I. Description

This policy governs the administration of sedatives and/or analgesics for the purpose of deep sedation.

II. Rationale

This policy governs the administration of sedatives and/or analgesics for the purpose of deep sedation under the medical direction of qualified, non-anesthesiologist physicians/dentists:

- to patients undergoing invasive, constraining, or manipulative procedures;

III. Policy

A. Deep Sedation/Analgesia

Defined as a drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. The ability to independently maintain ventilation may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. For the purposes of this policy, administration of intravenous anesthetic induction agents with their attendant narrow margin of safety and/or unique side effects profile will be considered deep sedation. Deep sedation must be administered only by a qualified provider, as defined below.

B. Exemptions

1. This policy does not apply to board eligible or certified anesthesiologists who are licensed to administer deep sedation drugs as part of their practice.

C. Privileging Requirements For Physicians

1. The following physician providers may request certification and clinical privileges to administer deep sedation:

   a. A dentist or oral surgeon who has advanced training in anesthesiology. This includes Oral & Maxillofacial Surgery residency and approved Dental Anesthesiology Residency training.
b. Required Resuscitation Competence: Advanced cardiac (cardiopulmonary) life support (ACLS) is required. The provider must have expertise in advanced airway management and advanced life support to rescue the patient from deeper levels of anesthesia than intended. The qualified provider must be capable of correcting adverse physiologic consequences of deeper than intended level of sedation and returning the patient to the originally intended level of sedation.

D. Requirements for Registered Nurses (RNs) and Respiratory Care Practitioners (RCPs)

RNs are permitted to participate in deep sedation within the scope of their practice. Deep sedation must be provided by a physician/dentist credentialed in deep sedation who is separate from the practitioner and who is performing/supervising the procedure for which the patient is being sedated. An RN is permitted to administer the medications, so long as the provider credentialed in deep sedation is directing the sedation and is present in its entirety. These practitioners may also assist with the sedation procedure by recording vital signs, assisting with positioning, application of monitors and general procedural assistance to facilitate safe patient care. At no time is the RN to be directing the sedation, which is the sole responsibility of the attending dentist who holds deep sedation privileges.

E. Requirements for Approved Deep Sedation Areas

Deep sedation may only be performed in approved areas (Appendix).

1. Personnel
   a. Provider(s) with privileges to administer deep sedation, and
   b. Adequate staff trained to support the provider administering sedation and analgesia.

2. Monitoring Capabilities
   The approved location will have staffing and equipment available to allow for the continuous monitoring and documentation every five (5) minutes of the following parameters:
   a. Level of responsiveness;
   b. Continuous cardiac rhythm;
   c. Blood pressure;
   d. Pulse rate;
   e. Respiratory rate;
   f. Oxygen Saturation, and
   g. End-tidal carbon dioxide (ETCO₂) in the procedure areas.

3. Equipment available in the room:
   a. Oxygen via wall outlet. There must be a back-up supply of oxygen immediately available. The back-up system should include the equivalent of at least a full E cylinder.
   b. Suction via wall outlet.
   c. Sufficient space to accommodate necessary equipment and personnel and that allows quick access to the patient and monitoring equipment.
   d. Sufficient emergency electrical outlets to satisfy monitoring equipment requirements.
   e. Adequate monitoring equipment (EKG, pulse oximetry, blood pressure, ETCO₂).
   g. Adequate sedative and analgesic medications for the intended deep sedation.
h. Ambu-bag and appropriately sized masks connected to 100% oxygen.

4. Equipment Available in Room (or within immediate proximity to room in the case of patients in isolation):
   a. Oxygen face mask;
   b. Nasal cannula;
   c. Oral/nasal airways

5. Equipment Available in the Immediate Area:
   a. Reversal agents must be available in the immediate area prior to the start of the procedure. Verification of the physical presence of these agents in the immediate area must be on the pre-procedure checklist.
   b. Code cart and defibrillator
   c. Intubation Equipment.
   d. Back up airway device such as Laryngeal Mask Airway (LMA).
   e. A phone to request assistance.

F. Pre-Sedation Evaluation

A pre-procedural evaluation must be performed for each patient who receives deep sedation. Pre-procedural evaluation must be performed by a provider certified to perform deep sedation, within forty-eight (48) hours of the procedure.

1. Consent
   Explanation of the risks, benefits, and alternatives to sedation must be provided to patient. When a procedure is being performed to conjunction with the sedation, written consent for sedation must be included with the procedural consent.

2. History
   a. Pertinent Medical Conditions must be included in the evaluation: (For example: cardiac, pulmonary, renal, hepatic, endocrine, head trauma, prior intubations, stridor, snoring, sleep apnea, baseline oxygen requirement).
   b. Previous adverse reactions to anesthesia/sedation.
   c. Present medication regimen, especially medication taken within the last 48 hours.
   d. Allergies.
   e. Pregnancy status, when applicable.
   f. Tobacco, alcohol, or substance use/abuse.
   g. Prior surgeries and/or airway issues.
   h. Last oral intake, which includes tube feedings.
   i. Exposure to infectious disease and the need for isolation precautions.

3. Physical Exam should focus on:
   a. Cardiac;
   b. Pulmonary;
   c. Airway (the following features indicate a potentially difficult airway);
   d. Habitus: Excessive facial hair, receding chin, or significant obesity especially involving the neck and facial structures (body mass index > 35);
   e. Head and Neck: Short neck, limited neck extension, decreased hyoid-mental distance (< 3 cm in adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (e.g., Pierre-Robin syndrome);
   f. Mouth: Small opening (< 3 cm in adult); edentulous, protruding incisors, loose or
capped teeth, dental appliances, high, arched palate, macroglossia, tonsillar hypertrophy, nonvisible uvula (Mallampati class 3 or 4);
g. Jaw: Micrognathia, retrognathia, trismus, or significant malocclusion;
h. Examination specific to the procedure proposed, and
i. Ability to lie in required position for the procedure.

4. Additional Evaluations should include:
   a. American Society of Anesthesiologists (ASA) physical status classification;
   b. Review of appropriate diagnostic/laboratory data.
   c. Interpretation of cardiac rhythm if other than regular rate and rhythm;
   d. Presence of satisfactory intravenous access;
   e. For elective procedures, the patient should be NPO (nothing b mouth):
      □ no solid foods for at least eight hours prior to the procedure; may have clear liquids up to two hours prior to procedure
      □ Note: this requirement may not apply for urgent/emergent procedures, and
   f. Presence of a responsible adult to accompany the discharged patient is required for outpatients.

G. Anesthesia Consultation

An Anesthesia consultation is suggested in elective procedures if a patient:
1. Is known to have significant respiratory compromise or hemodynamic instability;
2. Presents with significant co-morbid conditions or significant sleep apnea;
3. Has an ASA physical status of 4 or 5;
4. Has exam findings consistent with a high-risk airway;
5. Has a history of airway problems during sedation/analgesia or general anesthesia, and/or
6. Has a history of adverse reaction to sedation/analgesia or general anesthesia.

H. Medication Use

Practitioners must exercise caution when using any combination of drugs. This practice may result in additive or synergistic effects over that seen with the use of single agents. For the purposes of this policy, administration of intravenous anesthetic induction agents with their attendant narrow margin of safety and/or unique side effect profile will be considered deep sedation. These medications include: Propofol, Dexmedetomidine, Etomidate, Ketamine, and Methohexital. Other anesthetic induction agents may be used that are approved by the Adult

UNC Hospitals sedation committee and Pharmacy & Therapeutics Committee (P&T Committee). Approved medications are listed in the Appendix. Fentanyl, Midazolam (Versed) and Morphine are examples of other medications that may be used for deep sedation when used in doses appropriate for deep sedation.

I. Intraprocedure Monitoring

A level of surveillance of the patient that is continuous without any interruption at any time, and during which the deep sedation credentialed provider’s constant attendance is required. Evaluation of the patient’s response to the drugs is the primary responsibility of the deep sedation credentialed provider. This individual must NOT be the person performing the procedure.
An RN is permitted to administer the medications, so long as the provider credentialed in deep sedation is directing the sedation and is present in its entirety. RNs may also assist with the sedation procedure by recording vital signs, assisting with positioning, application of monitors and general procedural assistance to facilitate safe patient care. At no time is the RN to be directing the sedation, which is the sole responsibility of the attending physician/dentist who holds deep sedation privileges.

1. Monitor
   a. The following parameters are monitored continuously and recorded every 5 minutes:
      • Arousal score;
      • Cardiac rhythm;
      • Blood pressure (BP) (continuously if an intra-arterial catheter is in use, otherwise every 5 minutes);
      • Pulse rate;
      • Respiratory rate
      • Oxygen saturation, and
      • Monitoring of end-tidal carbon dioxide (ETCO₂).

J. Post-Procedure Monitoring

A post-procedure evaluation must be performed and documented in the patient’s medical record for each patient who receives deep sedation. The post-procedure evaluation to verify that the patient meets criteria for discharge or transfer must be performed by a provider certified to perform deep sedation.

1. The health care provider shall continuously monitor and observe the patient until the patient meets the discharge criteria noted in the Aldrete scoring system or is at pre-sedation baseline. At no time shall a sedated patient be left unattended.

2. The following parameters must be monitored and documented every fifteen (15) minutes until the patient meets the discharge criteria noted in the Aldrete scoring system or the patient is at pre-sedation baseline:
   a. Arousal score;
   b. Cardiac rhythm;
   c. Blood pressure (BP);
   d. Pulse rate;
   e. Respiratory rate;
   f. Oxygen saturation, and
   g. The Aldrete score will be documented at completion of sedation monitoring.

3. End-tidal carbon dioxide (ETCO₂) must be monitored and documented every fifteen (15) minutes until (1) the patient is breathing adequately and (2) ten (10) minutes after administration of IV sedation medication or reversal agent.

4. Intravenous access shall not be discontinued during the recovery period until the patient has received a post-procedure evaluation as described above.

5. Patients receiving reversal agents should be monitored for at least one (1) hour prior to discharge from the procedure area.

   **KEY POINT:** Reversal agents must never be used to expedite discharge
K. Post-Procedure Monitoring

1. Patients must have a post-procedure evaluation.

2. The Aldrete Scoring System (ranging from "10" for complete recovery to "0" in comatose patients) may be used to determine readiness of discharge/transfer. The Aldrete score should be documented on discharge/transfer.

3. Patients will be alert and oriented. Patients whose mental status was altered pre-procedure will have returned to baseline.

4. Patients discharged to home or other non-monitored area (e.g. lobby) should:
   a. Achieve pre-procedure baseline levels of oxygenation when removed from supplemental oxygen for a five (5) minute period.
   b. Be accompanied by a responsible adult who will:
      • Receive written instructions regarding post procedure diet, medications, activities, and a phone number to use in case of emergency;
      • Receive education regarding post-procedure complications and the appropriate reporting mechanism, and
      • Assume responsibility for transport.

Appendix

Definitions of levels of sedation/analgesia
As defined by the American Society of Anesthesiologists Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists.

1. Minimal Sedation (anxiolysis)
   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 not.

2. Moderate sedation
   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.

3. Deep sedation/analgesia
   A drug-induced depression of consciousness during which patients cannot be aroused easily but respond purposefully following repeated or noxious stimulation. The ability to independently maintain ventilatory function and a patent airway may be compromised. Cardiovascular function is usually not impaired. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes.
4. **General anesthesia**

General anesthesia is a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Anesthetized 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.

The transition from anxiolysis to moderate sedation to deep sedation, and from deep sedation to general anesthesia is a continuum. This transition can be difficult to predict and must be anticipated whenever sedation is administered. If this transition is not appreciated and appropriate measures not taken, the patient's condition can rapidly deteriorate resulting in hypoxemia, hypotension, respiratory arrest, cardiac arrest and even death.

The distinction between moderate sedation/analgesia and milder sedation or milder analgesia is not always completely clear. Sedation is a continuum, and it is not always possible to predict how an individual patient will respond. However, in general, one should consider the effect on the patient to be that of moderate sedation/analgesia under the following circumstances:

- The prescribing sedationist's intent is to produce a depression of consciousness that exceeds simple reduction of anxiety or simple relief of pain. For example, the sedation/analgesia may be intended to, among other things, produce amnesia for the diagnostic or therapeutic procedure.
- Sedatives or combinations of sedative and analgesic medications.
- The prescribing dentist reasonably expects the dose that is prescribed to produce a moderate sedating and analgesic effect for this individual patient.

In cases of milder sedation or milder anesthesia not intended to produce moderate sedation/analgesia as covered in this policy, the following parameters should still be maintained:

- Patients respond purposefully to verbal commands 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.
- Spontaneous ventilation is adequate.
- Cardiovascular function is maintained.

**Locations Approved for Deep Sedation**

Locations for consideration include:

- Oral & Maxillofacial Surgery Operating Rooms
- Oral & Maxillofacial Surgery Clinic Sedation Rooms
Approved anesthetic induction drugs for deep sedation:

- Etomidate
- Dexmedetomidine
- Propofol
- Ketamine

**NOTE:** Any sedative or narcotic given in larger doses may result in deep sedation.

**Oropharyngeal Classification for Airway Exam**

The patient is asked to open his/her mouth maximally, and stick out his/her tongue. The patient should not say "ah," for the purpose of this examination.

Class 1: Can visualize soft palate, fauces, uvula, tonsillar pillars. Class 2: Can visualize soft palate and fauces; tip of uvula is obscured. Class 3: Can visualize soft palate. Class 4: Can visualize hard palate only.
## Aldrete Scoring System and Arousal Scale

<table>
<thead>
<tr>
<th><strong>Activity</strong></th>
<th>Score</th>
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<tbody>
<tr>
<td>Voluntary movement of all limbs to command</td>
<td>2</td>
</tr>
<tr>
<td>Voluntary movement of 2 extremities to command</td>
<td>1</td>
</tr>
<tr>
<td>Unable to move</td>
<td>0</td>
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</tbody>
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<table>
<thead>
<tr>
<th><strong>Respiration</strong></th>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>Breathe deeply and cough</td>
<td>2</td>
</tr>
<tr>
<td>Dyspnea, hypoventilation</td>
<td>1</td>
</tr>
<tr>
<td>Apneic Unable to move</td>
<td>0</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th><strong>Circulation</strong></th>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>B/P + 20% of preanesthetic level</td>
<td>2</td>
</tr>
<tr>
<td>B/P + 20% - 50% of preanesthetic level</td>
<td>1</td>
</tr>
<tr>
<td>B/P + 50% of preanesthetic level</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Consciousness</strong></th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully awake</td>
<td>2</td>
</tr>
<tr>
<td>Arousable</td>
<td>1</td>
</tr>
<tr>
<td>Unresponsive</td>
<td>0</td>
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<table>
<thead>
<tr>
<th><strong>Color</strong></th>
<th>Score</th>
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<tbody>
<tr>
<td>Pink</td>
<td>2</td>
</tr>
<tr>
<td>Pale, dusky, blotchy, jaundice, other</td>
<td>1</td>
</tr>
<tr>
<td>Cyanotic</td>
<td>0</td>
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</tbody>
</table>

The score should be documented at discharge/transfer below. The range is 10 for complete recovery to 0 in comatose patients. Patients may be discharged without physician intervention with a score of 8, providing that activity, respiration, and color on the scale are scored as “2” and circulation and consciousness are scored at “1” or “2”.

Approved by:

University of North Carolina School of Dentistry Sedation Committee 2014:

Dr. Jay A. Anderson, Oral & Maxillofacial Surgery
Dr. George Blakey, Oral & Maxillofacial Surgery
Dr. Jessica Lee, Pediatric Dentistry
Dr. Antono Moretti, Periodontology
Dr. Allen Samuelson, Dental Ecology