

LOS ANGELES GENERAL MEDICAL CENTER POLICY

Subject: MODERATE SEDATION/DEEP SEDATION	Original Issue Date: 4/4/02	Policy # 905
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Policy Owner(s): Chief, Anesthesia Services Executive Sponsor(s): Chief Medical Officer		
Department(s) and Committee(s) Consulted: Department of Anesthesiology Dentistry Emergency Medicine Neurosurgery Otolaryngology Obstetrics/Gynecology Pediatrics Radiology Surgery Department of Quality Improvement Nursing Services and Education Medical Administration Pharmacy	Reviewed & Approved by: Attending Staff Association Executive Committee Senior Executive Officer	Approved by: Chief Medical Officer
		Chief Executive Officer

PURPOSE

To provide general guidelines for the provision of safe moderate / deep sedation throughout the Los Angeles General Medical Center regardless of the location, procedure performed, or personnel providing such service.

POLICY

This policy establishes procedures and general guidelines for the provision of safe moderate / deep sedation administration to be followed by Medical Center Attending Staff and employees. The policy and procedures will be followed wherever and whenever moderate / deep sedation is administered.

This policy is applicable to all cases of moderate / deep sedation and does not apply to minimal sedation (anxiolysis), or anesthesia. In addition, this policy does not apply to medications used for the management of pain control, seizures, sedation of a patient with a secured airway, or the administration of pre-operative medications.

Moderate / deep sedation practices and outcomes shall be monitored and evaluated by the Department of Anesthesiology on a regular basis. Identified concerns will be referred to the appropriate departments, and/or committees to assure that processes related to the use of moderate / deep sedation are continuously assessed and improved.

A consultation with the Department of Anesthesiology is recommended for patients classified as American Society of Anesthesiology (ASA) IV and a consultation with the Department of Anesthesiology is **required** for patients classified as ASA V except in the Emergency Department where Anesthesia consultation will be at the discretion of the Emergency Department Attending.

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DEFINITION

This policy applies to all patients receiving moderate / deep sedation in any setting, for any purpose, **by any route (Oral, IM, IV, or rectal)** as defined in this policy. The institution currently defines four (4) levels of sedation, analgesia, and anesthesia, including the following:

Minimal Sedation or Anxiolysis:
(Not addressed by this policy)

A drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia:

A drug induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a painful stimulus is *not* considered a purposeful response) 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 not affected.

Deep Sedation/Analgesia:

A drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually not affected. (While deep sedation may be an undesired effect when attempting moderate sedation, there are situations whereby deep sedation is a state that may be preferable.)

Anesthesia:
(Not addressed by this policy)

Consists of general anesthesia and spinal or major regional anesthesia and does not include local anesthesia. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable even by painful stimuli. The ability to independently maintain ventilatory function is often impaired.

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- **Supervision:** All moderate / deep sedation must be administered under the supervision of a licensed independent practitioner (Attending Staff) who has been granted clinical privileges for the administration of moderate / deep sedation.
- **Licensed Personnel:** A qualified registered nurse or qualified licensed practitioner (i.e., physician, dentist, podiatrist, or physician assistant) must have the primary responsibility for medication administration and/or monitoring of the patient's vital signs and level of sedation during the administration of moderate / deep sedation.
- **Staffing:** A sufficient number of qualified personnel shall participate in administering moderate / deep sedation in addition to the practitioner performing the procedure. Qualified personnel shall be present during the procedure using moderate / deep sedation to appropriately evaluate and monitor the patient during the procedure and recover and to discharge the patient from the post-sedation recovery area.
 - **Moderate Sedation:** The licensed personnel assigned to monitor the patient during moderate sedation may assist with minor, interruptible tasks once the level of sedation / analgesia and vital signs have stabilized, provided that adequate monitoring of the patient's level of sedation is maintained. A second nurse or assistant may be required to assist the physician with those procedures that are complicated either by the severity of the patient's illness and/or complexity of the diagnostic and therapeutic procedures being performed.
 - **Deep Sedation:** During deep sedation licensed personnel must be assigned to only monitor the patient without any other responsibilities.

Personnel (Competency) Requirements**Attending Staff (Faculty) and Mid-level Providers**

- All moderate / deep sedation will be supervised by a credentialed attending practitioner holding current privileges to administer moderate / deep sedation. Specific privileging criteria for moderate / deep sedation as defined by this policy will be utilized as approved by the Attending Staff Association Executive Committee.
- Attending Staff and privileged mid-level providers must demonstrate clinical competency in managing a compromised airway through recent experience or training before administering moderate / deep sedation, as follows:
 - **Moderate sedation** - provide adequate oxygenation and ventilation.
 - Basic Life Support Certification (BLS) or age-appropriate advanced life support training such as Advanced Cardiac Life Support (ACLS), Advanced Pediatric Advanced Life Support (PALS) or equivalent is required.
 - **Deep sedation** - provide adequate resuscitation.

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- Age-appropriate advanced life support training such as Advanced Cardiac Life Support (ACLS), Advanced Pediatric Advanced Life Support (PALS) or equivalent is required.
- All Attending Staff and privileged mid-level providers shall demonstrate didactic competency by completion of the Moderate Sedation Module (**Attachment A**) and attaining a satisfactory score on the posttest on moderate sedation (**Attachment B**).
- The Attending Staff and privileged mid-level providers responsible for providing moderate / deep sedation shall have age-specific training which includes:
 - Basic airway management:
 - Cardiac monitoring
 - Use of sedative/reversal agents and knowledge of their use
 - Ensuring adequacy of pulmonary ventilation
 - Administering oxygen therapy when needed
 - The ability to intervene in the event of complications
 - Implementation of required resuscitation efforts including summoning additional personnel with advanced life support skills.
 - Demonstration of knowledge of moderate / deep sedation policy and procedure
- Documentation of current competency related to the use of moderate / deep sedation shall be maintained by the Attending Staff Office. Renewing of privileges for moderate / deep sedation shall occur in conjunction with renewal of attending staff or mid-level provider privileges (no greater than every 2 years). Attending staff or privileged mid-level providers must either demonstrate having performed or supervised greater than 8 cases within the past 2 years or repeat the competency requirement as stated above. Physicians demonstrating competency by case completion will be required to familiarize themselves to the moderate / deep sedation policy at renewal of clinical privileges.

Resident Physicians and Resident Dentists

- All residents must demonstrate clinical competency in managing a compromised airway through recent experience or training before administering moderate / deep sedation, as follows:
 - **Moderate sedation** - provide adequate oxygenation and ventilation.
 - Basic Life Support Certification (BLS) **or** age-appropriate advanced life support training such as Advanced Cardiac Life Support (ACLS), Advanced Pediatric Advanced Life Support (PALS) or equivalent is required. Residency training programs may include additional requirements.
 - **Deep sedation** - provide adequate resuscitation.
 - Age-appropriate advanced life support training such as Advanced Cardiac Life Support (ACLS), Advanced Pediatric Advanced Life Support (PALS) or equivalent is required. Residency training programs may include additional requirements.

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- All residents shall demonstrate didactic competency by completion of the Moderate Sedation Module (**Attachment A**) and attaining a satisfactory score on the posttest on moderate sedation (**Attachment B**).
- The Resident responsible for providing moderate / deep sedation shall have age-specific training which includes:
 - Basic airway management:
 - Cardiac monitoring
 - Use of sedative/reversal agents and knowledge of their use
 - Ensuring adequacy of pulmonary ventilation
 - Administering oxygen therapy when needed
 - The ability to intervene in the event of complications
 - Implementation of required resuscitation efforts including summoning additional personnel with advanced life support skills.
 - Demonstration of knowledge of moderate / deep sedation policy and procedure
- Documentation of current competence related to the use of moderate / deep sedation as defined herein shall be maintained within each respective clinical department. Residents must either demonstrate having performed greater than 8 cases within the past 2 years or repeat the competency requirement as stated above. Resident physicians demonstrating competency by case completion will be required to familiarize themselves to the moderate/deep sedation policy.

Registered Nurses and Monitoring by Licensed Personnel

- Monitoring licensed personnel must be capable of providing basic life support and airway management. Basic Life Support Certification (BLS) or age-appropriate advanced life support training such as such as Advanced Cardiac Life Support (ACLS), Advanced Pediatric Advanced Life Support (PALS) or equivalent is required.
- The Registered Nurses assisting with moderate/deep sedation in the procedural areas shall receive orientation and training regarding their role in the assessment, monitoring and discharge education of the patient undergoing moderate/deep sedation and the completion of the moderate/deep sedation documentation form. The RN orientation and training shall be documented on the initial RN skills checklist. A review of the key elements of the moderate/deep sedation protocol as it pertains to the nurse's role and responsibilities will be included and reviewed in the annual skills validation.

Locations

This policy will apply to all locations in the hospital where moderate / deep sedation is administered. These locations include but are not limited to:

- Emergency Care Areas
- Radiology Suites, including the MRI center
- Dental and Oral-Maxillofacial Clinics
- Orthopedic Treatment Areas
- Pediatric Treatment Areas

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- Gynecology Treatment Areas
- Bronchoscopy Suites
- Endoscopy Suites
- Cardiac Catheterization Suites
- Cardiology Treatment Suites
- Operating Rooms
- Intensive Care Units
- Progressive Care Units

Attachment D

- **Medical Center Approved Areas** contains the list of locations that have been approved by medical and nursing administration to be site that meets the requirements in this policy in which moderate / deep sedation may be administered. Attachments including **Attachment D** will be updated as needed without requiring review and approval of this policy.

Equipment and Medication Requirements

- Oxygen Source (if tank is to be used, ascertain to be greater than half filled)
- Suction
- Appropriate selection of masks and airways
- Resuscitative Equipment
 - Bag - valve - mask device (“Ambu-bag”) with CO2 detector
 - Additional oxygen delivery devices (e.g., non-rebreather face mask)
 - Airway devices (e.g., oral/nasal airway)
 - Ancillary oxygen source
 - Emergency Crash Cart with Defibrillator
- Intravenous Fluids and Supplies
- Electrical outlet connected to emergency power supply system
- Telephone access in immediate vicinity
- Naloxone and Flumazenil be immediately available **prior** to the start of the procedure that uses opioid analgesics and/or benzodiazepines, respectively.

Medications that may be used in moderate / deep sedation

(Attachment E, Table of approved Moderate Sedation Medications)

- | | |
|-------------------------|--------------------------------------|
| • Diazepam | • Etomidate (deep sedative agent) |
| • Midazolam | • Lorazepam |
| • Morphine | • Methohexital (deep sedative agent) |
| • Meperidine | • Ketamine |
| • Fentanyl | • Propofol (deep sedative agent) |
| • Nitrous Oxide/ Oxygen | |

Note: The administration of any oral pharmacological sedative/analgesic agents combined with the administration of any other pharmacological sedative/analgesic agents by another route or dosage may result in the loss of protective reflexes (Coughing, gag, and corneal reflex).

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The following NPO guidelines apply to healthy patients for scheduled procedures. **Deviations** from these guidelines may be indicated because of the patient's clinical presentation.

Minimal NPO Guidelines

Clear Liquids (see below)	2 hours
Human Breast Milk	4 hours
Cow's milk or opaque formulas	6 hours
Light Meal (see below)	6 hours
Full Meal	8 hours

- **Clear liquids** are defined as water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. The volume of liquid ingested is less important than the type of liquid ingested.
- **Light meal:** While the ASA suggest that patients may have a light meal up to 6 hours before a procedure, a light meal is defined typically as toast and clear liquids. Heavier meals that include fried or fatty foods or meat may prolong gastric emptying and require a longer fasting period.
- In emergency situations where the procedure is necessary and moderate / deep sedation is required, these NPO guidelines do not apply. However, the risk of aspiration must be considered in determining the target of sedation, whether the procedure should be delayed or whether the trachea should be protected by intubation.

Patient Pre-Sedation Evaluation (Attachment F, Moderate/Deep Sedation Flow Sheet)

- Satisfactory arrangements for transportation after the procedure must be made before the patient receives moderate / deep sedation.
- **Practitioner** - The practitioner shall perform an appropriate patient assessment prior to the administration of moderate / deep sedation which must include:
 - Informed Consent - explanation of risks, benefits, and alternatives to procedure and/or moderate / deep sedation
 - Relevant history including past anesthetic history or airway issues, current medications, allergies, alcohol and other substance abuse history, and smoking history
 - Overall physical assessment of major organ system including cardiac and pulmonary
 - Examination of the patient's airway, recognition of high-risk airways and documentation of a Mallampati classification shall be made on assessment forms.
 - Ensuring NPO (nothing by mouth) status prior to the sedation and appropriate for the procedure
 - Pain assessment
 - Review of relevant diagnostic testing
 - ASA risk classification / stratification:

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- **I** - A normal, healthy patient
 - **II** - A patient with mild systemic disease (e.g., controlled HTN, controlled diabetes)
 - **III** - A patient with severe systemic disease (e.g., uncontrolled HTN, morbid obesity)
 - **IV** - A patient with severe systemic disease that is a constant threat to life (renal failure, end stage liver disease, CHF)
 - **V** - A moribund patient who is not expected to survive without the operation
 - Emergency status
 - Procedure plan with choice of moderate / deep sedation agents to be utilized
 - Assessment of the patient's ability to lie in a required position for the procedure
 - Pregnancy status
- The patient must be evaluated by an appropriately privileged attending practitioner or competent resident immediately before moderate / deep sedation use to ensure that the patient is still a suitable candidate for the sedation plan proposed (**Attachment F**).
 - **Monitoring Registered Nurse / Licensed personnel** - The pre-sedation / pre-procedure assessment to be performed by the registered nurse / licensed personnel shall include the following:
 - Baseline vital signs, including heart rate, cardiac rhythm, blood pressure, respiratory rate, and oxygen saturation
 - Pain assessment
 - Level of sedation / responsiveness (APVU):
 - A = Alert and Oriented
 - V = Responds to Verbal Stimuli with or without light tactile stimuli
 - P = Responds to Painful Stimuli
 - U = Unresponsive to Painful Stimuli
 - Fasting (NPO) status
 - **Intravenous access** should be secured in all patients receiving intravenous medications. For pediatric patients receiving moderate / deep sedation through routes other than intravenously, the patient's physician may determine if intravenous access is necessary. If it is determined that intravenous access is not necessary, then personnel and equipment necessary to start an intravenous line should be immediately available.
 - **Universal Protocol** - Implementation of Universal protocol should contain all the elements as required by current policy and include:
 - Pre-operative verification of the correct person, procedure, and site
 - Marking of the operative site, laterality
 - "Time Out" immediately before starting the procedure (identifies: The correct patient, side and site, procedure availability of correct implants and any special equipment or special requirements).

Moderate / Deep Sedation Treatment, Monitoring, and Documentation
(Attachment F, Moderate Sedation Flow Sheet)

- A physician, dentist, registered nurse, dental or physician assistant shall continuously monitor the patient throughout the procedure and recovery.

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- Supplemental oxygen shall be provided throughout the administration of moderate sedation and deep sedation.
- Monitoring of the patient is to be **continuous** throughout the procedure and shall include documentation of the following at a minimum of every 5 minutes or upon any significant change or event:
 - End-tidal CO₂ (ETCO₂) capnography
 - Level of sedation / responsiveness (APVU)
 - Electrocardiogram (EKG), preferably with respiratory component
 - Blood pressure, pulse, and respiratory rate
 - Oxygen saturation (oximetry) with functioning visible and audible displays and alarm

Capnography (ETCO₂) should be used during both moderate or deep sedation. In the event that capnography is not functioning visual respiratory efforts and audible confirmation of breathing must be directly observed.

The presence of monitor alarms should be confirmed and functioning.

- Moderate / deep sedation documentation shall also include the following:
 - Procedure performed
 - Patient identification and procedure site verified
 - Start time and end time
 - Personnel performing procedure and monitoring the patient
 - Name and dose of all medications used, including liters of oxygen administered
 - Type, rate, and amount of intravenous fluids infused
 - Record of all vital signs
 - Patient response to procedure/sedation
 - Patient status at the end of the procedure
 - Post-procedure findings
 - Unusual events or interventions
 - Aldrete Score
- **Significant changes** to be reported **immediately** by the registered nurse / licensed personnel to the provider include:
 - Loss of end-tidal CO₂
 - Heart rate < 60 or > 100 beats per minute, or bradycardia/tachycardia as determined by age-appropriate normal
 - Oxygen saturation changes:
 - Adults - 10% drop or saturation < 90%
 - Pediatrics - 5% drop or saturation <90%
 - Level of sedation changes:
 - Change in which the patient cannot communicate verbally or appropriately for age
 - Tissue perfusion changes with cyanosis, mottled skin, or clamminess
 - Pain

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- The provider performing the procedure should be informed of any significant changes or events during the procedure.
- Rescuing the patient from complications of deep sedation shall include the following as clinically appropriate:
 - Recognition of airway obstruction
 - Appropriate use of supplemental oxygen (increasing the concentration)
 - Insert airway devices (oral/nasal)
 - Perform jaw thrust/head tilt
 - Use Bag - Valve - Mask Resuscitation
 - Endotracheal intubation
 - Administration of Naloxone or Flumazenil

Post- Moderate / Deep Sedation Monitoring and Recovery

- **Aldrete Score:**

Activity

- 2 - Able to move 4 extremities
- 1 - Able to move 2 extremities
- 0 - Able to move 0 extremities

Respiration

- 2 - Able to deep breath/cough
- 1 - Dyspnea or limited breathing
- 0 - Apneic

Cardiovascular

- 2 - BP + 20% pre-anesthetic level
- 1 - BP + 20-50% pre-anesthetic level
- 0 - BP + 50% pre-anesthetic level

Color

- 2 - Pink or normal
- 1 - Pale or dusky
- 0 - Cyanotic

Patient Response

- 2 - For < 1 year old – strong cry
- 2 - For > 1 < 3 years old – awake, verbally responsive, and strong cry
- 2 - For >3 years (including adults) - Fully awake
- 1 - Arousable on calling
- 0 - Not responding

- Should a reversal agent (naloxone, flumazenil) be administered, sufficient time (up to 2 hours) should elapse to ensure that the patient does not become re-sedated after the reversal effects has worn off.
- Vital signs including blood pressure, pulse, respirations, and oxygen saturation shall be recorded at least every 15 minutes until discharge criteria are met.

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- Level of sedation shall be recorded every 15 minutes until discharge criteria are met, which includes an Aldrete Score of no less than 10, pre-procedural score, or at the clinical direction of the responsible attending physician.
- A written record or electronic medical record (EMR) is maintained which describes the following:
(Attachment F, Moderate Sedation Flow Sheet or EMR)
 - Intravenous fluids administered and time IV discontinued
 - Name and dosage of all medications used, including oxygen level
 - PO fluids and nourishment
 - Unusual events
 - Record of vital signs, including: cardiac rate and rhythm, blood pressure, oxygen saturation and temperature
 - Adequacy of ventilation (respiratory rate and effort, skin color)
 - Level of consciousness
 - Pain assessment
 - Discharge instructions
 - Disposition of the patient
- Medication Reconciliation must be completed at the end of the sedation and recovery.

Patient Recovery Locations

- All patients will be recovered in the procedural area or at an appropriate post-procedural area within this institution.
- Intensive Care Unit (ICU) patients will be returned to the ICU as soon as the patient can safely be transferred.

Discharge

- Any patient being discharged within 24 hours of a procedure requiring Moderate/Deep Sedation must be given proper written discharge instructions.
- The Post Moderate Sedation Discharge Instruction sheet must be discussed with the patient or responsible adult.
- A copy of the Post Moderate Sedation Discharge Instructions will be given to the patient.
- A signed copy of the Post Moderate Sedation Discharge Instructions will be placed in the patient's medical record
- Patients who have received procedural sedation are discharged in the company of an individual who accepts responsibility for the patient
- If there is no one available to accompany the patient home, the patient can be recovered until sufficiently awake from anesthesia and safely transported home by a contracted transportation company (e.g., Uber)

Performance Improvement

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Each approved unit will maintain performance indicators for focused review and evaluation of safe administration of moderate / deep sedation, and report findings to the Medical Center Quality Improvement Committee.

The Department of Anesthesiology will review unit performance of moderate / deep sedation at the Departmental Staff Meetings.

RESPONSIBILITY

Department of Anesthesiology
 Attending Staff
 Residents
 Nursing Staff
 Quality Improvement Department

ATTACHMENTS

A current list of attending staff and mid-level providers privileged to perform moderate / deep sedation will be maintained by the Attending Staff Office. Attachments may be modified and updated as needed without requiring review and approval of this policy.

Attachment A: Moderate/Deep Sedation Learning Module
 Attachment B: Moderate/Deep Sedation Examination for Physicians
 Attachment C: Moderate/Deep Sedation Examination for RNs
 Attachment D: Medical Center Approved Moderate/Deep Sedation Areas
 Attachment E: Approved Medications for Moderate/Deep Sedation (Adult and Pediatrics)
 Attachment F: Moderate/Deep Sedation Flow Sheet
 Attachment G: Post Moderate Sedation Discharge Instruction Sheet
 Attachment G-SP: Instrucciones de Alta Después de la Sedación Moderada/Profundo

REFERENCES

Practice Guidelines for Moderate Procedural Sedation and Analgesia, American Society of Anesthesiologists, March 2018

James N Allen, MD, et al, Moderate Sedation Best Practice Recommendations, 2005 University Health System Consortium.

REVISIONS

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