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Tier 1: Deep Sedation by Non-Anesthesiology Personnel Outside of the Operating Room

Scope

This policy applies to Medical Staff Members (e.g., physicians, dentists, podiatrists, etc.), nursing personnel, pharmacists, and other clinical staff participating in or directly providing deep sedation to patients outside of the operating room environment.

This policy **does not** apply to:

- Any member of the anesthesia care team.
- Patients on full mechanical ventilator support in critical care areas.

This policy operates in conjunction with [Procedural Sedation/Analgesia \(Moderate Sedation: Adult; Pediatric\) Outside of the Operating Room.](#)

Background

Deep sedation is required when a suppressed level of consciousness is necessary emergently to permit a procedure (e.g., Intubation, joint dislocation reduction, etc.) that carries an extremely noxious stimulus that would not ordinarily be tolerable by a patient. This usually requires the administration of potent anesthetic agents such as, propofol, etomidate, ketamine, or methohexital. Additionally, higher doses of various opiates or benzodiazepines may produce a similar physical state.

Definitions

Continuum of Sedation (see Appendix 2 [Continuum of Depth of Sedation as defined by the American Society of Anesthesiologists \(ASA\)](#))

In recognition that sedation is a continuum of relaxation (often unpredictable) with progressive loss of protective reflexes, motor control and consciousness, the practitioner must be able to recognize and articulate the varying levels of sedation in the pre, intra, and post procedure assessment. They are:

Minimal Sedation or Analgesia: 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. Minimal sedation rarely if ever utilizes, in combination, one sedative with one analgesic. Either a sedative or an analgesic is usually chosen, but not both. Minimal sedation is used to decrease the stimulus of a minimally invasive procedure. The amount of either medication starts with the

smallest amount, titrated slowly, never reaching a level of moderate sedation.

Moderate Sedation/Analgesia: A drug-induced depression of consciousness during which the patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/Analgesia: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after 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.

General Anesthesia: "A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation." This may involve multiple intravenous and/or inhalational anesthetic agents and prolonged neuromuscular blockade.

ASA Physical Classification System: This index is designed by the American Society of Anesthesiologists (ASA) to pre-operatively assess the overall physical status of the patient. All patients undergoing sedation must be assigned an ASA physical status classification by a provider, anesthesiologist, or CRNA. (see Appendix 2 [Continuum of Depth of Sedation as defined by the American Society of Anesthesiologists \(ASA\)](#))

Mallampati Classification: the Mallampati classification is used to indicate the potential ease or difficulty of intubation. It is determined by looking at the anatomy of the oral cavity; specifically, it is based on the visibility of the base of uvula, faucial pillars (the arches in front of and behind the tonsils) and soft palate. Scoring may be done with or without phonation. A high Mallampati score (class 4) may be associated with a more difficult intubation, as well as a higher incidence of sleep apnea. *All patients who receive sedation should be evaluated and assigned a Mallampati Classification by a provider, anesthesiologist, or CRNA.* (see Appendix 3 [Mallampati Classification](#)).

Rescue: Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxemia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

Policy

Administration of deep sedation for a procedure, without anesthesiology personnel involvement, is permitted only in the Emergency Department; an Intensive Care Unit, under the direction of a Medical Staff Member specifically privileged in the administration of deep sedation techniques; or in other areas of the facility when an emergency situation requires immediate intervention by qualified individuals.

Procedures performed outside of the operating room, the Emergency Department or an Intensive Care Unit that require monitored anesthesia care or deep sedation, require involvement and presence of a member of the anesthesiology care team.

Sedation is a continuum and it is not always possible to accurately predict how an individual will respond to sedative medications. Procedures, necessary equipment, and medications must be in place and available to rescue patients whose level of sedation becomes deeper than intended.

If there is any difficulty in supporting a patient who has passed to a deeper than intended level of sedation, the

appropriate emergency response team should be activated.

All patients undergoing sedation must be assigned an ASA physical status classification by a provider, anesthesiologist, or CRNA. (see Appendix 1 [ASA Physical Classification System](#))

Procedure

Oversight of Sedation Practices

In order to assure safe and consistent care across all clinical service, the System Chair of Anesthesiology, Medical Director of Anesthesia Services, or designee, oversees and participates with the chairs and medical directors in establishing the institutional policy for the administration of sedation by non-anesthesia personnel outside of the operating room.

Policies specific to the use of sedation in focused areas may be designed to meet or be more restrictive than this policy; however, no policy may be designed which does not meet the standards contained herein.

The director of the department/service (Service Chief, Chair, or Department Head) in which sedation services are provided is responsible for monitoring of compliance with the health system policy for sedation/analgesia.

Each Department Director is responsible for:

1. Identifying those practitioners eligible for privileges to prescribe sedative / analgesia for diagnostic and therapeutic procedures.
2. Compliance with policies and procedures including the requirement that all required equipment and personnel are present.
3. Appropriate documentation of the pre-sedation/analgesia evaluation, intra-procedure monitoring and post-sedation/analgesia care.
4. Implementation of a system for monitoring adverse outcomes.
 - a. Quality improvement measures related to procedural sedation.
 - b. Practitioner specific performance data regarding sedation/analgesia outcomes will be reviewed as part of the appointment and reappointment process.

Deep Sedation Procedures Outside Of Operating Rooms

Tracheal Intubation

Deep sedation for the purpose of establishing an artificial airway may be initiated at any point of patient location when the need has been deemed emergent by a properly authorized Medical Staff Member, house staff member (resident/fellow), or advanced practice provider (APP).

Intubations in the Emergency Department or intensive care unit by non-anesthesia personnel must have a Medical Staff Member present who has privileges for deep sedation and/or anesthesia for intubations.

Other Procedures

Deep sedation intended to facilitate performing life or body part preserving procedures, other than intubation, may only be initiated or supervised outside of the operating room environment (e.g., ICU, PACU, ED) by a Medical Staff Member .

Procedures extending over prolonged periods of time, especially those requiring neuromuscular blockade, are considered general anesthesia and should be managed by members of the anesthesia care team in a setting appropriate for delivery of general anesthesia.

Whenever possible, based on clinical conditions, proper NPO guidelines should be followed (see Appendix 4 [Fasting and NPO](#)).

Personnel Requirements for DEEP Procedural Sedation

Medical Staff Members

Emergency medicine practitioners and critical care specialists are the primary specialists with a recurrent need to provide deep sedation. The following is required to qualify for privileges in deep sedation:

- Successful completion of a training program (residency or fellowship) that includes training in sedation practice as a core competency.
- Advanced airway training and skills in airway management and cardiopulmonary resuscitation as documented with current ACLS and/or ATLS Certification or the equivalent as approved by departmental and anesthesiology leadership.

Aside from urgent or emergent intubations, the Medical Staff Member prescribing or providing deep sedation should neither be involved in performing the procedure itself, nor be actively responsible for other patients' care while deep sedation activities are ongoing.

Under conditions of imminent medical urgency or emergency, when no other physician or provider credentialed in deep sedation is physically available to provide the deep sedation, an APP or RN with appropriate credentials may assist a physician with deep sedation. In this case, the physician who is performing the emergent procedure and supervising the deep sedation must be able to interrupt their procedure to intervene in a life threatening situation.

Registered Nurses

A registered nurse, with certification in ACLS and completion of an HFHS system-assigned educational course in deep sedation, may administer medication for deep sedation for urgent/emergent intubations and procedures under the supervision of a privileged Medical Staff Member.

The registered nurse may not be primarily involved with assisting the provider performing the procedure. The registered nurse will assist in monitoring the patient's airway, cardiovascular, and neurologic status and documenting in the Electronic Health Record.

A privileged provider must be at bedside when medication is administered by the RN and must be able to interrupt their procedure to intervene in a life threatening situation.

Pharmacists

An ACLS and PALS certified Emergency Department Pharmacist who has completed education and competencies for deep sedation and medication administration may administer medications for deep sedation for emergent intubations under the supervision of a medical staff member privileged in deep sedation.

The privileged Medical Staff Member is required to be at the bedside during sedation/analgesia administration.

The pharmacist may not be primarily involved with assisting the provider performing the procedure. The pharmacist will assist in monitoring the patient and assure documentation is placed in the Electronic Health Record.

Procedure/Sedation Team

- a. Medical Staff Member, fellow, resident, advanced practice provider, or a combination thereof, performing the procedure and not involved with sedation administration.
- b. A qualified medical staff member, fellow, resident, midlevel provider, registered nurse or pharmacist, who is not directly performing the procedure, may administer prescribed medications, and monitor the patient's airway, cardiovascular, and neurologic status.

Medication for DEEP Sedation

Drug	Route	Adult Single Dose (mg/kg except fentanyl)		Pediatric Single Dose >12 years of age (mg/kg except fentanyl)		Comment
		Initial	Maximum	Initial	Maximum	
Propofol (may repeat doses every 3-5 minutes)	IV	1mg/kg	2mg/kg	1mg/kg	2mg/kg	Contraindicated in patients with known/suspected allergy to propofol, eggs, or soy products
Etomidate	IV	0.1mg/kg	0.3mg	0.1mg/kg	0.2mg/kg	
Methohexital	IV	1 mg/kg 1 ml of a 1% solution every 5 minutes	1.5 mg/kg	6.6 mg/kg IM (5% soln) 25 mg/kg rectally (1% soln)	10 mg/kg IM (5% soln) 25 mg/kg rectally (1% soln)	
Ketamine	IV	0.5 mg/kg	2 mg/kg	0.2 mg/kg	2 mg/kg	May cause increased salivation or bronchorrhea. Concurrent use of glycopyrrolate (0.4 mg IV/IM) may

						reduce secretions. There may also be emergence phenomena in adults. Benzodiazepines(lorazepam 1 mg IV/IM) may ameliorate symptoms.
	IM	3 mg/kg	5 mg/kg	3 mg/kg	5 mg/kg	

Medications for Neuromuscular Blockade

Ordering medications for deep sedation is restricted to anesthesiologists, emergency medicine providers and critical care physicians providers.

Drug	Route	Adult Single Dose (mg/kg)		Pediatric Single dose > 12 yrs. old (mg/kg)		Comment
		Initial	Maximum	Initial	Maximum	
Succinyl Choline	IV	0.6 to 1.5 mg/kg	1.5 mg/kg	1 mg/kg	1 mg/kg	Use in pediatrics for emergency only Caution in patient with risk for hyperkalemia
Cisatracurium (Nimbex)	IV	0.15 to 0.2 mg/kg	0.2 mg/kg	0.1 mg/kg	0.2 mg/kg	Not recommended for rapid sequence intubation
Rocuronium	IV	0.6 to 1 mg/kg	1.2 mg/kg	0.45 to 0.6 mg/kg	0.6 mg/kg	

Related Documents

[Tier 1: Procedural Sedation/Analgesia \(Moderate Sedation; Adult, Pediatric\) by Non-Anesthesiology Personnel Outside of the Operating Room](#)

References/External Regulations

American Society of Anesthesiologists: Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018. *Anesthesiology*, 2018; 128:437-79.

American Society of Anesthesiologists: Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures. *Anesthesiology*, 2017; 126:376-393.

The Joint Commission Standards, 2018. Program: Hospital; Chapter: Provision of Care, Treatment, and Services. PC.03.01.01: The hospital provides the patient with care before initiating operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.

Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department. *Ann Emerg Med* 2014; 63:247-258.

Validation of the Pediatric Sedation State Scale. *Pediatrics*, 2017; 139:2019-2897.

American Society of Anesthesiologists: Continuum of Depth of Sedation & General Anesthesia and Levels of Sedation/Analgesia (2009).

ASA statement of granting privileges for administration of moderate sedation to practitioners who are not anesthesia professionals 2011

ASA advisory on granting privileges for deep sedation to non-anesthesiologist sedation practitioners 2010 (amended 2012)

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS). Memorandum Summary: Revised Hospital Anesthesia Services Interpretive Guidelines- 4th Revision, February 14, 2011

Appendices

Appendix 1: ASA Physical Classification System

ASA I: Normal, healthy.

ASA II: Mild systemic disease.

ASA III: Severe systemic disease (may limit activity).

ASA IV: Severe systemic disease that is a constant life threat.

ASA V: Moribund, not expected to survive without the operation.

ASA VI: Brain dead for planned organ harvest (a.k.a., neomort).

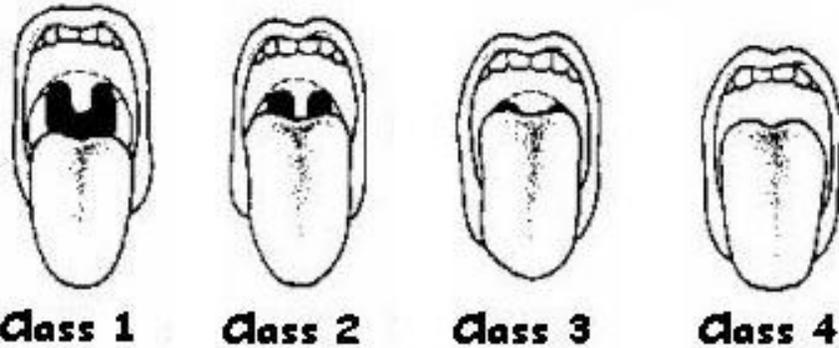
The designation of "E" in conjunction with the ASA score (e.g., II-E) indicates an emergency surgery where delay would result in an increased threat to life or body part.

Appendix 2: Continuum of Depth of Sedation as defined by the American Society of Anesthesiologists (ASA)

	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	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

- Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Appendix 3: Mallampati Classification



CLASS 1: soft palate, anterior and posterior tonsillar pillars, and uvula visible;

CLASS 2: tonsillar pillars and base of uvula hidden by base of tongue;

CLASS 3: only soft palate visible;

CLASS 4: soft palate not visible.

Appendix 4: Fasting and NPO

Fasting & NPO Guidelines	
Ingested Material	Minimum Fasting Period
Clear Liquids ¹	2 hours
Breast Milk	4 hours
Infant Formula	6 hours
Non-human milk ²	6 hours
Light meal ³	6 hours
Fried/fatty foods or meat	8 hours or more

Fasting periods apply to all age groups.

¹ Examples of clear liquids include water, fruit juice without pulp, carbonated beverages, clear tea and black coffee.

² Since non-human milk is similar to solids in gastric emptying, the amount ingested must be considered when determining an appropriate fasting time.

³ A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

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Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Chair, System Clinical Effectiveness Council	Adnan Munkarah: EVP & Chief Clinical Officer [SP]	4/21/2020
IT Clinical	Lori Doyle: IT Architect - Epic	4/16/2020
Pharmacy Review	Rox Gatia: Dir- Pharmacy	4/16/2020
System Policy Management Office	System Policy Management Office	4/16/2020
Document Owner	William Peruzzi: Anesthesiologist	4/16/2020

Applicability

Henry Ford Allegiance Health, Henry Ford Behavioral Health Services, Henry Ford Community Care Services, Henry Ford Health System, Henry Ford Hospital, Henry Ford Kingswood Hospital, Henry Ford Macomb Hospital, Henry Ford Medical Group, Henry Ford West Bloomfield Hospital, Henry Ford Wyandotte Hospital