Policy Statement

It shall be the policy of St. Joseph's/Candler (SJ/C) to provide guidelines for the administration of Moderate/Procedural Sedation and Analgesia and/or monitoring of patients receiving Moderate/Procedural Sedation and Analgesia as recommended by the Department of Anesthesia and the American Society of Anesthesia.

Definition of Terms

Four Levels of Sedation and Anesthesia:

American Society of Anesthesiologists (ASA) – The physical status classification is rated ASA I, ASA II, ASA III, ASA IV, or ASA V. The ASA classification system is useful in predicting perioperative risks.

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.

Deep Sedation/Analgesia - 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.

Invasive Procedure – Invasive Procedures involve the puncture or incision of the skin, insertion of an instrument, or insertion of foreign material into the body. Invasive Procedures may be performed for diagnostic or treatment-related purposes.

Licensed Independent Practitioner (LIP) – physician or any other individual permitted by law and by the Hospital to provide care and services without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges.

Minimal Sedation - A drug-induced state during which patients respond normally to verbal

commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate/Procedural Sedation and 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 patent airway, and spontaneous ventilation is adequate.

Qualified Licensed Independent Practitioner (LIP) - A LIP (M.D, D.O., D.D.S., D.M.D.) who has fulfilled the criteria for privileges for Moderate/Procedural Sedation and has been approved and granted the privileges through the Medical Staff credentialing process.

Qualified Staff - Must be an ACLS/PALS//NRP provider as indicated by the patient's age. The co-worker has met competency requirements to include education and applicable licensure, and/or professional registered status.

Qualified Trainer - This individual must be a staff RCP or RN who has successfully completed airway management training.

Time Out - All Invasive Procedures that expose patients to more than minimal risk will have a "Time Out". The Time Out is performed prior to the procedure will include a final verification of the correct patient, medication including dose, procedure, site, and, as applicable, implants and any special equipment. Refer to **Procedural Site Verification & Marking (Time Out), Patient Care Policy #6109-PC.**

Procedure

A. LIP Pre-Procedure Assessment and Process:

A medical history and assessment will be completed and current documentation available on all patients receiving Moderate Sedation. The LIP will determine and document that the patient is an acceptable candidate for sedation. Consideration is given to the type of procedure, the goals of sedation, risk factors related to sedating agents, the age and condition of the patients, and co-morbidity. Documentation of a baseline health assessment:

1. Informed consent is obtained for the administration of Moderate/Procedural Sedation and Analgesia and for the procedure, if applicable. Patients (or their legal guardians in the case of minors of a legally incompetent adult) will be informed of and agree to the administration of sedation/analgesia: the benefits, risks, and limitations associated with this therapy, as well as possible alternatives.
2. Vital signs.
3. Results of labs/x-ray ordered.
4. Health history:
    a. Age of patient.
    b. History of present illness.
    c. Past medical and surgical history.
    d. Allergies.

e. Previous adverse drug responses with Anesthesia and/or sedation.
f. Current medications.
g. Review of systems.
h. Disease, disorders, abnormalities.
i. Prior hospitalizations.
j. Results of physical exam, reflects:
(1) Pulmonary and cardiac examination;
(2) Risk assessment, including ASA classification;
(3) Plan of care for sedation; and
(4) Patent airway.

5. Procedure diagnosis/impression.
6. A reassessment of the patient prior to the procedure to be deemed an appropriate candidate for moderation sedation is done with the LIP's signature, date, and time recorded.
7. The LIP determines ASA Classification prior to the procedure. Patients who are ASA Classification IV or greater present special problems that require additional and individual consideration. A consult for an Anesthesiologist is considered subject to LIP's judgment for classes IV & V.
8. "Timeout" is documented in the electronic medical record (EMR).

B. Staff Pre-procedure Assessment and Process:
1. RN will supervise perioperative nursing care and an RN must complete and document the pre-procedure assessment in the EMR.
2. RN will verify:
a. Presence of informed consent;
b. History and physical are present on the chart prior to the procedure;
c. Responsible adult is available to drive the outpatient home;
d. A patent venous access is present;
e. The patient is identified by using the name and medical record number or account number and comparing it to one other document, examples are the patient identification band, MAR, face sheet, or specimen label. If the patient cannot speak, identification will be verified by one of the following individuals in the following order of priority: a durable power of attorney for healthcare, spouse, adult child, parent, other family members, individual involved in the plan of care or authorized agent. If patients have the same name, verification will be obtained by using the medical record number or account number and date of birth;
3. Significant variations in physiological parameters will be reported to the LIP prior to, during, and after the procedure.
4. Baseline Vital Signs (blood pressure, pulse, respirations, and oxygen saturation (SaO2) via pulse oximetry) are obtained and documented prior to the procedure.
5. Documentation of baseline includes:
a. Procedure planned;
b. Pre-procedure assessment;
c. Current medications;
d. Surgical and Anesthesia history;
e. Weight;
f. The last food/liquid ingestion;

g. Pain level;
h. Sedation level (level of consciousness);
i. Pre-procedure education; and
j. Cardiac rhythm.

6. Medication(s) ordered by the LIP will be documented on the procedure. The Qualified Staff member responsible for the administration and/or monitoring of the medication must review the appropriate dose, route, onset of action, duration of action, adverse effects, side effects, and appropriate actions during the pre-procedure period.
7. Appropriate equipment for care and resuscitation is available for monitoring vital signs including cardiac monitoring and oxygenation. A code cart and reversal agents are available where the procedure will be performed.
8. Minimum of two personnel (in addition to the LIP performing the procedure) are present during the procedure using Moderate/Procedural Sedation. The Qualified Staff member monitoring the patient will have no other responsibilities other than managing, monitoring, and administration of Moderate/Procedural Sedation and Analgesia. Changes in the patient's condition will be reported to the LIP.
9. The following applies whenever an anesthetic agent (Propofol, Etomidate, or Neuromuscular Blocking Agents) are to be used for Moderate/Procedural Sedation:
    a. Agents used as anesthetics agent: Propofol, Etomidate, and Neuromuscular Blocking Agents. An anesthetic agent should be administered only by persons trained and credentialed in the administration of general Anesthesia, or by LIPs who are trained and credentialed in emergency and critical care medicine, proficient in advanced airway management and life support and who are not simultaneously involved in these surgical or diagnostic procedures (unless the patient is intubated and mechanically ventilated).
    b. In the event that the LIP is involved in a surgical or diagnostic procedure (unless the patient is intubated and mechanically ventilated) a respiratory therapist will remain at bedside to monitor the patient's airway, breathing, and ETCO2 along with a nurse who will monitor the patient's vital signs or changes in the pre-anesthetic assessment.
    c. Continuous EtCO2 monitoring is used throughout the procedure until the patient returns to baseline status or meets discharge criteria.
    d. It is not within the scope of practice of the registered nurse (RN) who is not a Certified Registered Nurse Anesthetist (CRNA) to administer agents used as anesthetics for sedation, including Propofol (American Association of Nurse Anesthetists – American Society of Anesthesiologists Joint Statement Regarding Propofol Administration, 2004). This includes the non-intubated patient undergoing procedures, including but not limited to, invasive cardiology, invasive radiology, endoscopic gastrointestinal procedures, invasive bronchoscopy, and emergent procedures.

C. Intra-Procedure:

1. LIP is present to provide oversight of patient care and respond to any change in the patient's condition during Moderate/Procedural Sedation.
2. Qualified Staff not involved in the procedure must be present to administer medications and monitor patients.
3. Physiological parameters are continuously monitored and vital signs are documented at least every five minutes during the procedure to include:
    a. Blood pressure;

b. Respiratory rate;
c. Oxygen saturation (Sa02) via pulse oximetry;
d. Capnography;
e. Sedation level;
f. Cardiac rate/rhythm; and
g. Pain level.

4. Documentation in the EMR during the procedure will reflect evidence of continuous assessment and evaluation of the patient's condition. Documentation will include:
   a. Dosage, route, time, and effects of all medications;
   b. Type and amount of fluids administered, including blood and blood products;
   c. Physiological data from continuous monitoring;
   d. Any interventions and the patient's responses;
   e. Any untoward or significant patient reaction and its resolution; and
   f. Names of all personnel providing care or assisting with the procedure.

D. LIP Post-Procedure:
   1. Post-procedure documentation includes:
      a. Procedure performed;
      b. LIP performing procedure;
      c. Name of any assistant if applicable;
      d. Specimens removed (if any);
      e. Estimated blood loss if applicable;
      f. Condition of patient;
      g. Complication(s); and
      h. Finding/final diagnosis.

E. Nursing Post Procedure:
   1. Continuous monitoring is required until the patient returns to the pre-procedure level in all assessment criteria and the pain level is at an acceptable level for the patient. Physiological parameters to be monitored include:
      a. Documentation of patient status post-procedure;
      b. Vital signs at least every 15 minutes with continuous Sa02 monitoring, more often if indicated;
      c. Sedation level and orientation;
      d. Assessment and evaluation of the site, if applicable, at least post procedure, every 15 minutes, and at discharge;
      e. Pain level; and
      f. If a reversal agent is administered: The duration of action of reversal agents is shorter than the duration of action of the agent being reversed. Patients are monitored for signs and symptoms of possible re-sedation for a period of not less than 2 hours post administration of a reversal agent.
   2. Plan for Discharge to an Alternate Level of Care:
      Discharge criteria for patient transfer from the post-procedure area to an alternate level of care are defined as, but not limited to:
      a. Patient is awake, alert, and oriented to person, place, and time/or sensorium as pre-procedure;

b. Site, if any, has an absence of excessive bleeding, and dressing is intact;
c. Respirations are greater than 12 and less than 28;
d. SaO2 is greater than 92% or at the pre-procedure level;
e. Blood pressure; systolic is greater than 90 and less than 180; diastolic is less than 100 or as pre-procedure;
f. Skin is warm, dry, and appropriate color or as pre-procedure; and
g. Pain level is at acceptable level for patient.

NOTE: If the patient does not meet the above criteria, his/her failure to do so will be communicated to the appropriate LIP who may order further therapeutic interventions. The LIP's name, orders, and plan for care will be documented in the appropriate place in the patient's EMR.

3. Plan for Discharge from the Hospital (Outpatients)
Discharge criteria documentation for outpatients to be discharged home include, but are not limited to the following:
   a. Patient is awake, alert and oriented to person, place, and time; or sensorium as pre-procedure;
   b. Site, if any, has absence of excessive bleeding and dressing is intact;
   c. Respirations are greater than 12 and less than 28 or as pre-procedure;
   d. Sa02 is greater than 92% or at pre-procedure level;
   e. Blood pressure; systolic is greater than 90 and less than 180, diastolic is less than 100 or as pre-procedure;
   f. Skin is warm, dry, and appropriate color or as pre-procedure;
   g. Pain level is at an acceptable level for the patient;
   h. Functional assessment is consistent with pre-procedure;
   i. Nausea and vomiting are minimal or absent;
   j. Gag reflex and ability to cough are present;
   k. Postop instructions are reviewed with the patient and family;
   l. Disposition of belongings is reviewed; and
   m. A designated driver is present to drive the patient home.

   NOTE: If the patient does not meet the above criteria, his/her failure to do so will be communicated to the appropriate LIP who may order further therapeutic interventions or discharge. The discharging LIP's name and orders will be noted in the appropriate place in the patient's EMR.

<u>Performance Monitoring & Improvement:</u>

A. Competency assessment for Qualified Staff will include:
   1. Current ACLS/PALS/NRP provider;
   2. Successful completion of the online educational study guide on Moderate Sedation and Airway Management; and
   3. Airway Management competency will be verified via return demonstration to a Qualified Trainer.

B. <u>Reporting</u>:

SJ/C has a planned, systematic approach to process performance measurement, assessment, and improvement. These activities are collaborative and interdisciplinary. Indicators that measure patient satisfaction, safe treatment, and effectiveness are collected. Outcomes of the process are contemplated to ensure optimal coordination.

NOTE: Policies are intended to serve as training tools and as general guidelines for when questions arise or when unusual events occur. Personnel should not use policies as a substitute for the exercise of good judgment as it is recognized that a guideline may not be uniformly appropriate. If you have a specific question that is not addressed by this policy or if you have questions about the application of this policy, please contact a supervisor, the compliance officer, or legal department

Approved:

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Original Implementation Date: 03/01/01
Originating Department/Committee: Care of Patients Readiness Team
Next Review Date: 09/19/2027
Reviewed: 02/01/08, 09/08, 12/10, 05/11, 02/15, 05/18, 09/19, 03/23
Revised: 06/18/01; 03/02; 11/04; 02/08, 09/08, 12/10, 05/11, 02/15, 05/18, 09/19, 03/23
Rescinded:
Policy Number: 6061-PC
Effective Date: 04/04/02
Former Policy Number(s) #6061-PC
Original: 3/15/99
Effective Date: 04/01/99
Reviewed: 11/01/00
#8310 –122 (Conscious Sedation for operative and Invasive Procedures) (SJ)
Original: 6/90
Reviewed: 3/20/92, 9/10/97
Revised: 1/20/93, 12/06/94, 2/11/98
#662-02, 6026 (Conscious Sedation) (CH)
Original: 12/92
Reviewed: 2/95
Revised: 12/95

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