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January 31, 2022

Mr. Bobby D. White Chief Executive Officer NC State Board of Dental Examiners 2000 Perimeter Park Drive, #160 Morrisville, NC 27560

Dear Mr. White:

We are writing to provide comments on the proposed changes to the General Anesthesia and Sedation Rules, specifically regarding the impact of those changes on dental residency programs.

Several advanced dental education programs require sedation training as an integral part of the program and such training is required to maintain accreditation status. For example, Oral and Maxillofacial Surgery accreditation requires that "cumulative anesthetic experience of each graduating resident must include administration of general anesthesia/deep sedation for a minimum of 300 cases. This experience must involve care for 50 patients younger than 13. A minimum of 150 of the 300 cases must be ambulatory anesthetics for oral and maxillofacial surgery outside of the operating room." Similarly, Periodontics requires "clinical training to the level of competency in adult minimal enteral and moderate parenteral sedation." Finally, Pediatric Dentistry requires "a minimum of 50 patient encounters in which sedative agents other than nitrous oxide … are used. Of the 50 patient encounters, each student/resident must act as sole primary operator in a minimum of 25 sedation cases." The proposed changes in the Rules would make the required training very difficult in each of these disciplines.

The proposed rule change (21 NCAC 16Q.0105) mandates that practitioners using general anesthesia, deep sedation or moderate sedation for their cases utilize a "dedicated anesthesia provider." The proposed rule specifies four types of practitioners who qualify as "dedicated anesthesia providers;" however, none of those categories include a "resident in training" or similar designation. As such, UNC and ECU residents would not be eligible to provide deep sedation, moderate sedation or pediatric moderate sedation as required by CODA for accreditation, which could be a fatal blow to our programs.

UNC Adams School of Dentistry has sedation policies in place. These were developed by Dr. Jay Anderson MD, DDS, who was an anesthesiologist at UNC Healthcare and a faculty member of the Department of Maxillofacial Surgery. Enclosed is a copy of our policies for deep, moderate and pediatric sedation for review. ECU has similar policies available. If 21 NCAC 16Q.0105 is passed, it would seriously cripple our ability to train residents in multiple specialties and ultimately negatively affect access to care for the citizens of North Carolina.

Sincerely,

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Edward J. Swift, Jr., DMD, MS Interim Dean UNC Adams School of Dentistry

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D. Gregory Chadwick, DDS, MS Dean ECU School of Dental Medicine

University of North Carolina School of Dentistry

Policy:	Moderate Sedation Policy/Guidelines for Adults
Date Effective:	
Responsible for Content:	School of Dentistry Sedation Committee (see appendix)

I. Description

Requirements for management of adult patients receiving moderate sedation/analgesia while undergoing therapeutic or diagnostic procedures.

Table of Contents

I. Description	1
II. Rationale	1
III. Policy	
A. Exceptions	1
B. Definition of Moderate Sedation/Analgesia	2
C. Patients for Whom Adult Sedation Policy and Procedures Applicable	
IV. Competency Requirements	2
V. Pre-procedure Evaluation	
A. Consent	2
B. History	2
C. Physical Exam	
D. Additional Evaluation	
VI. Suggested and Required Physician Consultation	4
VII. Medication Use	
VIII. Intraprocedure Monitoring	
A. Monitor	
B. Resuscitative Equipment Available in Room	
C. Resuscitative Equipment Available in the Immediate Area	
IX. Post-Procedure Monitoring	
X. Discharge Guidelines	
5	.6-9

II. Rationale

The intent of this policy is to provide a consistent standard of care throughout the Care Clinics of the School of Dentistry for the management of adult patients receiving moderate sedation/analgesia while undergoing therapeutic or diagnostic procedures.

III. Policy

A. Exceptions

- 1. This policy does not apply when an anesthesiologist administers sedation during a procedure.
- This policy does not apply in situations when sedatives and analgesics are utilized for management of baseline, non-procedure related pain and/or anxiety, seizures, or physiological symptoms.

B. Definition of Moderate Sedation/Analgesia

"Conscious Sedation" or "MSA": 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. (Please see Appendix 1).

C. Patients for Whom Adult Sedation Policy and Procedures Applicable

Patients aged 18 and older are appropriate for adult sedation policy and procedures. A patient aged 14 to 17 years may be considered appropriate for adult sedation policy and procedures if that patient is 40kg or greater and post-pubescent without chronic pediatric disease.

IV. Competency Requirements

- A. Faculty, residents and fellows must be ACLS certified.
- B. Supervising faculty must hold an active North Carolina sedation permit and satisfy all requirements for that permit, including certification in Basic Life Support annually.
- C. During <u>moderate</u> sedation, a designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation. This individual may assist with minor, interruptible tasks once the patient's level of sedation-analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.
- D. Individuals responsible for patients receiving sedation-analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines.
- E. Individuals monitoring patients receiving sedation-analgesia should be able to recognize the associated complications and capable of assisting with procedures, problems, and emergency incidents.
- F. At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means of summoning additional assistance, should be present whenever sedation-analgesia is administered.

V. Pre-procedure Evaluation

A. Consent

- 1. Explanation of the risks, benefits, and alternatives to sedation must be provided to patient.
- 2. Written consent for procedural sedation must be included with the procedural consent.

B. History

- 1. Medical Conditions: (for example) cardiac, pulmonary, renal, hepatic, endocrine, head trauma, prior intubation, stridor, snoring, sleep apnea
- 2. Past medication history, including previous adverse reactions to anesthesia/sedation.
- 3. Prior surgeries and/or airway issues
- 4. Present medication regimen, especially medication taken within the last 48 hours
- 5. Allergies

- 6. Pregnancy status, when applicable
- 7. Tobacco, alcohol, or substance use/abuse
- 8. Last oral intake, which includes tube feedings
- 9. Exposure to infectious disease and the need for isolation procedures

C. Physical Exam

- 1. Cardiac
- 2. Pulmonary
- 3. Airway (Complicated airway examples include, but are not limited to):
 - a. Habitus: Excessive facial hair, receding chin, or significant obesity, especially involving the neck and facial structures (body mass index > 35)
 - b. 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)
 - c. Mouth: Small opening (< 3 cm in adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula
 - d. Jaw: Micrognathia, retrognathia, trismus, or significant malocclusion
- 4. Examination specific to the procedure proposed
- 5. Ability to lie in required position for the procedure

D. Additional Evaluation

- 1. The patient's physiological status must be re-evaluated immediately before administering moderate sedation and documented in the medical record.
- 2. American Society of Anesthesiologists (ASA) physical status classification documented.
- 3. Review of appropriate diagnostic/laboratory data.
- 4. Interpretation of cardiac rhythm if other than regular rate and rhythm.
- 5. Presence of satisfactory intravenous access if needed.
- 6. For elective procedures:
 - a. The patient should be NPO (nothing by mouth) prior to sedation for a duration that is appropriate for the procedure being performed and for the patient population being served.
 - b. The general requirement is: no solid foods for at least eight hours prior to the procedure; may have clear liquids up to two hours prior to procedure.
- 7. Presence of a responsible adult to accompany the discharged patient is required.

VI. Suggested and Required Physician Consultation

A. A Physician Consultation Is Suggested if a Patient:

- 1. Is known to have significant respiratory compromise or hemodynamic instability;
- 2. Presents with significant co-morbid conditions or sleep apnea.
- 3. Has an ASA physical status of 4;
- 4. Has a high-risk airway;
- 5. Has a history of airway problems during sedation/analgesia or general anesthesia; or
- 6. Has a history of adverse reaction to sedation/analgesia or general anesthesia.

VII. Medication Use

Medications used for moderate sedation are almost always, but not limited to, a combination of short-acting opioid and short- acting benzodiazepine. The use of general anesthetics for sedation is outside the scope of this policy. (Please refer to deep sedation policy for further information.)

VIII. Intraprocedure Monitoring

A level of surveillance of the patient that is continuous without any interruption at any time, and during which the health care provider is in constant attendance is required. Evaluation of the patient's response to the drugs is the primary responsibility of the individual administering the drugs and monitoring the patient. This individual must NOT be the person performing the procedure.

KEY POINT: Monitoring staff are empowered to stop the sedation process at any time during the procedure, including refusing to initiate sedation.

A. Monitor

- 1. The following parameters are monitored continuously and recorded every 5 minutes:
 - Arousal score
 - Cardiac rhythm
 - Blood pressure every 5 minutes
 - Pulse rate
 - Respiratory rate
 - Oxygen saturation
 - End-tidal carbon dioxide (ETCO₂) to assess adequacy of ventilation

B. Resuscitative Equipment Available in Room (or within immediate proximity to room)

- 1. Bag-valve-mask device
- 2. Oxygen face mask
- 3. Nasal cannula
- 4. Oxygen
- 5. Suction
- 6. Oral/nasal airways

C. Resuscitative Equipment Available in the Immediate Area

- 1. Reversal agents must be available in the immediate area prior to the start of the procedure.
- 2. Verification of the physical presence of these agents in the immediate area must be on the pre-procedure checklist.
- 3. Emergency cart

IX. Post-Procedure Monitoring

- A. A health care provider shall continuously monitor and observe the patient until the patient meets the discharge criteria noted in the Aldrete scoring system (See appendix) or is at pre-sedation baseline. At no time shall a sedated patient be left unattended.
- B. The following parameters must be monitored and documented every 15 minutes until the patient meets the discharge criteria noted in the Aldrete scoring system (Section VII.C.2 below) or is at pre-sedation baseline.
 - 1. Arousal score
 - 2. Cardiac rhythm prn
 - 3. Blood pressure (BP) every 15 minutes
 - 4. Pulse rate
 - 5. Respiratory rate
 - 6. Oxygen saturation
- C. Intravenous access shall not be discontinued during the recovery period until the patient has met the Aldrete scoring system discharge criteria or is at pre-sedation baseline.
- D. Patients receiving reversal agents should be monitored for at least one hour prior to discharge from the procedure area, regardless of Aldrete score.
- E. Patients receiving reversal agents should be monitored for at least one hour prior to discharge, regardless of Aldrete score.

KEY POINT: Reversal agents must never be used to expedite discharge.

- F. The monitoring health care provider shall notify the attending or resident dentist if the patient does not meet the discharge criteria or is not at pre-sedation baseline within 2 hours post-procedure/diagnostic test.
- G. The Aldrete score will be documented at completion of sedation monitoring.
- H. Patients may be sent to a non-monitored area (e.g. lobby) or discharged to home when he/she meets discharge criteria.

X. Discharge Guidelines

- A. Patients should be alert and oriented. Patients whose mental status was altered pre-procedure should have returned to baseline.
- B. Patients discharged to home or other non-monitored area (e.g. lobby) should achieve preprocedure baseline levels of oxygenation when removed from supplemental oxygen for a five-minute period.
- C. The Aldrete Scoring System (ranging from "10" for complete recovery to "0" in comatose patients) may be used to determine readiness of discharge.
 - 1. The Aldrete score should be documented on discharge/transfer.
 - 2. Patients may be discharged without dentist intervention with a score of "8" or above, provided that activity, respiration, and color on the scale are scored as "2" and circulation and consciousness are scored at "1" or "2."

- D. A responsible adult will be provided with written instructions regarding post procedure diet, medications, activities, and a phone number to use in case of emergency.
- E. Patients should be discharged to a responsible adult who assumes responsibility for transport and who has been educated to post-procedure complications and the appropriate reporting mechanism.

Appendix:

Definitions of levels of sedation/analgesia are 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 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 dentist'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 not intended to produce moderate sedation/analgesia as covered in this policy the following parameters should still be maintained:

- Patient responds 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.

Tonsillar pillar Fauces Tonsillar pillar

Oropharyngeal Classification For Airway Exam

a)

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.

ASA Physical Status Classification

Class 1	Healthy patient, no medical problems	
Class 2	Mild systemic disease	
Class 3	Severe systemic disease, but not incapacitating	
Class 4	Severe systemic disease that is a constant threat to life	
Class 5	Moribund, not expected to live 24 hours irrespective of operation	
An "e" is added to the status number to designate an emergency operation.		
An organ donor is usually designated as "Class 6."		

Aldrete Scoring System and Arousal Scale

Aldrete Scoring System – May be used without obtaining dentist order
Activity
Voluntary movement of all limbs to command2
Voluntary movement of 2 extremities to command
Unable to move 0
Respiration
Breathe deeply and cough2
Dyspnea, hypoventilation 1
Apneic, Unable to move 0
Circulation
B/P + 20% of preanesthetic level2
B/P + 20% - 50% of preanesthetic level1
B/P + 50% of preanesthetic level0
Consciousness
Fully awake
Arousable1
Unresponsive0
Color
Pink
Pale, dusky, blotchy, jaundice, other
Cyanotic

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 dentist intervention with a score of 8, provided that activity, respiration, and color on the scale are scored as "2" and circulation and consciousness are scored at "1" or "2".

	*UNC HOSPITALS AROUSAL SCALE
5	Fully awake
4	Arouses easily
3	Arouses with tactile stimuli
2	Arouses to vigorous stimuli
1	Responsive to painful stimuli
0	Unresponsive

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

University of North Carolina School of Dentistry

Policy:Deep Sedation Policy/GuidelinesDate Effective:School of Dentistry Sedation Committee (see appendix)

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 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, ETC02).
 - f. Provisions for adequate illumination of the patient and monitoring equipment.
 - 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):
 - *f* 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;
- 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 presedation 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.
- Patients will be alert and oriented. Patients whose mental status was altered preprocedure 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

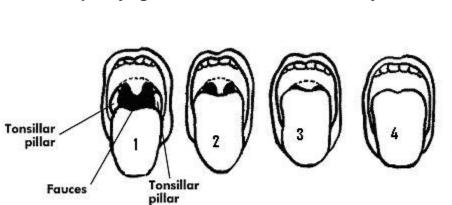
Locations for consideration include:

- 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

<u>Aldrete Scoring System</u> – May be used without obtaining MD order (circle) Activity
Voluntary movement of all limbs to command 2
Voluntary movement of 2 extremities to command1
Unable to move0
Respiration
Breathe deeply and cough
Dyspnea, hypoventilation
Apneic Unable to move0
B/P + 20% of preanesthetic level
B/P + 20% of preanesthetic level
B/P + 50% of preanesthetic level
Consciousness
Fully awake
Arousable1
Unresponsive0
<u>Color</u>
Pink
Pale, dusky, blotchy, jaundice, other
Cyanotic0
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. Antonio Moretti, Periodontology
- Dr. Allen Samuelson, Dental Ecology