

Moderate Sedation Privilege Criteria

Medical Staff Policies & Procedures	
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General Description

Purpose: To assure a consistent level of care related to minimal to moderate sedation/analgesia throughout the institution of JSUMC.

Scope: Jersey Shore University Medical Center

Policy: The Chair of the Department of Anesthesia directs this program. The program's Policy and Procedure is attached.

I. CREDENTIALING CRITERIA FOR PRIVILEGES TO ADMINISTER MINIMAL TO MODERATE SEDATION/ANALGESIA BY THE NON-ANESTHESIOLOGIST

II. THE POLICY FOR PRIVILEGES TO ADMINISTER MINIMAL TO MODERATE SEDATION/ANALGESIA BY THE NON-ANESTHESIOLOGIST AND THE CARE OF PATIENTS RECEIVING MINIMAL TO MODERATE SEDATION/ANALGESIA BY THE NON-ANESTHESIOLOGIST

I. Credentialing Criteria for Privileges to Administer Minimal to Moderate Sedation/Analgesia by the Non-Anesthesiologist

PURPOSE: Anesthesiologists possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason the Department of Anesthesiology at JSUMC has been called upon for the development of the institutional policies and procedures for sedation and analgesia for diagnostic and therapeutic procedures. The purpose of these policies are to allow the non-anesthesiologist clinician under the direction of the Department of Anesthesiology to provide their patients with the benefits of minimal to moderate sedation/analgesia while minimizing the associated risks.²

CREDENTIAL CRITERIA: In order for a physician to be granted privileges for the administration of sedation/analgesia, the following criteria must be met:

- Completion of the on line Moderate Sedation module and taking and passing the post test (required at initial credentialing and every two years). A minimum passing score of 80% is required; The training module can be found at <http://meridianhealth.sedationlearning.com/login.php>;
- Maintenance of current ACLS certification.

If at any time the certification or test expires, the practitioner's clinical privileges for moderate sedation shall be immediately "put on hold" and may be immediately reinstated upon presentation of required document(s).

- Members of the Emergency Department who are Board Certified in Emergency Medicine are exempt from maintaining current ACLS and completion of the module post test; and
- Members of the Department of Anesthesiology are exempt from completion of the module and post test but are required to maintain current ACLS certification
- Members of the Department of Anesthesiology, Section of Pain Management must complete the module and post test and maintain current ACLS certification.
- Members of the Department of Pediatrics may maintain PALS or NRP (for Neonatologists) certification in lieu of ACLS certification and are required to complete the module and take and pass the post test.

II. The Policy for Privileges to Administer Minimal to Moderate Sedation/Analgesia by the Non-Anesthesiologist and The Care of Patient's Receiving Minimal to Moderate Sedation/Analgesia by the Non-Anesthesiologist

DEFINITION: "Sedation and analgesia" comprise a continuum of states ranging from minimal sedation anxiolysis through general anesthesia. The American Society of Anesthesiologists (ASA) has defined four levels of sedation/ analgesia and anesthesia. They are as follows:

Minimal sedation (anxiolysis) is a drug induced state during which patients respond to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Light sedation occurs following the administration of medication for reduction of anxiety or pain and allows the patient to maintain normal respiration, eye movement and protective reflexes. Minimal sedation may be provided by the non-anesthesiologist physician approved to give minimal to moderate sedation/analgesia.

Moderate sedation/analgesia ("conscious sedation") is a drug induced depression of

consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.

Cardiovascular function is usually maintained. Moderate sedation may be provided by the non-anesthesiologist physician approved to give minimal to moderate sedation/analgesia.

Deep sedation/analgesia 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 maybe impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation maybe inadequate. Cardiovascular function is usually maintained. Deep sedation is restricted to use by an anesthesia provider.

Anesthesia consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. It is a drug induced loss of consciousness during which patients are not aroused 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 ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Anesthesia is restricted to use by an anesthesia provider.

The American Society of Anesthesiologists has published practice guidelines for Sedation/Analgesia by non-anesthesiologists. All practitioners applying for such privileges should be familiar with these guidelines.³

The American Academy of Pediatrics has published practice guidelines for monitoring and management of pediatric patients undergoing sedation for procedures.

Physicians providing sedation/analgesia for pediatric patients should be familiar with these guidelines.⁴

This policy will be applied when the non-anesthesiology physician/dentist administering or directing the administration of minimal to moderate sedation/analgesia:

1. Has a clinical appointment in a department other than the Department of Anesthesiology.
2. Is administering minimal to moderate sedation/analgesia to a patient undergoing surgery and/or invasive procedure, including, but not limited to, percutaneous aspiration and biopsy, cardiac and vascular catheterization, endoscopy, reconstructions, angioplasty, implantations, and reduction of fractures or dislocation-when the patient is not being ventilated mechanically.
3. Is administering minimal to moderate sedation/analgesia to a pediatric patient during EEG, CAT Scan, MRI or other diagnostic procedures requiring sedation/analgesia. (During MRI, ECG must be used with caution due to risk of

thermal injury).

N.B. Oral and rectal preparations are often used to sedate patients for nonpainful procedures such as EEG and radiologic studies. Drugs administered by these routes may produce a state of conscious or deep sedation and have the potential to cause respiratory depression. Patients who receive sedative medications require monitoring until fully alert regardless of the route of administration. Minimal monitoring must include BP, ECG, pulse oximetry and level of consciousness documented every five minutes.

This policy will not be applied when nitrous oxide 50% or less is used with oxygen to an otherwise healthy ASA I or II patient and verbal communication is maintained throughout the procedure and documented. Pulse oximeter is not required but recommended in this sub set of patients.

A. PURPOSE: The purposes of this document are:

1. To describe the procedure to obtain privileges to administer sedation/analgesia by the non-anesthesiologist at Jersey Shore University Medical Center.
2. To describe guidelines for the evaluation and care of patients receiving sedation/analgesia.
3. To apply this policy uniformly to all adult and pediatric patients receiving sedation/analgesia at Jersey Shore University Medical Center.
4. To provide guidelines for appropriate medications to be used by the non-anesthesiologist. (See attachment: Policy and Procedure for the Clinical Pharmacology of Useful Drugs for Sedation/Analgesia).

B. Physicians who want privileges to administer sedation/analgesia will need the approval of the Chair of Anesthesiology. Request for sedation/analgesia privileges should be submitted to the applicant's Department Chair with a copy to the Chair of Anesthesiology.

C. Privileges to administer sedation/analgesia will be recommended by the Chair of Anesthesiology to the Credentials Committee and the Medical Executive Committee for approval by the Hospital Board of Trustees. Elements to be considered are previous education, training, experience, knowledge of the pharmacology of drugs administered, and ability to manage untoward sequelae of the procedure and agents used-especially vagal reactions, hypotension and apnea.

This can be determined by:

1. The successful completion of on line module and post test, and
2. Practical evaluation of the patient with the documentation of the established ASA level (definition under Part E. of this Policy), patient history, and patient condition evaluated immediately prior to the administration of sedation/analgesia medication.
3. The physician will be observed a minimum of three cases by the **Chair of Anesthesiology** or assigned representative. (See Section I: Credentialing Criteria for Privileges to Administer Sedation/Analgesia).

D. The sedation plan, care and well being of patients receiving sedation /analgesia will be the responsibility of the physician administering the sedation/analgesia who must be continuously present during the procedure.

1. Sufficient number of qualified staff is required to monitor and recover the patient receiving sedation and/or anesthesia.
2. The anticipated needs of the patient are assessed to plan for post-procedure care.
3. Preprocedural education, treatments and services are provided according to the plan of care.

E. Care of the Patients:

Pre-procedure

1. Patients should be determined to be an appropriate candidate for sedation and analgesia by the use of:

a. The ASA physical guidelines and score

ASA 1 = A normally healthy patient.

ASA 2 = A patient with mild systemic disease.

ASA 3 = A patient with severe systemic disease that limits activity but is not incapacitating.

ASA 4 = A patient with severe systemic disease that is a constant threat to life.

ASA 5 = A morbid patient who is not expected to survive with or without the operation.

ASA 6 = A patient is declared brain dead on life support for organ donation.

Patients of ASA Status 4 or greater require mandatory anesthesiology consultation.

b. The modified Mallampati table and score

Class I = All the oropharynx (including tonsils, pillars, soft palate, and the tip of the uvula) are easily visible

Class II = The tonsils' upper pole and uvula are visible

Class III = The base of the uvula and the soft palate are visible

Class IV = Only the hard palate and a part of the soft palate are visible

All patients with airway assessment issues require mandatory anesthesiology consultation.

A Certified Registered Nurse Anesthetist (CRNA) is available for emergency intubation twenty-four (24) hours per day at JSUMC.

Cath Lab Exception: It may be necessary for the invasive cardiologist to treat patients in the Cath Lab who are ASA Status 3 or greater due to their cardiac disease. This exception has been recognized by the Department of Health in the State of New Jersey.

2. Pre-sedation preparation/ documentation for all Patients:

a. Standard fasting orders before elective sedation/analgesia:

Adults- eight (8) hours NPO (up to 8 oz. Of water may be taken up to two (2) hours before the procedure to facilitate administration of medication).

Children-may take water or clear liquids up to two (2) hours before the procedure- then NPO. Infants may take breast milk up to four (4) hours before the procedure. Infant formula may be given to a child up to six (6) hours before a procedure.

b. Pre-procedural fasting for the emergency patient:

The use of sedation must be preceded by an evaluation of food and fluid intake. When protective airway reflexes are lost, gastric contents may be regurgitated into the airway. Therefore, patients with a history of recent oral intake with other known risk factors, such as trauma decreased level of consciousness, extreme obesity, pregnancy, or bowel motility or function, require careful evaluation before administration of sedatives. If possible, such patients may benefit from delaying the procedure and administering appropriate pharmacologic treatment to reduce gastric volume and increase gastric pH. When pre-fasting has not been assured, the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. An emergency patient may require protection of the airway before sedation.

c. Documentation of the patient's History and Physical examination:

With review of systems, current medications and drug allergies prior to sedation/analgesia is required. Some patients with chronic or severe systemic illness, or premature infants less than 48 weeks past conceptual age, or with a history of apnea may not be suitable candidates for sedation/ analgesia. Anesthesiology Department involvement should be considered. Attention should be paid to any anatomic airway abnormality that may be a potential cause of airway obstruction, including tonsillar and adenoidal hypertrophy.

d. Laboratory studies or diagnostic screens in areas indicated by the patient's past medical history and present illness: The Department of Anesthesia at JSUMC requires that all menstruating women should receive a pregnancy test prior to sedation/analgesia. No other routine diagnostic or laboratory tests are required. These requirements must be considered prior to sedation of any patient.

e. An accurate, valid consent for the procedure that includes an explanation of sedation/analgesia, other risks and options.

f. The patient's status will be re-evaluated immediately prior to the procedure.

g. A registered nurse with sedation certification supervises perioperative care.

h. See Administrative Policy: Patient Safety Policy: Surgical and other procedure correct patient and site identification and verification policy.

i. **The following agents and equipment will be immediately available:**

1. Physician or procedural physician trained in airway management is present in the room during the titration administration of all IV sedation medications for procedure.
2. An oxygen source, ambu bag, laryngoscope, endotracheal tubes (sizes 5.0mm, 6.0mm, 7.0, 8.0mm), oral and nasal airways, defibrillator, code cart, emergency resuscitative drugs, including Flumazinal and Narcan or Nalmefene.
3. Endotracheal tube size for children older than 1 year may be estimated by the formula $16 + \text{age (years)}/4$. Tubes 0.5mm smaller and 0.5mm larger than calculated should be available.

Procedure

3. Care during the procedure

- a. Patients must be monitored. The monitoring must be documented on an appropriate record that remains with the patient's chart.
 - Vital signs (blood pressure, pulse, respiration) will be taken at least every five minutes and charted.
 - ECG will be monitored-the rhythm should be noted and charted every five minutes or more frequently as needed.
 - Oxygen saturation and Capnography will be monitored, documented and charted every five minutes or more frequently as needed.
 - Level of consciousness should be monitored and charted every five minutes or more frequently as needed.
- b. Supplemental oxygen should be administered to all patients receiving sedation/analgesia. If not used routinely, supplemental oxygen must be added if oxygen saturation drops to 92% or less.
- c. The route, time and dosage will be recorded on all drugs administered.
- d. If a patient demonstrates persistent oxygen desaturation (SaO₂ less than 90%) despite the use of supplemental oxygen or requires airway support, the case should be terminated unless an anesthesiologist and/or anesthesiologist-supervised nurse anesthetist is available to provide monitored anesthesia care.
- e. There must be IV access or immediate availability of IV access for all procedures done with PO or rectally administered agents, i.e., ECG, CT Scan, MRI, etc.
- f. Patients who exhibit hemodynamic instability, oxygen desaturation or respiratory depression/failure are not appropriate candidates for sedation/analgesia unless monitored anesthesia care (MAC) can be provided or the procedure is done in the ICU or CCU. Arrangements or MAC should

be made as early as possible through the Operating Room Booking Office.

g. The physician/dentist must administer the first dose of sedation/analgesia when intravenous agents are used (Cath Lab, Emergency Department, Interventional Radiology, and NICU exception noted below), and be present for the titration administration by a conscious sedation certified registered nurse.

N.B. Cath Lab and Interventional Radiology Exception: In the Cath Lab and Interventional Radiology due to the sterile presentation of the operating physician, the initial dose may be administered by a certified conscious sedation registered nurse.

N.B. Emergency Department: In the ED due to preparation for manipulation of joints and/or potential for immediate airway management by the Emergency Department physician, the initial dose may be administered by a certified conscious sedation registered nurse.

N.B. NICU Exception: In the NICU the initial dose may be administered by a certified moderate sedation registered nurse under the direction of the physician. The initial dose will be placed on an IV pump and infused over a minimum of 10 minutes. If the infant must leave the unit for a procedure after receiving sedation, a physician must accompany the RN and the patient to the testing area and remain in attendance throughout the procedure.

h. When non-IV agents are used for diagnostic procedures the physician/dentist prescribing the sedative dose of medication must be certified in sedation/analgesia at Jersey Shore University Medical Center. The medication must be administered by an appropriate certified practitioner (nurse and/or resident physician) who will remain in constant attendance with the patient until discharge to PACU environment. A competent Registered Nurse must remain present with the patient until appropriate discharge criteria are met.

i. **Anxiolysis/Relaxation Medication Use in Pediatrics.** Anxiolysis or minimal sedation medications such as Chloral Hydrate or other ordered medications given by oral route or by rectal suppository may be administered to the pediatric patient arriving in an ambulatory day stay unit at JSUMC by order of the physician to provide preprocedure relaxation and anxiety reduction in accepted drug dose range. Anxiolysis is utilized to provide relaxation and lessen anxiety and is not given in dosage to provide analgesia. The administered dosage of the ordered medication should be reflective of that goal or referred to the Department of Anesthesia for evaluation. However, these patients require monitoring continuously through out this process per requirements of this policy. 5-6-7-8-9

Anxiolysis/Relaxation Guidelines:

1) The Physician or Pediatrician ordering the procedure or monitoring the patient (EEG, CT, MRI) order the prescribed oral medication to be given for

anxiolysis/relaxation effect on the child.

-No orders are accepted from non-staff physicians.

-All medication orders are by mg/kg formula.

-All medication orders must be in total milligrams per dose (as in 50 mg) not in volume dose (as is 1/2 teaspoonful). This is to prevent medication error caused by different pharmaceutical concentration levels of medication available.

2) The patient must have a completed H&P by the ordering physician and a signed hospital consent by the parent or legal guardian.

3) No IV is required for the purpose of administration of oral medication for anxiolysis/relaxation.

4) Preprocedure fasting is required. Children must be NPO for four hours prior to the administration of medication. Children may take water or clear liquids up to two hours before the procedure.

5) Prior to the procedure baseline vital signs and minimal monitoring must be provided and documented including level of consciousness, heart rate, blood pressure, respiratory rate, oxygen saturation and temperature. Continuous monitoring is required throughout the procedure per policy.

6) Emergency equipment must be available in the unit for use if needed.

7) Medication is given by Physician or Registered Nurse. The child receives direct observation by PALS certified nurse.

8) The Department of Anesthesiology is available 24 hours per day to provide Anesthesiology services. All questions should be referred to Anesthesiology for clarification or intervention.

9) The time and condition of the child at discharge shall be documented including the child's vital signs and level of consciousness reflecting that the child has returned to a state that is safe for discharge and meets the discharge criteria by the Aldretti score.

j. Exception: Analgesia for Urgent Therapeutic Intervention in the Critically Ill

Patient. There are circumstances when the critical care physician may need to sedate a patient beyond "anxiolysis/ minimal "light" sedation to perform an urgently needed therapy. Some examples would be, but not limited to:

- Urgent endotracheal intubation.
- All painful procedures on the intubated and appropriately monitored critically ill patients.
- Pediatric critically ill non-intubated patients in the Pediatric Intensive Care Unit.
- Emergent therapeutic interventions performed in the Emergency Department by appropriately credentialed physicians.

k. Exception: Ketamine Use by Non-Anesthesiologists

Purpose: To present possible exceptions to the use of Ketamine by the non-anesthesiologist critical physician and the emergency department physician.

It is the belief of the Department of Anesthesiology that as a general rule Ketamine, a potent psychotropic anesthetic, should be reserved for use by members of the Department of Anesthesiology only. There are multitudes of other acceptable

sedating medications currently available to achieve the same effect with proper dosing.

However, if the non-anesthesiologist critical care specialist needs to perform an urgent therapeutic intervention such as, but not limited to:

Urgent endotracheal intubation or therapies on intubated and appropriately monitored critically ill patients, a deeper level of consciousness may be required.

In the Pediatric Emergency Department, the Pediatric Emergency Physician, and in the Pediatric ICU, the Pediatric Intensivist after appropriate credentialing may choose to use Ketamine in certain circumstances, for therapeutic and/or diagnostic interventions on the non-intubated critically ill pediatric patient.

Whenever non-anesthesiologists provide this level of sedation in such previously described conditions, all doses must be given and monitored by the MD personally.

The Department of Anesthesiology is available 24 hours per day to provide anesthesiology services. It is required in this institution that a member of the Department of Anesthesiology be consulted for all procedures requiring a deeper level of consciousness than allowed by the Hospital-wide sedation and analgesia policy except in the aforementioned circumstances.

I. Exception: Administration of Propofol to the Pediatric Patient in Pediatric ICU by the Pediatric Intensivist. This may not be in violation of this policy providing the following criteria are met:

- Propofol should only be administered by the pediatric intensivist trained in the administration of general anesthesia.
- Propofol should only be administered by the pediatric intensivist who is not simultaneously involved in the surgical or diagnostic procedures
- This justification to the pediatric intensivist is in concordance with specific language in the propofol package insert
- Failure to follow these recommendations could put patients at increased risk of significant injury and death. AANA-ASA Joint Statement (April 14, 2004) Propofol Administration

- Pain Management Exception for the Administration of Propofol by Registered Nurse with current Moderate Sedation Certification.
 - All Registered Nurses (RN) administering I.V. Conscious Sedation will be I.V. Conscious Sedation Certified as per this policy.
 - All Registered Nurses caring for patient's undergoing procedures for pain management and working directly with an anesthesiologist/pain medicine physician will be permitted to use Propofol (Diprivan) under the direct supervision of the physician.

Post-Procedure

5. Post-Procedure Care

- a. The patient's status is assessed immediately after the procedure and/or anesthesia.
- b. The patient should go to an appropriate post-anesthesia care area, transported by a physician or a registered nurse. An RN supervises perioperative care.
- c. Cases where reversal agents Romazicon and/or Narcon are used require at least two (2) hour of monitoring post procedure.
- d. Monitoring must be continued on all patients, adults and children, until the patient is fully alert, and documentation of the patient's physiological status, mental status, airway patency, pain level and level of consciousness is included in the medical record. Prior to discharge, the patient should be able to talk and sit unassisted (if developmentally appropriate). Very young or disabled children or adults should return to pre-sedation level of alertness and functioning prior to discharge.
- e. The patient will be discharged from the post-anesthesia recovery area by a physician or by a protocol with explicit criteria, approved by the Medical Executive Committee.
- f. Outpatients should be accompanied home by a responsible adult. Outpatients are informed not to drive or make important decisions until the next day.

6. Quality Improvement and Outcomes Management

The Chair of the Department of Anesthesiology will be responsible for the monitoring and evaluation of the appropriateness of clinical care provided in that Department consistent with current knowledge of anesthesia practice.

Adverse outcomes associated with the use of sedation/analgesia should be reviewed as a part of the systemic, ongoing Quality Improvement program in each Department where sedation/Analgesia is administered.

Elements of the Quality Improvement Program will include, but not be limited to, completeness of records, documentation of monitoring and drugs administered, review of patients with Post-Anesthesia Care Unit stay of more than two hours, respiratory arrest, cardiovascular instability and other untoward outcomes, as well as the use of reversal agents such as Romazicon and Narcan.

Deaths and/or unexpected intra-operative or post-operative events or outcomes related to sedation/analgesia in any anesthetizing location must be immediately reported to the Chair of the Department of Anesthesiology, who will notify the Division of Health Facilities Evaluation, as required under N.J.A.C.8:43G6.10(c).

approved by: Vincent Cirella, MD Chair of the Department of Anesthesia

