alarms [that] can lead to ‘alarm fatigue,’ which has been associated with deaths resulting from delayed responses to clinical deterioration.”⁶

Moreover, due to risks of bias in the studies used and statistical heterogeneity, Conway restricted its findings to “three similar trials that sedated participants during colonoscopy with propofol while supplying supplemental oxygen.”⁷ Emphasis added.

Accordingly, Conway further cautioned:

The evidence for an effect of capnography was limited to adults sedated with propofol: we do not know whether these results would be replicated for children or patients sedated with other drugs, such as benzodiazepines and opioids, which are being investigated in one ongoing trial [23]. Further research should also determine whether capnography reduces hypoxaemia in sedated patients receiving supplemental oxygen flow in excess of three litres, which, in the authors’ experience, is typical for sedated patients who can tolerate an oxygen mask. Researchers should concentrate on blinding interventions to limit bias and increase confidence in the effects of capnography for sedated patients.⁸

With Conway et al. (2016) expressly recommending AGAINST a capnograph mandate, CDEL appears to have sought other means to satisfy the demands of its pro-capnograph constituents.

Accordingly, CDEL, working with the ADA Science Institute, produced an “Update of Conway et al. (2016).” However, the new meta-analysis of the ADA Science Institute is not an update to Conway, but, rather a new meta-analysis that in no way invalidates or presupposes Conway’s 2016 recommendation against a capnograph mandate.

The new meta-analysis is comprised of eight studies, four of which were also included in Conway at al. Two studies used in Conway were excluded in the new meta-analysis, while four additional studies which were available but not included in Conway were included in the new meta-analysis. With CDEL

⁵ Id. at 452.
⁶ Id. at 450.
⁷ Id. at 451.
⁸ Id. at 454.
making available only a brief paragraph of the findings of its new meta-analysis, it is unclear as to how the inclusion and exclusion criteria of the new meta-analysis differed from that of Conway et al. (2016).

Moreover, the ADA Science Institute’s new meta-analysis does not meet the criteria recommended by Conway et al. (2016) for future research that would be necessary before consideration of a capnography mandate. First, Conway recommended research on “whether or not a benefit of capnography applies more generally to sedated patients” and “what mechanisms mediate any [adverse] effects” as a prerequisite to any consideration of a capnography mandate. Second, Conway recommended exploring the effects of other medications, as well the effects of supplementing oxygen. The new meta-analysis did neither. Instead, the ADA meta-analysis used similar patients using similar medical procedures, and entirely disregarded any analysis of adverse effects. The CDEL / ADA Science Institute’s meta-analysis simply picked different studies to claim the results it wanted.

Therefore, the ADA’s meta-analysis is not an update on Conway, but rather a new work product that requires peer-review before consideration. Even in the limited summary of the new meta-analysis released by CDEL, one can begin to see some potential errors or inconsistencies; for example, in stratification by hypoxemia definition, Slagelse et al. (2012) is categorized by the ADA’s new meta-analysis as having defined hypoxemia as $S_PO_2$ under 93%, but Conway et al. categorized the same study as having defined hypoxemia as $S_PO_2$ under 92%. While this inconsistency or error was unlikely to have materially affected the results, it underscores the need for thorough peer-review and circulation of ADA’s new meta-analysis among communities of interest before it can be considered. At a minimum, it certainly does not impeach or replace Conway et al. (2016), which recommended specific other research before considering a capnograph mandate.

II. Capnographs produce false-positives in an open airway system

Even with continuous observation, the use of a capnograph has long been known to be inaccurate under a number of conditions. Capnographs produce inaccurate data when either atmospheric air or $O_2$ administration dilute the expired $CO_2$, or when the patient is a mouth-breather.9

Additionally, a clinical trial presently underway to compare the administration of intravenous conscious sedation with or without use of a capnograph, states, “Studies from other settings where sedation is practiced suggest that an additional monitor with capnography facilitates early detection of depressed breathing. However, the results of studies from other medical settings cannot be generalised to dental sedation, because of different techniques used and the types of patients.”10

Clearly, there is a general lack of high-level research regarding enhanced patient safety in a dental setting due to the monitoring of end tidal $CO_2$ during moderate sedation. The implementation of any new standard that may add a cost to the healthcare system must be implemented only when a mass of strong evidence supports the need.

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In light of the concerns expressed above, adding a capnograph requirement at this time is premature, at best. At worst, it is an unsubstantiated onus that shall add to the cost of care, without proven reliability or need for use in moderate sedation.

“Level of sedation is entirely independent of the route of administration”
Page 2, Line 60; and Page 16, Line 745

AGD Recommendation:

Delete the statement, “Level of sedation is entirely independent of the route of administration,” in both the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists (Page 2, Line 60) and the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (Page 16, Line 745).

Rationale:

While the AGD appreciates CDEL’s desire to emphasize that it is possible to achieve moderate or deep sedation to an equal extent by any route of administration, the level of sedation and the route of administration are in-fact NOT “entirely independent.”

By virtue of logic, if the level and route were “entirely independent,” then administration of an equal dose of the same drug for the same amount of time by the same practitioner for the same patient in the same or similar condition should produce the same level of sedation at the same given amount of time after administration, regardless of whether administration was intravenous or enteral.

We know that this is not the case. As Dr. Mark Walker explained on behalf of ADA District XI:

    An orally administered drug is exposed to metabolic clearance mechanisms in the intestine and liver before it gets into the circulatory system. By comparison, an intravenously administered drug is deposited directly into the circulatory system. Factors such as gastric emptying, GI absorption, GI inactivation, first-pass hepatic metabolism and variability in patient response associated with using fixed doses raises patient safety concerns that can only be addressed by having training specific to the route of administration. The argument that “sedation is sedation” simply doesn’t hold true.11

State legislatures, other organizations, courts, and practitioners look to the ADA and its guidelines to understand what may or may not be acceptable in the practice of dentistry. By blanket denial of any and all relationship between the route of administration and the resulting level of sedation, the ADA sends a message that it is okay to ignore clinical differences between the effects of oral absorption and intravenous absorption by the human body.

To exercise in hyperbole merely to add emphasis is a dangerous game, and not one that should be played by an organization held in such high esteem.

**“Moderate Sedation Course Duration” (hours and content) by level of sedation**

*Page 27, Lines 1303-1304 and 1341 Page 28, Lines 1347-1392*

AGD Recommendations:

1. Revise Course Objectives 5 (Page 27, Lines 1303-1304) as follows: “Describe and demonstrate the technique of intravenous access, intramuscular injection and other parenteral techniques (for parenteral moderate sedation courses only).”
2. Revise Moderate Sedation Course Content 15 (Page 27, Line 1341): “Intravenous access: anatomy, equipment and technique (for parenteral moderate sedation courses only).”
3. Reject all proposed revisions to Page 28, Lines 1347-1392, and revert to existing language.

Rationale:

The comments of the AGD address the following CDEL response to ADA HOD Resolution 77H-2015:

>CDEL believes that depth of moderate sedation is entirely independent of the route of administration. Patients who arrive at a level of moderate sedation by an enteral or parenteral route are in the same clinical state. CDEL maintains that moderately sedated patients via either route require the same attentiveness and monitoring. There should be no difference in the training requirements for the routes of administration. CDEL continues to support course duration as 60 hours of instruction plus 20 patient experiences for moderate sedation. [Lines 1362-1365] The Council also proposes several competencies that must be certified by a course director, especially regarding rescue and emergency management. [Lines 1366-1372]

CDEL has simply reaffirmed its position without providing any further evidence in response to ADA HOD Resolution 77H-2015. The proposed revisions continue to impose the course requirements for parenteral sedation upon enteral sedation, increasing hours of instruction for enteral moderate sedation by 250% and cases by 100% (live cases by 667%).

The AGD understands and appreciates the trend toward the regulation of sedation practice by levels of sedation rather than routes of administration. However, when faced with a call to realign very different requirements by routes of sedation, into a singular requirement by level of sedation, the drafter must strive to maintain safety while mitigating costs and the onus to both the practitioner and efforts to improve access to care.

In that vein, CDEL has continued to offer no citation to support any safety need for an increase to the minimal hours of instruction and case experiences for enteral or enteral combination routes to moderate
sedation. As noted by the transcript of testimony provided by ADA District XI on April 20, 2016, “The oral route is inherently the safest route for drug administration.”

Moreover, we continue to be concerned that the revisions actually reduce the requirements upon providers that intend to administer IV sedation. The current guidelines require the administration of sedation to all 20 patients to be by intravenous route, for the purpose of parenteral sedation training. With the proposed language combining enteral and parenteral training, the route of administration for the 20 patients is unspecified, thus allowing administration of IV sedation for just 1 patient, and enteral administration to the remaining 19, to be sufficient for the provider that intends to practice IV sedation. Just as requirements should not exceed the requirements for safety at any additional cost without added benefit, requirements should also not dip below minimal needs of safety. Accordingly, we question the appropriateness of effectively causing up to a 95% reduction in the requirement of using parenteral administration techniques on live patients for training toward parenteral sedation.

Finally, as noted by a number of the written comments and correspondences received by CDEL during March and April 2016, the instances of harm or death to patients subsequent to the administration of sedatives in the dental practice have been due to a failure to comply with the current guidelines, not a deficiency in the guidelines themselves.

On behalf of the AGD, I thank you for this opportunity to provide input on CDEL’s consideration of submission of its proposed revisions to the 2016 ADA HOD. The AGD stands ready to work with CDEL and other ADA councils and committees to thoughtfully and deliberately address any concerns it may have had that led to the proposal of these revisions, as we believe a collaborative evidence-based approach provides a better pathway to consensus.

Sincerely,

[Signature]

W. Mark Donald, DMD, MAGD
President, Academy of General Dentistry

---

Dear Jane,

Please find below my public comment to the resolution.
Do you have an idea of what the 2016 resolution will be called?

Happy 4th of July.

Best,

Dear Council,

For the fourth time in two years, the same proposal to severely limit general dentists in the use of minimal and moderate enteral sedation, for patients who badly need it, is being quietly foisted upon the general dentist community.

In its call for comments and presentations at its April 20th meeting in Chicago, CDEL requested scientific information to support the positions of the communities of interest who were going to comment and present. The proponents of this revised proposal, however, provided nothing to back up their position.

However, sedation dentistry luminaries such as Dr. Raymond Dionne provided peer-reviewed articles, studies, and established research proving that oral sedation as provided by practitioners following the current ADA guidelines is safe and work. Tens of millions of patients have been treated safely, effectively, and without incident under existing ADA guidelines.

Once again, in its revised proposal, evidence-based dentistry is completely ignored by CDEL.

Respectfully submitted,

Michael Silverman

Michael D. Silverman, DMD, DICOI, FCID
**Founder and President**

DOCS Education  
106 Lenora Street  
Seattle, WA 98121  
P: (206) 812-7713  
F: (800) 719-8929  
Email: Michael.Silverman@DOCSeducation.com

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Appended are comments from a member of the Council on Dental Practice regarding proposed revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.

Please let me know if you have any questions.

Thank you,

Pam

Pamela Porembski D.D.S.  porembskip@ada.org  
Director, Council On Dental Practice / Practice Institute  
312.440.7463

American Dental Association  211 E. Chicago Ave.  Chicago, IL 60611  www.ada.org
I am not supportive of CDEL's proposed revisions to the ADA anesthesia guidelines. As you can clearly see by reading the COMMENTS, and if you were at the HOD last year, this is a very divisive issue and should not be taken lightly. The ramifications of this could potentially be detrimental to our membership recruitment and retention. As you may recall during our last CDP meeting, Dr. Gesek informed the Council, during our conference call with CDEL, that CDP would be given the CSA report as soon as it was released to CDEL. To date, CDP has not received this report although CDEL has received this report and moved forward with recommendations supposedly based upon this report. Instead CDEL released the attached "CAPNOGRAPHY REPORT" not the CSA report. By CDEL's own admission in the "Introduction" of this report, CDEL states "it is not clear that such episodes (hypoventilation) are clinically significant or if earlier detection with capnography has an effect on patient outcomes". Further in the report, upon reviewing "STAKEHOLDER RECOMMENDATIONS", AAOMS is the only "stakeholder" group that says capnography should be used in moderate sedation in adults. The American Society of Gastroenterologists states "inadequate data to support routine use of capnography". Furthermore, Page 11 "SUMMARY" of CDEL's report states "the evidence base is limited and there is a need for better designed and conducted studies for more definitive insight about whether and the extent to which capnography improves patient safety for dental patients across the age continuum".

This one statement by CDEL, by itself, is sufficient reason, particularly given the divisive nature of the CDEL recommendation, as to why these recommendations are pre-mature and should not be promulgated by CDEL.

I question that CDEL even fulfilled the mandate put forth to it by the 2015 House of Delegates. The language of Resolution RC 77-2015 clearly mandates that CDEL collaborate with CSA on three (3) bullet points:

1) Elimination of the mandate for capnography
2) Reconsider the section on Moderate Sedation Course Duration, with possible separation of course requirements for enteral and parenteral sedation
3) Making patient evaluations consistent throughout the document including rationale and guidelines for using BMI

In my opinion, and the opinion of other delegates, this adopted resolution calls for evidence that CSA has studied the available science, literature and documentation of all three bullet points and has made appropriate and scientific recommendations to CDEL for their deliberation. To avoid unnecessary time and confusion on the House floor this fall, it is of paramount importance that CSA's findings and recommendations to CDEL be made available to all delegates and that CDEL be transparent.

The documents given to us to date show no evidence of any collaborative effort between CDEL and CSA on any of the three bullet points. CDEL has only given us the "Capnography Report" which shows no evidence of collaboration with CSA. There is no mention of CSA's findings or recommendations within this report.

Given the available evidence, the three documents submitted to us from CDEL, one can only conclude that CDEL has not fulfilled its mandate as set forth by the 2015 House of Delegates.
July 4, 2016

Dr. Daniel J Gesek, Jr., Chair  
Council on Dental Education and Licensure  
American Dental Association  
211 East Chicago Avenue  
Chicago, IL 60611

RE: CSA Response to ADA Anesthesia & Sedation Guidelines Revisions

Dear Dr. Gesek:

The California Society of Anesthesiologists (CSA) greatly appreciates your invitation to provide comments regarding the proposed amendments to the American Dental Association’s (ADA) Guidelines for the Use of Sedation and General Anesthesia by Dentists and ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (Guidelines).

CSA has been on record several times this year by way of California Assembly Bill 2235 (Thurmond), stating that we collectively must do everything in our power to ensure the safest use of anesthesia/sedation to safeguard against the complications and possible adverse events that can result. To that end, we applaud the ADA in taking a leadership role in this area. Specifically, we are supportive of the proposed modifications mandating monitoring for end-tidal CO$_2$; acknowledging depth of sedation is independent of route of drug administration; supporting inclusion of Body Mass Index measurements as part of a pre-procedural workup; and that the ADA Guidelines should focus on adult patients.

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. 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. Additionally, we feel that at all times, at minimum, a second individual solely dedicated to continuously ensuring the adequacy of breath-to-breath ventilation, trained in patient monitoring, is necessary.

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1. *To Err is Human*, Institute of Medicine, 1999
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.” 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 (adults or children) is the administration of succinylcholine, a fast acting muscle relaxant (i.e. paralytic), (listed in Appendix 3, AAP/AAPD guideline4). 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. Please feel free to contact CSA Legislative Advocate Bryce Docherty, at 916-448-2162 or via e-mail at bdocherty@ka-pow.com should you have any further questions or need additional information.

Sincerely,

Mark Zakowski, M.D.
President

cc: Bryce Docherty, KP Public Affairs
David Butler, CSA Executive Director

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Resolution 1

Topic: Patient Safety and Sedation


Author: Mark Zakowski M.D.

Whereas, physician anesthesiologists are the only medical specialty to be singled out for significantly improving patient safety in the 1999 Institute of Medicine report, To Err is Human.

Whereas, physician anesthesiologists continue to innovate and advocate for the highest standards in patient safety.

Whereas, patient safety can be enhanced by adherence to the highest principles and standards.

Be resolved that:
The California Society of Anesthesiologists supports one standard of care on behalf of patient safety across the continuum of care for deep sedation/general anesthesia.

In doing so we affirm:
Patients have a right to the safe administration of sedatives and anesthetics.
Patients have a right to expect a uniform standard of care across the continuum of anesthesia administration, services and locations.
Pharmacologic principles prove that medications administered by any route may interact and/or cause cardiorespiratory depression.
All medications (e.g. sedatives, analgesics, anesthetics, narcotics, etc.), by all routes of administration (e.g. oral, intravenous, inhaled, transdermal, etc.), and patients’ medical history (e.g. obstructive sleep apnea, kidney or liver disease) may have an impact on the resulting level of sedation, individual response to medications, drug interaction(s) and potential for respiratory depression/cardiopulmonary arrest.
Sedation occurs across a continuum of effect, blurring the lines between deep sedation and general anesthesia.

CSA supports use of monitoring based on level of sedation/anesthesia achieved, based upon American Society of Anesthesiologists national guidelines and standards.

Administration and Monitoring for patients’ deep sedation/general anesthesia should follow uniform standards across the continuum of care and according to the national American Society of Anesthesiologists guidelines/standard regardless of location (e.g. hospital based operating room, procedure room, ambulatory surgery center, private physician offices, private dentist offices), in order to maintain the highest standards of patient safety.
July 1, 2016

Dr. Daniel J Gesek, Jr., Chair
Council, Dental Education & Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

Dear Dr. Gesek and Members of the Council:

The American Academy of Pediatrics, California (AAP-CA) representing the over 5,000 California pediatrician members statewide of the four AAP-CA regional chapters, appreciates this opportunity to comment on the American Dental Association (ADA) Council on Dental Education and Licensure’s proposed revisions to the *ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists* (Use Guidelines).

In the request for comment the ADA Council recommends the following:

*The current ADA Guidelines support the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry “Guidelines for Monitoring and Management of Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures.”* ...Because of this reference to and support of the AAP/AAPD Guidelines, coupled with the special circumstances of managing pediatric patients who undergo sedation and anesthesia, the Council is proposing that the ADA Sedation and Anesthesia Guidelines should focus on the adult patient population. Accordingly, the Council is recommending that the remaining references to pediatric patients in the ADA Sedation and Anesthesia Guidelines be deleted.

The AAP-CA appreciates the Council’s acknowledgment of the special circumstances of managing pediatric patients who undergo sedation and anesthesia. So long as (1) the phrase “under age 12” is deleted, as recommended by the Council (so that reliance on the AAP/AAPD guidelines applies to children of any age) and; (2) there is a link to the most recently updated version of the relevant collaborative AAP/AAPD guidelines included in the *ADA Sedation and Anesthesia Guidelines* (see below), the AAP-CA supports the Council's recommendation to move this endorsement to the introduction section and to remove other reference to children from the guidelines under review.

We applaud the ADA’s action to endorse the use of the evidence-based guidelines developed by the American Academy of Pediatric Dentistry and the American Academy of Pediatrics with respect to the monitoring and management of pediatric patients before, during and after sedation.
for diagnostic and therapeutic procedures. The most recent version of those guidelines is available here: Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016.

Thank you for your attention to this important issue and for your leadership in dental health and access to quality dental care.

Sincerely,

Kris Calvin
Chief Executive Officer
American Academy of Pediatrics, California

CC: AAP-CA Leadership, Assemblymember Tony Thurmond
July 4, 2016

Dr. Daniel J Gesek, Jr., Chair
Council on Dental Education and Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

[Submitted via Email: JasekJ@ada.org]

Re: June 2016 Proposed Revisions to the Current Sedation and Anesthesia Guidelines

Dear Dr. Gesek,

The American Society of Anesthesiologists (ASA) appreciates the opportunity to comment on the Council on Dental Education and Licensure’s (CDEL) proposed amendments to the American Dental Association’s (ADA) Guidelines for the Use of Sedation and General Anesthesia by Dentists and ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (Guidelines) that were published on the ADA’s website (http://www.ada.org/~/media/ADA/Education%20and%20Careers/Files/CDEL_ProposedGuidelines_2016June03.pdf?la=en). ASA is a 53,000 member educational, research, and advocacy organization dedicated to improving the medical care of patients and raising standards in the science and art of anesthesiology. Since its founding in 1905, the ASA’s achievements have made it the leading voice and the foremost expert in American medicine on matters of patient safety in the perioperative environment and pain medicine.

On behalf of ASA, I am writing to support these proposed changes. Our comments will address the following revisions within the proposal: end-tidal CO₂, independence of depth of sedation and route of administration, Body Mass Index (BMI) as part of a pre-procedural workup, and removal of pediatric patients from the Guidelines.

I. Mandating End-Tidal CO₂ Monitoring is Appropriate for Dental Patients Undergoing Moderate Sedation

ASA has a genuine concern that individuals, however well intentioned, who are not anesthesia professionals may not recognize that sedation and general anesthesia are on a continuum and thus deliver levels of sedation that are, in fact, general anesthesia without having the training and experience to recognize this state and respond appropriately. ASA’s Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals includes at I.A.8.f. “Capnography – During moderate 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.”¹ ASA’s Standards for Basic Anesthetic Monitoring similarly provide at 3.2.1 “Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated.

¹ Available at http://www.asahq.org/~/media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/statement-on-granting-privileges-for-administration-of-moderate-sedation-to-non-anesthesiologist.pdf
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.*

II. Independence of Depth of Sedation and Route of Administration

ASA’s document entitled Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia* provides in part: “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.”3 While the document provides definitions of the continuum of sedation and anesthesia from minimal sedation (anxiolysis) through general anesthesia, nowhere does the document reference achieving a specific level of sedation or anesthesia by route of administration including oral/enteral. ASA is pleased to see ADA’s Guidelines similarly recognized the independence of the depth of sedation from the route of administration.

III. Body Mass Index (BMI) as Part of a Pre-Procedural Workup

ASA’s Physical Status Classification System4 includes body Mass Index (BMI) among its determinants with ASA II and III. Inclusion of a BMI assessment as part of a pre-procedural workup is highly recommended.

IV. Removal of Pediatric Patients from the Guidelines

ASA supports ADA’s focus on adult patients in these guidelines. Pediatric anesthesia and sedation patients are unique. ASA supports ADA’s recognition of the special considerations that are necessary for this patient population, and that they should be addressed by pediatric specialists. If there are revised guidelines from the American Academy of Pediatrics / American Academy of Pediatric Dentistry, ASA may request the ability to further comment.

As a final note for consideration, ASA is aware of the increasing dialogue concerning operator administered anesthesia. ASA "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" state that "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

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2 Available at [http://www.asahq.org/~/media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/standards-for-basic-anesthetic-monitoring.pdf](http://www.asahq.org/~/media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/standards-for-basic-anesthetic-monitoring.pdf)


monitoring for the patient’s level of sedation is maintained.” Please refer to the complete ASA “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists”5 and ASA “Standards for Basic Anesthetic Monitoring” for more detail.6

Thank you again for the opportunity to provide comments on this important issue. If you have any questions or need additional information, please contact Jason Hansen, M.S., J.D., Director of State Affairs, at j.hansen@asahq.org or by phone at 202-289-2222.

Sincerely,

Daniel J. Cole, M.D.
President

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6 Available at http://www.asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/standards-for-basic-anesthetic-monitoring.pdf
Dear Dr. Gesek:

The American Society of Dentist Anesthesiologists (ASDA) would like to thank the American Dental Association (ADA) for the opportunity to provide comments on the ADA's Council on Dental Education and Licensure's Guidelines on the Use of Sedation and General Anesthesia by Dentists, and Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.

The latest iteration contains many suggestions that the ASDA have already recommended; however, three areas remain that deserve further consideration:

**Line 299, 403 and 406. Preoperative evaluation.**

The current guidelines cite different approaches to preoperative evaluation for minimal and moderate sedation. They should be the same. Minimal sedation providers need to be able to identify and appropriately manage patients that inadvertently progress to moderate sedation.

**Lines 466-472: Ventilation.**

We suggest replacement of the existing wording with: “The dentist must continuously observe chest excursions during the procedure. The dentist must employ multiple monitors of ventilation that may include direct observation of chest excursions, end-tidal carbon dioxide monitoring, auscultation of breath sounds and bidirectional verbal communication with the patient. End tidal-carbon dioxide must be immediately available in all circumstances.”

The ASDA believes separate educational guidelines for moderate enteral sedation and moderate parenteral sedation should be described. While we agree that moderate sedation can be gained or lost through different routes of administration, a significant number of states currently issue sedation permits with regard to route of administration. As a result, a number of educational programs still teach and describe enteral sedation as a distinct practice. We are concerned that policy makers will encounter ambiguity as they attempt to update their sedation permit rules, and would benefit by explicit description of educational guidelines for both practices.

Lastly, the ASDA would like to thank the ADA's Council on Dental Education and Licensure's hard work and your tireless efforts to enhance patients’ safety. We hope our recommendations will assist in your efforts.

Respectfully submitted,

Steve Nguyen DDS
President, American Society of Dentist Anesthesiologists