I. PURPOSE
To outline requirements for the administration of moderate and deep sedation and analgesia for diagnostic and therapeutic procedures. Sedative/analgesic medications are commonly needed and used in the performance of diagnostic and therapeutic procedures, which can be anxiety producing, uncomfortable, painful, or pose an increased risk for injury with movement without such medication.

II. SCOPE
This policy applies to physicians and dentists on the IU Health North Hospital Medical Staff and IU Health North Hospital employed or contracted nursing staff and allied health practitioners (NP, PA-C, CNS) who are involved in the administration of moderate or deep sedation and analgesia in IU Health North Hospital facilities. Medications given for pain, anxiety, or sleep that are not part of a diagnostic or therapeutic procedure are not considered moderate or deep sedation. This policy does not apply to
- Monitored Anesthesia Care, which is under separate Anesthesia standards;
- Medication(s) given for pain, anxiolysis or sleep unrelated to a diagnostic or therapeutic procedure;
- Patients who are intubated and mechanically ventilated or who are being sedated for the purpose of securing an airway.

III. EXCEPTIONS
Anesthesiologists, emergency physicians, oral surgeons, neonatologists, and physicians who have completed either a critical care residency or subspecialty training in pulmonary, surgical critical care, or critical care medicine are considered qualified to administer moderate or deep sedation and analgesia by virtue of their training and experience. They are therefore exempt from the requirements listed in Section IV B 1 – 2 of this document. No healthcare professional is exempt from the procedural requirements of this policy.

IV. DEFINITIONS
A. CONTINUUM OF SEDATION:

   Minimal Sedation
A drug induced state during which the patient responds normally to verbal commands. Cognitive function and coordination may be impaired. Ventilatory and cardiovascular functions are unaffected.

**Moderate Sedation and Analgesia**
A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. A patent airway is maintained without help. Spontaneous ventilation is adequate, and cardiovascular function is usually maintained. Moderate sedation enhances the patient’s cooperation and elevates the pain threshold. Loss of consciousness should not occur. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely.

**Deep Sedation and Analgesia**
A drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully to repeated or painful stimulation. It may be accompanied by a partial or complete loss of protective reflexes and includes the inability to maintain a patent airway independently; therefore patients may require assistance maintaining a patent airway. Spontaneous ventilation may be inadequate, and cardiovascular function is usually maintained.

**Anesthesia**
Patients are not arousalable, even by painful stimulation. Patients often require assistance in maintaining a patent airway. Positive pressure ventilation may be required due to respiratory depression or neuromuscular blockade. Cardiovascular function may be impaired.

**B. Immediately Prior**
Patient is on the procedure table, in the moments before sedation is to be administered.

**C. Immediate Proximity**
Present within the department or unit setting in which the sedation and analgesia is being administered. The physician or dentist may not be engaged in activities that could prevent him/her from immediately intervening and conducting hands-on interventions if the patient’s condition requires.

**D. Direct Proximity**
Present within the direct physical presences of the patient in which sedation and analgesia is being administered. The physician or dentist may not be engaged in activities that could prevent the practitioner from...
immediately intervening and conducting hands-on interventions if needed.

E. **Qualified Physician or Dentist:**
A Member of the IU Health North Medical staff who has the IU Health North privileges and experience necessary for supervision, direction, or administration of moderate and/or deep sedation and analgesia. Those individuals intending to induce moderate sedation and analgesia should be able to manage a compromised airway and inadequate oxygenation and ventilation. Those intending to induce deep sedation and analgesia should be able to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation. Therefore, current clinical qualifications are defined as follows:

1. **For Moderate Sedation and Analgesia:**
   a. Current American Heart Association (AHA) BLS certification or the hospital equivalent for adult or pediatric basic life support.
   b. Biennial review of sedation educational information and successful completion of a written sedation exam. (Score of 80% or higher.)
   c. Biennial moderate sedation case log that includes twenty five (25) cases from the preceding two years and/or verification of appropriate moderate sedation training by the appropriate Section Chief of the IU Health North Hospital Medical Staff.

2. **For Deep Sedation and Analgesia:**
   a. For current members of the IU Health North Hospital Medical Staff who have had existing privileges to perform deep sedation and analgesia for at least one appointment or reappointment cycle:
      - Current American Heart Association (AHA) ACLS, ATLS, PALS, NALS and/or NRP certification.
      - Every two years or at time of reappointment review of sedation educational information and successful completion of a written IU Health sedation exam.
      - A deep sedation case log that includes a minimum of twenty five (25) cases from the preceding two years and/or verification of appropriate deep sedation training by the appropriate Section Chief of the IU Health North Hospital Medical Staff.
   b. For those applying for membership to the IU Health North Hospital Medical Staff and those who are adding privileges for deep sedation and analgesia:
• Supervised administration of deep sedation for at least 25 patients and/or verification of appropriate deep sedation training by the appropriate Section Chief of the IU Health North Hospital Medical Staff.

• Candidates with initial requests for deep sedation and analgesia must provide one of the following:
  - Documented evidence of deep sedation training through a completed anesthesia residency or fellowship within the previous two years.
  - Or
    - Documented evidence of successful completion of a separate deep sedation and analgesia educational program.

• Current AHA ACLS, ATLS, PALS, NALS and/or NRP certification.

• Every two years or at time of reappointment review of sedation educational information and successful completion of a written IU Health sedation exam. (Score of 80% or higher.)

  c. Administering and monitoring Deep Sedation should only be performed by individuals appropriately trained and credentialed, and not involved in the conduct of the surgical or diagnostic procedure. Therefore, procedure must be scheduled when another physician with deep sedation privileges or an anesthesiologist can be present to provide anesthesia support.

F. Fellows and Residents:

  a. Fellows and residents may administer (if not participating in the procedure) or direct moderate sedation under the guidance of a physician or dentist who has been granted moderate or deep sedation privileges by IU Health North. A minimum of a BLS certification or hospital equivalent must be maintained. Individual programs are responsible for maintaining current qualifications of their fellows and residents.

  b. Fellows and residents are not permitted to administer deep sedation medications nor monitor patient responses to the medications. An exception applies to fellows who are in a non-ACGME accredited fellowship and therefore are required to become IU Health North Medical Staff members who may apply for deep sedation privileges as outlined in this policy.
G. **Supervised Sedation Professional:**
Registered Nurse or allied health practitioner (NP, PA-C, CNS) practicing under the supervision of a qualified physician or dentist, with current competency in the medication administration, nursing care, and monitoring of patients receiving moderate sedation and analgesia. Current competency for moderate sedation is defined as current AHA ACLS, ATLS, PALS, NALS and/or NRP certification and successful completion of competency training in the administration of moderate sedation and analgesia and the anticipated and/or potential physiological patient response.

V. **POLICY STATEMENTS**
A. This policy provides guidelines for monitoring procedural sedation administered to patients undergoing diagnostic and therapeutic procedures regardless of the care locations and inpatient or outpatient status.

B. This policy does not apply to patients receiving minimal sedation.

C. IV push or bolus of deep sedation medications must be administered by a physician or dentist who has been granted deep sedation privileges by IU Health North.

D. A registered nurse will supervise perioperative nursing care.

E. Individuals administering procedural sedation and analgesia are qualified and have the appropriate credentials to manage patients at whatever level of sedation or anesthesia achieved.

F. Propofol, methohexital, pentobarbital, ketamine, or any other "general anesthetics" are more likely to produce deep sedation. Therefore, physicians and dentists using these medications must meet the credentialing requirements for deep sedation and analgesia.

G. Physicians and dentists with IU Health North Medical Staff Privileges for deep sedation and analgesia are considered to be qualified to administer, supervise, or direct moderate sedation and analgesia.

VI. **PROCEDURE(S)**
A. **FACILITY AND EQUIPMENT**
It is anticipated that most deep sedation and analgesia will occur in the cardiology procedure areas, endoscopy suites, emergency departments, critical care areas, interventional radiology suites, MRI and CT areas. Additional deep sedation and analgesia areas must be approved by the IU Health North Hospital Medical Staff Executive Committee.
Each location in which moderate or deep sedation and analgesia is administered must have the following which is appropriate for patient age and size:
1. Oxygen supply from a portable or permanent source.
2. Airway equipment including nasal cannulas, oral airways, bag and mask ventilation and intubation equipment.
3. Continuous suction.
4. Age- appropriate emergency cart
5. Physiological monitoring equipment:
   a. Pulse oximetry
   b. Blood pressure
   c. ECG
   d. Capnography (Means of monitoring continuous ventilation)
7. Reversal agents.
8. Plan for summoning emergency personnel quickly if needed (Rapid Response Team or Code Team).

B. PRE-PROCEDURE (Within 48 hours preceding the Sedation Procedure)
1. All patients requiring procedural sedation will have a pre-sedation assessment documented within 48 hours prior to the procedure to safely select and plan care including, but not limited to:
   a. Review of the medical history, including anesthesia, drug and allergy history;
   b. Interview and examination of the patient;
   c. Review of systems specific to cardiopulmonary disease;
   d. Airway problems, either anatomical (i.e. micrognathia) or functional (i.e. obstructive sleep apnea, neck circumference greater than 16 inches for women and 17 inches for men);
   e. History of problems with sedation and analgesia, or anesthesia;
   f. Current medications and allergies;
   g. Vital signs and weight;
   h. Physical status classification
   i. The intended level of sedation and analgesia (moderate or deep);
2. Formulation of sedation plan and discussion of the risks and benefits of the plan (including discharge issues when indicated) with the patient or the patient’s legal representative and/or escort.
3. Patients deemed appropriate candidates for moderate or deep sedation and analgesia will be stratified by the qualified sedating physician or
dentist using the American Society of Anesthesiologists (ASA) physical status classification. The services of an Anesthesiologist should be considered for patients with a classification score of three or greater per below:

ASA Physical Status 1: A normal health patient
ASA Physical Status 2: A patient with mild systemic disease
ASA Physical Status 3: A patient with severe systemic disease
ASA Physical Status 4: A patient with severe systemic disease that is a constant threat to life.
ASA Physical Status 5: A moribund patient who is not expected to survive without the operation.

The qualified clinician signature on the IU Health North Hospital Sedation Flow sheet will indicate verification of all of the above information.

4. Moderate or deep sedation and analgesia may not be appropriate for patients presenting with any of the following:
   - History of adverse events associated with sedation and analgesia;
   - Airway problems: i.e. obstructive sleep apnea, difficult intubation, or syndromes involving airway abnormalities;
   - Delayed gastric emptying or increased risk of aspiration;
   - Pregnant or breast feeding females.
   NOTE: Clinician judgment of risk should always be evident in the decision making process when administering sedation to any of these patients.

5. The following fasting guidelines must be considered. Gastric emptying may be influenced by many factors such that the guidelines below do not guarantee that complete gastric emptying has occurred. Unless contraindicated, children should be offered clear liquids until 2-3 hours before sedation and analgesia to minimize the risk of dehydration.

<table>
<thead>
<tr>
<th>Age</th>
<th>Solids and Non-Clear Liquids (includes milk, formula, and breast milk)</th>
<th>Clear Liquids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults/Children &gt; 36 months old</td>
<td>6 - 8 hours</td>
<td>2 –3 hours</td>
</tr>
<tr>
<td>Children 6-36 months old</td>
<td>6 hours</td>
<td>2 - 3 hours</td>
</tr>
<tr>
<td>Children &lt; 6 months old</td>
<td>4 - 6 hours</td>
<td>2 hours</td>
</tr>
</tbody>
</table>
C. IMMEDIATELY PRIOR TO PROCEDURAL SEDATION (time based record of events)

1. Immediately prior to induction of sedation the patient is re-evaluated by the physician or dentist overseeing the sedation medication administration. The physician or dentist shall be responsible for evaluating and documenting the patient’s airway status, any physiological changes since the pre-sedation examination, fitness of the patient for sedation and analgesia, and the planned sedation level. If deep sedation is planned, the deep sedation administering practitioner shall record the immediately prior to sedation vital signs, patient level of consciousness, NPO status, and any changes to pre-sedation assessment documented previously.

2. The registered nurse should record the following for planned moderate sedation cases:
   a. Immediately prior to sedation vital signs (blood pressure, heart rate, respiration rate, oxygen saturation rate, and if indicated the temperature.
   b. Oxygen requirements
   c. NPO status
   d. Level of consciousness

The qualified physician or dentist’s signature on the IU Health North Hospital Sedation Flow sheet will indicate verification of all of the above information.

D. INTRA-PROCEDURE

1. The requirements of the IU Health North Hospital Universal Protocol Policy will be observed in patients receiving procedural sedation.

2. Propofol, methohexital, pentobarbital, ketamine, or any other “general anesthetics” are more likely to produce deep sedation. Therefore, physicians using these medications must meet the credentialing requirements for deep sedation and analgesia. A qualified physician or dentist who is not performing the procedure must administer deep sedation medications. A qualified registered nurse or allied health practitioner may assist in the monitoring and documentation of vital signs and response to the medication under the direction and supervision of a physician or dentist who has deep sedation privileges.

3. A qualified registered nurse or allied health practitioner (AHP) may provide moderate sedation and analgesia as long as it is under the direct supervision of a physician or dentist who has moderate sedation privileges and who is in immediate proximity to the patient. Registered
nurses and allied health practitioners are not qualified to administer deep sedation.

An **EXCEPTION** to this requirement is procedural analgesia in the Emergency Department. Medications for procedural analgesia (including but not limited to etomidate, propofol, ketamine, fentanyl and midazolam) may be administered by an Emergency Department Registered Nurse (RN) or Nurse Practitioner (NP) under the direct supervision of an emergency physician with deep sedation privileges at IU Health North for the following types of procedures:

- Orthopedic manipulation/reduction;
- Incision and drainage of abscesses;
- Cardioversion;
- Wound repair; and
- Other emergency procedures that would be expected to take 20 minutes or less.

An Emergency Department RN or NP may also monitor and record the patient's vital signs and response to procedural analgesia during the procedure. The supervising Emergency Medicine physician may be the same physician that is performing the procedure, provided that the procedure may be abandoned without compromise to patient safety. Procedural analgesia provided in the Emergency Department is unique when compared to sedation provided in other clinical venues. Emergency Department procedures are done on an unscheduled basis and are often done on an urgent or emergent basis in order to prevent morbidity or mortality. Procedures done in the Emergency Department are generally short in duration and can be abandoned by the physician without compromising patient safety. Emergency physicians possess airway management skills necessary to provide patient rescue and Emergency Department RNs and NPs possess critical evaluation and communication skills necessary in the monitoring and reporting of emergent patient needs.

An additional **EXCEPTION** to this requirement does allow an RN or NP to administer intravenous bolus analgesia and monitor and record the patient’s vital signs and response under the direct supervision and guidance of a physician who has deep sedation and analgesia privileges at IU Health North including those medications listed in V.F. of this policy when a physician possessing the appropriate procedural IU Health North privileges is performing one of the following procedures:

a. External cardioversion/defibrillation
b. Internal cardioversion/defibrillation using an implantable cardioverter defibrillator
c. Transesophageal echocardiogram (TEE) guided cardioversion

The following locations are where the Cardiologist directed procedures could occur:
- ICU;
- PCU;
- Cath lab;
- Cath lab holding; and
- Cardiac Unit

4. Supplemental oxygen will be administered during deep sedation and analgesia unless contraindicated.

5. Patients will not be transported while under deep sedation and analgesia unless that transport is taking place between induction areas, procedural areas, or recovery areas, and monitoring is maintained.

6. Monitoring:
   a. The patient’s level of sedation, determined by their response to commands and stimulation, should be monitored throughout the procedure. Children are sometimes an exception as verbal or tactile stimulation may disrupt an adequate level of sedation, and therefore, interfere with completion of the procedure.
   b. Continuous ventilation should be monitored throughout the procedure. Ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for presence of exhaled carbon dioxide unless impeded by procedure or equipment (MRI, extensive draping of a sterile field).
   c. Continuous pulse oximetry with appropriate alarms should be monitored for all patients.
   d. Continuous ECG and blood pressure every 5 minutes should be monitored for all patients undergoing deep sedation and analgesia. Some children may be exception to this requirement.
   e. For patients receiving deep sedation and analgesia, IV access must be maintained until they are no longer at risk for cardio respiratory depression.

7. Documentation
   For EVERY sedation procedure, current standard of care stipulates that an intra-sedation record should include at a minimum:
   
   a. Name and hospital identification number of the patient;
   b. Name of procedural practitioner;
c. Name, dosage, route, and time of all administered drugs;
d. Name and amounts of IV fluids, including blood or blood products if applicable;
e. Time-based documentation of vital signs, oxygenation and ventilation parameters, and level of sedation should be recorded at a minimum of every 5 minutes. Documentation will be completed on the IU Health North Sedation Flowsheet or elsewhere within the medical record that captures the same or similar data.
f. Any complications, adverse reactions, or problems occurring during sedation, including time and description of symptoms, vital signs, treatments rendered, and patient’s response to treatment.
g. Status of the patient at the conclusion of the sedation shall be recorded.
h. If the procedure is less than 5 minutes, documentation should occur at the minimum:
i. before the procedure;
ii. following administration of sedative/analgesia agents;
iii. upon completion of the procedure;
iv. during recovery; and
v. at discharge.

8. MODERATE SEDATION - Additional documentation requirements include:
   a. Name of RN or allied health practitioner who administered moderate sedation; and
   b. Name of practitioner who directed the moderate sedation administration.

9. DEEP SEDATION - Additional documentation requirements include:
   a. Name(s) of physician or dentist who administered deep sedation medications and monitored vital signs and patient response to deep sedation medications.
   b. Technique(s) used and patient position(s), including the insertion(s)/use of any intravascular or airway devices.

E. POST-PROCEDURE
1. The patient will be monitored and the same parameters listed above in the documentation section should be recorded every 15 minutes until the patient has returned to their baseline status.

2. Patients who received procedural deep sedation and analgesia must be monitored in accordance with post-anesthesia hospital requirements for
equipment, monitoring, and staffing.

3. **If a reversal agent is used, the patient will be monitored for a minimum of one hour after reversal agent administration.**

4. The qualified physician or dentist will remain in the clinical area and be immediately available for urgent patient concerns until the risk of sedation-related respiratory depression has passed.

5. For patients who received **MODERATE SEDATION** and analgesia, the physician or dentist who directed the moderate sedation and analgesia will document a patient post-procedure evaluation that should include at least the following:
   a. Vital signs
   b. Level of consciousness
   c. Any unusual events or post-procedure complications

6. For patients who received **DEEP SEDATION** and analgesia, the physician or dentist who administered the deep sedation and analgesia will perform and document a patient post-procedure evaluation no later than 48 hours following the deep sedation procedure. The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area. Except in cases where post-operative sedation is necessary for the optimum medical care of the patient (e.g. ICU), the evaluation generally would not be performed immediately at the point of movement from the procedural area to the designated recovery area. Acceptable standards of care indicate that the evaluation may not begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation (e.g. answer questions appropriately, perform simple tasks). The evaluation can occur in the PACU/ICU or other designated recovery location. For outpatients, the post-anesthesia evaluation must be completed prior to the patient’s discharge. The elements of an adequate post-anesthesia evaluation should be clearly documented and include the following:
   a. Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
   b. Cardiovascular function, including pulse rate and blood pressure;
   c. Mental status;
   d. Temperature;
   e. Pain;
   f. Nausea and vomiting;
   g. Post-procedure hydration.
7. For inpatients, recovery must be complete before transfer back to their unit. The nurse caring for the patient will arrange transport and determine type of personnel necessary for transport. The nurse caring for the patient will provide a hand-off report in accordance with facility hand-off communication policies to the accepting nurse. Post-procedure orders and documentation of care received during the procedure will accompany the patient to the unit.

8. For outpatients, the sedation directing physician or dentist will provide written discharge instructions related to the sedation and analgesia. The following criteria must also be met:
   a. Patient must be able to sit without assistance or at pre-procedure level;
   b. Discharge planning and patient/family education will be done and documented. Patient should be instructed to not operate equipment or drive for at least 24 hours post discharge;
   c. Emergency numbers must be provided to the patient;
   d. Patient and responsible adult understands written discharge instructions;
   e. Patient released to responsible adult present to escort patient home.

VII. OUTCOME MEASURES
Several adverse outcomes are listed on the IU Health North Hospital Sedation Flow sheet and should be documented if they occur. The completed audit tool should be forwarded to the IU North Hospital Quality Manager.

VIII. CROSS REFERENCE
MS 3.04 Completion of Medical Records
PC CP 1.24AP Guidelines for Optimal Intra-Hospital Transport of Acutely Ill Patients
Medical Staff Rules and Regulations

IX. REFERENCES/CITATIONS
“Revised Hospital Anesthesia Services Interpretive Guidelines – State Operations Manual, Appendix A” and FAQs Center of Medicare and Medicaid Services (CMS) 1/14/2011.
“Hospital Licensure Rules”, Indiana Administrative Code 410, Article 15-1.68, Surgical Services, (readopted July, 2001)
“Condition of Participation: Surgical Services,” Code of Federal Regulations, Chapter IV, Sec. 482.51. Centers for Medicare and Medicaid Services, Department of Health and Human Services

X. **RESPONSIBILITY**  
Department of Anesthesiology (for policy development)

XI. **APPROVAL BODY**  
Medical Executive Committee  
Patient Care and Nursing Executive Council  
Chair, Anesthesia

XII. **APPROVAL SIGNATURES**

_________________________________________          ____________________  
Ricky Cottrell, MD, Chair, Anesthesia          Date

_________________________________________          ____________________  
Suzanne DelBoccio, MS, RN, CENP, FACHE          Date  
Chief Nursing Officer and Vice President of Patient Care Services

_________________________________________         ____________________  
Jack Keene, MD          ____________________  
Medical Staff President, Chair, Executive Committee

_________________________________________   ____________________  
Paul Calkins, MD, Chief Medical Officer          Date