Boulder Community Health
Medical Staff Department

MODERATE/DEEP SEDATION SELF-STUDY GUIDE FOR NON-ANESTHESIOLOGISTS

The following self-study guide is provided for physicians eligible to apply for moderate or deep sedation privileges at BCH. This self-study guide is approximately 27 pages, so you may consider printing only the Test and reviewing the Study Guide on-line.

Once the test has been completed, fax only the test pages to Medical Staff Department at 303-415-7490 or x 7490, along with additional documentation required (see XII. Qualifications for Moderate and Deep Sedation Privileges, p21).

THIS PACKET INCLUDES THE FOLLOWING:

Appendices:

I. DEFINITIONS OF THE CONTINUUM OF SEDATION

Sedation and anesthesia exist along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications. The definitions below illustrate distinctions of the various types of "anesthesia services" offered at BCH.

General Anesthesia: A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support 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.

Regional Anesthesia: The delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. *Given the potential for the conversion and extension of regional to general anesthesia in certain procedures, administration of major regional and general anesthesia are performed only by LIPs (MD/DO) qualified to administer general anesthesia.*

Monitored anesthesia care (MAC): Anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). Indications for MAC depend on the nature of the procedure, the patient's clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MACby CMS but not by the ASA. MAC is administered only by practitioners qualified to administer general anesthesia. Deep sedation may be administered by other qualified practitioners.

> **Deep sedation/analgesia:** 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. Because of the potential for the unintentional progression to general anesthesia in certain procedures, the LIP qualified to administer deep sedation/analgesia cannot be the same LIP performing the procedure.

Moderate sedation/analgesia ("conscious 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. CMS, consistent with ASA guidelines, do not define moderate or conscious sedation as anesthesia.

Minimal sedation: 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. This is also not considered to be anesthesia.

Topical or local anesthesia: The application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications. They are not considered to be anesthesia for purposes of this policy, despite the name.

Rescue: Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

II. PRACTICE GUIDELINES SEDATION AND ANALGESIA by NON-ANESTHESIOLOGISTS

Pre-procedure preparation:
For moderate and deep sedation, appropriate pre-procedure counseling of patients regarding risks, benefits and alternatives to sedation and analgesia increases patient satisfaction.

Sedatives and analgesia tend to impair airway reflexes in proportion to the degree of sedation/analgesia achieved. Pre-procedure fasting decreases risks of both moderate and deep sedation. The ASA Pre-procedure Fasting Guidelines recommend a minimum fasting period of six hours for everything but clear liquids for healthy adults. Factors which may delay gastric emptying beyond this six-hour period include:

- Trauma or injury since last oral intake
- Diabetes mellitus
- Pregnancy
- Recent ingestion or injection of narcotic pain medications

In emergency situations, when pre-procedure fasting is not practical, the target level of sedation should be modified (less sedation should be administered). To decrease the potential for pulmonary aspiration of gastric contents, delaying the procedure and/or Anesthesiology consultation with general anesthesia and protecting the trachea by intubation should be considered.

When determining the appropriate doses of sedative/analgesic medication to be administered, the following must be considered:

- Patient age
- Existing medical conditions
- Duration of sedation desired
- Interactions with other medications
- Dosage-dependant side effects of sedative medication.

Prior to performing a procedure with sedation, patients (or their legal guardians) should be informed of and agree to the administration of sedation/analgesia including the risks, benefits and alternatives to this procedure. Written consent must be obtained prior to administration. In addition, the practitioner must perform the following:

- A detailed history and physical
- Evaluation of NPO status
- Specific evaluation of the airway

In patients with significant sedation-related risk factors (uncooperative patients, morbid obesity, potentially difficult airway, sleep apnea), pre-procedure consultation with an anesthesiologist may increase the likelihood of satisfactory moderate sedation and decrease adverse outcomes.

Availability of Emergency Equipment:
Suction, advanced airway equipment and resuscitation medications should be immediately available and in working order. A functional defibrillator should be immediately available whenever deep sedation is administered and when moderate sedation is administered to patients with cardiovascular disease. Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered. Supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure. If hypoxemia is anticipated or develops during sedation/analgesia, supplemental oxygen should be administered.

Monitoring:
The response of patients to commands during procedures performed with sedation/analgesia serves as a guide to their level of consciousness. Spoken responses also provide indication that the patients are breathing. Patients whose only response is reflex withdrawal from painful stimuli are *deeply sedated*, approaching a state of general anesthesia and should be treated accordingly. The patient's ability to maintain spontaneous ventilation is key to assessing their level of sedation and cardiovascular function. All patients undergoing sedation/analgesia procedures should be monitored by pulse oximetry with appropriate alarms. The Task Force emphasizes that because ventilation and oxygenation are separate though related physiological processes, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function.

In patients receiving intravenous medications for sedation/analgesia, vascular access should be maintained throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression.

Early detection of changes in a patient's heart rate and blood pressure may enable practitioners to detect problems and intervene in a timely fashion, reducing the risk of complications. Continuous monitoring of electrocardiography, pulse oximetry, and blood pressure monitoring every five minutes reduces risk of deep sedation. During procedures where a verbal response is not possible (eg.: esophagogastroduodenoscopy or oral surgery), the ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile stimulation suggests that the patient will be able to maintain a patent airway and take deep breaths if necessary, corresponding to a state of *moderate sedation*.

Vital signs and respiratory variables should be recorded before initiating sedation/analgesia, after administration of medications at regular or continuous intervals during the procedure, upon initiation of recovery and immediately before discharge.

The ASA recommends that at least one qualified practitioner trained in basic life support (CPR, bag-valve mask ventilation) should be present in the procedure room during both moderate and deep sedation and that a practitioner trained in advanced life support skills (tracheal intubation, defibrillation, use of resuscitation medications) must be no more than 5 minutes away for *moderate sedation*, and present in the procedure room for *deep sedation*.

Hospital policy at BCH requires that at least one person with current ACLS certification be in the room during sedation. This could be the nurse for moderate sedation, but must be a physician for deep sedation.

During *moderate sedation*, the individual monitoring the patient may assist the practitioner with interruptible tasks of short duration, however, during *deep sedation*, the physician responsible for monitoring the patient and administering sedation should have no other responsibilities.

Rescue from Deeper than Planned Sedation:
A major safety requirement for giving sedation is that the practitioner must be able to manage a patient who becomes more deeply sedated than originally planned. A patient may proceed directly into an untoward level of sedation without first exhibiting the desired sedative effects.
Practitioners administering sedation/analgesia for procedures must be able to rescue a patient from unintentional sedative effects. This would include:

- Ability to perform endotracheal intubation (for deep sedation)
- Airway management skills
- Advanced Cardiac Life Support certification
- Knowledge of reversal agents and of sedative medications with no available pharmacological reversal agents (Etomidate, Propofol, Dexmedetomidine, and Ketamine).

Specific antagonist agents are available for opioids and benzodiazepines. The literature supports the ability of naloxone to reverse opioid induced sedation and respiratory depression. Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia or pulmonary edema. Initial administration of naloxone may need to be repeated after 30-45 minutes, as its duration may be shorter than the duration of the sedation medication. Prior to or concomitantly with pharmacologic reversal, patients who become hypoxemic or apneic during sedation/analgesia should:

- Be encouraged or stimulated to breathe deeply.
- Receive supplemental oxygen.
- Receive airway maintenance maneuvers and positive pressure ventilation if spontaneous ventilation is inadequate.

Discharge Criteria:
Written discharge criteria should be designed to minimize the risk of central nervous system or cardiorespiratory depression following discharge from observation by trained personnel.

The effects of sedation may last longer than the duration of the procedure. It is the responsibility of the practitioner supervising the sedation to ensure that the patient is protected until they recover their ability to protect themselves. A practitioner with advanced Life Support training must remain physically present at the patient bedside until the patient recovers at least to a level of moderate sedation. The patient must remain in the care of a Registered Nurse skilled in recovery of sedated patients until the patient meets pre-determined discharge criteria.

[Condensed from "Practice guidelines for Sedation and Analgesia by Non-anesthesiologists." (ASA 10/01)
A report by the American Society of Anesthesiologists Task Force on Sedation. 10/17/2001.]

III. UNDESIRABLE EFFECTS OF SEDATION

As with most invasive measures, there are possible undesirable effects of procedural sedation

- Non-arousable sleep
- Airway obstruction
- Apnea
- Cardiac arrhythmia
- Respiratory insufficiency
- Thrombophlebitis
- Injection site pain
- Nystagmus (may be normal with large doses of diazepam)
- Allergic reactions (e.g., rash, redness, itching, hives, edema, hypotension, syncope, bronchoconstriction, or respiratory distress)
- Paradoxical response

Paradoxical Response

A paradoxical response manifests as non-cooperation, mental confusion, agitation or combativeness as additional sedative medication is administered. It is seen most often in alcoholic patients and/or IV drug abusers, who have a higher tolerance for the effects of sedative drugs. Such responses can also result from inadequate or excessive dosing or improper administration of the drug. Consideration should also be given to the possibility of cerebral hypoxia or a true paradoxical reaction.

Agitation/excitement is also frequently seen in adolescents (especially males). Large doses of sedating medications (to the point of general anesthesia and assisted ventilation) may be necessary to overcome this reaction in adolescents. Consultation with anesthesiology or a practitioner experienced in deep sedation of adolescents may be necessary for patients who exhibit this response.

Prompt recognition of a paradoxical reaction is important to avoid the complications of every medication. The paradoxical response should not be interpreted as a need for additional sedation. The sedative dose on board should be allowed to take effect before making further attempts to initiate the procedure on an agitated, uncooperative patient. If necessary, intravenous flumazenil (which reverses the effects of benzodiazepine-induced sedation) can be administered. The procedure should continue only when the patient becomes cooperative and exhibits other signs of adequate conscious sedation.

IV. REVIEW OF SEDATIVE AND ANALGESIC AGENTS

The choice of agent for sedation/analgesia should be dictated by the needs of the patient, his medical condition, the requirements of the procedure and the expertise of the practitioner. No single drug or drug dosage can (or should) be used in all situations. Remember that the elderly and frail may be more sensitive to medications and to start with the lower initial dose and then slowly increase the dose as needed.

An "ideal agent" would...

1. Exhibit a rapid and predictable onset of action following administration.
2. Have a predictable dose-effect relationship, uniform and narrow dose response, a wide therapeutic ratio, and would allow for a quick recovery.
3. Feature minimal respiratory or cardiovascular depressant effects, and minimal excitatory effects on the central nervous system.
4. Have predictable anxiolysis and amnesia with no post-sedation confusion, a lack of accumulation and a low incidence of post-procedure nausea or vomiting.
5. Be soluble in water, stable in solution and non-irritating on injection, and be physically compatible with other agents.
6. Possess some analgesic properties and have no potential for allergic or hypersensitive reactions.
7. Have a reversal agent available that is safe and predictable.

Therefore, in attempting to achieve these goals, sometimes sedative agents from two or more classes are used. This practice takes advantage of the synergy between classes of sedative agents, such as the combination of effects from opioids and benzodiazepines.

A sedative alone may be appropriate for some patients undergoing non-painful procedures, while other patients may require an opioid analgesic. Some drugs, particularly the benzodiazepines, show tremendous variability in patient response. Therefore, individual titration of sedative and analgesic agents is essential.

V. BENZODIAZEPINES

- Diazepam
- Midazolam
- Lorazepam

As a class, the benzodiazepines act by enhancing the inhibitory effects of gamma-aminobutyric (GABA) on chloride channels in neurons at all levels of the neuraxis. This yields the effects of anxiolysis, sedation, hypnosis, amnesia, muscle relaxation, and anti-convulsant activity. The variety of effects and the extent of the effects vary according to the particular agent and the dose. Although large doses of benzodiazepines are required to cause respiratory depression, combining these agents with opioids during procedural sedation procedures potentiates the risk of respiratory depression.

Diazepam (Valium)

Diazepam is an agent that is poorly soluble in water, and therefore is solubilized in propylene glycol, ethyl alcohol, benzoic acid, and benzyl alcohol. This preparation, when administered intravenously, is notorious for causing pain and venous irritation. Dilution of diazepam in water or saline causes cloudiness, but does not affect potency.

Onset of action (min): Less than 2 minutes.

Peak effect (min): 3-4 minutes; duration of sedation 15-60 minutes; residual effects may be seen for up to 4 hours or longer. An active metabolite of diazepam has a long half life and may cause confusion or amnesia (especially in the elderly) for more than 90 (ninety) hours.

Side-Effects: Diazepam can produce respiratory depression, hypotension, excessive sedation, and apnea, especially in the presence of opioids. Liver and renal disease can cause accumulation of the drug and its metabolites, causing prolonged sedation. Accumulation effect is also likely to occur in elderly & in patients with congestive heart failure.

Recommended Doses: Usual dose to achieve anxiolysis and anterograde amnesia is 2-5 mg. Age 18-60 years: 2.5 mg IV over 3-5 minutes to maximum of 0.2 mg/kg if opioids not administered. Age over 60 &/or poor risk: 1.5 mg IV over 3-5 minutes to maximum of 0.1 mg/kg if opioids not administered.

Reversal Agent: For reversal of conscious sedation from benzodiazepine, Flumazenil 0.2 mg IV over 15 seconds may be given. After waiting 45 seconds, an additional 0.2 mg may be given and repeated at 60-second intervals up to 1 mg. If re-sedation occurs, re-titrate Flumazenil in 0.2 mg/minute increments, to a total of 1 mg every 20 minutes, not to exceed 3.0 mg over one hour. Patients should be watched for re-sedation for at least 1 hour after the last dose of Flumazenil.

Midazolam (Versed)

This agent is one of the most widely used agents in procedures requiring procedural sedation (usually in combination with fentanyl as the opioid). It provides profound procedural amnesia and sedation. Midazolam is water-soluble, so it is well-tolerated when administered intravenously.

Midazolam is approximately three-times as potent as diazepam. The elimination half-life may be doubled in the elderly, reflecting decreased hepatic blood flow and enzyme activity.

Onset of Action: 30 seconds to 1 minute.

Peak effect (min): 3-5 minutes; duration of sedation is 15-80 minutes. Anterograde amnesia occurs within 1-5 minutes & persists for 20-40 minutes or longer.

Side-Effects: Midazolam can produce respiratory depression, hypotension, excessive sedation, and apnea, especially in the presence of opioids in the elderly. Midazolam is capable of producing all levels of CNS depression from mild sedation to respiratory depression to coma.

Recommended Doses: Doses greater than 5 mg should be administered only by a physician. Age 18-60 years: 1-5 mg IV over 2 minutes; titrate in 1 mg increments to maximum total dose of up to 0.2 mg/kg when used without an opioid; decrease dose by 30% when given with an opioid. Age over 60 years &/or poor risk: 0.5-1.5 mg IV over 2-3 minutes to maximum total dose of up to 0.1 mg/kg when used without an opioid; decrease dose 33-50% when given with an opioid.

Reversal Agent: For reversal of conscious sedation from benzodiazepine, Flumazenil 0.2 mg IV over 15 seconds may be given. After waiting 45 seconds, an additional 0.2 mg may be given and repeated at 60-second intervals up to 1 mg. If re-sedation occurs, re-titrate Flumazenil in 0.2 mg/minute increments, to a total of 1 mg every 20 minutes, not to exceed 3.0 mg over one hour. Patients should be watched for re-sedation for at least 1 hour after the last dose of Flumazenil.

Lorazepam (Ativan)

Lorazepam is a potent amnesic, and has a significantly slower onset and longer duration of action than either midazolam or diazepam. The slow onset and long duration of action limit its use for intravenous sedation in the ambulatory procedural areas.

Onset of Action: 1-5 minutes.

Peak effect (min): 15-20 minutes; duration of sedation is 6-10 hours.

Side-Effects: Respiratory depression in elderly or when combined with opioids. Hypotension when combined with opioids.

Recommended Doses: Age 18-60 years: 1-2 mg IV over 1-2 minutes to maximum of 0.04 mg/kg. Age over 60 &/or poor risk: 0.5-1 mg IV; give in 0.5 mg increments every 5 minutes to maximum of 0.03 mg/kg. Decrease dose by 30% when given with opioids.

Reversal Agent: For reversal of conscious sedation from benzodiazepine, Flumazenil 0.2 mg IV over 15 seconds may be given. After waiting 45 seconds, an additional 0.2 mg may be given and repeated at 60-second intervals up to 1 mg. If re-sedation occurs, re-titrate Flumazenil in 0.2 mg/minute increments, to a total of 1 mg every 20 minutes, not to exceed 3.0 mg over one hour. Patients should be watched for re-sedation for at least 1 hour after the last dose of Flumazenil.

VI. BENZODIAZEPINE ANTAGONISTS

Flumazenil (Romazicon)

Flumazenil is a competitive antagonist with a high affinity for benzodiazepine receptors. Flumazenil's elimination half-life is approximately one hour. Although effective as an antagonist, its action is sometimes thwarted by the longer half-life of the agent it is meant to oppose. The efficacy of Flumazenil depends on the agent and dose of benzodiazepine it is meant to oppose. Administration of Flumazenil in patients with a considerable tissue level of benzodiazepine can cause reversal of the effects, followed by a period of re-obtundation after the effects of the reversal have worn off. For this reason, the use of Flumazenil requires an extended observation period before the patient can be declared no longer under the influence of the benzodiazepine.

Flumazenil may precipitate seizures in patients with convulsive disorders, CNS pathology, benzodiazepine tolerance/dependent, or multiple-drug overdose (especially tricyclic antidepressants). Adequate oxygenation and ventilation should be ensured prior to administration of Flumazenil. In situations of suspected benzodiazepine overdose, the airway should be secured prior to administration of Flumazenil. Flumazenil is an adjuvant to – not a substitute for – proper airway management.

Adverse Side-Effects: Nausea and vomiting, dizziness, pain on injection, agitation/anxiety, resedation and convulsions.

VII. OPIATES

All of the opiates interact with the opiate receptors in the central nervous system to produce analgesia and other side-effects. The use of opioids should be reserved for procedures that are painful. Opioids are not indicated for amnesia or anxiolysis. The three major designations of opioid receptors are mu, kappa, and delta. These receptors are connected with analgesia and each has identified subtypes that are respectively connected with such opiate side-effects as respiratory depression, constipation, physical dependence and sedation. The differences in onset and duration of the opiates can be attributed to their affinity for the receptors, their lipid solubility (reflecting their ability to cross the blood-brain barrier), half-life and the presence or absence of active metabolite. Side-effects of all these agents increase with the dose and the rate of administration. All opiates are metabolized in the liver, with the metabolites largely excreted by the kidneys.

Remember the respiratory depression effect of opiates when combining them with benzodiazepines.

Fentanyl

Fentanyl is more lipophilic than morphine and crosses the blood-brain barrier faster. Because the opioid receptors are situated primarily in spinal and supraspinal sites, the rapidity with which the drug passes from the circulation into the central nervous system dictates how rapidly analgesic effect can be achieved. Onset is usually within 30 seconds. Lipid-solubility of this drug also accounts for its short action, via re-distribution away from the central nervous system to peripheral lipid stores. A dose of 100 mcg (2 ml) is approximately equivalent in analgesic activity to 10 mg of morphine or 75 mg of meperidine.

Onset of Action: Within 1 minute.

Peak effect (min): Peak analgesia within 1-3 minutes; duration of analgesia 30-60 minutes after a single dose of up to 100 mcg.

Side-Effects: Rapid IV push of more than 100 mcg may cause chest wall muscle rigidity. Fentanyl can cause ventilatory depression, apnea, sedation, hypotension, nausea, vomiting, cardiovascular depression and euphoria.

Recommended Doses: Age 18-60 years: 25-50 mcg over 1-2 minutes to max of 100 mcg/hr. Age over 60 &/or poor risk: 12.5 mcg IV over 1-2 minutes to max of 50 mcg/hr.

Reversal Agent: Naloxone (Narcan) 1 to 5 mcg/kg, depending upon the urgency of the situation. If the situation permits, naloxone should be titrated carefully to avoid complete reversal of analgesia and ensuing hypertension and tachycardia. In emergency situations, one amp (400 mcg) can be given IV. Keep in mind that the duration of naloxone is shorter than the opioid's duration, so prolonged observation is necessary after giving naloxone, and repeat doses may be necessary.

Morphine

Morphine is a prototypical opioid analgesic agent to which all other opioids are compared. In humans, morphine produces analgesia, euphoria, sedation, and diminished ability to concentrate. Other sensations include nausea, a feeling of body warmth, heaviness of extremities, dryness of the mouth, and pruritus, especially around the nose. Morphine is poorly soluble in lipids, limiting its access through the blood-brain barrier. Morphine has a relatively slow onset and long duration of action, limiting its use in procedural sedation.

Onset of Action: Within 1-3 minutes.

Peak effect (min): Peak analgesia occurs within 20 minutes and may last up to 7 hours. Maximal respiratory depression usually occurs within 7 minutes.

Side-Effects: Morphine can cause ventilatory depression, apnea, sedation, hypotension, nausea, vomiting, chest-wall rigidity, cardiovascular depression and euphoria.

Recommended Doses: Age 18-60 years: 1-2 mg IV over 2 minutes every 5 minutes to maximum of 0.1 mg/kg. Age over 60 &/or poor risk: 0.5-1 mg IV over 2 minutes every 5 minutes to maximum of 7.5 mg.

Reversal Agent: Naloxone (Narcan) 1 to 5 mcg/kg, depending upon the urgency of the situation. If the situation permits, naloxone should be titrated carefully to avoid complete reversal of analgesia and ensuing hypertension and tachycardia. In emergency situations, one amp (400 mcg) can be given IV. Keep in mind that the duration of naloxone is shorter than the opioid's duration, so prolonged observation is necessary after giving naloxone, and repeat doses may be necessary.

VIII. OPIOID ANTAGONISTS

Naloxone

Naloxone, an opioid antagonist, has affinity for all three of the opioid receptors. Because its halflife is similar to that of the agents it antagonizes, often one dose or a series of doses given 20 minutes apart is sufficient to reverse the central nervous system and respiratory depression of the opioid. Antagonism of opioid-induced ventilatory depression is accompanied by an inevitable reversal of analgesia. It may be possible, however, to titrate the dose of naloxone such that depression of ventilation is partially but acceptably antagonized, so as to maintain partial analgesia.

Side-Effects: Nausea and vomiting appear to be closely related to the dose and speed of injection of naloxone. Administration of naloxone slowly, over 2-3 minutes, rather than as a bolus, seems to reduce the incidence of nausea and vomiting. Cardiovascular stimulation following administration of naloxone manifests as increased sympathetic nervous system activity (presumably reflecting the abrupt reversal of analgesia and the sudden perception of severe pain), pulmonary edema, and cardiac dysrhythmias. Ventricular fibrillation has even occurred following intravenous administration of naloxone.

IX. BCH POLICY/PROCEDURE: MODERATE SEDATION BY NON-ANESTHESIOLOGISTS

PURPOSE

The purpose of this policy is to provide guidelines to allow qualified providers in the appropriate setting to administer moderate sedation while minimizing associated risks to the patient.

These guidelines are designed to ensure all patients receiving moderate sedation will receive comparable standards of care including assessment, management, monitoring, evaluation and documentation. These standards of care are followed before, during and after administration of moderate sedation until such point that the patient achieves a satisfactory discharge score.

SCOPE

The scope of this policy is to outline the care of patients receiving moderate sedation by all routes (IV, IM, PO) provided by non-anesthesiologist care providers for the purpose of diagnostic or therapeutic interventions.
Since levels of sedation are a continuum, licensed independent practitioners (**LIP**) (MD/DO/DMD/DDS/DPMs) providing or supervising moderate sedation (sedation practitioners) must have had, at a minimum, competency-based education, training, and experience to manage a compromised airway and to provide adequate oxygenation and ventilation, including demonstrated proficiency in airway management with a facemask and positive pressure ventilation as evidenced by completion of a course in basic airway management.

Specially trained sedation professionals (RN) with sedation competencies and current ACLS certification can administer moderate sedation on the order and under the direct supervision of the sedation practitioner.

This policy applies to the following settings where moderate sedation is administered: 3W, CMC, CVC, Cath Lab, EP, ED, Endo, ICU, CCC, FBC, Imaging, F-2NW.

Continuous Quality Improvement.

The purpose of the CQI program is to reduce patient risk and improve quality of care for patients undergoing moderate sedation. A listing of Indicators/events which must be reported by the practitioner performing the moderate sedation and/or by a facility employee (e.g.: RN assisting with the NAAS) who is aware of the event are on the Non-anesthesiology Anesthesia Services Performance Improvement (PI) reporting for BCH form. Report events on this form only if potentially related to the sedation. Report events unrelated to anesthesia services to the appropriate department or section.

PROCEDURE *-- Requires an LIP order*

Responsible Person	A. PRIOR TO MODERATE SEDATION ADMINISTRATION
RN	1. Verify the following prior to giving sedation for planned and unplanned procedures: a. An order for procedural (moderate) sedation is documented. b. The correct patient using two patient identifiers c. Type of procedure to be performed. 2. For planned procedures, verify the following. For unplanned procedures, verify as many as possible: a. Written consent for the procedure or treatment, including for the procedural sedation b. Allergies c. NPO status: (1) only clear liquids eight hours prior to patient check-in; (2) nothing by mouth three hours prior to procedure. d. Presence of sleep apnea symptoms, including: • Diagnosis of sleep apnea • Apneic periods when sleeping

	• Gasping or choking when asleep • Loud or frequent snoring • Obesity/ BMI > 35 • Daytime sleepiness • Short chin or other airway abnormalities e. How to report any symptoms/signs of over-sedation or cardiovascular compromise to the LIP during procedure. f. Patient education: • Patient understands effects of sedation and the precautions to take for 24 hours after receiving sedation, including: • Do not drive a car or take public transportation independently. • Do not make major decisions or sign legal documents. • Do no activities requiring skilled physical coordination or hand-eye coordination. • Alcohol should be avoided for a period of 24 hours. • Conditions under which immediate emergency care should be sought. • A responsible adult is available for 24 hours. **PATIENTS BEING DISCHARGED LESS THAN 24 HOURS AFTER RECEIVING SEDATION NEED TO MAKE ARRANGEMENTS TO HAVE A RESPONSIBLE ADULT DRIVE OR ACCOMPANY THEM HOME AND TO HAVE A RESPONSIBLE ADULT AVAILABLE IN CASE OF AN EMERGENCY.** 3. Check that the following is available for immediate use in the treatment room. Follow infection control policies regarding equipment cleaning and usage: • Oxygen delivery system • Suction delivery system • Suction equipment • Blood pressure measuring device • Pulse oximeter • End-tidal CO2 monitor – if moderate sedation is to be administered in settings where patients' ventilatory function cannot be directly monitored (e.g. MRI suite) • Emergency Code Blue cart • Cardiac monitor (EKG is monitored on patients with significant cardiovascular disease or when dysrhythmias are anticipated or detected as determined by the prescribing LIP.) . • Sedating medication, emergency medications, and reversal agents
LIP	4. Update the history and physical within 24 hours prior to procedure. 5. Assess and document the patient's suitability for sedation prior to any medication administration, including at a minimum: • Airway evaluation • ASA status • Time of last oral intake 6. Discuss the plan, risks, alternatives and benefits of sedation and the procedure with the patient. 7. **Pre-sedation evaluation:** a. The pre-sedation evaluation of the patient includes, at a minimum, **ELEMENTS THAT MUST BE PERFORMED WITHIN A 48-HOUR TIMEFRAME PRIOR TO ADMINISTRATION OF SEDATION:** • Review of the medical history, adverse reactions to prior anesthetics or sedatives, current medications, and allergies to medications, and • Interview, if possible given the patient's condition, and • Examination of the patient. **ELEMENTS THAT MUST BE REVIEWED AND UPDATED AS NECESSARY WITHIN 48 HOURS PRIOR TO SEDATION, BUT WHICH MAY ALSO HAVE BEEN PERFORMED DURING OR WITHIN THE 30-DAYS PRIOR TO THE 48-HOUR TIME PERIOD, IN PREPARATION FOR THE PROCEDURE:**

	• Notation of sedation risk according to established standards of practice (e.g., ASA classification of physical status I-VI); • Identification of potential sedation problems, particularly those that may suggest potential complications or contraindications to the planned procedures (e.g., difficult airway, ongoing infection, limited intravascular access); • Additional pre- sedation data or information, if applicable and as required in accordance with standard practice prior to administering sedation (e.g., stress tests, additional specialist consultation); • Development of the plan for the patient's sedation care, including the type of medications for moderate sedation, maintenance and post-procedure care and discussion with the patient (or patient's representative) of the risks and benefits of the delivery of sedation. • Delegation of the pre- sedation evaluation to practitioners who are not qualified to administer sedation is not permitted at BCH. Qualified practitioners at BCH include only MD/DO/DMD/DDS/DPMs. b. Mark site of procedure according to the Site Marking policy.
RN	8. Obtain baseline vital signs, including: • Temperature • Height and weight • Respiratory rate • Blood pressure • End tidal CO2 monitor – if moderate sedation is to be administered in settings where patients' ventilatory function cannot be directly monitored (e.g. MRI suite) • O2 saturation • Heart rate/rhythm 9. Document • Level of sedation • Patient's baseline pain level (0-10 numeric scale or PABS scale) • Baseline Aldrete Score
LIP & RN	10. Perform time out, including: a. Identify and verify correct patient using two identifiers from two sources. b. Verify site marking and procedure. 11. Document safety pause — "time out". Airway assessment is announced.
	I. ADMINISTRATION, ONGOING ASSESSMENT AND MONITORING
RN	1. Administer all drugs used for the purpose of moderate sedation according to individual drug/dosing protocols and Medication Administration Safety and Infection Control policies. 2. Assess and monitor all patients receiving moderate sedation, either inpatients or outpatients as outlined below. 3. Report to LIP immediately any adverse reactions, complications, or side effects, such as respiratory depression or hypotension. 4. If the patient's level of sedation exceeds moderate at any time during the procedure, the RN must notify the LIP and cease giving sedating medications until the patient returns to a moderate level of sedation. This may also require taking steps (e.g.: airway management) to rescue the patient from a too deep level of sedation. A level of sedation deeper than planned must be reported on the QAPI report. ***In the event of a life support emergency, call a CODE BLUE, page an anesthesiologist, or call STAT team as needed.***
LIP	5. If the procedure cannot be completed with a moderate level of sedation the LIP must stop the procedure (if it does not endanger the patient) and/or make arrangements for the provision of deep sedation or anesthesia as appropriate.

RN	6. At the time sedation drugs are being given and during the procedure, monitor the following, recorded at least every five minutes in the Procedural Sedation Flow sheet: • Respiratory rate • Blood pressure • End tidal CO2 monitor – if moderate sedation is to be administered in settings where patients' ventilatory function cannot be directly monitored (e.g. MRI suite) • Oxygen saturation • Heart rate/rhythm • Level of sedation • Pain level (0-10 numeric scale or PABS scale) • Any abnormal baseline parameters (such as cardiac rhythm or breathing) 7. After the procedure or test, monitor the following, recorded every five minutes until stable for three readings in a row. Then, monitor every 15 minutes. Record in the Procedural Sedation Flow Sheet: • Respiratory rate • Blood pressure • End tidal CO2 monitor – if moderate sedation is to be administered in settings where patients' ventilatory function cannot be directly monitored (e.g. MRI suite) • Oxygen saturation • Heart rate/rhythm • Level of sedation • Pain level (0-10 numeric scale or PABS scale) • Any abnormal baseline parameters (such as cardiac rhythm or breathing) 8. The patient cannot be transferred to another unit, other than PACU, ICU, ED, CVC or OCC, until: • The patient's Aldrete score is 9 or greater or returned to pre-procedure value; AND • Vital signs are stable for a minimum of 15 minutes. ► **RESUMING PRE-PROCEDURE MONITORING OR BEING TRANSFERRED BACK TO THE UNIT WITHOUT MEETING THESE REQUIREMENTS REQUIRES A PHYSICIAN ORDER.** 9. **Outpatients:** May be discharged from the hospital when all of the following discharge criteria are met: • The patient's Aldrete score is 9 or greater with no zeros or returned to pre-procedure value; AND • Vital signs are stable for a minimum of 15 minutes • Minimal to no nausea • Able to ambulate • No need for parenteral medications • Patient and a responsible adult have been educated regarding the effects of procedure, sedation, symptoms to report, and how to seek emergency care, and the importance of having someone available.
	II. POST-SEDATION EVALUATION
LIP	1. While patients receiving moderate sedation are monitored and evaluated before, during, and after the procedure by trained practitioners, a complete post-anesthesia evaluation is not required. 2. Depending on the specific procedure performed, additional types of monitoring and assessment may be necessary

X. BCH POLICY/PROCEDURE: DEEP SEDATION BY NON-ANESTHESIOLOGISTS

PURPOSE
To provide clinical management guidelines for the purpose of ensuring uniformity of care provided to patients receiving deep sedation by non-anesthesiologists.

SCOPE
This policy applies to: Deep Sedation administered by non-anesthesiologists for various procedures throughout the BCH system.

Deep Sedation Privileges
Privileges to perform Deep Sedation must be granted by the Medical Staff at BCH. Qualifications include:

- Practitioner must be qualified to rescue patients from unintentional general anesthesia during deep sedation. This requires that the practitioner have advanced airway skills, advanced life support skills, and familiarity with medications which may be needed to rescue patients from deeper than intended sedation/general anesthesia.

Practitioner must be familiar with:

- The ASA guidelines for deep sedation by non-anesthesiologists
- The CMS interpretive guidelines for Anesthesia Services
- The ASA guidelines for NPO status,
- Approved protocols for administration of sedating mediations which do not have reversal agents (if these medications are to be used by the practitioner), and
- All required monitoring modalities (including capnography).
- Practitioner must personally administer the deep sedation; it cannot be administered by another person under the supervision of the practitioner. The deep sedation practitioner cannot both administer the sedation and perform the procedure for which it is being given (EDP/CCP exception only).
- Practitioner must demonstrate ongoing competence in deep sedation to maintain their privileges and participate in the hospital continuous quality improvement program.

I. PROCEDURE

Responsible Person	B. DEEP SEDATION ADMINISTRATION
LIP	*Deep Sedation Practitioner* • Evaluate the patient for suitability for deep sedation. The evaluation must include all elements of a pre-anesthesia evaluation and must be completed within 48 hours before the administration of the sedation. (EDP/CCP exception only). • Confirm that all necessary age-appropriate equipment and medications are present and functional in the immediate area where the sedation is to be performed. (EDP/CCP exception only). • Obtain written consent for the sedation. (*A separate consent and proper site marking for the procedure being performed would also be needed by the practitioner performing the procedure for which the sedation is being given*). • Continuously monitor the patient throughout the sedation according to the monitoring standards of the ASA (American Society of Anesthesiologists). Document the results of the monitoring appropriately. • Transfer care only to an appropriately trained person (e.g.: PACU or ICU nurse if the patient is still significantly sedated at the end of the sedation) or personally remain with the patient until they recover sufficiently to be safe (Aldrete score of 9 or better with no zeros or to pre-procedure value). • Evaluate the patient after sedation is concluded and the patient is able to participate with the evaluation in a meaningful way. A full post-anesthesia evaluation must be completed within 48 hours after the sedation. Delegation of the post-anesthesia evaluation to practitioners who are not

	qualified to administer deep sedation/anesthesia is not permitted
RN	*RN/PA/NP Assistant* • A registered nurse, physician assistant or nurse practitioner may assist with the sedation or with the procedure but may not perform the sedation. • Confirm proper permits, i.e. consent forms • Confirm proper equipment present and functioning • Confirm patient identify

CONTINUOUS QUALITY IMPROVEMENT (CQI)

The purpose of the CQI program is to reduce patient risk and improve quality of care for patients undergoing moderate sedation, deep sedation/analgesia. A listing of Indicators/events which must be reported by the practitioner performing the deep sedation and/or by a facility employee (e.g.: RN assisting with the NAAS) who is aware of the event are on the Non-anesthesiology Anesthesia Services Performance Improvement (PI) Reporting for BCH form. Report events on this form only if potentially related to the sedation/anesthesia. Report events unrelated to anesthesia services to the appropriate department or section.

XI. NON-ANESTHESIOLOGY ANESTHESIA SERVICES PERFORMANCE IMPROVEMENT (PI) REPORTABLE EVENTS

The following indicators/events must be reported for non-anesthesiology anesthesia services (NAAS) by the practitioner performing the sedation and/or by a BCH employee (e.g.: RN assisting with the NAAS) who is aware of the event.

- Filing of an occurrence report related to the Anesthesia Service
- Anaphylaxis or moderate/severe allergic reaction
- Major adverse cardiac event (eg: cardiac arrest, MI, persistent/severe dysrhythmia, etc)
- Major adverse respiratory event (eg: aspiration, pulmonary edema, severe asthma, etc)
- Major adverse neurological event (eg: new stroke, seizure, peripheral neuro deficit, etc)
- Local anesthetic toxicity or allergy (eg: seizure, cardiac arrest, jittery, metal taste in mouth)
- Deeper than planned level of sedation lasting longer than 2 minutes or requiring airway interventions (chin lift, jaw thrust, intubation, etc) and/or assisted ventilation

XII. QUALIFICATIONS FOR MODERATE AND DEEP SEDATION PRIVILEGES

MODERATE SEDATION PRIVILEGING REQUIREMENTS:

Initial Appointment:

A. Completion of the sedation self-study packet, including post-test with a passing score of 85%.
B. Provide evidence of current ACLS certification, which included an airway management module
   OR
   Completion of an approved Airway Management Skills Lab, including hands on practice with OPAs, LMA and ET intubation on airway simulators.
C. Provide evidence of current PALS certification if practice will include children/infants/newborns.

Maintenance of Moderate Sedation Privileges (Every 2 years):

A. Completion of the sedation self-study packet, including post-test with a passing score of 85%.
B. Provide evidence of current ACLS certification, which included an airway management module
   OR
   Completion of an approved Airway Management Skills Lab, including hands on practice with OPAs, LMA and ET intubation on airway simulators.
C. Provide evidence of current PALS certification if practice will include children/infants/newborns.

DEEP SEDATION PRIVILEGING REQUIREMENTS:

Initial Appointment:

A. Completion of the sedation self-study packet, including post-test with a passing score of 85%
B. Provide evidence of current ACLS certification
   AND
   Completion of an approved Airway Management Skills Lab, including hands on practice with OPAs, LMA and ET intubation on airway simulators.
C. Provide documentation of 3 proctored cases by a practitioner with deep sedation privileges.
D. Provide evidence of current PALS certification if practice will include children/infants/newborns.

Maintenance of Deep Sedation Privileges (Every 2 years):

A. Completion of the sedation self-study packet, including post-test with a passing score of 85%.
B. Provide evidence of current ACLS certification, which included an airway management module
   AND
   Completion of an approved Airway Management Skills Lab, including hands on practice with OPAs, LMA and ET intubation on airway simulators.
C. Provide evidence of current PALS certification if practice will include children/infants/newborns.

USE OF SEDATIVE MEDICATIONS WHICH DO NOT HAVE REVERSAL AGENTS:

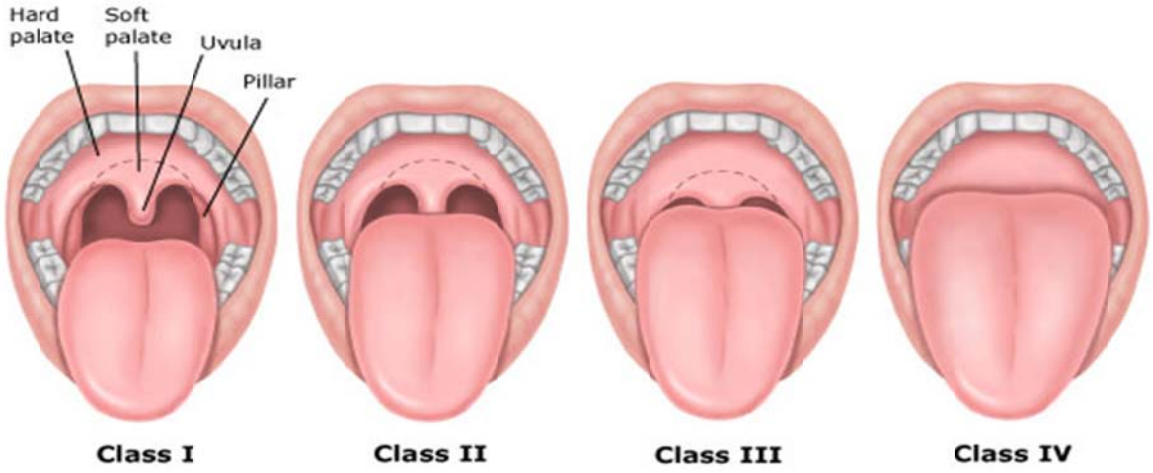
IF YOU ARE APPLYING FOR PRIVILEGES TO ADMINISTER SEDATION USING MEDICATIONS WHICH DO NOT HAVE A PHARMACOLOGIC REVERSAL AGENT (SUCH AS: PROPOFOL, ETOMIDATE, KETAMINE, METHOHEXITAL, OR DEXMEDETOMIDINE), YOU WILL NEED TO PROVIDE THE DETAILS OF THE PROTOCOL YOU WILL BE USING TO ADMINISTER THOSE MEDICATIONS. THIS PROTOCOL NEEDS TO BE APPROVED BY THE MEDICAL DIRECTOR OF ANESTHESIA SERVICES BEFORE PRIVILEGES CAN BE GRANTED FOR THE USE OF EACH THOSE MEDICATIONS.

APPENDIX A

AIRWAY ASSESSMENT

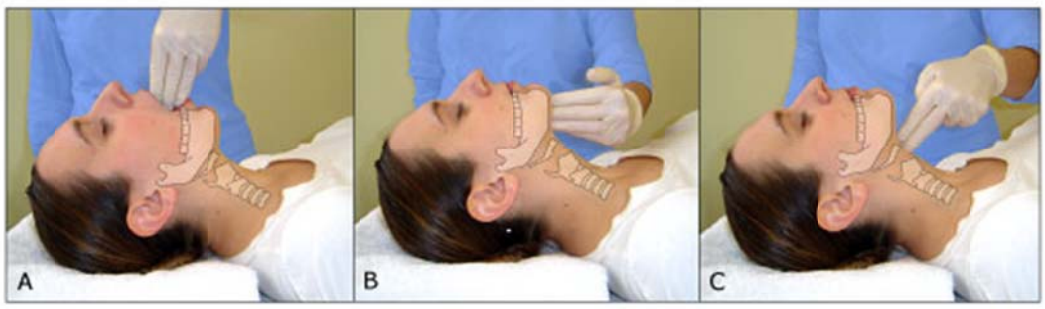
MALLAMPATI CLASSIFICATION

The Mallampati classification is a simple scoring system that relates the amount of mouth opening to the size of the tongue, and provides an estimate of space available for oral intubation by direct laryngoscopy. According to the Mallampati scale, class one is present when the soft palate, uvula, and pillars are visible, class two when the soft palate and the uvula are visible, class three when only the soft palate is visible, and class four when only the hard plate is visible. A High Mallampati score (class four) is associated with more difficult intubation as well as a higher incidence of sleep apnea.



THE 3-3-2 RULE

The spatial relationships depicted here are important determinants of successful direct laryngoscopy. A) The patient can open his/her mouth sufficiently to admit three of his/her own fingers. B) The distance between the mentum and the neck/mandible junction (near the hyoid bone) is the width of three of the patient's fingers. C) The space between the superior notch of the thyroid cartilage and the neck/mandible junction, near the hyoid bone, is the width of two of the patient's fingers.



APPENDIX B

ALDRETE SCORING SYSTEM

Respiration	Score
Able to take deep breath and cough = 2	2
Dyspnea/shallow breathing = 2	1
Apnea = 0	0
Oxygen saturation	
S_aO_2 >95 percent on room air = 2	2
S_aO_2 = 90-95 percent on room air = 1	1
S_aO_2 <90 percent even with supplemental O_2 = 0	0
Consciousness	
Full awake = 2	2
Arousable on calling = 1	1
Not responding = 0	0
Circulation	
BP ± 20 mm Hg baseline = 2	2
BP ± 20-50 mm Hg baseline = 1	1
BP ± 50 mm Hg baseline = 0	0
Activity	
Able to move 4 extremities = 2	2
Able to move 2 extremities = 1	1
Able to move 0 extremities = 0	0

Monitoring may be discontinued and patient discharged to home or appropriate unit when Aldrete score is $\geq$9, unless pre-existing conditions have altered the score.
Exceptions:

- <8-ICU
- Predisposing condition
- Approved by anesthesia

APPENDIX C

AMERICAN SOCIETY OF ANESTHESIOLOGY PHYSCIAL STATUS CLASSIFICATION

The ASA physical status classification system is a system for assessing the fitness of patients before surgery. These categories are:

ASA I A normal healthy patient.

ASA II A patient with mild systemic disease and no functional limitations.

ASA III A patient with moderate to severe systemic disease that that results in some functional limitation.

ASA IV A patient with severe systemic disease that is a constant threat to life and functionally incapacitating.

ASA V A moribund patient that is not expected to survive within twenty-four hours without the Procedure/operation.

ASA VI A declared brain-dead patient whose organs are being removed for donor purposes.

E For emergency procedures

APPENDIX D

PAIN SCALES

Utilize the FLACC Behavioral Pain Assessment Scale in the event the patient is unable to verbalize his or her response to the pain intensity scale.

CATEGORIES	SCORING		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown; Withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs; frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractable	Difficult to console or comfort

In patients who are awake: observe for 1 to 5 minutes or longer. Observe legs and body uncovered. Reposition patient or observe activity. Assess body for tenseness and tone. Initiate consoling interventions if needed.

In patients who are asleep: observe for 5 minutes or longer. Observe body and legs uncovered. If possible, reposition the patient. Touch the body and assess for tenseness and tone.

Instructions:

1. Rate patient in each of the five measurement categories
2. Add Together
3. Document total pain score

Interpreting the Behavioral Score	Score
Relaxed and comfortable	0
Mild discomfort	1 - 3
Moderate pain	4 - 6
Severe discomfort or pain or both	7 - 10
Total Score	

APPENDIX E

PRE – PROCEDURE FASTING GUIDELINES

For patients between 3 months and 104 years of age in whom there does not appear to be reason for clinical concern about increased risk for aspiration (eg: pregnancy, obesity, narcotic usage, gastric reflux, etc), the following guidelines should be observed in non-emergent ("elective") situations:

INGESTED MATERIAL	MINIMAL FASTING PERIOD
Clear liquids*	2 hours
Breast milk	4 hours
Infant formula	6 hours
Non-human milk	6 hours
Light meal (toast, clear liquids)	6-8 hours

*****Clear liquids include water, clear juices without pulp, clear carbonated beverages, black tea or coffee.

NOTE: PATIENTS WHO ARE DIABETIC, OBESE, PREGNANT OR TAKING NARCOTIC PAIN MEDICATION FAST FOR 8 HOURS

APPENDIX F

EQUIPMENT AND MONITORING

1. Age appropriate emergency equipment and drugs should be available whenever deep sedation/analgesia is dministered.
2. Appropriate monitors for deep sedation must include pulse oximeter, electrocardiogram, non-invasive blood pressure, and capnography.
3. Intravenous access should be established in all patients receiving deep sedation regardless of the route of drug administration.
4. Availability of Basic Airway management equipment:
    a. Oxygen source (pipeline or tank with regulator),
    b. Face mask or nasal cannula
    c. Oral and nasal airways
    d. Positive pressure ventilation device (self-inflating breathing bag valve set)
    e. Suction source and catheters
    f. End-tidal carbon dioxide detective device or monitor
5. Advanced Airway Equipment should be immediately available:
    a. Laryngeal mask airways
    b. Age appropriate laryngoscope and endotracheal tubes
    c. Stylet appropriately sized for endotracheal tubes
6. Emergency Equipment:
    a. Defibrillator should be immediately available.
    b. Emergency drugs including pharmacological antagonists:
        i. Pharmacological Antagosists: (reversal agents)
            1. Naloxone
            2. Flumazenil
        ii. Emergency Medicines:
            1. Epinephrine
            2. Ephedrine
            3. Vasopressin
            4. Atropine
            5. Nitroglycerin
            6. Amiodarone
            7. Lidocaine
            8. Glucose (10%, 25%, or 50%)
            9. Diphenhydramine
            10. Hydrocortisone
            11. Dexamethasone
            12. Calcium chloride or Calcium gluconate
            13. Sodium bicarbonate (4.2% and 8.4%)

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