Policy Title: **Sedation, Moderate and Deep**

Last Review Date: September 20, 2022 **Date of Origin:** February 7, 1994

Policy:

ChristianaCare is committed to the safe administration and monitoring of sedation for patients undergoing operative, invasive, diagnostic or manipulative procedures.

Purpose:

To outline the process for care of patients receiving moderate or deep sedation, while undergoing operative, invasive, diagnostic or manipulative procedures.

Scope:

Select applicable:

☒ **Christiana Care Health Services and the Medical Dental Staff**
  ☒ Christiana Hospital ☒ Wilmington Hospital ☐ Union Hospital
☐ **Christiana Care Home Health and Community Services**
☐ **Christiana Care Health Initiatives**

This policy is **not** intended to apply to the following:

- Anesthesia and Sedation provided by an anesthesiologist/Certified Registered Nurse Anesthetists (CRNA)
- Sedation used during the placement or maintenance of an artificial airway (e.g. mechanical ventilation)
- Administration of anxiolytic or analgesic agents when administered routinely to alleviate pain and agitation. (e.g., sedation for treatment of insomnia, pre-or post-operative analgesia)
- Palliative sedation

Definitions:

For purposes of this policy the following definitions apply:

American Society of Anesthesiology (ASA) Score:

This index is designed to pre- operatively assess the overall physical status of the patient. ASA Score selection criteria:

Class I:	Healthy patient
Class II:	Patient with mild systemic disease- no functional limitations
Class III:	Patient with severe systemic disease that limits activity but is not incapacitating
Class IV:	Patient with an incapacitating systemic disease that is a constant threat to life.
Class V:	Moribund patient not expected to survive 24 hours with or without an operation.

Anesthesia:

Consists of general anesthesia and spinal or major regional anesthesia.

Deep Sedation:

A drug induced depression of consciousness during which patient cannot be easily aroused but respond purposefully following repeated or painful stimulation.

A. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a member of Anesthesia Services or a Medical-Dental Staff Member whose ability to administer deep sedation is delineated in their core privileges.

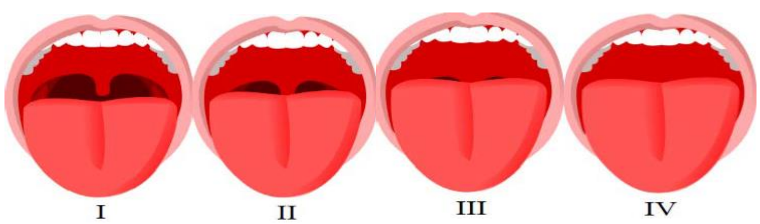
Inhalation Sedation:

A technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

Life Threatening Emergency:

Situation in which immediate treatment is necessary to preserve the patient's life or prevent serious, permanent injury or impairment.

Mallampati:



Class I:	Soft palate, uvula, fauces, pillars visible.
Class II:	Soft palate, uvula, fauces visible.
Class III:	Soft palate, base of uvula visible.
Class IV:	Only hard palate visible

Minimal Sedation (Anxiolysis):

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 Sedation:

A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

A. Reflex withdrawal from painful stimulus is not considered purposeful response.
B. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.
C. Cardiovascular function is usually maintained.

Privileged Provider:

A ChristianaCare Medical Staff Member, Physician Assistant or Advance Practice Nurse who holds moderate sedation privileges and is qualified to manage and rescue patients from the development of deeper levels of sedation than intended.

A. The Department Chair and the Chair of Anesthesiology are responsible for assessing an individual's qualifications and granting privileges to administer sedation. Further qualifications are defined as part of the privileging process.

Procedural Sedation:

Procedural sedation and analgesia refer to the technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness.

A. Allows the patient to tolerate painful unpleasant procedures while preserving cardiorespiratory function.

B. Propofol as used in the Emergency Department is an example of procedural sedation.

Sedation:

Sequential deepening of consciousness from the fully awake state to the anesthetized state represents a continuum of sedation levels that seamlessly move from one to another, not always predictably.

A. A dose of sedation that may be inadequate to induce sedation in one patient may render another patient deeply unconscious, with the potential of airway compromise.

B. Appropriate monitoring of all patients receiving sedative medications for procedures is necessary.

LEVEL OF CONSCIOUSNESS	→ AWAKE	→ MINIMAL SEDATION	→ MODERATE SEDATION	→ DEEP SEDATION	→ GENERAL ANESTHESIA
PROTECTIVE REFLEXES	→ PRESENT	→ PRESENT	→ PRESENT/ POTENTIAL LOSS	→ PROBABLE LOSS	→ TOTAL LOSS

Start Time:

Start of administration of the sedation drug

Stop Time:

Time when the SSP determines that the patient meets criteria for post procedure recovery with conversion from continuous to intermittent monitoring.

Supervised Sedation:

Procedural sedation and analgesia refer to the technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness which allows the patient to tolerate painful unpleasant procedures while preserving cardiorespiratory function.

- Propofol as used in the Emergency Department is an example of procedural sedation.

Supervised Sedation Professional (SSP):

Current competency for moderate sedation is defined as current (Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), Advanced Trauma Life Support (ATLS), Pediatric Advanced Life Support (PALS), Neonatal Advanced Life Support (NALS) and/or Neonatal Rescuscitation Program (NRP) certification, as appropriate and successful completion of competency training in the administration of sedation and analgesia and the anticipated and/or potential physiological patient response.

- Training must also include the recognition of adverse reactions, precautions, recovery criteria and documentation requirements.

Exceptions to Training:

I. Board Eligible Emergency Medicine Physicians are required to maintain ACLS or ATLS certification until achieving Board Certification by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine (Once certification has been achieved, maintenance of ACLS or ATLS is not required)

II. Physicians who have completed either a critical care fellowship or subspecialty training in pulmonology, Emergency Medicine or Oral Maxillofacial Surgery are considered qualified to administer deep and moderate sedation by virtue of their training and are exempted from the training requirements.

A. Maintenance of ACLS certification is at the discretion of the individual departments.

III. Neonatologists and neonatal nurse practitioners are considered qualified to administer moderate sedation by virtue of their training and are exempted from the training requirements but must maintain NRP or PALS certification.

IV. Pediatric Emergency Medicine physicians are considered qualified to administer moderate and deep sedation by virtue of their training and are exempted from the training requirements but must maintain NRP and PALS or ACLS certifications.

Procedure:

I. Privileging and Skill Competency Requirements

A. Providers responsible for the administration of sedation will be privileged as delineated in the Sedation Privileging Policy.

B. Supervised Sedation Professional (SSP) will complete an education module at the time of initial orientation and annually thereafter.

II. Pre-Procedure Evaluation and Assessment

A. **Privileged Provider**

is responsible for assuring completion and documentation of the following: (Please note: For Deep Sedation procedures not considered emergencies, the pre-procedure assessment is completed within 48 hours prior to the procedure)

1. Perform a focused physical exam, including an airway assessment (Mallampati Score), review history, and assign American Society of Anesthesiology (ASA) score prior to the administration of any sedation medications.
   a) The exam should include the identification of potential airway difficulties, ongoing infections or limited vascular access.
   b) An ASA or Mallampati score greater than three (3) requires the provider to review the appropriateness of proceeding with the sedation or to consider an Anesthesiology consult.
2. If deep sedation is planned, a focused exam will be completed by the appropriately privileged provider,
   a) A plan for the patient's anesthesia care, including type of medications for induction, maintenance, and post-operative care documented in the patient's medical record.
   b) Monitoring by a qualified member of Department of Anesthesiology recommended for:
      (1) Uncooperative patients (obtunded, severely injured, etc.)
      (2) Patients < 12 years old
      (3) Procedures anticipated to last more than 90 minutes.
3. Obtain and verify that there is an informed consent from patient or their decision- maker for the procedure with sedation.
4. Consider transfer of patients with multiple co-morbidities, (i.e. ASA 4) to OR or ICU setting and consult the Department of Anesthesiology.
5. Assess NPO Status:
   a) Adults with normal gastric motility.
      (1) Clear Liquids: (Clear liquids are defined as a translucent fluid without pulp, e.g. water, apple juice, plain coffee, plain tea.)
         (a) 2 hour fast prior to arrival is recommended to facilitate operational efficiency.
         (b) Some medications may be given up to 2 hours before: seek providers recommendations.
      (2) All Other Liquids:
         (a) 8 hour fast is required
   b) Adults with abnormal gastric motility:
      (1) Those with abnormal gastric motility and emptying require an 8 hour fast of material except medication with sip of water.
   c) Pediatrics (≤ 12 years of age):
      (1) Infant Formula/Milk Solid:
         (a) 6 hour fast is required
      (2) Breast Milk:
         (a) 4 hour fast is required

(3) Clear Liquids: (Clear liquids are defined as water, apple juice, Popsicle, Pedialyte, and sugar water.)
   (a) 2 hour fast is required.

6. Deviation from NPO guidelines is at the discretion of the Privileged Provider performing the procedure, NPO status may be waived in emergency encounters or life threatening situations.
7. Re-assessment of the airway immediately prior to the administration of sedation.
8. Communicate the Mallampati and ASA score to the SSP prior to the procedure.

B. **Supervised Sedation Professional (SSP) Responsibilities:**

1. Procure age and size specific emergency equipment to be available in the room where sedation is administered including:
   a) Oxygen
   b) Suction device
   c) Airways/masks
   d) Bag-valve mask device
   e) Emergency and reversal pharmaceutical agents
   f) Intubation equipment
   g) Physiologic monitoring equipment:
      (1) Pulse oximetry
      (2) Blood pressure
      (3) Cardiac Monitoring
   h) Broselow cart/bag for pediatric patients (for Deep Sedation)
2. Confirm that patient has assistance for transportation home (Patient will not be permitted to drive him or herself home).
3. Assess/Maintain NPO Status as outlined in II.5 above.
4. Complete a pre-procedure assessment, including: baseline vital signs, baseline pulse oximetry, medications, allergies and pregnancy status for women of childbearing age See policy - Pregnancy Screening in Non-OB Locations
5. Assign a pre-sedation score. *See Appendix A*
6. Establish intravenous access prior to the administration of any medications to achieve Sedation. (Maintain intravenous access until discharge criteria are met.)
7. Immediately prior to administration of medication, re-assess and document the following:
   a) Response to pre-procedure medications, as applicable
   b) Oxygen saturation (pulse oximetry)
   c) Blood pressure
   d) Pulse

e) Respiratory rate
f) Cardiac rhythm

8. Initiate the Universal Protocol prior to the start of surgical or invasive Procedure:
9. Provide pre and post procedure patient education and document in the medical record.
    a) Patient education may include but not limited to: eating and drinking restrictions, monitoring during and after procedure, and post procedure care.

III. Requirements during procedure:

A. Privileged provider shall:
   1. Be present from the initial administration of medications
   2. Be present for the duration of the procedure
   3. Interpret monitoring data

B. Deep Sedation and Administration of IV Sedatives:
   1. A SSP, in the presence of and under the direct supervision of the privileged physician may administer medications for producing deep sedation.

C. SSP shall:
   1. Have capability to monitor the presence of exhaled carbon dioxide available for use if requested.
   2. EKG, pulse oximetry, ventilation and circulation are continuously monitored during the procedure.
      a) Blood pressure, heart rate, pulse oximetry level and level of consciousness are monitored and documented on the Sedation Flow Sheet or electronic system at a minimum of 5-minutes intervals.
      b) Monitor pain level at a frequency based on clinical judgement consistent with the potential effect of the procedure.
   3. Document information including:
      a) Name, dosage, route and time of administration of drugs
      b) Names and amounts of intravenous fluids including blood products if applicable.
      c) Complications, adverse reactions or problems occurring during sedation including time and description of symptoms, treatment rendered and patient's response.
   4. Administer supplemental oxygen, as required.

      a) Alert privileged provider, if oxygen saturation falls below baseline or respiratory distress.
      b) See Fire Safety and Fire Risk Assessment Policy for information on assessment.

5. Administer Sedation Medication under the direct supervision of the privileged provider following the "[Read / Repeat Back]" policy.
    a) Medications commonly used include, but are not limited to:
        (1) Fentanyl (Sublimaze)
        (2) Morphine Sulfate
        (3) Hydromorphone (Dilaudid)
        (4) Midazolam Hydrochloride (Versed)
        (5) Diazepam (Valium)
        (6) Lorazepam (Ativan)
        (7) Ketamine, under special circumstances
    b) Please refer to the Formulary for medication specific information.
    c) For procedural analgesia in the Emergency Departments and Pediatric Care Center:
        (1) sedation medications may be administered by an appropriately trained SSP under the direct supervision of the Emergency Physician or Pediatric Emergency Physician.
        (2) In the Pediatric Care Center, a Pediatric Urgent Care or Pediatric Hospitalist physician with appropriate privileges may administer moderate sedation

IV. Post Procedure Requirements

A. **Privileged Provider shall:**
1. Document a post procedural/sedation progress note within 48 hours.
2. Provide discharge and follow-up instructions.
3. Discharge the patient when the patient meets discharge criteria.

B. **SSP shall:**
1. Assess blood pressure, heart rate, pulse oximetry and level of consciousness after the procedure on the basis of every 15 minutes for 30 minutes or until patient meets recovery criteria according to the post sedation score.
2. Document pain assessment, as appropriate
3. Observe patient until they reach baseline level of consciousness and they are no longer at risk for cardiorespiratory depression.
4. Assess patient for discharge.
    a) Patient must meet established discharge criteria before being allowed to be discharged or transferred:
    b) Assign a Post Sedation score. (*See Appendix A*)
        (1) The Post Sedation Score > 9 (12 pt scale); > 11 (14 pt scale), or no less than pre-sedation score, unless a "0" is scored in a category.
            (a) In the event of a score of "0" in any one of the categories the patient will not be considered for discharge until assessed by a privileged provider.

(2) Neonatal patients are excluded from the Sedation Score but should return to their pre-sedation assessment parameters (Vital signs, oxygen saturation, Level of Consciousness).

c) Sedation has not been administered within 30 minutes.

d) A reversal agent has not been administered for at least two hours.

e) Notify the privileged provider if the patient exhibits any of the following:

(1) Severe pain requiring parenteral medication

(2) Dressing with increasing area of drainage

(3) Dizziness

(4) Nausea and vomiting

(5) Unable to void and is uncomfortable

5. Notify the privileged provider for intervention/plan of care and approval for discharge.

6. Provide appropriate discharge planning/instructions and education and document same.

7. Caution patient against the following:

a) Driving a car, operating equipment or drinking alcohol for at least 24 hours post procedure

b) Making any important decisions or signing any legal documents until you are recovered.

8. Confirm that patient has assistance for transportation home.

a) Patients who receive moderate or deep sedation will not be allowed to drive themselves home.

Responsibilities:

The Department of Anesthesiology is responsible for the development of standards of practice and oversight for moderate and deep sedation.

Adverse Events related to moderate or deep sedation are reviewed by Service Line Event Review Teams with oversight by the Moderate Sedation Committee.

References:

American Society of Anesthesiologists: Practice Guidelines for Sedation and Analgesia by Non- Anesthesiologist, an Updated Report by the American Society of Anesthesiologist Task Force on Sedation and Analgesia by Non-Anesthesiologists. Park Ridge IL. ASA, 2003.

Beagley, L. & Smith, R. (Eds). A Competency Based Orientation Program for the Registered in the Perianesthesia Setting, American Society of PeriAnesthesia Nurses, 2014.

Godwin SA, Caro DA, Wolf SJ, et al. American College of Emergency Physicians. ACEP clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2005;45:177-196.

Appendix A:

CATEGORY	ADULT	PEDIATRIC	Score
Respiratory	Able to breathe deeply and cough freely	Crying	**= 2**
	Dyspnea or limited breathing	Dyspnea or limited breathing	**= 1**
	Apneic or on mechanical ventilator	Apneic or obstructed requiring assistance to maintain airway	**= 0**
O_2 Saturation	Able to maintain O_2 Sat >/=92% on room air or return to baseline	Able to maintain O_2 Sat > 92% on room air	**= 2**
	Needs O_2 inhalation to maintain O_2 Sat > 90%	Needs O_2 supplement to maintain O2 Sat > 92%	**= 1**
	O_2 Sat < 90% with O_2 supplement	O_2 Sat < 92% with O_2 supplement	**= 0**
Circulation	BP +/- 20% of preanesthetic level	Within 10% of pre-sedation level	
	BP +/- 20-49% of preanesthetic level	Within 25 % of pre-sedation level	**= 1**
	BP +/- 50% of preanesthetic level B-	More than 25% higher/lower than pre-sedation level	**= 0**
Consciousness	Easily arousable and oriented or return to baseline	Awake and Alert, turning towards voice	**= 2**
	Arousable with moderate stimulation;	Arousable; drifts back to sleep	**= 1**
	Responsive only to tactile stimulation or no response	Unresponsive	**= 0**
Pain	None or mild discomfort (Pain scale 0-4)	No pain/minimal Pain (Pain scale 0-3)	**= 2**
	Moderate to severe pain controlled with IV or oral analgesics (Pain scale 5-7)	Moderate Pain (Pain scale 4 - 6)	**= 1**
	Persistent or severe pain controlled with IV Analgesics (Pain scale 8-10)	Significant Pain (Pain scale >7)	**= 0**
Muscle Activity	Able to move all extremities on	Moving limb purposefully	**= 2**
	Some weakness in movement of	Non-purposeful movements	**= 1**
	Unable to voluntarily move extremities	Not moving	**= 0**
Post Procedure Emetic Symptoms *(for use with 14 point scale)*	None or mild nausea with no active vomiting	None or mild nausea with no active vomiting	**= 2**
	Transient vomiting or retching	Transient vomiting or retching	**= 1**
	Persistent moderate - severe nausea & vomiting	Persistent moderate - severe nausea & vomiting	**= 0**

Recovery Criteria: Score > 9 (12 pt scale); > 11 (14 pt scale), or no less than pre-sedation score.

****NOTE: Appendix A** represents a modified Aldrete Scoring System. The specific post-anaesthesia recovery scoring tool used should reflect the patient population served (e.g. inpatient vs outpatient). Prior to discharge, if the patient exhibits any of the following, the physician must be notified for intervention/plan of care and approval for discharge:

- A score of "0" in any category
- Dressing with increasing area of drainage;
- Dizzy/light headed when supine;
- Nausea and vomiting;
- Unable to void and uncomfortable.

Please note: Neonatal patients are excluded from the Sedation Score but should return to their pre-sedation assessment parameters (Vital signs, oxygen saturation, Level of Consciousness).