

Moderate Sedation Provider Packet

An Educational Packet for Review by Non-Anesthesiologists Providing Moderate Sedation During Elective, Diagnostic and Therapeutic Procedures

INTRODUCTIONS

The National Integrated Accreditation for Healthcare Organizations (NIAHO) standards for Anesthesia Services taken from the Accreditation Requirements' Interpretive Guidelines & Surveyor Guidance Revision 8.0 states "If a hospital does provide any degree of anesthesia/sedation service to its patients, these services will be provided in an organized manner. The anesthesia/sedation services will be offered under the direction of a qualified doctor of medicine or osteopathy. This individual will be responsible for all anesthesia/sedation administered throughout the organization." The Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS) in May 2010 provided Clarification of the Interpretive Guidelines for the Anesthesia Services Condition of Participation. Det Norske Veritas (DNV GL) standards, based on NIAHO and CMS requirements provided in August 2014 Standard, Interpretive Guidelines and Surveyor Guidance for Hospitals.

Sedation is a continuum. It is not always possible to predict how an individual patient receiving sedation will respond. Qualified individuals must be trained to monitor patients carefully to maintain them at the desired level of sedation, to recognize problems and to promptly institute appropriate interventions.

The purpose of University Hospital's Moderate Sedation Policy, as outlined below, is to establish hospital-wide standards for the safe administration of moderate sedation and the monitoring of patients who receive it. This policy applies to all patients who receive moderate sedation in any setting, by any route for any diagnostic, therapeutic or surgical procedure. This policy specifically excludes therapeutic management of pain or seizures, pre-operative sedation, sedation for anxiety control and sedation for mechanically ventilated patients. The administration of regional, general anesthesia or monitored anesthesia care (MAC) outside the OR by an anesthesiologist is also excluded and is addressed by policies and procedures developed by the Department of Anesthesiology. All areas that administer moderate sedation may develop specific policies that exceed the standards contained herein.

Moderate sedation is produced by the administration of pharmacological agents which alone or in combination produce a depressed level of consciousness but the ability to independently and continuously maintain a patent airway and respond appropriately to physical stimulation is retained. Our goal in providing the practitioner with this educational module is to assure the same level of quality patient care by all individuals with delineated clinical privileges, within medical staff departments, and across all departments and services at University Hospital. These materials and the questions that follow are a guideline for <u>EDUCATIONAL</u> <u>PURPOSES ONLY</u>. They are <u>NOT</u> designed to establish or reflect standards, nor are they intended to be used for legal purposes.

This packet contains material which is essential in providing <u>the moderate sedation</u> <u>provider</u> – Physicians, Physician Assistants (PA) and Nurse Practitioners (NP), with information on administering moderate sedation and becoming credentialed to provide moderate sedation. This packet includes:

- 1. Definitions
- 2. Information on the credentialing process
- 3. "Perspectives on Sedation and Analgesia"
- 4. Sedation and Analgesia Medication Guidelines (Table)
- 5. Moderate Sedation Post Test and Answer Sheet
- 6. Ambulatory Surgical History and Physical (Form 40981)
- 7. Monitor's Sedation and Analgesia Procedural Record (Form 40043)
- 8. Consent for Diagnostic and Therapeutic Procedures (Form 40616)
- 9. University Hospital's Policy CM C-16: "Guidelines for Use of Moderate Sedation and Analgesia

All providers i.e., Physicians, PAs and NPs (unless already credentialed), who are expected to provide moderate (conscious) sedation are required to have completed all the steps including review of this packet.

DEFINITIONS

(Based on CMS Manual System: Clarification of Interpretive Guidelines for the Anesthesia Services Condition of Participation, May 21, 2010, the Revised Hospital Anesthesia Services Guidelines-State Operations Manual Appendix A, Rev. 137, 4-1-2015)

Anesthesia: involves the administration of a medication to produce a blunting or loss of:

- pain perception (analgesia);
- voluntary and involuntary movements;
- autonomic function;
- memory and/or consciousness

depending on the where along the brain and spinal cord the medication is delivered.

Analgesia: involves the use of a medication to provide pain relief through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness. The patient does not perceive pain to the extent that may otherwise prevail.

Anesthesia Services: (delivered by qualified individuals trained in the administration of general anesthesia)

General Anesthesia: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway and may require positive pressure ventilation because of depressed spontaneous ventilation or drug- induced depression of neuromuscular function. Cardiovascular function may be impaired. This is used for procedures requiring loss of consciousness for safe and effective conditions for the surgery or procedure.

Regional Anesthesia: involves delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves. This includes epidurals, spinals, other central neuraxial nerve blocks and peripheral nerve blocks. Sufficient analgesia and loss of voluntary and involuntary movement is required. Medications may or may not be administered to modify the patient's level of sedation.

Monitored Anesthesia Care (MAC): administration of medications and monitoring of a patient by a practitioner who is qualified to administer anesthesia.

Deep Sedation and Analgesia- (included under MAC) a drug-induced depression of consciousness during which patients cannot be easily aroused but responds purposefully following repeated or painful stimuli. The ability to maintain independent 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.

At University Hospital, the <u>Guidelines for Use of Deep Sedation and Analgesia</u> (Policy CM D-05) states "Deep sedation may be provided by specially credentialed attending physicians in critical care medicine or emergency medicine who by nature of their training and medical practice have the skills necessary to safely manage deeply sedated patients. This provider shall have no other duties than to administer the deep sedation and monitor the patient

Anesthesia Services: (include the following which may be appropriate for use by non-anesthesiologists)

Minimal sedation (anxiolysis): 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.

Moderate Sedation: ("Conscious Sedation"): A drug-induced state that allows a patient to tolerate an unpleasant procedure **while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation.** It 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 required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response (ASA approved House of Delegates definition October 13, 1999).

Rescue Capacity: Sedation is a continuum and it is not always possible to predict how an individual patient receiving sedation will respond. For some medications there is no bright line that distinguishes when the pharmacologic

properties bring about the physiologic transition from analgesic/sedative to the anesthetic effects. Therefore, hospitals must insure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended. Intervention by a practitioner with expertise in management of sedated patients and advanced life support is required. The qualified practitioner corrects the adverse physiologic consequences of the deeper-than- intended level of sedation and returns the patient to the originally intended level of sedation. Rescue capacity is consistent with the requirement under the Patients' Rights standard, guaranteeing patients care in safe settings.

At University Hospital, <u>The Guidelines for the Use of Moderate Sedation and</u> <u>Analgesia (Policy CM-C16)</u> must be adhered to in any instance where the <u>intent</u> of the provider is to manage a patient's behavior or alter their level of consciousness or pain threshold during a diagnostic, therapeutic, or minor surgical procedure.

<u>Credentialed Monitor:</u> A Registered Nurse (RN) who has completed University Hospital (UH) requirements for the assistance, monitoring and care of the patient receiving sedation by a privileged provider at University Hospital.

<u>**Credentialed Provider:**</u> A physician, Nurse Practitioner or Physician Assistant who has completed University Hospital requirements for the provision of moderate sedation, including competency demonstration for 5 separate moderate sedation events. The provider shall be privileged through the Medical Staff Office.

Local Anesthesia: The introduction of a local anesthetic drug by injection in subcutaneous tissue, in close proximity to a peripheral nerve, or applied topically in such a fashion as to avoid intravascular injection. All local anesthetics possess both excitatory (seizure) and depressant (loss of consciousness) central nervous system effects in sufficient blood levels and may additionally have profound cardiovascular depressant effects. There may also be interactive effects between local anesthetic drugs and sedative medications. Major nerve conduction blocks (referred to as regional anesthetics such as spinal, epidural or axillary blocks among others) are also accomplished through the use of local anesthetic agents but are only performed by anesthesiologists.

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 when used in therapeutic doses.

<u>Pre-medication:</u> Considered to be a single dose of medication, given prior to a procedure to produce minimal sedation or anxiolysis (see definitions in "introduction"). The drug is usually given by either the oral, intramuscular, intravenous or intranasal route. An example is the administration of oral diazepam prior to colonoscopy. The dosages of drugs used for pre-medication and the routes by which they are administered are not expected to affect ventilatory and cardiac function, so the standards for moderate sedation do not apply.

<u>Post-Procedure (or post-operative) Pain Management:</u> Administration of analgesic medications given to treat post-operative or post-procedural pain or discomfort does not constitute sedation and the standards for moderate sedation do not apply.

CREDENTIALLING PROCESS FOR PROVIDERS

Credentialing of providers who wish to administer moderate sedation is required and is limited to attending physicians, resident physicians of PGY-2 and above status, PAs, and NPs who will need to provide moderate sedation. (PGY-1 house staff may begin the credentialing process in the second half of their 1st year, at the discretion of their Residency Program Director.) The privilege to administer moderate sedation is for a two-year period. All providers must complete the following process in order to be credentialed.

All providers will be required to maintain ACLS training (or PALS, as appropriate) as part of the credentialing process, effective July 1, 2002, and provide evidence of such to Medical Staff Services.

Exceptions: ACLS/PALS training will be waived for those <u>MDs who are Board</u> <u>Certified/Eligible in Critical Care. Emergency Medicine and Anesthesiology.</u> Sedation practice is part of the scope of training for these professionals and the skills they have exceed those presented in ACLS/PALS.

The credentialing process for Providers is as follows:

- 1. Review educational packet for moderate sedation.
- 2. View online digital version of the lecture "Moderate Sedation for Credentialed Providers"
- 3. Complete post-session post test with at least 80% accuracy.
- 4. Demonstrate current competency in the provision of moderate sedation for a minimum of 5 separate supervised moderate sedation events.

The educational materials and policy will be updated as necessary to reflect changes in recommendations and current practice (i.e. development of new monitoring modalities, drugs, procedures, etc.). This material will be included with all appointment/reappointment packages that are distributed by Medical Staff Services. Updates of policies regarding moderate sedation will be mailed to credentialed providers between reappointments should changes in policy or current standards of practice deem it necessary to do so.

Recredentialing at the end of the two years will require proof of continued competency by the documentation of regular provision of moderate sedation, review of current policies and educational materials, and continued certification in ACLS/PALS as appropriate.

Credentialed Monitor's Responsibilities

- The RN may ask the provider if they are specifically credentialed to provide sedation and are qualified to rescue patients who intentional or unintentionally slip deeper than desired level.
- If there is a question regarding providers status the RN will
 - Call Medical Staff Services
 - * UUH at 464-5733
 - * UUHCG at 492-5553
 - Go to MedStaff page Link: <u>http://www.upstate.edu/medstaff/</u> or
 - Get there directly by copying & pasting this link into browser: <u>https://login.mdstaff.com/sunyupstate/epriv</u>

Refer to policy OMS C-01 Medical Staff Services (Credentialing Policy) <u>http://www.upstate.edu/policies/documents/intra/OMS_C-01.pdf</u> for the hyperlink and password for the online privileges portal <u>This should be done before the procedure begins!</u> If the monitor is unsure or uncomfortable with the situation, he/she can contact the Patient Service Manager, Patient Service Director, or Administrative Supervisor.

It is the responsibility of the provider to assure that s/he is properly credentialed to provide moderate sedation before doing so.

- Is competent in the provision of basic life support skills (CPR)
- Is competent in the operation of a bag-valve-mask and one-way valve mask
- Has knowledge of the pharmacologic actions of the drugs administered
- Completes pre-procedural assessment including verification of consent and NPO status
- Ensures that an additional staff member is available (in the clinical area to respond to calls for assistance) until the patient reaches level 2 on the Ramsey scale or Level 8 on the Aldrete scale
- Provides continuous monitoring of the patient throughout the moderate sedation procedure
- While acting as a monitor the individual is to have no other responsibilities

Perspectives on Sedation and Analgesia: Pharmacology, Monitoring and Educational Materials to Supplement the Moderate Sedation Policy

The DNV GL has guidelines for the use of drugs that trigger the use of anesthesia standards. The pharmacological classification of the drug is not the sole determinant. The dose and route of administration are also factors because this combination determines the risk for loss of the patient's protective airway reflexes. Because sedation is a continuum, it is not always possible to predict how an individual patient receiving sedation will respond. Therefore, each institution has been asked to develop specific protocols for the care of patients receiving sedation which carries a reasonable risk of loss of protective reflexes.

The objectives for the patient include:

- Alteration of level of consciousness/mood
- Maintenance of consciousness
- Cooperation
- Elevation of the pain threshold
- Minimal variation of vital signs
- Rapid onset of amnesia
- Safe return to baseline

The <u>desired effects</u> include:

- Relaxation
- Cooperation

<u>Undesirable effects of sedation and analgesia are:</u>

- Deep unarousable sleep
- Hypotension
- Bradycardia
- Agitation and combativeness
- Hypoventilation
- Respiratory depression
- Airway obstruction
- Apnea

MODERATE SEDATION as defined by DNV GL, CMS and University Hospital's Policy and Procedures, 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 required to maintain a patent airway, and spontaneous ventilation is adequate.

<u>Cardiovascular function is usually maintained</u>. It must be distinguished from premedication and pain management which are not governed by the Moderate Sedation Policy. Although the drugs may be the same as some of those used for moderate sedation, the circumstances surrounding their use and the dosages used for premedication or for pain management are not considered to pose a risk of impairing the patient's protective airway reflexes.

MODERATE SEDATION must also be distinguished from deep sedation. **DEEP SEDATION** is 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. Deep sedation may only be administered by an anesthesiologist or other specially credentialed physicians (see Deep Sedation Policy CM D-05).

Sedation of intubated mechanically ventilated patients are <u>excluded</u> from this policy. These patients are already sedated and ventilated.

<u>Ketamine. etomidate. pentothal. methohexital and propofol</u> are only to be administered to unventilated patients by physicians who are separately credentialed to provide deep sedation. These drugs are <u>not</u> to be given by credentialed moderate sedation providers.

This perspective will consider the pharmacology of some of the drugs which may be used for sedation and analgesia, as defined above, as well as the personnel, monitoring and patient evaluation necessary for procedures requiring sedation and analgesia.

Pharmacologic Principles of Sedation and Analgesia

Sedation and analgesia may be provided by a variety of drugs which differ significantly in their pharmacologic classification and effects. The most widely used drugs include the benzodiazepines and the narcotics. Other intravenous anesthetic agents are sometimes used for deep sedation. These include pentothal, methohexital, etomidate, ketamine and propofol. Due to the greater propensity for respiratory depression and other reactions, they may only be administered by anesthesiologists, certified registered nurse anesthetists (CRNAs) and appropriately credentialed ATTENDING PHYSICIANS or Emergency Medicine residents working in the Emergency Room who are separately credentialed to provide deep sedation <u>under the direct supervision of an</u> <u>attending physician.</u>

Benzodiazepines are widely used for sedation and analgesia. They are considered to be sedative-hypnotics or tranquilizers. They are used for anxiolysis, sedation and amnesia. The most widely used include diazepam (Valium), midazolam (Versed) and lorazepam (Ativan). Midazolam use has overtaken that of diazepam due to its shorter duration of action and water solubility which helps to decrease the pain associated with injection.

The benzodiazepines produce a spectrum of effects. Depending upon the dose, they range from tranquility and drowsiness to sedation, and ultimately, unconsciousness. Anterograde amnesia is associated with all of the benzodiazepines. The most significant side effect of any of the benzodiazepines is severe respiratory depression, particularly when used in combination with other CNS depressants. Benzodiazepines cause minimal cardiac depression when used alone. However, when combined with other anesthetic agents, including narcotics, (which, by themselves are a relatively cardiostable drug) cardiovascular depression and even hemodynamic collapse may occur. Refer to chart on pages 38-40.

*For Pediatric doses, refer to the Harriet Lane Handbook and Lexicomp.

Flumazenil (Romazicon), a benzodiazepine antagonist, can reverse the effects of the agents above. It should be used cautiously because it can precipitate acute withdrawal in patients who are chronically dependent on benzodiazepines. It can also cause seizures. When given intravenously, Flumazenil may be repeated at 1 minute intervals to a maximum of 0.05mg/kg or 1 mg whichever is lower. Refer to page 40 for individual dosing guidelines. The onset of action is usually within 2 minutes. While flumazenil reliably antagonizes the sedative effects of benzodiazepines, its antagonism of respiratory depression is not as reliable and should not be depended upon. Respiratory depression should be initially treated with needed, positive pressure ventilation by a supplemental oxygen, and if bag/valve/mask (Ambu) system. Furthermore, the duration of action of the benzodiazepine used may exceed that of flumazenil. Continued monitoring is essential even after flumazenil use.

<u>Narcotics</u>, which are routinely used for sedation and analgesia, act at a variety of different receptor sites. The use of narcotics serves to produce analgesia. In combination with a benzodiazepine, this provides sedation, anxiolysis and analgesia achieving the goal of moderate sedation. In addition, a local anesthetic injection or topical anesthetic may then be used to provide anesthesia for a specific indication such as catheterization of an artery, excision of skin lesion or introduction of an endoscope.

The <u>**narcotics**</u> can be divided into several classes. They include naturally occurring opioids, semi-synthetic opioids and synthetic opioids. The potency and duration of action between these different classes varies considerably.

For analgesia, a mu receptor agonist is ideal. They act centrally in pain-suppressing areas of the brain and spinal cord. These areas include the periaqueductal gray, medial thalamus, substantia gelatinosa and laminae I and II of the spinal cord. Sufentanil (which should not be used for moderate sedation) is the clinical standard for mu efficacy. While it can render a patient apneic, and completely unresponsive to noxious stimulation, the patient may retain enough residual awareness to later recall the procedural events. For this reason, a narcotic is rarely given alone. Administration with a benzodiazepine produces more reliable amnesia.

Anxiety and discomfort from a procedure can produce stress, which causes large swings in hemodynamic variables, as well as increased catabolism. This stress may also cause abrupt release of epinephrine, norepinephrine, glucagon, cortisol, growth hormone and antidiuretic hormone which increases the cardiovascular stress. These considerations are of major importance to patients with marginal hemodynamic and metabolic reserves, such as neonates or those with advanced cardiac, vascular or renal disease.

Widely recognized mu receptor agonists include morphine sulfate, methadone hydrochloride, meperidine hydrochloride, fentanyl citrate, sufentanil citrate and alfentanil hydrochloride. Of these, fentanyl and morphine are usually chosen for moderate sedation. The only approved indication for meperidine at University Hospital is post-anesthesia shivering. Agonist-antagonist opioids are also used. They have different actions at different receptor sites, resulting in diverse pharmacologic effects. They may also precipitate withdrawal in narcotic-addicted patients. Agents in this class include butorphanol tartrate (Stadol) and nalbuphine (Nubain).

The **narcotic antagonists** include naloxone hydrochloride and naltrexone. Both are non-selective. Naloxone is a pure antagonist of all opioid effects except those mediated by the sigma receptor. It is used primarily to antagonize respiratory depression and acute opioid overdose. Naloxone is administered IV at 2 minute intervals until the desired effect is reached. Refer to page 40 for individual dosing When one ampule (0.4 mg) of Naloxone is diluted in 9 ml of normal quidelines. saline, the resulting mixture will be 40 mcg of Naloxone per millimeter. The duration of action of naloxone is about 20 to 30 minutes. Repeat boluses or a continuous infusion may be used to maintain adequate blood levels until the opioid agonist is eliminated. It is important to recognize that both the opioid-analgesia and respiratory depression are antagonized. This antagonism can precipitate acute withdrawal in opioid-addicted patients. Rare, but potentially fatal reactions to naloxone include pulmonary edema, seizures, hypertension, arrhythmias, and cardiovascular collapse. Careful titration and close monitoring are essential. Naltrexone is also a pure antagonist. Clinically it is used for antagonism of opioids with long elimination half-lives such as normeperidine or methadone. It has no use in the antagonism of medications used for sedation and analgesia.

Pre-Procedural Evaluation

Medical History

The practitioner administering sedation and analgesia must review and document relevant aspects of the patient's medical history. These include:

- (1)) an assessment of the patient for severe systemic diseases or co-morbidities which would increase the risk for administration of moderate sedation;
- (2) notation of any problems with major procedures or previous experiences with sedation/analgesia, as well as regional and general anesthesia;
- (3) current medication list including contraceptives, over the counter medications or herbal preparations;
- (4) current drug allergies with their reactions;
- (5) the time and nature of the last oral intake;
- (6) history of alcohol, tobacco or substance abuse.

Physical Examination

The pre-procedural examination includes a brief review of systems and a focused evaluation of the airway, heart and lungs. The practitioner should be alerted to the possibility of difficult mask ventilation and tracheal intubation in patients with significant obesity, especially involving the neck and facial structures. Individuals with a short neck, a small jaw or a receding chin (micrognathia, retrognathia) may be difficult to intubate in an emergency. Medical conditions such as rheumatoid arthritis or other conditions which limit the range of motion of the neck or jaw, or significant maxillary/mandibular malocclusion may also present a challenge to tracheal intubation.

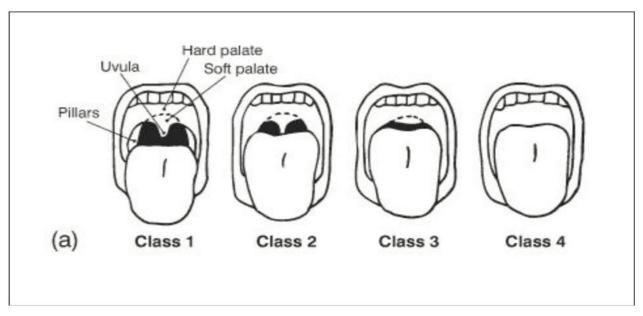
Airway Assessment

The airway is assessed to identify predictors of difficult mask ventilation and/or intubation.

(1) Mallampti Score

The oropharyngeal airway space is assessed with the patient's head in a neutral position with the mouth opened maximally and the tongue protruding (with no phonation).

The Mallampti class is correlated with the view during laryngoscopy and difficult intubation



Class 1: Complete visualization of the uvula Class 2: Visualization of only the base of the uvula Class 3: Only soft and hard palates are visible Class 4: Only hard palate is visible Reference: Ginapp, T. (2012). Ask the Instructor. Retrieved from http://www.cathlabdigest.com/files.

(2)) Other factors to assess:

- Mouth opening
- Neck extension and thickness
- Thyromental distance >6 cm/presence of micrognathia/retrognathia
- Teeth: long incisors, poor dentition, edentulous
- Jaw protrusion

(3) Factors associated with difficult mask ventilation

- Beard
- Edentululous
- Obesity
- Large tongue
- Age > 55 years
- Severely limited jaw protrusion
- Abnormal neck anatomy
- Obstructive sleep apnea (OSA)/snoring
- Mallampati score of 3 or 4
- Active airway obstruction (tumor, abscess)`

Laboratory Test Results

Laboratory tests should be guided by the patient's medical condition and how their results will affect the management of sedation. The provider will determine the appropriateness of electrocardiograph monitoring during the procedure. The preprocedure evaluation also includes assignment of an assessment score from the American Society of Anesthesiologists' Physical Status Classification Scale.

Consultation for Sedation and Analgesia

The American Society of Anesthesiologists has established criteria by which a patient's physical status is evaluated pre-operatively (pre procedurally). It is a scale ranging from 1 to 5 and uses the additional designation of "E" for an emergency procedure. The description is as follows:

ASA Physical Status	Description
1	No Systemic Disease
2	Mild, or Well Controlled Systemic Disease, No Functional Limitations
3	Severe Systemic Disease, Definite Functional Limitations
4	Severe Systemic Disease, Constant Threat to Life
5	Moribund, Not Expected to Survive for 24 Hours, Irrespective of Operation.
E	Emergency – a modifier to ASA status

The patient with a physical status rating of ASA 3 or higher should alert the practitioner that a higher level of vigilance is required. In patients of ASA physical status 3, 4 or 5 (e.g., severe cardiac, pulmonary, hepatic, renal, CNS disease, morbid obesity, sleep apnea, others), or in certain selected classes of patients such as uncooperative patients, extremes of age (under 1 year or over 70 years of age), the pregnant patient, those with sleep apnea or drug/alcohol abusers there is an increased risk of developing complications related to sedation and analgesia unless special precautions are taken. This risk may be reduced by preprocedure consultation with appropriate specialists including, but not limited to anesthesiologists, cardiologists, pulmonologists, nephrologists, obstetricians or pediatricians. The provider must assign an ASA physiologic status classification based on the patient's history and physical examination.

Whenever possible, appropriate medical specialists should be consulted before the administration of sedation and analgesia to a patient with significant underlying conditions.

If it appears likely that sedation to the point of unresponsiveness or even general anesthesia may be necessary to obtain adequate conditions to perform the procedure, an anesthesiologist should be consulted prior to planning the procedure. At the Downtown Campus, the Department of Anesthesiology may be contacted at 464-4720 (office) or in the operating room at 464-4640; ask for "the Officer of the Day". At the Community Campus, the requesting MD will contact the operating room at 492-5522 to book the case, then ask for the anesthesia "Officer of the Day".

During the administration of sedation and analgesia, should a situation become unmanageable or life-threatening, the hospital operator should be instructed to page Code Blue (Adult) or Code White (Pediatric) to your location.

Monitoring and Equipment for Moderate Sedation

The following equipment must be present and ready for use in any area where moderate sedation is administered:

- Oxygen
- Oxygen delivery devices (flow meters, nasal cannula, face masks, etc.)
- Suction
- Ambu bag and masks in appropriate sizes for positive pressure ventilation
- Airways (oral/nasopharyngeal) in appropriate sizes
- Intubation equipment (ET tubes, laryngoscopes, stylets)
- Pulse oximeter
- Cardiac monitor EKG
- Non-invasive blood pressure monitor
- Code cart/defibrillator
- ETCO₂ monitoring equipment (when requested by provider)

Monitoring level of consciousness, respiratory function and hemodynamics reduces the risk of adverse outcomes. The patient's ventilatory status and level of oxygenation as well as hemodynamic variables should be recorded at a frequency determined by the type and amount of medication administered, duration of the procedure, and patient's general medical condition. At a minimum, this should be done immediately prior to the administration of sedative medication, after administration of sedative or analgesic agents, every 5 minutes during the procedure, upon completion of the procedure, and every 15 minutes during the initial recovery phase and at the time of discharge.

Documentation in the patient record during the administration of sedation and analgesia will include:

- Dose, route, time, effects of drugs used
- Type/amount of IV fluids/blood/blood products used
- Physiological data (recorded at least every 5 minutes)
- Level of consciousness
- Pain assessment
- Untoward/significant reactions and resolutions

A designated individual, other than the provider performing the procedure, will be continuously present to monitor the patient throughout the procedure. The monitor will have an understanding of the pharmacology of the agents administered as well as the role of antagonists. The monitor will also be able to recognize associated complications. According to University Hospital policy the monitor can be a credentialed RN (see definition of Credentialed Monitor). At least one member of the care team must be capable of establishing a patent airway and providing positive pressure ventilation. There will also be a means for summoning additional assistance whenever sedation is administered.

In addition to the drugs used for sedation, pharmacologic antagonists (naloxone, and flumazenil at the provider's request) and emergency equipment will be immediately available in the procedural area. An example of the emergency equipment and drugs to be available during sedation and analgesia would include: (This is a guide, which may be modified depending upon the individual practice circumstances).

Intravenous Equipment

- Gloves, tourniquets, alcohol wipes or chloroprep, gauze pads
- IV catheters (20, 22, 24 gauge) and IV tubing, IV fluids
- Three-way stopcocks, assorted needles, syringes, tape

Airway Management Equipment

- Oxygen source (with regulator/flowmeter, i.e., positive pressure)
- Suction, suction catheters (soft and Yankauer type)
- Face masks (appropriate sizes)
- Self-inflating breathing bag-valve set (BVM, Ambu bag)
- Oral/nasal airways (appropriate sizes) and lubricant
- Laryngoscope handles/blades (pretested)
- Endotracheal tubes (sizes 6.0, 7.0, 8.0 for adults) and/or
- Pediatric endotracheal tubes (sizes 2.5 to 6.0) as indicated
- Endotracheal tube stylets (appropriate sizes)

Pharmacological Antagonists of Narcotics/Benzodiazepines

- Naloxone
- Flumazenil (if desired, provider must request presence at bedside before initiation of procedure)

Emergency Medications

- Epinephrine
- Atropine
- Lidocaine
- Glucose, 50%
- Diphenhydramine
- Hydrocortisone, methylprednisolone or dexamethasone
- Diazepam or midazolam (for treatment of local anesthetic toxicity)
- Ammonia spirits

The use of a combination of drugs (i.e. a benzodiazepine and a narcotic) may be more effective in providing the desired sedation. However, literature also suggests that the combination of sedatives and opioids may increase the likelihood of adverse outcomes such as ventilatory depression and hypoxemia. Fixed combinations of sedatives and analgesic agents may not meet the individual patient's needs for sedation and analgesia. Therefore, if a combination of agents is used, they are administered separately and titrated to effect. **Sufficient time must elapse between doses to observe the effect before subsequent drug administration.** The propensity for combinations to produce respiratory depression emphasizes the need to reduce the dose of each drug accordingly and to continually monitor vital signs. If patients have received antagonists (flumazenil and/or naloxone) they should be encouraged or stimulated to breathe deeply, receive supplemental oxygen and may require positive pressure ventilation. These patients must be monitored long enough after the administration of antagonists to ensure that cardiorespiratory depression does not recur. Generally, this should be considered to be 2 hours.

All patients receiving sedation and analgesia should have intravenous access maintained throughout the procedure and until such time that the patient is no longer at risk for cardiorespiratory depression. If a patient has received sedation by a non-intravenous route or if the IV has become dislodged or blocked, the practitioner should determine the advisability of establishing or re-establishing IV access. In any event, an individual with the skill to establish intravenous access (especially if an emergency arises) will be immediately available.

Monitoring during Sedation

Pulse Oximeter

The pulse oximeter is a non-invasive device that measures a pulse and oxygenhemoglobin saturation (SaO₂). Pulse oximetry must be continuously monitored during sedation.

The operating principle of a pulse oximeter involves absorption of different wavelengths of red and infrared light by oxygenated and deoxygenated hemoglobin as it is transmitted through, and reflected by a tissue bed. Pulse oximeters use the pulse to distinguish between blood and tissue absorptions (only arterial blood pulsates). The pulse oximeter uses two specific wavelengths of light: 660 NM (red light) and 940 NM (near-infrared light). The pulse oximeter is subject to signal artifacts that are usually related to ambient light, low perfusion and patient motion. It can also be affected by injected dyes like methylene blue, which have absorbances similar to deoxygenated hemoglobin and can cause brief artifactual oxygen desaturation when administered by intravenous injection.

When used in conjunction with the other required monitors, the noninvasive pulse oximeter represents a significant advance in patient safety. It provides important information about oxygenation on a beat-to-beat basis and confirms ECG pulse tracings. The pulse oximeter must be used routinely.

Oxygen saturation is not the same as oxygen partial pressure, which is measured by blood gas analysis. Oxygen saturation will be 100% when the oxygen partial pressure is 100 mmHg or greater. While partial pressures of oxygen can be several hundred mm Hg, the oxygen saturation remains at 100% and oxygen is dissolved in the blood. Despite the differences, saturation is very useful because it is an early warning indicator of low-oxygen states. The partial pressure of oxygen and oxygen saturation can be approximated at lower oxygen levels.

Partial Pressure of Oxygen	Oxygen Saturation		
(PO ₂ - Blood Gas)	(SO ₂ - Pulse Oximeter)		
80 mmHg	95% Saturation		
60 mmHg	90% Saturation		
50 mmHg	80% Saturation		
40 mmHg	70% Saturation		

Cardiac monitoring

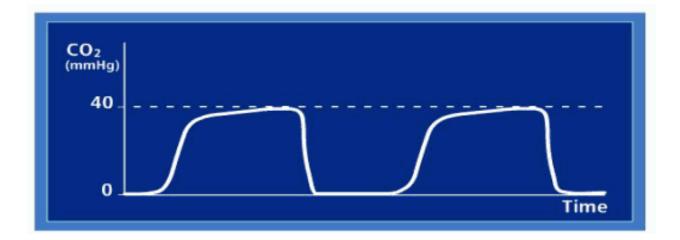
Electrocardiographic monitoring **will be used in all patients** receiving moderate sedation. The credentialed monitor must have an established competency in dysrhythmia recognition and interpretation.

End Tidal C0₂

End Tidal CO₂ (ETCO₂) monitoring is also a non-invasive monitoring tool that is used to assess ventilation. It allows for the continuous graphic display of exhaled carbon dioxide. ETCO₂ is the earliest indicator of airway or respiratory compromise and monitoring can aid the practitioner in rapidly identifying potential adverse events associate with procedural sedation and analgesia including apnea, upper airway obstruction, laryngospasm, bronchospasm and respiratory failure.

End Tidal CO₂ monitoring produces a numerical value and a waveform called a capnogram. Each waveform represents one respiratory cycle. The waveform has several components:

- A. The first segment of the waveform is the flat area before exhalation.
- B. The second segment is a sharp rise (beginning of exhalation) followed by a curve that then starts to level out. The highest portion of this segment of the waveform is called the ET CO₂ point and represents exhalation of alveolar CO₂.
- C. The third segment is a sharp drop representing the start of inhalation.

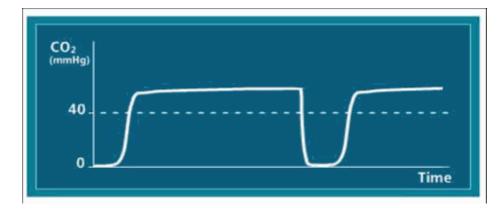


Indicators of respiratory depression or hypoventilation:

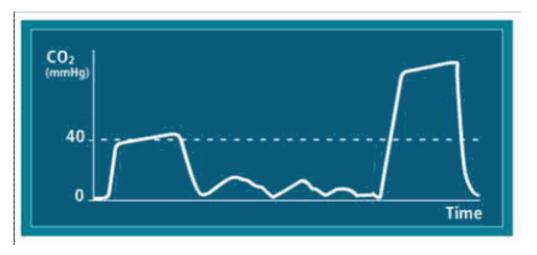
- ET CO₂ of > 50
- No waveform for any period of time
- Change in ET CO₂ of 10 below or above baseline

<u>Hypoventilation</u>: Decreased Respiratory Rate with an elevated EtCO₂. Waveform shape will represent a taller waveform (higher CO₂) EtCO₂. May have a prolonged flat area (alveolar plateau)

Hypoventilation

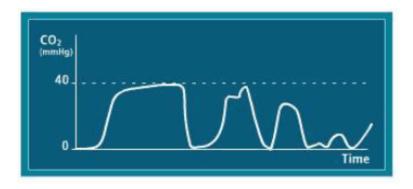


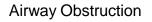
<u>Shallow Breathing Hypoventilation</u>: Respiratory Rate may or may not change with a decrease in EtCO₂. Waveform will be abnormal in shape, shorter and smaller. It may be rounded and choppy in shape.



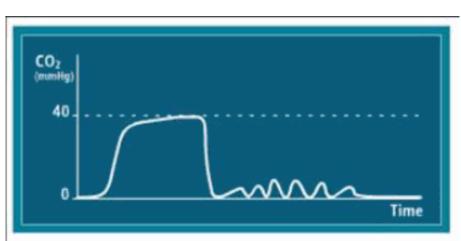
Shallow Breathing Hypoventilation

<u>Partial Airway obstruction</u>: Respiratory Rate may or may not change with a decrease in EtCO₂. Waveform shape will be abnormal with elongated upstroke or down stroke. Waveform will be shorter, rounded, and choppy.





<u>Complete airway obstruction/Apnea/Loss of waveform</u>: Waveform, EtCO₂ value, and Respiratory Rate will be absent. No air exchange is taking place due to cessation of breathing or total airway obstruction.



Apnea

NOTE: ALWAYS OBTAIN A BASELINE ETCO₂ AND TRACING READING PRIOR TO ADMINISTRATION OF MODERATE SEDATION

Recovery and Discharge after Moderate Sedation

Patients may continue to be at significant risk for complications after completion of a procedure. Lack of stimulation, prolonged drug absorption or post-procedural hemorrhage may contribute to cardiorespiratory depression. After administration of sedation and analgesia, patients are observed until they are no longer at an increased risk for cardiorespiratory depression. Vital signs and respiratory function are monitored every 15 minutes until the vital signs and pulse oximetry are consistent with the range of pre-procedural norms and level of consciousness is no more than 2 on the Ramsey scale or less than 8 on the Aldrete scale. A patient should not be discharged until specific discharge criteria are met which are designed to minimize the risk of complications from central nervous system and/or cardiorespiratory depression.

The recovery area is equipped in a similar fashion to the procedure room. It should have appropriate monitoring and resuscitation equipment. An R.N. or other trained individual should be in attendance until discharge criteria are fulfilled. An individual capable of maintaining the airway and administering positive pressure ventilations must be immediately available. The practitioner is notified immediately if dramatic changes occur or if the parameters are not within the established limits for that patient.

The Aldrete score has been used for more then 25 years in postanesthesia care units to clinically assess the physical status of patients recovering from an anesthetic and follow their awakening process. This method of assessment has been adopted as the suggested criteria for discharge from the post-anesthesia care unit by the Joint Commission. For intra-hospital transfers after receiving moderate sedation, the patient should achieve an Aldrete score of 8 based upon criteria including activity, respiration, circulation, consciousness and oxygen saturation. For discharge home, in addition to these criteria, patients must meet satisfactory discharge criteria including a dry dressing, pain control, ability to ambulate, ability to take nutrition and adequate urine output. The Aldrete scoring system is shown in the table. Guidelines for discharge from procedural monitoring may include:

- Level of consciousness:
 - Patient is alert and oriented or
 - Infants or patients with altered mental status have returned s to preprocedural baseline or
 - Is no more than a level 2 on the Ramsey scale or no less than a level 8 on the Aldrete Scale
- Patient must have;
 - Ability to swallow or gag reflex
 - Ability to ambulate with assistance or be at pre-procedural norm
 - Limited nausea and/or vomiting
 - Minimal or no pain resulting from the procedure
 - Dressings dry/intact
- Observation for 2 hours after the LAST ADMINISTRATION OF ANTAGONISTS (reversal agents). A UHC Safety Intelligence Report (Occurrence Report) <u>must be completed.</u>

When the post-procedural discharge criteria are met:

- Inpatients
 - Return to their inpatient unit
- Outpatient
 - Patient has eaten a light snack (i.e., crackers and juice), voided, and ambulated without difficulty (i.e., dizziness, nausea or vomiting).
 - Patient is discharged to the care of a <u>RESPONSIBLE ADULT</u> who will accompany them home (i.e., drive them) and be able to report any post-procedure complications.
 - If no adult is available patient remains a minimum of 4 hours post administration of sedative medication and/or post administration of reversal agent.
 - Patient or accompanying adult has received <u>WRITTEN</u> instructions regarding diet, activity, medication and has an emergency phone number.

Documentation Requirements for Moderate Sedation Providers

All moderate sedation providers are required to follow current policy and procedures regarding documentation of the moderate sedation event. These include:

Pre-procedure:

- Pre-procedure evaluation will include:
 - Assessment of the patient for significant severe systemic diseases or comorbidities which would increase the risk for administration of moderate sedation.
 - Brief review of systems and physical exam including an assessment of airway, lungs heart and mental status.
 - Major procedures and notation of any problems with sedation and anesthesia.
 - Current medications and potential drug/sedative interactions.
 - Allergies and patient reaction.

*Inpatient history and physical can be used to meet these requirements

- Provided that all the above elements are documented including assessment of the airway, heart, lungs, mental status, and the Provider co-signs and dates the admission H&P.
 - A re-evaluation of the patient must be done **immediately** prior to the procedure.
 - Informed consent must be obtained including sedation plan, options, and risks.
 - Patient will be informed of the rationale for the procedure and plan for moderate sedation including options and risks. Credentialed provider must document assessment of patient's status immediately prior to start of procedure. Pre-procedure evaluation will include:
 - Assessment of the patient for significant severe systemic disease or comorbidities.
 - Brief review of systems and physical exam including an assessment of airway, lungs, heart and mental status.
 - Major procedures and any notation with problems with sedation/analgesia.
 - Current medication list with identification of any drug/sedative interactions.
 - Any allergies and their reactions
 - Assure availability of appropriate monitors and equipment.

Post-procedure

- Documentation
 - o In EPIC, the provider is responsible for
 - Writing a procedural note
 - Signing off on procedure itself
 - The provider can document this by either
 - Using the nurse's computer after they have completed their documentation
 - Signing into any computer and going to Summary, find the sign off report and link
 - Order any post-procedure instructions
 - For inpatients, a post sedation note must be written not less than 3 or greater than 48 hours after the procedure documenting satisfactory recovery

We hope this educational module has been useful. Please refer to it as you consider the questions on the following pages.

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Upstate University Hospital Policies:

Capnography (ETCO2) CM C-02

Guidelines for Use of Moderate Sedation and Analgesia CM C-16

Guidelines for Use of Deep Sedation and Analgesia CM D-05

Moderate and Deep Sedation and Anesthesia Practice Requirements for Physicians, Nurse Practitioners, and Physician Assistants

The following information is applicable to all physicians, Nurse Practitioners, and Physician Assistants who perform procedures during which the patient receives moderate sedation, deep sedation, or anesthesia. All are required to comply with these standards at the **100% level**. Failure to comply will put the provider (you) at considerable professional risk, and an individual's lack of compliance can furthermore put University Hospital and Upstate Medical University at risk for unwelcome consequences.

This educational module is organized according to the standards established by:

- CMS Conditions of Participation for Anesthesia Services Appendix A/§482.52
- National Integrated Accreditation for Healthcare Organizations (NIAHO) Interpretive Guidelines and Surveyor Guidance (DNV Healthcare Inc.) Revision August 2014 Version
- Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists (An updated report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists, Anesthesiology, V96 No4 April 2002.
- University Hospital's clinical Policy # CM C-16: Guidelines for Use of Moderate Sedation and Analgesia

Each standard from Det Norske Veritas Healthcare (DNV) is identified briefly, explained and accompanied by the interpretive guidelines.

AS.3 POLICIES AND PROCEDURES

SR.1 Policies on anesthesia/sedation procedures must include the delineation of pre-anesthesia and post- anesthesia responsibilities.

SR.2The policies must ensure that the following are provided for each patient:

SR.2a a pre-anesthesia or pre-sedation evaluation, to include a documented airway assessment, anesthesia risk assessment, and anesthesia drug and allergy history, by an individual qualified and privileged to administer anesthesia/sedation, performed no more than 48 hours prior to surgery or procedure requiring

anesthesia/sedation, performed no more than 48 hours prior to surgery or procedure requiring anesthesia services

SR.2b an intra-operative anesthesia/sedation record;

SR.2c for inpatient surgery, a post-anesthesia evaluation for proper anesthesia recovery is completed and documented within 48 hours after surgery by the individual who administers the anesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anesthesia;

SR.2c(1) A post-anesthesia evaluation for anesthesia recovery is required and must be completed in accordance with State law and hospital policies and procedures approved by the medical staff and reflect current standards of care anytime general, regional, or monitored (This would include deep sedation/analgesia has been administered to the patient).

SR.2c (2) If the patient is discharged less than 48 hours after the procedure, completion and documentation of the post-anesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged.

Interpretive Guidelines

Pre-anesthesia/sedation responsibilities

- Physical examination of the airway (by those qualified and privileged to administer sedation) must be performed within 48 hours of administration of anesthesia/sedation;
- Assessment of risk to the patient for receiving anesthesia/sedation;
- Drug and allergy history regarding anesthesia/sedation;
- Physical condition of the patient prior to induction of anesthesia/sedation;
- Patient consent for administration of anesthesia/sedation;
- Equipment requirements, as well as the monitoring, inspection, testing and maintenance of anesthesia/sedation equipment in the hospital's biomedical equipment program;
- Infection control practices in place;
- Safety measures in place in areas where anesthesia/sedation is administered (including a protocol for supportive life functions, e.g., cardiac and respiratory emergencies).

Reporting and documentation requirements

Intra-operative anesthesia/sedation/sedation record including:

- Name and hospital identification number of the patient
- Name of practitioner who administered anesthesia/sedation, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner
- Name, dosage, route and time of administration of drugs and anesthesia/sedation agents;
- IV fluids;
- Blood or blood products;
- Oxygen flow rate;
- Continuous recordings of patient status noting blood pressure, heart and respiration rate;

 Any complications or problems occurring during anesthesia/sedation, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.

Post-anesthesia/sedation follow-up report including:

- Cardiopulmonary status
- Level of consciousness
- Any follow-up care and/or observations
- Any complications occurring during post-anesthesia/sedation recovery
- Any follow-up care needed or patient instructions given.
 - Note: This report must be completed and documented within 48 hours following the procedure in which anesthesia/sedation has been administered.

Patient Evaluation:

Recommendations: Clinicians administering sedation/analgesia should be familiar with sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia. These include:

1) abnormalities of the major organ systems; 2) previous adverse experience with sedation/analgesia as well as regional and general anesthesia; 3) drug allergies, current medications and potential drug interactions; 4) time and nature of last oral intake; and 5) history of tobacco, alcohol or substance abuse. Patients presenting for sedation/analgesia should undergo a focused physical examination including vital signs, auscultation of the heart and lungs, and evaluation of the airway......These evaluations should be confirmed immediately before sedation is initiated.

Sedation and Analgesia – Medication Guidelines Doses may need to be reduced when agents are combined.

Some patients/procedures may require unique medications that may not be included in these guidelines.

Ketamine and propofol are anesthetics not sedatives. When used for "sedation purposes" the use of these agents is restricted to Anesthesiologists and specifically credentialed physicians, e.g. Adult and Pediatric Emergency Medicine Physicians, and Adult & Pediatric Intensivists

	Pediatric Dose Neonate- 14yrs	Adult Dose	Administration	Pharmacokinetics	Side Effects	Drug Interactions/ Contraindications	Important Information
Midazolam (Versed) Benzodiazepine	Neonate: 0.05-0.1mg/kg Age 6 mo to 5 yrs: Intravenous 0.05 to 0.1 mg/kg Repeat dose if needed in 2-3 minutes, max total dose of 0.6mg/kg, Total dose not to exceed 6mg Age 6 to 12 years: Intravenous: Initial: 0.025-0.05mg/kg Repeat dose if needed in 2-3 minutes, max total dose up to 0.4mg/kg, Total max not to exceed 10mg. Age 12-16 years: Dose as adults; Maximum total dose - 10 mg. Intranasal: 1-5 months: 0.2mg/kg single dose >or=6 months: 0.2-0.5 mg/kg Max dose per nostril 5 mg Max total dose: 10 mg Repeat dose in 5-15 min to a total max of 0.5mg/kg or 10 mg whichever is smaller Oral Dose 0.25 - 0.5 mg/kg Max total oral dose: 1mg/kg or 20 mg whichever is less	Healthy adults under age 60: 1 to 2 mg IV May repeat in increments of 0.5-1mg every 2- 3 min. until patient achieves desired effect. Total dose: > 5mg usually not necessary ACCP Consensus Statement Dose: 0.06-0.07mg/kg Age 60 or older, chronically ill or debilitated: 0.5- 1.5mg IV over 2 min. May repeat in increments of 0.5-1 mg every 2- 3 min. until patient achieves desired effect. Total dose > 3.5mg usually not necessary	Administer IV slowly over 2 minutes. IV doses: Give 3 minutes prior to the procedure. No more than 2.5mg should be administere d over a period of two minutes Oral doses: Administer 30- 40 minutes prior to procedure	Onset: IV: within 1 to 5 minutes Peak: 5-30 minutes Duration: 2-6 hours Metabolism: Hepatic	 Respiratory depression/apnea Muscle tremor Hypotension Tachycardia Phlebitis Fluctuation in vital signs Nausea/vomiting Coughing Headache Drowsiness Nasal-burning 	Drugs that increase midazolam concentrations: • Ketoconazole, • Erythromycin • Diltiazem and verapamil • Protease Inhibitors Drugs that decrease midazolam concentrations: • Phenytoin • Carbamazepine Contraindication/Precaution • Contraindicated in acute narrow-angle glaucoma unless patients are receiving appropriate therapy. • Hypersensitivity	REVERSE WITH FLUMAZENIL (Romazicon) Consider decreasing dose b 20-50% in patient receiving opioids or other CNS depressants, chronically ill, debilitated patients, or decreased pulmonary reserve. Patients with COPD/OSA are unusually sensitive to the respiratory depressant effects Use with caution i patients with any degree of hepatic impairment. Note: Midazolam Injection containss 1% benzyl alcohol – See Neofax

	Pediatric Dose Neonate- 14yrs	Adult Dose	Administration	Pharmacokinetics	Side Effects	Drug Interactions/ Contraindications	Important Information
Fentanyl (Sublimaze) Opioid	Intravenous: 0.5-1 mcg/kg/dose Max dose 50 mcg May repeat ½ of original dose if needed every 3-5 min Max Total Dose: 5 mcg/kg Intranasal: For infants and Children > or = 10 kg 1.5mcg/kg Max dose 100 mcg	25-50 mcg IV May repeat if needed in increments of 25- 50 mcg every 2-5 minutes until patient achieves desired effect. The max dose is generally 5 mcg/kg or approx. 250 mcg but higher doses may be needed in some instances. (eg: opioid tolerant patients) Elderly patients have been found to be twice as sensitive as younger patients to the effects of fentanyl.	IV over 2 minutes	Onset: within 30 seconds Peak Effect 5-15 minutes <u>Duration:</u> 30-60 minutes <u>Metabolism:</u> Hepatic	 Respiratory depression/apnea Dizziness Bradycardia Hypotension Hypertension Cardiac dysrhythmia Urinary Retention Nausea/vomiting Laryngospasm Diaphoresis Chest wall rigidity - if severe, patient can be INTUBATED and effects can be reversed with Neuromuscular Blockade 	Monoamine oxidase inhibitors – Should not be used if MAOI (Marplan, Nardil, Parnate, Eldepryl) has been used within 14 days. Drugs that increase Fentanyl Effect CNS Depressants TCA Phenothiazines Contraindications/Precautions Hypersensitivity to fentanyl Increased Intracranial pressure Use with caution in patients with pulmonary, hepatic, renal disorders.	REVERSE WITH NALOXONE (Narcan) Decrease dose in elderly patients, hypovolemia, high risk patients or if used with other sedative/narcotics. Can be used in patients with a true codeine/morphine allergy Use with caution in patients with renal or hepatic impairment.

	Pediatric Dose Neonate- 14yrs	Adult Dose	Administration	Pharmacokinetics	Side Effects	Drug Interactions/ Contraindications	Important Information
Morphine Intravenous Opioid	Intravenous: 0.05 –0.1 mg/kg Max dose: 1mo-1year 2 mg 1-6 years 4 mg 7-12 years 8 mg Adolescents 10mg May repeat dose in 5 min if needed CrCl < 10ml/min or on dialysis reduce dose by 50%	2-10mg IV May repeat in increments of 1- 2mg every 10-20 minutes until patient achieves desired effect. Max 10 mg CrCl < 10ml/min or on dialysis reduce dose by 50%	IV administration must be given slowly over 5 minutes.	Onset: Immediate Peak: 5-20 minutes Duration: 2-7 hours Metabolism: hepatic	 Respiratory depression/apnea Dizziness Bradycardia Hypotension 	Drugs that increase morphine effects: CNS depressants TCA Phenothiazines Contraindications/Precaution Hypersensitivity Use with caution in patients with pulmonary, hepatic, renal disorders, and increased intracranial pressure.	REVERSE WITH NALOXONE (Narcan) Decrease dose in elderly patients, high-risk surgical patients, hypovolemia, or if used with other sedatives/narcotics.
Diphenhydramin e (Benadryl) Histamine H1 antagonist	0.5-1 mg/kg Max dose 50mg Contraindicated in neonates and premature infants	10-50 mg IV >60 years more sensitive to sedative effects	Administer IV at rate of <25mg/minutes		 Confusion Parodoxical excitement Chest tightness Tachycardia Hypotension Xtrasystoles 	May enhance the adverse toxic effects of CNS depressants May enhance QTc prolonging effect of QTC prolonging agents May increase serum concentration of metoprol	Local necrosis may result with subQ or intra-dermal use

	Pediatric Dose Neonate- 14yrs	Adult Dose	Administration	Pharmacokinetics		Side Effects	Drug Interactions/ Contraindications	Important Information
Diazepam (Valium) Benzodiazepin e Midazolam is the preferred agent	Oral 0.15 - 0.3mg/kg max dose 10mg IV 0.05 - 0.08 mg/kg max IV dose 0.25 mg/kg	IV Initial dose 2-3 mg May give increments up to 10 mg	Slow IV Push	Onset: IV: < 2 minutes PO: 60-90 minutes Peak Effect IV: 3- 4 minutes Maximum Respiratory Depression occurs 5 minutes post IV dose. Duration: 15 minutes – 1 hour Sedative effects may last 20-80 hours dependent on age Metabolism: Hepatic	• • • • • •	Drowsiness, Dizziness Irritating to Veins: Thrombosis +/- Phlebitis at injection site Respiratory depression/apnea Confusion Irritability Abdominal cramps/nausea Headache Bradycardia,hypotension Skin rash	Cimetidine decreases clearance, prolongs sedation dof Parkinson's symptoms Contraindications • Acute narrow-angle or open-angle glaucoma patients unless receiving appropriate treatment. • Pregnancy • Hypersensitivity	REVERSAL WITH FLUMAZENIL (Romazicon) May cause hypotension, bradycardia and respiratory depression if drug is administered too rapidly IV. Decrease dose in elderly and debilitated patients.

REVERSAL AGENTS - FOR BENZODIAZEPINES AND OPIOIDS

	Pediatric Does	Adult Dose	Administration	Pharmacokinetics	Side Effects	Important Information
	Neonatal – 14yrs					
Flumazenil Romazicon for reversal of benzodiazepines	Neonate: 0.01 mg/kg Max Total Dose: 0.05mg/kg > 1 month of age: Start with 0.01 mg/kg IV (Max dose 0.2 mg) If no response, repeat dose of 0.01 mg/kg (max dose 0.2 mg) q 1 minute Dose may be repeated to a maximum total cumulative dose of 0.05mg/kg or 1mg whichever is lower	0.2mg IV wait 45 seconds. Give additional 0.2mg doses at 1 minute intervals until an adequate response is achieved or a max of 4 additional doses are administered. (max 1mg during initial 5 min period) Regimen may be repeated – (Max 3mg in any 1 hour period) (Would replace with dose below from Lexi-Comp) Initial dose: 0.2mg over 15 seconds Repeat Doses (Max 4 doses): If desired level of consciousness is not obtained, 0.2mg may be repeat at one minute intervals. Max Dose: 1mg For re-sedation: Repeat 0.2mg doses may be given at 20 minute intervals up to 1mg max	Give IVP over 15 seconds Best to administer through a large vein to decrease chance of pain and phlebitis	Onset: 1-2 minutes Peak: 6 to 10 minutes Duration: usually <1 hour (dose to related) Metabolism: Hepatic	Nausea/vomiting Dizziness Agitation Injection site pain Seizures Headache Sweating Flushing Hot flashes Paresthesia Impaired Vision Fatigue	Duration of benzodiazepines greatly exceeds Flumazenil, so continue careful monitoring fo 2 hours after reversal.
Naloxone (Narcan) for reversal of opioids	0.01 – 0.1 mg/kg IV or IM May repeat dose every 2 to 3 minutes if necessary Max single dose 2 mg	0.4 – 2mg IV administered at 2-3 minute intervals Lexi-comp 2016: Initial dose 0.04-4mg; May repeat until desired dose is achieved.	IV Push Do not mix in an alkaline solution.	Onset: IV: 1-2 minutes IM: within 2-5 minutes Duration: 20 to 60 minutes Metabolism: hepatic	Excitement Hypotension Ventricular tachycardia or Fibrillation Nausea/vomiting Seizure Pain	Duration of opioids may excer that of Naloxone (Narcan) so continue careful monitoring fo 2 hours after reversal. Too rapid reversal may induce nausea, vomiting, and sweating or circulatory stress.

Reference: Policy CM C-16 Use of Moderate Sedation and Analgesia, Attachment A

Moderate Sedation Post-Test

For All Questions: Select the one BEST answer. You will need to achieve a score of 80% (12/15) correct on the real exam to be credentialed to administer moderate sedation. Read and review the policy and educational materials as you consider these questions.

- 1. Moderate sedation is defined as:
 - A) Any depressed level of consciousness
 - B) A depressed level of consciousness, retaining the ability to independently and continuously maintain a patent airway and respond purposefully to verbal and tactile stimulation.
 - *C*) A depressed level of consciousness, retaining the ability to independently and continuously maintain a patent airway while not responding to physical stimulation.
 - D) A controlled state of depressed consciousness from which the patient is not easily aroused, and is unable to respond purposefully to physical stimulation or verbal command.
- 2. Medications used for moderate sedation routinely include:
 - A) Benzodiazepines and narcotics
 - B) Benzodiazepines, narcotics, and barbiturates
 - *C*) Narcotics and propofol
 - D) Nitrous oxide and pentothal
 - E) Narcotics and nitrous oxide

- 3. Desired effects of moderate sedation include:
 - 1) Relaxation
 - 2) Cooperation
 - 3) Deep, unarousable sleep
 - 4) Elevation of pain threshold
 - A) 1 and 2
 - B) 1 and 3
 - *C*) 1, 2 and 3
 - D) 1, 2, and 4
- 4. Benzodiazepines:
 - 1) Provide anterograde amnesia
 - 2) Provide analgesia
 - 3) Are antagonized with flumazenil
 - A) 1 and 2
 - B) 1 and 3
 - *C*) 2 and 3
 - D) 1, 2, and 3
- 5. Narcotics:
 - 1) Provide analgesia
 - 2) Provide anterograde amnesia
 - 3) Are antagonized with naloxone
 - A) 1 and 2
 - B) 1 and 3
 - *C*) 2 and 3
 - D) 1, 2 and 3

- 6. In a medical evaluation prior to administration of moderate sedation, the history and physical examination should include:
 - 1) A focused examination of the airway, heart, and lungs
 - 2) Assessment of ASA physical status classification
 - 3) A determination of the last PO intake
 - 4) Past history of problems with anesthesia
 - A) 1 and 2
 - B) 3 and 4
 - *C*) 1, 2 and 3
 - D) All of the above
- 7. A 42-year-old man scheduled for a colonoscopy has a history of non-insulin dependent diabetes and hypertension that is well controlled. His history is otherwise unremarkable. He would be best classified as:
 - A) ASA 1
 - B) ASA 2
 - C) ASA 3
 - D) ASA 4
 - E) ASA 5
- 8. When performing a procedure using moderate sedation:
 - 1) The provider and monitor must be present
 - 2) Monitoring includes ECG and non-invasive blood pressure.
 - 3) Vital signs need to be recorded only at the beginning and end of the procedure.
 - 4) The procedure room should have a pulse oximeter available for emergency.
 - 5) A pulse oximeter should be in use throughout the procedure

- A) 1 and 2
- B) 1, 2 and 3
- *C*) 1, 2 and 5
- D) 2, 3 and 5

9. Documentation during a procedure with moderate sedation should include:

- 1) Dose, route, time and effects of drugs used
- 2) Type/amount of IV fluid given
- 3) Vital signs/respiratory function every 5 minutes
- 4) Level of consciousness
- 5) Comments about the procedure
- A) 1, 3 and 5
- B) 1, 2 and 3
- C) 1, 2, 4 and 5
- D) all of the above
- 10. Discharge criteria after a procedure with moderate sedation include:
 - 1) Patient's level of consciousness is no more than a 2 on the Ramsey scale and no less than a level 8 on the Aldrete scale
 - 2) Patient is able to swallow or has a gag reflex
 - 3) Is able to ambulate with assistance or is at pre procedure norm
 - 4) Feels well and is ready to drive himself home
 - 5) Has instructions regarding diet, activity, and medications
 - A) 1, 2
 - B) 1, 2, 3 and 5
 - *C*) 1, 2 and 4
 - D) All of the above

- 11. Pulse oximetry:
 - Provides the same information about arterial oxygenation as a blood gas
 - 2) Is not necessary if blood gases are monitored during the procedure
 - 3) Measures the absorbance's of light at 660 NM (red light) and 940 NM (nearinfrared light)
 - 4) Provides a non-invasive method of estimating the partial pressure of oxygen in arterial blood
 - 5) May be affected by ambient light, low-perfusion, motion artifacts and dye injection
 - A) 1, 2 and 3
 - B) 1, 2 and 4
 - *C*) 3, 4 and 5
 - D) 1, 3 and 4
- 12. Which of the following describes flumazenil?
 - 1) When given intravenously, flumazenil may be repeated at one minute intervals to a maximum of 0.05mg/kg or 1 mg whichever is lower.
 - 2) Onset of action usually within 2 minutes
 - 3) Use cautiously in patients who are chronically dependent on benzodiazepines because it can precipitate acute withdrawal.
 - 4) Respiratory depression is reliably antagonized and supplemental oxygen is NOT needed
 - A) 1 and 2
 - B) 2, 3 and 4
 - *C*) 1, 2 and 3
 - D) All of the above

- 13. Physicians that are to be credentialed to provide moderate sedation:
 - A) Can also provide deep sedation
 - B) Must demonstrate competency in provision of moderate sedation for 1 event
 - *C*) Must demonstrate competency in the provision of moderate sedation for 5 events
- 14. Which of the following describes the provider's responsibilities regarding documentation of a moderate sedation event?
 - A) The provider is responsible for writing a procedural note and must sign off on the procedure itself.
 - B) The provider may complete the documentation by using the nurse's computer after their charting is completed.
 - C) The provider may complete the documentation by signing into any computer and going to the Summary page, find the sign off report and link.
 - D) All of the above
- 15. After receiving morphine and diazepam for sedation and analgesia for a procedure, the patient loses consciousness and becomes dusky in appearance as the oxygen saturation decreases rapidly from 95% to 75%. Reasonable initial responses include:
 - 1) Administration of oxygen via an ambu bag to improve oxygen saturation
 - 2) Giving naloxone and flumazenil IV
 - 3) Increase the oxygen flow through the nasal cannula
 - 4) Begin the procedure as planned (which will stimulate respirations)
 - A) 1 and 4
 - B) 2 and 3
 - *C*) 1 and 2
 - D) 4 only

Moderate Sedation Post-test Answer Sheet

Answers are not provided

- 1) _____
- 2) _____
- 3) _____
- 4) _____
- 5) _____
- 6) _____
- 7)
- 8)
- 9)
- 10) _____
- 11) _____
- 12)
- 13)
- 14)
- 15)

Note: You must achieve a score of <u>80% (12/15 correct)</u> for credentialing on the post lecture exam.

ATTENDING PHYSICIAN

MODERATE SEDATION CREDENTIALING CHECKLIST

Requirements for initial granting of Moderate Sedation privileges:

- **View video digital version of conscious (moderate) sedation lecture
- **Read moderate sedation self-study booklet
- **Successful completion of moderate sedation post-test
- Provide documentation of satisfactorily administering moderate sedation in a minimum of 5 cases under supervision of a credentialed provider of moderate sedation (date, procedure, signature of credentialed supervisor)
- Approval of Department Chair
- ACLS (PALS for Pediatric Physicians) certification must be current and maintained; (documentation of same provided to Medical Staff Office). ACLS/PALS training will be waived for those <u>MDs who are Board</u> <u>Certified/Eligible in Critical Care. Emergency Medicine and</u> <u>Anesthesiology.</u> Sedation practice is part of the scope of training for these professionals and that the skills they have exceed those presented in ACLS/PALS.

Upon completion, please return checklist to Medical Staff Services. Medical Staff Services will then notify Administrative Supervisors of credentialed status.

** Are available online at

http://www.upstate.edu/medstaff/forms/mod_sedation.php

ATTENDING PHYSICIAN

MODERATE SEDATION CREDENTIALING CHECKLIST

Print name:

Department:

Signature _____

This checklist **MUST** be completed and returned to Medical Staff Services (MSS) (1100 UH) Privileges <u>may not</u> be granted until signed by the Chief of Services or his designee and returned to the MSS.

CRITERIA	
**Digital version video Moderate Sedation lecture:	Date:
**Test (80% score or above) (graded by MSS)	Date:
(graded by MOO)	Score:
Case #1:	Patient:
	Date:
	Supervisor:
Case #2:	Patient:
	Date:
	Supervisor:
Case #3:	Patient:
	Date:
	Supervisor:
Case #4:	Patient:
	Date:
	Supervisor:

Case #5:	Patient:
	Date:
	Supervisor:
ACLS/PALS Completion (If currently certified, please attach copy of card.)	Effective dates:

Based on the completion of the above criteria, I grant approval of moderate sedation privileges.

Chief of	Service of	or Designee	Print N	ame/Signature
		n Designee	I IIIIU IN	ame/orgnature

Date

** Are available online at http://www.upstate.edu/medstaff/forms/mod_sedation.php

PLEASE NOTE: MODERATE SEDATION PRIVILEGES WILL BE REVIEWED EVERY TWO YEARS AT REAPPOINTMENT AND GRANTED ONLY UPON CONTINUED NEED AND COMPETENCY

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RESIDENT

MODERATE SEDATION CREDENTIALING CHECKLIST

Requirements for initial granting of Moderate Sedation privileges for Residents PGY2 and above:

- *Attend conscious (moderate) sedation lecture OR **View digital version of conscious (moderate) sedation lecture
- **Read moderate sedation self-study booklet
- **Successful completion of moderate sedation post-test
- Provide documentation of satisfactorily administering moderate sedation in a minimum of 5 cases under supervision of a credentialed provider of moderate sedation (date, procedure, signature of credentialed supervisor)
- Approval of Program Director
- ACLS (PALS for Pediatric Physicians) certification must be current and maintained throughout residency; (documentation of same provided to Medical Staff Office).

Upon completion, please return checklist to Medical Staff Services. Medical Staff Service will then notify Administrative Supervisors of credentialed status.

** Are available online at

http://www.upstate.edu/medstaff/forms/mod_sedation.php

RESIDENTS PGY1:

After January 1 of their start date, first year residents may begin the training process by obtaining ACLS/PALS certification and taking the course or video.

Observations may begin after January but PGY 1 residents may not be credentialed to perform moderate sedation unsupervised before their second year. All other requirements are the same.

RESIDENT

MODERATE SEDATION CREDENTIALING CHECKLIST

Print name:_____ Department _____

Signature: _____

This checklist MUST be completed and returned to the Medical Staff Office (MSO) (2 nd floor, CWB) Privileges <u>may not</u> be granted until signed by Program Director and returned to the MSO. CRITERIA	
**Video Digital version moderate sedation lecture:	Date:
**Test (80% score or above)	Date:
(graded by MSO)	Score:
Case #1:	Patient:
	Date:
	Supervisor:
Case #2:	Patient:
	Date:
	Supervisor:
Case #3:	Patient:
	Date:
	Supervisor:

Case #4:	Patient:
	Date:
	Supervisor:
Case #5:	Patient:
	Date:
	Supervisor:
ACLS/PALS Completion	Effective dates:
(ACLS/PALS Completion (If currently certified, please attach	
copy of card.)	

** Are available online at http://www.upstate.edu/medstaff/forms/mod_sedation.php

Based on the completion of the above criteria, I grant approval of moderate sedation privileges.

Program Director Print Name/Signature

Date:

HEALTH PROFESSIONAL

MODERATE SEDATION CREDENTIALING CHECKLIST

Moderate sedation **MUST** be required as a portion of the scope of duties of a Health Professional. Requirements for initial granting of Moderate sedation privileges:

- *Attend conscious (moderate) sedation lecture **OR** **View digital version conscious (moderate) sedation lecture
- **Read moderate sedation self-study booklet
- **Successful completion of moderate sedation post-test
- Provide documentation of satisfactorily administering moderate sedation in a minimum of 5 cases under supervision of a credentialed provider of moderate sedation (date, procedure, signature of credentialed supervisor)
- Approval of Supervising Physician
- ACLS (PALS for Pediatric Practitioners) certification must be current and maintained; (documentation of same provided to Medical Staff Office).

Upon completion, please return checklist to Medical Staff Services. Medical Staff Services will then notify Administrative Supervisors of credentialed status.

** Are available online at

http://www.upstate.edu/medstaff/forms/mod_sedation.php

HEALTH PROFESSIONAL

MODERATE SEDATION CREDENTIALING CHECKLIST

Print name _____Department _____

Signature _____

This checklist MUST be completed and returned to Medical Staff Services (MSS) (1100 UH) Privileges may not be granted until signed by Supervising Physician and returned to the MSS.

CRITERIA	
**Video Digital version moderate sedation lecture:	Date:
**Test (80% score or above)	Date:
(graded by MSO)	Score:
Case #1:	Patient:
	Date:
	Supervisor:
Case #2:	Patient:
	Date:
	Supervisor:
Case #3:	Patient:
	Date:
	Supervisor:

Case #4:	Patient:
	Date:
	Supervisor:
Case #5:	Patient:
	Date:
	Supervisor:
ACLS/PALS Completion (If currently certified, please attach	Effective dates:
copy of card.)	
** Are available online at http://	www.upstate.edu/medstaff/forms/mod_sedation.php

Based on the completion of the above criteria, I grant approval of moderate sedation privileges.

Su	pervisina	Physician	Print Name/	Signature
Cu	porvioling	i nyololai		Orginataro

Date

Available at Medical Staff Services, 1100 UH (464-5733)

<u>PLEASE NOTE</u>: MODERATE SEDATION PRIVILEGES WILL BE REVIEWED EVERY TWO YEARS AT REAPPOINTMENT AND GRANTED ONLY UPON CONTINUED NEED AND COMPETENCY

Resource Contacts

Medical Staff Services Room 1100 University Hospital 464-5733

Sedation Task Force Dr. Sebastian Thomas 464-4891