GENERAL POLICY STATEMENT: Level II Deep Sedation may be provided to patients undergoing diagnostic, therapeutic or surgical procedures when deep sedation is clinically indicated. Level II Deep Sedation will only be administered following identified standards required for qualified anesthesia professionals, as defined in CMS regulation 42 CFR 482.52. A qualified anesthesia professional must possess Level II Sedation privileges as defined in SWMC Medical Staff Bylaws.

KEY POINT: Administration of planned Level II Deep Sedation is outside the scope of practice of the Registered Nurse. Registered Cardiovascular Technicians (RCT’s) by organization policy will not administer planned Level II Deep Sedation.

PURPOSE: To establish standards for the safe and consistent care of patients receiving deep sedation in all settings throughout the continuum of care.

DEFINITIONS: Level II 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. (Developed by the American Society of Anesthesiologists; approved by ASA House of Delegates October 27, 2004).

KEYPOINT: * Reflex withdrawal from a painful stimulus is not considered a purposeful response.

KEYPOINT: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation must be able to rescue patients whose level of sedation becomes deeper than initially intended (a state of general anesthesia).

Qualified Anesthesia Professional:
- A qualified anesthesiologist
- A doctor of medicine or osteopathy
- Dentist, oral surgeon or podiatrist who is qualified under state law and privileged by SWMC
- CRNA
- Anesthesia assistant under the supervision of an anesthesiologist as defined in Section 410.69(b) of CMS regulations

Pediatric: For deep sedation, a pediatric patient is defined as age 15 or under and 100 lbs. or less.
Qualified RN or RCT: All RN/RCT personnel assigned to assist with monitoring a patient during or after procedural sedation will have successfully completed/demonstrated the specific competency requirements.

EXCLUSIONS:
1) Does not include oral pre-medication
2) Does not apply to administration of narcotics and sedatives for pain or anxiety
3) Excludes preoperative medication of patients prior to their transport to the procedure room
4) Excludes patients receiving inhalation anesthetics
5) Excludes patients who receive continuous IV sedation per protocol to manage conditions requiring mechanical ventilation (e.g., traumatic injury, post-surgical intervention).
6) Excludes patients who are receiving sedation for the purpose of intubation

PROCEDURE:
A. Pre-Anesthesia Evaluation/ Practitioner Responsibilities

KEY POINT: The deep sedation-privileged provider must perform a pre-anesthesia evaluation within 48 hours prior to any inpatient or outpatient surgery or procedure requiring anesthesia services, and be familiar with sedation-oriented aspects of the patient’s medical history and how these might alter the patient’s response to anesthesia/sedation.

1. The following will be completed by the practitioner and documented in the medical record prior to procedure.
   a. At a minimum, the pre-anesthesia evaluation must be documented to include:
      1) Abnormalities of the major organ systems
      2) Review of the medical history, including drug and allergy history
      3) History of tobacco, alcohol, or substance use or abuse
      4) Interview and physical examination of the patient to include airway evaluation (refer to Appendix A)
      5) Notation of anesthesia risk according to ASA Classification of Risk
         a) Class I:
            i) Normally healthy individual with no systemic disease
            ii) Patient not at extremes of age
         b) Class II:
            i) Individual with one system, well-controlled disease
            ii) Mild obesity, alcoholism, and smoking may be incorporated here
            KEYPOINT: Class I and II are appropriate for deep sedation
         c) Class III:
            i) Individual with multiple system disease or well controlled major system disease
            ii) Disease status may limit daily activity
            iii) No immediate danger of death from any individual disease
         d) Class IV:
            i) Individual with severe, incapacitating disease
            ii) Disease state is poorly controlled or end-stage
            iii) Danger of death due to organ failure is always present
e) Class V:
   i  Patient who is in imminent danger of death
   ii  Patient not expected to live through the next 24 hours

**KEYPOINT:** Class III, IV, and V require additional individual consideration and documentation of rationale for procedure. Class III patients requiring Level II deep sedation will be considered for support from an anesthesiologist; Class IV and V patients are not appropriate for deep sedation by non-anesthesia providers.

6) An airway assessment immediately prior to the procedure including:
   a) Mallampatti classification using the graphic assessment tool
   b) Mandible measurement (finger distance from the inner surface of mandible to hyoid bone during neck extension)
   c) Neck range of motion
   d) Condition of teeth
      i  Previous anesthesia history including poor or questionable outcomes
      ii  Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access)

b. Time and nature of last oral intake
Evaluate and document NPO/fasting status

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids³</td>
<td>2 h</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 h</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 h</td>
</tr>
<tr>
<td>Non-human milk⁴</td>
<td>6 h</td>
</tr>
<tr>
<td>Light meal⁵</td>
<td>6 h</td>
</tr>
<tr>
<td>Regular meal</td>
<td>8 h</td>
</tr>
</tbody>
</table>

¹ These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee that complete gastric emptying has occurred. Causes of delayed gastric emptying include: diabetes, narcotic use, presence of ascites or other intra-abdominal processes which may make the stomach smaller than normal, significant uremia, chronic significant neurological disease, etc.

² The fasting periods noted above apply to all ages.

³ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

⁴ Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

⁵ A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

**KEY POINT:** In emergent situations or when patients are at risk for pulmonary aspiration of gastric contents, appropriate pharmacologic treatment to reduce gastric volume and increase gastric pH may be of benefit prior to sedation and/or airway protection may be required. In emergency situations when pre-procedure fasting is not
practical, the targeted level of sedation should be modified (i.e. less sedation should be administered). The use of cricoid pressure should be considered in these cases or when the level of sedation achieved is deeper than the level anticipated. Consideration should be given for consultation with an anesthesia credentialed practitioner.

c. Pre-procedure laboratory testing should be guided by the patient’s underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia
   1) These evaluations should be confirmed immediately before sedation is initiated

2. Complete the informed consent process for sedation (refer to: Intranet; Forms & Printing; Form # 450 or department specific consent form)
   **KEYPOINT:** Surgical consent form may be used, unless approved department specific consent is standard.

3. Complete sedation plan and orders prior to initiating procedure
   **KEYPOINT:** Implement Sedation Plan Interdisciplinary Progress Record: (refer to: Intranet: Forms & Printing: Form #2077) and/or Deep Sedation Flow Record Form #5601).

**B. RN Responsibilities**

1. Provider privileges for Level II Deep Sedation are confirmed by contacting Medical Staff office during normal business hours and contacting Administrative Manager during off-hours
   a. Privileges are also posted in “MIDAS Live and Privilege Inquiry” on SWMC Intranet
   **KEYPOINT:** Refer to the physician privileging website on the SWMC Intranet to identify level of physician sedation privileging. All physicians ordering/performing deep sedation must meet the specific competency requirements identified in the credentialing process.

2. Verify completion of:
   a. Informed Consent
   b. Pre-Anesthesia Evaluation
   c. Airway Assessment and Plan for Sedation
   d. Pre-Procedure Checklist

3. Assessment: Registered Nurse (RN) responsibility
   a. Baseline pain assessment
   b. Baseline Aldrete score
   c. Baseline Vital Signs (BP, P, R, T, O2 sat)
   d. Height and weight
   e. Allergies/sensitivities
   f. Verification of appropriate transportation home will be obtained (i.e. the patient is not driving) when the patient is expected to be discharged following the procedure

4. Establish IV Access
   a. Vascular access must be established prior to administration of deep sedation

**C. Personnel– Level II Deep Sedation**

1. Anesthesia-qualified professional to be present to administer the sedation and remain present during the entire procedure
   **KEYPOINT:** This practitioner is independent from the practitioner performing the invasive procedure. Practitioners intending to produce a given level of sedation must be able to rescue a patient who enters a state of general anesthesia.
2. ACLS certified Respiratory Therapist, ACLS certified RN, or ACLS certified Registered Cardiovascular Technologist to assist the physician with monitoring as needed during procedure

D. Equipment/Supplies for Deep Sedation
1. The following supplies/equipment must be present:
   a. Continuous oxygen saturation monitor
   b. Intravenous access supplies, fluids
   c. Supplemental oxygen including nasal cannulas, masks, regulator and equipment to perform positive pressure ventilation (i.e. Ambu bag)
   d. Blood pressure monitoring equipment
   e. Suction and suction catheters present and set up for immediate use
   f. Reversal agents to be at the bedside prior to the start of the procedure
   g. Cardiac monitoring
   h. Code Blue cart present

KEYPOINT: All equipment and supplies must be suitable for the age and size of the patient being treated.

E. Intra-Procedural Care
1. Final Verification and Time Out
   a. The credentialed physician performing the procedure, as well as all personnel present, will participate in completing the final check in the location where the procedure is to be performed, immediately prior to the beginning of the procedure (refer to Universal Protocol: Patient, Procedure and Site Verification policy # 8720.103)

2. Medication Administration
   a. Anesthesia-qualified professional must administer the IV sedation and remain present during the procedure
   b. Dosage and rate of administration must be individualized based on patient condition (drug manufacturer’s recommendations, response to previous dose)
   c. Medication administration is performed incrementally
      1) Dosages and rates of administration must be individualized with adequate time between doses to assess full pharmacologic effects
   d. The administration of each dose is to be documented on the intra-procedural record

KEYPOINT: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. The patient’s age and pre-existing medical conditions may significantly alter the dosing requirements needed for sedation.
   e. Reversal agents used at the discretion of the physician
   f. The deep sedation-privileged provider must remain present until the vital signs are stable and the patient is sufficiently recovered to maintain a patent airway

3. Airway management
   a. Supplemental oxygen by mask or cannula may vary according to individual patient assessment and medical condition. The deep sedation-privileged provider will supervise the administration of oxygen and is responsible for maintaining a patent airway

KEYPOINT: Do not use supplemental oxygen when procedure site is near nares and electrosurgical equipment is being utilized.
4. Intra-procedural Patient Monitoring and Documentation
   a. Name of practitioner administering deep sedation
   b. Continuous visual monitoring with documentation upon initiation and a minimum of every 5 minutes for the following:
      1) Patient’s level of consciousness and responsiveness (OAA/S)
      2) Heart rate
      3) Blood pressure
      4) Respiratory rate
      5) Continuous pulse oximetry
      6) ECG
      7) End tidal CO₂ (optional consideration if patient is prone or in an area where visual observation of ventilatory function is compromised)
   c. Name, dosage, route and time of administration of drugs and anesthesia agents
   d. Technique(s) used and patient position(s), including the insertion/use of any intravascular or airway devices
   e. Name and amounts of IV fluids, including blood or blood products if applicable
   f. Any complications, adverse reactions, or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient’s response to treatment

F. Post-anesthesia Evaluation, Post-procedure Care and Documentation
   1. A post-anesthesia evaluation must be completed and documented no later than 48 hours after surgery or a procedure requiring deep sedation services
   KEYPOINT: The evaluation must be completed and documented by a practitioner who is qualified to administer anesthesia. (Post-Anesthesia Evaluation form #5372)
      a. The elements of an adequate post-anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care and CMS requirements, including:
         1) Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
         2) Cardiovascular function, including pulse rate and blood pressure;
         3) Mental status;
         4) Temperature;
         5) Pain;
         6) Nausea and vomiting; and
         7) Postoperative hydration.
   2. The evaluation may not begin until the patient is sufficiently recovered so as to participate in the evaluation.
   3. Monitoring
      a. Monitor and document vital signs and oxygen saturation every 10 minutes or more frequently as indicated by patient response until patient reaches a modified Aldrete Score of 8 (Attachment A)
      b. Report significant variations in physiologic parameters to the physician immediately, including but not limited to:
         1) Variation of \( \leq \pm 20\% \) of baseline
         2) Arrhythmia
         3) Oxygen saturation \( \leq 90\% \) or \( \geq 5\% \) below baseline
4) Dyspnea, apnea, or hypoventilation
5) Diaphoresis
6) Inability to arouse patient
7) Other untoward or unexpected patient response
c. Patient will not be discharged prior to a minimum of 30 minutes since last dose of sedation medication
d. Follow Standard of Care (refer to Post Anesthetic and Post Procedural Care for Non Critical Care, (#2019), Outpatient Surgical or Invasive Procedure (#2033)

4. Patient Discharge
   a. Maintain IV access until discharge criteria are met
   b. Discharge Criteria:
      1) Return to pre-procedural Aldrete Score or Aldrete score of 8
      2) Vital Signs within ±20% of pre-op/pre-procedural
      3) Absence of vomiting, minimal nausea after PO fluids (notify attending physician of vomiting)
      4) Able to ambulate with minimal dizziness, sit up unassisted as appropriate for age and/or return to pre-operative status
      5) Dressing, if present, dry and intact
      6) Responsible adult present to escort/drive patient home
      7) When discharge criteria are not met, notify physician for further orders

   KEYPONTE: Pediatric patients will demonstrate pre-procedural developmental tasks such as sitting or talking and an adequate state of hydration prior to discharge.

   8) When a reversal agent is administered, prolonged observation (minimum of two (2) hours from time of administration) is recommended

   9) Document time and condition of patient at discharge

   10) Provide patient with discharge instructions

G. Quality Improvement
1. Random chart audits will be conducted for compliance with regulatory standards as current

2. Adverse events and/or patterns during procedural sedation will be documented and submitted electronically via the Safety Reporting Gateway to Quality Care Resources within 24 hours of occurrence (notify manager/director)
   a. Adverse events include (not limited to):
      1) Adverse patient reaction
      2) Sedation deeper than the level intended in the Plan for Sedation
      3) Administration of a reversal agent
      4) Respiratory and cardiac depression requiring Code Blue
      5) Patient expiration
   b. Manager/Supervisor/Director investigates the occurrence.

H. Competency Requirements
1. Physician must maintain privileges and competency requirements as outlined in Medical Staff Bylaws for Level II Deep Sedation

2. Staff assisting with monitoring patients receiving deep sedation will have completed the Sedation competency and education requirements (refer to: Intranet: Manuals; Competency; Targeted; #645 - Procedural Sedation)
3. Pediatric Procedural Sedation Competency must be completed to be deemed competent to assist with monitoring the pediatric patient undergoing deep sedation

Appendix A  Airway Assessment Procedures for Sedation

ATTACHMENTS:
A. Modified ALDRETE Scoring System, OAS/S Sedation

RELATED POLICIES:
8720.103 Universal Protocol: Patient, Procedure and Site Verification

FORMS, STANDARDS OF CARE:
5372  Post-Anesthesia Evaluation
5601  Deep Sedation Flow Record
450   Patient Informed Consent
2077  Procedural Sedation Interdisciplinary Progress Record
Standard of Care #2033  Outpatient Surgical or Invasive Procedure

REFERENCES:
Center for Medicare and Medicaid Services (CMS) Conditions of Participation #CFR 482.52: Anesthesia Services, December 2009
Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists:
   Anesthesiology, V 96, No 4, April 2002, pgs, 1004 – 1017
A Clinical Sign to Predict Difficult Tracheal Intubation, a Prospective Study:
Continuum of Depth of Sedation Definition of General Anesthesia and Levels of Sedation/Analgesia:
   Approved by ASA House of Delegates on October 13, 1999, and amended on October 27, 2004
Washington State Nursing Care Quality Assurance Commission Position Statement:
   “Scope of Practice for the Registered Nurse in the Administration of Procedural Sedation and the Management of Patients Receiving Procedural Sedation”
Airway Assessment Procedures for Sedation

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during sedation-analgesia. This may be more difficult in patients with atypical airway anatomy. In addition, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors that may be associated with difficulty in airway management are:

History:
- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (e.g., trisomy 21)

Physical Examination
- Habitus
  - Significant obesity (especially involving the neck and facial structures)
- Head and Neck
  - Short neck, limited neck extension, decreased hyoid-mental distance (< 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (e.g., Pierre-Robin syndrome)
- Mouth
  - Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula
- Jaw
  - Micrognathia, retrognathia, trismus, significant malocclusion
Modified ALDRETE Scoring System:

Patients receiving procedural sedation shall be assessed according to the Modified Aldrete Scoring System prior to discharge from the procedure. A score of 8 or greater is required for discharge from the procedure except on written order from the attending physician.

| RESPIRATIONS | 2 = Free deep breathing | 1 = Dyspneic, hyperventilating, obstructed breathing | 0 = Apneic or  
| CIRCULATION | 2 = Blood pressure within 20% of pre-op level | 1 = Blood pressure within 50%-20% of pre-op level | 0 = Blood pressure 50%, or less, of pre-op level  
| LOC (Level of Consciousness) | 2 = Fully Awake | 1 = Responds to name | 0 = No response  
| ACTIVITY ON COMMAND | 2 = Moves all extremities | 1 = Moves two extremities | 0 = No movement  
| OXYGEN SATURATION | 2 = SpO₂ >92% on room air | 1 = Supplemental O₂ required to maintain SpO₂ >92% | 0 = SpO₂ >92% with O₂ supplementation  

OBSERVER’S ASSESSMENT OF ALERTNESS / SEDATION (OAA/S) SCALE

| OAA/S SCALE: 5 | OAA/S SCALE: 4 | OAA/S SCALE: 3 | OAA/S SCALE: 2 | OAA/S SCALE: 1 |
| Responds readily to name spoken in normal tone | Lethargic response to name spoken in normal tone | Responds only after name is called loudly and/or repeatedly | Responds only after mild prodding or shaking | Does not respond to mild prodding or shaking  
| Normal speech | Mild slowing or thickening of speech | Slurring or prominent slowing of speech | Few recognizable words |
| Normal facial expression | Mild relaxation of facial expression | Marked relaxation of jaw |
| Eyes clear, no ptosis | Eyes glazed or mild ptosis | Eyes glazed or marked ptosis |