HIGH DESERT HEALTH SYSTEM
AMBULATORY SURGICAL CENTER

SUBJECT: VI-118 MODERATE SEDATION	**POLICY #**: 1152
	VERSION: 1
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PURPOSE: To provide guidelines for the safe care of patients during the delivery of medications for the provision of moderate sedation by non-anesthesiologists during diagnostic or therapeutic procedures. Such procedures may include, but are not limited to, gastrointestinal endoscopy, percutaneous aspirations and biopsies.

DEFINITIONS: (As Approved by the American Society of Anesthesiologists House of Delegates on October 13.1999 and amended on October 27, 2004) (See Appendix A):

MINIMAL SEDATION (ANXIOLYSIS): A controlled lessening of a patient's awareness of the environment and pain perception, achieved through the administration of oral pharmacological agents with or without analgesia. The patient maintains stable vital signs, independently maintains his/her airway with intact protective reflexes, has adequate, spontaneous respiration and responds normally to verbal commands. Though cognitive function and coordination may be impaired, the patient does not meet the criteria for sedation unless the drug dosage exceeds the hypnotic level for that individual.

MODERATE SEDATION/ANALGESIA: A controlled state of depressed consciousness achieved through the administration of pharmacological agents by any route or dosage, with or without analgesia, that (1) allows protective (gag and cough) reflexes to be maintained; (2) retains the patient's ability to maintain patent airway independently with preservation of adequate spontaneous ventilation; (3) permits the patient to respond appropriately (purposefully) to physical (light tactile) stimulation and follow verbal commands, e.g. "Open your eyes." Cardiovascular function is usually maintained.

DEEP SEDATION/ ANALGESIA: A medically controlled state of depressed consciousness or unconsciousness achieved through the administration of intravenous sedative and/or analgesic agents from which the patient is not easily aroused. It may be accompanied by a partial or complete loss of protective reflexes (defined as coughing, gag, and/or corneal reflexes), may include the inability of the patient to independently maintain a patent airway, and may be associated with impaired ability to maintain ventilatory function and adequate spontaneous ventilation. Patients may not respond purposefully to physical stimulation or verbal command, but do respond purposefully following repeated or painful stimulation. Cardiovascular function is usually maintained.

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GENERAL ANESTHESIA: A medically controlled state of loss of consciousness during which, patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

POLICY: This policy establishes procedures and general guidelines for the provision of moderate sedation (formerly Conscious Sedation) administration. The policy and procedures will be followed wherever moderate sedation is administered during a diagnostic or therapeutic procedure. This policy applies to all patients where there is a reasonable expectation that, in the manner used, the sedation may result in loss of protective reflexes for patients.

PROCEDURE:

I. AREAS WHERE SEDATION CAN BE ADMINISTERED

Moderate sedation is administered in the Operating Room (OR) of the Ambulatory Surgical Center (ASC) provided that appropriate nurse/physician support and monitoring equipment are available as defined in this policy and procedure.

II. PATIENT SELECTION

A. Candidates for moderate sedation are those patients who must undergo painful or difficult procedures, where cooperation and/or comfort will be difficult or impossible without pharmacological support through the titration of narcotics and sedatives.

B. Patients must be screened for potential risk factors for any pharmacological agents selected. The decision on which agent to use will be based physician's preference on the goals of the sedation, the type of procedure being performed, and the age and physiologic condition of the patient. It is the responsibility of the physician to select only those patients who can safely undergo the required procedure with the use of moderate sedation. The risk of each case should be assessed and documented in the pre-procedure note.

C. The following patients are at increased risk during moderate sedation:

1. Elderly patients (>70 years of age)
2. Morbidly obese patients

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3. Patients at increased risk of aspiration (full stomach, trauma, and hiatal hernia)
4. Patients with chronic diseases, especially cardiovascular and pulmonary
5. Patients with difficult airway (known difficult intubation, neck injury, facial trauma or anomalies, etc.)

D. All patients will be pre-screened by the ordering physician for risk factors utilizing the ASA (American Society of Anesthesiologists) Physical Status Classification Scale. Patients falling into ASA classification of 1 to 2 are eligible for moderate sedation. An Anesthesiologist/CRNA is available for consultation if classification is unable to be determined. ASA 3 classifications should be consulted with anesthesia prior to scheduling.

ASA PHYSICIAN STATUS CLASSIFICATION

ASA 1	A normal healthy patient
ASA 2	A patient with mild to moderate systemic disease (e.g. controlled hypertension or diabetes)
ASA 3	A patient with severe systemic disease that is not incapacitated (e.g. poorly controlled hypertension, heart disease, insulin dependent diabetes)

III. CREDENTIALING, TRAINING, COMPETENCY AND STAFFING,

A. All moderate sedations must be administered under the direction of a licensed independent practitioner (Physician) who has been granted privileges for the administration of moderate sedation.

B. The practitioners (physician and registered nurse) responsible for the administration of sedative/analgesic drugs and/or monitoring of sedation shall be appropriately educated and trained to assure competence in both monitoring and sedation techniques.

C. Physicians involved with the management-of moderate sedation will be authorized to do so through the clinical privilege delineation process.

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D. A Sedation Self-Instruction Guide is available for the medical staff for educational purposes. For those requesting the privilege for sedation the first time, successful completion of the teaching module and passing the Post Test with a score of at least 80% is currently utilized to document education and grant the privilege. A test score of less than 80% requires a Retake Test prior to granting the privilege.

E. During reappointment, the privilege will be granted based on either quality assessment, obtained from retrospective review of a selected number of patients records, or on repeat completion of the teaching module as described, if no sedation administered since last time the privilege was granted.

F. The Registered Nurse (RN) responsible for managing and monitoring the care of patients receiving moderate sedation (including the administration of prescribed medication and/or monitoring the patient) will complete and maintain skills annually through Competency Testing. The RN will be certified in Basic Life Support and Advanced Life Support certification.

G. All personnel involved in the administration of moderate sedation and monitoring patients are required to demonstrate-knowledge and skills related to:

1. Recognition of the compromised airway and basic airway management, which may include, but is not limited to: proper positioning of the head, clearing the airway, use of oropharyngeal or nasopharyngeal airways, the application of positive pressure ventilation by bag and mask, and the use of various modes of supplemental oxygen.
2. Basic monitoring techniques consistent with assessment of patient care including respiratory rate, oxygen saturation, blood pressure, heart rate and rhythm recognition, and assessment of level of consciousness.
3. Basic pharmacology of moderate sedation medication(s), including proper dosages, onset and duration of action, desired effects, drug interactions, adverse reactions and interventions for adverse reactions and overdose.

H. A minimum of four (4) personnel must be directly involved in the care of patients undergoing moderate sedation. All must be present during the entirety of the procedure:

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1. The physician who performs the diagnostic, therapeutic or surgical procedures and
2. The RN, whose responsibility is directed only to the patient: to administer medication, to monitor the patient, and to observe the patient's response to both the sedation and the procedure.
3. An RN to function in a circulating role, handling specimens and assisting with the patient.
4. A scrub to assist the physician with equipment and scopes.

I. The Physician will be physically present in the OR suite at the time of administration of moderate sedation and be available until discharge.

J. Nursing personnel shall be present during the recovery period and discharge of the patient from the post-sedation recovery area. Additional staffing shall be determined on the basis of patient's acuity, procedure, and the potential response to the medications administered.

K. Anesthesia personnel will be available as backup, if available.

IV. EQUIPMENT AND MAINTENANCE REQUIREMENTS

The following equipment MUST be i1mnediately available at all locations where moderate sedation is being performed:

A. Oxygen source (pipeline and Oxygen tank as backup)

B. Functioning suction source with appropriate size suction catheters and Yankauer

C. Cardiac monitoring equipment.

D. Automated blood pressure monitoring.

E. Pulse oximetry.

F. Appropriate selection of masks and airways.

G. Airway devices (e.g. oral/nasal airway).

H. Resuscitative equipment (e.g. laryngoscopy, endotracheal tubes and stylets).

I. Bag-valve-mask device (e.g. Ambu bag)

J. Additional oxygen delivery devices (e.g. face mask, nasal cannula, non-rebreather face mask).

K. Emergency Crash Cart with defibrillator.

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V. EVALUATION AND PREPARATION OF PATIENTS PRE-PROCEDURE:

A. Physician

1. The Physician must determine if the patient is an appropriate candidate for moderate sedation; if the patient is deemed to be at high risk due to medical condition(s) (ASA physical status > 3), the physician shall schedule the patient for monitored anesthesia care. Anesthesia may also be consulted for determination of classification.

2. A pre-procedure evaluation with emphasis on pertinent history and physical exam will be done and documented by the patient's physician (Appendix H) to include but not limited to:
    a. The present and past medical history, prior hospitalizations, previous anesthesia/sedation experience(s) and pertinent family history of prior anesthetics.
    b. Current medications and past drug history (including allergies and previous adverse drug reactions).
    c. Airway assessment through history and physical examination (See Appendix B)
    d. Physical examination to include a pulmonary cardiac and any other pertinent exam. Vital signs, height and weight should be documented.
    e. Patient classification as per the American Society of Anesthesiologists Physical Status classification (See Appendix C).

3. NPO recommendations (verbal or written).
The patient will be NPO for solids and milk at least six (6) hours prior to the procedure. Clear liquids can be taken up to four (4) hours prior to the procedure.
    a. **Clear liquids include only water, apple juice, soft drinks, Kool-Aid, Jell-0 and popsicles.**
    b. **Clear liquids *do not* include milk, any liquid with particulate matter, such as orange juice with pulp, hard candy or gum.**

    *Patients taking oral medications such as sedatives or antibiotics may take these medications with a sip of water, if recommended by the responsible physician.

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4. A plan for moderate sedation based on patient evaluation and the demands of the procedure should be documented in the patient's medical record.

5. Informed consent: It is the responsibility of the physician performing the procedure to inform the patient/guardian about the risks, benefits and alternatives to sedation as a component of the planned procedure, obtain the informed consent and document it in the patient's medical record.

6. There must be a reassessment of the patient immediately pre-procedure; to ensure no change in patient status has occurred since the patient was last evaluated. This reassessment must be documented on the Monitoring Form (see Appendix D).

B. Registered Nurse (RN)/Monitoring Nurse will:

1. Assess, verify and document:
    a. Presence of current history and physical
    b. Presence of signed/completed informed consent, including procedure and moderate sedation
    c. Baseline vital signs, including heart rate, cardiac rhythm, blood pressure, respiratory rate, and oxygen saturation
    d. Pain Assessment
    e. Fasting (NPO) status
    f. Level of sedation / responsiveness
    g. Placement of blood pressure cuff, pulse oximeter, and cardiac monitoring equipment.
    h. Administration of oxygen via nasal cannula/mask per physician order.
    i. Provides teaching to patient/family related to the procedure, medication administration and monitoring
    j. Obtain baseline values, including cardiac rate and rhythm, oxygen saturation, blood pressure, respiratory rate, level of consciousness and activity, and record a pre-procedure Modified Aldrete Score (see Appendix E).

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k. Universal Protocol- Implementation of Universal protocol should contain all the elements as required by current policy and include:

1. Pre-operative verification of the correct person, procedure and site
2. Marking of the operative site and laterality, where applicable
3. "Time Out" immediately before starting the procedure

l. Remain with the patient throughout the sedation.

VI. DURING THE PROCEDURE

A. Medication Administration

1. The physician ordering/directing the administration of sedation is expected to be aware of the dosage, adverse reaction and reversals of medications administered.

2. Patient's response will be monitored continuously after administration of each medication.

3. Atropine and reversal medications such as naloxone and flumazenil for all sedatives/analgesics used will be immediately available.

4. Range and dosage of medication will be determined by the physician and will be based on his/her direct observation of the patient receiving the sedation. Other medications may be appropriate to administer based on each individual patient's history and condition, and determined at the physician's discretion.

B. Patient Monitoring

1. Continuous assessment and documentation of vital signs at a minimum frequency of every 5 minutes, including respiratory rate, blood pressure and cardiac rate. Cardiac rhythm will be documented with an ECG strip prior to sedation. If arrhythmia occurs during procedure, a record shall be made for accurate diagnosis and treatment and physician should be notified immediately.

2. Oxygen saturation will be monitored continuously and recorded every 15 minutes.

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3. Continuous assessment of the level of sedation with documentation every 15 minutes according to the. Moderate aldarete score.

MODIFIED ALDRETE SCORE

Modified Aldarte Scoring System	Points	IN	15 min	30 min	45 min	OUT
Fully Aware Arousable on calling Not Responding	2 1 0					
Able to Breathe Deeply and/or cough Hypoventilation, limited breathing Apneic	2 1 0					
Moving 4 Extremities Moving 2 Extremities Not moving	2 1 0					
BP=20% of preanesthetic Level BP=20-50% of preanesthetic Level BP=50% or more of preanesthetic Level	2 1 0					
Able to Maintain O2 Saturation>92% on Room Air Needs O2 Inhalation to Maintain O2>90% O2 Saturation <90% even with Or Supplement						
	Totals					
	Initials					

4. The presence of monitor alarms will be confirmed and functioning.

C. Management Guidelines- Any changes in patient's conditions indicated below should be reported to the physician.

1. **Respiration** - Spontaneous respiration should be present throughout the procedure, with a minimum respiratory rate (RR) of 8/min.

2. **Oxygen Saturation** - Adequate oxygenation must be maintained. The lowest acceptable pulse oximeter reading (Sp02) is 92% in the usual patient. Sp02 of lower than 92% sustained for 5 minutes calls for interventions to improve oxygenation (relieving soft tissue obstruction, administering 02, etc.). Such interventions may be required at even higher Sp02 numbers in some patients.

3. **Hemodynamic Alterations** -Any significant alterations in blood pressure, heart rate or ECG rhythm should be reported to the physician immediately. Appropriate action should then be implemented and documented. It is the responsibility of the physician to appropriately intervene and/or request assistance from anesthesia personnel if needed.

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4. **Allergic Reactions** -Any physical manifestations (i.e. pruritus, skin rash, shortness of breath) suggestive of allergic reaction should immediately be reported to the physician. Appropriate action should then be implemented and response documented. If this occurs a SI is completed and noted in the medical record.

5. **Cardiovascular or Respiratory Arrest-** The RN should immediately call a Code and initiate CPR.

6. **Other Unusual Events** - Any unusual event such as restlessness, agitation, combativeness, severe slurred speech, non-arousal, pallor, cyanosis, diaphoresis, nausea, vomiting or aspiration, should be immediately reported to the physician for evaluation and recommendation of appropriate action.

D. Documentation

There shall be written documentation, in Nursing Monitoring Form or unit specific flow sheet, of all aspects of care rendered to the patient, include the following (if applicable:

1. Pre-procedural assessment and teaching (including baseline Modified Aldrete Score and level of comprehension).

2. Location of IV access site.

3. Dosage, route, and time of all drugs and agents administered, including local anesthesia infiltrated by the Physician.

4. Type and amount of IV fluids.

5. Oxygen therapy if administered (liters/minute and method of delivery).

6. Vital signs documented every five (5) minutes and during any significant event.

7. Oxygen saturation documented every 15 minutes.

8. Level of sedation assessment according to the Modified Aldrete Scoring System.

9. Pain level every five (5) minutes according to the 0-10 numeric scoring system (Appendix G).

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10. Management of any unusual events during the procedure (distress, significant change in vital 'signs, etc.)

11. Status of the patient upon completion of the procedure, as measured by the Modified Aldrete Score.

12. The area to which the patient was transported after the procedure.

13. Physician is responsible for writing orders for all medications administered.

VII. POST -PROCEDURE PHASE (IMMEDIATE RECOVERY)

A. All patients will be recovered in the Post Anesthesia Care Unit(PACU) or procedural area

B. All patients receiving sedation will be monitored for a minimum of 30 minutes past the completion of the procedure. If a reversal agent (naloxone, flumazenil) is used, the patient must be monitored for at least 1.5 hours after administration, due to the possibility of resedation.

C. The following parameters must be assessed and documented upon admission and then at least every 5 minutes until discharge criteria (Phase I) have been met:

1. Vital signs (blood pressure, heart rate, and respiratory rate) continuously.
2. Oxygen saturation
3. Cardiac rhythm
4. Level of consciousness
5. Activity

D. Patients will be observed continuously and not be returned to the POHA area until discharge criteria (Phase I) are met. Modified Aldrete Score of 8 or greater, or equal to pre-sedation Modified Aldrete Score.

E. Discontinue monitoring when the patient returns to the baseline pre-procedure physiologic and psychological status (except for patients who received a reversal agent - must be monitored for 1.5 hours after administration, even if they meet the Discharge Criteria).

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F. A written record must be maintained that includes the following elements:

1. IV fluids administered
2. Name and dosage of all drugs used including oxygen (time, route, and administered by whom)
3. Vital signs
4. Adequacy of ventilation (respiratory rate and effort, skin color)
5. Pain assessment
6. Level of consciousness
7. Mode of transportation
8. Any unusual events or post procedure complications, the management of those events, and the patients' response

VIII. DISCHARGE FROM PHASE I (PACU) TO PHASE II

A. Criteria for Discharge to Phase II:

1. The discharge criteria to Phase II- shall include:
    a. Modified Aldrete Score of 8 or greater, or equal to pre-sedation Modified Aldrete Score.
    b. Vital signs are stable and/or vital signs have returned to pre-sedation level.
    c. Swallow, cough and gag reflexes are present. If topical pharyngeal anesthesia has been used, NPO order to be maintained until swallow, cough and gag reflexes is present.
    d. There is no protracted nausea or vomiting.
    e. Patient is appropriately responsive and oriented, similar to patient's preprocedure status.
    f. Patients cannot be discharged from the Phase I with persistent pain; if persistent pain is present, the MD must be called to assess the patient.
2. Patient is evaluated for discharge and an order written by the physician.
3. If the patient care during Phase II is a different nurse than Phase I, Nurse-to-Nurse Hand off communication report is given.

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4. Patients are monitored and discharged from the Phase II according to policy and procedure, "Admission and Discharge from Ambulatory Surgical Center (Phase II)"

ATTACHMENTS:

A. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, ASA approved October 13, 1999 and amended October 27, 2004)

B. Airway Assessment and Anesthetic History

C. ASA Physical Status Classification

D. Monitoring Form

E. Modified Aldrete Score

F. Suggested Drugs for Sedation

G. Ramsey Sedation Scale

REFERENCES:

AORN Ambulatory Surgery Standards; AORN LACDHS Best Practices on Sedation; JC Standards; CMS

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