Emergency Department (ED) Procedural Sedation

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Summary of revisions : Modification to adult Ketamine dosing	

1) **General Policy Statement:**
It is the policy of Iredell Memorial Hospital to outline the responsibilities and requirements in the administration of medication used for procedural sedation during invasive or non-invasive procedures in the ED.

a) **Scope:** The Department of Emergency Medicine, the Department of Anesthesia, Iredell Medical Staff, Administration, Pharmacy and the Department of Nursing are responsible and accountable for assuring the safe implementation of this policy and procedure in the Emergency Department.

This policy is applicable only to ED patients receiving procedural sedation under the direct medical supervision of appropriately-credentialed emergency medicine attending physicians. This policy does not apply to the administration of sedation by infusion to critically ill, mechanically ventilated patients with secured airways who are awaiting Critical Care bed availability/transport or the acute sedation of patients for behavioral/ psychiatric disturbances deemed potentially harmful to the patient, family, visitors and / or health care providers.

This policy is not applicable to the administration of minimal analgesia or anxiolysis in the setting of painful underlying medical conditions requiring a procedure in appropriately selected patients, not to exceed the following age-specific, analgesic-specific dosing thresholds over any given one hour time period and administered as an individualized one-time dose in the absence of any other anxiolytic/analgesic agent.

b) **Responsible Department/Party/Parties:**
   i. Policy Owner: Department of Emergency Medicine
   ii. Procedure: Department of Emergency Medicine
   iii. Supervision: Department of Emergency Medicine; Department of Nursing
   iv. Implementation: Department of Emergency Medicine; Department of Anesthesia, Iredell Medical Staff, Department of Pharmacy, and the Department of Nursing

2) **Definitions:** For purposes of this policy, the follow terms and definitions apply:

a) ***Procedural sedation and Analgesia***: Procedural sedation and analgesia refers to the technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness that allows the patient to tolerate painful or unpleasant procedures while preserving cardiorespiratory function. The intent of the sedation, not necessarily the agent itself, determines whether medication is being delivered to relieve anxiety (anxiolysis) or to facilitate a specific procedure as with procedural sedation.

b) ***Minimal sedation***: Minimal sedation describes a patient with a near-baseline level of alertness, a pharmacologically induced state during which patients respond normally to verbal commands. Although cognitive function and coordination might be impaired, ventilator and cardiovascular functions are unaffected. In the ED, minimal sedation is commonly administered to facilitate minor procedures.

c) ***Moderate sedation***: Moderate sedation is a pharmacologically induced depression of consciousness during which patients respond purposeful 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. Cardiovascular function is usually maintained. Moderate sedation patients often exhibit eyelid ptosis, slurred speech, and delayed or altered responses to verbal stimuli. Event amnesia will frequently occur under moderate sedation levels. In the ED, moderate sedation is commonly achieved with benzodiazepine, often in conjunction with an opioid such as fentanyl. **Moderate sedation must only be administered under the direct medical supervision and continuous physical presence of an appropriately credentialed licensed independent practitioner.**

d) ***Dissociative sedation***: Dissociative sedation is a trance-like cataleptic state characterized by profound analgesia and amnesia, with retention of protective airway reflexes and spontaneous breathing. In the ED, ketamine is commonly administered to evoke dissociative levels of sedation. Dissociative state can facilitate moderate to severely painful procedures, as well as procedures requiring immobilization in uncooperative patients. **Dissociative sedation must only be administered under the direct medical supervision and continuous physical presence of an appropriately credentialed licensed independent practitioner.**

e) ***Deep sedation***: Deep sedation is a pharmacologically induced depression of consciousness during which patients cannot be easily aroused or respond purposefully after repeated or painful stimulation. The ability to independently maintain ventilator function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Monitoring for deep sedation encounters should emphasize the potential for reduction in ventilation and cardiovascular complications, including changes to pulse rate, heart rhythm, and blood pressure. Deep sedation is commonly achieved with short-acting sedative agents such as propofol, etomidate, or a benzodiazepine. For painful procedures, an opioid such as fentanyl or morphine sulfate may be used in concert with the sedative. Many recent studies have described the use of ketamine administered with propofol to evoke deep sedation levels during painful ED procedures. **Deep sedation must only be administered under the direct medical supervision and continuous physical presence of an appropriately credentialed licensed independent practitioner.**

f) ***General anesthesia*****:** General anesthesia describes a depth of sedation characterized by unresponsiveness to all stimuli and the absence of airway protective reflexes, a pharmacologically 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.

g) ***Immediately available*** – Physically present in the specific procedural moderate sedation area, not engaged in uninterruptible tasks, and capable of rapidly responding to urgent/emergent patient care needs.

Single Agent Minimal ANALGESIA Hourly Dosing Thresholds:

Analgesic Agent	Age < 16 years ◡	Age 16-70	Age > 70
Fentanyl	< 2mcg/kg IV/IM	< 2 mcg/kg IV/IM	<1.5 mcg/kg IV/IM
Morphine	≤ 0.2 mg /kg IM; < 0.15 mg/kg IV	≤ 0.2 mg/kg IV/IM	≤ 0.15 mg/kg IV/IM
Hydromorphone	< 0.02 mg/kg IV/ IM	< 0.02 mg/kg IV/ IM	< 0.15 mg/kg IV/ IM

NOTE: Maximal IV/IM pediatric doses must not exceed minimal analgesic dose for ages 16-70

Single Agent Minimal ANXIOLYSIS Hourly Dosing Thresholds:

Anxiolytic Agent	Age < 16 years ◡	Age 16-70	Age > 70
Midazolam	≤0.2mg/kg IM; <0.1mg/kg IV	≤ 5 mg IV/IM	≤2 mg IV/IM
Diazepam	< 0.2 mg /kg IV;	< 5 mg IV	< 2 mg IV
Lorazepam	< 0.1 mg/kg IV	< 2 mg IV	< 1 mg IV

NOTE: Maximal IV/IM pediatric doses must not exceed minimal sedation dose for ages 16-70

Table 1: Levels of Sedation

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/ Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation		Adequate	May be adequate	Frequently inadequate

Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

3) Policy Guidelines:

A. Personnel Requirements and Qualifications:

Licensed Independent Practitioner (LIP) - Any individual permitted by law and credentialed by the organization to provide care, treatment, and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. Within the emergency department LIPs are Emergency Department physician members who are American Board of Emergency Medicine or American Osteopathic Board of Emergency Medicine board certified or board-eligible and, in addition, have a minimum of 6 months of supervised fellowship experience in procedural sedation administration within the organization.

B. The ED Medical Director is responsible for reviewing if the LIP performing procedures has current procedural sedation credentials appropriate for utilizing the sedative medications to be administered.

C. Personnel: The minimum number of health care providers physically attending the patient receiving procedural sedation shall be two, i.e., the LIP responsible for performing the diagnostic/therapeutic procedure and a second designated, properly trained monitoring healthcare professional (Registered Nurse, Advanced Practice Provider, or LIP) who is not otherwise involved in procedure performance. At least one attending physician with sedation privileges shall be present.

1. The monitoring health care professional participating in the procedural sedation patient is responsible for 1) continuously monitoring and documenting at frequent intervals the patient's clinical and physiologic status during procedure performance and 2) activating appropriate emergency response processes as clinically indicated. These professionals can include Registered Nurses, Advanced Practice Providers, and LIPs as defined above. Such individuals should not carry out additional functions during the procedure except for brief, minor, interruptible tasks in patients with stable sedation/analgesia levels and vital signs. Health care professionals charged with monitoring the patient will be trained in appropriate procedural sedation processes and techniques.

2. The LIP is responsible for the overall medical management of the procedural sedation patient as well as for supervising the patient's monitoring health care professional. The Center for Medicare Services (CMS) requires that "Rescue" from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation and returns the patient to the originally intended level of sedation. Such LIP's will demonstrate current, competency-based training, education, and experience in appropriate procedural sedation patient evaluation/selection processes, safe administration of sedative/analgesic medications, patient clinical/physiologic monitoring during the procedural sedation continuum, and ability to rescue patients who unavoidably or unintentionally manifest deeper-than-desired levels of sedation (i.e., moderate sedation → deep sedation or deep sedation → general anesthesia).

3. Demonstration of the above qualifications falls into the 5 main areas of competency detailed below, all of which must be supported by LIP-specific documentation. Baseline qualifications for all LIP's (includes all of the following):

    a. A current, unrestricted NCMB/NCNB Certificate of Registration (training or provisional licenses will not satisfy this criteria)
    b. A current, unrestricted DEA Controlled Substances Registration Certificate

c. A current American Heart Association Health Care Professional Card (i.e., BLS, ACLS and/or PALS required) AND/OR Board Certified/Eligible in Emergency Medicine and maintenance of board certification per ACEP / ABP standards
d. Satisfactory completion signifying the LIP has read/reviewed the contents of this policy and agrees to abide by its terms, processes, and procedures

D. Capabilities:

1. Each procedural sedation site and its respective recovery site (if physically separate from the procedural sedation site) must have the following minimum equipment present and in working order:

   a. Cardiac monitor with alarm capabilities
   b. Pulse oximeter with alarm capabilities
   c. Blood pressure measurement device with alarm capabilities
   d. Suction capabilities with appropriate devices, attachments, and tubing
   e. A high pressure oxygen source capable of delivering a 15 l/min inspiratory flow rate for at least 30 minutes
   f. A self-inflating reservoir bag-valve-mask system capable of both supporting ventilation as well delivering > 90% oxygen concentration at the above flow rates
   g. Capnography equipment (required for Deep Sedation)

2. In addition, each procedural sedation clinical area and its respective recovery area (if physically separate from the procedural sedation area) must have the following emergency response capabilities immediately available:

   a. A fully stocked and appropriately maintained emergency resuscitation cart (which contains the reversal agents naloxone and flumazenil) consistent with current Medical Center Code Blue Committee recommendations
   b. A summary of current, age-appropriate resuscitation algorithms (i.e., ACLS, PALS)
   c. A summary of age-appropriate doses of naloxone and flumazenil

E. Pre-Procedure Processes and Informed Consent:

1. In compliance with medical staff rules and regulations, all patients receiving procedural sedation must receive a pre-procedure medical evaluation under the medical supervision of the LIP focusing on major organ systems to assess their current overall medical condition and determine if they are suitable procedural sedation candidates.

2. While components of this required pre-assessment may be delegated to appropriately licensed health care professionals operating within their legal scope of practice, the LIP is ultimately responsible for reviewing and confirming the accuracy of all information so collected. Such responsibility must be documented by the LIP's signature in the pre- assessment area in the medical record.

3. The pre-procedure history must include at least:

   a. Review of pertinent medical records and current hospital course as appropriate
   b. A brief past medical history and review of systems, with particular emphasis on the airway, respiratory, cardiovascular, and central nervous systems. Special emphasis should be placed

on soliciting a history of/signs and symptoms consistent with a diagnosis of obstructive sleep apnea (OSA) [i.e., BMI > 35 kg/cm2, nighttime CPAP use, loud snoring, etc.].

c. Review of current medications, including both pertinent nonprescription and herbal "supplements".
d. Medication allergies/adverse reactions and their specific clinical manifestations
e. Previous responses to sedatives, analgesics, and/or anesthesia
f. Tobacco, alcohol, and/or illicit drug use
g. Last menstrual period and/or pregnancy test results in females of childbearing age
h. Results of any pertinent diagnostic studies (including resistant organism precautions)
i. Patients requiring emergent procedures in the setting of inadequate fasting periods are at increased risk for aspiration of gastric contents and must undergo an individualized risk-benefit analysis with regards to proceeding immediately under such conditions versus appropriately delaying the procedure to meet these fasting criteria.

F. Fasting Guidelines:

NPO status for liquids and solids is not an independent predictor of major complications or aspiration in a pediatric sedation/anesthesia setting.

1. For healthy patients undergoing elective sedation/analgesia, other professional society guidelines outside of emergency medicine recommend:
   a. ≥2-hour fasting time for clear liquids
   b. ≥6-hour fasting time for solids

2. Applying these guidelines to ED procedural sedation and analgesia may not change the risk of emesis or aspiration. Even within the strict framework of these guidelines, emergent sedations are an exclusion from fasting requirements, although care must be made for airway protection.

3. As a result, guidelines for elective procedures in the operating room (e.g., nothing by mouth, preoperative fasting guidelines) are not directly applicable in the ED. In addition, multiple other practice guidelines and systematic reviews do not find evidence to support a specific fasting period before ED procedural sedation. Care, however, must be used in the patient in whom deep sedation may occur. In essence, specific risk factors for regurgitation and aspiration (bowel obstruction, gastroparesis, poor existing airway reflexes) should be balanced with the type of sedation and urgency of the procedure needing to be performed. Patients requiring emergent procedures in the setting of inadequate fasting periods may be at increased risk for aspiration of gastric contents and must undergo an individualized risk- benefit analysis with regards to proceeding immediately under such conditions, consulting Anesthesia, or appropriately delaying the procedure to meet fasting criteria.

G. Pre-Procedural Physical Exam*:*

1. The pre-procedure physical examination should follow established Emergency Department Policy and include at least:
   a. Height, weight, and BMI
   b. Baseline blood pressure, pulse, respiratory rate, and pulse oximetry measurements
   c. An evaluation of baseline mental status and level of consciousness
   d. Airway exam
   e. Cardiac and pulmonary exams

2. Although ED Physicians regularly deal with critically ill patients and strong sedation/anesthetic medications expected in a high acuity setting, sedation on patients at higher risk for complications for non-emergent procedures may be more appropriate for another setting. Consultation with Anesthesiology is available when significant risk factors (such as ASA classification >3) for procedural sedation complications are identified during the pre-procedure assessment process.

H. Informed Consent and Immediate Pre-Procedure Processes and Documentation*:*

1. Following completion of the pre-procedure assessment, the patient or guardian must be informed of the risks, benefits, and alternatives to procedural sedation as a component of the planned procedure by a health care professional with current, active procedural sedation credentials. Risks of sedation in non-fasting patients must be specifically and separately discussed and documented. Such informed consent must be appropriately documented in the patient's permanent medical record prior to initiating procedural sedation administration, and the current institution universal procedure protocol must be followed in all appropriate patients and documented in the medical record.

2. Immediate pre-procedure baseline vital signs [to include blood pressure, pulse, respiratory rate, pulse oximetry measurement, level of consciousness/mental status, visual analog pain score (adults and older children only), and temperature (infants and younger children only)] and the patient's airway status must be documented in all patients and determined to be acceptable for proceeding.

I. Intra-procedure Processes and Documentation

1. With the possible exception of infants/children, it is strongly recommended that adequate intravenous (IV) access be obtained in all patients requiring procedural sedation and that IV administration of sedatives and analgesics be utilized due to its more rapid and predictable onset of action. All IV sedatives and analgesics so administered must be drawn aseptically into separate syringes and labeled with the medication name and concentration. The choice of procedural sedation agent(s) and dosage(s) administered is the responsibility of the LIP and should be individualized based upon patient-specific factors identified during the pre-procedure assessment as well as conditions required for acceptable procedure performance.

Table 2: IV SEDATION and reversal medication GUIDELINES FOR ADULTS

Medication	Initial IV dose	Onset of action	Incremental IV dose
Ketamine	0.5-1 mg/kg	3-5 minutes	0.5 mg/kg q1 min, up to total of 2 mg/kg in first 3 mins. May repeat q5 mins as needed.
Morphine	0.05-0.1 mg/kg	5 minutes	2-3 mg
Fentanyl	1-2 mcg/kg	3-5 minutes	25-50 mcg
Midazolam	0.05 mg/kg	3-5 minutes	0.5-1 mg

Etomidate	0.1 - 0.15 mg/kg	Less than 1 minute	0.05-0.1 mg/kg
Flumazenil	0.01 mg/kg up to 0.2 mg	1-3 min	0.01mg/kg every 2-3 min 0.01 up to 0.05 mg/kg 0.02 maximum
Naloxone	0.01 mg/kg	2 min	0.01 mg/kg every 2-3 min 0.02 up to 10 mg 0.03 maximum

Table 3: PROPOFOL I.V. DOSING GUIDELINES

INDICATION	Age > 18years	Usual onset/dosing interval
Rapid endotracheal intubation	0.5-1 mg/kg IV bolus	Onset 45-60 seconds; may repeat once in 3-5 minutes at 25-50% of initial dose
Brief (< 10 minutes) procedures with unsecured airway	Initial: 0.5-1.5 mg/kg Increment: 0.25-0.5 mg/kg	Onset 45-60 seconds; may repeat every 2-3 minutes

2. The above IV sedation dosing guidelines come with the following caveats:

   a. The elderly and patients with diminished mental faculties/cognitive decline are generally more sensitive to sedative and analgesic agents. Lower initial and incremental doses are strongly recommended in such patients.
   b. The elderly are also more prone to paradoxical reactions (confusion, agitation, etc.) from benzodiazepine administration.
   c. The elderly similarly tend to have slower circulation times, and longer intervals between dosing increments are strongly recommended.
   d. Benzodiazepine use during pregnancy has been associated with cleft palate/lip deformities.
   e. Propofol must only be administered in an appropriate emergency department location by a properly credentialed physician under close medical direction and supervision of the LIP (as detailed above). Bolus administration is best reserved for brief (< 10 minutes) procedures such as rapid endotracheal intubation, cardioversion, and shoulder relocation. The dose of propofol and its mode of administration must be individualized to the patient's cardiorespiratory status, mentation, age, and the desired clinical end point. Suggested propofol dosages for all indications (as detailed below) should be decreased by at least 25% in all patients who have received other sedatives/analgesics by any route of administration in the hour preceding propofol administration.
   f. Concurrent administration of other sedatives and analgesics (i.e., opioids, benzodiazepines, etc.) by any route of administration is expressly forbidden during titrated propofol sedation administration due to the unpredictable synergistic effects on protective airway reflexes, airway patency, ventilation, and hemodynamics. The addition of ketamine to propofol is acceptable as "Ketafol" may help reduce airway events as compared to propofol alone, since it allows for the propofol dose to be reduced. Precautions include a longer recovery time if greater than 0.5 mg/kg of ketamine is

administered versus propofol alone.

3. All patients to whom procedural sedation is administered must have their clinical and physiologic status continuously monitored by a designated, properly trained, and competent care professional under the medical direction and supervision of the LIP. Such monitoring will consist of multiple parameters in a given patient as detailed in the table below. Physiologic monitor alarm capabilities must be active and utilize appropriate age-specific, patient-specific thresholds.

Table 4. PROCEDURAL SEDATION MONITORING PARAMETERS

System	Clinical Parameters	Physiological	Comments
Mental Status / Level of Consciousness	Appropriate response to light/moderate stimulation	No widely used or validated methodologies	Appropriate verbal response → patent airway, adequate cerebral perfusion, adequate cerebral oxygenation
Oxygenation	Mental status; Skin color	Pulse oximetry	Adequate ambient lighting and patient exposure during the procedure if possible
Ventilation	Airway position and patency; Respiratory rate/pattern; chest excursion; accessory muscle use; snoring respirations; auscultation	End-tidal CO2 measurement; waveform capnography	Pulse oximetry is not a measure of adequate ventilation, especially when supplemental oxygen is being administered; Also see caveat 4 below
Circulation	Mental status; skin color/temperature; pulse rate/quality; capillary refill	Blood pressure; pulse rate; Continuous EKG monitoring (required)	

4. The above monitoring parameters must be documented in the medical record. At a minimum, such information should be documented at least (a) at baseline prior to procedural sedation administration, (b) immediately prior to beginning the diagnostic/therapeutic procedure, (c) at least every 5 minutes during procedural sedation, and (d) immediately following completion of the diagnostic/therapeutic procedure. Additional required documentation should include, but is not limited to (a) intravenous access (size, site, amount and type of fluid administered), (b) sedatives and/or analgesics administered (specific agents, dosages, time of administration), and (c) supplemental oxygen administration, if any (delivery system, inspired concentration, l/min flow rate).

J. Recovery and Discharge Processes and Documentation:

1. Following procedure completion, all procedural sedation patients will undergo an individualized recovery period to ensure that there has been an acceptable return to their pre- procedure condition. Patients with a history of OSA or a BMI > 35 kg/m2 should in general undergo longer periods of recovery observation under most circumstances due to their increased risk of sedation-related airway obstruction prior to being discharged home.

2. Recovery areas other than the procedure room itself must meet the same standards as the procedure room and must be physically located such that the LIP is rapidly available within the ED premises should complications related to the procedure and/or procedural sedation occur. Any patient transported to a separate, designated recovery area must be accompanied and

continuously evaluated by an appropriately credentialed monitoring health care professional.

3. During recovery, the patient must be immediately reassessed with baseline vital signs [to include blood pressure, pulse, respiratory rate, pulse oximetry measurement, level of consciousness/mental status, pain score and temperature (in infants and children less than 3 years only)] obtained. Parameters monitored during the recovery phase should be identical to those monitored during the procedure and must be documented in the medical record. At a minimum, such information should be documented at least (a) baseline at the beginning of the recovery period, (b) at least every 10 minutes following procedural sedation until 3 consecutive sets of stable readings are obtained, then at least every 15 minutes thereafter until:

    a. If returning to their prior domicile, consistently returned to the pre-procedure baseline or,
    b. If being admitted to the hospital, vital signs are considered adequately stable for transport, and their physical status is considered appropriate for their next planned level of care

4. Additional required documentation should include, but is not limited to (a) intravenous access (size, site, amount and type of fluid administered), (b) sedatives and/or analgesics administered (specific agents, dosages, time of administration), and (c) supplemental oxygen administration, if any (delivery system, inspired concentration, l/min flow rate). All patients receiving pharmacologic reversal with either flumazenil and/or naloxone at any point during their care continuum must be recovered for a minimum of 60 minutes after reversal drug administration and continuously monitored for possible rebound sedation.

5. After the patient's level of consciousness and vital signs are documented to have consistently returned to their pre-procedure baseline, the LIP is responsible for patient disposition as clinically indicated. For any patient transferred to another patient care area within the institution, relevant information regarding the patient's pre-procedure assessment, current condition, and responses during the procedure and recovery phase will be verbally transmitted (and appropriately documented) prior to transport by the procedural sedation recovery health care professional to the receiving nurse assuming ongoing care of the patient.

6. Adults and older children being discharged home must be capable of adequate oral/enteral intake, sitting unaided (if able to do so pre-procedure), and ambulating with minimal assistance (if ambulatory prior to the procedure and assuming no procedural contraindications to ambulation). Infants and young children will not be required to meet such pre-discharge activity criteria, although they should clinically appear to have adequate hydration, a comfortable respiratory pattern, and intact airway reflexes. It is preferable to have 2 or more adults accompany infants and young children who are still in car seats if transportation to and from the institution is provided by one of the adults.

7. All patients must be discharged to the care of a competent adult of legal age who accepts responsibility for driving the patient home as well as observing the patient for a minimum of 6 hours and reporting any potential post-procedure complications. This responsible caretaker will be given both written and verbal discharge instructions including, but not limited to: (a) diet, (b) medications, (c) acceptable and unacceptable behaviors/activities, (d) signs/symptoms of complications potentially related to both the procedure as well as to procedural sedation administration, (e) careful observation for head position and possible airway obstruction in infants and children being transported home in car safety seats and, (f) appropriate course of action to take and a 24 hour phone number to contact should any complications arise. In addition, patients with OSA should receive detailed instructions for appropriate home use of ventilatory adjuncts. Such discharge

documentation should be placed in the EHR. While current practice dictates that the patient receiving sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a post- anesthesia evaluation performed by someone qualified to administer anesthesia is not required by CMS.

K. Pediatric Sedation:

1. The pre-procedure assessment process in pediatric patients (institutionally defined as those patients < 18 years of age) should, in addition, evaluate for specific/unique pediatric conditions which may potentially increase a given infant/child's risk for procedural sedation complications.

   a. Prematurity (< 38 weeks gestation and < 60 weeks post-conceptual age)
   b. Term infants (> 38 weeks gestation and < 48 weeks post-conceptual age)
   c. Obesity BMI > 40
   d. Known sleep apnea

2. In addition, choices of sedative and analgesic medications remain similar to older patients but do possess a few differences. In as much as IV access may be more difficult in infants and toddler, other routes of medication administration may prove useful. Duration of sedation is more dependent on drug distribution and redistribution because these processes generally proceed well before elimination comes into play. Thus route of administration and dose are the primarily determinants in duration of action (Table 5) Phenobarbital and chloral hydrate not recommended due to relative lack of efficacy and prolonged sedation.

Table 5: SEDATION, ANALGESIC, AND REVERSAL MEDICATION GUIDELINES FOR PEDIATRICS

Medication	Route	Dose	Clinical Onset	Duration*	Positives	Negatives
Midazolam	IV	0.02-0.05 mg/kg	5-10 min	20-60 min	Fast onset	need IV
	Intranasal	0.2-0.4 mg/kg	10-15 min	60 min	Fast onset	Irritating
	Rectal	0.3-0.75 mg/kg	15-20 min	Variable	Ok for age < 3 y.o.	Not for older children
	Oral	0.3-0.75 mg/kg (avoid > 20 ml)	15-30 min	1-2 hrs.	Easy delivery	Variable onset, bad taste
Fentanyl	IV	0.5-2 mcg/kg	2-5 min	20-60 min	Fast onset	
Morphine	IV	0.05-0.1 mg/kg	5-10 min	1-2 hrs.		Need IV
Ketamine	IV	0.5-2 mg/kg	1-2 minutes	15-60 min	Fast onset	Prolonged sedation
	IM	3-5 mg/kg	5-10 minutes	2-4 hours	Easy delivery	
	PO	5-10 mg/kg	15 minutes	2-6 hours		+ emetic; Excitement phase with agitation in some
Etomidate	IV	0.1-0.2 mg/kg	1-2 min	20-60 min	Rapid onset	
Flumazenil	IV	0.01 mg/kg	1-3 min	<60 min		Can become re-sedated if effect fades prior to elimination of opioid

Naloxone	IV	0.01 mg/kg	2 min	20-60 min		Can become re-sedated if effect fades prior to elimination of opioid

L. Recovery and discharge of infants and children:

a. Recovery and discharge of infants and children receiving procedural sedation should adhere to the following guidelines (Table 6). These published guidelines come from prior studies involving general anesthesia and newborn infants, both premature and full-term. Therefore, they may not relate well to current practice, particularly if using short-acting sedation medications (propofol, e.g.). However, the developing brain, particularly up to 56-60 weeks in post-conceptual age, demonstrates profound sensitivity to all sedating and anesthetic agents, much like the elderly brain.

Table 4. PEDIATRIC PROCEDURAL SEDATION

Pediatric Population	Applicable Age Range	Observation Required for Apnea and Bradycardia	Minimum Individualized Apnea- Free
Infants	Infants > 3 months, but < 6 months actual or corrected gestational age	Yes	> 1hr
Infants, toddlers, and older children	> 6 months	No	Individualized – refer to caveats below

NOTE: Infants < 3months or < 52 weeks post-conceptual age will not be sedated in the ED for procedures. Anesthesia will be consulted.

The ability of a healthy post-full term infant or young child to remain spontaneously awake and alert for at least 20 minutes in a minimally stimulating environment represents an acceptable recovery in most circumstances. Consultation with a faculty member of the Section of Department of Anesthesiology is strongly encouraged when questions arise regarding the appropriate disposition of any pediatric patient.

M. Quality Monitoring of Processes and Outcomes

All patient care areas where procedural sedation (as defined by the terms of this policy) is administered shall monitor their procedural sedation processes and outcomes by extracting appropriate patient data consistent with other areas in the hospital where sedation is administered and reporting that data to the Quality Coordinating Council and Department of Emergency Medicine.

N. Procedural Sedation Quality Indicators

a. Process Indicators: Review of documentation of patient assessment and processes, including documentation of NPO status, Informed consent, compliance with Universal Protocol and other pre-procedure, intra-procedure, and recovery processes consistent with this policy's requirements.

b. Outcome Indicators: Review of potential/actual adverse outcomes, including administration of reversal agents, respiratory compromise, or other complications associated with procedural sedation performed by the Department of Emergency Medicine.

4) Review/Revision/Implementation

a) **Review Cycle:** This policy shall be reviewed by the Emergency Department and Anesthesia at least every 3 years from the effective date.
b) **Office of Record:** After authorization, the policy database and shall be the office of record for this policy.

5) References:

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