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

RE: CSA Response to Dental Board of California Subcommittee "Working Document" Regarding the Progress of the Pediatric Anesthesia Study Requested by Senator Jerry Hill

Dear Dr. Morrow:

The California Society of Anesthesiologists (CSA) appreciates the opportunity to comment on the important work that the Dental Board of California has undertaken to review current laws and regulations pertaining to pediatric dental anesthesia. Our first written response dated June 30 provided information to the Subcommittee concerning current standards of care, as delineated in practice guidelines and statements from the American Society of Anesthesiologists (ASA).

In further written response to your letter of June 1, we would like to offer the opinion to the Board that California's present laws, regulations, and policies are *not* sufficient to provide protection of pediatric patients during dental anesthesia.

Anesthesiology is the only medical profession recognized by the Institute of Medicine for implementing patient safety measures and protocols that have resulted in a 50-fold decrease in anesthesia-related deaths, due to physician anesthesiologist efforts.¹ We can offer assistance as the national experts in anesthesia safety, anesthesia medications, clinical monitoring, and airway management during sedation and anesthesia.

We strongly believe that the standard of care regarding sedation and anesthesia services for children must be consistent regardless of the route of administration, and regardless of the presence or absence of an airway device. Children easily pass from an intended level of moderate sedation to an unintended level of deep sedation or general anesthesia, with the potential danger of cardiorespiratory arrest. Therefore, standards of care for personnel, equipment, emergency medications, and monitoring should not differ.

To summarize, we recommend:

- Revision of terminology in California laws and regulations to replace the terms "oral conscious sedation" and "conscious sedation" with the standard terminology of minimal sedation, moderate sedation, and deep sedation/general anesthesia.
- Elimination of the route of administration (oral vs. parenteral) as a distinction among types of sedation permit.
- One standard of care for children undergoing moderate sedation and deep sedation/general anesthesia, to include full respiratory monitoring, and the presence of a second anesthesia provider in addition to the operating dentist or oral surgeon.

1. Terminology

The terminology used in the existing laws, regulations and permits is out of date, specifically in its use of the terms "oral conscious sedation" and "conscious sedation" to refer to all states of sedation other than general anesthesia. As a first step, we recommend revision of the Business and Professions Code, AB 2235 (Thurmond), and all applicable regulations to reflect the current classification of states of sedation and anesthesia. These have been agreed upon by the ASA and by the Centers for Medicare and Medicaid Services (CMS):

- a. Minimal Sedation
- b. Moderate Sedation
- c. Deep Sedation
 - A state of deep sedation is considered to be in most respects identical to general anesthesia by the ASA, by the Dental Board of California, and by CMS.
- d. General Anesthesia

The current categories are described in detail in the recently updated "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016", from the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD).² The full definitions are appended at the conclusion of this letter.

2. Distinction between oral and parenteral sedation

The distinction between oral and parenteral techniques of sedation should be abandoned, in our opinion. All levels of sedation – minimal, moderate, and deep – may be reached with oral medications in sufficient doses as well as with parenteral means. Independent of the medication given, or the presence or absence of an airway device, a patient who responds purposefully only to pain is in a state of deep sedation, and one who does not respond even to pain is in a state of general anesthesia.

Some of the patients in the cases that were reviewed by the Subcommittee suffered adverse outcomes, including death, as a result of oral medications alone. The practice of giving repeated doses of oral medications ("medication stacking") has proved on many occasions to be hazardous, as both the onset and the duration of action may be difficult to predict. We recommend categorization by depth of sedation, not by the route of administration.

3. Revision of existing dental anesthesia regulations for office practice

We strongly recommend the definition of new permit categories to replace those currently in existence, in order to eliminate use of the term "conscious sedation" and to stratify permits by depth of sedation.

Children with significant underlying health problems may not be appropriate candidates for sedation or anesthesia in the dental office setting. This would include ASA Physical Class 3 and 4 patients. Further guidance about the classification of patients as ASA 3 or 4 may be found on the ASA's website, under the heading of Resources (<u>http://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system</u>). In children, these conditions could include (but not be limited to) asthma, enlarged tonsils, obesity, sleep apnea, congenital heart disease, a history of prematurity, significant developmental delay, and abnormal airway anatomy. Such cases should be performed in an ambulatory surgery center or hospital.

We recommend recognition of the fact that children **under 7 years of age** are different from older children, teenagers, and adults in these respects:

• They represent the highest risk of life-threatening complications under sedation or anesthesia due to small airways and reduced physiologic reserve;³

- Those who are unable to cooperate or hold still sometimes referred to as "pre-cooperative" in developmental age – require a deeper level of sedation/anesthesia in order to control behavior and ensure relaxation;
- California law, AB 2003 (1998), already sets the precedent of requiring health plans to pay for anesthesia and associated facility charges when anesthesia is indicated for enrollees under 7 years of age, or enrollees who are developmentally disabled, regardless of age.

Therefore, we recommend creation of **two new categories** of pediatric dental sedation/anesthesia permits for children of pre-cooperative age. This may be defined either as a chronological age under 7, or a child of 7 years or older with a developmental age that renders the child unable to tolerate a dental/oral surgery procedure with local anesthesia and distraction techniques.

A. Minimal sedation for children

The rationale for this category is to preserve access to care for children, otherwise in good health, requiring brief, limited dental procedures in the office setting. Criteria would mandate:

- Meeting all existing requirements of the current "oral conscious sedation for minors" permit;
- Adherence to AAP/AAPD guidelines for monitoring and staffing of cases under minimal sedation;²
- Medication use restricted to nitrous oxide and one dose of a single oral agent;
- No use of halogenated inhalational agents, or of medications administered by the intranasal, rectal, intravenous, or intramuscular route.

B. Moderate sedation, deep sedation, general anesthesia for children

The rationale for including moderate sedation in this category is the recognition that levels of sedation are on a spectrum, and children may progress unpredictably from a lighter to a deeper level of sedation, and into a state of general anesthesia, during the course of a procedure. Criteria would mandate:

- AAP/AAPD guidelines for monitoring, including the use of respiratory monitoring (pulse oximetry, capnography) for all cases whether or not endotracheal intubation is utilized.
- The continuous presence of a second provider **in addition to** the operating dentist or oral surgeon. This individual's sole responsibility would be "to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration," as stated in the AAP/AAPD guidelines.²
- The second provider should be a qualified, licensed, independent anesthesia provider, trained in Pediatric Advanced Life Support (PALS). Qualified providers would include a dentist with appropriate additional training in anesthesia as defined by California law, an oral surgeon, a dentist anesthesiologist, a certified registered nurse anesthetist, or a physician anesthesiologist.
- Performance of a defined minimum number of pediatric cases per year.

It is our belief that implementation of these recommendations would improve safety for pediatric patients undergoing dental procedures, but would not unduly restrict access to care. The literature strongly supports the view that advances in monitoring, continuous practice with pediatric cases, and prompt recognition of high-risk situations have reduced the incidence of cardiac arrest in anesthetized children.³ Adoption of the medical model of documenting and reviewing adverse events and near-misses, as recommended in AB 2235 (Thurmond), may identify system issues. Occasional adverse outcomes tend to reflect system-wide deficiencies, rather than individual misdeeds, and are likely to be amenable to solutions that improve care system-wide.

We look forward to further productive discussion, and again appreciate the opportunity to work with you on this important issue for the health and safety of California children. Please feel free to contact CSA Legislative Advocates Bryce Docherty or Vanessa Cajina, at 916-448-2162 or via e-mail at <u>bdocherty@ka-pow.com</u> or <u>vcajina@ka-pow.com</u> should you have any further questions or need additional information.

Respectfully submitted on behalf of the California Society of Anesthesiologists,

Sincerely,

Murk Jakundri Mo

Mark Zakowski, MD President

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

References:

- 1. To Err is Human: Building a Safer Health System. Publication of the Institute of Medicine, National Academy Press, November, 1999.
- Cote CJ, Wilson S. American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. Pediatrics 2016; 138(1): e20161212.
- 3. Morray, JP. Cardiac arrest in anesthetized children: recent advances and challenges for the future. Pediatric Anesthesia 21 (2011) 722-729.

Definitions for levels of sedation and anesthesia:

- a. **Minimal Sedation**: a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, breathing and cardiovascular functions are unaffected.
- b. **Moderate Sedation**: a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- c. **Deep Sedation**: a drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully after repeated verbal or painful stimulation. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may readily pass from a state of deep sedation to the state of general anesthesia.
- d. **General Anesthesia**: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilation is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required. Cardiovascular function may be impaired.