

1 **21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS**

2 For the purpose of these Rules relative to the administration of minimal conscious sedation, moderate
3 conscious sedation, moderate conscious sedation limited to oral routes or nitrous oxide inhalation, moderate
4 pediatric conscious sedation or general anesthesia by or under the direction of a dentist, the following
5 definitions shall apply:

- 6 (1) "Analgesia" – the diminution or elimination of pain.
- 7 (2) "Anti-anxiety sedative" – a sedative agent administered in a dosage intended to reduce
8 anxiety without diminishing consciousness or protective reflexes.
- 9 (3) "Anxiolysis" – pharmacological reduction of anxiety through the administration of a
10 single dose of a minor psychosedative, possibly in combination with nitrous oxide, to
11 children or adults prior to commencement of treatment on the day of the appointment
12 which allows for uninterrupted interactive ability in a totally awake patient with no
13 compromise in the ability to maintain a patent airway continuously and without
14 assistance. Nitrous oxide may be administered in addition to the minor psychosedative
15 without constituting multiple dosing for purpose of these Rules.
- 16 (4) "Behavior control" – the use of pharmacological techniques to control behavior to a level
17 that dental treatment can be performed effectively and efficiently.
- 18 (5) "Behavioral management" – the use of pharmacological or psychological techniques,
19 singly or in combination, to modify behavior to a level that dental treatment can be
20 performed effectively and efficiently.
- 21 (6) "Competent" – displaying special skill or knowledge derived from training and
22 experience.
- 23 (7) "Conscious sedation" - an induced state of a depressed level of consciousness that retains
24 the patient's ability to independently and continuously maintain an airway and respond
25 appropriately to physical stimulation and verbal command, and that is produced by
26 pharmacologic or non-pharmacologic agents, or a combination thereof. In accordance
27 with this particular definition, the drugs or techniques used shall carry a margin of safety
28 wide enough to render unintended loss of consciousness unlikely.
- 29 (8) "Deep sedation" – an induced state of a depressed level of consciousness accompanied
30 by partial loss of protective reflexes, including the ability to continually maintain an
31 airway independently or respond purposefully to verbal command, and is produced by
32 pharmacological agents.
- 33 (9) "Direct supervision" – the dentist responsible for the sedation/anesthesia procedure shall
34 be physically present in the facility and shall be continuously aware of the patient's
35 physical status and well being.
- 36 (10) "Facility" – the location where a permit holder practices dentistry and provides
37 anesthesia/sedation services.

- 1 (11) "Facility inspection" - an on-site inspection to determine if a facility where the applicant
2 proposes to provide anesthesia/sedation is supplied, equipped, staffed and maintained in a
3 condition to support provision of anesthesia/sedation services that meet the minimum
4 standard of care.
- 5 (12) "General anesthesia" -- the intended controlled state of a depressed level of
6 consciousness that is produced by pharmacologic agents and accompanied by a partial or
7 complete loss of protective reflexes, including the ability to maintain an airway and
8 respond purposefully to physical stimulation or verbal commands.
- 9 (13) "Immediately available" – on-site in the facility and available for immediate use.
- 10 (14) "Local anesthesia" – the elimination of sensations, especially pain, in one part of the
11 body by the regional application or injection of a drug.
- 12 (15) "May" – indicates freedom or liberty to follow a reasonable alternative.
- 13 (16) "Minimal conscious sedation" – conscious sedation characterized by a minimally
14 depressed level of consciousness, in which patient retains the ability to independently and
15 continuously maintain an airway and respond normally to tactile stimulation and verbal
16 command, provided to patients 13 years or older, by oral or rectal routes of
17 administration of a single pharmacological agent, in one or more doses, not to exceed the
18 manufacturer's maximum recommended dose, at the time of treatment, possibly in
19 combination with nitrous oxide. Minimal conscious sedation is provided for behavioral
20 management.
- 21 (17) "Minor psychosedative/Minor tranquilizer" – pharmacological agents which allow for
22 uninterrupted interactive ability in a patient with no compromise in the ability to maintain
23 a patent airway continuously and without assistance and carry a margin of safety wide
24 enough to render unintended loss of consciousness unlikely.
- 25 (18) "Moderate conscious sedation" – conscious sedation characterized by a drug induced
26 depression of consciousness, during which patients respond purposefully to verbal
27 commands, either alone or accompanied by light tactile stimulation, provided to patients
28 13 years or older, by oral, nasal, rectal or parenteral routes of administration of multiple
29 pharmacological agents, in multiple doses, within a 24 hour period, including the time of
30 treatment, possibly in combination with nitrous oxide. Moderate conscious sedation is
31 provided for behavior control.
- 32 (19) "Moderate conscious sedation limited to oral routes and nitrous oxide inhalation" –
33 conscious sedation characterized by a drug induced depression of consciousness during
34 which patients respond purposefully to verbal commands, either alone or accompanied by
35 light tactile stimulation, provided to patients 13 years or older, by oral routes of
36 administration and nitrous oxide inhalation, of single or multiple pharmacological agents,

1 in single or multiple doses, within a 24 hour period. Moderate conscious sedation
2 limited to oral routes and nitrous oxide inhalation is provided for behavior control.

3 (20) “Moderate pediatric conscious sedation” -- conscious sedation characterized by a drug
4 induced depression of consciousness, during which patients respond purposefully to
5 verbal commands, either alone or accompanied by light tactile stimulation, provided to
6 patients under 13 years of age, by oral, nasal, rectal or parenteral routes of administration
7 of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour
8 period, including the time of treatment, possibly in combination with nitrous oxide.
9 Moderate pediatric conscious sedation is provided for behavior control.

10 (21) “Must” or “shall” – indicates an imperative need or duty or both; an essential or
11 indispensable item; mandatory.

12 (22) “Parenteral” --the administration of pharmacological agents intravenously,
13 intraosseously, intramuscularly, subcutaneously, submucosally, intranasally, or
14 transdermally.

15 (23) “Protective reflexes” – includes the ability to swallow and cough.

16 (24) “Supplemental dosing” – the oral administration of a pharmacological agent that results
17 in an enhanced level of conscious sedation when added to the primary sedative agent
18 administered for the purpose of oral moderate conscious sedation, and which, when
19 added to the primary agent, does not exceed the maximum safe dose of either agent,
20 separately or synergistically.

21 (25) “Vested adult” – a responsible adult who is the legal parent or guardian, or designee of a
22 legal parent or guardian, entrusted with the care of a minor following the administration
23 of general anesthesia or conscious sedation.

24 *History Note: Statutory authority G.S. 90-28; 90-30.1;*
25 *Eff. February 1, 1990;*
26 *Temporary Amendment Eff. December 11, 2002;*
27 *Amended Eff. Sept. 1, 2007; August 1, 2004.*

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2 **21 NCAC 16Q .0301 CREDENTIALS AND PERMITS FOR MODERATE CONSCIOUS**
3 **SEDATION, MODERATE PEDIATRIC CONSCIOUS SEDATION AND MODERATE**
4 **CONSCIOUS SEDATION LIMITED TO ORAL ROUTES OF ADMINISTRATION AND**
5 **NITROUS OXIDE**

6 (a) Before a dentist licensed to practice in North Carolina may administer or supervise a certified
7 registered nurse anesthetist (CRNA) to administer moderate conscious sedation, moderate pediatric
8 conscious sedation or moderate conscious sedation limited to oral routes of administration and nitrous
9 oxide to dental patients on an outpatient basis, the dentist shall obtain a permit from the Board by
10 completing an application form provided by the Board and paying a fee of one hundred dollars (\$100.00).
11 Such permit shall be renewed annually and shall be displayed with the current renewal at all times in a
12 conspicuous place in the facility of the permit holder.

13 (b) For a dentist to employ a certified registered nurse anesthetist to administer moderate conscious
14 sedation, moderate conscious sedation limited to oral routes and nitrous oxide or moderate pediatric
15 conscious sedation, the dentist must demonstrate through the permitting process that he/she is capable of
16 performing all duties and procedures to be delegated to the CRNA. The dentist must not delegate said
17 CRNA to perform procedures outside of the scope of the technique and purpose of moderate conscious
18 sedation, moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes and
19 nitrous oxide as defined in Rule .0101 of this Subchapter.

20 (c) A dentist applying for a permit to administer moderate conscious sedation or moderate pediatric
21 conscious sedation must meet at least one of the following criteria:

- 22 (1) Satisfactory completion of a minimum of 60 hours of didactic training, including PALS,
23 and instruction in intravenous conscious sedation and satisfactory management of a
24 minimum of 10 patients, under supervision, using intravenous sedation; or
25 (2) Satisfactory completion of a pre-doctoral dental or postgraduate program which included
26 intravenous conscious sedation training equivalent to that defined in Subparagraph (c)(1)
27 of this Rule; or
28 (3) Satisfactory completion of an internship or residency which included intravenous
29 conscious sedation training equivalent to that defined in Subparagraph (c)(1) of this Rule;
30 or

31 (d) A dentist may modify his/her moderate conscious sedation permit to include the privilege of moderate
32 pediatric conscious sedation by completing a Board approved pediatric dental degree or pediatric dental
33 residency program or obtaining the equivalent hours of continuing education program in pediatric dental
34 anesthesia. If said qualifications are satisfied, it shall be so designated on the dentist's moderate conscious
35 sedation permit and will be subject to the renewal requirements stated in .0501(d) of this Subchapter.

36 (e) To be eligible for a moderate conscious sedation permit, moderate conscious sedation limited oral
37 routes and nitrous oxide inhalation or moderate pediatric conscious sedation permit, a dentist must operate
38 within a facility which includes the capability of delivering positive pressure oxygen, and is staffed with

1 supervised auxiliary personnel for each procedure performed. The dentist shall ensure that auxiliary
2 personnel document annual, successful completion of basic life support (BLS) training and are capable of
3 assisting with procedures, problems and emergencies incident thereto.

4 (f) Prior to issuance of a moderate conscious sedation permit, moderate conscious pediatric sedation permit
5 or moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation permit, the
6 applicant shall undergo an evaluation which includes a facility inspection. The Board shall direct an
7 evaluator to perform this evaluation. The applicant shall be notified in writing that an evaluation and
8 facility inspection is required and provided with the name of the evaluator who shall perform the evaluation
9 and facility inspection. The applicant shall be responsible for successful completion of the evaluation and
10 inspection of his or her facility within three months of notification. An extension of no more than 90 days
11 shall be granted if the designated evaluator or applicant requests one.

12 (g) The evaluator shall assign a grade of pass or fail and shall report his recommendation to the Board,
13 setting out the basis for his conclusion. The Board is not bound by the evaluator's recommendation and
14 shall make a final determination regarding whether the applicant has passed the evaluation. The applicant
15 shall be notified of the Board's decision in writing.

16 (h) A dentist who holds a moderate conscious sedation, moderate conscious sedation limited to oral routes
17 and nitrous oxide inhalation or moderate pediatric conscious sedation permit shall not intentionally
18 administer deep sedation although deep sedation may occur briefly and unintentionally.

19 (i) A dentist may obtain a moderate conscious sedation permit limited to oral routes of administration and
20 nitrous oxide inhalation, including the ability to add supplemental dosing to the techniques set out in Rule
21 .0101(23) of this Subchapter upon compliance with the following requirements:

22 (1) successfully complete 24 hours of didactic training and manage at least 10 adult case
23 experiences, including at least three live clinical dental experiences. The live clinical cases shall not be
24 handled by groups with more than five participants. The remaining cases may include simulations, video
25 presentations or both, but must include one experience in returning/rescuing a patient from deep to
26 moderate sedation. or

27 (2) document, with patient names and dates of completion, at least 100 cases of oral
28 moderate conscious sedation procedures successfully completed within one year preceding the effective
29 date of these rules and;

30 (3) fulfill all the requirements listed in .0401 for minimal conscious sedation.

31 (j) A dentist who is qualified to administer general anesthesia, moderate conscious sedation or moderate
32 pediatric conscious sedation and holds a general anesthesia, moderate conscious sedation permit or a
33 moderate pediatric conscious sedation permit may administer minimal conscious sedation without
34 obtaining a separate minimal conscious sedation permit.

35 (l) Any dentist who holds an active parenteral conscious sedation permit as of the effective date of these
36 amendments shall be deemed to hold an active moderate conscious sedation permit. Such permits shall be
37 subject to the renewal requirements set out in .0501 of this Subchapter.

1 *History Note: Authority G.S. 90-28; 90-30.1;*
2 *Eff. February 1, 1990;*
3 *Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;*
4 *Temporary Amendment Eff. December 11, 2002;*
5 *Amended Eff. Sept. 1, 2007; August 1, 2004;*
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21 NCAC 16Q .0302 CLINICAL REQUIREMENTS AND EQUIPMENT

(a) A dentist administering moderate conscious sedation or moderate pediatric conscious sedation or supervising the administration of moderate conscious sedation by a certified registered nurse anesthetist shall ensure that the facility in which the sedation is to be administered meets the following requirements:

- (1) The facility is equipped with:
 - (A) An operatory of size and design to permit access of emergency equipment and personnel and to permit effective emergency management;
 - (B) A dental chair suitable for providing emergency treatment without enhancements or a CPR board;
 - (C) Lighting as necessary for specific procedures; and
 - (D) Suction equipment as necessary for specific procedures, including non-electrical back-up suction.
- (2) The following equipment is maintained:
 - (A) Positive oxygen delivery system, including full face mask for adults and pediatric patients and back-up E-cylinder portable oxygen tank apart from the central system;
 - (B) Oral and nasal airways of various sizes;
 - (C) Blood pressure monitoring device;
 - (D) Pulse oximeter; and
 - (E) Automatic External Defibrillator (AED).
- (3) The following emergency equipment is maintained:
 - (A) I.V. set-up as necessary for specific procedures, including hardware and fluids, if anesthesia is intravenous;
 - (B) Syringes as necessary for specific procedures; and
 - (C) Tourniquet and tape.
- (4) The following drugs are maintained with a current shelf life and within easy access from the operatory and recovery area:
 - (A) Epinephrine;
 - (B) Atropine;
 - (C) Narcotic antagonist;
 - (D) Antihistamine;
 - (E) Corticosteroid;
 - (F) Nitroglycerine;
 - (G) Bronchial dilator;
 - (H) Antiemetic;
 - (I) Benzodiazepine antagonist; and

- 1 (J) 50% Dextrose.
- 2 (5) Written emergency and patient discharge protocols are maintained and training to
3 familiarize office personnel in the treatment of clinical emergencies is provided; and
- 4 (6) The following records are maintained for at least 10 years:
- 5 (A) Patient's current written medical history, including known allergies and
6 previous surgery;
- 7 (B) Drugs administered during the procedure, including route of administration,
8 dosage, strength, time and sequence of administration;
- 9 (C) A sedation record which shall include:
- 10 (i) blood pressure;
- 11 (ii) pulse rate;
- 12 (iii) respiration;
- 13 (iv) duration of procedure;
- 14 (v) documentation of complications or morbidity; and
- 15 (vi) status of patient upon discharge.

16 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration
17 of moderate conscious sedation on a patient, or where applicable, moderate pediatric conscious sedation on
18 a patient, including the deployment of an intravenous delivery system, while the evaluator observes.
19 Practices limited to pediatric dentistry will not be required to demonstrate the deployment of an intravenous
20 delivery system. Instead, they will orally describe to the evaluator the technique of their training in
21 intravenous and intraosseous deployment. During the demonstration, the applicant or permit holder shall
22 demonstrate competency in the following areas:

- 23 (1) Monitoring blood pressure, pulse, and respiration;
- 24 (2) Drug dosage and administration;
- 25 (3) Treatment of untoward reactions including respiratory or cardiac depression, if
26 applicable;
- 27 (4) Sterile technique;
- 28 (5) Use of CPR certified personnel;
- 29 (6) Monitoring of patient during recovery; and
- 30 (7) Sufficiency of patient recovery time.

31 (c) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate
32 competency to the evaluator in the treatment of the following clinical emergencies:

- 33 (1) Laryngospasm;
- 34 (2) Bronchospasm;
- 35 (3) Emesis and aspiration;
- 36 (4) Respiratory depression and arrest;
- 37 (5) Angina pectoris;

- 1 (6) Myocardial infarction;
- 2 (7) Hypertension/Hypotension;
- 3 (8) Allergic reactions;
- 4 (9) Convulsions;
- 5 (10) Syncope;
- 6 (11) Bradycardia;
- 7 (12) Insulin shock; and
- 8 (13) Cardiac arrest.

9 (d) A dentist administering moderate conscious sedation or moderate pediatric conscious sedation shall
10 ensure that the facility is staffed with sufficient auxiliary personnel for each procedure performed who shall
11 document annual successful completion of basic life support training and be capable of assisting with
12 procedures, problems, and emergency incidents that may occur as a result of the sedation or secondary to
13 an unexpected medical complication.

14 (e) Upon request, the holder of a moderate pediatric conscious sedation or moderate conscious sedation
15 permit may travel to the office of a licensed dentist who does not hold such a permit and provide minimal
16 sedation, moderate conscious sedation or moderate pediatric conscious sedation services for the patients of
17 that dentist who are undergoing dental procedures. The permit holder is solely responsible for providing
18 that the facility in which the sedation is administered meets the requirements established by the Board, that
19 the required drugs and equipment are present, and that the permit holder utilizes sufficient auxiliary
20 personnel for each procedure performed who shall document annual successful completion of basic life
21 support training and be capable of assisting with procedures, problems, and emergency incidents that may
22 occur as a result of the sedation or secondary to an unexpected medical complication. Holders of moderate
23 conscious sedation permits limited to oral routes and nitrous oxide inhalation may not provide sedation at
24 the office of a licensed dentist who does not hold an appropriate sedation permit.

25 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
26 *Eff. February 1, 1990;*
27 *Amended Eff. August 1, 2002; August 1, 2000;*
28 *Temporary Amendment Eff. December 11, 2002.*
29 *Amended Eff. Sept. 1, 2007; August 1, 2004.*

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1 **21 NCAC 16Q .0303 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION**

2 (a) If a dentist meets the requirements of Paragraphs (a) – (e) of Rule .0301 of this Subchapter, he/she shall
3 be granted temporary approval to administer moderate conscious sedation, or moderate pediatric conscious
4 sedation until a permit can be issued. If a dentist meets the requirements of Paragraph (j) of Rule .0301 of
5 this Subchapter, he/she shall be granted temporary approval to administer moderate conscious sedation
6 limited to oral routes and nitrous oxide inhalation. Temporary approval may be granted based solely on
7 credentials until all processing and investigation has been completed. Temporary approval may not exceed
8 three months. An on-site evaluation of the facilities, equipment, procedures, and personnel shall be
9 required prior to issuance of a permanent permit. The evaluation shall be conducted in accordance with
10 Rules .0204 -.0205 of this Subchapter, except that evaluations of dentists applying for moderate conscious
11 sedation permits may be conducted by dentists who have been issued moderate conscious sedation permits
12 by the Board and who have been approved by the Board, as set out in these Rules. Fees required by Rule
13 .0204 of this Subchapter shall apply.

14 (b) An inspection may be made upon renewal of the permit or for cause.

15 (c) Temporary approval shall not be granted to a provisional licensee or applicants who are the subject of a
16 pending Board disciplinary investigation or whose licenses have been revoked, suspended or are subject to
17 an order of stayed suspension or probation.

18 *History Note: Authority G.S. 90-28; 90-30.1;*

19 *Eff. February 1, 1990;*

20 *Amended Eff. August 1, 2002; January 1, 1994;*

21 *Temporary Amendment Eff. December 11, 2002;*

22 *Amended Eff. Sept. 1, 2007; August 1, 2004.*

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26 **21 NCAC 16Q .0401 MINIMAL CONSCIOUS SEDATION CREDENTIALS, EVALUATION**
27 **AND PERMIT**

28 (a) Before a dentist licensed to practice in North Carolina may administer or supervise a certified
29 registered nurse anesthetist to administer minimal conscious sedation, the dentist shall obtain a Board-
30 issued permit for minimal conscious sedation, moderate pediatric conscious sedation, moderate conscious
31 sedation or general anesthesia. A permit is not required for prescription administration of DEA controlled
32 drugs prescribed for postoperative pain control intended for home use. A dentist may obtain a minimal
33 conscious sedation permit from the Board by completing an application form provided by the Board and
34 paying a fee of one hundred dollars (\$100.00). Such permit must be renewed annually and shall be
35 displayed with the current renewal at all times in a conspicuous place in the office of the permit holder.

36 (b) Only a dentist who holds a general anesthesia license may administer deep sedation or general
37 anesthesia.

1 (c) Application:

- 2 (1) A minimal conscious sedation permit may be obtained by completing an application form
3 provided by Board, a copy of which may be obtained from the Board office, and meeting
4 the requirements of Section .0400 of this Subchapter.
- 5 (2) The application form must be filled out completely and appropriate fees paid.
- 6 (3) An applicant for a minimal conscious sedation permit shall be licensed and in good
7 standing with the Board in order to be approved. For purposes of these Rules “good
8 standing” means that the applicant is not subject to a disciplinary investigation and his or
9 her licensee has not been revoked or suspended and is not subject to a probation or stayed
10 suspension order,

11 (d) Evaluation:

- 12 (1) Prior to issuance of a minimal conscious sedation permit the applicant shall undergo a
13 facility inspection. The Board shall direct an evaluator qualified to administer minimal
14 sedation to perform this inspection. The applicant shall be notified in writing that an
15 inspection is required and provided with the name of the evaluator who shall perform the
16 inspection. The applicant shall be responsible for successful completion of inspection of
17 his or her facility within three months of notification. An extension of no more than 90
18 days shall be granted if the designated evaluator or applicant requests one.
- 19 (2) During an inspection or evaluation, the applicant or permit holder shall demonstrate
20 competency in the following areas:
- 21 (A) Monitoring of blood pressure, pulse, pulse oximetry and respiration;
 - 22 (B) Drug dosage and administration (by verbal demonstration);
 - 23 (C) Treatment of untoward reactions including respiratory or cardiac depression (by
24 verbal demonstration);
 - 25 (D) Sterilization;
 - 26 (E) Use of CPR certified personnel;
 - 27 (F) Monitoring of patient during recovery (by verbal demonstration); and
 - 28 (G) Sufficiency of patient recovery time (by verbal demonstration).
- 29 (3) During an inspection or evaluation, the applicant or permit holder shall verbally
30 demonstrate competency to the evaluator in the treatment of the following clinical
31 emergencies:
- 32 (A) Laryngospasm;
 - 33 (B) Bronchospasm;
 - 34 (C) Emesis and aspiration;
 - 35 (D) Respiratory depression and arrest;
 - 36 (E) Angina pectoris;
 - 37 (F) Myocardial infarction;

- 1 (G) Hypertension/Hypotension;
- 2 (H) Syncope;
- 3 (I) Allergic reactions;
- 4 (J) Convulsions;
- 5 (K) Bradycardia;
- 6 (L) Insulin shock; and
- 7 (M) Cardiac arrest.

8 (4) The evaluator shall assign a grade of pass or fail and shall report his recommendation to
9 the Board, setting out the basis for his conclusion. The Board is not bound by the
10 evaluator's recommendation and shall make a final determination regarding whether the
11 applicant has passed the evaluation. The applicant shall be notified of the Board's
12 decision in writing.

13 (e) Educational/Professional Requirements:

- 14 (1) The dentist applying for a minimal conscious sedation permit shall meet one of the
15 following criteria:
 - 16 (A) successful completion of training consistent with that described in Part I or Part
17 III of the American Dental Association (ADA) Guidelines for Teaching the
18 Comprehensive Control of Pain and Anxiety in Dentistry, and have documented
19 administration of minimal conscious sedation in a minimum of five cases;
 - 20 (B) successful completion of an ADA accredited post-doctoral training program
21 which affords comprehensive training necessary to administer and manage
22 minimal conscious sedation;
 - 23 (C) successful completion of an 18-hour minimal conscious sedation course which
24 must be approved by the Board based on whether it affords comprehensive
25 training necessary to administer and manage minimal conscious sedation;
 - 26 (D) successful completion of an ADA accredited postgraduate program in pediatric
27 dentistry; or
 - 28 (E) is a North Carolina licensed dentist in good standing who has been using
29 minimal conscious sedation in a competent manner for at least one year
30 immediately preceding the effective date of this Rule and his or her office
31 facility has passed an on-site inspection by a Board evaluator as required in
32 Paragraph (d) of this Rule. Competency shall be determined by presentation of
33 successful administration of minimal conscious sedation in a minimum of five
34 clinical cases.
- 35 (2) All applicants for a minimal sedation permit must document successful completion of a
36 Basic Life Saving (BLS) course within the 12 months prior to the date of application.

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1 *History Note: Authority G.S. 90-28; 90-30.1;*
2 *Temporary Adoption Eff. March 13, 2003; December 11, 2002;*
3 *Amended Eff. Sept. 1, 2007; August 1, 2004.*
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**21 NCAC 16Q. 0402 MINIMAL CONSCIOUS SEDATION PERMIT REQUIREMENTS,
CLINICAL PROVISIONS AND EQUIPMENT**

(a) Minimal conscious sedation is indicated for use only as defined in Rule .0101(15) of this Subchapter (relating to Definitions). Minimal conscious sedation is not indicated for use to achieve deep sedation.

(b) A minimal conscious sedation permit is not required for minor psychosedatives used for anxiolysis prescribed for administration outside of the dental office when pre-procedure instructions are likely to be followed. Medication administered for the purpose of minimal conscious sedation shall not exceed the maximum doses recommended by the drug manufacturer, sedation textbooks, or juried sedation journals. Except for nitrous inhalation, drugs in combination are not permitted for minimal conscious sedation. During longer periods of minimal conscious sedation, in which the amount of time of the procedures exceeds the effective duration of the sedative effect of the drug used, the incremental doses of the sedative shall not exceed total safe dosage levels based on the effective half-life of the drug used.

(c) Each dentist shall:

- (1) adhere to the clinical requirements as detailed in Paragraph (e) of this Rule;
- (2) maintain under continuous direct supervision any auxiliary personnel, who shall be capable of assisting in procedures, problems, and emergencies incident to the use of minimal conscious sedation or secondary to an unexpected medical complication;
- (3) utilize sufficient auxiliary personnel for each procedure performed who shall document annual successful completion of basic life support training; and
- (4) not allow a minimal conscious sedation procedure to be performed in his or her office by a Certified Registered Nurse Anesthetist (CRNA) unless the dentist holds a permit issued by the Board for the procedure being performed. This provision addresses dentists and is not intended to address the scope of practice of persons licensed by any other agency.

(d) Each dentist shall meet the following requirements:

- (1) Patient Evaluation. Patients who are administered minimal conscious sedation must be evaluated for medical health risks prior to the start of any sedative procedure. A patient receiving minimal conscious sedation must be healthy or medically stable (ASA I, or ASA II as defined by the American Society of Anesthesiologists). An evaluation is a review of the patient's current medical history and medication use. However, for individuals who are not medically stable or who have a significant health disability Physical Status III (ASA III, as defined by the American Society of Anesthesiologists) a consultation with their primary care physician or consulting medical specialist regarding potential procedure risk is required.
- (2) Pre-procedure preparation, informed consent:
 - (A) The patient or guardian must be advised of the procedure associated with the delivery of the minimal conscious sedation.
 - (B) Equipment must be evaluated and maintained for proper operation.

- (C) Baseline vital signs shall be obtained at the discretion of the operator depending on the medical status of the patient and the nature of the procedure to be performed.
- (D) Dentists administering minimal conscious sedation shall use sedative agents that he/she is competent to administer and shall administer such agents in a manner that is within the standard of care.

(e) Patient monitoring:

- (1) Patients who have been administered minimal conscious sedation shall be monitored during waiting periods prior to operative procedures. An adult who has accepted responsibility for the patient and been given written pre-procedural instruction may provide such monitoring. The patient shall be monitored for alertness, responsiveness, breathing and skin coloration.
- (2) Dentists administering minimal conscious sedation shall maintain direct supervision of the patient during the operative procedure and for such a period of time necessary to establish pharmacologic and physiologic vital sign stability.
 - (A) Oxygenation. Color of mucosa, skin or blood shall be continually evaluated. Oxygen saturation shall be evaluated continuously by pulse oximetry, except as provided in Paragraph (e) (4) of this Rule.
 - (B) Ventilation. Observation of chest excursions or auscultation of breath sounds or both shall be performed.
 - (C) Circulation. Blood pressure and pulse shall be taken and recorded initially and thereafter as appropriate except as provided in Paragraph (e)(4) of this Rule.
 - (D) AED. Dentists administering minimal conscious sedation shall maintain a functioning automatic external defibrillator (AED).
- (3) An appropriate time oriented anesthetic record of vital signs shall be maintained in the permanent record including documentation of individual(s) administering the drug and showing the name of drug, strength and dosage used.
- (4) If the dentist responsible for administering minimal conscious sedation must deviate from the requirements set out in this Rule, he or she shall document the occurrence of such deviation and the reasons for such deviation.

(f) Post-operative procedures:

- (1) Following the operative procedure, positive pressure oxygen and suction equipment shall be immediately available in the recovery area or operatory.
- (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation

and circulation are stable and the patient is sufficiently responsive for discharge from the office.

(3) Patients who have adverse reactions to minimal conscious sedation shall be assisted and monitored either in an operatory chair or recovery area until stable for discharge.

(4) Recovery from minimal conscious sedation shall include:

- (A) cardiovascular function stable;
- (B) airway patency uncompromised;
- (C) patient easily arousable and protective reflexes intact;
- (D) state of hydration within normal limits;
- (E) patient can talk, if applicable;
- (F) patient can sit unaided, if applicable;
- (G) patient can ambulate, if applicable, with minimal assistance; and
- (H) for the patient who is disabled, or incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

(5) Prior to allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Paragraph (f)(4) of this Rule and the following discharge criteria:

- (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and stable and have been documented;
- (B) explanation and documentation of written postoperative instructions have been provided to the patient or a responsible adult at time of discharge;
- (C) responsible individual is available for the patient to transport the patient after discharge;
- (D) A vested adult must be available to transport patients for whom a motor vehicle restraint system is required and an additional responsible individual must be available to attend to the patients.

(g) The dentist, personnel and facility shall be prepared to treat emergencies that may arise from the administration of minimal conscious sedation, and shall have the ability to provide positive pressure ventilation with 100% oxygen with an age appropriate device.

*History Note: Authority G.S. 90-28; 90-30.1;
Temporary Adoption Eff. December 11, 2002;
Amended Eff. Sept. 1, 2007; August 1, 2004.*

21 NCAC 16Q .0403 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION

(a) A dentist whose facility has not been inspected but who has otherwise met the requirements of Rule .0401 of this Section may seek temporary approval to administer minimal conscious sedation until a permit can be issued. Temporary approval may be granted based solely on credentials until all processing and investigation has been completed. Temporary approval may not exceed three months.

(b) Temporary approval shall not be granted to a provisional licensee or to an applicant who is the subject of a disciplinary investigation or whose license has been revoked or suspended or is the subject of a probation or stayed suspension order.

(c) A two hundred seventy five dollar (\$275.00) fee shall be collected for each site inspected pursuant to Rule .0401 of this Section.

*History Note: Authority G.S. 90-28; 90-30.1.
 Temporary Adoption Eff. December 11, 2002;
 Eff. August 1, 2004;
 Amended Eff. February 1, 2009; July 3, 2008.*

21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED

(a) General anesthesia and all sedation permits shall be renewed by the Board annually. Such renewal shall be accomplished in conjunction with the license renewal process, and applications for permits shall be made at the same time as applications for renewal of licenses. A one hundred (\$100.00) annual renewal fee shall be paid at the time of renewal.

(b) All sedation permits shall be subject to the same renewal deadlines as are dental practice licenses, in accordance with G.S. 90-31. If the permit renewal application is not received by the date specified in G.S. 90-31, continued administration of general anesthesia or any level of conscious sedation shall be unlawful and shall subject the dentist to the penalties prescribed by Section .0700 of this Subchapter.

(c) As a condition for renewal of the general anesthesia permit, the permit holder shall meet the requirements of 21 NCAC 16Q .0202 and document current, successful completion of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other equivalent course, and auxiliary personnel shall document annual, successful completion of basic life support (BLS) training.

(d) As a condition for renewal of the moderate conscious sedation permit or moderate pediatric conscious sedation permit, the permit holder shall meet the requirements of 21 NCAC 16Q .0302 and the following criteria:

- (1) document annual, successful completion of BLS training and obtain three hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:
 - (A) sedation;
 - (B) medical emergencies;
 - (C) monitoring IV sedation and the use of monitoring equipment;
 - (D) pharmacology of drugs and agents used in IV sedation;
 - (E) physical evaluation, risk assessment, or behavioral management; or
 - (F) audit ACLS/Pediatric Advanced Life Support (PALS) courses.
- (2) document current, successful completion of ACLS training or its age-specific equivalent, or other equivalent course and annual successful completion of BLS; and
- (3) moderate pediatric conscious sedation permit holders must have current PALS at all times.

(e) As a condition for renewal of the minimal conscious sedation permit and the moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation, the permit holder shall meet the requirements of 16Q .0402 and shall document annual, successful completion of BLS training and obtain six hours of continuing education every two years in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:

- (1) pediatric or adult sedation;
- (2) medical emergencies;
- (3) monitoring sedation and the use of monitoring equipment;
- (4) pharmacology of drugs and agents used in sedation;
- (5) physical evaluation, risk assessment, or behavioral management; or
- (6) audit ACLS/PALS courses.

(f) Any dentist who fails to renew a general anesthesia or sedation permit on or before March 31 of each year must complete a reinstatement application, pay the \$100 renewal fee and a \$100 penalty and comply with all conditions for renewal set out in this Rule for the permit sought. Dentists whose anesthesia or sedation permits have been lapsed for more than 12 calendar months must pass a facilities inspection as part of the reinstatement process.

*History Note: Statutory authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Amended Eff. August 1, 2002;
Transferred and Recodified from 16Q .0401 to 16Q .0501;
Temporary Amendment Eff. December 11, 2002;
Amended Eff. Sept. 1, 2007; August 1, 2004.*