

# APPENDIX C

## SHADY GROVE MEDICAL CENTER MEDICAL STAFF POLICY MANUAL

### SEDATION/ANALGESIA

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#### PURPOSE

To optimize patient safety by establishing consistent hospital-wide processes for the management of patients receiving procedural sedation by non-anesthesiologists. In general, non-anesthesiologists will administer sedative medications in doses intended to produce moderate levels of sedation.\*

#### Related Policies

Discharge Criteria from PACU #101-08-002, Fast-Track Policy for PACU #101-08-003, Propofol Sedation Policy #019, Surgical/Invasive Procedure Site Verification Process #101-10-131, Advanced Procedural Sedation #022

#### POLICY

Moderate sedation is intended to reduce patients' pain and awareness during diagnostic or therapeutic procedures. The sedative medication dosages are not intended to result in loss of protective airway reflexes, significantly depress ventilation, or cause cardiovascular compromise. However, because sedation is a continuum and because there is wide variation in patient response to sedative agents, it is not always possible to predict how an individual patient will respond. Occasionally a patient who receives sedation medication in doses that typically produce moderate sedation will slip into a deeper level of sedation. The deeper level of sedation may be associated with potentially catastrophic airway obstruction, hypoventilation, or cardiovascular instability. At Shady Grove Medical Center medical staff and nurses who participate in moderate sedation will have the skills and equipment necessary to recognize the different levels of sedation and then "rescue" patients who slip into deeper-than-intended levels of sedation. Pre-sedation evaluation will be designed to identify appropriate candidates for sedation by non-anesthesiologists and then optimize these patients prior to sedation. Intra-procedure monitoring and post-sedation care will insure that adverse physiologic changes are rapidly recognized and corrected. The processes included in this policy are based upon standards and guidelines developed by the American Society of Anesthesiologists, the American Academy of Pediatrics, and the Joint Commission on Accreditation of Healthcare Organizations.

\*Only specially-credentialed emergency medicine physicians may administer sedation in doses intended to produce deep sedation. Please see Shady Grove Hospital policy on the advanced procedural sedation by non-anesthesiologists for specific requirements.

**Exceptions.** The moderate sedation policy applies only when sedation is given under the direction of a non-anesthesiologist for patients undergoing diagnostic or therapeutic procedures. The policy specifically excludes the following:

1. Sedation/Analgesia for the control of pain, anxiety, seizures or insomnia.
2. Sedation of patients on ventilators.
3. Sedation/Analgesia used in obstetrical labor.
4. Patients requiring urgent intubation.
5. Sedation/Analgesia given by an anesthesiologist's order in the pre-operative or PACU areas.
6. Sedation/Analgesia administered in the NICU under the direction of a neonatologist.

**Locations.** This policy applies to moderate sedation in all locations within Shady Grove Medical Center and the Germantown Emergency Center. This includes the Cardiovascular/Interventional Radiology Labs, Emergency Department, Critical Care areas, Surgical Services, GI endoscopy, and any other area at the discretion of the supervising physician where appropriate staff and equipment are available.

**Staff.** A physician and registered nurse must be involved in the care of each patient undergoing moderate sedation during the entire procedure:

1. A qualified physician who performs the diagnostic or therapeutic procedure supervises the administration of sedation. The physician must remain immediately available from the time of the first dose of sedation until the patient is accepted by a recovery room nurse.
2. A Registered Nurse with special training is responsible for administering sedation and monitoring the patient at the direction of the physician. The nurse should remain at the head of the bed whenever possible to facilitate direct observation of the airway.
3. If assistance is required with the procedure, then additional personnel (>2) must be utilized. The nurse monitoring the patient may not assist with the procedure.

**Essential Equipment.** The following equipment and supplies must be available wherever sedation is to be used:

1. Minimal monitoring equipment includes non-invasive blood pressure, continuous EKG, pulse oximeter, and end-tidal CO<sub>2</sub> monitor. Whenever possible the monitor alarms will be set to indicate oxygen saturation less than 90% and apnea  $\geq$  30 seconds. In addition, when available, the pulse oximeter will be set to have a variable-pitch tone that is audible to the supervising physician. When audible alarms are not available the sedation nurse will remain at the head of bed in continuous visual contact with both the patient and display of vital signs.
2. Resuscitation equipment for management of the airway (including ambu-bag and intubation tray) along with a fully assembled and functioning suction apparatus must be immediately available. Airway equipment must be of appropriate size for the patient.
3. A defibrillator and cardiac resuscitation drugs in accordance with ACLS standards must be readily available.
4. Reversal agents must be immediately available.
5. Wall oxygen source must be present and at least one full oxygen E-cylinder with regulator as back-up must be readily available.
6. Appropriate equipment to administer intravenous fluids and drugs must be immediately available.

## **DEFINITIONS**

Definitions of four levels of sedation and anesthesia include the following:

1. 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.
2. Moderate sedation/analgesia (formerly conscious sedation)  
A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Note: reflex withdrawal from a painful stimulus is not considered a purposeful response). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
3. Deep Sedation  
A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation

may be inadequate. Cardiovascular function is usually maintained. Deep sedation is restricted for use by anesthesiologists and specially-credentialed emergency medicine physicians.

4. Anesthesia

Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Anesthesia is restricted for use by anesthesia providers.

5. Aldrete Score

Physiologic assessment scoring system used to evaluate patients' recovery from sedation or anesthesia (Appendix 1).

6. ASA Score

American Society of Anesthesiologists physical status classification system (Appendix 2).

7. Mallampati Classification

Airway evaluation technique that predicts difficult intubation using direct laryngoscopy (Appendix 3).

8. Motor Activity Assessment Scale

Scale used to assess level of sedation (Appendix 4)

9. Fasting Protocol

Nationally recognized guidelines that establish the safe length of time from intake of food or liquid until administration of sedation. It represents the time necessary to ensure gastric emptying and is intended to reduce the risk of catastrophic aspiration of gastric contents (Appendix 5)

10. Recommended Doses of Sedative Medications

Institution specific guidelines for drug dosages intended to produce a moderate level of sedation (Appendix 6)

11. Immediately available

Located at the bedside and obtainable within seconds.

12. Readily available

Located within the same suite and obtainable within one to two minutes.

### **CREDENTIALING REQUIREMENTS**

Only physicians are qualified by specialized training will be permitted to supervise the administration of moderate sedation. Physicians must demonstrate competency in: (1) the safe administration of sedative and analgesic drugs used to establish a moderate level of sedation, (2) rescue of patients who exhibit adverse physiologic consequences of a deeper-than-intended level of sedation, and (3) awareness of the patient care processes outlined in this policy. The Chairman of the Department of Anesthesia is responsible for reviewing each application for privileges in moderate sedation and making a recommendation to the Credentials Committee regarding competency

**Physician Adult Sedation Privileges.** Physicians with adult sedation privileges may provide sedation care to patients fifteen years of age and older. Adult moderate sedation privileges are part of core privileges for the Department of Emergency Medicine. Physicians who are not members of the Department of Emergency Medicine must fulfill the following requirements:

1. Initial Competency Requirements.
  - a. Current ACLS certificate.
  - b. Completion of a residency/fellowship training program within the last two (2) years that includes a formalized education component on the safe administration of sedative drugs. (letter from the residency director required).

**OR**

Review of the Shady Grove self-education module on moderate sedation including:

- a) ASA Guidelines on Preoperative Fasting
  - b) ASA Guidelines for Administration of Moderate Sedation
  - c) ASA Video on Sedation and Analgesia by Non-Anesthesiologists
- c. Review of the Shady Grove Medical Center Policy on Moderate Sedation.
  - d. Score of  $\geq 80\%$  on the Shady Grove Medical Center Moderate Sedation Competency Test.
2. Ongoing Competency Requirements. Recredentialing of sedation privileges will be evaluated on the same two year cycle as staff appointments.
    - a. Current ACLS certificate.
    - b. Review of the most recent revision of the Shady Grove Medical Center Hospital Policy on Moderate Sedation.
    - c. Evidence of at least eight (8) sedations during the previous two years submitted by the requesting physician.

**OR**

Completion of the above Initial Competency Requirements in Moderate Sedation.

**Pediatric Sedation Privileges.** Only physicians with pediatric moderate sedation privileges may administer moderate sedation to patients less than fifteen (15) years of age, Pediatric moderate sedation privileges are part of core privileges for the Department of Emergency Medicine. Privileges to administer moderate and deep sedation to patients admitted to the NICU are part of core privileges for the Neonatology Subsection.

**Competency Requirements for Nurses.**

1. Only Registered Nurses who have completed the Shady Grove sedation competency module may assist in the administration of sedation.
2. Current ACLS certification or PALS certification (for those nurses who assist in the administration of sedation to patients less than fifteen years of age).

### **Special Considerations for Pediatric Sedation**

Sedation of pediatric patients has serious associated risks such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment. Because pediatric patients have less physiologic reserve than adult patients, a more rapid deterioration in vital signs usually follows an adverse respiratory event. Therefore the presence of appropriate resuscitation equipment as well as a physician with advanced pediatric airway skills are essential. Younger children (less than six years of age) and those with developmental delays frequently require deep levels of sedation in order to cooperate with even relatively minor procedures.

**Equipment.** Locations where pediatric sedation is administered must be equipped with resuscitation equipment of appropriate age-specific sizes. This includes laryngoscope blades, endotracheal tubes, oral/nasal airways, suction catheters, yankauer tips, defibrillator and pads, monitoring equipment and resuscitation drugs. Typically airway supplies (airways, endotracheal tubes) of the patient's size and one size smaller should be immediately available.

**Pre-procedure Evaluation.** The pre-procedure evaluation must include the patient's weight, history of reactive airway disease, symptoms of upper respiratory infection (if present), and family history of anesthetic complications.

**Consent.** A responsible adult must understand and sign a consent form for patients less than eighteen (18) years of age unless the patient is an emancipated minor.

**Monitoring.** It is recognized that some children will not tolerate placement of routine sedation monitors without becoming agitated. In this circumstance, it is acceptable to administer sedation under careful observation until the child shows clinical signs such as drowsiness or spontaneous eye closure. At this point, monitors should be placed and the child should be monitored according to the standards detailed in this policy.

### **Patient Care Process**

#### **Pre-procedure Care.**

**RN Responsibilities.** Nursing is responsible for collecting pertinent data and preparing the patient for the physician pre-sedation assessment. The nurse performs this task by completing The standard Pre-procedure Checklist which includes:

- a. Confirmation that a valid history and physical exam is part of the medical record (the H&P must be performed within 30 days with updated heart and lung assessment within 7 days). The history and physical must be signed or co-signed by a credentialed member of the Shady Grove medical staff.
- b. Most recent laboratory values.
- c. Pregnancy tests should be considered for females greater than 12 years of age.
- d. Point of care blood glucose measurement is performed for diabetic patients.
- e. Consent signed by the performing physician and patient. The consent must include The name of the procedure, the side (for procedures that involve laterality), and designate that moderate sedation will be used.
- f. Completed nursing assessment.
- g. DNR status documented, if applicable
- h. Up-to-date medication administration record.
- i. Pre-procedure vital signs.
- j. NPO status. The physician should be notified whenever a patient does not Meet the criteria set forth in the fasting protocol.
- k. Confirmation that the anatomical site is marked by the physician.

#### 2. **Physician Responsibilities**

- a. **Informed Consent.** The physician performing the procedure and supervising the sedation must inform the patient/guardian about the risks, possible complications benefits and alternatives to sedation as a component of the planned procedure. Patients or their authorized representatives should agree to the administration of moderate sedation before the procedure begins.
- b. The physician orders and reviews the results of pertinent laboratory testing. Pre-sedation testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation.

- c. The physician conducts and documents a pre-sedation assessment within 24 hours of the start of the procedure. The assessment may be documented on the standard "Pre-sedation Assessment Form" (appendix 6) and must include the following:
  - i. Physical Status Classification.
  - ii. Focused history documenting any interim changes in health or previous adverse reaction to sedation/anesthesia.
  - iii. Airway Examination.
  - iv. NPO status\*.
  - v. Review of pertinent lab values (patients with end-stage renal disease must have a basic metabolic panel within 24 hours of sedation).
  - vi. Plan for sedation.
  - vii. Re-evaluation of the patient (including vital signs and mental status) just prior to sedation.
- d. The physician conducts a "Time-Out" according to the Shady Grove Policy# 101-10131 just prior to starting the procedure.
- e. For outpatients, the physician will confirm that appropriate arrangements have been made for a responsible adult to drive the patient home.
- f. The physician will consider consultation with an anesthesiologist for high-risk patients. The criteria listed in Appendix 7 may be used as guide to help determine when consultation is indicated.

\*The NPO protocol should be observed whenever a delay will not jeopardize the well being of the patient. Emergent and urgent clinical situations are expected to arise that preclude strict adherence to these guidelines. In these cases the amount of sedation should be minimized and carefully titrated in order to prevent the loss of protective airway reflexes. The risk of aspiration pneumonitis may be further reduced by the use of a non-particulate antacid (bicitra), H2-blockers and/or metoclopramide prior to sedation.

#### **Intra-Procedure Care.**

1. RN responsibilities. The nurse is responsible for administering sedation at the order of the physician while continuously assessing the patient's physiologic status.
  - a.
    - i. Vital signs including blood pressure, heart rate, respiratory rate, oxygen saturation and mental status level will be assessed and recorded prior to initiation of the procedure and on arrival to the recovery area.
    - ii. Blood pressure and heart rate will be assessed and documented every five minutes during the procedure. Cardiac rhythm, respiratory rate, level of consciousness, presence of EtCO<sub>2</sub> and oxygen saturation will be continuously monitored and recorded at least every fifteen minutes.
    - iii. Medication administration, including dose, route, and times.
    - iv. EtCO<sub>2</sub>- Adequacy of ventilation will be monitored by observing the contours of the EtCO<sub>2</sub> waveform.
  - b. The nurse will be positioned at the head of the bed and assess the patient continuously for changes in condition or appearance. The nurse will report any of these changes to the responsible physician immediately and initiate the appropriate intervention.
  - c. Administer oxygen as needed. Typically oxygen via nasal cannula will be administered in order to maintain oxygen saturation above 92% with the following considerations:
    - i. The application of oxygen reduces the incidence and severity of hypoxemia during moderate sedation. However, it must be remembered that the use of supplemental oxygen will delay the detection of apnea by the pulse oximeter. This emphasizes the importance of monitoring respiratory function by observation of chest excursion and EtCO<sub>2</sub> detection.

- ii. **Fire Safety:** If electrocautery is to be used near the airway, then oxygen flow should be minimized to the lowest amount necessary to maintain acceptable hemoglobin saturation. Sedation providers must minimize the build-up of oxygen beneath drapes and in oropharynx and position drapes so that gases will not collect. If possible, supplemental oxygen should be stopped at least one minute before and during the activation of the electrosurgical unit.

2. Physician Responsibilities. The physician orders sedative medication, determines dosage, and responds to adverse physiologic effects.

- a. The responsible physician selects and orders all sedative medication.
- b. The physician is responsible for airway interventions, if necessary.
- c. The physician orders the administration of reversal agents when indicated.

Note: Because reversal agents may have serious side-effects their use should be minimized and their dose titrated to effect (see recommended drug doses). Naloxone is relatively contraindicated in patients with a history of narcotic tolerance. Flumazenil is relatively contraindicated in patients with a history of alcohol abuse or long-standing benzodiazepine use.

### **Post-Procedure Care**

1. RN Responsibilities. Nursing is responsible for collecting pertinent data and preparing the patient for the physician pre-sedation assessment. The nurse performs this task by completing the standard Pre-procedure Checklist which includes:

- a. Confirmation that a valid history and physical exam is part of the medical record (the H&P must be performed within 30 days with updated heart and lung assessment within 7 days). The history and physical must be signed or co-signed by a credentialed member of the Shady Grove medical staff.
- b. Most recent laboratory values.
- c. Pregnancy tests should be considered for females greater than 10 years of age.
- d. Point of care blood glucose measurement is performed for diabetic patients.
- e. Consent signed by the performing physician and patient. The consent must include the name of the procedure, the side (for procedures that involve laterality), and designate that moderate sedation will be used.
- f. Completed nursing assessment.
- g. DNR status documented, if applicable
- h. Up-to-date medication administration record.
- i. Pre-procedure vital signs.
- j. NPO status. The physician should be notified whenever a patient does not meet the criteria set forth in the fasting protocol.
- k. Confirmation that the anatomical site is marked by the physician.

2. Physician Responsibilities

- a. **Informed Consent.** The physician performing the procedure and supervising the sedation must inform the patient/guardian about the risks, possible complications, benefits and alternatives to sedation as a component of the planned procedure. Patients or their authorized representatives should agree to the administration of moderate sedation before the procedure begins.
- b. The physician orders and reviews the results of pertinent laboratory testing. Pre-sedation testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation.
- c. The physician conducts and documents a pre-sedation assessment within 24 hours of the start of the procedure. The assessment may be documented in the EMR or on the standard "Pre-sedation Assessment Form" (appendix 6) and must include the following:
  - i. Physical Status Classification.
  - ii. Focused history documenting any interim changes in health or previous adverse reaction to sedation/anesthesia.
  - iii. Airway Examination.
  - iv. NPO status\*.

- v. Review of pertinent lab values (patients with end-stage renal disease must have a basic metabolic panel within 24 hours of sedation).
  - vi. Plan for sedation.
  - vii. Re-evaluation of the patient (including vital signs and mental status) just prior to sedation.
- d. The physician conducts a "Time-Out" according to the Shady Grove Policy# 101-10-131 just prior to starting the procedure.
  - e. For outpatients, the physician will confirm that appropriate arrangements have been made for a responsible adult to drive the patient home.
  - f. The physician will consider consultation with an anesthesiologist for high-risk patients. The criteria listed in Appendix 7 may be used as guide to help determine when consultation is indicated.

*\*The NPO protocol should be observed whenever a delay will not jeopardize the well being of the patient. Emergent and urgent clinical situations are expected to arise that preclude strict adherence to these guidelines. In these cases the amount of sedation should be minimized and carefully titrated in order to prevent the loss of protective airway reflexes. The risk of aspiration pneumonitis may be further reduced by the use of a non-particulate antacid (bicitra), H2-blockers and/or metoclopramide prior to sedation.*

### **Intra-Procedure Care**

1. RN responsibilities. The nurse is responsible for administering sedation at the order of the physician while continuously assessing the patient's physiologic status.
  - a. Documentation of the physiologic status of the patient may be in the EMR or on the Shady Grove Sedation and Analgesia Flowsheet (Appendix 9).
    - i. Vital signs including blood pressure, heart rate, respiratory rate, oxygen saturation, and level of consciousness will be assessed and recorded prior to initiation of the procedure and on arrival to the recovery area.
    - ii. Blood pressure and heart rate will be assessed and documented every five minutes during the procedure. Cardiac rhythm, respiratory rate, level of consciousness, presence of EtCO<sub>2</sub> and oxygen saturation will be continuously monitored and recorded at least every fifteen minutes.
    - iii. Medication administration, including dose, route, and times.
    - iv. IV fluid replacement.
  - b. Whenever possible the nurse will be positioned at the head of the bed and assess the patient continuously for changes in condition or appearance. The nurse will report any of these changes to the responsible physician immediately and initiate the appropriate intervention.
  - c. Administer oxygen. Typically oxygen via nasal cannula will be administered in order to maintain oxygen saturation above 92% with the following considerations:
    - i. The application of oxygen reduces the incidence and severity of hypoxemia during moderate sedation. However, it must be remembered that the use of supplemental oxygen will delay the detection of apnea by the pulse oximeter. This emphasizes the importance of monitoring respiratory function by observation of chest excursion and EtCO<sub>2</sub> detection.
    - ii. Fire Safety: If electrocautery is to be used near the airway, then oxygen flow should be minimized to the lowest amount necessary to maintain acceptable hemoglobin saturation. Sedation providers must minimize the build-up of oxygen beneath drapes and in oropharynx and position drapes so that gases will not collect. If possible, supplemental oxygen should be stopped at least one minute before and during the activation of the electrosurgical unit.
2. Physician Responsibilities. The physician orders sedative medication, determines dosage, and responds to adverse physiologic effects.
  - a. The responsible physician selects and orders all sedative medication.
  - b. The physician is responsible for airway interventions, if necessary.
  - c. The physician orders the administration of reversal agents when indicated.

*Note: Because reversal agents may have serious side-effects their use should be minimized and their dose titrated to effect (see recommended drug doses). Naloxone is relatively contraindicated in patients with a history of narcotic tolerance. Flumazenil is relatively contraindicated in patients with a history of alcohol abuse or long-standing benzodiazepine use.*

**Post-Procedure Care**

1. RN Responsibilities. Nursing is responsible for monitoring the patient until their physiologic status has returned to a level at or close to their baseline. The following standards for monitoring and discharge criteria will be used:
  - a. Oxygen saturation and EKG will be continuously monitored. Vital signs including blood pressure, heart rate, oxygen saturation, level of consciousness and respiratory rate will be documented on arrival to the recovery area and every fifteen (15) minutes thereafter.
  - b. Significant changes in the patient's condition are reported to the physician immediately. These include:
    - i. Symptomatic changes in blood pressure.
    - ii. Oxygen saturation less than 90% with supplemental oxygen.
    - iii. Heart rate <45 or >110.
    - iv. Dyspnea, apnea, diaphoresis.
    - v. Inability to arouse.
    - vi. Need for mechanical airway support.
    - vii. Any other unexpected patient response
  - c. Pain level will be assessed every fifteen (15) minutes using a visual analog scale. Pain score greater than five (5) not easily controlled with ordered post-procedure analgesics will be reported to the responsible physician.
  - d. The nurse will assess the Aldrete score every fifteen minutes and discharge the patient according to the below criteria as approved by the Medical Staff.
  - e. Those patients who meet the criteria for the SGMC Fast-Track Protocol at the conclusion of the procedure may be admitted directly to Phase II PACU and be advanced immediately to the Phase II care guidelines
2. Physician Responsibilities.
  - a. The procedural physician is responsible for all orders in the recovery phase including but not limited to: analgesics, oxygen therapy, hemodynamic medications and reversal agents.
  - b. The procedural physician signs the discharge order.
  - c. The procedural physician documents a post-procedure/sedation progress note immediately following the procedure.
3. Discharge Criteria.
  - a. Inpatients will be discharged from the recovery area to other inpatient areas when they have met the following criteria and after SBAR report is given to the receiving nurse. Inpatients will be transported via stretcher or wheelchair accompanied by a staff member. Patients will be instructed regarding post-procedure status and activities.
    - i. Aldrete score of ten (10). Patients with an Aldrete score less than ten may be discharged only by physician order.
    - ii. If reversal agents are used then the patient must be observed for two hours after the last dose of an antagonist to insure that respiratory depression does not recur.
    - ii. Stable vital signs over a period of at least fifteen minutes.
    - iv. Adequate ventilation and oxygenation as evidenced by a stable respiratory rate and oxygen saturation appropriate for the patient. (Patients with room air oxygen saturation of less than 90 percent will be transported with supplemental oxygen).
    - v. Ability to maintain/protect airway with level of alertness and orientation appropriate to pre-procedure status.

- b. Outpatients will be discharged to home from the recovery area when they have met the following criteria:
- i. All discharge criteria listed above for inpatients have been met.
  - ii. Patients who have received sedation are discharged in the company of a responsible adult. The patient will have arrangements for transportation home. Patients who have received sedation will not be allowed to drive themselves home.
  - iii. The patient has received written discharge instructions that have been reviewed with the patient and/or escort.

### **Performance Improvement**

#### **Data Collection.**

1. Peer Review. Each Department will review adverse sedation related events as part of their peer review process. Cases that receive a standard of care score of III or IV will be forwarded to the multidisciplinary Professional Peer Evaluation Committee for action.
2. Performance Improvement Indicators. The following adverse sedation-related events will be reported through the hospital's incident reporting system.

#### Reportable adverse events:

- i. Sustained SpO<sub>2</sub> < 88% (>3 minutes) with supplemental oxygen.
- ii. Prolonged unresponsiveness (>30 minutes).
- iii. Sedation related death.
- iv. Sedation related cardiac/respiratory arrest.
- v. Aspiration pneumonia.
- vi. Sedation related rapid response or "Anesthesia stat" call

### **References**

#### American Society of Anesthesiologists Standards and Guidelines:

1. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation, October 2014
2. Statement on Granting Privileges for Administration of Moderate Sedation to Non-Anesthesiologists, October 2011
3. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, March 2002
4. Standards for Basic Anesthesia Monitoring, October 2015
5. Standards for Postanesthesia Care, October 2014
6. Practice Guidelines for Post-Anesthesia Care, October 2012
7. Basic Standards for Preanesthesia Care, October 2015
8. Practice Guidelines for Preop Fasting, October 2010

**Appendix 1.**

**Aldrete Scoring System**

<u>Activity</u>	<u>Score</u>
Able to move four extremities voluntarily or on command	2
Able to move two extremities voluntarily or on command	1
Unable to move extremities voluntarily or on command	0
<u>Respiration</u>	
Able to breathe freely and cough deeply	2
Dyspnea or limited breathing	1
Apneic	0
<u>Circulation</u>	
BP within 20% of pre-sedation level	2
BP within 21 to 49% of pre-sedation level	1
BP more than 50% different from pre-sedation level	0
<u>Consciousness</u>	
Fully awake	2
Arousable on calling	1
No response	0
<u>Oxygen saturation</u>	
Able to maintain O2 saturation greater than 92% on room air	2
Needs O2 inhalation to maintain O2 saturation greater than 90%	1
O2 saturation 90% or less even with O2 supplementation	0

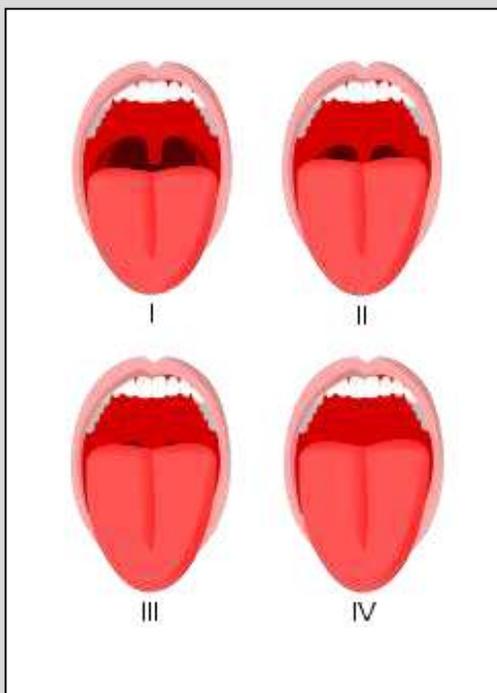
**Appendix 2.**

**ASA Physical Status Classification**

Status I	Normal healthy patient
Status II	Mild systemic disease
Status III	Severe systemic disease with definite functional impairment
Status IV	Severe systemic disease that is a constant threat to life
Status V	Moribund patient, not expected to survive

Appendix 3.

Mallampati Classification



The Mallampati classification is a tool used to predict the ease or difficulty of intubation. It is determined by looking at the anatomy of the oral cavity. A high classification score (class 3 or 4) is predictive of difficult intubation and sleep apnea.

Technique:

The patient sits upright with head tipped back, mouth opened and tongue protruded. Classifications are described below.

- Class I: Can visualize soft palate, all of uvula, tonsillar pillars
- Class II: Can visualize soft palate, tip of uvula is obscured
- Class III: Can visualize soft palate
- Class IV: Can visualize hard palate only

**Appendix 4.**

**Motor Activity Assessment Scale**

The MAAS is a standardized method for describing level of sedation. Target MAAS scores for patients under moderate sedation are 2 to 3.

<b>Clinical Score</b>	<b>MAAS – Level of Sedation Achieved</b>
0	Unresponsive - Does not move with noxious stimuli
1	Responsive only to noxious stimuli - Opens eyes, OR raises eyebrows, OR turns head toward stimulus, OR moves limbs with noxious stimuli
2	Responsive only to touch - Opens eyes, OR raises eyebrows, OR turns head toward stimulus, OR moves limbs when touched, OR when name loudly spoken
3	Calm & cooperative - No external stimulus required to elicit movement AND patient adjusts sheets or clothes purposefully and follows Commands
4	Restless & cooperative - No external stimulus required to elicit Movement AND patient picks at sheets or tubes uncovering self AND follows command
5	Agitated - No external stimulus required to elicit movement AND patient attempts to sit up or move limbs out of bed AND does not consistently follow commands
6	Dangerously agitated - No external stimulus required to elicit movement AND patient pulls at tubes or catheters, OR thrashes side to side, OR strikes at staff, OR tries to climb out of bed and does not calm down when asked

**Appendix 5.**  
**Fasting Protocol**

The following is a summary of American Society of Anesthesiologists Pre-procedure Fasting Guidelines:

<b>Ingested Material</b>	<b>Minimum Fasting Period</b>
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Non-human milk	6 hours
Light meal	6 hours
Full meal	8 hours

Please note:

1. These recommendations apply to healthy patients who are undergoing elective procedures. Following these guidelines does not guarantee that complete gastric emptying has occurred.
2. In emergency situations, when following the guidelines might result in patient harm, the physician providing sedation may proceed with the procedure while using precautions to minimize the risk of pulmonary aspiration.
3. Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.
4. A light meal typically consists of toast and clear liquids.
5. Full meals include fried, fatty foods, or meats.

**SHADY GROVE MEDICAL CENTER MODERATE SEDATION  
ADULT DOSING SCHEDULE**

Generic Name (Trade Name)	Use	Dosing Guidelines	Onset, Peak, Duration of Action	Adverse Effects	Reversal
<b>BENZODIAZEPINES</b>					
Midazolam (Versed)	Sedation Amnesia Anxiolysis	<p><i>Adults &lt;60 years old:</i>  IV: 0.5mg to 2.5mg over  2 to 3 minutes.  <i>Wait 2 minutes to evaluate sedative  effect before giving  additional doses.</i>  IM: 0.07 to 0.08mg/kg as  one time dose</p> <p style="text-align: center;">Total Dose- 7.5 mg IV</p> <p><i>Adults ≥60 years old:</i>  IV: 0.5 to 1.5mg IV over 2  to 3 minutes.  <i>Titrate as above.</i>  IM: 0.02 to 0.05mg/kg</p> <p style="text-align: center;">Total Dose- 5mg IV</p>	<p>Onset:  IV: 1-5 min  IM: 15 min</p> <p>Peak:  IV: 20-60 min  IM: 30-60 min</p> <p>Duration:  IV: 1-2 hours  IM: 6 hours</p>	Respiratory depression Paradoxical agitation Hypotension (especially with opioid) Arrhythmias Nausea/emesis/ Headache Hallucinations Hiccoughs	Flumazenil (Watch for rebound sedation)
Lorazepam (Ativan)	Sedation Amnesia	<p>IV: 2-3 mg over 2-5 min  IM: 0.025 to 0.05mg/kg  PO: 2 to 4mg</p> <p><u>Total Dose- 4mg</u></p>	<p>Onset:  IV: 1-5 min  IM: 15 min  PO: 30-60 minutes</p> <p>Peak:  IV: 15-20 min  IM: 2-3 hours  PO: 2 hours</p> <p>Duration: 4-8 hours</p>	See Midazolam	Flumazenil

**SHADY GROVE MEDICAL CENTER MODERATE SEDATION  
ADULT DOSING SCHEDULE (CON'T)**

**OPIOIDS**

<b>Generic Name (Trade Name)</b>	<b>Use</b>	<b>Dosing Guidelines</b>	<b>Onset, Peak, Duration of Action</b>	<b>Adverse Effects</b>	<b>Reversal</b>
Fentanyl (Sublimaze)	Sedation Analgesia	0.5-1.0 mcg/kg/dose IV/IM <b>Administer slowly over 1-2 minutes</b> Total Dose 3mcg/kg	Onset: IV: 1 minutes IM: 7-8 minutes  Peak: IV: 3-5 minutes IM: No data  Duration: IV: 30-60 minutes IM: 1-2 hours	Respiratory depression Hypotension Bradycardia Chest wall rigidity with rapid dosing	Naloxone
Morphine Sulfate	Sedation Analgesia	<b>Adults &lt;60 years old:</b> 2-5 mg/dose IV Total dose- 15 mg  <b>Adults &gt;= 60 years old:</b> 2-3 mg/dose IV <u>Total dose- 10 mg</u>	Onset: IV: 5-10 minutes  Peak: IV: 20 minutes  Duration: IV: 4-5 hours	Respiratory depression Hypotension Bradycardia Nausea Pruritis Urinary retention	Naloxone
Dexmedetomidine	Sedation	Moderate Sedation IV Bolus: 1-2 mcg/kg once Infusion: 0.6-1 mcg/kg/hr Max Dose: 1 mcg/kg/hr  For elderly reduce to 0.5 mcg/kg/hr	Onset: IV: 5 minutes Peak: 15 minutes	Bradycardia Hypotension Atrial Fibrillation  Contraindicated in the presence of heart block severe renal/hepatic impairment & use of beta blockers	N/A
Hydromorphone (Dialoid)	Sedation Analgesia	Adults <60 years old: 0.5-1.0 mg IV Total dose- 2mg Adults >60 years old: 0.25-0.5 mg IV Total dose- 1mg			

**SHADY GROVE MEDICAL CENTER MODERATE SEDATION  
ADULT DOSING SCHEDULE (CON'T)**

**REVERSAL AGENTS**

<b>Generic Name (Trade Name)</b>	<b>Use</b>	<b>Dosing Guidelines</b>	<b>Onset, Peak Duration of Action</b>	<b>Adverse Effects</b>	<b>Reversal</b>
Naloxone (Narcan)	Reverses opioid induced analgesia & sedation	<p>For Respiratory Depression:  0.1 mg IV every 2-3 minutes with 0.1 mg increments</p> <p><u>Total dose- 1 mg in 5 min</u></p> <p>For Apnea/Arrest:  0.4 to 2mg IV/IM every 2-3 minutes</p> <p><u>Total dose- 10 mg</u></p>	<p>Onset:  IV: 1-2 minutes  IM: 2-4 minutes</p> <p>Peak: No data</p> <p>Duration:  IV: &lt;45 minutes  IM: 60 minutes</p> <p>The duration of opioid may be longer than the duration of the antagonist</p>	<p>Nausea/Vomiting  Diaphoresis  Seizures  Severe pain  Excitement  Hypertension  Tachycardia  Ventricular arrhythmia  Pulmonary edema  Myocardial ischemia</p> <p>Watch for return of respiratory depression</p>	N/A
Flumazeil (Romazicon)	Complete or partial reversal of benzodiazepine sedation	<p>0.3 mg IV followed in one minute by 0.3 mg then 0.5 mg IV q 1 min</p> <p><u>Total dose- 3 mg IV</u></p>	<p>Onset:IV: 1-2 minutes</p> <p>Peak:  IV: 6-10 minutes</p> <p>Duration  IV: 60 minutes</p>	May precipitate seizures	N/A

**SHADY GROVE MEDICAL CENTER MODERATE SEDATION  
PEDIATRIC DOSING SCHEDULE**

Generic Name	Use	Dosing Guidelines	Onset and Duration of Action	Adverse Effects	Reversals	Comments
Dexmedtomidine	Sedation	<p>Moderate Sedation</p> <p>IV: Bolus 0.5-1.5 mcg/kg (over 10min) infusion 1-2 mcg/kg/hr</p> <p>IN: 3-4 mcg/kg per dose Mac Cum Dose 100mcg</p> <p>IM: 2-3 mcg/kg/dose</p> <p>Minimal Sedation IN: 1-2 mcg/kg per dose Max Cum Dose 100 mcg</p>	<p>IV:</p> <p>Onset: 5 to 10 minutes</p> <p>Duration:60-120 min</p> <p>IN: Onset: 15-25 min</p> <p>Duration: 85 minutes</p>	Bradycardia Hypotension	None	<p>Contraindications :</p> <p>Age &lt;6 months Heart block Severe renal/hepatic impairment Use of beta blockers</p>

**BENZODIAZEPINES**

Generic Name	Use	Dosing Guidelines	Onset and Duration of Action	Adverse Effects	Reversals	Comments
Midazolam (Versed)  Versed syrup (10 mg/2 cc)	Sedation Amnesia Anxiolytic	<p>Moderate Sedation</p> <p>IV: 0.05-0.1 mg/kg/dose IV</p> <p>Max Cum IV Dose: 0.2 mg/kg</p> <p>PO 0.5-0.75 mg/kg</p> <p>Max Cum dose: 15 mg PO</p> <p>IM 0.1-0.2 mg/kg/dose</p> <p>IN: 0.5 mg/kg/dose Max Cum Dose 10mg</p> <p>Minimal Sedation PO: 0.25-0.4 mg/kg</p>	<p>Onset :</p> <p>IV: 1-5 min IN: 10-15 min PO: 15 min</p> <p>Duration: 20-60 min</p> <p>PO: up to 2 hours</p>	<p>Resp Depression</p> <p>Paradoxical agitation Hypotension (esp w opioid) Arrhythmias Nausea/ vomiting Headache Hallucinations Hiccoughs</p>	Flumazenil:	Reduce dose by 25-50% when giving with narcotic (e.g Fentanyl) and wait 10 min for desired effect

		Max Cum Dose 20 mg  IN: 0.2-0.4 mg/kg/dose Max Cum Dose 10mg (5mg/nare)				
Lorazepam (Ativan)	Sedation Amnesia	Moderate Sedation  IV: 0.05-0.1 mg/kg Max Cum Dose: 4 mg IV  IM:0.1-0.2 mg/kg one time dose  PO: 0.05-0.2 mg/kg	Onset: IV: 1-5 min Duration: 4-6 hours	See Midazolam	Flumazenil	Midazolam a better choice unless desire a long duration of action

**MEDICAL STAFF POLICY**  
**SEDATION/ ANALGESIA**

**Policy #005**  
**Page 19 of 23**

**SHADY GROVE MEDICAL CENTER MODERATE SEDATION  
PEDIATRIC DOSING SCHEDULE (con't)**

**OPIOIDS**

- Avoid repeat IM dosing
- If titrating to response, IV route is recommended

<b>Generic Name (Trade Name)</b>	<b>Use</b>	<b>Dosing Guidelines</b>	<b>Onset and Duration of Action</b>	<b>Adverse Effects</b>	<b>Reversals</b>	<b>Comments</b>
Fentanyl (Sublimaze)	Sedation Analgesia	Moderate Sedation  IV: 0.7-1.0 mcg/kg/dose May repeat in 2-3 min Total dose:5 mcg/kg IN: 1.5-2mcg/kg (50mcg/nare)  Minimal Sedation: (Analgesia) 1-1.4 mg/kg Max 50mcg	Onset: 1 min IV Duration 30-60 min IV	Respiratory depression Hypotension Bradycardia Chest wall rigidity w/ rapid admin. Facial pruritis Nasal irritation	Naloxone	Do NOT exceed rate of admin of 1 mcg/kg/min IV  Reduce max dose by 50% if used with benzodiazepines
Morphine sulfate	Sedation Analgesia	0.05-0.15 mg/kg/dose IV 0.1 mg/kg IM or SC  Total dose: 0.2 mg/kg	Onset: 5 min IV 15-30 min IM or SC  Duration: 1-5 hr	Resp depression Hypotension Bradycardia Nausea Pruritis Urinary retention Epileptogenic	Naloxone	Reduce dose by 50% if given with Benzodiazepine

**SHADY GROVE MEDICAL CENTER MODERATE SEDATION  
PEDIATRIC DOSING SCHEDULE (con't)**

**REVERSAL AGENTS**

<b>Generic name (Trade name)</b>	<b>Use</b>	<b>Dosing Guidelines</b>	<b>Onset and Duration of Action</b>	<b>Adverse Effects</b>	<b>Comments</b>
Naloxone (Narcan)	Reverses opioid induced analgesia & sedation  May reverse chest wall rigidity	Apnea or arrest: 0.01-0.1 mg/kg; redose at 2 min intervals to effect  Resp depression: 0.001 mg/kg/dose  OR Narcan drip: 1-30 ug/kg/hour	IV: 1-2 min IM/ETT: 2-5 min  Duration: < 45 min  <i>The duration of the opioid may be longer than the duration of the antagonist</i>	Severe pain Excitement Hypertension Tachycardia Ventricular arrhythmia Pulmonary edema Myocardial Ischemia	<i>Watch for return of respiratory depression</i>
Flumazenil (Romazicon)	Complete or partial reversal of benzodiazepine Sedation	0.01 mg/kg IV q 1 min Total dose: 0.2 mg	Onset 1-3 min IV  Duration: 45-60 min	May precipitate seizures	<i>Use with extreme caution</i>  <i>Watch for return of sedation/ respiratory depression</i>

### **Guidelines for Determining Need for Anesthesia Consultation**

This document is intended to serve as a guide for physicians when deciding on the need for consultation with an anesthesiologist prior to sedation. These recommendations have been developed by consensus opinion of the Department of Anesthesia and are based on the best available medical evidence. The incidence of adverse outcomes related to sedation is increased in the presence of multiple risk factors and is especially high when risk factors from multiple categories (medical, behavioral, procedure- related) are present. In general, consultation is usually only necessary for the highest risk patients.

#### **Patient related medical risk factors:**

- ASA status  $\geq 3$  (especially due to end-stage renal/liver disease, severe pulmonary disease, obstructive sleep apnea, morbid obesity, ejection fraction  $< 25\%$ )
- History of drug reaction to sedative agent
- History of drug or alcohol abuse/dependence
- Orthopnea
- Pregnancy
- Difficult airway by history or exam (Mallampati score  $\geq 3$ , rigid c-spine, mouth opening  $< 3\text{cm}$ , prominent incisors)

#### **Patient behavioral risk factors:**

- Dementia
- Highly anxious
- Uncooperative/hostile
- Altered mental status/delirium
- Significant mental illness (schizophrenia, bipolar)
- Autism

#### **Procedure related risk factors:**

- Procedures with the potential for causing significant pain
- Prolonged procedures ( $> 2$  hours)
- Procedures requiring unusual positioning (prone)

Anesthesia consultation should be considered whenever one of the above risk factors is present. Consultation is recommended whenever risk factors from more than one category are present. For emergency procedures the physician should weigh the risk of proceeding immediately against the risk of delay associated with obtaining consultation.

Appendix 8.

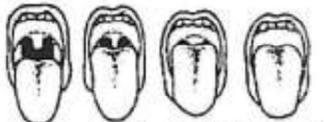
This supplemental form must be completed by the procedural physician in addition to the History and Physical examination prior to implementation of sedation.

**Pre-sedation Assessment:**

- Morbid obesity\*
- History adverse reaction to sedation\*
- History of alcohol or narcotic dependence\*
- End stage renal/liver disease\*
- Other: \_\_\_\_\_
- Changes present since H&P. Explain: \_\_\_\_\_
- Orthopnea\*
- Pregnancy\*
- Obstructive sleep apnea\*
- Severe pulmonary disease (O2 sat < 92% on room air)\*

**Airway Assessment:**

1. Circle patient's Mallampati classification:



Class 1   Class 2   Class 3\*   Class 4\*

2. Check appropriate box(es):

- Neck:  limited range of motion\*
- circumference > 43cm (17 inches)\*
- short neck
- Mouth:  Prominent incisors\*    Loose teeth\*
- Broken teeth\*    Mouth opening <3cm\*
- Dentures    Capped teeth

**ASA Classification:**

- Status I   Normal healthy patient
- Status II   Mild systemic disease
- Status III\*   Severe organic disease with functional impairment
- Status IV\*   Severe systemic disease that is a constant threat to life
- Status V\*   Moribund patient, not expected to survive

**NPO Status:**   Last solid food intake: \_\_\_\_\_   Last clear liquid intake: \_\_\_\_\_

*\*Associated with increased risk of an adverse sedation related event. Anesthesia consult should be considered when one or more of the above risk factors are present. Consult is recommended when risk factors exist and patient is uncooperative or undergoing high risk procedure.*

In light of the above evaluation, I believe this patient is an acceptable candidate for sedation/analgesia and have discussed the sedation/anesthesia alternatives, indications for, and risks of sedation with the patient/parent/guardian, who understands and consents.    Yes    No

Comments: \_\_\_\_\_

Signature of MD \_\_\_\_\_ ID # \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

**\*IMMEDIATE PREOPERATIVE ASSESSMENT\***

I have re-evaluated the patient immediately prior to the administration of sedation/analgesia medication and: (check appropriate box)

- The status is unchanged and I consider the patient an acceptable candidate for the procedure/sedation.
- Status has changed but still consider the patient to be an appropriate candidate for the procedure/sedation.

Comment: \_\_\_\_\_

- Due to a change in status the procedure will be canceled at the current time.

Comment: \_\_\_\_\_

Signature of MD \_\_\_\_\_ ID # \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_



**PRE-SEDATION/  
ANALGESIA  
ASSESSMENT FORM**

6600-188 (11/10)

Patient Identification

