Caleb's Law

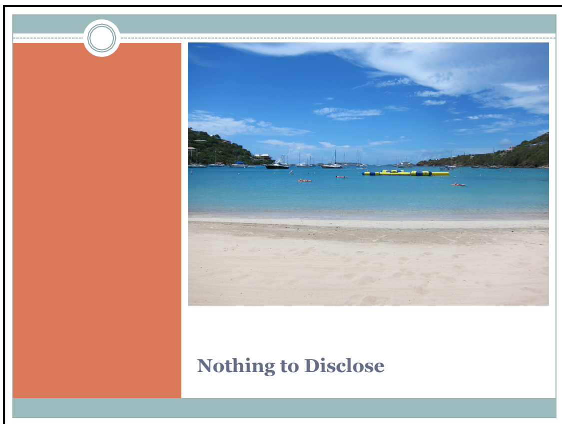
MICHAEL MASHNI, DDS
DENTIST ANESTHESIOLOGIST

NEW JERSEY DENTAL SOCIETY OF ANESTHESIOLOGY
WEDNESDAY OCTOBER 3, 2018

Disclosures

- President, American Board of Dental Specialties
- President Elect, Tri-County Dental Society
- Past President, American Society of Dentist Anesthesiologists

- I am not representing or speaking on behalf of any of these past/present positions



Nothing to Disclose

calebslaw.org

- March 13, 2015

- 6 y/o Healthy boy

- Removal of mesiodens under general anesthesia

AB2235

- 2016 legislative session
- Prompted by treatment of Caleb Sears

- Sought to ban operator anesthesia for deep sedation and general anesthesia

AB2235

Support	Opposition
• American Academy of Pediatrics – California • California Society of Anesthesiologists • American Society of Dentist Anesthesiologists	• California Dental Association • California Association of Oral and Maxillofacial Surgeons • California Society of Pediatric Dentistry*****

AB2235

- Requirement in Consent Form
- Dental Board to Study pediatric anesthesia outcomes
  - Dental Board meeting had a presentation on using Pediatric Sedation Research Consortium led by Joe Cravero, MD
- Dental Board to establish a committee to study Pediatric anesthesia

CA B&P Code 1682(2)

- The written informed consent, in the case of a minor, shall include, but not be limited to, the following information:
- "The administration and monitoring of general anesthesia may vary depending on the type of procedure, the type of practitioner, the age and health of the patient, and the setting in which anesthesia is provided. Risks may vary with each specific situation. You are encouraged to explore all the options available for your child's anesthesia for his or her dental treatment, and consult with your dentist or pediatrician as needed."

AB 2643 Proposed Changes

- "The administration and monitoring of general anesthesia may vary depending on the type of procedure, the type of practitioner, the age and health of the patient, and the setting in which anesthesia is provided. Risks may vary with each specific situation. You are encouraged to explore all the options available for your child's anesthesia for his or her dental ~~treatment, including nonsurgical treatment options,~~ *treatment* and consult with your dentist or pediatrician as ~~needed."~~ *needed. You are further encouraged to consult with your dentist on all of the nonsurgical dental treatment options available that may reduce, delay, or eliminate the need for* anesthesia *for surgical dental treatment prior to granting this consent."*

Senator Jerry Hill

California Legislature

SENATE COMMITTEE ON BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT

SENATOR JERRY HILL, CHAIR

DBC Pediatric Study

PEDIATRIC ANESTHESIA STUDY

DECEMBER 2016

DENTAL BOARD OF CALIFORNIA

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

AAP/AAPD Guidelines

- http://www.aapd.org/media/Policies_Guidelines/BP_MonitoringSedation.pdf

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

Developed and Endorsed by
American Academy of Pediatric Dentistry and American Academy of Pediatrics
Latest Revision*
2016

AAP

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®
AMERICAN ACADEMY OF PEDIATRICS, CALIFORNIA

American Academy of Pediatrics, California
921 11th Street, Suite 1100, Sacramento CA 95814
Phone (626) 796 1632 | **Fax** (626) 628-3382
Email office@aap-ca.org | **Website** www.AAP-CA.org

March 23, 2017

The Honorable Rudy Salas
Chair, Assembly Business and Professions Committee
State Capitol Room 2188
Sacramento, CA 95814
Fax: (916) 319-2132

RE: AB 224 (Thurmond): Dental Anesthesia and Children
AAP-CA Position: SPONSOR

Dear Chairman Salas:

The American Academy of Pediatrics, California (AAP-CA), representing over 5,000 California pediatricians, strongly supports proposed legislation AB 224 (Thurmond). This bill would increase the safety of administering anesthesia and sedation to children in outpatient settings by requiring the implementation of the California Dental Board's recommendations regarding safe access to dental anesthesia for children, including (among others) that a general anesthesia permit holder, separate from the operating dentist, be present when a child under age 7 undergoes general anesthesia or deep sedation. The bill would also update the permit structure for dental sedation and anesthesia in California and the definitions of sedation and anesthesia contained within California statue in order to conform with modern terminology.

The mission of the AAP-CA is to protect and promote the health and well-being of all children and youth living in California. **Pediatricians have no financial interest in who administers and monitors anesthesia in a dental office—our interest stems solely from our mission to protect and promote children's health and well-being.**

The American Academy of Pediatrics, in conjunction with the American Academy of Pediatric Dentistry, has published national guidelines that set a standard of care for children undergoing sedation and anesthesia for dental procedures. These guidelines recognize that young children "are particularly vulnerable to the sedating medication's effects," including its rare but dangerous side effects. Their airways are smaller, and they need more anesthesia in order to remain still during painful procedures. Due to this increased vulnerability, the guidelines call for a second qualified provider to be solely dedicated to the task of administering and monitoring a child during deep sedation and general anesthesia, as in every other health care profession in California. **The standard of care is no longer the single operator-anesthetist model** in which the operating surgeon takes on both jobs of administering and monitoring the patient while also performing the operation.

We decided to sponsor this legislation because we believe that all children, regardless of income, deserve one standard of care when they require sedation and anesthesia. The California Dental Board has recognized the need for high standards of care for our state's youngest residents by recommending further safety measures be taken in the administration of pediatric dental anesthesia, which would help bring state law in line with the AAP-AAPD guidelines. **AB 224 (Thurmond) would do right by our state's children in codifying the Dental Board's recommendations into California law.**

The American Academy of Pediatrics, California (AAP-CA) is a 501(c)4 nonprofit organization, legally incorporated separately from the National American Academy of Pediatrics.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®
AMERICAN ACADEMY OF PEDIATRICS, CALIFORNIA

Pediatricians strongly support AB 224 (Thurmond). Thank you for your public service and leadership on behalf of the health and wellbeing of children, youth, and families in California.

Sincerely,

Kris E. Calvin

Kris Calvin
Chief Executive Officer
American Academy of Pediatrics, California

Cc: The Honorable Tony Thurmond
Members of the Assembly Business and Professions Committee
Le Ondra Clark Harvey, Chief Consultant, Assembly Business and Professions Committee
Bill Lewis, Consultant, Assembly Republican Caucus

The American Academy of Pediatrics, California (AAP-CA) is a 501(c)4 nonprofit organization, legally incorporated separately from the National American Academy of Pediatrics.

AAPD

- http://www.aapd.org/media/Policies_Guidelines/BP_AnesthesiaPersonnel.pdf

Use of Anesthesia Providers in the Administration of Office-based Deep Sedation/General Anesthesia to the Pediatric Dental Patient

Review Council
Council on Clinical Affairs
Latest Revision
2017

AAP 2017 Resolution #42

- **Resolution #42 Not One More Child Should Die in a Dental Chair: Remembering Caleb**
- RESOLVED, that the Academy develop, promote, and advocate for model legislation to phase out the single, operator-anesthesia model to comply with *American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentists (AAPD) Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016* for deep sedation and general anesthesia for the pediatric patient in the dental setting, and be it further

https://downloads.aap.org/DOCCSA/2017DistrictIII&XMeetingAgendaBook.pdf pages 36-37

AAP 2017 Resolution #42

- RESOLVED, that the Academy educate pediatricians and the public to understand the need for every dentist and oral maxillofacial surgeon performing pediatric sedation to comply with the AAP *AAPD Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016* in dental settings.

https://downloads.aap.org/DOCCSA/2017DistrictIII&XMeetingAgendaBook.pdf pages 36-37

Update

- The Section on Anesthesiology and Pain Medicine (SOA) served as the lead authoring group of the AAP/American Academy of Pediatric Dentistry (AAPD) "*Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016*"

https://downloads.aap.org/DOCCSA/2017DistrictIII&XMeetingAgendaBook.pdf pages 36-37

Update

- . The Section on Oral Health (SOOH) is also in support of these guidelines. The clinical report recommends against the *single dental operator-anesthesia model*, whereby a dentist administers and monitors deep sedation and general anesthesia while simultaneously performing dental procedures.

https://downloads.aap.org/DOCCSA/2017DistrictIII&XMeetingAgendaBook.pdf pages 36-37

Update

- However, since the publication of the document, the SOA leadership has learned that many dental providers are now assigning their dental assistant the task of monitoring the sedated patient to technically move away from the single dental operator-anesthesia model (in that there is a second person present).

https://downloads.aap.org/DOCCSA/2017DistrictIII&XMeetingAgendaBook.pdf pages 36-37

Update

- However, the second person should be an independently qualified and licensed professional, who possesses advanced airway skills consistent with the AAP/AAPD Guidelines.
- Currently, in many states, dental assistants are not even required to have a high school diploma (eg California); even if they take a Pediatric Advanced Life Support (PALS) course, in most cases they simply do not have the training necessary to provide the appropriate standard of care that pediatric patients require while sedated for dental procedures.

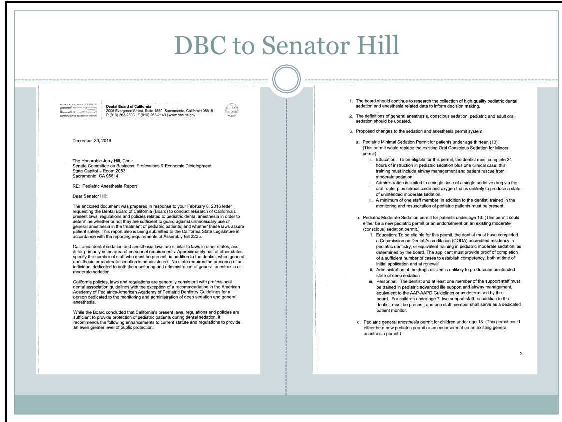
https://downloads.aap.org/DOCCSA/2017DistrictIII&XMeetingAgendaBook.pdf pages 36-37

Charlie Cote, MD

Stephen Wilson, DDS

Dental Board Decision

- Committee Report given to Full Dental Board
- President made a plea and recommendation to amend
  - Include a ban on OA for deep sedation/ga for pediatric patients under the age of 7
- Passed overwhelmingly
  - Opposed by OS on committee



DBC to Senator Hill

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Dental Board of California
2005 Evergreen Street, Suite 1550, Sacramento, California 95815
P (916) 263-2300 | F (916) 263-2140 | www.dbc.ca.gov

December 30, 2016

The Honorable Jerry Hill, Chair
Senate Committee on Business, Professions & Economic Development
State Capitol – Room 2053
Sacramento, CA 95814

RE: Pediatric Anesthesia Report

Dear Senator Hill:

The enclosed document was prepared in response to your February 8, 2016 letter requesting the Dental Board of California (Board) to conduct research of California's present laws, regulations and policies related to pediatric dental anesthesia in order to determine whether or not they are sufficient to guard against unnecessary use of general anesthesia in the treatment of pediatric patients, and whether these laws assure patient safety. This report also is being submitted to the California State Legislature in accordance with the reporting requirements of Assembly Bill 2235.

California dental sedation and anesthesia laws are similar to laws in other states, and differ primarily in the area of personnel requirements. Approximately half of other states specify the number of staff who must be present, in addition to the dentist, when general anesthesia or moderate sedation is administered. No state requires the presence of an individual dedicated to both the monitoring and administration of general anesthesia or moderate sedation.

California policies, laws and regulations are generally consistent with professional dental association guidelines with the exception of a recommendation in the American Academy of Pediatrics-American Academy of Pediatric Dentistry Guidelines for a person dedicated to the monitoring and administration of deep sedation and general anesthesia.

While the Board concluded that California's present laws, regulations and policies are sufficient to provide protection of pediatric patients during dental sedation, it recommends the following enhancements to current statute and regulations to provide an even greater level of public protection:

1. The board should continue to research the collection of high quality pediatric dental sedation and anesthesia related data to inform decision making.
2. The definitions of general anesthesia, conscious sedation, pediatric and adult oral sedation should be updated.
3. Proposed changes to the sedation and anesthesia permit system:
   a. Pediatric Minimal Sedation Permit for patients under age thirteen (13). (This permit would replace the existing Oral Conscious Sedation for Minors permit)
      i. Education: To be eligible for this permit, the dentist must complete 24 hours of instruction in pediatric sedation plus one clinical case; this training must include airway management and patient rescue from moderate sedation.
      ii. Administration is limited to a single dose of a single sedative drug via the oral route, plus nitrous oxide and oxygen that is unlikely to produce a state of unintended moderate sedation.
      iii. A minimum of one staff member, in addition to the dentist, trained in the monitoring and resuscitation of pediatric patients must be present.
   b. Pediatric Moderate Sedation permit for patients under age 13. (This permit could either be a new pediatric permit or an endorsement on an existing moderate (conscious) sedation permit.)
      i. Education: To be eligible for this permit, the dentist must have completed a Commission on Dental Accreditation (CODA) accredited residency in pediatric dentistry, or equivalent training in pediatric moderate sedation, as determined by the board. The applicant must provide proof of completion of a sufficient number of cases to establish competency, both at time of initial application and at renewal.
      ii. Administration of the drugs utilized is unlikely to produce an unintended state of deep sedation
      iii. Personnel: The dentist and at least one member of the support staff must be trained in pediatric advanced life support and airway management, equivalent to the AAP-AAPD Guidelines or as determined by the board. For children under age 7, two support staff, in addition to the dentist, must be present, and one staff member shall serve as a dedicated patient monitor.
   c. Pediatric general anesthesia permit for children under age 13. (This permit could either be a new pediatric permit or an endorsement on an existing general anesthesia permit.)

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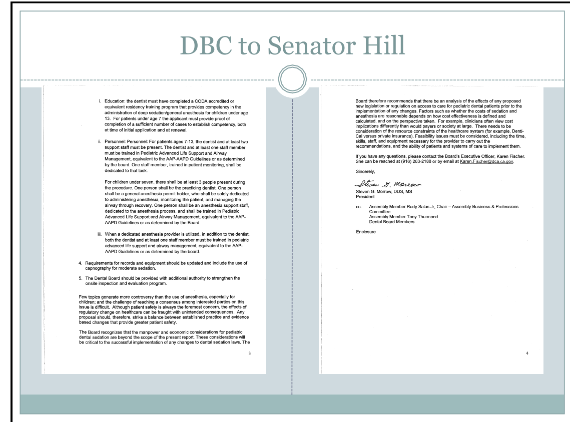

DBC to Senator Hill

i. Education: the dentist must have completed a CODA accredited or equivalent residency training program that provides competency in the administration of deep sedation/general anesthesia for children under age 13. For patients under age 7 the applicant must provide proof of completion of a sufficient number of cases to establish competency, both at time of initial application and at renewal.

ii. Personnel: Personnel: For patients ages 7-13, the dentist and at least two support staff must be present. The dentist and at least one staff member must be trained in Pediatric Advanced Life Support and Airway Management, equivalent to the AAP-AAPD Guidelines or as determined by the board. One staff member, trained in patient monitoring, shall be dedicated to that task.

For children under seven, there shall be at least 3 people present during the procedure. One person shall be the practicing dentist. One person shall be a general anesthesia permit holder, who shall be solely dedicated to administering anesthesia, monitoring the patient, and managing the airway through recovery. One person shall be an anesthesia support staff, dedicated to the anesthesia process, and shall be trained in Pediatric Advanced Life Support and Airway Management, equivalent to the AAP-AAPD Guidelines or as determined by the Board.

iii. When a dedicated anesthesia provider is utilized, in addition to the dentist, both the dentist and at least one staff member must be trained in pediatric advanced life support and airway management, equivalent to the AAP-AAPD Guidelines or as determined by the board.

4. Requirements for records and equipment should be updated and include the use of capnography for moderate sedation.
5. The Dental Board should be provided with additional authority to strengthen the onsite inspection and evaluation program.

Few topics generate more controversy than the use of anesthesia, especially for children; and the challenge of reaching a consensus among interested parties on this issue is difficult. 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 provide greater patient safety.

The Board recognizes that the manpower and economic considerations for pediatric dental sedation are beyond the scope of the present report. These considerations will be critical to the successful implementation of any changes to dental sedation laws. The

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Board therefore recommends that there be an analysis of the effects of any proposed new legislation or regulation on access to care for pediatric dental patients prior to the implementation of any changes. Factors such as whether the costs of sedation and anesthesia are reasonable depends on how cost effectiveness is defined and calculated, and on the perspective taken. For example, clinicians often view cost implications differently than would payers or society at large. There needs to be consideration of the resource constraints of the healthcare system (for example, Denti-Cal versus private insurance). Feasibility issues must be considered, including the time, skills, staff, and equipment necessary for the provider to carry out the recommendations, and the ability of patients and systems of care to implement them.

If you have any questions, please contact the Board's Executive Officer, Karen Fischer. She can be reached at (916) 263-2188 or by email at Karen.Fischer@dca.ca.gov.

Sincerely,

Steven G. Morrow, DDS, MS
President

cc: Assembly Member Rudy Salas Jr, Chair – Assembly Business & Professions Committee
Assembly Member Tony Thurmond
Dental Board Members

Enclosure

4

Dental Board Recommendations

- Collect pediatric anesthesia data
- Update definitions of GA, conscious sedation, pediatric and adult oral sedation
- Change permit system
  - Pediatric minimal sedation under 13 y/o
  - Pediatric moderate sedation under 13 y/o
  - Pediatric general anesthesia under 13 y/o

Dental Board Recommendations

- Pediatric minimal sedation
  - Education 24 hours plus 1 case
  - Single dose of a single drug +/- nitrous oxide
  - Minimum of 1 staff member in addition to dentist trained in monitoring and resuscitation of pediatric patients

Dental Board Recommendations

- Pediatric moderate sedation
  - Education: CODA pediatric residency or equivalent training
  - Drugs unlikely to produce deep sedation
  - Personnel
    - Dentist and 1 staff member trained in PALS consistent with AAP/AAPD guidelines
    - Under age 7, Dentist and 2 staff members, one of which must be a dedicated monitor

Dental Board Recommendations

- Pediatric general anesthesia permit
  - Education:
    - CODA program or equivalent training to competency under age 13
    - For under age 7, proof of sufficient cases
  - Personnel
    - Ages 7-13, dentist and 2 staff members. Dentist and one staff member must be trained in PALS. One member must be trained in monitoring and dedicated to monitoring
    - Under 7 year old, 3 people, Dentist, Anesthesia provider, one anesthesia support staff trained in PALS
    - Dentist, anesthesia provider and one staff must be PALS certified
    - No operator anesthesia

Dental Board Recommendations

- Update records and equipment requirements
- Mandate capnography for moderate sedation
- Dental Board should have additional authority to strengthen the onsite inspection and evaluation program

2017 California Legislature

- AB224 Thurmond
- Dental Board Report
- Hostile amendment to remove OA ban

- SB501 Glazer
- SB392 Bates
- Dental Board Committee Report
- Glazer is suspended in appropriations
- Bates has changed bill

ASA Moderate Sedation Guidelines

- Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018: A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology*

ASA Moderate Sedation Guidelines

- http://anesthesiology.pubs.asahq.org/article.aspx?articleid=2670190&_ga=2.58273130.1105670935.1526535109-247053706.1475206279
- ASAHQ.org
  - Quality & Practice Management Tab
  - Search Standards, Guidelines and Related Resources
  - Narrow search by Document type – Practice Guidelines
  - Narrow search by Clinical Topics - Sedation

ASA Moderate Sedation Guidelines

- Specifically address moderate sedation.
- Does not address mild or deep sedation
- Does not address the educational, training, or certification requirements for providers of moderate procedural sedation.
- Separate Practice Guidelines are under development that will address deep procedural sedation.

ASA Moderate Sedation Guidelines

- Differ from previous guidelines in that they were developed by a multidisciplinary task force of physicians from several medical and dental specialty organizations with the intent of specifically addressing moderate procedural sedation provided by any medical specialty in any location.
- American Dental Association
- American Society of Dentist Anesthesiologists
- American Association of Oral and Maxillofacial Surgeons

Patient Evaluation

- Review of medical history
  - Major organ systems, obesity, OSA, congenital syndromes
  - Sedation/anesthesia and surgical history
  - History of a difficult airway
  - Medications and allergies, drug interactions, nutraceuticals
  - Family history
  - Drug/alcohol/tobacco use
- Focused physical examination
  - Auscultation of the heart and lungs, airway evaluation
- Pre-procedural laboratory testing (when indicated)

Patient Preparation

- Consult with a medical specialist
  - Based on underlying condition
  - Severely compromised
- Prior to procedure
  - RBA's
  - Limits of moderate sedation
- NPO instructions

Patient Preparation

- Day of treatment
  - Assess time and nature of last oral intake
  - Evaluate risk of pulmonary aspiration
    - Target level of anesthesia
    - Should procedure be delayed
- In urgent or emergent situations where comoplete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone
  - Define urgent or emergent in dentistry

Monitoring

- Level of consciousness
  - Verbal response
  - Thumbs up
- Ventilation and oxygenation
  - Continually monitor qualitative clinical signs
  - Continually monitor ventilatory function with capnography unless precluded or invalidated by the nature of the patient, procedure, or equipment
  - Continuously monitor by pulse oximetry
    - With appropriate alarms

Definitions

- Continually
  - "repeated regularly and frequently in steady rapid succession"
- Continuously
  - "prolonged without any interruption at any time"

Monitoring

- Hemodynamics
  - Determine BP preoperatively
  - Continually at 5 min intervals
  - Electrocardiograph when clinically indicated
- Contemporaneous record
  - Before sedating
  - After administration of sedatives
  - At regular intervals
  - At the start of recovery
  - Just prior to discharge

Personnel

- Designated individual other than practitioner is present to monitor the patient
  - Should be trained in the recognition of apnea and airway obstruction
  - "The designated individual should not be a member of the procedural team but may assist with minor interruptible tasks once the patient's level of sedation/analgesia and vital signs have stabilized, provided that adequate monitoring for the patients level of sedation is maintained"

Oxygen

- Recommends use of supplemental oxygen

Emergency Support

- Pharmacologic antagonists
- Appropriately sized airways
- One individual capable of establishing a patent airway and positive pressure oxygen
- Suction and advanced airway equipment, positive pressure device are immediately available and working
- Individual trained in IV access
- Individual trained in BLS

Emergency Support

- Individual or service with ALS skills
- Assure members of the procedural team are able to recognize the need for help and know how to access emergency services

Drugs for Moderate Sedation

- Termed "Sedative/Analgesic Medications Not Intended for General Anesthesia"
- Combination of sedative and analgesic agents may be appropriate
  - Administer each component individually
- Dexmedetomidine may be administered as an alternative to benzodiazepines

Drugs for Moderate Sedation

- IV route, maintain vascular access until patient is no longer at risk for cardiorespiratory depression
- Oral or blocked line, re-establish IV on a case by case basis
- Titrate to effect
  - Allow sufficient time to elapse between doses
  - Non IV routes, allow sufficient time for absorption and peak effect before supplementation

Drugs for General Anesthesia

- Moderate procedural sedation prior to GA then must be prepared for GA
- Must be prepared to rescue
- Maintain vascular access
  - Re-establish vascular access on a case by case basis
- Titrate to effect
  - Allow sufficient time for drug to peak

Reversal Agents

- Naloxone and flumazenil
  - Immediately available
- Hypoxemia, significant hypoventilation or apnea
  - Physically stimulate patient to breathe
  - Supplemental oxygen
  - Positive pressure
- Reversal agents when above is inadequate
  - Naloxone for opioid induced depression
  - Flumazenil to reverse benzodiazepine
  - Monitor for sufficient time to ensure no re-sedation
- No routine use of reversals

Recovery Care

- After sedation, monitor until near baseline
- Monitor oxygen continuously until no risk of hypoxemia
- Monitor ventilation and circulation regularly
  - 5 to 15 min intervals
- Discharge criteria that minimizes risk after discharge

QI Process

- Create and implement QI process
  - National standards
  - Periodically update
- Strengthen patient safety culture
  - Team training, simulation, checklists
- Create an emergency response plan
  - Activate "code blue" team
  - Assign duties

2018 Legislative Session September 29, 2018

- AB224 Died in committee
- SB392 No action

- SB501
- On Governor Edmund G Brown's desk
- Has until Sept. 30, 2018 to sign, veto or do nothing
- SB501 will become law unless Governor vetoes the bill