

1 21 NCAC 16Q .0101 is proposed for amendment as follows:

2

3 **21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS**

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

7 (1) "Analgesia" – the diminution or elimination of pain.

8 (2) "Anti-anxiety sedative" – a sedative agent administered in a dosage intended to reduce anxiety
9 without diminishing consciousness or protective reflexes.

10 (3) "Anxiolysis" – pharmacological reduction of anxiety through the administration of a single dose of
11 a minor psychosedative, possibly in combination with nitrous oxide, to children or adults prior to
12 commencement of treatment on the day of the appointment which allows for uninterrupted
13 interactive ability in a totally awake patient with no compromise in the ability to maintain a patent
14 airway continuously and without assistance. Nitrous oxide may be administered in addition to the
15 minor psychosedative without constituting multiple dosing for purpose of these Rules.

16 (4) "ACLS" – Advanced Cardiac Life Support.

17 (5) "Administer" – to direct, manage, supervise, control, and have charge of all aspects of selection,
18 dosage, timing, and method of delivery to the patient of any pharmacologic agent intended to reduce
19 anxiety or depress consciousness.

20 (6) "ASA" – American Society of Anesthesiologists.

21 (7) "Auxiliaries" – non-dentist staff members involved in general anesthesia or sedation procedures.

22 (8) "BLS" – Basic Life Support.

23 (4)(9) "Behavior control" – the use of pharmacological techniques to control behavior to a level that dental
24 treatment ~~can~~ may be performed without injury to the patient or dentist, effectively and efficiently.

25 (5)(10) "Behavioral management" – the use of pharmacological or psychological techniques, singly or in
26 combination, to modify behavior to a level that dental treatment ~~can~~ may be performed effectively
27 and efficiently, without injury to the patient or dentist.

28 (6)(11) "Competent" – displaying special skill or knowledge derived from training and experience.

29 (7)(12) "Conscious sedation" - an induced state of a depressed level of consciousness that retains the patient's
30 ability to ~~independently and continuously~~ maintain an airway without assistance and respond
31 ~~appropriately~~ to physical stimulation and ~~obey~~ verbal command, commands, and that is produced
32 by pharmacologic or non-pharmacologic agents, or a combination thereof. ~~In accordance with this~~
33 ~~particular definition, the drugs or techniques used shall carry a margin of safety wide enough to~~
34 ~~render unintended loss of consciousness unlikely.~~ All dentists who perform conscious sedation
35 shall have an unexpired sedation permit from the Dental Board.

36 (13) "CRNA" – Certified Registered Nurse Anesthetist.

- 1 ~~(8)~~(14) “Deep sedation” – an induced state of a depressed level of consciousness accompanied by partial
2 loss of protective reflexes, including the ability to ~~continually~~ maintain an airway ~~independently~~
3 without assistance or respond ~~purposefully~~ to verbal command, ~~and is produced by pharmacological~~
4 agents. All dentists who perform deep sedation shall have an unexpired general anesthesia permit
5 from the Dental Board.
- 6 (15) “Deliver” – to assist a permitted dentist in administering sedation or anesthesia drugs by providing
7 the drugs to the patient pursuant to a direct order from the dentist and while under the dentist’s direct
8 supervision.
- 9 ~~(9)~~(16) “Direct supervision” – the dentist responsible for the ~~sedation/anesthesia~~ sedation or anesthesia
10 procedure shall be physically present in the facility immediately available and shall be continuously
11 aware of the patient's physical status and well being. being at all times.
- 12 (17) “Emergencies manual” – a written manual that documents:
- 13 a) the location of all emergency equipment and medications in each facility;
14 b) each staff member’s role during medical emergencies; and
15 c) the appropriate treatment for laryngospasm, bronchospasm, emesis and
16 aspiration, respiratory depression and arrest, angina pectoris, myocardial
17 infarction, hypertension, hypotension, allergic reactions, convulsions, syncope,
18 bradycardia, [insulin shock] hypoglycemia, cardiac arrest, and airway
19 obstruction.
- 20 (18) “Enteral” - the administration of pharmacological agents orally, intranasally, sublingually, or
21 rectally.
- 22 (19) “ET CO2” —end tidal carbon dioxide.
- 23 ~~(10)~~(20) “Facility” – the location where a permit holder practices dentistry and provides ~~anesthesia/sedation~~
24 anesthesia or sedation services.
- 25 ~~(11)~~(21) “Facility inspection” – an on-site inspection to determine if a facility where the applicant proposes
26 to provide ~~anesthesia/sedation~~ anesthesia or sedation is supplied, equipped, ~~staffed~~ staffed, and
27 maintained in a condition to support provision of ~~anesthesia/sedation~~ anesthesia or sedation services
28 that meet the minimum standard of care. in compliance with the Dental Practice Act set forth in
29 Article 2 of G.S. 90 and the Board’s rules of this Chapter.
- 30 ~~(12)~~(22) “General anesthesia” - the intended controlled state of a depressed level of consciousness that is
31 produced by pharmacologic agents and accompanied by a partial or complete loss of protective
32 reflexes, including the ability to maintain an airway and respond ~~purposefully~~ to physical
33 stimulation and ~~obey~~ obey or verbal commands. All dentists who perform general anesthesia shall have
34 an unexpired general anesthesia permit from the Dental Board.
- 35 (23) “Good standing” – a licensee whose license is not suspended or revoked and who is not subject to a
36 current disciplinary order imposing probationary terms.
- 37 ~~(13)~~(24) “Immediately available” – on-site in the facility and available for ~~immediate use.~~ use without delay.

1 (25) "Itinerant general anesthesia provider"- a permittee who has complied with Rule .0206 of this
2 Subchapter and who administers general anesthesia at another practitioner's facility.

3 ~~(14)~~(26) "Local anesthesia" – the elimination of sensations, ~~especially including~~ pain, in one part of the body
4 by the regional application or injection of a drug.

5 ~~(15) "May" indicates freedom or liberty to follow a reasonable alternative.~~

6 ~~(16)~~(27) "Minimal conscious sedation" – conscious sedation characterized by a minimally depressed level of
7 consciousness, in which the patient retains the ability to independently and continuously maintain
8 an airway and respond normally to tactile stimulation and verbal command, provided to patients 13
9 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or
10 more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment,
11 possibly in combination with nitrous oxide. Minimal conscious sedation is provided for behavioral
12 management.

13 ~~(17)~~(28) "Minor psychosedative/Minor tranquilizer" – pharmacological agents which allow for uninterrupted
14 interactive ability in a patient with no compromise in the ability to maintain a patent airway
15 continuously and without assistance and carry a margin of safety wide enough to render unintended
16 loss of consciousness unlikely.

17 ~~(18)~~(29) "Moderate conscious sedation" – conscious sedation characterized by a drug induced depression of
18 consciousness, during which patients ~~obey~~ respond purposefully to verbal commands, either alone
19 or accompanied by light tactile stimulation, provided to patients 13 years of age or older, by oral,
20 nasal, ~~rectal~~ rectal, or parenteral routes of administration of ~~single or~~ multiple pharmacological
21 agents, in ~~single or~~ multiple doses, within a 24 hour period, including the time of treatment, possibly
22 in combination with nitrous oxide. Moderate conscious sedation is ~~may be~~ provided for behavior
23 ~~control. control by licensed dentists who comply with the terms of Rule .0301 of this Subchapter. A~~
24 moderate conscious sedation provider shall not use the following:

25 (a) drugs designed by the manufacturer for use in administering general anesthesia or
26 deep sedation; or

27 (b) drugs contraindicated for use in moderate conscious sedation.

28 ~~(19) "Moderate conscious sedation limited to oral routes and nitrous oxide inhalation" – conscious sedation~~
29 ~~characterized by a drug induced depression of consciousness during which patients respond~~
30 ~~purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided~~
31 ~~to patients 13 years or older, by oral routes of administration and nitrous oxide inhalation, of single~~
32 ~~or multiple pharmacological agents, in single or multiple doses, within a 24 hour period. Moderate~~
33 ~~conscious sedation limited to oral routes and nitrous oxide inhalation is provided for behavior~~
34 ~~control.~~

35 ~~(20)~~(30) "Moderate pediatric conscious sedation" - conscious sedation characterized by a drug induced
36 depression of consciousness, during which patients ~~obey~~ respond purposefully to ~~obey~~ verbal
37 commands, either alone or accompanied by light tactile stimulation, provided to patients up to 18

1 under 13 years of age, or special needs patients, by oral, nasal, ~~rectal~~ rectal, or parenteral routes of
2 administration of single or multiple pharmacological agents, in single or multiple doses, within a 24
3 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate
4 pediatric conscious sedation ~~is~~ may be provided for behavior-~~control~~. control by licensed dentists
5 who comply with the terms of Rule .0404 of this Subchapter. A moderate pediatric conscious
6 sedation permit holder shall not use the following:

7 (a) drugs designed by the manufacturer for use in administering general anesthesia or
8 deep sedation; or

9 (b) drugs contraindicated for use in moderate pediatric conscious sedation.

10 ~~(22)~~ (31) "Must" or "shall" indicates an imperative need or duty or both; an essential or indispensable item;
11 mandatory.

12 ~~(23)~~ (31) "Parenteral" - the administration of pharmacological agents intravenously, intraosseously,
13 intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.

14 (32) "PALS" – Pediatric Advanced Life Support.

15 ~~(23)~~ (33) "Protective reflexes" – includes the ability to swallow and cough.

16 (34) "RN" – Registered Nurse licensed by the North Carolina Board of Nursing.

17 (35) "Sedation Procedure" – begins when any pharmacological agent is first administered to a patient to
18 induce general anesthesia or sedation and continues until the dentist permit holder determines that
19 the patient has met the applicable recovery and discharge criteria set forth in the applicable Rules in
20 this Subchapter.

21 (36) "Special needs patients" – patients with diminished mental and or physical capacity who are unable
22 to cooperate to receive ambulatory dental care without sedation or anesthesia.

23 ~~(24)~~ (37) "Supplemental dosing" – the oral administration of a pharmacological agent that results in an
24 enhanced level of conscious sedation when added to the primary sedative agent administered for the
25 purpose of oral moderate conscious sedation, and ~~which~~, when added to the primary agent, does not
26 exceed the maximum safe dose of either agent, separately or synergistically.

27 ~~(25)~~ (38) "Vested adult" – a responsible adult who is the legal parent or guardian, or designee of a legal parent
28 or guardian, entrusted with the care of a ~~minor~~ patient following the administration of general
29 anesthesia or conscious sedation.

30
31 *History Note:* Authority G.S. 90-28; 90-30.1; 90-48;
32 Eff. February 1, 1990;
33 Temporary Amendment Eff. December 11, 2002;
34 Amended Eff. _____; July 3, 2008; August 1, 2004.
35
36

1 21 NCAC 16Q .0201 is proposed for amendment as follows:

2

3 **21 NCAC 16Q .0201 GENERAL ANESTHESIA CREDENTIALS AND PERMIT**

4 ~~(a) No dentist shall employ or use general anesthesia on an outpatient basis for dental patients unless the dentist~~
5 ~~possesses a permit issued by the Board. A dentist holding a permit shall be subject to review and shall only employ or~~
6 ~~use general anesthesia at a facility located in the State of North Carolina in accordance with 21 NCAC 16Q .0202.~~
7 ~~Such permit must be renewed annually and shall be displayed with the current renewal at all times in a conspicuous~~
8 ~~place in the office of the permit holder.~~

9 (a) Before a dentist licensed to practice in North Carolina may administer or supervise a CRNA to administer general
10 anesthesia or perform deep sedation, the dentist shall obtain a general anesthesia permit from the Board by completing
11 an application form and paying a four hundred seventy-five dollar (\$475.00) fee. The application form is available
12 on the Board's website: www.ncdentalboard.org. The permit shall be renewed annually and shall be displayed with
13 the current renewal at all times in the permit holder's facility where it is visible to patients receiving treatment.

14 ~~(b) Any dentist who wishes to administer general anesthesia to patients must apply to the Board for the required~~
15 ~~permit on a prescribed application form, submit an application fee of one hundred dollars (\$100.00) and produce~~
16 ~~evidence showing~~ A dentist applying for a general anesthesia permit shall be in good standing with the Board and
17 demonstrate that he or she:

- 18 (1) Has completed a minimum of ~~one year~~ two years of advanced training in anesthesiology and related
19 academic subjects ~~(or its equivalent)~~ beyond the undergraduate dental school level; or
20 (2) Has graduated from a program certified by the American Dental Association in Oral and
21 Maxillofacial Surgery; or
22 (3) Is a Diplomate of or eligible for examination by the American Board of Oral and Maxillofacial
23 Surgery; or
24 (4) Is a Fellow of the American Dental Society of Anesthesiology; ~~or and~~
25 (5) ~~Is a dentist who has been administering general anesthetics in a competent manner for the five years~~
26 ~~preceding the effective date of this Rule.~~ Has an unexpired ACLS certification.

27 (c) Before receiving a general anesthesia permit, all applicants shall pass an evaluation and inspection as set out in
28 Rule .0202 of this Section. Every location other than a hospital or credentialed surgery center where a general
29 anesthesia permit holder administers general anesthesia shall pass an inspection as set out in Rule .0204 of this Section.

30 ~~(e)(d) A dentist who is qualified to administer general anesthesia in accordance with this Section and holds a general~~
31 ~~anesthesia permit may is also authorized to administer any level of sedation without obtaining a separate sedation~~
32 ~~permit.~~

33 ~~(d) The dentist involved with the administration of general anesthesia shall document current, successful completion~~
34 ~~of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other Board-approved equivalent~~
35 ~~course and auxiliary personnel shall document annual, successful completion of basic life support (BLS) training.~~

1 (e) A dentist who does not hold a general anesthesia permit may not employ a CRNA to administer general anesthesia
2 services. A dentist who holds a general anesthesia permit may permit a CRNA to administer general anesthesia
3 services under ~~direct~~ supervision of the dentist.

4 (f) A general anesthesia permit holder may provide general anesthesia at the office of another licensed dentist,
5 regardless of the permit, if any held, by the hosting dentist. The permit holder shall ensure that the facility where the
6 general anesthesia is administered has been inspected and complies with the requirements set out in Rule .0202 of this
7 Section ~~or~~ and shall obtain an itinerant general anesthesia permit and comply with the provisions of Rule .0206 of
8 this Section.

9

10 *History Note: Authority G.S. 90-28; 90-30.1;*
11 *Eff. February 1, 1990;*
12 *Amended Eff. April 1, 2001; August 1, 2000;*
13 *Temporary Amendment Eff. December 11, 2002;*
14 *Amended Eff. _____; February 5, 2008.*

1 21 NCAC 16Q .0202 is proposed for amendment as follows:

2

3 **21 NCAC 16Q .0202 GENERAL ANESTHESIA EQUIPMENT AND CLINICAL REQUIREMENTS**

4 (a) A dentist administering general anesthesia is ~~solely responsible for providing~~ shall be responsible to ensure that
5 the ~~environment in which~~ facility where the general anesthesia is to be administered meets the following requirements:

6 (1) The facility is ~~shall be equipped with:~~ with the following:

7 (A) ~~An~~ an operatory of size and design to permit access of emergency equipment and personnel
8 and to permit effective emergency management;

9 (B) ~~A chair or table for emergency treatment, including chair suitable for CPR or CPR Board;~~
10 a CPR board or dental chair without enhancements, suitable for providing emergency
11 treatment;

12 (C) ~~Lighting~~ lighting as necessary for specific ~~procedures~~ procedures; ~~and back-up lighting;~~
13 and

14 (D) ~~Suction~~ suction equipment as necessary for specific procedures, including non-electrical
15 back-up suction;

16 (2) ~~—~~ The following equipment is maintained:

17 (A)(E) ~~Positive~~ positive pressure oxygen delivery system, including full face masks for small,
18 medium, and large [adults and pediatric] patients, patients; and back-up E-cylinder portable
19 oxygen tank apart from the central system;

20 (B)(F) ~~Oral~~ small, medium, and large oral and nasal airways of various sizes; ~~airways;~~

21 (C)(G) ~~Blood~~ blood pressure monitoring device;

22 (D)(H) ~~Electrocardiograph;~~ EKG monitor; electrocardiograph;

23 (E)(I) ~~Pulse~~ pulse oximeter; and

24 (F)(J) ~~Defibrillator;~~ defibrillator;

25 (K) precordial stethoscope or capnograph;

26 (L) thermometer;

27 (3) The following emergency equipment is maintained:

28 (A)(M) ~~I.V. set-up~~ vascular access as necessary for specific procedures, including hardware and
29 fluids;

30 (B)(N) ~~Laryngoscope~~ laryngoscope with ~~current~~ working batteries;

31 (C)(O) ~~Intubation~~ intubation forceps and ~~endotracheal tubes;~~ advanced airway devices;

32 (D)(P) ~~Tonsillar~~ tonsillar suction with back-up suction;

33 (E)(Q) ~~Syringes~~ syringes as necessary for specific procedures; and

34 (F)(R) ~~Tourniquet & tape;~~ tourniquet and tape.

35 (G) ~~—~~ Blood pressure monitoring device;

- 1 (4) ~~(2)~~ The following drugs are maintained with a current shelf life and with access from the operatory and
2 recovery room: The following unexpired drugs shall be maintained in the facility and with access
3 from the operatory and recovery rooms:
- 4 (A) ~~Epinephrine; Epinephrine;~~
5 (B) ~~Atropine;~~
6 (C) ~~Lidocaine; antiarrhythmic;~~
7 (D) ~~Antihistamine; antihistamine;~~
8 (E) ~~Antihypertensive; antihypertensive;~~
9 (F) ~~Bronchial dilator; bronchodilator;~~
10 (G) ~~Antihypoglycemic-antihypoglycemic agent;~~
11 (H) ~~Vasopressor; vasopressor;~~
12 (I) ~~Corticosteroid; corticosteroid;~~
13 (J) ~~Anticonvulsant; anticonvulsant;~~
14 (K) ~~Muscle-muscle relaxant;~~
15 (L) ~~Appropriate appropriate reversal agents;~~
16 ~~(M) — Appropriate anti-arrhythmic medication;~~
17 ~~(M) (N) Nitroglycerine; nitroglycerine;~~ and
18 ~~(N) (O) Antiemetic; antiemetic.~~
- 19 ~~(5) (3) Written~~ The permit holder shall maintain written emergency and patient discharge protocols and
20 training to familiarize ~~office personnel auxiliaries~~ in the treatment of clinical emergencies are shall
21 be provided; and
- 22 ~~(6)-(4)~~ The permit holder shall maintain the following records-are maintained: for 10 years:
- 23 (A) Patient's current written medical history, including a record of known allergies and
24 previous ~~surgery; surgeries;~~
25 (B) Consent to general anesthesia, signed by the patient or guardian, identifying the risks and
26 benefits, level of anesthesia, and date signed;
27 (C) Consent to the procedure, signed by the patient or guardian identifying the risks, benefits,
28 and date signed; and
29 (D) ~~(B)~~ Patient Base base line vital signs, including temperature, SPO2, blood pressure pressure,
30 and pulse;
31 ~~(C) — An anesthesia record which shall include:~~
- 32 ~~(i) — Periodic vital signs taken at intervals during the procedure;~~
33 ~~(ii) — Drugs administered during the procedure, including route of administration,~~
34 dosage, time and sequence of administration;
35 ~~(iii) — Duration of the procedure;~~
36 ~~(iv) — Documentation of complications or morbidity; and~~
37 ~~(v) — Status of patient upon discharge.~~

- 1 (5) The anesthesia record shall include:
- 2 (A) base line vital signs, blood pressure (unless patient behavior prevents recording),
- 3 oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the
- 4 patient recorded in real time at 15 minute intervals;
- 5 (B) procedure start and end times;
- 6 (C) gauge of needle and location of IV on the patient, if used;
- 7 (D) status of patient upon discharge; and
- 8 (E) documentation of complications or morbidity.
- 9 (6) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to
- 10 patient monitoring and recording general anesthesia or sedation data throughout the sedation procedure. This
- 11 requirement shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding
- 12 general anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other
- 13 dental procedure.
- 14 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of
- 15 anesthesia while the evaluator observes. ~~During the demonstration, the applicant or permit holder observes,~~
- 16 and shall demonstrate competency in the following areas:
- 17 (1) ~~Monitoring~~ monitoring of blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
- 18 (2) ~~Drug-drug~~ dosage and administration;
- 19 (3) ~~Treatment~~ treatment of untoward reactions including respiratory or cardiac depression;
- 20 (4) ~~Sterilization;~~ sterile technique;
- 21 (5) ~~Use~~ use of CPR BLS certified ~~personnel;~~ auxiliaries;
- 22 (6) ~~Monitoring~~ monitoring of patient during recovery; and
- 23 (7) ~~Sufficiency~~ sufficiency of patient recovery time.
- 24 (c) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to
- 25 ~~the evaluator~~ in the treatment of the following clinical emergencies:
- 26 (1) ~~Laryngospasm;~~ laryngospasm;
- 27 (2) ~~Bronchospasm;~~ bronchospasm;
- 28 (3) ~~Emesis~~ emesis and aspiration;
- 29 (4) ~~Respiratory~~ respiratory depression and arrest;
- 30 (5) ~~Angina~~ angina pectoris;
- 31 (6) ~~Myocardial~~ myocardial infarction;
- 32 (7) ~~Hypertension/Hypotension;~~ hypertension and hypotension;
- 33 (8) ~~Syncope;~~ syncope;
- 34 (9) ~~Allergie~~ allergic reactions;
- 35 (10) ~~Convulsions;~~ convulsions;
- 36 (11) ~~Bradycardia;~~ bradycardia;
- 37 (12) ~~Insulin~~ insulin shock hypoglycemia; and

1 (13) ~~Cardiac cardiac~~ arrest; and

2 (14) ~~airway~~ obstruction.

3 ~~(d) A dentist administering general anesthesia shall ensure that the facility is staffed with auxiliary personnel who~~
4 ~~shall document annual successful completion of basic life support training and be capable of assisting with~~
5 ~~procedures, problems, and emergency incidents that may occur as a result of the general anesthetic or~~
6 ~~secondary to an unexpected medical complication.~~

7 (d) A general anesthesia permit holder shall evaluate a patient for health risks before starting any anesthesia procedure.

8 (e) Post-operative monitoring and discharge shall include the following:

9 (1) vital signs shall be continuously monitored when the sedation is no longer being administered and
10 the patient shall have direct continuous supervision until oxygenation and circulation are stable and
11 the patient is recovered as defined by Subparagraph (e)(2) of this Rule and is ready for discharge
12 from the office; and

13 (2) recovery from general anesthesia shall include documentation of the following:

14 (A) cardiovascular function stable;

15 (B) airway patency uncompromised;

16 (C) patient arousable and protective reflexes intact;

17 (D) state of hydration within normal limits;

18 (E) patient can talk, if applicable;

19 (F) patient can sit unaided, if applicable;

20 (G) patient can ambulate, if applicable, with minimal assistance; and

21 (H) for the special needs patient or a patient incapable of the usually expected responses, the
22 pre-sedation level of responsiveness or the level as close as possible for that patient shall
23 be achieved; and

24 (3) before allowing the patient to leave the office, the dentist shall determine that the patient has met
25 the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:

26 (A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient,
27 stable, and have been documented;

28 (B) explanation and documentation of written postoperative instructions have been provided
29 to the patient or a responsible adult at time of discharge; and

30 (C) vested adult is available to transport the patient after discharge.

31
32 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*

33 *Effective February 1, 1990;*

34 *Amended Eff. _____; November 1, 2013; August 1, 2002; August 1, 2000.*

1 21 NCAC 16Q .0206 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0206 ITINERANT (MOBILE) GENERAL ANESTHESIA PERMIT, EQUIPMENT**
4 **AND EVALUATION**

5 (a) A dentist who holds a general anesthesia permit from the Board and who wishes to provide general anesthesia or
6 other sedation services in the office of another practitioner shall obtain a mobile general anesthesia permit from the
7 Board. The application form may be obtained on the Board's website: www.ncdentalboard.org and shall be
8 accompanied by a one hundred (\$100.00) fee. No mobile permit shall be required to administer general anesthesia
9 in a hospital or credentialed surgery center.

10 (b) Before a mobile general anesthesia permit may be issued, a general anesthesia permit holder appointed by the
11 Board shall inspect the applicant's equipment and medications to ensure that they comply with Paragraphs (c) and (d)
12 of this Rule.

13 (c) The permit holder shall maintain the following equipment:

- 14 (1) positive pressure ventilation system and back-up E cylinder portable oxygen tank;
- 15 (2) standard ASA monitors with back-up power;
- 16 (3) EKG monitor;
- 17 (4) precordial stethoscope or capnograph;
- 18 (5) small, medium, and large oral airways and nasal trumpets;
- 19 (6) small, medium, and large laryngoscope blades and back-up laryngoscope;
- 20 (7) small, medium, and large nasal and oral endotracheal tubes;
- 21 (8) Magill forceps;
- 22 (9) small, medium, and large supraglottic airway devices;
- 23 (10) back-up suction;
- 24 (11) defibrillator with pediatric capability;
- 25 (12) small, medium, and large anesthesia circuits;
- 26 (13) back-up lighting;
- 27 (14) gastric suction device;
- 28 (15) endotracheal tube and pulmonary suction device;
- 29 (16) equipment for performing emergency cricothyrotomies and delivering positive pressure ventilation;
- 30 (17) back-up ventilation measurement;
- 31 (18) rebreathing device;
- 32 (19) scavenging system;
- 33 (20) intermittent compression devices;
- 34 (21) CPR board or dental chair without enhancements suitable for providing emergency treatment;
- 35 (22) laryngoscope with working batteries; and
- 36 (23) tourniquet and tape.

37 (d) The following unexpired medications shall be immediately accessible to the permit holder:

- 1 (1) Epinephrine;
- 2 (2) Atropine;
- 3 (3) antiarrhythmic;
- 4 (4) antihistamine;
- 5 (5) antihypertensive;
- 6 (6) bronchodilator;
- 7 (7) antihypoglycemic agent;
- 8 (8) vasopressor;
- 9 (9) corticosteroid;
- 10 (10) anticonvulsant;
- 11 (11) muscle relaxant;
- 12 (12) appropriate reversal agents;
- 13 (13) nitroglycerine;
- 14 (14) antiemetic;
- 15 (15) neuromuscular blocking agent; and
- 16 (16) anti-malignant hyperthermia agent.

17 (e) The evaluation and on-site inspection shall be conducted as set out in Rule .0204 of this Section.

18 (f) Before administering general anesthesia or sedation at another provider's office, the mobile permit holder shall
19 inspect the host facility to ensure that:

- 20 (1) the operator's size and design permit emergency management and access of emergency equipment
21 and personnel;
- 22 (2) there is a CPR board or dental chair without enhancements suitable for providing emergency
23 treatment;
- 24 (3) there is lighting to permit performance of all procedures planned for the facility;
- 25 (4) there is suction equipment, including non-electrical back-up suction; and
- 26 (5) the facility shall be staffed with at least two BLS certified auxiliaries one of whom shall be dedicated
27 to patient monitoring and recording general anesthesia or sedation data throughout the sedation
28 procedure. This requirement shall not apply if the dentist permit holder is dedicated to patient care
29 and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is
30 not performing the surgery or other dental procedure.

31 (g) At least 24 hours before the procedure is scheduled to begin, the mobile permit holder shall send written notice to
32 the Board office confirming that the facility where the general anesthesia or sedation will be performed meets the
33 requirements of Paragraph (f) of this Rule and documenting when the inspection was conducted. The permit holder
34 shall retain a copy of the written notice for 10 years following the procedure. No procedure shall be performed until
35 the report required by this Paragraph is filed.

36 (h) The mobile general anesthesia permit shall be displayed in the host facility where it is visible to patients receiving
37 treatment.

1 (i) All applicants for mobile general anesthesia permit shall be in good standing with the Board.

2 *History Note: Authority G.S. 90-28; 90-30.1; 90-39; 90-48;*

3 *Eff. _____.*

4

1 21 NCAC 16Q .0207 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0207 ANNUAL RENEWAL OF GENERAL ANESTHESIA AND ITINERANT**
4 **(MOBILE) GENERAL ANESTHESIA PERMIT REQUIRED**

5 (a) General anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by paying
6 a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:
7 www.ncdentalboard.org. If the completed renewal application and renewal fee are not received before January 31 of
8 each year, a one hundred dollar (\$100.00) late fee shall be paid.

9 (b) Itinerant general anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by
10 paying a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:
11 www.ncdentalboard.org. If the completed itinerant general sedation permit and renewal fee are not received before
12 January 31 of each year, a one hundred dollar (\$100.00) late fee shall be paid.

13 (c) Any dentist who fails to renew a general anesthesia permit or itinerant general anesthesia permit before March 31
14 of each year shall complete a reinstatement application, pay the renewal fee, late fee, and comply with all conditions
15 for renewal set out in this Rule. Dentists whose anesthesia permits or itinerant general anesthesia permits have been
16 lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process.

17 (d) A dentist who administers general anesthesia in violation of this Rule shall be subject to the penalties prescribed
18 by Rule .0701 of this Subchapter.

19 (e) As a condition for renewal of the general anesthesia and itinerant general anesthesia permit, the permit holder
20 shall maintain the clinical equipment and requirements set out in Rules .0202 and .0206 of this Section and shall
21 document the following:

22 (1) six hours of continuing education each year in one or more of the following areas, which may be
23 counted toward fulfillment of the continuing education required each calendar year for license
24 renewal:

25 (A) sedation;

26 (B) medical emergencies;

27 (C) monitoring IV sedation and the use of monitoring equipment;

28 (D) pharmacology of drugs and agents used in general anesthesia and IV sedation;

29 (E) physical evaluation, risk assessment, or behavioral management; or

30 (F) airway management;

31 (2) unexpired ACLS certification, which shall not count towards the six hours required in Subparagraph
32 (e)(1) of this Rule;

33 (3) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have
34 practiced responding to dental emergencies as a team at least once every six months in the preceding
35 year;

36 (4) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have read the
37 practice's emergency manual in the preceding year; and

1 (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
2 of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this rule.

3 (f) All permit holders applying for renewal of a general anesthesia or itinerant general anesthesia permit shall be in
4 good standing and their office shall be subject to inspection by the Board.

5 *History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;*

6 *Eff. _____.*

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

1 21 NCAC 16Q .0301 is proposed for amendment as follows:

2

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

7 (a) Before a dentist licensed to practice in North Carolina may administer or supervise a ~~certified registered nurse~~
8 ~~anesthetist (CRNA)~~ CRNA employed to administer or RN employed to deliver moderate conscious sedation,
9 moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes of administration and
10 nitrous oxide to dental patients on an outpatient basis, the dentist shall obtain a permit from the Board by completing
11 an application form ~~provided by the Board~~ and paying a fee of ~~one hundred dollars (\$100.00)~~ three hundred seventy
12 five dollars (\$375.00). The application form is available on the Board's website: www.ncdentalboard.org. ~~Such~~ The
13 permit shall be renewed annually and shall be displayed with the current renewal at all times ~~in a conspicuous place~~
14 ~~in the facility of the permit holder.~~ holder where it is visible to patients receiving treatment.

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

21 (b) The permit holder shall provide direct supervision to any CRNA employed to administer or RN employed to
22 deliver sedation, and shall ensure that the level and duration of the sedation does not exceed the permit holder's permit.

23 (c) A dentist applying for a permit to administer moderate conscious sedation ~~or moderate pediatric conscious sedation~~
24 ~~must meet at least one of the following criteria:~~ shall document the following:

25 (1) Training which may consist of either:
26 (A) Satisfactory completion of a minimum Completion of 60 hours of Board approved didactic
27 training, including PALS (Pediatric Advanced Life Support), and instruction training in intravenous
28 conscious sedation sedation, and satisfactory 30 hours of clinical training, that shall include
29 successful management of a minimum of 10 20 live patients, under supervision, supervision of the
30 course instructor, using intravenous sedation; sedation. Training shall be provided by one or more
31 individuals who meet the American Dental Association Guidelines for Teaching Pain Control and
32 Sedation to Dentists that is hereby incorporated by reference, including subsequent amendments and
33 editions. The guidelines may be found at www.ada.org/coda; or

34 (2) ~~(B) Satisfactory completion~~ Completion of a pre-doctoral dental or postgraduate program which
35 that included intravenous conscious sedation training equivalent to that defined in Subparagraph

36 (c)(1) (a) of this Rule; ~~or~~

37 (2) Unexpired ACLS certification; and

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

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

9 ~~(2) — document, with patient names and dates of completion, at least 100 cases of oral moderate conscious~~
10 ~~sedation procedures successfully completed within one year preceding June 3, 2008; and fulfill all~~
11 ~~the requirements listed in Rule .0401 of this Subchapter for minimal conscious sedation.~~

12 ~~(k) A dentist who is qualified to administer general anesthesia, moderate conscious sedation or moderate pediatric~~
13 ~~conscious sedation and holds a general anesthesia, moderate conscious sedation permit or a moderate pediatric~~
14 ~~conscious sedation permit may administer minimal conscious sedation without obtaining a separate minimal conscious~~
15 ~~sedation permit.~~

16 ~~(l) Any dentist who holds an active parenteral conscious sedation permit as of October 1, 2007 shall be deemed to~~
17 ~~hold an active moderate conscious sedation permit. Such permits shall be subject to the renewal requirements set out~~
18 ~~in Rule .0501 of this Subchapter.~~

19
20 *History Note: Authority G.S. 90-28; 90-30.1; 90-39(12); 90-48;*
21 *Eff. February 1, 1990;*
22 *Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;*
23 *Temporary Amendment Eff. December 11, 2002;*
24 *Amended Eff. _____; July 1, 2010, July 3, 2008; August 1, 2004.*
25
26
27
28
29
30
31
32
33
34
35
36
37

1 21 NCAC 16Q .0302 is proposed for amendment as follows:

2

3 **21 NCAC 16Q .0302 MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION**
4 **CLINICAL REQUIREMENTS AND EQUIPMENT**

5 (a) A dentist administering moderate conscious sedation ~~or moderate pediatric conscious sedation~~ or supervising **any**
6 **CRNA employed to administer or RN employed to deliver** the administration ~~[delivery]~~ of moderate conscious
7 sedation ~~or moderate pediatric conscious sedation~~ by a certified registered nurse anesthetist **[by a CRNA or RN]** shall
8 **be responsible to** ensure that the facility ~~in which~~ where the sedation is ~~to be~~ administered meets the following
9 requirements:

- 10 (1) The facility ~~is~~ shall be equipped ~~with the following:~~ with:
- 11 (A) ~~An~~ an operatory of size and design to permit access of emergency equipment and personnel
12 and to permit effective emergency management;
 - 13 (B) ~~A~~ a CPR ~~Board~~ board or a dental chair without enhancements, suitable for providing
14 emergency treatment;
 - 15 (C) ~~Lighting~~ lighting as necessary for specific ~~procedures;~~ procedures and back-up lighting;
16 and
 - 17 (D) ~~Suction~~ suction equipment as necessary for specific procedures, including non-electrical
18 back-up suction.
- 19 (2) ~~The following equipment is maintained:~~
- 20 (A)~~(E)~~ Positive positive oxygen delivery system, including full face masks for adults and pediatric
21 small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from
22 the central system;
 - 23 ~~(B)~~ (F) small, medium, and large ~~Oral~~ oral and nasal airways of various sizes; airways;
 - 24 ~~(C)~~ (G) Blood blood pressure monitoring device;
 - 25 ~~(D)~~ (H) Pulse pulse oximeter; ~~and~~
 - 26 ~~(E)~~ (I) Automatic External Defibrillator (AED); automatic external defibrillator (AED);
 - 27 (J) EKG monitor;
 - 28 (K) precordial stethoscope or capnograph;
 - 29 (L) thermometer;
- 30 (3) ~~The following emergency equipment is maintained:~~
- 31 (A)~~(M)~~ I.V. vascular access set-up as necessary for specific procedures, including hardware and
32 fluids; if anesthesia is intravenous; fluids;
 - 33 ~~(B)~~ (N) Syringes syringes as necessary for specific procedures; ~~and~~
 - 34 ~~(C)~~ (O) tourniquet Tourniquet and ~~tape;~~ tape;
 - 35 (P) advanced airway devices; and
 - 36 (Q) tonsillar suction with back-up suction.

1 ~~(4)(2) The following drugs are maintained with a current shelf life and with access from the operatory and~~
2 ~~recovery area: The following unexpired drugs shall be maintained in the facility and with access~~
3 ~~from the operatory and recovery rooms:~~

- 4 (A) ~~Epinephrine; injectable epinephrine;~~
- 5 (B) ~~Atropine; injectable Atropine;~~
- 6 (C) ~~Appropriate injectable appropriate reversal agents;~~
- 7 (D) ~~Antihistamine; injectable antihistamine;~~
- 8 (E) ~~Corticosteroid; injectable corticosteroid;~~
- 9 (F) ~~Nitroglycerine; nitroglycerine;~~
- 10 (G) ~~Bronchial dilator; bronchodilator;~~
- 11 (H) ~~Antiemetic; and injectable antiemetic;~~
- 12 (I) ~~injectable 50% Dextrose Dextrose; and~~
- 13 (J) ~~injectable anti-arrhythmic.~~

14 ~~(5)(3) Written~~ The permit holder shall maintain written emergency and patient discharge protocols are
15 ~~maintained and training to familiarize office personnel auxiliaries in the treatment of clinical~~
16 ~~emergencies is shall be provided; and~~

17 ~~(6)(4) The dentist shall maintain the following records are maintained for at least 10 years:~~

- 18 (A) ~~Patient's current written medical history, history and pre-operative assessment; and~~
19 ~~including known allergies and previous surgery;~~
- 20 (B) ~~Drugs administered during the procedure, including route of administration, dosage,~~
21 ~~strength, time and sequence of administration; administration.~~
- 22 (C) ~~A sedation record which shall include:~~
 - 23 (i) ~~blood pressure;~~
 - 24 (ii) ~~pulse rate;~~
 - 25 (iii) ~~respiration;~~
 - 26 (iv) ~~duration of procedure;~~
 - 27 (v) ~~documentation of complications or morbidity; and~~
 - 28 (vi) ~~status of patient upon discharge.~~

29 ~~(5)~~ The sedation record shall include:

- 30 (A) ~~base line vital signs, blood pressure (unless patient behavior prevents recording),~~
31 ~~oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the~~
32 ~~patient recorded in real time at 15 minute intervals;~~
- 33 (B) ~~procedure start and end times;~~
- 34 (C) ~~gauge of needle and location of IV on the patient, if used;~~
- 35 (D) ~~status of patient upon discharge;~~
- 36 (E) ~~documentation of complications or morbidity; and~~

- 1 (F) consent form, signed by the patient or guardian, identifying the procedure, risks and
2 benefits, level of sedation, and date signed.
- 3 (6) The following conditions shall be satisfied during a sedation procedure:
- 4 (A) The facility shall be staffed with at least two BLS certified auxiliaries one of whom shall
5 be dedicated to patient monitoring and recording sedation data throughout the sedation
6 procedure. This requirement shall not apply if the dentist permit holder is dedicated to
7 patient care and monitoring regarding general anesthesia or sedation throughout the
8 sedation procedure and is not performing the surgery or other dental procedure.
- 9 (B) If IV sedation is used, IV infusion shall be administered before the
10 start of the procedure and maintained until the patient is ready for discharge.
- 11 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate
12 conscious sedation on a patient, ~~or where applicable, moderate pediatric conscious sedation on a patient,~~ including the
13 deployment of an intravenous delivery system, while the evaluator observes. ~~Practices limited to pediatric dentistry~~
14 ~~will not be required to demonstrate the deployment of an intravenous delivery system. Instead, they will orally~~
15 ~~describe to the evaluator the technique of their training in intravenous and intraosseous deployment.~~ During the
16 demonstration, the applicant or permit holder shall demonstrate competency in the following areas:
- 17 (1) ~~Monitoring~~ monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
18 (2) ~~Drug-drug~~ dosage and administration;
19 (3) ~~Treatment~~ treatment of untoward reactions including respiratory or cardiac depression if applicable;
20 (4) ~~Sterile-sterile~~ technique;
21 (5) ~~Use of~~ CPR BLS certified personnel; auxiliaries;
22 (6) ~~Monitoring~~ monitoring of patient during recovery; and
23 (7) ~~Sufficiency~~ sufficiency of patient recovery time.
- 24 (c) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to the
25 evaluator in the treatment of the following clinical emergencies:
- 26 (1) ~~Laryngospasm;~~ laryngospasm;
27 (2) ~~Bronchospasm;~~ bronchospasm;
28 (3) ~~Emesis~~ emesis and aspiration;
29 (4) ~~Respiratory~~ respiratory depression and arrest;
30 (5) ~~Angina~~ angina pectoris;
31 (6) ~~Myocardial-myocardial~~ infarction;
32 (7) ~~Hypertension/Hypotension;~~ hypertension and hypotension;
33 (8) ~~Allergie~~ allergic reactions;
34 (9) ~~Convulsions;~~ convulsions;
35 (10) ~~Syneope;~~ syncope;
36
37 (11) ~~Bradycardia;~~ bradycardia
38 (12) ~~Insulin~~ [insulin] shock hypoglycemia; and

1 (13) Cardiac arrest, cardiac arrest; and

2 (14) airway obstruction.

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

7 (d) A moderate conscious sedation permit holder shall evaluate a patient for health risks before starting any sedation
8 procedure as follows:

9 (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's
10 current medical history and medication use or;

11 (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation
12 with the patient's primary care physician or consulting medical specialist regarding the potential
13 risks posed by the procedure.

14 (e) Post-operative monitoring and discharge:

15 (1) vital signs shall be continuously monitored when the sedation is no longer being administered and
16 the patient shall have direct continuous supervision until oxygenation and circulation are stable and
17 the patient is recovered as defined in Subparagraph (e)(2) of this Rule and is ready for discharge
18 from the office.

19 (2) recovery from moderate conscious sedation shall include documentation of the following:

20 (A) cardiovascular function stable;

21 (B) airway patency uncompromised;

22 (C) patient arousable and protective reflexes intact;

23 (D) state of hydration within normal limits;

24 (E) patient can talk, if applicable;

25 (F) patient can sit unaided, if applicable;

26 (G) patient can ambulate, if applicable, with minimal assistance; and

27 (H) for special needs patients or patients incapable of the usually expected responses, the pre-
28 sedation level of responsiveness or the level as close as possible for that patient shall be
29 achieved.

30 (3) before allowing the patient to leave the office, the dentist shall determine that the patient has met
31 the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:

32 (A) oxygenation, circulation, activity, skin color, and level of consciousness are stable, and
33 have been documented;

34 (B) explanation and documentation of written postoperative instructions have been provided
35 to the patient or a responsible adult at time of discharge; and

36 (C) a vested adult is available to transport the patient after discharge.

37

1 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
2 *Eff. February 1, 1990;*
3 *Amended Eff. August 1, 2002; August 1, 2000;*
4 *Temporary Amendment Eff. December 11, 2002;*
5 *Amended Eff. _____; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004.*
6

1 21 NCAC 16Q .0304 is proposed for amendment as follows:

2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29

21 NCAC 16Q .0304 OFF SITE USE OF MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION PERMITS

(a) ~~Upon request, the~~ The holder of a moderate pediatric conscious sedation or moderate conscious sedation permit may travel to the office of a licensed dentist who does not hold such a permit and provide moderate conscious sedation services at the level for which the traveling dentist holds a valid permit, as well as minimal sedation or moderate conscious sedation limited to oral routes for the patients of that dentist who are undergoing dental procedures. The permit holder is solely responsible for providing shall be responsible to ensure that the facility in which where the sedation is administered meets the requirements established by the Board, that the required drugs and equipment are present, and that the permit holder shall be responsible to ensure that utilizes sufficient auxiliary personnel for each procedure performed based on the standard of care who shall document annual successful completion of basic life support training two BLS certified auxiliaries are available for each procedure. and be capable of assisting with procedures, problems, and emergency incidents that may occur as a result of the sedation or secondary to an unexpected medical complication. has passed inspection by the Board and meets the requirements set out in Rule .0302 of this Section. The permit holder shall be responsible to ensure that the facility is staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation data throughout the sedation procedure. This requirement shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other dental procedure.

(b) ~~Holders of moderate conscious sedation permits limited to oral routes and nitrous oxide inhalation may not provide sedation at the office of a licensed dentist who does not hold an appropriate sedation permit.~~

*History Note: Authority G.S. 90-28; 90-30; 90-30.1; 90-48;
Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013.
Amended Eff. _____.*

1 21 NCAC 16Q .0305 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0305 ANNUAL RENEWAL OF MODERATE PARENTERAL AND ENTERAL**
4 **CONSCIOUS SEDATION PERMIT REQUIRED**

5 (a) Moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses
6 by paying a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:
7 www.ncdentalboard.org.

8 (b) If the completed permit renewal application and renewal fee are not received before January 31 of each year, a
9 one hundred dollar (\$100.00) late fee shall be paid.

10 (c) Any dentist who fails to renew a moderate conscious sedation permit before March 31 of each year shall
11 complete a reinstatement application, pay the renewal fee, late fee, and comply with all conditions for renewal set
12 out in this Rule. Dentists whose sedation permits have been lapsed for more than 12 calendar months shall pass an
13 inspection and an evaluation as part of the reinstatement process.

14 (d) A dentist who administers moderate conscious sedation in violation of this Rule shall be subject to the penalties
15 prescribed by Rule .0701 of this Subchapter.

16 (e) As a condition for renewal of the moderate conscious sedation permit, the permit holder shall meet the clinical
17 and equipment requirements of Rule .0302 of this Section and shall document the following:

18 (1) six hours of continuing education each year in one or more of the following areas, which may be
19 counted toward fulfillment of the continuing education required each calendar year for license
20 renewal:

21 (A) sedation;

22 (B) medical emergencies;

23 (C) monitoring IV sedation and the use of monitoring equipment;

24 (D) pharmacology of drugs and agents used in IV sedation;

25 (E) physical evaluation, risk assessment, or behavioral management; or

26 (F) airway management;

27 (2) unexpired ACLS certification, which shall not count towards the six hours of continuing education
28 required in Subparagraph (e)(1) Rule;

29 (3) that the permit holder and all auxiliaries involved in sedation procedures have practiced
30 responding to dental emergencies as a team at least once every six months in the preceding year;

31 (4) that the permit holder and all auxiliaries involved in sedation procedures have read the practice's
32 emergency manual in the preceding year; and

33 (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three
34 hours of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this
35 rule.

36 (f) ~~All Permit~~ permit holders applying for renewal of a moderate conscious sedation permit shall be in good standing
37 and their office shall be subject to inspection by the Board.

1
2
3

History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
Eff. _____.

1 21 NCAC 16Q .0404 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0404 CREDENTIALS AND PERMITS FOR MODERATE PEDIATRIC CONSCIOUS**
4 **SEDATION**

5 (a) Before a dentist licensed to practice in North Carolina may administer moderate pediatric conscious sedation, the
6 dentist shall obtain a general anesthesia or moderate pediatric conscious sedation permit from the Board by completing
7 an application form and paying a fee of three hundred seventy-five dollars (\$375.00). The application form is available
8 on the Board's website: www.ncdentalboard.org. The permit shall be renewed annually and shall be displayed with
9 the unexpired renewal at all times in the permit holder's facility where it is visible to patients receiving treatment.

10 (b) A dentist applying for a permit to administer moderate pediatric conscious sedation shall meet at least one of the
11 following criteria:

12 (1) completion of a postgraduate program that included pediatric intravenous conscious sedation
13 training;

14 (2) completion of a ~~Council~~ Commission On Dental Accreditation (CODA) approved pediatric
15 residency that included intravenous conscious sedation training; or

16 (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that includes
17 training in the use and placement of IVs or intraosseous vascular access. A list of CODA approved
18 institutions that is hereby incorporated by reference, including subsequent amendments and editions,
19 appears at www.ada.org/coda and is available at no cost.

20 (c) All applicants for moderate pediatric conscious sedation permits shall have completed the training required by
21 Paragraph (b) of this Rule within the last two years or show evidence of moderate pediatric conscious sedation practice
22 within the last two years in another state or U.S. Territory.

23 (d) All applicants for moderate pediatric conscious sedation permits shall be in good standing with the Board.

24

25

26 *History Note: Authority G.S. 90-30.1; 90-39(12); 90-48;*

27 *Eff. _____.*

1 21 NCAC 16Q .0405 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0405 MODERATE PEDIATRIC CONSCIOUS SEDATION CLINICAL**
4 **REQUIREMENTS AND EQUIPMENT**

5 (a) A dentist administering moderate pediatric conscious sedation shall be responsible to ensure that the facility where
6 the sedation is administered meets the following requirements:

7 (1) The facility shall be equipped with the following:

8 (A) an operatory of size and design to permit access of emergency equipment and personnel
9 and to permit emergency management;

10 (B) a CPR board or a dental chair without enhancements, suitable for providing emergency
11 treatment;

12 (C) lighting as necessary for specific procedures and back-up lighting;

13 (D) suction equipment as necessary for specific procedures, including non-electrical back-up
14 suction;

15 (E) positive oxygen delivery system, including full face masks for small, medium, and large
16 and back-up E-cylinder portable oxygen tank apart from the central system;

17 (F) oral and nasal airways of various sizes;

18 (G) blood pressure monitoring device;

19 (H) pulse oximeter;

20 (I) precordial stethoscope or capnograph;

21 (J) defibrillator;

22 (K) EKG monitor;

23 (L) thermometer;

24 (M) vascular access set-up as necessary for specific procedures, including hardware and fluids;

25 (N) syringes as necessary for specific procedures;

26 (O) advanced-airways; and

27 (P) tourniquet and tape.

28 (2) The following unexpired drugs shall be maintained in the facility and with access from the operatory
29 and recovery rooms:

30 (A) epinephrine;

31 (B) Atropine;

32 (C) appropriate reversal agents;

33 (D) antihistamine;

34 (E) corticosteroid;

35 (F) nitroglycerine;

36 (G) bronchodilator;

37 (H) antiemetic; and

- 1 (I) Dextrose.
- 2 (3) The permit holder shall maintain written emergency and patient discharge protocols and training to
3 familiarize auxiliaries in the treatment of clinical emergencies is shall be provided;
- 4 (4) The following records are maintained for at least 10 years:
- 5 (A) patient's current written medical history and pre-operative assessment;
- 6 (B) drugs administered during the procedure, including route of administration, dosage,
7 strength, time and sequence of administration;
- 8 (C) a sedation record;
- 9 (D) a consent form, signed by the patient or a guardian, identifying the procedure,
10 risks and benefits, level of sedation and date signed.
- 11 (5) The sedation record shall include:
- 12 (A) base line vital signs, blood pressure (unless patient behavior prevents recording); oxygen
13 saturation, ET CO₂ if capnography is utilized, pulse and respiration rates of the patient
14 recorded in real time at 15 minute intervals;
- 15 (B) procedure start and end times;
- 16 (C) gauge of needle and location of IV on the patient, if used;
- 17 (D) status of patient upon discharge; and
- 18 (E) documentation of complications or morbidity; and
- 19 (6) The following conditions shall be satisfied during a sedation procedure:
- 20 (A) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall
21 be dedicated to patient monitoring and recording sedation data throughout the sedation
22 procedure. This requirement shall not apply if the dentist permit holder is dedicated to
23 patient care and monitoring regarding general anesthesia or sedation throughout the
24 sedation procedure and is not performing the surgery or other dental procedure; and
- 25 (B) when IV sedation is used, IV infusion shall be administered before the commencement of
26 the procedure and maintained until the patient is ready for discharge.
- 27 (b) During an inspection or evaluation, applicants and permit holders who use intravenous sedation shall demonstrate
28 the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an
29 intravenous delivery system, while the evaluator observes. Applicants and permit holders who do not use IV sedation
30 shall describe the proper deployment of an intravenous delivery system to the evaluator and shall demonstrate the
31 administration of moderate pediatric conscious sedation on a live patient while the evaluator observes.
- 32 (c) During the demonstration, all applicants and permit holders shall demonstrate competency in the following areas:
- 33 (1) monitoring blood pressure, pulse, and respiration;
- 34 (2) drug dosage and administration;
- 35 (3) treatment of untoward reactions including respiratory or cardiac depression if applicable;
- 36 (4) sterile technique;
- 37 (5) use of BLS certified auxiliaries;

- 1 (6) monitoring of patient during recovery; and
2 (7) sufficiency of patient recovery time.
- 3 (d) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the
4 treatment of the following clinical emergencies:
- 5 (1) laryngospasm;
6 (2) bronchospasm;
7 (3) emesis and aspiration;
8 (4) respiratory depression and arrest;
9 (5) angina pectoris;
10 (6) myocardial infarction;
11 (7) hypertension and hypotension;
12 (8) allergic reactions;
13 (9) convulsions;
14 (10) syncope;
15 (11) bradycardia;
16 (12) ~~insulin shock~~ hypoglycemia;
17 (13) cardiac arrest;
18 (14) airway obstruction; and
19 (15) vascular access.
- 20 (e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any
21 sedation procedure as follows:
- 22 (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's
23 current medical history and medication use; or
24 (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation
25 with the patient's primary care physician or consulting medical specialist regarding the potential
26 risks posed by the procedure.
- 27 (f) Patient monitoring:
- 28 (1) Patients who have been administered moderate pediatric conscious sedation shall be monitored for
29 alertness, responsiveness, breathing, and skin coloration during waiting periods before operative
30 procedures.
31 (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and
32 the patient shall have direct continuous supervision until oxygenation and circulation are stable and
33 the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge
34 from the office.
35 (3) Recovery from moderate pediatric conscious sedation shall include documentation of the following:
36 (A) cardiovascular function stable;
37 (B) airway patency uncompromised;

- 1 (C) patient arousable and protective reflexes intact;
- 2 (D) state of hydration within normal limits;
- 3 (E) patient can talk, if applicable;
- 4 (F) patient can sit unaided, if applicable;
- 5 (G) patient can ambulate, if applicable, with minimal assistance; and
- 6 (H) for the special needs patient or a patient incapable of the usually expected responses, the
- 7 pre-sedation level of responsiveness or the level as close as possible for that patient shall
- 8 be achieved.

9 (4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met
10 the recovery criteria set out in Subparagraph (f)(3) of this Rule and the following discharge criteria:

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

19
20 *History Note:* Authority G.S. 90-28; 90-30.1; 90-48;
21 Eff. _____.

22

1 21 NCAC 16Q .0406 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0406 OFF SITE USE OF MODERATE PEDIATRIC CONSCIOUS SEDATION**
4 **PERMITS**

5 The holder of a moderate pediatric conscious sedation permit may travel to the office of a licensed dentist and provide
6 moderate pediatric conscious sedation. The permit holder shall be responsible to ensure that the facility where the
7 sedation is administered has been inspected by the Board as required by Rule .0404 of this Section, and that the
8 equipment, facility, and auxiliaries meet the requirements of Rule .0405 of this Section.

9

10 *History Note:* Authority G.S. 90-28; 90-30.1; 90-48;

11 *Eff.* _____.

1 21 NCAC 16Q .0407 is proposed for adoption as follows:

2

3 **21 NCAC 16Q .0407 ANNUAL RENEWAL OF MODERATE PEDIATRIC CONSCIOUS SEDATION**
4 **PERMIT REQUIRED**

5 (a) Moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as dental
6 licenses by paying a one hundred (\$100.00) fee and completing an application available from the Board's website:
7 www.ncdentalboard.org.

8 (b) If the completed renewal application and renewal fee are not received before January 31 of each year, a one hundred
9 (\$100.00) late fee shall be paid.

10 (c) Any dentist who fails to renew a moderate pediatric conscious sedation permit before March 31 of each year shall
11 complete a reinstatement application, pay the renewal fee, late fee, and comply with all conditions for renewal set out
12 in this Rule. Dentists whose sedation permits have been lapsed for more than 12 calendar months shall pass an
13 inspection and an evaluation as part of the reinstatement process.

14 (d) A dentist who administers moderate pediatric conscious sedation in violation of this Rule shall be subject to the
15 penalties prescribed by Rule .0701 of this Subchapter.

16 (e) As a condition for renewal of the moderate pediatric conscious sedation permit, the permit holder shall meet the
17 clinical and equipment requirements of Rule .0405 of this Section and shall document the following:

18 (1) six hours of continuing education each year in one or more of the following areas, which may be
19 counted toward fulfillment of the continuing education required each calendar year for license
20 renewal:

21 (A) sedation;

22 (B) medical emergencies;

23 (C) monitoring IV sedation and the use of monitoring equipment;

24 (D) pharmacology of drugs and agents used in IV sedation;

25 (E) physical evaluation, risk assessment, or behavioral management; or

26 (F) airway management;

27 (2) unexpired PALS certification which shall not count towards the six hours of continuing education
28 required in Subparagraph (e)(1) of this rule;

29 (3) that the permit holder and all auxiliaries involved in sedation procedures have practiced responding
30 to dental emergencies as a team at least once every six months in the preceding year.

31 (4) that the permit holder and all auxiliaries involved in sedation procedures have read the practice's
32 emergency manual in the preceding year; and

33 (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
34 of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this rule.

35 (f) All permit holders applying for renewal of a moderate pediatric conscious sedation permit shall be in good standing
36 and their office shall be subject to inspection by the Board.

37

1 *History Note:* *Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;*
2 *Eff. _____.*
3