Bayshore Community Hospital

A Division of Meridian Hospitals Corporation

Moderate Sedation for Non-Anesthesiologists

I. **Policy:** This policy will explain the privileging and guidelines for administration or directing the administration of moderate sedation/analgesia by non-anesthesiologists.

II. **Purpose:** This policy was designed with patient safety in mind and will lead to optimal conditions for a successful and efficient diagnostic or therapeutic procedure. This policy will be under the direction of the Chair of the Department of Anesthesiology or his/her designee. The privileging aspect of this policy is not applicable to emergency room physicians who are board certified in Emergency Medicine.

Anesthesia and Levels of Sedation Defined

"Anesthesia" involves the administration of medication to produce a blunting or loss of:

- Pain perception (analgesia);
- Voluntary and involuntary movements;
- Autonomic function; and
- Memory and/or consciousness

In contrast, "analgesia" involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness, but does not perceive pain to the extent that may otherwise prevail.

Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications.

a) Minimal Sedation (anxiolysis) – This is a drug-induced state during which patients respond normally to verbal commands, although cognitive function and coordination may be impaired. This is not anesthesia.
b) Moderate Sedation/Analgesia – A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patient airway, and spontaneous ventilation is adequate. Additionally, cardiovascular function is usually

maintained. Since the response of patients vary a higher level of assessment and monitoring of these patients is required.

c) 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. Because of the potential for the inadvertent progression to general anesthesia, deep sedation may only be administered by a practitioner who is 1) qualified to administer anesthesia or 2) board certified in Emergency Medicine.
d) Regional Anesthesia – the delivery of anesthesia medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinal and other central neuraxial nerve block, is used when a loss consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Given the potential for conversion and extension of regional to general anesthesia in certain procedures, regional anesthesia may only be administered by a practitioner who is qualified to administer anesthesia.
e) General Anesthesia - a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support 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. General anesthesia is used for those procedures when loss of consciousness and/or muscle relaxation is required for the safe and effective delivery of surgical services.

III. Procedure:

Credentialing Criteria for Moderate Sedation

Bayshore Community Hospital Medical Staff Office staff will administer the daily activity of moderate sedation privileging. The Chair of the Department of Anesthesia will oversee the process. In order for a physician to be granted privileges for the administration of sedation/analgesia, the following criteria must be met:

a) The physician must be on the medical staff of BCH and be in good standing. For new physicians to BCH, a letter from their residency director or prior department chairperson must be submitted. A minimum of three cases will be reviewed either concurrently or

retrospectively by the Chair of the Anesthesia Department or his/her designee as part of their Focused Professional Practice Evaluation (FPPE).

b) Completion of the on line Moderate Sedation module and taking and passing the post test (required at initial credentialing and every two years). A minimum passing score of 80% is required;

The training module can be found at http://meridianhealth.sedationelearning.com/login.php;

c) Maintenance of current ACLS certification.

If at any time the certification or test expires, the practitioner's clinical privileges for moderate sedation shall be immediately "put on hold" and may be immediately reinstated upon presentation of required document(s).

d) Members of the Emergency Department who are Board Certified in Emergency Medicine are exempt from maintaining current ACLS and completion of the module post- test; and
e) Members of the Department of Anesthesiology are exempt from completion of the module and post-test but are required to maintain current ACLS certification
f) Members of the Department of Anesthesiology, Section of Pain Management must complete the module and post- test and maintain current ACLS certification.
g) Members of the Department of Pediatrics may maintain PALS or NRP (for Neonatologists) certification in lieu of ACLS certification and are required to complete the module and take and pass the post test.
h) All providers must be familiar with the medications being used with respect to dosage, administration route, adverse reactions, methods of reversals, and interventions.
i) All providers must be able to recognize and correct an obstructed airway, assess the patients physiological status utilizing cardiac monitoring or rate and rhythm, oxygen saturation, blood pressure, and level of consciousness.

Patient Assessment and Criteria for 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) The patient must be screened for potential risk factors for any pharmacological agents selected. The decision on which agent to use will be based on the goals of sedation, the type of procedure being performed, and the age and physiologic condition of the patient.
c) Risk Assessment: 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 for each case should be assessed and documented in the pre-procedure note. The following patients are at risk during moderate sedation:

a. Elderly Patients (>70 years of age)
b. Pediatric Patients
c. Morbidly obese patients
d. Patients at increased risk of aspiration (full stomach, trauma, and hiatal hernia)
e. Patients with concomitant diseases, especially cardiovascular disease and pulmonary diseases
f. Pregnant patients
g. Patients with a known difficult intubation
h. Patients with neck injury, facial trauma, radiation to head and neck or other anomalies

d) All patients will be pre-screened by the ordering physician for risk factors utilizing the ASA (American Society Anesthesiologists) Physical Status Classification Scale, as documented on the pre-procedure notes.
e) All patients appropriate for moderate sedation by a non-anesthesiologist are classified ASA III or less.
f) All patients who are ASA IV or ASA V or who present special considerations (i.e. mental disorders, psychosis, dementia, drug dependency, and alcohol abuse requiring greater than normal doses for moderate sedation) will require consultation and possible participation by the Anesthesia Department.
g) The physician providing the moderate sedation must call an anesthesiologist if the patient's ASA physical status is ASA IV or ASA V. A telephone consultation and verbal acknowledgment are necessary as to whether they may proceed or whether an anesthesia provider should be present for the procedure. This conversation will be documented in the medical record.
h) A medical history and physical examination must be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. Any changes in the patient's

condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. These entries must be dated, timed, and authenticated.

ASA Physical status Clarification

Class I	Normal healthy patient. No organic, physiologic, biochemical, or psychiatric disturbance
Class II	A patient with mild to moderate systemic disturbance: may or may not be related to the reason for the procedure (e.g. controlled hypertension, diabetes, or chronic bronchitis).
Class III	A patient with severe systemic disease that is not incapacitating (e.g. poorly controlled hypertension, heart disease, insulin dependent diabetes, or pulmonary insufficiency).
Class IV	A patient with constant life-threatening systemic disturbance.(e.g. cardiac failure, major organ insufficiency).
Class V	A moribund patient not expected to survive 24 hours with or without Intervention (e.g.intracranial hemorrhage in a comatose state).
Class VI	A declared brain-dead patient whose organs are being removed for donor purposes.
E is added	If the procedure is performed as an emergency.

Recommended NPO Periods for Non-Pregnant Healthy Patients

a) For non-emergent cases, a licensed practitioner with conscious sedation privileges, weighing the risks and benefits of the procedure on a case-by-case basis should make the decision regarding NPO status.
b) Gastric emptying may be influenced by many factors, including anxiety, pain, abnormal autonomic function (e.g.diabetes), pregnancy, and mechanical obstruction. Therefore, the suggestions listed do not guarantee that complete gastric emptying has occurred.
c) Recommended NPO periods:
    a. Clear liquids - 2-3 hours (e.g. Water, fruit juices without pulp, clear tea, black coffee, Gatorade)
    b. Light meal - 6 hours (e.g. Toast and clear liquids)
    c. Regular meal - 8 hours (any meat, fatty or fried foods which will delay gastric emptying)
    d. NPO After midnight
d) High-risk patients should have the standard 8-hour fasting prior to sedation when possible. These conditions may include, but are not limited to:
    a. Obesity
    b. Diabetes

c. Hiatal hernia
d. Gastroesophageal reflux
e. Ileus or bowel obstruction
f. Possible difficult airway management

e) When proper fasting has not been ensured, or in the case of a valid emergency, the increased risks of sedation shall be weighed against its benefits and the lightest level of effective sedation employed.
f) An emergency procedure may require intubation to protect the patient's airway against aspiration prior to sedation

Recommended NPO Period for Pregnant Patients

a) Pregnant patients should have the standard 8-hour fasting prior to sedation when possible.

Locations for Moderate Sedation

a. Moderate Sedation may be performed in the following areas:
- Diagnostic Imaging
- Emergency Department
- Special Procedure Rooms
- Cardiac Cath Lab
- Intensive Care Units

Monitoring and Resuscitation Equipment

a) The following equipment, in good working order, must be immediately available and patient age appropriate:
   a. Pulse oximeter
   b. Non-invasive blood pressure cuff
   c. Cardiac monitoring equipment
   d. Suction with appropriate suction catheters
   e. Oxygen supply with self- inflating bag and mask
   f. Crash cart and defibrillator (including laryngoscope and blades, endotracheal tubes, oral/nasal airways,anticholinergic, pressor agents, and drug-specific reversal agents Naloxone hydrochloride/Narcan and Flumazenil/Romazicon)
   g. ETC02 Monitor if feasible

IV. PERFORMANCE OF PROCEDURE

Pre-procedure preparation:

a) Physician Responsibility:

a. Obtain an informed consent for the proposed procedure and the administration of moderate sedation.
b. Complete the sedation/analgesia pre-procedure note. This note includes:

    1. Previous sedation/anesthesia problems
    2. ASA Physical Status
    3. Mallampati Classification
    4. Plan for moderate sedation
    5. Post-sedation plan
    6. Immediate reassessment prior to the administration of moderate sedation

c. Write pre-procedure orders as needed, including specific drug, dose, and route of administration (Physician Order Sheet).
d. Perform time out immediately prior to the procedure.

Intra-Procedure

a) The patient is to be continuously monitored and evaluated throughout the procedure using an EKG, pulse oximeter, blood pressure cuff, ETCO2 monitor if feasible, and patient interaction to establish a levelof consciousness and tolerance of procedure, sedation and pain scale.
b) The first dose of medication must be administered by the physician. Supplement doses may be administered by a qualified RN as directed by the physician.
c) Agent and dosage must be documented.
d) The registered nurse monitoring the patient should not be part of the procedural team or used as an assistant.
e) All vital signs and assessments are to be documented not less than every 5 minutes on the Moderate Sedation Flow Sheet.
f) The registered nurse monitoring the patient will **report immediately** to the physician any sudden and/or significant changes in monitoring parameters and document on the Moderate Sedation flow sheet. For the adult and children 10 years and older this would include:
    a. Respiratory rate less than 10 or greater than 24 per minute
    b. Heart rate plus or minus 15 per minute from baseline
    c. Systolic blood pressure or diastolic blood pressure plus or minus 15 mm Hg from baseline
    d. 02 saturation equal to or less than 93% despite administration of supplemental 02
    e. Modified Aldrete score of less than 9.
    f. The patient's airway status must be constantly assessed and patency maintained throughout the procedure. An obstructed airway must be dealt with immediately and if unable to restore ventilation, the procedure should end at once.

Post-Procedure

a) The physician will assess the patient postoperatively and complete the **Post-Moderate Sedation Evaluation.** This includes respiratory function, mental status, pain, nausea and vomiting, hydration status, cardiovascular function, airway, vital signs including temperature, and the patient's ability to participate in the evaluation.
b) The physician will write specific discharge orders. The recovery period extends from completion of the procedure until a responsible provider documents that the patient has sufficiently recovered from the effects of the medication, including level of consciousness and vital signs using the Modified Aldrete Score. A responsible adult must accompany outpatients home with written discharge instructions.

QUALITY ASSURANCE RISK MANAGEMENT

All of the following events shall be referred to the Department of Anesthesia Quality Assurance Committee (or other performance improvement committee) for evaluation:

a. Unplanned admission
b. Cardiac/Respiratory arrest
c. Use of reversal agents
d. Use of assistance with ventilation (ambu bag)
e. Prolonged periods of oxygen desaturation (<85% for 3 minutes)
f. Failure of the patient to return to with 20% of pre-procedure vital signs
g. Use of doses of sedatives/analgesics outside the recommended dosages

Monitoring and evaluation of moderate sedation procedures performed by non-anesthesiologists will be assessed on a monthly basis and will be integrated into the hospital performance improvement program. Each area where moderate sedation by non-anesthesiologists is administered will use the moderate sedation PI monitoring tool. Adverse outcomes will be reviewed by the Anesthesia Department as part of an ongoing PI/QA program.

Approved by Medical Executive Committee: 2/07

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