GENERAL POLICY STATEMENT: Level I (Moderate Procedural) Sedation will be provided to patients undergoing diagnostic, therapeutic, or surgical procedures following identified standards required for non-anesthesiologist physicians and qualified RN or RCT staff in all inpatient and ambulatory settings.

The Washington State Nursing Care Quality Assurance Commission affirms that it is within the role and scope of practice for the registered nurse (RN) to administer procedural sedation (known as Level I, Moderate Procedural Sedation at PHSW), upon order of a qualified licensed independent practitioner, and to manage patients who are receiving and recovering from procedural sedation.


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

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 Operating 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, postsurgical intervention)
6) Excludes patients who are receiving sedation for the purpose of intubation

PROCEDURE:
A. Pre-Procedural
   1. Clinicians administering sedation/analgesia will be familiar with sedation-oriented aspects of the patient’s medical history and how these might alter the patient’s response to sedation/analgesia, including
      ● abnormalities of the major organ systems
      ● previous adverse experience with sedation/analgesia as well as regional and general anesthesia
      ● drug allergies, current medications, and potential drug interactions
      ● time and nature of first oral intake; and
      ● history of tobacco, alcohol, or substance use or abuse
   a. Patients presenting for sedation/analgesia will undergo a focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway (see Appendix A)
b. Evaluate and document NPO/fasting status

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</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 milk</td>
<td>6 h</td>
</tr>
<tr>
<td>Light meal</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).

c. Pre-procedure laboratory testing will 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. Practitioner Responsibilities for Pre-Procedural

a. Providers administering procedural sedation must be privileged for Level I sedation and are responsible to know if the privilege is current

b. The following will be completed by the practitioner and documented in the medical record prior to procedure

KEYPOINT: Document assessment on Procedural Sedation Interdisciplinary Progress Record (refer to: Intranet; Forms database; # 2077) or department specific form.

1) Assessment:

   a) An appropriate history and physical assessment with other pertinent information

   b) An airway assessment immediately prior to the procedure including:

      i) Mallampatti classification using the graphic assessment tool

      ii) Mandible measurement (finger distance from the inner surface of mandible to hyoid bone during neck extension)
iii  Neck range of motion
iv  Condition of teeth
c) Previous anesthesia history including poor or questionable outcomes
d) Physical Status Classification (ASA Score):
   i  Class I:
      a) Normally healthy individual with no systemic disease
      b) Patient not at extremes of age
   ii Class II:
      a) Individual with one system, well-controlled disease
      b) Mild obesity, alcoholism, and smoking may be incorporated here

**KEYPOINT:** Class I and II are appropriate for procedural sedation

iii Class III:
   a) Individual with multiple system disease or well-controlled major system disease
   b) Disease status may limit daily activity
   c) No immediate danger of death from any individual disease

iv Class IV:
   a) Individual with severe, incapacitating disease
   b) Disease state is poorly controlled or end-stage
   c) Danger of death due to organ failure is always present

v Class V:
   a) Patient who is in imminent danger of death
   b) 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 IV or V patients requiring procedural sedation will be considered for anesthesia provider support.

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 procedural sedation plan and orders prior to initiating procedure

**KEYPOINT:** Implement Procedural Sedation Plan, Interdisciplinary Progress Record: (refer to: Intranet: Forms & Printing: Form #2077) and/or department specific Pre Printed Order: (ED implements Procedural Sedation Flow Record; see Intranet: Forms & Printing: Forms Database #2329)

3. RN or Registered Cardiovascular Technician Responsibilities
   a. Provider privileges for Procedural Sedation (Moderate) are confirmed by contacting Medical Staff office during normal business hours and contacting Administrative Manager during off-hours
      1) Privileges are also posted in “MIDAS Live and Privilege Inquiry” on PHSW Intranet

**KEYPOINT:** Refer to the physician privileging website on the PHSW Intranet to identify level of physician sedation privileging. All physicians ordering/performing procedural sedation (moderate) must meet the specific competency requirements identified in the credentialing process.
b. Verify completion of:
   1) Informed Consent for sedation
   2) History and Physical
   3) Pre-Procedure Airway Assessment and Plan for Sedation

c. Assessment: Registered Nurse (RN) or Registered Cardiovascular Technician responsibility
   1) Baseline pain assessment
   2) Baseline Aldrete score
   3) Baseline Vital Signs (BP, P, R, T, O₂ sat)
   4) Height and weight
   5) Allergies/sensitivities
   6) 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

d. Establish IV Access
   1) Vascular access must be established prior to administration of procedural sedation.

e. Personnel - Procedural Sedation (the Sedation Plan will determine personnel requirements)
   1) Personnel – Level I Moderate Procedural Sedation
      a) The Physician or PA:
         i) Be present during the initial administration of IV sedation
         ii) Be readily available within the department until the patient meets the pre-procedure Aldrete Score
      b) Additional care providers
         i) One RN or Registered Cardiovascular Technologist whose primary responsibility during the procedure is to monitor the patient, maintain the airway and be qualified and competent to identify and manage a compromised airway must be present
            **KEYPOINT:** The qualified RN or RCT responsible for monitoring the patient may not engage in tasks that would compromise continual assessment.
         ii) Advanced Cardiac Life Support (ACLS) certified personnel immediately available (i.e. Code Blue team available by page)
            **KEYPOINT:** A sufficient number of staff will be in attendance to safely monitor and provide care to the patient based on patient health status and complexity of intended procedure, complying with all regulatory standards and published National Specialty Organization Standards.

f. Equipment/Supplies for Moderate Procedural Sedation
   1) Continuous oxygen saturation monitor
   2) Intravenous access supplies, fluids
   3) Supplemental oxygen including nasal cannulas, masks, regulator and equipment to perform positive pressure ventilation (i.e. Ambu bag)
   4) Blood pressure monitoring equipment
   5) Suction and suction catheters present
   6) Reversal agents to be at the bedside prior to the start of the procedure
   7) Cardiac monitoring
   8) Code Blue cart present
KEYPOINT: All equipment and supplies must be suitable for the age and size of the patient being treated.

B. Intra-Procedural Care

1. Final Verification and Time Out
   a. The credentialed Practitioner 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 policy # 8720.103, “Universal Protocol: Patient, Procedure and Site Verification”)

2. Medication administration
   a. Level I Procedural Sedation (Moderate)
      1) Physician or PA must be present in the work area during IV sedation medication administration and readily available within the department until the patient meets the pre-procedure modified Aldrete Score
   b. Dosage and rate of administration must be individualized based on patient condition (drug manufacturer’s recommendations, response to previous dose)
   c. Medication administration will be 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 will be by the order of the physician performing the procedure

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 will be used at the discretion of the Physician or PA or as outlined in Procedural Sedation Reversal Policy #8720.717

3. Airway management
   a. Supplemental oxygen at 2 liter per nasal canula, given as indicated by patient condition (oxygen flow rate may vary according to individual patient assessment and medical condition)

KEYPOINT: Do not use open delivery oxygen when electrosurgical equipment is utilized in procedures performed above the T5 dermatome involving the head, neck or chest to prevent the possibility of fire. Patient’s sedation level should be maintained to allow the maintenance of baseline oxygen saturation without supplemental oxygen. If sedation requiring oxygen is required, consultation with anesthesiologist to perform the procedure with a laryngeal mask airway or endotracheal tube should be considered.

4. Patient monitoring will include:
   a. Continuous visual monitoring with documentation upon initiation and every 10 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
C. Post Procedure Care

1. 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 or pre-procedure Aldrete score (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, and Outpatient Surgical or Invasive Procedure #2033)

2. Documentation for Procedural Sedation (Moderate)
   a. Complete Procedural Sedation Flow Record (refer to: Intranet; Forms database; #2097)
   b. Physician performing procedure will sign the Procedural Sedation Plan Interdisciplinary Progress Record (refer to: Intranet; Forms; Forms database; # 2077), or department specific form/order set

3. Patient Discharge for Procedural Sedation (Moderate)
   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 $\pm 20\%$ 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

KEYPOINT: 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
D. Quality Improvement
1. Random chart audits will be conducted for compliance with regulatory standards

2. Adverse events and/or patterns during Procedural Sedation (Moderate) will be documented and submitted to the appropriate supervisor/manager/director within 24 hours of occurrence
   a. Adverse events include (not limited to):
      1) Adverse patient reaction
      2) Sedation deeper than the level intended in the Plan for Sedation
      3) Respiratory depression requiring ventilatory assistance
      4) Administration of a reversal agent
      5) Respiratory and cardiac depression requiring Code Blue
      6) Patient expiration
   b. Manager/Supervisor/Director investigates the occurrence, completes the documentation and submits to Quality Care Resources for appropriate review (refer to: Intranet; Forms; Forms database; # 050)

E. Competency Requirements
1. Physician must maintain privileges and competency requirements as outlined in Medical Staff Bylaws for Level I Procedural Sedation (Moderate)

2. Procedural Sedation (Moderate) Competency must be completed to be deemed competent

3. Pediatric Procedural Sedation (Moderate) Competency must be completed to be deemed competent for pediatric procedural sedation.

DEFINITIONS:
The American Society of Anesthesiologists (2004) defines:

**Level I** (Moderate Sedation): a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands either alone or accompanied by light tactile stimulation. A patient receiving Level I (Moderate Sedation) ideally has a minimally depressed level of consciousness and retains the ability to continuously and independently maintain a patent airway and respond appropriately to physical stimulation and verbal commands. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained.

**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 should be able to rescue patients whose level of sedation becomes deeper than initially intended.

❖ Individuals administering Level I (Moderate Procedural Sedation) should be able to rescue patients who enter a state of Deep Sedation.
Pediatric: For procedural or deep sedation, a pediatric patient is defined as age 15 or under and 100 lbs. or less.

Registered Cardiovascular Technologist (RCT): Includes Registered Cardiovascular Radiologic Technologists and Registered Cardiovascular Invasive Specialists who complete specialized training and are certified as Washington State Health Care Assistants Levels A,B,D,F, and maintain ACLS certification allowing them to participate in providing procedural sedation in the presence of a physician.

Qualified RN or RCT: All RN/RCT personnel assigned to assist with or monitor a patient during or after procedural sedation will have successfully completed/demonstrated the specific competency requirements.

APPENDIX A Airway Assessment Procedures for Sedation and Analgesia

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

RELATED POLICIES:
8720.717 Procedural Sedation Reversal
8720.103 Universal Protocol: Patient, Procedure and Site Verification

RELATED FORMS, STANDARDS OF CARE:
Diagnostic Imaging Admission/Intra Procedure Record Form #2644
Emergency Department Procedural Sedation Checklist Form #2328
Endoscopy Consent Forms #2213, 2214, 2215, 2216, 2400
Endoscopy Services Procedure Record Form #2126
Informed Consent for Cardiac Catheterization Form #2623
Occurrence Report Form #50
Outpatient Surgical or Invasive Procedure Standard of Care #2033
Patient Informed Consent Form #450
Post Anesthetic and Post Procedural Care for Non Critical Care Standard of Care #2019
Procedural Sedation Chart Review Form #2910
Procedural Sedation Flow Record Form #2097
Procedural Sedation Flow Records Emergency Department Form #2329
Procedural Sedation Interdisciplinary Progress Record Form #2077

REFERENCES:
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: Journal of Canadian Anesthesia Society, Vol 32, 1985, pg 429 – 434 (Mallampati SR, GATT, SP)
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

End of Policy
The last page of this policy document contains approval, review and revision information only.
**CREATION (Original Version):**

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<thead>
<tr>
<th>Author:</th>
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<tr>
<td>Responsible Party:</td>
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<tr>
<td>Reviewed By:</td>
</tr>
<tr>
<td>Approved By: Elaine Sibley</td>
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**PERIODIC REVIEW:**

| Reviewer: Jay Sleesman | Date: 02/12 |
| Reviewer: Barb Yoder | Date: 02/12 |
| Reviewer: Cathy King | Date: 02/12 |

**REVISIONS:**

| Responsible Party: Barb Yoder, Cathy King |  
| Revised By: Jay Sleesman |  
| Approved By: Cathy King | Date: 05/12 |
| Reason/Summary of Changes: 3 year review |  
| Replaces: |  

**RETIRED:**

| Requested By: |  
| Approved By: | Date: |
| Reason for Retirement: |  

Airway Assessment Procedures for Sedation and Analgesia

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.

<table>
<thead>
<tr>
<th>RESPIRATIONS</th>
<th>2 = Free deep breathing</th>
<th>1 = Dyspneic, hyperventilating, obstructed breathing</th>
<th>0 = Apneic or</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CIRCULATION</td>
<td>2 = Blood pressure within 20% of pre-op level</td>
<td>1 = Blood pressure within 50%-20% of pre-op level</td>
<td>0 = Blood pressure 50%, or less, of pre-op level</td>
<td></td>
</tr>
<tr>
<td>LOC (Level of Consciousness)</td>
<td>2 = Fully Awake</td>
<td>1 = Responds to name</td>
<td>0 = No response</td>
<td></td>
</tr>
<tr>
<td>ACTIVITY ON COMMAND</td>
<td>2 = Moves all extremities</td>
<td>1 = Moves two extremities</td>
<td>0 = No movement</td>
<td></td>
</tr>
<tr>
<td>OXYGEN SATURATION</td>
<td>2 = SpO₂ &gt;92% on room air</td>
<td>1 = Supplemental O₂ required to maintain SpO₂ &gt;92%</td>
<td>0 = SpO₂ &gt;92% with O₂ supplementation</td>
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</tbody>
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**OBSERVER’S ASSESSMENT OF ALERTNESS / SEDATION (OAA/S) SCALE**

<table>
<thead>
<tr>
<th>OAA/S SCALE: 5</th>
<th>OAA/S SCALE: 4</th>
<th>OAA/S SCALE: 3</th>
<th>OAA/S SCALE: 2</th>
<th>OAA/S SCALE: 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Responds readily to name spoken in normal tone&lt;br&gt;• Normal speech&lt;br&gt;• Normal facial expression&lt;br&gt;• Eyes clear, no ptosis</td>
<td>• Lethargic response to name spoken in normal tone&lt;br&gt;• Mild slowing or thickening of speech&lt;br&gt;• Mild relaxation of facial expression&lt;br&gt;• Eyes glazed or mild ptosis</td>
<td>• Responds only after name is called loudly and/or repeatedly&lt;br&gt;• Slurring or prominent slowing of speech&lt;br&gt;• Marked relaxation of jaw&lt;br&gt;• Eyes glazed or marked ptosis</td>
<td>• Responds only after mild prodding or shaking&lt;br&gt;• Few recognizable words</td>
<td>• Does not respond to mild prodding or shaking</td>
</tr>
</tbody>
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