

## **Non-anesthesia Provider Procedural Sedation and Analgesia** *Policy Considerations*

### **Purpose**

The purpose of this document is to provide considerations for policy development for the safe administration of procedural sedation by a non-anesthesia sedation team in a hospital, ambulatory surgical center, or office setting. Procedural sedation, also referred to as moderate sedation, is a technique to administer “sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia is intended to result in a depressed level of consciousness that allows the patient to maintain their oxygenation and airway control independently.”<sup>1</sup>

It is important to keep patient safety and not cost of care central in delivery of procedural sedation and analgesia. The administration of even small doses of anesthesia induction drugs such as propofol and ketamine may induce irreversible, unintended levels of deep and general anesthesia. It is the responsibility of each member of the sedation team to carefully titrate sedatives and analgesics for sedation and to be prepared to rescue from deep sedation. Administration of general anesthesia is limited to anesthesia professionals.<sup>2-5</sup>

The following considerations apply to the administration of procedural sedation for adults, with additional considerations noted for pediatric and older adult populations (see the “Special Considerations” section). They are not intended to address delivery of monitored anesthesia care (MAC), general or regional anesthesia, and services provided by an anesthesia professional. These considerations do not supersede statute, accepted standards, or facility policy. These considerations do not include:<sup>1</sup>

- Patients receiving monitored anesthesia care, regional or general anesthesia
- Patients receiving analgesia for pain control without sedation
- Patients receiving sedation to manage behavioral emergencies
- Patients who have an artificial airway in place and are mechanically ventilated

### **Introduction**

Patient specific, procedural sedation for diagnostic, therapeutic, or invasive procedures is planned and administered to alleviate the patient’s anxiety, discomfort, and pain in a safe manner.<sup>6</sup> Over the past decade, there has been a significant increase in the number of procedures performed using procedural sedation both in and outside of the operating room. These areas include minor surgery, radiology, cardiac electrophysiology lab, emergency department, endoscopy centers, ambulatory facilities, and office-based practices.<sup>7-10</sup>

Non-anesthesia professionals are becoming increasingly involved in the administration of procedural sedation. Factors such as cost-containment, advancements in technology, increased demand for sedation services, and increased numbers of diagnostic, therapeutic, or invasive procedures performed with procedural sedation have contributed to this trend.<sup>3,8</sup> Procedural sedation may be administered by a non-anesthesia physician and registered nurse (RN) sedation team.

The administration of safe procedural sedation requires specific provider competencies that include patient pre-sedation assessment and evaluation, patient education, cardiovascular monitoring, drug selection and administration, management of potential adverse reactions or complications, post-sedation recovery, and appropriate use of available and emerging technology. Non-anesthesia medical staff that are appropriately credentialed and privileged, may provide minimal and moderate sedation consistent with federal and state laws and the provider's scope of practice, education, and training.

### ***Role of Anesthesia in Sedation Services***

The policies, procedures, and accountability for the administration of procedural sedation by all healthcare professionals within a facility are the responsibility of one organized anesthesia service. It is important to note that the regulations and corresponding interpretive guidelines issued by the Centers for Medicare & Medicaid Services (CMS) require that the anesthesia service in CMS-certified hospitals develop policies and procedures governing the provision of all categories of anesthesia services including specifying the minimum qualifications for each category of practitioner permitted to provide procedural sedation.<sup>2</sup> State survey agencies, which may include state departments of health and several accrediting organizations, follow CMS interpretive guidelines to determine a facility's compliance with the Medicare Conditions of Participation (CoPs). State laws, state health department requirements, professional boards, accrediting organization standards, and facility bylaws and policy may exceed CMS requirements.

Procedural sedation services are also provided outside of the hospital. Ambulatory surgical centers or office-based practices typically have streamlined processes with fewer levels of leadership and staff. In these facilities, anesthesia providers may have greater opportunity to participate in development of policies, procedures, provider competency assessment, and continuous quality improvement programs.

Regardless of facility type, all healthcare professionals who provide procedural sedation must be aware of the statutes, regulations, and standards which govern their licensure, facility and clinical practice.

### **Policy Considerations**

Facility policies outline roles, requirements, and responsibilities of all healthcare providers involved in procedural sedation and patient care. For additional guidance, review *AANA Standards for Nurse Anesthesia Practice*,<sup>11</sup> *Standards for Office Based Anesthesia Practice*,<sup>12</sup> *The Role of the CRNA on the Procedure Team*,<sup>13</sup> *Documenting Anesthesia Care*,<sup>14</sup> and *Informed Consent in Anesthesia*.<sup>15</sup>

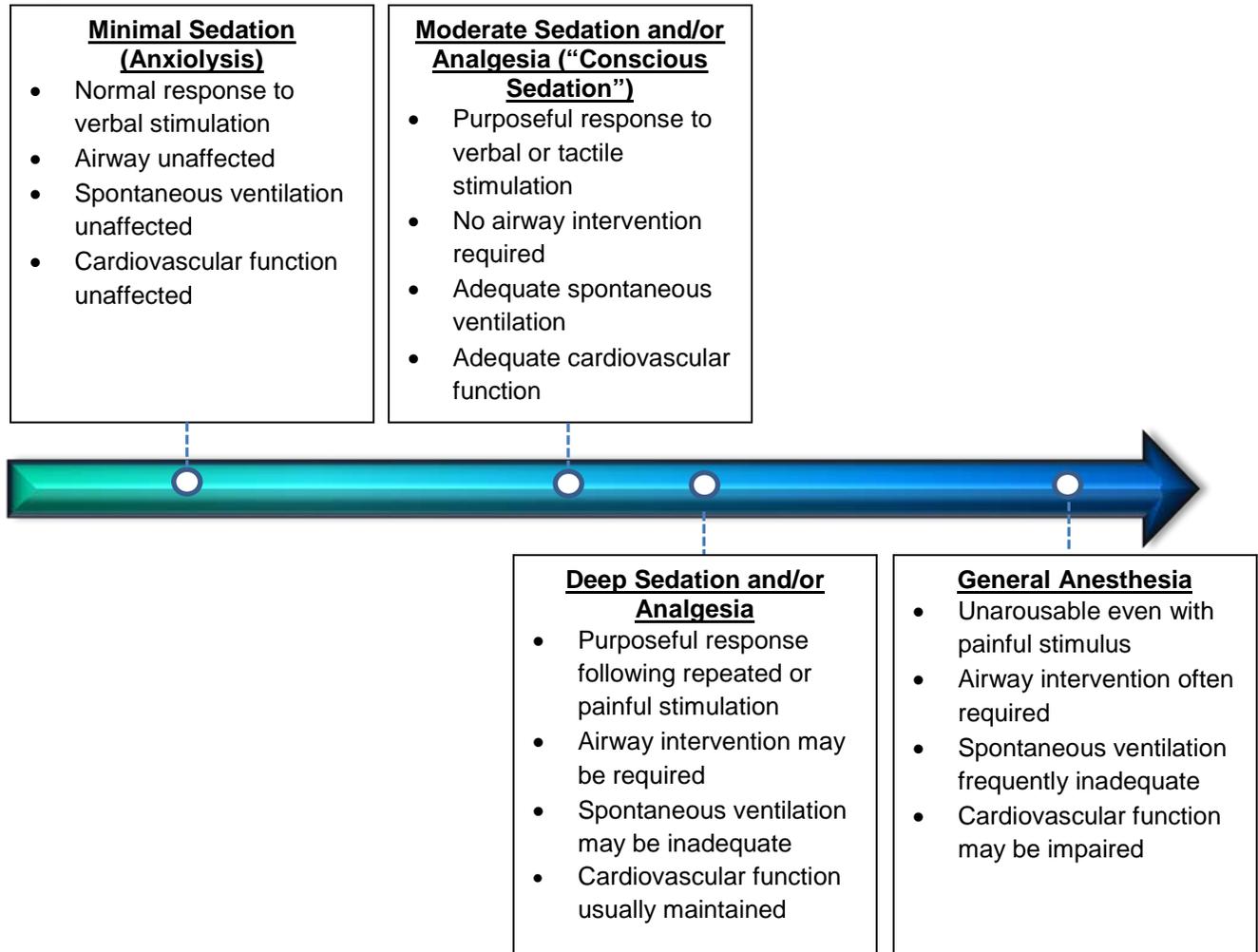
Policy considerations include:

- Levels of Sedation
- Sedation Competencies
- Pre-Procedure Phase
- Intra-Procedure Phase
- Post-Procedure Phase
- Documentation
- Quality Improvement Program

**Levels of Sedation**

Sedation represents a continuum.<sup>10</sup> This continuum encompasses four levels that include minimal sedation (anxiolysis), moderate sedation/analgesia (“conscious sedation”), deep sedation/analgesia, and general anesthesia (see Figure 1).<sup>2,10,16</sup>

**Figure 1. Levels of Sedation**



Adapted from the American Society of Anesthesiologists *Continuum of depth of sedation: definition of general anesthesia and levels of sedation/analgesia*<sup>17</sup>

**Competencies to Administer Sedation and Analgesia**

An appropriately credentialed and privileged provider selects and orders agents to achieve sedation and if indicated, analgesia.

Facilities have a process for evaluating and documenting an individual’s competency to administer procedural sedation and manage patients receiving procedural sedation and/or analgesia.<sup>7</sup> Healthcare providers demonstrate continued competency for procedural sedation administration and technology employed. Initial competency may

be acquired through a plan of study with post-test, mentored practice, and/or Advanced Cardiovascular Life Support (ACLS) or Pediatric Advanced Life Support (PALS) certification.<sup>7,18</sup> During initial and ongoing sedation and analgesia pharmacology education reversal agents are discussed, to include drugs that do not have a reversal agent (e.g., propofol, ketamine). Ongoing assessment of provider competencies, documentation and outcomes occurs through a quality improvement program and annual competency assessment.

### ***Pre-Procedure Phase***

#### *Pre-Sedation Assessment and Evaluation*

Healthcare providers use clinical judgment when assessing and evaluating whether a patient is optimized for procedural sedation. A patient health assessment and evaluation is completed to determine the baseline status of the patient and identify factors that may increase risk during sedation. A pre-sedation assessment and evaluation includes, though is not limited to, a review of health history, NPO status, allergies, relevant diagnostic tests, airway assessment, previous issues with sedation and/or analgesia and anesthesia, and other relevant health, surgical, medication, and social history.<sup>18</sup>

For medically complex patients (e.g., physical status 3 or 4), consultation with an anesthesia professional and/or the patient's other clinical providers may be indicated to develop the plan of care.

#### *Patient Education*

Patient and family member/caregiver education is provided to discuss and answer questions regarding the risks, benefits and potential adverse effects of procedural sedation, anticipated sedative effects and alternative methods of treatment. To help reduce patient's anxiety, providers should communicate clearly, assess the patient's needs, and provide additional information and support where needed.<sup>19,20</sup> The patient is actively engaged in education and discussion to understand what to anticipate before, during, and after procedural sedation including signs and side effects to report after discharge. Patient and family education may improve patient safety and increase engagement in care.

#### *Patient-Specific Plan of Care and Informed Consent*

A patient-specific procedural sedation plan is developed based on the assessment, evaluation, and additional considerations related to the patient and procedure:<sup>21</sup>

- Characteristics of the procedure (e.g., length, level of the patient's anxiety)
- Patient preferences
- Need for patient cooperation

Informed consent for the procedural sedation plan is obtained and documented.<sup>15</sup> The informed consent process should include a discussion of the individualized treatment plan, planned procedures, alternatives methods of treatment, and risks and benefits of the plan.

#### *Intravenous Access*

Continuous IV access is available until the patient has returned to pre-procedure state.

## ***Intra-Procedure Phase***

### *“Time Out” Immediately Before Starting the Procedure*

The procedure team conducts a “time out” before the start of the procedure for which sedation is being administered to confirm that the correct patient, site, and procedure have been identified; that all required documents are complete; equipment is available and ready for; and use team concerns have been addressed.<sup>22</sup>

### *Medication Selection and Titration*

The patient’s response may vary according to physical status, age, weight, comorbidities, and medication history. Select appropriate drugs and doses that are individualized to the patient. Sedative and/or analgesic drugs have varying onset of action, peak effects, rate of elimination, and elimination pathway. Administer the smallest effective dose to achieve the appropriate level of procedural sedation by using incremental dosing or variable rate infusion to titrate each drug and dose to the patient’s individual response. Allow sufficient time to elapse between doses to avoid potential drug interactions.

### *Monitoring*

Transition between levels of sedation is not clearly defined. Continuous evaluation of patient responsiveness to verbal and tactile stimuli, and monitoring of vital signs help identify the intended level of sedation. Patients receiving procedural sedation are continuously monitored for the patient’s level of sedation, blood pressure, heart rate, rhythm, and when applicable, ST segment analysis using the EKG, end-tidal CO<sub>2</sub>, and oxygenation using pulse oximetry.<sup>11,18</sup>

There is a sedation team member whose sole responsibility is the administration and monitoring of the patient’s hemodynamic status and responsiveness. This provider should not be engaged in uninterruptable tasks associated with the diagnostic, therapeutic, or invasive procedure or otherwise compromise the continuous monitoring of the patient.<sup>13</sup>

### *Use of Supplemental Oxygen*

Supplemental oxygen is available for patients receiving moderate sedation and when indicated during the post-procedure period.<sup>10</sup>

### *Resuscitation and Rescue Equipment, Drugs, and Personnel*

An emergency cart must be immediately accessible to every location where sedation and analgesia is administered. This cart must include emergency resuscitation drugs, airway equipment and supplies, a defibrillator, and a source for administration of 100 percent oxygen. A positive pressure breathing device, oxygen, suction, and appropriate airways must be placed in each room where sedation and analgesia is administered.

Prior to the procedure, the post sedation and procedure areas are checked for availability of resuscitation supplies, operational emergency rescue equipment and reversal drugs.<sup>18,23</sup> Confirmation of the availability of personnel who are proficient in emergency airway management, intubation, and advanced cardiopulmonary resuscitation occurs prior to the procedure.

The sedation team is competent to assess and maintain the airway, breathing, hemodynamic status, and administer indicated reversal agent(s) in the event that the patient moves to a deeper than intended level of sedation. Airway management may include insertion jaw thrust, insertion of an artificial airway and/or bag valve mask ventilation, administration of reversal agent(s) and/or initiate the appropriate facility emergency team response plan.

### **Post-Procedure Phase**

#### *Recovery Care*

The facility delineates specific criteria for patient assessment, evaluation, monitoring, and documentation intervals during the recovery period. The patient is assessed and evaluated, noting the patient's recovery status and return to adequate function (e.g., level of consciousness, ability to ambulate, etc.). A qualified professional capable of managing complications is present in the facility and remains in the facility until the patient is stable.

#### *Discharge*

Discharge criteria are established by the facility, with a focus on patient safety. Upon discharge from the facility, the patient receives detailed verbal and written instructions regarding diet, medications, activities, and how to effectively engage in self-care to facilitate their recovery. Potential complications and management of complications or emergencies, including a phone number to call, are discussed. The patient should be instructed to keep follow-up appointments with their healthcare provider.<sup>18,24</sup> Discharged patients should be accompanied by a responsible adult.

### **Documentation**

Documentation of pertinent information in the patient's medical record in an accurate, complete, legible, and timely manner begins with the handoff of care. The patient's record may include, but is not limited to, the results of the patient assessment and evaluation; the patient-specific care plan; informed consent; the type of monitoring modalities used (e.g., EKG lead selection, computerized ST segment analysis), pre-procedure, intra-procedure, and post-procedure assessments and interventions including specific information on medication dosage and times, patient response, and type and amounts of fluids; unusual, unanticipated, or adverse events; discharge instructions. For additional guidance, review AANA *Documenting Anesthesia Care*.<sup>14</sup>

### **Quality Improvement**

A quality improvement program includes procedural sedation performance metrics that are tracked within all procedure areas where sedation services are provided. This information is used to analyze patient outcomes and identify opportunities to improve patient care. Anesthesia services policies and procedures should undergo periodic re-evaluation which includes review of these performance metrics by quality improvement representatives and sedation staff.<sup>2</sup>

### **Special Considerations**

#### ***Pediatric Patient***

"Children differ from adults anatomically, physiologically, immunologically, psychologically, developmentally and metabolically."<sup>25</sup> The life span of a pediatric

patient includes neonate, infant, toddler, preschool, grade school, teen, and young adult.

Additional considerations regarding pediatric sedation include:<sup>19</sup>

- During the pre-sedation assessment and evaluation, which includes patient's age, weight, developmental stage, health history, and physical exam, consultation with the pediatrician and/or other clinical specialist, such as an anesthesia professional, may be necessary when treating high-risk pediatric patients (e.g., physical status 3 and 4).
- Doses of sedatives in children are calculated based on weight.
- During procedural sedation, at least one sedation provider present should have specialized training in pediatric procedural sedation and rescue techniques.
- Age and size-appropriate equipment and medications for resuscitation should be immediately available during and after sedation.
- Upon discharge, a responsible adult who has accompanied the child to the procedure receives specific oral and written discharge instructions that include:
  - Special instructions of observing child's head position to prevent airway occlusion if child will travel in a car seat.
  - Signs and symptoms of potential complications.
  - Steps to follow in case of complications including a 24-hour emergency telephone number.

Additional pediatric considerations are available from:

- [The Society for Pediatric Anesthesia](#)
- [The American Academy of Pediatrics](#)
- [Society of Gastroenterology Nurses and Associates](#)
- [The American Heart Association's Pediatric Advanced Life Support \(PALS\) program](#)
- [The American Academy of Pediatrics and American College of Emergency Physicians' Advanced Pediatric Life Support \(APLS\) program](#)

### **Older Adult**

As life span has become longer with improved management of health, a single definition of how society defines "senior" citizens has become arbitrary. In general, the chronological age of 60 to 65 is still used by many healthcare providers as a gross guide.<sup>26</sup> As such, there are several considerations regarding senior patients that should be considered when developing the plan for sedation include:<sup>20,27</sup>

- Existing, procedure or sedation related physical and/or cognitive limitations to optimize safety after discharge.
- When indicated for any physical status 3 or 4 patients, consult the patient's primary care physician to optimize the patient prior to sedation and/or include an anesthesia provider in the plan of care.
- Carefully *titrates* each drug to evaluate effect. Weight based dosing may cause the patient to move to an unintended level of sedation.
- Risk for hypothermia during procedures due to impaired thermoregulation.

- During airway evaluation, identify degree of flexion and extension of the neck that is tolerated to properly position the head and neck to avoid injury.
- An accompanying spouse, friend, another family member or living situation may not be capable of providing the needed assistance after discharge. Develop a post discharge plan with patient and caregivers to optimize safety.

Additional geriatric considerations are available from:

- [The Society for the Advancement of Geriatric Anesthesia](#)
- [Society of Gastroenterology Nurses and Associates](#)

### **Emerging Technology: Computer-Assisted Personalized Sedation**

The computer-assisted personalized sedation (CAPS) system integrates the physician and RN sedation team with physiologic monitoring and drug delivery through a computer interface to provide safeguards and facilitate drug titration personalized to the needs of each patient.<sup>28</sup> Anesthesia professionals, including CRNAs, should be involved in policy development, staff education, device implementation, ongoing quality improvement program, and available in the facility when the CAPS system is being used to participate as necessary in patient resuscitation.

The CAPS system facilitates the administration of minimal to moderate propofol sedation using drug delivery algorithms that calculate and deliver appropriate amounts of drug, based on the patient's physiological measurements and response to tactile and voice stimulation.<sup>32</sup> CAPS is not intended for administration of deep sedation, general anesthesia or for sedation of high-risk patients (e.g., physical status 3 or 4, morbidly obese, difficult airway, risk of aspiration, complex procedure).<sup>29,30,31</sup>

The CAPS system incorporates cardiovascular and respiratory monitors, such as the electrocardiogram, pulse oximeter, end-tidal carbon dioxide, respiratory rate, heart rate, blood pressure, and responsiveness.<sup>28,31</sup> The CAPS system processes hemodynamic parameters and patient responsiveness to titrate the amount of propofol administered intravenously.<sup>28,31</sup> The system will increase oxygen delivery based on the patient's peripheral oxygen saturation.<sup>28,31</sup> The system detects signs associated with over sedation and will automatically modify or stop the propofol infusion.<sup>32</sup> As with any procedural sedation policy, emergency protocols are initiated as necessary.

CRNA participation in policy development and implementation phases include:

- Evaluation of the CAPS devices
- Development of protocols to maintain sedation standards
- Development of emergency and resuscitation procedures
- Education of the sedation team, comprised of healthcare providers being trained to use the CAPS devices
- Integration of CAPS with existing processes of care
- Development and measurement of outcomes metrics for continuous quality improvement
- Ongoing assessment of competencies

As of this document publication date, the SEDASYS<sup>®</sup> System is the only U.S. Food and Drug Administration (FDA)-approved CAPS device on the market used for the delivery of propofol for minimal-to-moderate sedation in patients undergoing elective colonoscopy or esophagogastroduodenoscopy (EGD). Information regarding the SEDASYS<sup>®</sup> System is available on the FDA website:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p080009>.

Facilities and providers who implement a CAPS system should follow the manufacturer's guidelines and FDA's labeling requirements pertaining to the use of the device.

## Conclusion

With increasing numbers of diagnostic, therapeutic, or invasive procedures taking place in and outside of the operating room, non-anesthesia professionals administering procedural sedation must be prepared, competent, and skilled to achieve optimal patient outcomes and satisfaction.

Detailed facility policies and ongoing quality improvement efforts support providers in the delivery of safe, high-quality patient care.

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The AANA Board of Directors adopted the position statement titled *Qualified Providers of Sedation and Analgesia* in May 1988 and revised it in April 1991, June 1996 and June 2003. The AANA Board of Directors adopted the considerations for policy development titled *Registered Nurses Engaged in the Administration of Sedation and Analgesia* in June 1996 and revised it in June 2003 and November 2005. Both of these documents were archived in February 2016.

The AANA Board of Directors adopted the considerations for policy development titled *Non-anesthesia Provider Procedural Sedation and Analgesia* in February 2016.

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