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Owner: CNO/CMO	Governing Board Approval Date:	6-24-15	

I. SCOPE: This policy applies to Saint Francis Hospital, its employees, medical staff, contractors, patients and visitors regardless of service location or category of patient. This policy pertains to all patient care settings within the hospital.

II. PURPOSE: To provide guidelines and a standard of care for all patients receiving sedation/analgesia for diagnostic, noninvasive and invasive procedures.

III. DEFINITIONS:

A. "**Level(s) of Sedation**" means the various drug-induced states along a sedation continuum that allows the patient to tolerate procedures while maintaining adequate respiratory and cardiovascular function. It is variable and depends on each patient's response to various drugs. Levels of sedation may range from minimal sedation to anesthesia. The four levels of sedation are defined as follows:

1. **Minimal sedation (anxiolysis):** A drug induced state in which the patient responds normally to verbal commands. Cognitive function and coordination may be impaired, but airway reflexes and ventilatory and cardiovascular functions should remain unaffected. Examples of minimal sedation may include preprocedure and preoperative medications.
2. **Moderate sedation/analgesia (conscious sedation):** A drug induced depressed level of consciousness in which the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and protective reflexes; spontaneous ventilation is adequate. Cardiovascular function is also usually maintained. This level of sedation is often used for short procedures and diagnostic exams.
3. **Deep sedation/analgesia:** A drug induced depressed level of consciousness in which the patient cannot be easily aroused but responds purposefully to repeated or painful stimulation. The ability to maintain independent ventilatory function and a patent airway may be impaired. The patient may need assistance to maintain a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

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4. **General Anesthesia:** Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. General anesthesia is a drug-induced 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.

- B. **"Protective Reflexes"** means the patient's ability to manage secretions without aspiration.
- C. **"Monitored Anesthesia Care"** means a specific anesthesia service in which an anesthesiologist participates in the care of a patient undergoing a diagnostic or therapeutic procedure.
- D. **"Mallampati Score"** (Appendix 1): means a clinical assessment tool used to assess the ease of obtaining an airway.
- E. **"Aldrete Score"** (Appendix 2) means a measurement of recovery after anesthesia that includes gauging consciousness, activity, respiration, and blood pressure.
- F. **"Discharge Criteria"** means that a patient demonstrates an Aldrete Score of 9 or 10 (or at least pre-procedural score).

IV. POLICY:

A. This policy applies to all hospital areas that administer Moderate Sedation. Areas and conditions not included are:

- Pain management
- Seizure activity
- The use of sedation in the general operating room, ambulatory surgery center and post anesthesia care unit.
- The sedation of mechanically ventilated patients.

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- The patient who has an anesthesia provider administering sedation, which includes patients receiving monitored anesthesia care (MAC), deep sedation, and general anesthesia.

B. The following was approved by the American Society of Anesthesiologists:

- 1) Non-anesthesiologist Sedation Practitioners (a licensed physician) is qualified to administer anesthesia under State law; who has not completed postgraduate training in anesthesiology but is specifically trained to administer personally or to supervise the administration of moderate sedation.
 - a) These recommendations do not lead to the granting of privileges to administer general anesthesia. The granting, reappraisal and revision of clinical privileges will be awarded on a time limited basis in accordance with rules and regulations of the health care facility, its medical staff, organizations accrediting the health care facility, and relevant local, state and federal governmental agencies.
- 2) Any professional who administers moderate sedation must be accompanied by an additional licensed health care professional who is able to assist in monitoring the procedure.
- 3) A knowledge based test is necessary to objectively demonstrate the knowledge of concepts required to obtain privileges.
- 4) Appropriate methods for obtaining informed consent through pre-procedure counseling must be performed.
- 5) The non-anesthesia provider must complete the moderate sedation assessment plan including assessment of the airway for anatomic and mobility characteristics suggestive of potentially difficult airway management. The non-anesthesiologist sedation practitioner will be able to recognize those patients whose medical condition requires that sedation needs to be provided by an anesthesia professional, such as the following:
 - a) morbidly obese patients;
 - b) elderly patients;
 - c) pregnant patients;
 - d) patients with severe systemic disease;
 - e) patients with obstructive sleep apnea; &

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- f) or patients with delayed gastric emptying.
 - i) Assessment of the patient's risk for aspiration of gastric contents must be performed. In urgent, emergent or other situation where gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining:
 - (1) The target level of sedation.
 - (2) Whether the procedure should be delayed.
 - (3) Whether the sedation care should be transferred to an anesthesia professional for the delivery of general anesthesia with endotracheal intubation.
- 6) The non-anesthesiologist practitioner must demonstrate the ability to reliably perform the following:
 - i) Bag-valve mask ventilation.
 - ii) Insertion and use of oro- and nasopharyngeal airways.
 - iii) Insertion and ventilation through a laryngeal mask airway.
 - iv) Direct laryngoscopy and endotracheal intubation.
- 7) Monitoring of physiological variables, including the following:
 - i) Blood pressure.
 - ii) Respiratory rate.
 - iii) Oxygen saturation by pulse oximetry with audible variable pitch pulse tone.
 - iv) Capnographic monitoring. The non-anesthesiologist practitioner shall be familiar with the use and interpretation of capnographic waveforms to determine the adequacy of ventilation during deep sedation.
 - v) Electrocardiographic monitoring. Education in electrocardiographic (EKG) monitoring will include instruction in the most common dysrhythmias seen during sedation and anesthesia, their causes and their potential clinical implications (e.g. hypercapnia), as well as electrocardiographic signs of cardiac ischemia.
 - vi) Depth of sedation.
- 8) Documenting the drugs administered, the patient's physiologic condition and depth of sedation at five (5) minute intervals throughout the period of sedation and analgesia.

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- 9) Monitoring the patient through the recovery period and the inclusion of specific discharge criteria.
 - 10) The non-anesthesiologist practitioner will be certified in Advanced Cardiac Life Support (ACLS). When administering to pediatric patients, the non-anesthesiologist practitioner will be certified in Pediatric Advanced Life Support (PALS).
 - 11) Required participation in a quality assurance system to track adverse outcomes, and unusual events including respiratory arrests, use of reversal agents, prolonged sedation in recovery process, larger than expected medication doses, and occurrence of general anesthesia, with oversight by the Director of Anesthesia services or their designee.
 - 12) The Director of Anesthesia Services with oversight by the facility governing body will determine the number of cases that need to be performed in order to determine independent competency in deep sedation.
- C. The physician performing the procedure will complete the appropriate sedation documentation in the medical record.
- D. A Registered Nurse managing the care of patients during moderate sedation/analgesia must have demonstrated competencies and will not have any other responsibilities during the monitoring and care of the patient during the procedure.
- E. Patients with an ASA score of three (3) or less may be monitored by an RN with demonstrated Moderate Sedation Competencies. Patients with a score of four (4) or greater require an Anesthesia Consult and monitored anesthesia care.
- F. Pharmacologic agents and reversal agents will be immediately available in the sedation area and only administered in the sedation location. Guidelines for the dosage of common pharmacological agents used at Saint Francis Hospital - Bartlett is provided in Appendix 3.
- G. Emergency equipment must be immediately available and appropriate for the patient's age and size including but not limited to:
- Bag-valve-mask device.

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- Appropriate sizes of airway management equipment (e.g., oral and nasal airways, endotracheal tubes, masks, and laryngoscopes).
- Suction and supplies.
- Monitors able to display:
 - Blood pressure intermittently
 - Oxygenation by pulse oximetry continuously
 - Heart rate and rhythm by ECG continuously
- Supplemental oxygen and delivery devices.
- Emergency crash cart as approved by the hospital including a defibrillator.
- Telephone or other device capable of calling for assistance in an emergency.

H. Post procedure monitoring will be completed in a designated recovery or procedure area and will include emergency equipment outlined above

V. PROCEDURE

- A. Pre-procedure Care will include baseline vital signs assessed and documented before administering sedation/analgesia.
- B. During sedation, the following will be continuously monitored/observed and documented in the moderate sedation record at five (5) minute intervals:
1. Vital Signs: BP, P, RR, O2 saturation
 2. Activity and neurologic status as defined by Aldrete Score
 3. Pain
- C. Post procedure monitoring will include VS, pain assessment, and Aldrete Score every ten (10) minutes times three and then every fifteen (15) minutes until discharge criteria are met.
- D. If reversal agents are used in the area where moderate sedation was administered the patient must be monitored by a Registered Nurse for one (1) hour.
- E. If reversal agents are used, patients must be observed prior to discharge from the hospital for two (2) hours after the last dose of an antagonist to ensure that respiratory depression does not occur.

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- F. Discharge instructions will be printed and the person responsible for the patient shall receive printed instructions prior to discharge from the hospital that include:
1. Information about expected behavior following sedation.
 2. Instructions for eating.
 3. Warning signs of complications.
 4. Special instructions in case of emergency.
 5. A telephone number to contact the medical service responsible for the patient's care that is available twenty-four (24) hours per day.
 6. Instructions to avoid driving, operating machinery, drinking of alcoholic beverages, and making important decisions for twenty-four (24) hours.

- G. A copy of the signed discharge instructions will be placed in the medical record.

- H. Responsible Person

The **Chief Nursing Officer** is responsible for the nursing staff and the **Chief Medical Officer** is responsible for medical staff, each ensuring that all individuals adhere to the requirements of this policy, that these procedures are implemented and followed at Saint Francis Hospital - Bartlett and that instances of non-compliance with this policy are reported to the appropriate individual for oversight, i.e. **Chief Nursing Officer** for nursing staff non-compliance and the **Chief Medical Officer** for medical staff non-compliance.

- I. Auditing and Monitoring

The Quality Department is responsible for performing a focused review of all moderate sedation areas to ensure compliance with this policy and procedure. Non-compliance/adverse events should be reported via an electronic occurrence report.

- J. Enforcement

All employees and non-anesthesia providers whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management pursuant to all applicable

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policies and procedures, up to and including termination.

VI. REFERENCES:

Advisory on Granting Privileges for Deep Sedation to Non- Anesthesiologist Sedation Practitioners.

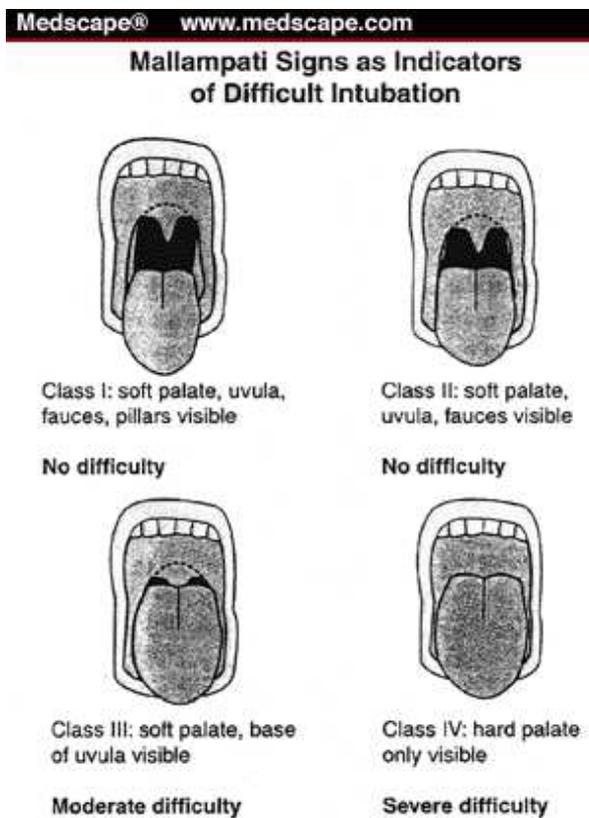
VII. ATTACHMENTS:

- Appendix 1: Mallampati Score (1 page);
- Appendix 2: Aldrete Scoring System (1 page); &
- Appendix 3: Recommended Drugs and Reversals for Moderate Sedation (2 pages).

Appendix 1: Mallampati Score

Scoring is as follows:

- Class 1: Full visibility of tonsils, uvula and soft palate
- Class 2: Visibility of hard and soft palate, upper portion of tonsils and uvula
- Class 3: Soft and hard palate and base of the uvula are visible
- Class 4: Only Hard Palate visible



Appendix 2: Aldrete Scoring System

The Aldrete Scoring System is located on the back of the first page of the moderate sedation record. Each parameter is rated on a scale of 0-2, the latter being the higher score.

- A. **Activity:** An evaluation of the muscular activity of the body assessed by observation.
- 2 - Indicates ability to move all four extremities voluntarily or on command. Can lift head and has controlled movement. Exceptions: patients with a prolonged block such as Marcaine may not move an affected extremity for as long as 18 hours; patients who were immobile preoperatively.
 - 1 - Move two extremities voluntarily or on command and can lift head.
 - 0 - Unable to lift head or move extremities voluntarily or on command.
- B. **Respiration:** An evaluation of respiratory efficiency. No complicated apparatus or sophisticated physical tests are utilized.
- 2 - Can take a deep breath and cough well; has normal respiratory rate and depth.
 - 1 - Labored or limited respirations. Breathes by self but has shallow, slow respirations; may have an airway device.
 - 0 - Apneic; condition necessitates ventilator or assisted respiration.
- C. **Circulation:** A measurement of cardiovascular hemostasis and a comparison with previous blood pressures excluding intra-operative.
- 2 - Stable B/P and pulse. B/P 20mm/Hg of preanesthetic level (minimum 90 mm/Hg systolic). Exception: anesthesia provider may release patient after drug therapy.
 - 1 - B/P within 20-50 mm/Hg of pre-anesthetic level.
 - 0 - Has abnormally high or low blood pressure: B/P 50 mm/Hg pre-anesthetic level.
- NOTE: Great differences in diastolic pressure should be noted.
- D. **Neurologic Status:** Ability of patient to answer simple questions and follow verbal commands - verbal stimuli only (unless patient is deaf).
- 2 - Awake and alert: oriented to time, place, and person.
 - 1 - Responds to verbal stimuli but drifts off to sleep easily.
 - 0 - Not responding or responding only to painful stimuli.
- E. **Oxygen Saturation:**
- 2 - Able to maintain oxygen saturation greater than 92% on room air.
 - 1 - Needs oxygen inhalation to maintain oxygen saturation greater than 90%.
 - 0 - Oxygen saturation less than 90% even with oxygen supplement.

The Aldrete Score must be documented on the moderate sedation nurses notes. The time of the evaluation and the score are placed in the appropriate boxes.

Appendix 3: Recommended Drugs and Reversals for Moderate Sedation (Page 1 of 2):

***RE: OPIOIDS**

DRUG	ROUTE	ADULT DOSAGE RANGE	ONSET	DURATION	NOTES/MONITORING
Fentanyl (Sublimaze)	IV	25-100 mcg give over 1-2 mins., repeat every 1-15 mins.	1-5 mins.	30 mins.	Rapid I.V. injection may cause chest wall rigidity, resp. depression, and bradycardia.
Hydromorphone (Dilaudid)	IV, IM, PO	0.5-2 mg. IV titrated slowly over 2-5 minutes	5 mins.	2-3 hrs.	Hydromorphone is 7-10 times more analgesic than Morphine I.V.
Morphine	IV	0.5-2 mg. titrated	2-5 mins.	4-5 hrs.	Monitor respiratory rate and depth continuously; respiratory depression may occur. Hypotension is possible especially if patient is hypovolemic.
<u>Reversal Agent</u> Naloxone (Narcan)	IV	0.2 mg IV slowly, may repeat to desired effect.	1-2 mins.	As short as 30 mins.	If no response look for other causes. Duration depends on dose and route administered.

***RE: BENZODIAZEPINES**

DRUG	ROUTE	ADULT DOSAGE RANGE	ONSET	DURATION	NOTES/MONITORING
Diazepam (Valium)	IV	1-5 mg. slowly over 2 mins. May repeat every 15 mins. times 4 doses.	30 mins.- 10 mins.	2-8 hrs.	Give IV slowly over 2 mins.
Midazolam (Versed)	IV	Initial dose: 0.5-2mg. slowly. May repeat dose every 2-3 mins. as needed; usual total dose of 2-5 mg.	1-5 mins.	2.5 hr.	Give IV slowly over 2 mins. in elderly, debilitated or chronically ill patients, limit initial dose to 1 mg. Must wait 2-3 mins. for effect. May potentiate adverse effects of opioids. Reduce dose in patients with compromised renal or hepatic function.
<u>Reversal Agent</u> Flumazenil (Romazicon)	IV	0.2 mg. increments every 1 min. to maximum cumulative dose of 1 mg; for re-sedation repeat doses at 20 min. intervals; maximum 3 mg. in 1 hr.	30 secs.- 2 mins.	40-80 mins.	Does not reverse respiratory depression, even in alert patients; re-sedation may occur in patients who have received longer acting benzodiazepines.

Appendix 3: Recommended Drugs and Reversals for Moderate Sedation (Page 2 of 2):

Drug	Patient Population	Dose & Route	Onset	Duration	Special Considerations	Reversal
Etomidate	Children	----	5-15 seconds	3-15 minutes	Not recommended in children under 10 y of age	There is no known antidote for overdose.
	Adults	0.1- 0.15 mg/kg IV over 30 to 60 seconds, followed by 0.05 mg/kg every 3 to 5 minutes as needed for sedation maximum total dose of 0.6 mg/kg				
Ketamine	Children	PO: 5-8 mg/kg PO (mixed in cola or other beverage) given 30 minutes before procedure	30-40 seconds	5-10 minutes	Hepatic insufficiency; consider dose reduction due to longer half-life	Antidote: None.
		IV: Usual dosage is 0.5—1 mg/kg IV Do not exceed 0.5 mg/kg/min or administer any dose faster than over 60 seconds				
	Adults	0.2 to 0.75 mg/kg IV over 1 to 2 min				
Propofol	Children	0.5-1 mg/kg IV followed by 0.5 mg/kg every 3 to 5 minutes as needed for sedation	10-50 seconds	3-10 minutes	Allergies to eggs, egg products, soybeans, soy products, or peanuts The manufacturer recommends that doses in elderly patients be reduced by 20% and that the drug be administered more slowly (over 3-5 minutes).	There is no specific antidote for Propofol.
	Adults	0.5-1 mg/kg IV followed by 0.5 mg/kg every 3 to 5 minutes as needed for sedation				