Since spring 2016, the Dental Board of California (Board) has been conducting research into whether or not California's present laws, regulations, and policies are sufficient to provide protection of pediatric patients during dental sedation.

The Board released its working document July 21, 2016, and conducted outreach to stakeholders and the public, including a public workshop held on July 28, 2016 in Sacramento, an invitation to submit comments, and opportunity for comment at a full board meeting held in Sacramento on Friday August 19, 2016.

Since that time, the Board has received numerous comments on the issue of pediatric sedation and anesthesia. The subcommittee has now received sufficient input to make preliminary recommendations.

After carefully weighing the available options, the subcommittee recommends the following:

1. The board should continue to research the collection of high quality pediatric outcomes data to inform decision making.

2. Update definitions of general anesthesia, conscious sedation, pediatric and adult oral sedation for consistency with the definitions of minimal sedation, moderate sedation, deep sedation, and general anesthesia.

3. Restructure the dental sedation and anesthesia permit system.
   a. General anesthesia/deep sedation
      i. Educational requirements for a general anesthesia permit: – completion of a minimum of one year of Commission on Dental Accreditation (CODA) approved advanced residency training that provides competency in the administration of general anesthesia. (existing)
         1. Monitoring to include P/BP/pulse oximetry/precordial stethoscope/ECG and capnography. (done, but not required)
         2. A minimum of two staff members shall be present, with at least one trained in monitoring and resuscitation of sedated patients, who shall be dedicated solely to monitoring the patient. (done, but not required)
         3. Completion of training in adult advanced life support or an equivalent course as determined by the board, plus additional hours of anesthesia related continuing education per renewal. (existing)
4. Permit holders treating patients under the age of 13 shall be required to complete education in pediatric advanced life support as determined by the board. (new)

ii. Additional requirements for a general anesthesia permit holder to treat patients under age 7: (new)
   1. Completion of an appropriate number of hours of education related to pediatric anesthesia as determined by the Board.
   2. Documentation of a sufficient number of cases for children under age 7 for an initial application and for each permit renewal.
   3. The holder of an age restricted (no patients under age 7) general anesthesia permit, may administer general anesthesia to patients under the age of 7 under the supervision of the holder of an unrestricted general anesthesia permit.
   4. Supervised cases shall be submitted to the board as documentation to allow an age restricted anesthesia permit holder to qualify for an unrestricted general anesthesia permit.

b. Moderate sedation (new)
   i. Adult moderate sedation permit requirements for administration of moderate sedation by any route to patients age 13 or older.
      1. Education – completion of course of instruction plus a sufficient number of clinical cases consistent with ADA Guidelines. (existing)
      2. Monitoring to include P/BP/pulse oximetry/precordial stethoscope/ECG and capnography when feasible.
      3. A minimum of one staff member trained in the monitoring and resuscitation of sedated patients must be present.

   ii. Pediatric moderate sedation permit requirements – for the administration of moderate sedation by any route to patients under age 13. (new - adds requirements for patients under age 13)
      1. Education – completion of a course of instruction plus a sufficient number of clinical cases for pediatric patients under age 13, or completion of equivalent training (i.e. a pediatric dental residency or other advanced residency program) as determined by the board.
      2. Monitoring to include P/BP/pulse oximetry/precordial stethoscope/ECG and capnography whenever feasible.
      3. A minimum of one staff member trained in the monitoring and resuscitation of pediatric patients must be present.
4. Continuing education related to pediatric sedation for renewal, including pediatric advanced life support training or equivalent as determined by the board.

c. Pediatric Minimal Sedation – required for oral minimal sedation of patients under age seven (7). (new section)
   i. Education – similar to current pediatric oral conscious sedation permit requirements- (instruction in pediatric sedation plus one clinical case; training in airway management and patient rescue from moderate sedation.)
   ii. Administration limited to a single dose of a single sedative drug, plus nitrous oxide and oxygen that is unlikely to produce a state of unintended moderate sedation.
   iii. A single additional dose of the initial drug may be necessary for prolonged procedures. The additional dose should not exceed one-half of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed.
   iv. Monitoring to include BP/Pulse oximetry/precordial stethoscope (existing)
   v. A minimum of one staff member trained in the monitoring and resuscitation of pediatric patients must be present. (existing)
   vi. Continuing education related to pediatric sedation per renewal period, plus basic life support training. (existing)

4. Update requirements for records and equipment to include the following:
   a. Age and size appropriate equipment must be available for all patients.
   b. Body mass index (BMI) should be recorded as part of the preoperative evaluation.
   c. Documentation that pre operative instructions, including fasting instructions appropriate for the planned level of sedation, have been given to the patient, escort, parent, or guardian.

5. Collect data that will allow the future study and reporting of dental sedation and anesthesia outcomes.
   a. 1680 (z) reports should include detailed information in a format suitable for an electronic database.
   b. Require sedation and anesthesia permit holders to report, at time of permit renewal, their annual number of administrations of minimal, moderate, and deep sedation/general anesthesia, and other parameters to be determined.

6. Improve the Dental Board’s onsite inspection and evaluation program.
   a. Use a single evaluator (rather than current two) under specified circumstances for routine renewal evaluations.
b. Seek authority to require completion of specific remedial education prior to reissuance of a permit following an evaluation failure.

The subcommittee recognizes that few topics generate more controversy than the use of anesthesia, especially in children, and that no proposal will satisfy all interested parties. Although patient safety is always the foremost concern, the effects of regulatory change on healthcare can be fraught with unintended consequences. Any proposal should, therefore, strike a balance between established practice and evidence based changes that have a reasonable chance of improving outcomes.

The Board will be discussing these preliminary subcommittee recommendations at the October 13, 2016 meeting being held in Sacramento. All persons are encouraged to comment in person and/or in writing. Written comments should be directed to the Board at 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815 or via email Karen.Fischer@dca.ca.gov and should be received before close of business on October 28, 2016 in order to be considered in the final report.

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**Definitions for levels of sedation and anesthesia:**

- **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.

- **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.

- **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.

- **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.
Continual monitoring of ECG and for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. When not used, it should be so stated (including the reasons) in a note in the patient's medical record.