TRIHEALTH, INC.
CORPORATE POLICY

TITLE: Sedation Policy: Moderate and Deep	
SECTION: 02	**POLICY NUMBER: 27.00**
EFFECTIVE DATE: 07/1999	**REVIEWED/REVISED DATE(S): 03/2001, 07/2004, 11/2006, 03/2007, 05/2011, 04/2016, 03/2018**
AFFECTED AREAS All TriHealth Hospitals Patient Care Areas: See Appendix B This policy acknowledges that other relevant and applicable policies and procedures exist that have been drafted, approved, and adopted by entities (and departments) within TriHealth and are specific to those departments or entities. Interpretation of these other policies must comply with the principles adopted by Corporate Policy #12_01.00, "Corporate Policies, Development & Implementation".	
POLICY OWNER: Senior VP, Chief Nursing Executive	
APPROVED BY: **Good Samaritan Patient Care Committee** **Bethesda Patient Care Committee** **TriHealth Medical Executive Committee** **Corporate Policy & Procedure Committee** **President of Health Services & System COO** **President & CEO**	

PURPOSE

This policy does not apply to patients receiving general or major conductive anesthesia, whose care should be provided, medically directed, or supervised by an anesthesiologist.

This policy addresses moderate and deep sedation for all patients. This policy does not apply to patients receiving pharmacologic agents for anxiolysis, intubated patients (refer to Article IX "Intensive Care" in the Good Samaritan and Bethesda North Medical/Dental Rules and Regulations), and neonates in the Neonatal Intensive Care Unit.

This policy is designed to provide specific recommendations for the safe care of patients receiving sedation during diagnostic and therapeutic procedures performed. This policy applies to the parenteral administration of drugs.

The purpose of this policy is to allow clinicians to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. While they are primarily meant to address patients receiving moderate and, occasionally, deep sedation; sedation is realized to be a continuum from anxiolysis to inadvertent general anesthesia. It is not always possible to predict how an individual will respond to pharmacological agents. At times, these sedation

practices may result in cardiac or respiratory depression which must be rapidly recognized and appropriately managed to avoid the risk of hypoxic brain damage, cardiac arrest or death.

For pediatric patients (ages 2-13 years of age) receiving Ketamine for procedural/dissociative sedation in the Emergency Department refer to Appendix F & G.

BACKGROUND:

- TJC Std: PC 03.01.01-03.01.07
- Regulatory Agencies: OBN, CMS §482.52
- Licensure:
- Other:

POLICY

I. The practitioner responsible for the treatment of the patient and/or the administration of drugs for moderate or deep sedation shall be appropriately trained. Because moderate or deep sedation by non-anesthesiologists is a continuum from anxiolysis to inadvertent general anesthesia, it is not always possible to predict how an individual will respond to pharmacologic agents. Therefore, practitioners of moderate or deep sedation must be capable of rescuing patients from an unexpected higher level of sedation, e.g. deep sedation progressing to apnea.

A. Definitions for Levels of Sedation (ref: Centers for Medicare and Medicaid Services (CMS) State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals)

1. Minimal Sedation (anxiolysis) is a drug-induced state during which patients responds normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. This is also not anesthesia.

2. Moderate sedation/analgesia is 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. Cardiovascular function is usually maintained. CMS, consistent with ASA guidelines, does not define moderate or conscious sedation as anesthesia.

3. Deep sedation/analgesia is 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. 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 an approved practitioner.

A continuum exists between these levels of sedation. The patient's age and preexisting medical conditions may significantly alter the dosing requirements needed for moderate sedation.

B. Clinical Sites Approved for Moderate or Deep Sedation

1. The administration of moderate or deep sedation by a credentialed Medical Staff appointee is permitted only in designated areas listed in Appendix B. Moderate or deep Sedation is prohibited in any other location.

2. Credentialed medical staff appointees should work with the respective nurse managers and physician leaders to propose any requests for additional clinical sites for moderate or deep sedation in writing to the policy clinical content owners (Directors of Perioperative Services) for review and evaluation by the appropriate institutional bodies.

II. Qualifications

A. Clinical privileges to administer moderate sedation, deep sedation, and general anesthesia are separately delineated by the Medical staff.

B. Qualifications are to be met at the time of initial appointment and each reappointment thereafter.

C. Monitoring Registered Nurse qualifications include:

1. ACLS Certification
2. Knowledge of the pharmacology and side effects of medications used in moderate or deep sedation
3. Successful completion of the Sedation Study Packet (formerly called IV Conscious Sedation Study Packet)
4. Completion of EKG monitoring course or proof of competency
5. Knowledge of capnography monitoring.

III. Moderate or Deep Sedation Staffing

A. A minimum of two individuals credentialed/trained in moderate or deep sedation is required: the credentialed Medical Staff appointee, who performs the surgical or diagnostic procedure, and the Registered Nurse who administers the drugs (except for those agents which can only be administered by a physician, dentist, or CRNA) and monitors the patient's vital signs.

1. The credentialed Medical Staff appointee will be immediately available (within 1 to 5 minutes) to the patient post-procedurally until the patient has completed post-sedation recovery.

2. A designated, appropriately credentialed/trained RN other than the practitioner performing the procedure should be present to monitor the patient throughout a procedure performed with sedation/analgesia.

3. The RN managing the care of the patient receiving moderate or deep sedation shall have no other responsibilities that would leave the patient unattended or compromise continuous monitoring during the procedure.

B. The Medical Director and/or Clinical Manager of the clinical area where moderate or deep sedation is performed shall ensure that the providers of moderate or deep sedation have been granted the necessary/appropriate clinical privileges.

IV. Transportation and care of sedated patients from one approved site to another

A. In those locations where moderate or deep sedation is not allowed, it is prohibited to initiate sedation prior to transport to an approved site unless it is a life-threatening event.

B. Patients who have undergone moderate or deep sedation must achieve an Aldrete score (see Appendix E) of eight (8) or better or have achieved their baseline score prior to transport to another unit.

V. Equipment required for moderate or deep sedation

A. Minimal equipment required for the performance of moderate or deep sedation includes:

1. Oxygen source

2. Oral/Pharyngeal suction

3. Airway management equipment

a. Face masks of various sizes
b. Oral and Nasal airways
c. Endotracheal tubes
d. Laryngoscope and Blades
e. Ambu Bag

4. Resuscitative equipment and medications including Code Cart

5. Reversal agents including Naloxone (Narcan) and Flumazenil (Romazicon)

6. Continuous pulse oximeter

7. Blood Pressure machine (automatic preferred)

8. Cardiac monitor/Defibrillator with printer

9. Capnography, when ordered by physician

VI. Agents used for Moderate or Deep Sedation: Refer to Appendix A for medication guidelines

A. The following short acting/general anesthesia drugs cannot be administered by an RN (with the exception of a CRNA) when the intent is moderate sedation:

- Etomidate - amidate
- Sodium Pentothal
- Sodium Brevital
- Innovar – fentanyl and droperidol
- Sufenta - sufentanil
- Alfentanil - Alfenta
- Propofol -Diprivan
- Drugs classified for deep/general anesthesia administered by anesthesia care providers, including CRNAs.

B. For the administration by an RN of Ketamine intended for purposes other than anesthesia (i.e., pain control) refer to Nursing Policy NR-27 Low Dose IV Ketamine Infusion for Opioid Resistant Pain Control.

C. To produce an amnestic, pain-free, sedate patient, a combination of sedative, hypnotic, and opioid medications is required. Through pharmacologic intervention, the patient's perception of time is altered and cooperation is enhanced. Titration of medications is required to achieve the planned state of moderate sedation or deep sedation; which occurs on a continuum.

D. The simultaneous administration of benzodiazepines and narcotics constitute the majority of moderate sedation techniques. The specific diagnostic or surgical procedure, patient population, or desired level of consciousness determines the choice of a variety of medication regimens.

E. The clinical endpoints of moderate sedation are nystagmus, slurred speech, and decreased patient anxiety. Unconsciousness, unresponsiveness, and deep sedation are not the objectives of moderate sedation, whose complications - hypoxia, hypercarbia, cardiopulmonary depression, and delayed recovery- rise proportionately as sedation deepens.

PROCEDURE

VII. Assessment and Documentation Requirements

A. Pre-procedure

1. The physician performing the pre-sedation assessment selects and orders diagnostic tests as clinically indicated for the procedure (see Appendix C). The assessment and documentation will be completed within 30 days and include, but not be limited to:
    a. History and Physical (with 24 hour update if applicable)
    b. Brief history and physical with review of systems pertinent to the procedure
    c. Pre-procedural/Sedation Assessment, including assessment of airway patency
    d. Results of pre-procedure diagnostic tests, if applicable.
    e. Allergies and response
2. The physician performing the procedure obtains informed consent from the patient prior to the procedure. This consent should include the risks/benefits of moderate or deep sedation.
3. The physician or qualified designee will assess and document in the progress notes the status of the patient's airway immediately prior to the administration of sedative agents using Mallampati Classification and ASA Scoring.
    a. Obstructive Sleep apnea patients: Use capnography monitoring and instruct these patients to bring their CPAP machine or have similar equipment available.

4. Use of IV sedative agents must be preceded by an evaluation of food and fluid intake. Patients receiving IV sedative agents should be NPO for an appropriate time prior to the procedure (to be determined by the physician). See Appendix D for NPO guidelines.

5. If a reversal agent is administered, the patient must be monitored for an additional two hours from the time the reversal agent is administered.

6. The incident report is to be completed when a reversal agent is used, when resuscitation is needed, airway support using an ambu bag or intubation, vomiting/aspiration occurs, or if the patient has any indication of a negative outcome.

7. The RN will confirm assessment and/or documentation of the following:
    a. Consent form and procedure verification checklist
    b. Baseline vital signs, including oxygen saturation, baseline cardiac rhythm, and capnography, when ordered by the physician.
    c. Level of consciousness/emotional status
    d. Evaluation of pregnancy status via urine HCG testing for all menstruating females up to greater than to 2 years post menopausal, except if menopause is surgically induced. (Non-emergent cases only). If patient unable to provide urine, serum testing will be performed. Physician discretion will be used if patient refuses serum testing or when serum testing is not available on site.
    e. IV access
    f. Current medications and allergies
    g. Pain level using 0-10 pain score with 0 as no pain and 10 as the worst pain
    h. NPO status see Appendix D
    i. Aldrete pre-sedation assessment (Aldrete baseline) using the Aldrete Assessment Score (See Appendix E) immediately prior to sedation on Sedation Record
    j. All necessary equipment is available and the appropriate monitoring equipment is attached to the patient
    k. The physician is notified of any abnormal findings in diagnostic test results or vital signs

B. Intra-procedure

1. Appropriate safety measures are implemented prior to the initiation of the procedure, e.g. check all monitoring devices and ensure pre-set alarm limits are engaged.

2. During the procedure, the following physiological parameters are monitored and documented at least every five (5) minutes:
    a. Heart Rate and Rhythm
    b. Oxygenation via pulse oximetry
    c. Blood Pressure
    d. Respiratory Rate
    e. Level of Consciousness

f. Medications administered including drug, dosage, route, site, and patient's response (includes supplemental oxygen)
g. Capnography, when ordered by the physician

C. Post-procedure

1. The patient will be assessed by an RN post-procedurally every 15 minutes for at least 30 minutes or until the patient returns to a score of eight (8) or a score equal to the Aldrete baseline score. The assessment will include, but not be limited to:

    a. blood pressure, pulse, oxygen saturation, respiratory rate
    b. level of consciousness
    c. activity – movement of extremities
    d. capnography, when ordered by the physician

2. Physician will be notified of changes in patient condition.

3. Patient may be discharged to nursing unit or home when stable with appropriate physician discharge order.

D. Discharge Criteria

1. Any patient receiving naloxone or flumazenil will require a minimum two-hour period of observation following the last administration of the reversal agent.

2. Discharge to home or to a lower level of care is permitted only when:

    a. Upon assessment, patients achieve an Aldrete score of eight (8) or a score equal to their Aldrete baseline score
    b. Patient can sit unaided, if appropriate to baseline assessment and procedure
    c. Patient can walk with assistance, if appropriate to baseline assessment and procedure
    d. Patient is tolerating fluids without nausea or vomiting

3. Written and verbal post-procedure instructions will be given to the patient being discharged and an accompanying adult prior to the patient's discharge

4. Patients may not drive a car the day of the procedure

5. Patient is encouraged to have a responsible person available for 24 hours post procedure

6. For patients transferred for further care within the institution, standard criteria shall be applied for transfer of care

E. Patients in Isolation:

Patients in strict isolation for whom movement to an approved location may compromise their health status or endanger the health of others, may have moderate or deep sedation performed in the isolation area. It is the responsibility of the service performing the procedure to provide a qualified monitoring person for the procedure and until there is complete

recovery to baseline. The physician performing the procedure must be immediately available until the recovery is complete.

OTHER AREAS/POLICIES OR PROCEDURES OF REFERENCE

Good Samaritan and Bethesda North Medical/Dental Rules and Regulations

APPENDIX A
GUIDELINES FOR MEDICATION DOSING*

Drug	Moderate/Deep (i.e., cardioversion, rapid sequence intubation, endoscopy, bone marrow biopsy)	Side Effects
Midazolam (Versed) 1 mg/ml, 5 mg/ml	0.5 mg - 5 mg over 5 minutes in incremental doses	Over sedation Respiratory depression Apnea
Fentanyl[1] (Sublimaze) 50 mcg/ml	50 mcg - 200 mcg over 1-2 minutes in incremental doses	Apnea Hypotension Chest Rigidity (in higher doses)
Demerol (Meperidine) 50 mg/ml, 100 mg/ml	25 mg - 100 mg over 5 minutes in incremental doses	Respiratory depression Apnea Hypotension
Deep or general anesthesia, even for brief periods may occur with the following list of drugs. In selected circumstances, these may be used for cardioversion, defibrillation threshold during Implantable Cardioverter - Defibrillator (ICD) implants, or situations requiring emergent intervention. To administer these drugs, the practitioner must demonstrate appropriate competency/credentials. The delineation of privileges is separate and on file.		
Brevital (Methohexital) 500 mg in D5W or NS	50 mg - 120 mg (1 - 1.5 mg/kg) IVP 10 mg/ml at 1 ml/5 seconds	Lasts 5 - 7 minutes for cardioversion Apnea, Hiccups, Bronchospasm, Coughing, Nausea, Vomiting
Etomidate 2 mg/ml	0.1 mg - 0.3 mg/kg over 60 seconds	Apnea, Nausea, Hiccups, Hypotension, Myotonic twitching, Adrenal suppression, Phlebitis
Ketamine (Ketalar) (See Nursing Policy NUR-27 for use of Ketamine as an analgesic)	0.2 mg - 1 mg/kg over 2 minutes (OB - post delivery hemorrhaging emergency only: 10 - 20 mg IVP x 1) IM dosing option of 4-5 mg/kg for patients presenting with a syndrome of excitatory delirium *Pre-medicate with a benzodiazepine	Apnea Increase in bronchial secretions SNS Hyperactivity (tonic clonic movements seen) Hallucinations Increases ICP
Propofol (Diprivan) 200 mg/20 ml	0.5 mg - 1 mg/kg over 60 seconds (may administer lidocaine 25 mg - 50 mg IVP prior to giving propofol to reduce the incidence of propofol-related injection-site discomfort)	Apnea Profound hypotension Cardiac depression

*Dosing guidelines are not intended to be exhaustive, understanding that clinical situations warrant patient-specific medication titration, which can extend beyond the ranges listed above. Caution should be exercised when exceeding the range to predict and manage monitoring requirements accordingly. Sheath pull and chest tube removal are examples of minimal sedation (anxiolysis). Anxiolysis medications may be administered in any patient care area providing personnel are appropriately trained (see Appendix B).

[1]Fentanyl or other opioids (Morphine, Demerol) may be used alone for pain management. When used alone or in combination with benzodiazepines for moderate sedation, this policy will be implemented. Combination therapy may double the sedation effect.

Reversal Agents:

Reversal Agent	Dose and Infusion Rate	Onset and Duration of Action	Nursing Considerations
Flumazenil (Romazicon), used to reverse the effects of the benzodiazepine sedatives	0.2 mg over 15 seconds. After 1 minute, another dose of 0.2 mg may be given and repeated every minute until reaching a maximum of 1.0 mg.	Onset: 1 - 2 minutes, with a maximum effect in 6 - 10 minutes. Duration: 30 - 60 minutes	Because of the duration of benzodiazepines, such as Valium and Versed, is longer than the duration of Flumazenil, it's possible for re-sedation to occur. Patient must be watched very carefully.
Naloxone (Narcan), used to reverse the effects of opioid analgesics	0.1 - 0.2 mg, IV push, titrated as needed. May repeat in 2 - 3 minute intervals. May also consider dilution protocol from PCA order set: Dilute 0.4 mg (1 ml vial) of Naloxone in 9 ml of sodium chloride 0.9% for a 0.04 mg/ml solution. Administer slow IVP 0.5 ml (0.02 mg) over 2 minutes. May repeat in 2 minutes as needed at the same rate up to 0.8 mg or 20 ml maximum until respiratory rate is at a safe level but analgesia is not reversed.	Onset: 2 - 3 minutes Duration: 30 - 60 minutes	Although the drug can reverse respiratory depression, it also can eliminate narcotics, such as Demerol and Morphine's analgesic effect. If you give too much, the patient will experience pain that cannot be managed with any narcotic for 60 minutes. On the other hand, it's also possible for Naloxone's effects to wear off too soon, so watch for re-emergence of respiratory depression.

APPENDIX B
CLINICAL SITES APPROVED FOR MODERATE SEDATION

The administration of moderate sedation by appropriately trained/privileged personnel is permitted only in designated areas. These locations include:

Bethesda Hospital*	**Good Samaritan Hospital***	**TriHealth Hospital (Evendale)**
Cardiology Department: Cardiac Catheterization Echocardiology Electrophysiology	Cardiology Department: Cardiac Catheterization Echocardiology Electrophysiology	Main Operating Room
Special Procedures	Special Procedures	Post Anesthesia Care Unit
Endoscopy Unit (including Bethesda Butler)	Endoscopy Unit	Endoscopy (including Endoscopy Center North)
Main Operating Rooms (including Bethesda Butler)	Operating Rooms	Same Day Surgery
Post Anesthesia Care Unit (including Bethesda Butler)	Post Anesthesia Care Unit	Outpatient Treatment Center (OTC)
Cardiovascular Recovery Unit (CVRU)	CVICU and MSICU	Hand Surgery Center
Emergency Department (including Arrow Springs; Bethesda Butler)	Emergency Department (including Western Ridge)	Surgery Center West
MSICU	Medical/Surgical ICU	
Radiology Department (including Medicenter North Diagnostics)	Radiology Department	
	Neuroscience Intensive Care Unit	
Ambulatory Surgery Center (Minimally Invasive Surgery Center; BSC)		
Ambulatory Treatment Center	Outpatient Treatment Center (OTC)	
Radiation Oncology	Radiation Oncology	
Telemetry Unit	Telemetry Unit	

*Inpatient medical units at Bethesda North Hospital and Good Samaritan Hospital (e.g. Behavioral Health Services Department when there is concern that a patient may be negatively impacted by change in environment) may perform moderate sedation only with the assistance from a competent, ACLS-trained registered nurse (e.g. the ICU Charge Nurse or CNS), and with rescue equipment readily available.

CLINICAL SITES APPROVED FOR DEEP SEDATION

The administration of deep sedation by appropriately trained/privileged personnel is permitted only in designated areas. These locations include:

Bethesda North Hospital	**Good Samaritan Hospital**	**TriHealth Hospital (Evendale)**
Emergency Department (including Arrow Springs; Bethesda Butler)	Emergency Department (including Western Ridge)	
	Electrophysiology Lab	
Locations cardioversions* are performed: • Cath Lab • Telemetry	Locations cardioversions* are performed: • Cath Lab • Telemetry	
All intensive care units (including Bethesda Butler)	All intensive care units	ICU

*Respiratory Therapist is present to assist with airway management

APPENDIX C

PRE PROCEDURAL SEDATION / ANESTHESIA PLAN	
□	**ASA Physical Status Classification**
	ASA I - Healthy, no systemic disease.
	ASA II - Mild to moderate systemic disease not life-style limiting (asymptomatic hypertension, diabetes without end-organ dysfunction).
	ASA III - Severe systemic disturbance which is life-style limiting (exercise induced angina, severe asthma limiting activity, s/p CVA with weakness).
	ASA IV - Severe systemic disturbance which is life-threatening (congestive heart failure, rest angina).
	ASA V - Moribund patient with little chance of survival submitted to a procedure as a last resort.

The Mallampati classification is performed with the patient in the sitting position, the head held in a neutral position, the mouth wide open, and the tongue protruding to the maximum. The subsequent classification is assigned based upon the pharyngeal structures that are visible.

□	Visualization	Mallampati classification
	 Class I	Class I - visualization of the soft palate, fauces, uvula, anterior and posterior pillars. A class I view suggests ease of intubation and correlates with a laryngoscopic view grade I 99 to 100% of the time
	 Class II	Class II - visualization of the soft palate, fauces and uvula.
	 Class III	Class III - visualization of the soft palate and the base of the uvula
	 Class IV	Class IV - soft palate is not visible at all. Class IV view suggests a poor laryngoscopic view, grade III or IV 100% of the time

SEDATION PLAN □ appropriate boxes

	Midazolam		Etomidate		Fentanyl		Ketamine		Flumazenil
	Diazepam		Droperidol		Brevital		Propofol		Other:

MD Signature: _____ Date: _____

APPENDIX D

NPO GUIDELINES FOR ADULT AND PEDIATRIC PATIENTS
(Non-emergent cases only)

ADULT NPO GUIDELINES
For patients over the age of 15

Milk, solids, and other opaque liquids (e.g., orange juice, tomato juice)	6 hours
Clear liquids (water, apple juice, black coffee, black tea)	2 hours

PEDIATRIC NPO GUIDELINES
For children 1 day to 15 years

Nonhuman milk and solids	6 hours
Clear liquids	2-3 hours
Breast milk	4 hours

Please Note:

1. For patients scheduled after 12:00 noon the morning meal should be a clear liquid breakfast.

2. Patients with gastrointestinal disorders or reflux might require longer NPO times.

APPENDIX E
MONITORING SCALES

SEDATION SCALE

1 - Awake, alert, readily follows commands
2 - Occasionally drowsy, easy to arouse
3 - Frequently drowsy
4 - Somnolent, difficult to arouse – call MD
5 – Unresponsive, does not awaken to stimuli – call MD

ALDRETE ASSESSMENT SCORE

Aldrete Assessment **Must have a pre/post score for each episode of sedation**			**Aldrete BASELINE**	**Aldrete POST SCORE**
Moves extremities voluntarily or on command Moves extremities weakly No movement	- 2 - 1 - 0	Activity		
Spontaneous respiration – needs no support Spontaneous respiration – needs artificial airway Needs mechanical ventilation	- 2 - 1 - 0	Respiration		
SBP ± 20 % of pre-anesthesia level SBP ± 20 – 50 % of pre-anesthesia level SBP ± 50 % of pre-anesthesia level	- 2 - 1 - 0	Circulation		
Awake – seldom dozes Awakens when stimulated Unresponsive	- 2 - 1 - 0	Consciousness		
Maintains O2 saturation greater than 92% on room air Requires O2 inhalation to maintain O2 saturation greater than 90% O2 saturation less than 90% even with supplemental O2	- 2 - 1 - 0	Oxygenation		
If a reversal agent is used, patient must be monitored for an additional 2 hours from the time it is administered. The sedation monitoring form must be completed.		**TOTALS**		
		Initials		

APPENDIX F
CLINICAL PRACTICE GUIDELINE
FOR PEDIATRIC KETAMINE ADMINISTRATION ED

PURPOSE

The purpose of this guideline is to define pediatric patient selection, administration and recovery for ED dissociative sedation and to allow clinicians to provide their pediatric patients with the benefits of sedation/analgesia while minimizing the associated anxiety and pain.

This guideline is designed to provide specific recommendations for the safe care of pediatric patients receiving dissociative sedation during therapeutic procedures performed in the ED. This guideline applies to the administration of ketamine.

DEFINITION OF DISSOCIATIVE SEDATION

A trancelike cataleptic state induced by the dissociative agent ketamine, characterized by profound analgesia and amnesia, with the retention of protective airway reflexes and spontaneous respirations and cardiopulmonary stability.

CHARACTERISTICS OF THE KETAMINE "DISSOCIATIVE STATE"

Dissociation: After administration of ketamine, the patient passes into a fugue state of trance. The eyes may remain open, but the patient does not respond.
Catalepsy: Normal or slightly enhanced muscle tone is maintained. On occasion, the patient may move or be moved into a position that is self-maintaining. Occasional muscular clonus may be observed.
Analgesia: Analgesia is typically sustained or complete.
Amnesia**:** Total amnesia is typical.
Maintenance of airway reflexes: Upper airway reflexes remain intact and may be slightly exaggerated. Intubation is unnecessary, but occasional repositioning of the head may be necessary for optimal airway patency. Suctioning of hypersalivation may occasionally be necessary.
Cardiovascular stability: Blood pressure and pulse rate are not decreased and typically are mildly increased.
Nystagmus: Nystagmus is typical.

POLICY

I. Indications
Short, painful procedures, especially those requiring immobilization (e.g. facial lacerations, fracture relocation, abscess incision and drainage).

II. Qualifications

A. Monitoring Registered Nurse qualifications include:

1. ACLS/PALS Certification.
2. Knowledge of the pharmacology and side effects of ketamine.
3. Successful completion of the Sedation Study Packet
4. Completion of EKG monitoring course or proof of competency.
5. Knowledge of capnography monitoring.

III. Staffing

A. A minimum of two individuals credentialed/trained in procedural sedation is required: the credentialed Medical Staff appointee, who administers ketamine and performs the surgical or diagnostic procedure, and the Registered Nurse who monitors the patient's vital signs.

1. The credentialed Medical Staff appointee will be immediately available (within 1 to 5 minutes) to the patient post-procedurally until the patient has completed post-sedation recovery.

2. A designated, appropriately credentialed/trained RN other than the practitioner performing the procedure should be present to monitor the patient throughout a procedure performed with dissociative sedation.

3. The RN managing the care of the patient receiving ketamine sedation shall have no other responsibilities that would leave the patient unattended or compromise continuous monitoring during the procedure.

IV. Equipment required for ketamine sedation

A. Minimal equipment required for the performance of ketamine sedation includes:

1. Oxygen source

2. Oral/Pharyngeal suction

3. Airway management equipment (readily available if needed)
    a. Face masks of various sizes
    b. Oral and Nasal airways
    c. Endotracheal tubes
    d. Laryngoscope and Blades
    e. Ambu Bag

4. Resuscitative equipment and medications including Pediatric Code Cart

5. Continuous pulse oximeter

6. Blood Pressure machine (automatic preferred)

7. Cardiac monitor/Defibrillator with printer

8. Capnography, required

PROCEDURE

V. Assessment and Documentation Requirements

A. Pre-procedure

1. The physician performing the pre-sedation assessment selects and orders diagnostic tests as clinically indicated for the procedure (see Appendix C). The assessment and documentation will be completed within 30 days and include, but not be limited to:

    a. History and Physical (with 24-hour update if applicable)

b. Brief history and physical with review of systems pertinent to the procedure
c. Pre-procedural/Sedation Assessment, including assessment of airway patency
d. Results of pre-procedure diagnostic tests, if applicable.
e. Allergies and response

2. The physician performing the procedure obtains informed consent from the patient prior to the procedure. This consent should include the risks/benefits of ketamine sedation.

3. The physician or qualified designee will assess and document in the progress notes the status of the patient's airway immediately prior to the administration of sedative agents using Mallampati Classification and ASA Scoring.

4. An incident report is to be completed when resuscitation is needed, airway support using an ambu bag or intubation, vomiting/aspiration occurs, or if the patient has any indication of a negative outcome.

5. The RN will confirm assessment and/or documentation of the following:
    a. Consent form and procedure verification checklist
    b. Baseline vital signs, including oxygen saturation, baseline cardiac rhythm, and capnography.
    c. Level of consciousness/emotional status
    d. Evaluation of pregnancy status via urine HCG testing for all menstruating females.
    e. If administering IV Ketamine, IV access (See Appendix G)
    f. Current medications and allergies
    g. Pain level using 0-10 pain score with 0 as no pain and 10 as the worst pain or FLACC score.
    h. Aldrete pre-sedation assessment (Aldrete baseline) using the Aldrete Assessment Score (See Appendix E) immediately prior to sedation on Sedation Record
    i. All necessary equipment is available and the appropriate monitoring equipment is attached to the patient

6. The physician is notified of any abnormal findings in diagnostic test results or vital signs

7. Educate the accompanying family about the unique characteristics of the dissociative state if they will be present during the procedure or recovery.

8. Frame the dissociative encounter as a positive encounter. Consider encouraging older children to "plan" specific, pleasant topics in advance of sedation (believed to decrease unpleasant recovery reactions). Emphasize that ketamine delivers sufficient analgesia, so there will be no pain.

9. Ketamine administration
    a. Ketamine is initially administered as a single IV loading dose, IM injection, or IN inhalation.

b. The IM route is especially useful when IV access cannot be consistently obtained with minimal upset, and for patients who are uncooperative or combative (e.g. the mentally disabled).
c. IV access is unnecessary for children receiving IM or IN ketamine (unpleasant recovery reactions are more common in adults). Evidence strongly supports similar safety between IV, IM, and IN routes.
d. Dosage, Route and Side Effects of Ketamine (See Appendix G)

B. Intra-procedure

1. Appropriate safety measures are implemented prior to the initiation of the procedure, e.g. check all monitoring devices and ensure pre-set alarm limits are engaged.

2. During the procedure, the following physiological parameters are monitored and documented at least every five (5) minutes:

    a. Heart Rate and Rhythm
    b. Oxygenation via pulse oximetry
    c. Blood Pressure
    d. Respiratory Rate
    e. Level of Consciousness
    f. Medications administered including drug, dosage, route, site, and patient's response (includes supplemental oxygen)
    g. Capnography, required

C. Post-procedure

1. The patient will be assessed by an RN post-procedurally every 15 minutes for at least 30 minutes or until the patient returns to a score of eight (8) or a score equal to the Aldrete baseline score. The assessment will include, but not be limited to:

    a. blood pressure, pulse, oxygen saturation, respiratory rate
    b. level of consciousness
    c. activity – movement of extremities
    d. capnography

2. Physician will be notified of changes in patient condition.

3. Patient may be discharged to nursing unit or home when stable with appropriate physician discharge order.

D. Discharge Criteria

1. Discharge to home or to a lower level of care is permitted only when:

    a. Upon assessment, patients achieve an Aldrete score of eight (8) or a score equal to their Aldrete baseline score.
    b. Patient can sit unaided, if appropriate to baseline assessment and procedure.
    c. Patient can walk with assistance, if appropriate, to baseline assessment and procedure.

2. Patient is to have a responsible person available for 24 hours post procedure

E. Discharge Instructions

1. Nothing by mouth for approximately 2 hours.
2. Careful parent/caregiver observation and no independent ambulation for approximately 2 hours.
3. Written and verbal post-procedure instructions will be given to parent/caregiver prior to the patient's discharge.

APPENDIX G
PEDIATRIC KETAMINE DOSAGE AND ADMINISTRATION

Administration Route	IV	IM	IN
Dosage	• 1.5 to 2.0 mg/kg IV as loading dose over 30 to 60 sec. • May repeat 0.5 to 1.0 mg/kg in incremental doses if needed	• 4 to 5 mg/kg as loading dose • May repeat full or half dose after 5 to 10 minutes if needed	• 3-9mg/kg IN • ½ of total dose per nostril • May repeat initial dose after 5 minutes for a total of 9mg/kg.
Advantages	Ease of repeated doses, less vomiting, faster recovery	No IV access necessary	No IV access necessary
Peak concentration and onset, min.	1	5	5-20
Typical duration of effective dissociation, min.	5-10	20-30	25-60
Typical time from dosage to discharge, min.	50-110	60-140	60-140

Potential Adverse Effects
(Percentage estimates are for children)

- Airway misalignment requiring repositioning of the head (occasional)
- Transient laryngospasm (0.3%)
- Transient apnea or respiratory depression (0.8%)
- Hypersalivation (rare)
- Emesis, usually well into recovery (8.4%)
- Recovery agitation (mild in 6.3%, important in 1.4%)
- Muscular hypertonicity and random, purposeless movements (common)
- Clonus, hiccupping, or short-lived non-allergic rash of face and neck