GREATER NEW YORK DENTAL MEETING
95th Annual Session

NOVEMBER 29 - DECEMBER 4, 2019

12-Hour New York State Anesthesia Sedation Requirement Program

Marc Gottlieb
Welcome to the Greater New York Dental Meeting

Pre-registration is required for all continuing education courses with the exception of the “Live” Dentistry and Affiliated Groups. Your seat will be held for 15 minutes after the start of the course; after that, those without tickets will be seated according to space availability. When the room is filled, no additional people will be admitted due to fire department regulations. If you have not pre-registered, please be prepared to select an alternate session to attend.

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The GNYDM CE Passport Bundle includes Seminar and Essay courses. When purchasing a bundle, attendees can register for as many Seminars and Essay courses as they want during all six days of the show. Registration for all courses is required.

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所有课程（除“现场牙科”课程外）需提前预登记。您的座位将保留15分钟，从课程开始后。之后，如果没有门票的客人将被安排在空间允许的情况下。当房间满员时，不再允许额外人员入内，因消防部门规定。如果您未预登记，请准备选择一个备用的课程。

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Celebrity Luncheon Speaker

John Quiñones
Monday, December 2nd
12:00 - 2:00 - Ticket 4010
$125.00

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After seven years of working and reworking various draft proposals, the New York State Education Department has finally approved new dental anesthesia regulations. The regulations were officially adopted on Dec. 28. They will be rolled out in two stages: changes to various definitions and to dental anesthesia practice requirements will take effect on July 1, 2017; changes to dental anesthesia certification and to dental anesthesia education and training requirements will take effect on Jan. 1, 2018.

The changes are extensive; and the regulations are quite complex. This article will delve into all of the nuances and specifics, so it is lengthy and bears saving as a future reference tool. Beware that it calls for close reading, though not always easy reading.

The most notable changes are to the certification and education and training requirements. The new regulations create two new categories of dental anesthesia certification: 1. a new certification to provide dental anesthesia services to patients 12 years old or younger; and 2. a new certification to provide dental anesthesia services to patients 13 years old or older. The education and training criteria for providing any dental anesthesia services to patients 12 years old or younger are new and more rigorous than for providing dental anesthesia services to those over 12 years of age. There is no genuine grandfathering of existing dental anesthesia certifications, because everyone will have to adapt to certain changes to some extent. But for some existing certificate holders, renewals will be less complicated than for those seeking new, original certification.

The new dental anesthesia practice requirements are substantially changed as well, with an unusual level of attention to detail now called for by the regulations.

The dental anesthesia regulations are divided into four parts. They are: definitions; certification requirements; education and training requirements; and practice requirements. We will deal with them in the order they will take effect.

Dental Anesthesia Definitions – July 1, 2017
The chief change to the definitions of dental anesthesia is the incorporation of the concept of “moderate” sedation into the definition of “conscious” sedation. Thus, the new definition of conscious (moderate) sedation is: “a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.”

“Deep” sedation is also redefined as: “a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is inadequate. Cardiovascular function is usually maintained.”

“General anesthesia” is redefined as: “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.”

Two other new definitions of note are for time-oriented anesthesia records—the first time that term has been clearly defined—and for the American Society of Anesthesiologists (ASA) Patient Physical Status Classification, which is now a factor to be considered as part of new practice requirements.

Time-oriented anesthesia record means an organized document that shows at appropriate time intervals, drugs and doses administered, and physiologic data obtained through patient monitoring during the course of conscious (moderate) sedation, deep sedation or general anesthesia, to include the preoperative, intraoperative and recovery stages of treatment. The ASA classifications are:

- **ASA I** – A normal, healthy patient.
- **ASA II** – A patient with mild systemic disease.
- **ASA III** – A patient with severe systemic disease.
- **ASA IV** – A patient with severe systemic disease that is a constant threat to life.
- **ASA V** – A moribund patient who is not expected to survive without the operation.
- **ASA VI** – A declared brain-dead patient whose organs are being removed for donor purposes.
- **E** – Emergency operation of any variety (used to modify one of the above classifications, i.e., ASA III-E).

**Dental Anesthesia Practice Requirements – July 1, 2017**

The new dental anesthesia practice requirements pick up on the definitions and add in other things too. All dentists who provide any type of dental anesthesia must now have Advanced Cardiac Life Support (ACLS) certification. No longer is Basic Life Support (BLS) certification good enough. In addition, dentists who provide dental anesthesia services of any kind to patients 12 years old and younger must also have Pediatric Advanced Life Support (PALS) certification.

The rule about administering dental anesthesia to only one patient at a time remains unchanged, but an exception has been added to allow for supervising no more than two dental students or residents at one time in a teaching institution.

The new regulations make it clear that a dentist is responsible for preoperative preparation and evaluation of the patient, as well as for discharge of the patient. Those items had not previously been included in the list of dentists’
duties. As part of this, all the practice requirements for preparing and monitoring the patient have changed and have been broken into requirements specific to deep sedation and general anesthesia and requirements specific to all forms of conscious (moderate) sedation. For deep sedation and general anesthesia, all of the following preparatory requirements must be met:

- A written and oral medical history shall be obtained.
- Consultation with the patient’s physician, as appropriate, for patients ASA III (a patient with severe systemic disease, according to the American Society of Anesthesiologists [ASA] patient physical status classification system) or greater.
- Preoperative instructions shall be given to the patient, parent, escort, guardian or caregiver.
- Preoperative dietary restrictions shall be considered based upon the anesthetic/sedative technique planned.
- The patient, parent, guardian or caregiver shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents, and informed consent for the proposed anesthesia/sedation shall be obtained.
- A focused physical evaluation shall be performed as deemed appropriate.
- Baseline vital signs shall be obtained unless the patient’s behavior prohibits such determination and, in any such case, this fact shall be noted in the time-oriented anesthesia record.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure shall be completed.
- An intravenous line, which is secured throughout the procedure, shall be established. If, due to lack of patient cooperation, the intravenous line cannot be maintained throughout the procedure, the inability to maintain such shall be documented in the anesthesia record.

Monitoring requirements for deep sedation and general anesthesia include all of the following:

1. **Oxygenation**
   - Color of mucosa, skin or blood shall be continually evaluated.
   - Oxygen saturation shall be evaluated continuously by pulse oximetry.
2. **Ventilation**
   - Intubated patient: end-tidal CO2 shall be continuously monitored and evaluated.
   - Non-intubated patient: breath sounds via auscultation and/or end-tidal CO2 shall be continuously monitored and evaluated.
   - Respiration rate shall be continually monitored and evaluated.
   - When agents implicated in precipitating malignant hyperthermia are utilized, end-tidal CO2 shall be continuously monitored and evaluated.
3. **Circulation**
   - The dentist shall continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
   - The dentist shall continually evaluate blood pressure.
4. **Temperature**
   - A device capable of measuring body temperature shall be readily available during the administration of deep sedation or general anesthesia.
   - When agents implicated in precipitating malignant hyperthermia are utilized, continuous monitoring of body temperature shall be performed.

For all types of conscious (moderate) sedation, all of the following preparatory requirements must be met:

1. A written and oral medical history shall be obtained.
2. Consultation with the patient’s physician, as appropriate, for patients ASA III (a patient with severe systemic disease, according to the American Society of Anesthesiologists [ASA] patient physical status classification system) or greater.
3. Preoperative instructions shall be given to the patient, parent, escort, guardian or caregiver.
4. Preoperative dietary restrictions shall be considered based upon the anesthetic/sedative technique planned.
5. The patient, parent, guardian or caregiver shall be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed anesthesia/sedation shall be obtained.
6. A focused physical evaluation shall be performed as deemed appropriate.
7. Baseline vital signs shall be obtained unless the patient’s behavior prohibits such determination and, in any such case, this fact shall be noted in the time-oriented anesthesia record.
8. Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure shall be completed.
9. An intravenous line, which is secured throughout the procedure, shall be established when parenteral sedation is being administered by way of an intravenous route. If, due to lack of patient cooperation, the intravenous line cannot be maintained throughout the procedure, the inability to maintain such shall be documented on the anesthesia record.

Monitoring requirements for all types of conscious (moderate) sedation include all of the following:

1. **Consciousness**
   - Level of consciousness (e.g., responsiveness to verbal command) shall be continually assessed.
2. Oxygenation
   - Color of mucosa, skin or blood shall be continually evaluated.
   - Oxygen saturation shall be evaluated continuously by pulse oximetry.

3. Ventilation
   - The dentist shall observe chest excursions continually.
   - The dentist shall monitor ventilation by auscultation of breath sounds, monitoring end-tidal CO2 or by verbal communication with the patient.

4. Circulation
   - The dentist shall continually evaluate blood pressure and heart rate (unless the patient is unable to tolerate the monitoring and this is noted in the time-oriented anesthesia record).
   - During the administration of dental conscious (moderate) enteral sedation, continuous evaluation of ECG shall be done when there is a finding of cardiovascular disease that warrants such monitoring.
   - During the administration of dental conscious (moderate) parenteral sedation, the dentist shall continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.

With respect to discharge for all patients undergoing any form of dental anesthesia, the following requirements must be met:

The recovery and discharge of the patient is the responsibility of any of the following: the licensed dentist providing the anesthesia/sedation management for that patient; another licensed dentist with an anesthesia/sedation certificate permitting him or her to provide the same level of anesthesia/sedation administered to the patient treated; or a licensed physician with the appropriate anesthesia training. Prior to discharge, the patient shall meet the following discharge criteria, which shall be documented in the patient’s chart:
   - Alert and responsive.
   - Patient can maintain and support his or her airway without intervention.
   - Vital signs, including oxygenation on room air, are within acceptable limits.
   - Patient is ambulatory with assistance.
   - Responsible adult is present to escort the patient from the office.
Clinical care, including all enteral, parenteral and inhalation agents administered; dosage of these drugs according to the time administered preoperatively, intraoperatively and during the in-office recovery phase; type and placement of intravenous access; type and total amount of intravenous fluids administered; type of advanced airway management used; all types of monitoring used; the physiologic findings of preoperative (base-line findings), intraoperative and pre-discharge monitoring, including but not limited to the following: blood pressure; heart rate; respiratory rate; end tidal CO2 (ETCO2); temperature and ECG rhythm if monitored; oxygen saturation, except that records of oxygen saturation and blood pressure shall not be required when conscious (moderate) sedation using an enteral route, with or without inhalation agents, is employed and the patient’s conduct prohibits the monitoring of oxygen saturation and blood pressure, in which case, the record shall document this fact; and if a physiologic parameter cannot be monitored, the reason should be reflected on the anesthesia record, as follows:

- the time of placement and removal of a throat pack or throat drape when used;
- persons present in the treatment room who are providing care or assisting during the procedure;
- name of the individual holding an anesthesia certificate responsible for recovery and discharge;
- any irreversible morbidity that occurs during the treatment and in-office recovery period.

The new regulations make it clear that the dentist administering conscious (moderate) sedation, deep sedation or general anesthesia is responsible for anesthetic/sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of conscious (moderate) sedation, deep sedation, or general anesthesia and provision of the equipment, drugs and protocols for patient rescue. This provision of the regulations is striking in that it creates obvious liability issues for failure to be prepared for any emergency situation whenever dental anesthesia service is being provided. Dentists should carefully review all their emergency preparations to ensure adequate compliance with this particular regulation.

Finally, with respect to practice requirements, the new regulations require reporting in writing by the dental anesthesia certificate holder to the New York State Education Department within 30 days of any mortality or irreversible morbidity occurring during or within 48 hours following, or otherwise related to, the administration of conscious (moderate) sedation or deep sedation or general anesthesia. The critical changes to this provision are that it now only calls for reporting irreversible morbidity rather than any morbidity, but it also now requires a written report and adds in the 48 hours following discharge extension period. Obviously, dentists will need to follow a patient closely for that 48-hour period.

**Dental Anesthesia Certification Requirements – January 1, 2018**

A major change in the new dental anesthesia regulations is the addition of certification requirements based upon the age of the patient being given dental anesthesia. A new certification is created for providing dental anesthesia to children 12 years of age or younger, and the requirements for that certification are rigorous. There will now be five different certifications rather than three. Dentists can be certified in the following dental anesthesia categories:

1. General anesthesia.
2. Parenteral conscious (moderate) sedation for patients 13 years old or younger.
3. Parenteral conscious (moderate) sedation for patients 12 years old or younger.
4. Enteral conscious (moderate) sedation for patients 13 years old or older.
5. Enteral conscious (moderate) sedation for patients 12 years old or younger.

It should be noted that if a dentist obtains either of the certifications to provide dental anesthesia to children 12 years old or younger, that certification also allows for providing dental anesthesia to older patients, but the reverse is not true. A certification to provide dental anesthesia to patients 13 years old or older does not allow providing dental anesthesia to any patients 12 years old or younger.

For people who hold existing dental anesthesia certificates issued prior to January 1, 2018, the certificates are good until their normal expiration date. But future renewal will depend upon the age of the patients being provided dental anesthesia and the type of certification sought. Dentists seeking to renew a general anesthesia certification must complete an ACLS course; a PALS course, if providing any dental anesthesia of any type to patients 12 years old or younger; and an additional 12 clock hours of education (exclusive of the ACLS and PALS requirements) in anesthesia/sedation techniques approved by an acceptable accrediting body and the New York State Education Department, including but not limited to, coursework in medications and recognition and management of complications and emergencies, including rescue from deeper levels of sedation as may occur in both pediatric and adult patient populations.

The new regulations make substantial changes to the education and training required for clinicians seeking their first, original certification to provide dental anesthesia services on or after Jan. 1, 2018. Again, the age of the patient population sought to be treated is a key factor for initial education and training for certification in dental anesthesia.

For an initial certification in general anesthesia, the dentist must have completed an ACLS course, a PALS course—if the dentist intends to provide dental anesthesia of any type to patients 12 years old or younger—and one of the following four options:
1. A graduate level program in oral and maxillofacial surgery acceptable to the New York State Education Department and accredited by an approved accrediting body, which shall include but not be limited to instruction in general anesthesia, parenteral sedation, and anxiety and pain control.
2. At least three years of postdoctoral education acceptable to the New York State Education Department and accredited by an approved body, which shall include but not be limited to coursework in anesthesia and anxiety and pain control, and one year devoted exclusively to clinical training in general anesthesia and

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1. A graduate level program in oral and maxillofacial surgery acceptable to the New York State Education Department and accredited by an approved accrediting body, which shall include but not be limited to instruction in general anesthesia, parenteral sedation, and anxiety and pain control.
2. At least three years of postdoctoral education acceptable to the New York State Education Department and accredited by an approved body, which shall include but not be limited to coursework in anesthesia and anxiety and pain control, and one year devoted exclusively to clinical training in general anesthesia and
related subjects, such as establishing and maintaining an emergency airway and use and interpretation of appropriate monitoring as of Jan. 1, 2019.

3. At least two years of postdoctoral education acceptable to the department and accredited by an approved body, which shall include but not be limited to coursework in anesthesia and anxiety and pain control, and one year devoted exclusively to clinical training in general anesthesia and related subjects, such as establishing and maintaining an emergency airway and use and interpretation of appropriate monitoring prior to Jan. 1, 2019.

4. For postdoctoral education completed prior to Jan. 1, 2002, at least one year of such education in anesthesia acceptable to the department, which shall include but not be limited to, coursework in anesthesia, anxiety and pain control, establishing and maintaining emergency airway, and use and interpretation of appropriate monitoring, or at least two years of such education in an approved specialty program or residency, which includes acceptable training and experience, including but not limited to, instruction in general anesthesia and parenteral sedation, provided the candidate has applied to the department for the initial certificate to employ conscious (moderate) sedation (enteral or parenteral route with or without inhalation agents), deep sedation and general anesthesia prior to Jan. 1, 2004.

Note that the dates are significant here. Option #4 effectively is historical in nature and is retained only to show how some dentists received an initial certification before Jan. 1, 2004. Options #1 and #2 are the only ongoing paths to general anesthesia certification. Option #3 is good for the one-year window between Jan. 1, 2018, and Jan. 1, 2019. After that, it too becomes effectively historical in nature.

For an initial certification for dental parenteral conscious (moderate) sedation for patients 13 years old and older, a dentist must complete an ACLS course, a PALS course, and predoctoral or postdoctoral education accredited by an approved body, which must include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the New York State Education Department. Simulation experiences can be part of the coursework, which must include, but not be limited to, coursework in patient evaluation and monitoring, management of emergencies, rescue of patients from deep sedation, management of pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and control of pain and anxiety. In addition to the 60 clock hours of coursework, a clinical experience acceptable to and previously approved by the New York State Education Department, demonstrating the successful use of general anesthesia and related subjects, such as establishing and maintaining an emergency airway and use and interpretation of appropriate monitoring as of Jan. 1, 2019.

For an initial certification for dental parenteral conscious (moderate) sedation for patients 12 years old or younger, a dentist must complete an ACLS course, a PALS course, and predoctoral or postdoctoral education accredited by an approved body, which must include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the New York State Education Department. Simulation experiences can be part of the coursework, which must include, but not be limited to, coursework in patient evaluation and monitoring, management of emergencies, rescue of patients from deep sedation, management of pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and control of pain and anxiety.

In addition to the 60 clock hours of coursework, a clinical experience demonstrating the successful use of dental parenteral conscious (moderate) sedation on no fewer than 20 live dental patients via the intravenous route who shall be 13 years old or older in a one-dentist-to-one-patient ratio. The dentist enrolled in the course shall have his or her name listed on the anesthesia record and shall be the individual administering the medications and documenting said administration, as well as the physiologic findings required on the anesthesia record. The patients shall be monitored, at a minimum, pursuant to the practice requirements explained earlier in this article. If the clinical portion of the course is given outside of a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.
include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the New York State Education Department. Simulation experiences may be part of the required coursework, which shall include, but not be limited to, coursework in patient evaluation and monitoring, management of emergencies, including IV access, rescue of patients from deep sedation, management of pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and control of pain and anxiety.

In addition to the 60 clock hours of coursework, a clinical experience, acceptable to and previously approved by the Education Department, demonstrating the successful use of dental enteral conscious (moderate) sedation on no fewer than 10 live clinical dental patients who shall be 13 years old or older and who are physically present in the same location as the dentists. The dentists may be in groups of no more than five people. The patients shall be monitored, at a minimum, pursuant to the practice requirements explained earlier in this article. If the clinical portion of the course is given outside of a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.

For an initial certification for dental enteral conscious (moderate) sedation for patients 12 years old or younger, a dentist must complete an ACLS course, a PALS course and predoctoral or postdoctoral education acceptable to the New York State Education Department and accredited by an approved body, which must include a formal course consisting of at least 60 clock hours of coursework that is provided through didactic instruction and/or an anesthesia rotation, which has been previously approved by the Education Department. Simulation experiences can be part of the coursework, which shall include, but not be limited to, coursework in patient evaluation and monitoring, management of emergencies, including IV access, rescue of patients from deep sedation, management of pediatric and adult airways, pediatric and adult cardiac and pulmonary anatomy and physiology, pediatric and adult pharmacology, and control of pain and anxiety.

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conscious (moderate) sedation on no fewer than 15 live clinical dental patients 12 years old or younger and five live clinical dental patients 13 years old or older in a two-to-one-dentist-to-patient ratio. This two-to-one ratio means that the dentist providing dental care to the patient and a second dentist monitoring and documenting the sedation care can receive credit for the procedure as it relates to the minimum number of sedations required for certification. Both of these dentists must be with the patient during the entire time of treatment and cannot be involved with any other activities or responsibilities. Only the two dentists involved in direct patient care/monitoring can receive credit for treating the patient undergoing the procedure and sedation. The dentist enrolled in the course shall have his or her name listed on the anesthesia record and shall be the individual administering the medications and documenting said administration, as well as the physiologic findings required on the anesthesia record. The patients shall be monitored, at a minimum, pursuant to the practice requirements explained earlier in this article. If the clinical portion of the course is given outside of a teaching institution, a formal memorandum of understanding (MOU) between the teaching institution and the clinical teaching center (facility) shall be in place attesting that the clinical facility is held to the same practice standards as the teaching institution.

Finally, for the first time ever, the new regulations spell out what is needed if a dentist seeks endorsement of an anesthesia certification from another state or from Canada. The regulations here are quite restrictive. The dentist must first be registered to practice dentistry in New York State and submit a certificate of good standing from the jurisdiction from which the dental anesthesia endorsement is being sought. Then requirements vary depending upon the type of dental anesthesia certification sought to be endorsed. For general anesthesia, only a certificate of completion of a Commission on Dental Accreditation (CODA) accredited oral and maxillofacial surgery program or a CODA-accredited dental anesthesia program will be accepted for endorsement purposes.

For endorsement of certification for dental parenteral conscious (moderate) sedation for patients 13 years old and older, the dentist must have had a certificate to provide parenteral conscious (moderate) sedation from the other jurisdiction for at least three years immediately preceding the dentist’s submission of his or her endorsement application to the Education Department for review, must provide proof of current completion of an ACLS course, and must provide 15 anesthesia records of patients 12 years old and younger and five anesthesia records of patients 13 years old and older, to whom the dentist has administered parenteral conscious (moderate) sedation (via the intravenous route) in the licensed jurisdiction within the three years immediately preceding the dentist’s submission of his or her endorsement application to the Education Department for review with no patients having had irreversible morbidity or mortality due to the sedation provided by the dentist. These records must include monitoring that is required under the dental anesthesia practice requirements explained earlier in this article. If the dentist has ever had any patients with irreversible morbidity or mortality due to the sedation he or she provided, the dentist must provide an explanation of the incident(s) to the Education Department for review, in a form prescribed by the Education Department. Depending upon the circumstances, the Education Department may require remediation before a dental parenteral conscious (moderate) sedation for patients 13 years old and older certificate based on endorsement will be issued.

For endorsement of certification for dental enteral conscious (moderate) sedation for patients 13 years old and older, the dentist must provide proof of current completion of an ACLS course, provide 20 anesthesia records of patients to whom the dentist has administered enteral conscious (moderate) sedation (by the intravenous route) in the licensed jurisdiction within the three years immediately preceding the dentist’s submission of his or her application for endorsement to the Education Department for review with no patients having had irreversible morbidity or mortality due to the sedation provided by the dentist. These records must include monitoring that is required under the dental anesthesia practice requirements explained earlier in this article. If the dentist has ever had any patients with irreversible morbidity or mortality due to the sedation he or she provided, the dentist must provide an explanation of the incident(s) to the Education Department for review, in a form prescribed by the Education Department. Depending upon
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years old and younger and five anesthesia records of patients 13
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Endnote
These regulations received surprisingly little comment in New
York State. They appear not to have been, for all their convolu-
tions and excruciating detail, controversial. How well they serve
the public and the dental profession only time will tell. One thing
is certain. They are much longer than the previous regulations.

The material contained in this column is informational only and does not
constitute legal advice. For specific questions, dentists should contact their
own attorney. An archive of previously published legal articles can be ac-
cessed in the members-only area of the NYSDA website, www.nysdental.org.
I. Introduction

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.

Dentists must comply with their state laws, rules and/or regulations when providing sedation and anesthesia and will only be subject to Section III. Educational Requirements as required by those state laws, rules and/or regulations.

Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved via any route of administration and thus an appropriately consistent level of training must be established.

For children, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

II. Definitions

Methods of Anxiety and Pain Control

**minimal sedation (previously known as anxiolysis)** - a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.¹

Patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

The following definitions apply to administration of minimal sedation:

- **maximum recommended dose (MRD)** - maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

- **dosing for minimal sedation via the enteral route** – minimal sedation may be achieved by the administration of a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the maximum recommended dose (MRD).

The administration of enteral drugs exceeding the maximum recommended dose during a single appointment is considered to be moderate sedation and the moderate sedation guidelines apply.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.
If more than one enteral drug is administered to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. The use of the MRD to guide dosing for minimal sedation is intended to create this margin of safety.

**moderate sedation** - a drug-induced depression of consciousness during which patients respond *purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.¹

Note: In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to the administration of moderate or greater sedation:

**titration** - administration of incremental doses of an intravenous or inhalation drug until a desired effect is reached. Knowledge of each drug’s time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.

**deep sedation** - a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.¹

**general anesthesia** - a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation and general anesthesia are 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 diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.¹

For all levels of sedation, the qualified dentist must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

**Routes of Administration**

*ental - any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa [i.e., oral, rectal, sublingual].

**ental** - a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)].
transdermal - a technique of administration in which the drug is administered by patch or iontophoresis through skin.

transmucosal - a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

inhalation - a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

Terms

analgesia – the diminution or elimination of pain.

local anesthesia - the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression, especially in combination with sedative agents.

qualified dentist - a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations.

operating dentist – dentist with primary responsibility for providing operative dental care while a qualified dentist or independently practicing qualified anesthesia healthcare provider administers minimal, moderate or deep sedation or general anesthesia.

competency – displaying special skill or knowledge derived from training and experience.

must/shall - indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

should - indicates the recommended manner to obtain the standard; highly desirable.

may - indicates freedom or liberty to follow a reasonable alternative.

continual - repeated regularly and frequently in a steady succession.

continuous - prolonged without any interruption at any time.

time-oriented anesthesia record - documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

immediately available – on site in the facility and available for immediate use.
### American Society of Anesthesiologists (ASA) Patient Physical Status Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Examples, including but not limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA I</td>
<td>A normal healthy patient</td>
<td>Healthy, non-smoking, no or minimal alcohol use</td>
</tr>
<tr>
<td>ASA II</td>
<td>A patient with mild systemic disease</td>
<td>Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 &lt; BMI &lt; 40), well-controlled DM/HTN, mild lung disease</td>
</tr>
<tr>
<td>ASA III</td>
<td>A patient with severe systemic disease</td>
<td>Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, *ESRD undergoing regularly scheduled dialysis, premature infant PCA &lt; 60 weeks, history (&gt;3 months) of MI, CVA, TIA, or CAD/stents.</td>
</tr>
<tr>
<td>ASA IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
<td>Examples include (but not limited to): recent (&lt;3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or *ESRD not undergoing regularly scheduled dialysis</td>
</tr>
<tr>
<td>ASA V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
<td>Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction</td>
</tr>
<tr>
<td>ASA VI</td>
<td>A declared brain-dead patient whose organs are being removed for donor purposes</td>
<td></td>
</tr>
</tbody>
</table>

*The addition of “E” denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

### American Society of Anesthesiologists Fasting Guidelines

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</td>
<td>2 hours</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 hours</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 hours</td>
</tr>
<tr>
<td>Nonhuman milk</td>
<td>6 hours</td>
</tr>
<tr>
<td>Light meal</td>
<td>6 hours</td>
</tr>
<tr>
<td>Fatty meal</td>
<td>8 hours</td>
</tr>
</tbody>
</table>

### III. Educational Requirements

#### A. Minimal Sedation

1. To administer minimal sedation the dentist must demonstrate competency by having successfully completed:

   a. training in minimal sedation consistent with that prescribed in the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students,
b. comprehensive training in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced,

or

c. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage minimal sedation commensurate with these guidelines;

and

d. a current certification in Basic Life Support for Healthcare Providers.

2. Administration of minimal sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

B. Moderate Sedation

1. To administer moderate sedation, the dentist must demonstrate competency by having successfully completed:

   a. a comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced,

   or

   b. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines;

   and

   c. 1) A current certification in Basic Life Support for Healthcare Providers and

      2) Either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

2. Administration of moderate sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

C. Deep Sedation or General Anesthesia

1. To administer deep sedation or general anesthesia, the dentist must demonstrate competency by having completed:

   a. An advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part IV.C of these guidelines;

   and
b. 1) A current certification in Basic Life Support for Healthcare Providers and
  2) either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an
appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is
required for ACLS.

2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing
qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current
certification in Basic Life Support (BLS) Course for the Healthcare Provider.

IV. Clinical Guidelines

A. Minimal sedation

1. Patient History and Evaluation

Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative
procedure. In healthy or medically stable individuals (ASA I, II) this should consist of a review of their current
medical history and medication use. In addition, patients with significant medical considerations (ASA III, IV)
may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with
  the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive
  pressure must be completed.
- An appropriate focused physical evaluation should be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, and respiration rate must be
  obtained unless invalidated by the nature of the patient, procedure or equipment. Body temperature
  should be measured when clinically indicated.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian
  or care giver.

3. Personnel and Equipment Requirements

Personnel:
- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in
  addition to the dentist.

Equipment:
- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately
  available.
- Documentation of compliance with manufacturers’ recommended maintenance of monitors, anesthesia
delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check
of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and
  calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less
than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible
alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
4. Monitoring and Documentation

Monitoring: A dentist, or at the dentist’s direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

Consciousness:
- Level of sedation (e.g., responsiveness to verbal commands) must be continually assessed.

Oxygenation:
- Oxygen saturation by pulse oximetry may be clinically useful and should be considered.

Ventilation:
- The dentist and/or appropriately trained individual must observe chest excursions.
- The dentist and/or appropriately trained individual must verify respirations.

Circulation:
- Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, time administered and route of administration, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
- The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns is returned to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.

B. Moderate Sedation

1. Patient History and Evaluation

Patients considered for moderate sedation must undergo an evaluation prior to the administration of any sedative. This should consist of at least a review at an appropriate time of their medical history and
medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI) should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation must be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless precluded by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Pre-operative verbal or written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.

3. Personnel and Equipment Requirements

Personnel:
- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:
- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers’ recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravascular or intraosseous access should be available until the patient meets discharge criteria.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:
Consciousness:
- Level of sedation (e.g., responsiveness to verbal command) must be continually assessed.

Oxygenation:
- Oxygen saturation must be evaluated by pulse oximetry continuously.

Ventilation:
- The dentist must observe chest excursions continually.
- The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO$_2$ 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 auscultation of breath sounds with a precordial or pretracheal stethoscope.

Circulation:
- The dentist must continually evaluate blood pressure and heart rate unless invalidated by the nature of the patient, procedure or equipment and this is noted in the time-oriented anesthesia record.
- Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.

Documentation:
- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics, dosages and monitored physiological parameters.
- Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.

5. Recovery and Discharge
- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must continually monitor the patient’s blood pressure, heart rate, oxygenation and level of consciousness.
- The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.
- If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management
- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient is returned to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.
C. Deep Sedation or General Anesthesia

1. Patient History and Evaluation

Patients considered for deep sedation or general anesthesia must undergo an evaluation prior to the administration of any sedative. This must consist of at least a review of their medical history and medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI) should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- A focused physical evaluation must be performed as deemed appropriate.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless invalidated by the patient, procedure or equipment. In addition, body temperature should be measured when clinically appropriate.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.
- An intravenous line, which is secured throughout the procedure, must be established except as provided in part IV. C.6. Special Needs Patients.

3. Personnel and Equipment Requirements

**Personnel:** A minimum of three (3) individuals must be present.

- A dentist qualified in accordance with part III. C. of these Guidelines to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

**Equipment:**

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers’ recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
• An appropriate scavenging system must be available if gases other than oxygen or air are used.
• The equipment necessary to establish intravenous access must be available.
• Equipment and drugs necessary to provide advanced airway management, and advanced cardiac life support must be immediately available.
• The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.
• Resuscitation medications and an appropriate defibrillator must be immediately available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

Oxygenation:
• Oxygenation saturation must be evaluated continuously by pulse oximetry.

Ventilation:
• Intubated patient: End-tidal CO₂ must be continuously monitored and evaluated.
• Non-intubated patient: 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 qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.
• Respiration rate must be continually monitored and evaluated.

Circulation:
• The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
• The dentist must continually evaluate blood pressure.

Temperature:
• A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.
• The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

Documentation:
• Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters.
• Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.

5. Recovery and Discharge

• Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
• The dentist or clinical staff must continually monitor the patient’s blood pressure, heart rate, oxygenation and level of consciousness.
• The dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
• Post-operative verbal and written instructions must be given to the patient, and parent, escort, guardian or care giver.

6. Special Needs Patients

Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative management.

In selected circumstances, deep sedation or general anesthesia may be utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some patients; or the establishment of intravenous access after deep sedation or general anesthesia has been induced because of poor patient cooperation.

7. Emergency Management

The qualified dentist is responsible for sedative/anesthetic management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of deep sedation or general anesthesia and providing the equipment, drugs and protocols for patient rescue.

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1 Excerpted from Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2014, of the American Society of Anesthesiologists (ASA)
2 ASA Physical Status Classification System is reprinted with permission of the American Society of Anesthesiologists, Updated by ASA House of Delegates, October 15, 2014.
4 Standardized BMI category definitions can be obtained from the Centers for Disease Control and Prevention or the American Society of Anesthesiologists.
GUIDELINES for the Use of Sedation and General Anesthesia by Dentists

Adopted by the ADA House of Delegates, October 2016

I. INTRODUCTION
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.

Dentists must comply with their state laws, rules and/or regulations when providing sedation and anesthesia and will only be subject to Section III. Educational Requirements as required by those state laws, rules and/or regulations.

Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved via any route of administration and thus an appropriately consistent level of training must be established.

For children, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.
II. DEFINITIONS
METHODS OF ANXIETY AND PAIN CONTROL

MINIMAL SEDATION (previously known as anxiolysis) – a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.¹

Patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

The following definitions apply to administration of minimal sedation:

maximum recommended dose (MRD) – maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

dosing for minimal sedation via the enteral route – minimal sedation may be achieved by the administration of a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the maximum recommended dose (MRD).

The administration of enteral drugs exceeding the maximum recommended dose during a single appointment is considered to be moderate sedation and the moderate sedation guidelines apply.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

If more than one enteral drug is administered to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. The use of the MRD to guide dosing for minimal sedation is intended to create this margin of safety.
MODERATE SEDATION – a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.¹

Note: In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to the administration of moderate or greater sedation:

titration – administration of incremental doses of an intravenous or inhalation drug until a desired effect is reached. Knowledge of each drug’s time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.

DEEP SEDATION AND GENERAL ANESTHESIA

deep sedation – a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.¹

general anesthesia – a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation and general anesthesia are 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 diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.¹

For all levels of sedation, the qualified dentist must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.
ROUTES OF ADMINISTRATION

**enteral** – any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa [i.e., oral, rectal, sublingual].

**parenteral** – a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)].

**transdermal** – a technique of administration in which the drug is administered by patch or iontophoresis through skin.

**transmucosal** – a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

**inhalation** – a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

TERMS

**analgesia** – the diminution or elimination of pain.

**local anesthesia** – the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

*Note:* Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression, especially in combination with sedative agents.

**qualified dentist** – a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations.

**operating dentist** – dentist with primary responsibility for providing operative dental care while a qualified dentist or independently practicing qualified anesthesia healthcare provider administers minimal, moderate or deep sedation or general anesthesia.

**competency** – displaying special skill or knowledge derived from training and experience.

**must/shall** – indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

**should** – indicates the recommended manner to obtain the standard; highly desirable.

**may** – indicates freedom or liberty to follow a reasonable alternative.

**continual** – repeated regularly and frequently in a steady succession.

**continuous** – prolonged without any interruption at any time.

**time-oriented anesthesia record** – documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

**immediately available** – on site in the facility and available for immediate use.
AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) PATIENT PHYSICAL STATUS CLASSIFICATION

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Examples, including but not limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA I</td>
<td>A normal healthy patient</td>
<td>Healthy, non-smoking, no or minimal alcohol use</td>
</tr>
<tr>
<td>ASA II</td>
<td>A patient with mild systemic disease</td>
<td>Mild diseases only without substantive functional limitations. Examples include (but not limited to):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>current smoker, social alcohol drinker, pregnancy, obesity (30 &lt; BMI &lt; 40), well-controlled DM/HTN,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mild lung disease</td>
</tr>
<tr>
<td>ASA III</td>
<td>A patient with severe systemic disease</td>
<td>Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not</td>
</tr>
<tr>
<td></td>
<td></td>
<td>limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, *ESRD undergoing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>regularly scheduled dialysis, premature infant PCA &lt; 60 weeks, history (&gt;3 months) of MI, CVA, TIA,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>or CAD/stents.</td>
</tr>
<tr>
<td>ASA IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
<td>Examples include (but not limited to): recent (&lt; 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or *ESRD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>not undergoing regularly scheduled dialysis</td>
</tr>
<tr>
<td>ASA V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
<td>Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/</td>
</tr>
<tr>
<td></td>
<td></td>
<td>system dysfunction</td>
</tr>
<tr>
<td>ASA VI</td>
<td>A declared brain-dead patient whose organs are being removed for donor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>purposes</td>
<td></td>
</tr>
</tbody>
</table>

*The addition of “E” denotes emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

AMERICAN SOCIETY OF ANESTHESIOLOGISTS’ FASTING GUIDELINES

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</td>
<td>2 hours</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 hours</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 hours</td>
</tr>
<tr>
<td>Nonhuman milk</td>
<td>6 hours</td>
</tr>
<tr>
<td>Light meal</td>
<td>6 hours</td>
</tr>
<tr>
<td>Fatty meal</td>
<td>8 hours</td>
</tr>
</tbody>
</table>
III. EDUCATIONAL REQUIREMENTS

A. Minimal Sedation

1. To administer minimal sedation the dentist must demonstrate competency by having successfully completed:
   a. training in minimal sedation consistent with that prescribed in the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students;
   or
   b. comprehensive training in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced;
   or
   c. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage minimal sedation commensurate with these guidelines;
   and
   d. a current certification in Basic Life Support for Healthcare Providers.

2. Administration of minimal sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

B. Moderate Sedation

1. To administer moderate sedation, the dentist must demonstrate competency by having successfully completed:
   a. a comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced;
   or
   b. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines;
   and
   c. 1) A current certification in Basic Life Support for Healthcare Providers and
      2) Either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.
2. Administration of moderate sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

C. Deep Sedation or General Anesthesia

1. To administer deep sedation or general anesthesia, the dentist must demonstrate competency by having completed:
   a. An advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part IV.C of these guidelines;
   and
   b. 1) A current certification in Basic Life Support for Healthcare Providers and
       2) either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is required for ACLS.

2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support (BLS) Course for the Healthcare Provider.
A. Minimal sedation

1. Patient History and Evaluation

Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this should consist of a review of their current medical history and medication use. In addition, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation should be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, and respiration rate must be obtained unless invalidated by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

3. Personnel and Equipment Requirements

Personnel: At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers’ recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
4. Monitoring and Documentation

Monitoring: A dentist, or at the dentist’s direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

- **Consciousness:** Level of sedation (e.g., responsiveness to verbal commands) must be continually assessed.
- **Oxygenation:** Oxygen saturation by pulse oximetry may be clinically useful and should be considered.
- **Ventilation:**
  - The dentist and/or appropriately trained individual must observe chest excursions.
  - The dentist and/or appropriately trained individual must verify respirations.
- **Circulation:** Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

**Documentation:** An appropriate sedative record must be maintained, including the names of all drugs administered, time administered and route of administration, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
- The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns is returned to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.
B. Moderate Sedation

1. Patient History and Evaluation

Patients considered for moderate sedation must undergo an evaluation prior to the administration of any sedative. This should consist of at least a review at an appropriate time of their medical history and medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI) should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation must be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless precluded by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Pre-operative verbal or written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.

3. Personnel and Equipment Requirements

Personnel: At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers’ recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia–related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in–line oxygen analyzer with audible alarm.
- The equipment necessary for monitoring end–tidal CO₂ and auscultation of breath sounds must be immediately available.
• An appropriate scavenging system must be available if gases other than oxygen or air are used.
• The equipment necessary to establish intravascular or intraosseous access should be available until the patient meets discharge criteria.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

  **Consciousness:** Level of sedation (e.g., responsiveness to verbal command) must be continually assessed.

  **Oxygenation:** Oxygen saturation must be evaluated by pulse oximetry continuously.

  **Ventilation:**
  • The dentist must observe chest excursions continually.
  • 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 auscultation of breath sounds with a precordial or pretracheal stethoscope.

  **Circulation:**
  • The dentist must continually evaluate blood pressure and heart rate unless invalidated by the nature of the patient, procedure or equipment and this is noted in the time-oriented anesthesia record.
  • Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.

  **Documentation:**
  • Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics, dosages and monitored physiological parameters.
  • Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.

5. Recovery and Discharge

• Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
• The qualified dentist or appropriately trained clinical staff must continually monitor the patient’s blood pressure, heart rate, oxygenation and level of consciousness.
• The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
• Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.
• If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management
• If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient is returned to the intended level of sedation.
• The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.

C. Deep Sedation or General Anesthesia

1. Patient History and Evaluation
Patients considered for deep sedation or general anesthesia must undergo an evaluation prior to the administration of any sedative. This must consist of at least a review of their medical history and medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI) should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation
• The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.
• Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
• A focused physical evaluation must be performed as deemed appropriate.
• Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless invalidated by the patient, procedure or equipment. In addition, body temperature should be measured when clinically appropriate.
• Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.
• An intravenous line, which is secured throughout the procedure, must be established except as provided in part IV. C.6., Special Needs Patients.
3. Personnel and Equipment Requirements

Personnel: A minimum of three (3) individuals must be present.

- A dentist qualified in accordance with part III. C. of these Guidelines to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers’ recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.
- Equipment and drugs necessary to provide advanced airway management, and advanced cardiac life support must be immediately available.
- The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.
- Resuscitation medications and an appropriate defibrillator must be immediately available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

**Oxygenation:** Oxygenation saturation must be evaluated continuously by pulse oximetry.

**Ventilation:**
- Intubated patient: End-tidal CO₂ must be continuously monitored and evaluated.
- Non-intubated patient: 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 qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.
- Respiration rate must be continually monitored and evaluated.
Circulation:
- The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
- The dentist must continually evaluate blood pressure.

Temperature:
- A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.
- The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

Documentation:
- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters.
- Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.

5. Recovery and Discharge
- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The dentist or clinical staff must continually monitor the patient’s blood pressure, heart rate, oxygenation and level of consciousness.
- The dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, and parent, escort, guardian or care giver.

6. Special Needs Patients
Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative management.

In selected circumstances, deep sedation or general anesthesia may be utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some patients; or the establishment of intravenous access after deep sedation or general anesthesia has been induced because of poor patient cooperation.

7. Emergency Management
The qualified dentist is responsible for sedative/anesthetic management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of deep sedation or general anesthesia and providing the equipment, drugs and protocols for patient rescue.
ENDNOTES

1 Excerpted from Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2014, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.

2 Excerpted from Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2014, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.

3 Excerpted from 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. Anesthesiology, 2011. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.

4 Standardized BMI category definitions can be obtained from the Centers for Disease Control and Prevention or the American Society of Anesthesiologists.
Moderate Sedation Consent Form

AUTHORIZATION for the ADMINISTRATION of CONSCIOUS (MODERATE) SEDATION

It has been explained to me that a dentist or that a credentialed dental assistant or dental hygienist nurse under the direct supervision by a dentist will administer Conscious Sedation (also known as moderate sedation, procedural sedation, or sedation and analgesia) for the following procedure:

I hereby authorize such administration of conscious sedation. I understand that conscious sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone, or accompanied by light tactile stimulation. No interventions are usually required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

I also understand that during the course of the proposed conscious sedation unforeseen conditions may arise. I authorize the dentist to perform any additional procedures deemed necessary. I authorize the utilization of emergency resuscitative measures, emergency Endotracheal Intubation or other necessary measures to maintain the airway, and transfer to another facility as needed for any advanced level of care.

I understand that conscious sedation involves potential risks, which may include drowsiness, nausea, vomiting, and amnesia, awareness during the procedure, headaches, muscle aches, sore throat, hoarseness, and feelings of weakness or breathlessness. There is a significant risk I may slip into a deeper state of sedation than anticipated or planned including the state of full general anesthesia. Rare potential risks include injury to teeth, vocal cords, peripheral nerves, skin, respiratory and cardiovascular problems, and loss of function of any and all organ systems, loss of sensation, muscle weakness, infection, allergic reaction, drug reaction, nerve injury, sexual or other hallucinations, heart attack, cardiac arrest, brain damage, stroke or death.

I am aware that other unexpected complications may occur and I acknowledge that no guarantees or warranties have been made to me concerning the results of the administration of conscious sedation. The potential benefits and risks of the proposed procedure and the administration of conscious sedation have been explained to me, the likely results without conscious sedation and the available alternatives have been explained to me. I hereby certify that I have fully understood the above treatment plan and authorization, and that all my questions have been answered.

__________________________________ _____________________          __________________________
Signature of Patient or Surrogate                  Date & Time                            Witness

I have explained the risks, benefits, and alternative to the patient or authorized representative whose signature is affixed above.

__________________________________ __________________________
Independent Licensed Practitioner                                                              Date & Time
## Sedation and Anesthesia Record

**Patient:** ______________________

**ID#:** ______________________

- [ ] Premed 
- [ ] Equipment Check
- [ ] Pre-operative Time Out

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**MONITORS**

- [ ] AUTO BP R L
- [ ] ECG (Lead II)
- [ ] PULSE OXIMETER
- [ ] STETHESCOPE
- [ ] CAPNOGRAPH
- [ ] BIS
- [ ] TEMP

**SYMBOLS**

- [ ] SBP  
- [ ] DBP  
- [ ] PULSE  
- [ ] RESP  
- [ ] Anes ✗ (Start)  
- [ ] Anes ✗ (Stop)  
- [ ] Surg ○ (Start)  
- [ ] Surg ○ (Stop)  

**POSITION**

- [ ] RECLINED
- [ ] SUPINE

**DX:**

**TX:**

**REMARKS:** ________________________________________________________________

**DR. SIGNATURE:** __________________________________________________________
Guideline for 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

Abstract
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.1–52 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.3,4,11,18,20,21,23,24,33,39,41,44,47,51,62–73 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

ABBREVIATIONS

* This guideline was originally adopted in 2006 and reaffirmed in 2011.
principles have been widely implemented and shown to reduce morbidity.\textsuperscript{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.\textsuperscript{38,43,45,47,48,59,62,63,85–112}

Procedural sedation of pediatric patients has serious associated risks.\textsuperscript{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.\textsuperscript{74,78,105}

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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 (e.g., 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.\textsuperscript{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.\textsuperscript{86,87,103} Children younger than 6 years (particularly those younger than 6 months) may be at greatest risk of an adverse event.\textsuperscript{129} Children in this age group are particularly vulnerable to the sedating medication’s effects on respiratory drive, airway patency, and protective airway reflexes.\textsuperscript{52,65} 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.\textsuperscript{20,46,49,182–211}

Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation,\textsuperscript{85,88,212,213} 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 (e.g., 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.\textsuperscript{63,214} Rescue techniques require specific training and skills.\textsuperscript{63,74,215,216} 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.\textsuperscript{128,130,217–220} Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue (see Figs. 1, 2, and 3).\textsuperscript{215,216,221–223}

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.\textsuperscript{30,39,65,75,171,172,201,224–233} 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.

Goals of Sedation

The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are as follows: (1) to guard the patient’s safety and welfare; (2) to minimize physical discomfort and pain; (3) to control anxiety, minimize psychological trauma, and maximize the potential for amnesia; (4) to modify behavior and/or movement so as to allow the safe completion of the procedure; and (5) to return the patient to a state in which discharge from medical/dental supervision is safe, as determined by recognized criteria (Supplemental Appendix 1).

These goals can best be achieved by selecting the lowest dose of drug with the highest therapeutic index for the procedure. It is beyond the scope of this document to specify which drugs are appropriate for which procedures; however, the selection of the fewest number of drugs and matching

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

**Figure 2.** Suggested management of laryngospasm.

**Figure 3.** Suggested management of apnea.
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 MRI, sedatives/hypnotics are preferred. When both sedation and analgesia are desirable (e.g., 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.\(^{236}\)\(^{236}\)\(^{236}\)

Knowledge of each drug’s time of onset, peak response, and duration of action is important (e.g., the peak EEG effect of intravenous midazolam occurs at \(-4.8\) minutes, compared with that of diazepam at \(-1.6\) minutes\(^{237}\)\(^{237}\)). Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drugs.\(^{237}\) 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.\(^{238}\)\(^{238}\)\(^{238}\)\(^{238}\) This concept is particularly important for infants and toddlers transported in car safety seats; re-sedation after discharge attributable to residual prolonged drug effects may lead to airway obstruction.\(^{236}\)\(^{236}\)\(^{236}\) In particular, promethazine (Phenergan; Wyeth Pharmaceuticals, Philadelphia, PA) has a “black box warning” regarding fatal respiratory depression in children younger than 2 years.\(^{243}\) 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.\(^{244}\)\(^{244}\)\(^{244}\)\(^{244}\) Practitioners are encouraged to consult with appropriate subspecialists and/or an anesthesiologist for patients at increased risk of experiencing adverse sedation events because of their underlying medical/surgical conditions.

**Responsible person**

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

**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.\(^{242}\)\(^{242}\)\(^{97}\)\(^{125}\)\(^{125}\)\(^{132}\)\(^{139}\)\(^{139}\) 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.\(^{24}\) 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’s 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/](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.¹²¹,²⁵²

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.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.²⁵²,²⁶⁰–²⁶³,²⁶⁵–²⁶⁷ Consideration for a longer period of observation shall be given if the responsible person’s ability to observe the child is limited (e.g., 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’ post-conceptional age. A 24-hour telephone number for the practitioner or his/her associates shall be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.

Table 1. APPROPRIATE INTAKE OF FOOD AND LIQUIDS BEFORE ELECTIVE SEDATION

<table>
<thead>
<tr>
<th>Ingested material</th>
<th>Minimum fasting period (h)</th>
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<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>
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<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>
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<tr>
<td>Light meal: a light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.</td>
<td>6</td>
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Source: American Society of Anesthesiologists. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. An updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. Available at: “https://www.asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx”. For emergent sedation, the practitioner must balance the depth of sedation versus the risk of possible aspiration; see also Mace et al.²⁷⁰ and Green et al.²⁷⁰

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.³⁵,¹²⁷,²⁵⁸ 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.²⁵⁹,²⁶⁰ However, the absolute risk of aspiration during elective procedural sedation is not yet known; the reported incidence varies from -1 in 825 to -1 in 30,037.³⁵,¹²⁷,¹²⁹,¹³³,²⁴⁴,²⁶¹ 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.²⁶²,²⁶³

For emergency procedures in children undergoing general anesthesia, the reported incidence of pulmonary aspiration of gastric contents from 1 institution is -1 in 373 compared with ~1 in 4544 for elective anesthetics.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,³⁵,¹²⁷,¹²⁹,¹³³,²⁴⁴,²⁶¹,²⁶⁴–²⁶⁶ it is unknown whether the risk of aspiration is reduced when airway manipulation is not performed/anticipated (e.g., 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.²⁶⁰,²⁶⁴,²⁶⁸; however, each of these reports have, for the most part, clearly balanced the urgency of the procedure with the need for and depth of sedation.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.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). It is permissible for routine necessary medications (e.g., 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 ≥95% for age and sex), pregnancy, or bowel motility dysfunction, require careful evaluation before the administration of sedatives. When proper fasting has not been ensured, the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. In this circumstance, additional techniques for achieving analgesia and patient cooperation, such as distraction, guided imagery, video games, topical and local anesthetics, hematoma block or nerve blocks, and other techniques advised by child life specialists, are particularly helpful and should be considered. 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. Some emergency patients requiring deep sedation (e.g., 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. 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. 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 (e.g., 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). Kava may increase the effects of sedatives by potentiating γ-aminobutyric acid inhibitory neurotransmission and may increase acetaminophen-induced liver toxicity. Valerian may itself produce sedation that is apparently mediated through the modulation of γ-aminobutyric acid neurotransmission and receptor function. 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. 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. 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.

The health evaluation should include the following:

- Age and weight (in kg) and gestational age at birth (preterm infants may have associated sequelae such as apnea of prematurity) and weight (in kg) and gestational age at birth (preterm infants may have associated sequelae such as apnea of prematurity); and
- Health history, including (1) food and medication allergies and previous allergic or adverse drug reactions; (2) medication/drug history, including dosage, time, route, and site of administration for prescription, over-the-counter, herbal, or illicit drugs; (3) relevant diseases, physical abnormalities (including genetic syndromes), neurologic impairments that might increase the potential for airway obstruction, obesity, a history of snoring or OSAs, 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 (e.g., 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 [e.g., mandibular hypoplasia], high Mallampati score [i.e., ability to visualize only the hard palate or tip of the uvula]) to determine whether there is an increased risk of airway obstruction;
- 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 (i.e., 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. Adverse events and their treatment shall be documented.

Documentation after treatment

A dedicated and properly equipped recovery area is recommended (see Appendices 3 and 4). The time and condition of the child at discharge from the treatment area or facility shall be documented, which should include documentation that the child’s level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria (see Appendix 1). Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure. Because some sedation medications are known to have a long half-life and may delay a patient’s complete return to baseline or pose the risk of re-sedation, and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (e.g., a step-down observation area) before discharge from medical/dental supervision may be indicated. Several scales to evaluate recovery have been devised and validated. 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.
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. 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. 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 (e.g., Yankauer-type suction).
O = an adequate Oxygen supply and functioning flow meters or other devices to allow its delivery.
A = size-appropriate Airway equipment (e.g., bag-valve-mask or equivalent device [functioning]), nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (checked and functioning), endotracheal tubes, styles, 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, end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (e.g., noninvasive blood pressure, ECG, stethoscope).
E = special Equipment or drugs for a particular case (e.g., 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.

Moderate sedation
Moderate sedation (old terminology, “conscious sedation” or “sedation/analgesia”) is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation; drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Because the patient who receives moderate sedation may progress into a state of deep sedation and obtundation, the practitioner should be prepared to increase the level of vigilance corresponding to what is necessary for deep sedation.

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 (i.e., 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 (e.g., pediatric advanced life support [PALS]); regular skills reinforcement with simulation is strongly encouraged.

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. This individual should be trained in and capable of providing advanced airway skills (e.g., 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.

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 (i.e., patient is developmentally able and purposefully communicates), monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (e.g., Bluetooth™ technology) or precordial stethoscope is strongly recommended. If bi-directional 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 (e.g., 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

### Table 2. COMPARISON OF MODERATE AND DEEP SEDATION EQUIPMENT AND PERSONNEL REQUIREMENTS

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Moderate sedation</th>
<th>Deep sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible practitioner</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Pulse oximetry</td>
<td>Pulse oximetry</td>
</tr>
<tr>
<td></td>
<td>ECG recommended</td>
<td>ECG required</td>
</tr>
<tr>
<td></td>
<td>Heart rate</td>
<td>Heart rate</td>
</tr>
<tr>
<td></td>
<td>Blood pressure</td>
<td>Blood pressure</td>
</tr>
<tr>
<td></td>
<td>Respiration</td>
<td>Respiration</td>
</tr>
<tr>
<td></td>
<td>Capnography recommended</td>
<td>Capnography required</td>
</tr>
<tr>
<td>Other equipment</td>
<td>Suction equipment, adequate oxygen source/supply</td>
<td>Suction equipment, adequate oxygen source/supply, defibrillator required</td>
</tr>
<tr>
<td>Documentation</td>
<td>Name, route, site, time of administration, and dosage of all drugs administered</td>
<td>Name, route, site, time of administration, and dosage of all drugs administered; continuous oxygen saturation, heart rate, and ventilation (capnography recommended); parameters recorded every 10 minutes</td>
</tr>
<tr>
<td>Emergency checklists</td>
<td>Recommended</td>
<td>Recommended</td>
</tr>
<tr>
<td>Rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4)</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Dedicated recovery area with rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4) and dedicated recovery personnel; adequate oxygen supply</td>
<td>Recommended; initial recording of vital signs may be needed at least every 10 minutes until the child begins to awaken, then recording intervals may be increased</td>
<td>Recommended; initial recording of vital signs may be needed for at least 5-minute intervals until the child begins to awaken, then recording intervals may be increased to 10–15 minutes</td>
</tr>
<tr>
<td>Discharge criteria</td>
<td>See Appendix 1</td>
<td>See Appendix 1</td>
</tr>
</tbody>
</table>
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 (e.g., 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 (e.g., 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 (e.g., 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.

### Table 3. COMMONLY USED LOCAL ANESTHETIC AGENTS FOR NERVE BLOCK OR INFILTRATION: DOSES, DURATION, AND CALCULATIONS

<table>
<thead>
<tr>
<th>Local anesthetic</th>
<th>Medical Maximum dose with Epinephrine a (mg/kg)</th>
<th>Medical Maximum dose without Epinephrine (mg/kg)</th>
<th>Dental Maximum dose with Epinephrine a (mg/kg)</th>
<th>Dental Maximum dose without Epinephrine (mg/kg)</th>
<th>Duration of action b (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Esters</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procaine</td>
<td>10.0</td>
<td>7</td>
<td>6</td>
<td>6</td>
<td>60-90</td>
</tr>
<tr>
<td>Chloroprocaine</td>
<td>20.0</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>30-60</td>
</tr>
<tr>
<td>Tetracaine</td>
<td>1.5</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>180-600</td>
</tr>
<tr>
<td><strong>Amides</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lidocaine</td>
<td>7.0</td>
<td>4.4</td>
<td>4</td>
<td>4</td>
<td>90-200</td>
</tr>
<tr>
<td>Mepivacaine</td>
<td>7.0</td>
<td>4.4</td>
<td>5</td>
<td>4.4</td>
<td>120-240</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>3.0</td>
<td>13</td>
<td>2.5</td>
<td>13</td>
<td>180-600</td>
</tr>
<tr>
<td>Levobupivacaine  c</td>
<td>3.0</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>180-600</td>
</tr>
<tr>
<td>Ropivacaine</td>
<td>3.0</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>180-600</td>
</tr>
<tr>
<td>Articaine d</td>
<td>—</td>
<td>7</td>
<td>—</td>
<td>7</td>
<td>60-230</td>
</tr>
</tbody>
</table>

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

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 (e.g., 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.

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

c Levobupivacaine is not available in the United States.

d Use in pediatric patients under 4 years of age is not recommended.
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 airflow, 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 (i.e., continuous waveform). Capnography is particularly useful for patients who are difficult to observe (e.g., 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. The inspired concentrations of inhalation sedation agents and oxygen and the duration of administration shall be documented.

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

Special considerations
Neonates and former preterm infants
Neonates and former preterm infants require specific management, because immaturity of hepatic and renal function may alter the ability to metabolize and excrete sedating medications, resulting in prolonged sedation and the need for extended post-sedation 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.

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>

Table 5. TREATMENT OF LOCAL ANESTHETIC TOXICITY

1. Get help. Ventilate with 100% oxygen. Alert nearest facility with cardiopulmonary bypass capability.
2. Resuscitation: airway/ventilatory support, chest compressions, etc. Avoid vasopressin, calcium channel blockers, ß-blockers, or additional local anesthetic. Reduce epihodrine dosages. Prolonged effort may be required.
3. Seizure management: benzodiazepines preferred (e.g., intravenous midazolam 0.1–0.2 mg/kg); avoid propofol if cardiovascular instability.
4. Administer 15 mL/kg 20% lipid emulsion over ~1 minute to trap unbound amide local anesthetics. Repeat bolus once or twice for persistent cardiovascular collapse.
5. Initiate 20% lipid infusion (0.25 mL/kg per minute) until circulation is restored; double the infusion rate if blood pressure remains low. Continue infusion for at least 10 minutes after attaining circulatory stability. Recommended upper limit of ~10 mL/kg.
6. A fluid bolus of 10–20 mL/kg balanced salt solution and an infusion of phenylephrine (0.1 μg/kg per minute to start) may be needed to correct peripheral vasodilation.

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.\(^{118,120,125,383–386}\) To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (e.g., 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).\(^{118,125,387–400}\) In general, when administering local 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.\(^{401}\) 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).\(^{402–409}\) 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.\(^{410–415}\)

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

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.\(^{64,66,67,72,90,96,110,159–162,164–170,372–375,421–427}\) 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.\(^{161}\) One study in children sedated in the emergency department found that the use of capnography reduced the incidence of hypoventilation and desaturation (7% to 1%).\(^{174}\) 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.\(^{421,422,427}\) 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.\(^{164,168,169}\) 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.\(^{428}\) 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.\(^{429,430}\)

Opioids and benzodiazepines have minimal and variable effects on the BIS. Dexmedetomidine has minimal effect with EEG patterns, consistent with stage 2 sleep.\(^{401}\) Several sedation studies have examined the utility of this device and degree of correlation with standard sedation scales.\(^{347,363,432–435}\) 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.\(^{432}\) Presently, it would appear that BIS monitoring might provide useful information only when used for sedation with propofol;\(^{367}\) in general, it is still considered a research tool and not recommended for routine use.

Adjuncts to airway management and resuscitation

The vast majority of sedation complications can be managed with simple maneuvers, such as supplemental oxygen, opening the airway, suctioning, placement of an oral or nasopharyngeal airway, and bag-mask-valve ventilation. Rarely, tracheal intubation is required for more prolonged ventilatory support.
In addition to standard tracheal intubation techniques, a number of supraglottic devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the LMA, the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.456–457

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.458–442

The LMA can also serve as a bridge to secure airway management in children with anatomic airway abnormalities.443, 444 Practitioners are encouraged to gain experience with these techniques as they become incorporated into PALS courses.

Another valuable emergency technique is intraosseous needle placement for vascular access. Intraosseous needles are available in several sizes; insertion can be life-saving when rapid intravenous access is difficult. A relatively new intraosseous device (EZ-IO Vidacare, now part of Teleflex, Research Triangle Park, NC) is similar to a hand-held battery-powered drill. It allows rapid placement with minimal chance of misplacement; it also has a low-profile intravenous adapter.445–450 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.133,220,450–452 The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events.128, 131,451,453–459 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.456

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.457–459 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.460–463 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.464 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.34,36, 49,86,465–493 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.107,197,492,494,495 In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient’s response.496

References


328. Coté CJ, Posner KL, Domino KB. Death or neurologic injury after tonsillectomy in children with a focus on obstructive sleep apnea: Houston, we have a problem! Anesth Analg 2014;118(6):1276-83.


Supplemental Information

**Appendix 1. Recommended Discharge Criteria**

1. Cardiovascular function and airway patency are satisfactory and stable.
2. The patient is easily arousable, and protective reflexes are intact.
3. The patient can talk (if age appropriate).
4. The patient can sit up unaided (if age appropriate).
5. For a very young or handicapped child incapable of the usually expected responses, the premedication level of responsiveness or a level as close as possible to the normal level for that child should be achieved.
6. The state of hydration is adequate.

**Appendix 2. ASA Physical Status Classification**

- **Class I**: A normally healthy patient.
- **Class II**: A patient with mild systemic disease (e.g., controlled reactive airway disease).
- **Class III**: A patient with severe systemic disease (e.g., a child who is actively wheezing).
- **Class IV**: A patient with severe systemic disease that is a constant threat to life (e.g., a child with status asthmaticus).
- **Class V**: A moribund patient who is not expected to survive without the operation (e.g., a patient with severe cardiomyopathy requiring heart transplantation).

**Appendix 3. Drugs* That May Be Needed to Rescue a Sedated Patient†**

- Albuterol for inhalation
- Ammonia spirits
- Atropine
- Diphenhydramine
- Diazepam
- Epinephrine (1:1000, 1:10 000)
- Flumazenil
- Glucose (25 percent or 50 percent)
- Lidocaine (cardiac lidocaine, local infiltration)
- Lorazepam
- Methylprednisolone
- Naloxone
- Oxygen
- Fosphenytoin
- Racemic epinephrine
- Rocuronium
- Sodium bicarbonate
- Succinylcholine

* The choice of emergency drugs may vary according to individual or procedural needs.

**Appendix 4. Emergency Equipment‡ That May Be Needed to Rescue a Sedated Patient†**

**Intravenous Equipment**

- Assorted IV catheters (e.g., 24-, 22-, 20-, 18-, 16-gauge)
- Tourniquets
- Alcohol wipes
- Adhesive tape
- Assorted syringes (e.g., 1-, 3-, 5-, 10-mL)
- IV tubing
  - Pediatric drip (60 drops/mL)
  - Pediatric burette
  - Adult drip (10 drops/mL)
  - Extension tubing
  - 3-way stopcocks
- IV fluid
  - Lactated Ringer solution
  - Normal saline solution
  - D_2_5 normal saline solution
- Pediatric IV boards
- Assorted IV needles (e.g., 25-, 22-, 20-, and 18-gauge)
- Intraosseous bone marrow needle
- Sterile gauze pads

**Airway Management Equipment**

- Face masks (infant, child, small adult, medium adult, large adult)
- Breathing bag and valve set
- Oropharyngeal airways (infant, child, small adult, medium adult, large adult)
- Nasopharyngeal airways (small, medium, large)
- Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)
- Laryngoscope handles (with extra batteries)
- Laryngoscope blades (with extra light bulbs)
  - Straight (Miller) No. 1, 2, and 3
  - Curved (Macintosh) No. 2 and 3
- Endotracheal tubes (2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, and 6.0 uncuffed and 6.0, 7.0, and 8.0 cuffed)
- Stylettes (appropriate sizes for endotracheal tubes)
- Surgical lubricant
- Suction catheters (appropriate sizes for endotracheal tubes)
- Yankauer-type suction
- Nasogastric tubes
- Nebulizer with medication kits
- Gloves (sterile and nonsterile, latex free)

† The choice of emergency equipment may vary according to individual or procedural needs.
‡ The practitioner is referred to the SOAPME acronym described in the text in preparation for sedating a child for a procedure.