Sedation (Minimal, Moderate, and Deep)

APPLIES TO: All physicians, dentists, podiatrists, and advanced practice professionals as defined in the Medical Staff Rules and Regulations, and Registered Nurses competent in sedation.

PURPOSE: To ensure that all patients receive equally safe and effective levels of sedation care which is consistent throughout Mercy Health Muskegon (MHM), and is provided by qualified, competent practitioners. Sedation is a continuum and this policy is designed to ensure that if patients slip into a deeper level of sedation it will be recognized and monitored by medical personnel with an adequate level of training. This policy is written in accordance with regulatory requirements outlined by the Centers for Medicare and Medicaid Services and based on guidelines published by the American Society of Anesthesiologists and the American College of Emergency Physicians.

INCLUSIONS:

1. Any diagnostic or therapeutic procedural sedation when the intent is moderate sedation or deep sedation.

2. Any parenteral procedural sedation when midazolam is administered alone or when two or more agents are administered. For the purpose of this policy, this will be considered at least moderate sedation.

EXCLUSIONS:

1. Comfort care orders for patients designated “Do Not Resuscitate”.

2. Analgesics used for the purpose of pain control.

3. Preoperative medications given prior to transport to the operating room.

4. Patients who are not undergoing a diagnostic or therapeutic procedure (i.e., post-operative analgesia, sedation for treatment of delirium, ongoing ventilation therapy, pain control therapy, or treatment for mild anxiety).
5. Patients receiving minimal sedation for purposes of anxiolysis such as small oral doses of diazepam or lorazepam.

6. Perioperative sedation administered by those with core privileges in Anesthesiology.

7. Intubated patients in Critical Care Units

A. **DEFINITIONS**

1. **Sedation for Procedures (Procedural Sedation):**
   Sedation administered for diagnostic, therapeutic, or invasive procedures, where the intended duration of sedation is limited to the duration of the procedure and/or the immediate post procedure recovery period.

2. **Minimal Sedation:**
   A drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

3. **Moderate Sedation:**
   A minimally depressed level of consciousness in which the patient retains the ability to maintain a patent airway independently and continuously, as evidenced by appropriate response to verbal or physical stimulation. Cardiovascular function is usually unaffected. (For example: Endoscopic procedures; wound vacuum dressing change).

   Signs of Moderate Sedation:
   - Mood altered
   - Patient cooperative
   - Protective reflexes intact

4. **Deep Sedation:**
   A controlled state of depressed consciousness from which the patient is not easily aroused but responds 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. (For example: Cardioversion).

   **NOTE:** Planned deep procedural sedation is provided only by those with core privileges in Anesthesiology and Emergency Medicine (while in the Emergency Department).
Signs of Deep Sedation:
- Patient unable to cooperate purposefully
- Partial or complete loss of protective reflexes
- Vital Signs labile
- Pain eliminated centrally
- Amnesia frequently present

**NOTE**: The following procedures will not ordinarily require sedation:
- Placement of central lines or temporary dialysis catheters
- Arterial line placements
- Suturing of minor lacerations
- Minor debridement of devitalized tissue
- Placing a limited number of superficial sutures
- Other procedures of a minor nature, similar to the ones listed above

5. Evaluation Tools

**Pre-Sedation**
This scoring is recommended for pre-sedation evaluations:

ASA 1: A normal, healthy adult
ASA 2: A patient with mild systemic disease (mild diabetes mellitus, controlled hypertension, anemia, chronic bronchitis, morbid obesity).
ASA 3: A patient with severe systemic disease that limits activity (angina pectoris, obstructive pulmonary disease, prior myocardial infarction).
ASA 4: A patient with an incapacitating disease that is a constant threat to life (congestive heart failure, renal failure).
ASA 5: A moribund patient not expected to survive longer than twenty-four (24) hours (ruptured aortic aneurysm, head trauma with increased intracranial pressure).
- For emergency operations, add the letter E after classification.

**Monitoring during Sedation**
This scoring is recommended for evaluation during the procedure:

0 = agitated
1 = awake
2 = asleep eyes open spontaneously to surroundings
3 = asleep eyes open to name
4 = asleep eyes open to physical stimulation
5 = asleep reacts to physical stimuli to arouse
6 = unconscious and unarousable
Recovery
This scoring is recommended for evaluation post-procedure:

**ALDRETE SCORE:**

*Activity*:
- Move four (4) extremities = 2
- Move two (2) extremities = 1
- Move zero (0) extremities = 0

*Respiration*:
- Deep breath and cough = 2
- Dyspnea or limited = 1
- Apnea = 0

*Circulation*:
- B/P less than 20% change from pre-op value = 2
- B/P within 20–50% change from pre-op value = 1
- B/P greater than 50% change of pre-op value = 0

*Consciousness*:
- Fully awake = 2
- Arousable = 1
- Non-responsive = 0

*Color*:
- Pink, dry, or normal = 2
- Pale, dusky, blotchy, flushed = 1
- Cyanotic = 0

*Discharge criteria:* Total Aldrete score = 8 – 10

*Chronically debilitated, senile, or paralyzed patients may never achieve discharge criteria scores. In such cases, individual discharge criteria should be based on the patient’s preoperative baseline assessment.

**Great differences in diastolic BP should be noted.

B. POLICY STATEMENTS

1. Physicians providing/ordering sedation must be granted privileges through the Medical Staff credentialing process. The policy, attached guidelines, and educational packets will be provided to physicians when applying for sedation privileges.

2. Areas in addition to the operating room where moderate or deep sedation may be administered include: Endoscopy, Emergency Department, Cardiac Catheterization Laboratory, Radiology including MRI at all campuses, Special Procedures, Vascular Services, Critical Care and the Johnson Family Cancer Center.

*NOTE:* Nurse administered moderate sedation, to non-intubated patients, in the MRI department is limited to normal hours of operation for the sedating staff RNs.
3. Recommended NPO status is no solids or full liquids for at least 6 hours and no clear liquids for at least two hours. Emergency procedures need to be considered on a case-by-case basis to determine appropriate level of sedation to reduce the risk of aspiration.  
   **NOTE:** Routine oral medications should be given at least two (2) hours pre-sedation. If clinically indicated, oral medications given within two (2) hours of moderate or deep sedation, with a small sip of water, do not violate the NPO recommendations above.

4. The use of anesthetic induction agents by non-anesthesiologists performing emergent endotracheal intubation is permitted.

5. The use of propofol, ketamine, and etomidate for procedural sedation is limited to Anesthesiology and Emergency Medicine (while in the Emergency Department).  
   **NOTE:** Adherence to recommended NPO status guidelines for the use of propofol and etomidate for all non-emergent procedural sedation cases is required. In emergent situations the benefit of utilizing these agents in patients who do not meet the NPO status guidelines must outweigh the risks associated with the use of these agents, and this risk/benefit decision shall be documented by the physician.

6. The goal of dosing sedative medications is to achieve a predetermined level of sedation; however, patients may progress from minimal to moderate to deep sedation depending on their underlying medical status, the medications and doses used, and the route of administration. Continued monitoring to recognize this change and appropriate responses to support the patient, the use of appropriate antagonist medications and the addition of staff are all essential for patient safety.

7. A competent RN will be designated the responsibility for all monitoring and documentation of events during moderate sedation cases. For intended deep sedation, a physician with core privileges in Anesthesiology or Emergency Medicine (while in the Emergency Department) will administer the sedation, monitor the patient, and have no other role during the course of the procedure. The physician administering deep sedation must be different from the individual performing the diagnostic or therapeutic procedure. Each department will be responsible for maintenance of staff competence for sedation according to this policy.

8. Patients who have sedation shall have a responsible adult to provide transportation following the procedure. Arrangements for the patient to be supervised by a responsible adult following discharge shall be known to staff, prior to the initiation of the procedure.

9. Each department providing sedation must have oxygen, suction, and age appropriate equipment available to monitor the patient, provide airway assistance including intubation, and/or treat cardiac arrest (an Emergency cart with ACLS/PALS supplies).
10. The physician directing the sedation/care of the patient is responsible for discharge of the patient from the recovery process. The patient is discharged either by a qualified licensed independent practitioner or by use of Medical Staff approved criteria. (H-RR-7).

11. For all cases of moderate or deep sedation the sedating physician must be present in the department and available when sedation is initiated.

12. Patient’s comfort with sedation depends on their understanding of their options and risk. Education is part of the full explanation of sedation options and only when patients have a full understanding can they reach a level of comfort that enables them to provide informed consent. Therefore, in non-emergent situations, the patient shall receive a clear explanation of his/her health status, diagnosis, prognosis and proposed invasive procedures or of proposed noninvasive procedures that carry a material risk of adverse outcome. The patient shall be informed of the possible benefits of the care, treatment, and services, possibilities of any material risks of side effects of the care, treatment, and services, and alternative forms of care, treatment, and services including the possible results of not receiving care, treatment, and services, to include refusal of medical or surgical interventions. The patient will be allowed to participate in the development of the plan of care, and care after discharge from the hospital.

13. For non-emergent procedures, pregnancy status for all female patients of childbearing potential shall be assessed by blood or urine testing within 48 hours prior to sedation administration, unless:
   - Known history of hysterectomy
   - Know history of tubal ligations
   - At time of menopause, absence of menses for a continuous 12-month period.

14. The physician ordering sedation will determine whether the patient is an appropriate candidate for nurse administered sedation. Each individual patient is reevaluated before the procedure begins. For non-emergent procedures ASA I, II, and III, are considered appropriate candidates. ASA IV and V patients shall require consultation and collaboration by the health care team to determine if they are appropriate candidates for nurse administered sedation. Where the health care team is unable to reach consensus, an anesthesiologist shall be consulted.

15. Quality assurance monitoring will be reviewed by the Sedation Oversight Committee and reported to the Medical Executive Committee.
C. PROCEDURE FOR MODERATE OR DEEP SEDATION

1. **Documentation:**
   - All medications used will be documented including dose, route, time and effect. This includes type and amounts of fluids administered.
   - Heart rate, rhythm, blood pressure, respiratory rate, O2 saturation and level of consciousness (sedation score) at least every 15 minutes during moderate sedation and at least every 5 minutes during deep sedation procedures. During deep sedation, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.
   - Any unexpected responses by the patient including dyspnea, apnea, hypoventilation, O2 saturation more than 5% below baseline, inability to arouse the patient or need to maintain the patients airway mechanically.
   - Highest sedation score will be documented.
   - A continuous, comprehensive nursing assessment will be completed.
   - All orders pertaining to sedation will be entered in the medical record (refer to moderate sedation care set).
   - All documentation will be completed on the sedation flow record, or as designated per unit specific specialty area policies and procedures.

2. **Roles and Responsibilities**

   **Pre-Sedation Assessment**

   **Responsibilities of the RN include:**
   - Knowledge of the goals and objectives of sedation.
   - The assessment shall include, but is not limited to, NPO status, baseline vital signs, actual weight, current medications, allergies, pertinent medical and anesthetic history, pain measurements, mental status, and review of relevant lab studies.
   - Communicate the sedation plan to the patient and document that informed consent has been obtained.
   - Each patient will have an identification band.
   - For Moderate or Deep sedation each patient shall have a secure and patent IV.
   - Equipment - Prior to sedation all monitoring equipment must be present including:
     - O₂ system capable of delivering 100% at 10 L/minute
     - Suction
     - Airway equipment (Emergency intubation equipment, nasal airways, oral airways)
     - Monitors - pulse oximeter, EKG, automated blood pressure
• Resuscitative Equipment - emergency cart (including appropriate reversal agents) and ambu bag.

**Responsibilities of the Physician include:**
- Completion of history and physical.
- Providing for informed consent prior to patient signature.
- Documentation of an Airway assessment, ASA scoring, and performance of an immediate pre-sedation assessment of the patient.  
  **NOTE:** The immediate pre-sedation assessment requires review of the most recent pre-sedation vital signs.
- Documenting the planned sedation level (anesthesia plan of care).
- Review of nursing pre-sedation documentation.
- Completion of all applicable components consistent with MHM’s policy on Universal Protocol.

3. **During Sedation:**

**Responsibilities of the RN include:**
- Patient assessment.
- During moderate sedation, administration of medications per physician’s orders.
- During moderate sedation, uninterrupted observation and monitoring of the patient from time of sedation to discharge including respiratory frequency and pulse oximetry.
- Documentation.
- Provision of appropriate emergency intervention as necessary.

**Responsibilities of the Physician include:**
- Ordering of medication, dosage and route of administration.
- Directing and providing of emergency interventions as necessary.
- During deep sedation, a privileged physician solely tasked to administration of medications and monitoring of patient until recovery from deep sedation levels (different from provider doing procedure).
- If moderate sedation becomes deep sedation and appropriate staff or interventions are not successful in reversing that level, then a qualified anesthesia provider should be contacted to provide assistance.

4. **Post Procedure**

**Responsibilities of the RN include:**
- Monitoring into the recovery phase.
• Frequency: At least every 15 minutes in an appropriate recovery area.
• Duration: Until the patient returns to pre-sedation levels or has achieved an Aldrete score of at least 8, with a minimum score of 1 in each category. Assessment of pain should be documented at this stage.

**Discharge criteria include:**
• Aldrete score of 8 – 10 with a minimum score of 1 in each category.
• Stable vital signs (as defined in the Aldrete scoring system).
• Able to retain oral fluids, or pre-existing means of fluid intake such as N/G or peg tube.
• Under observation of a responsible adult, and have transportation provided by a fully licensed driver.
• Written discharge instructions shall be given to the patient/responsible adult.

**Responsibilities of the Physician include:**
• The physician ordering the sedation is responsible for the care of the patient until discharge criteria are achieved.
• For patients receiving deep sedation, the sedation physician will document a post-sedation note including the following elements:
  ▪ Respiratory function, including respiratory rate, airway patency, and oxygen saturation
  ▪ Cardiovascular function, including pulse rate and blood pressure
  ▪ Mental status
  ▪ Temperature
  ▪ Pain
  ▪ Nausea and vomiting
  ▪ Hydration status.

D. **CREDENTIALING**

**Medical Staff**

1. Physicians performing procedural sedation will practice within the guidelines outlined in this policy.

2. Procedural sedation must be administered under the direct supervision of a sedation privileged physician. Privileging is achieved by fulfilling the requirements established by the Medical Staff.

3. Applicants wishing to be credentialed in moderate sedation must satisfactorily complete the Moderate Sedation pre-test with a score of 80% or better.
a) If a passing score is not achieved, watch video entitled, "Sedation and Analgesia by Non-Anesthesiologists" and read "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists", Anesthesiology 2002;96:1004-17, available in the Medical Staff Office, and complete test with a score of 80% or better.

4. To maintain privileges in moderate sedation, physicians are required to demonstrate competency for a minimum of 4 moderate sedation cases within the last 24 months of ongoing professional practice evaluation, beginning with the next credentialing cycle subsequent to the approval date of this policy. If 4 cases cannot be documented within the 24 month OPPE cycle, then the physician will be required to repeat the Moderate Sedation Pre-test and achieve a score of 80% or better, as if they were applying for initial privileges.

5. Moderate and deep sedation will be considered a core privilege of Anesthesiology and Emergency Medicine. No other physicians will be granted privileges to give deep sedation.

Nursing Staff

ACLS certification, including training in emergency airway management is required. The nursing department provides an education and competency process for RN’s annually.

E. OUTCOMES and PROCESS MEASUREMENT

Each area that provides moderate or deep sedation will provide the following data for analysis by the Sedation Oversight Committee:

- Airway compromise with need for airway rescue (bag-mask ventilation, oral or nasal airway insertion, intubation or anesthesia assistance),
- Episodes of aspiration
- Bradycardia requiring treatment
- Cardiopulmonary arrest
- Death
- Hypotension requiring treatment
- Prolonged hypoxemia (<95% ≠ baseline)
- New neurological deficit
- Prolonged sedation > 2 hours
- Sedation Level higher than intended
- Need to use reversal agents
- Unplanned admissions or any unexpected events.

Evidence of complete documentation and appropriate monitoring will be collected at monthly intervals from each location.
F. GUIDELINES FOR PEDIATRIC SEDATION

The definition for moderate and deep sedation for pediatric patients (under 18 years old, not neonates) is the same as for adult patients. These patients will need to be evaluated for past medical history, ability to cooperate, psychological or developmental disabilities, NPO status and ability to communicate. Informed consent must be obtained from the parent or guardian prior to medication administration. Education about the sedation procedures, options, risks and follow up care needs to be presented to the patient and the adults accompanying the child.

<table>
<thead>
<tr>
<th>NPO Guidelines</th>
<th>&lt; 6 months</th>
<th>&gt; 6 months</th>
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<tr>
<td>Solids and non-clear liquids</td>
<td>6 hours</td>
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<td>Clear liquids</td>
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Monitoring standards are the same as adults however equipment needs to be age appropriate including resuscitative equipment. Correct dosing based on weight is extremely important. Discharge criteria are the same as adult and accompanying adults should be aware of the duration of sedation and any untoward side effects that may occur.

Knowledge of effective non-pharmacological pain relief techniques for children are important adjuncts to the safe delivery of sedation. Educational material will be available to those areas that have pediatric patients.

G. MODERATE SEDATION MEDICATION DOSING GUIDELINES:

- Drugs should be given incrementally with a specified time interval to allow titration of the drug effect.
- Sedation scores are required to document the depth of the sedation achieved and guide the required level of monitoring (light vs. deep).
- Specific updated guidelines can be referenced via Up to Date which can be accessed through the Library-Up to Date icon on the computer workstation.

H. DRUGS APPROVED FOR MODERATE OR DEEP SEDATION:

- Diazepam (Valium)
- Midazolam (Versed)
- Morphine
- Pentobarbital (Nembutal)
- Meperidine (Demerol)
- Fentanyl (Sublimaze)
- Etomidate: Only by Anesthesia and Emergency physicians when used for moderate or deep sedation.
- Propofol (Diprivan): Only by Anesthesia and Emergency physicians when used for moderate or deep sedation. **NOTE:** Nurse administration of Propofol (Diprivan) is limited to the following areas: Critical Care Unit, Emergency Department, Imaging Services, Cardiac Catheterization Lab and Special Procedures, and is limited to adult, intubated and mechanically ventilated patients.
Ketamine: Only by Anesthesia and Emergency physicians when used for moderate or deep sedation.

This medication list may be modified as required from time to time due to drug availability. This will be done in conjunction and communication with the Department of Pharmacy.

I. MODERATE SEDATION MEDICATIONS, NURSING CONSIDERATIONS AT MERCY HEALTH

**Flumazenil (Romazicon):** The patient will be monitored an additional 60 minutes if they have received Romazicon.

**Naloxone (Narcan):** The patient will be monitored an additional 60 minutes if they have received Narcan.

**Propofol (Diprivan):** Nurse administration of Propofol (Diprivan) is limited to the following areas: Critical Care Unit, Emergency Department, Imaging Services, Cardiac Catheterization Lab and Special Procedures, and is limited to adult, intubated and mechanically ventilated patients.

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