

21 NCAC 16Q .0101 is amended with changes as published in 31:14 NCR 1389-92 as follows:

21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS

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

- (1) "Analgesia" – the diminution or elimination of pain.
- (2) "Anti-anxiety sedative" – a sedative agent administered in a dosage intended to reduce anxiety without diminishing consciousness or protective reflexes.
- (3) "Anxiolysis" – pharmacological reduction of anxiety through the administration of a single dose of a minor psychosedative, possibly in combination with nitrous oxide, to children or adults prior to commencement of treatment on the day of the appointment ~~which that~~ allows for uninterrupted interactive ability in ~~a totally an~~ awake patient with no compromise in the ability to maintain a patent airway independently and continuously ~~and without assistance~~. Nitrous oxide may be administered in addition to the minor psychosedative without constituting multiple dosing for purpose of these Rules.
- (4) "ACLS" – Advanced Cardiac Life Support.
- (5) "Administer" – to direct, manage, supervise, control, and have charge of all aspects of selection, dosage, timing, and method of delivery to the patient of any pharmacologic agent intended to reduce anxiety or depress consciousness.
- (6) "ASA" – American Society of Anesthesiologists.
- (7) "Auxiliaries" – non-dentist staff members involved in general anesthesia or sedation procedures.
- (8) "BLS" – Basic Life Support.
- ~~(4)(9)~~ (9) "Behavior control" – the use of pharmacological techniques to control behavior to a level that dental treatment ~~can may~~ be performed without injury to the patient or dentist, effectively and efficiently.
- ~~(5)(10)~~ (10) "Behavioral management" – the use of pharmacological or psychological techniques, singly or in combination, to modify behavior to a level that dental treatment ~~can may~~ be performed effectively and efficiently, without injury to the patient or dentist.
- ~~(6)(11)~~ (11) "Competent" – displaying special skill or knowledge derived from training and experience.
- ~~(7)(12)~~ (12) "Conscious sedation" - an induced state of a depressed level of consciousness that retains the patient's ability to ~~independently and continuously~~ maintain an airway without assistance and respond ~~appropriately~~ to physical stimulation and ~~obey~~ verbal ~~command,~~ commands, and that is produced by pharmacologic or non-pharmacologic agents, or a combination thereof. ~~In accordance with this particular definition, the drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of consciousness unlikely.~~ All dentists who perform conscious sedation shall have an unexpired sedation permit from the Dental Board.
- (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~~ 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 may be provided for
12 behavioral management.

13 ~~(17)(28)~~ "Minor psychosedative/Minor tranquilizer" – pharmacological agents which that allow for
14 uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent
15 airway continuously and without assistance and carry a margin of safety wide enough to render
16 unintended 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 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 ~~(21)~~ “Must” or “shall” indicates an imperative need or duty or both; an essential or indispensable item;
11 mandatory.

12 ~~(22)~~(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” – **process** begins when any pharmacological agent is first administered to a
18 patient to induce general anesthesia or sedation and continues until the dentist permit holder
19 determines that the patient has met the **[applicable]** recovery and discharge criteria set forth in the
20 applicable Rules in 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. **June 1, 2017**; July 3, 2008; August 1, 2004.

1 21 NCAC 16Q .0201 is amended with changes as published in 31:14 NCR 1392 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], the application requirements of this Rule and paying a four hundred seventy-five dollar (\$475.00)
12 fee that includes the one-hundred dollar (\$100.00) application fee and the three-hundred seventy-five dollar (\$375.00)
13 inspection fee. [The application form is available on the Board's website: www.ncdentalboard.org.] The permit shall
14 be renewed annually and shall be displayed with the current renewal at all times in the permit holder's facility where
15 it is visible to patients receiving treatment.

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

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

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

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

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

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

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

12
13 *History Note: Authority G.S. 90-28; 90-30.1; 90-39*
14 *Eff. February 1, 1990;*
15 *Amended Eff. April 1, 2001; August 1, 2000;*
16 *Temporary Amendment Eff. December 11, 2002;*
17 *Amended Eff. June 1, 2017; February 5, 2008.*

21 NCAC 16Q .0202 is amended with changes as published in 31:14 NCR 1392-94 as follows:

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

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

- (1) The facility ~~is~~ shall be equipped ~~with:~~ with the following:
 - (A) ~~An~~ an operatory of size and design to permit access of emergency equipment and personnel and to permit ~~effective~~ emergency management;
 - (B) ~~A chair or table for emergency treatment, including chair suitable for CPR or CPR Board;~~ a CPR board or dental chair without enhancements, suitable for providing emergency treatment;
 - (C) ~~Lighting~~ lighting as necessary for specific ~~procedures~~ procedures; ~~and back-up lighting;~~ and
 - (D) ~~Suction~~ suction equipment as necessary for specific procedures, including non-electrical back-up suction;

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

- ~~(A)~~(E) Positive ~~positive~~ pressure oxygen delivery system, including full face masks for small, medium, and large ~~[adults and pediatric] patients, patients;~~ and back-up E-cylinder portable oxygen tank apart from the central system;
- ~~(B)~~(F) Oral ~~small, medium, and large oral and nasal airways of various sizes;~~ airways;
- ~~(C)~~(G) Blood ~~blood~~ pressure monitoring device;
- ~~(D)~~(H) Electrocardiograph; ~~EKG monitor; electrocardiograph;~~
- ~~(E)~~(I) Pulse ~~pulse~~ oximeter; ~~and~~
- ~~(F)~~(J) Defibrillator; ~~defibrillator;~~
- (K) precordial stethoscope or capnograph;
- (L) thermometer;

~~(3) The following emergency equipment is maintained:~~

- ~~(A)~~(M) I.V. set up ~~vascular access~~ as necessary for specific procedures, including hardware and fluids;
- ~~(B)~~(N) Laryngoscope ~~laryngoscope~~ with ~~current~~ working batteries;
- ~~(C)~~(O) Intubation ~~intubation~~ forceps and ~~endotracheal tubes;~~ advanced airway devices;
- ~~(D)~~(P) Tonsillar ~~tonsillar~~ suction with back-up suction;
- ~~(E)~~(Q) Syringes ~~syringes~~ as necessary for specific procedures; ~~and~~
- ~~(F)~~(R) Tourniquet & tape; ~~tourniquet and tape.~~
- ~~(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;] morbidity; and

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] Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and
12 monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not performing
13 the surgery or other 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) ~~Allergic~~ 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. June 1, 2017; November 1, 2013; August 1, 2002; August 1, 2000.*

1 21 NCAC 16Q .0206 is adopted with changes as published in 31:14 NCR 1394-95 as follows:

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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. Board by completing the application requirements of this Rule and paying~~ ~~The application form may be~~
8 ~~obtained on the Board's website: www.ncdentalboard.org and shall be accompanied by~~ a one hundred (\$100.00)
9 application fee. No mobile permit shall be required to administer general anesthesia in a hospital or credentialed
10 surgery center.

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

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

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

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

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

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

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

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

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

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

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

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

5 *Eff. June 1, 2017.*

1 21 NCAC 16Q .0207 is adopted with changes as published in 31:14 NCR 1395-96 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 the application requirements of this Rule. ~~an application available~~
7 ~~from the Board's website: www.ncdentalboard.org.~~ If the completed renewal application and renewal fee are not
8 received before January 31 of 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. June 1, 2017.*

1 21 NCAC 16Q .0301 is amended with changes as published in 31:14 NCR 1396-97 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 the~~ application requirements in this Rule form provided by the Board and paying a fee of ~~one hundred dollars~~
12 ~~(\$100.00)-three hundred seventy five dollars (\$375.00) fee~~ that includes the one-hundred dollar (\$100.00) application
13 fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. [The application form is available on the
14 Board's website: www.ncdentalboard.org.] ~~Such~~ The permit shall be renewed annually and shall be displayed with
15 the current renewal at all times ~~in a conspicuous place in the facility of the permit holder-~~holder where it is visible to
16 patients receiving treatment.

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

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

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

27 (1) Training which may consist of either:

28 (A) Satisfactory completion of a minimum Completion of 60 hours of Board approved didactic
29 training, including PALS (Pediatric Advanced Life Support), and instruction training in intravenous
30 conscious sedation sedation, and satisfactory 30 hours of clinical training [training,] that shall
31 include successful management of a minimum of 40 20 live patients, under [supervision,]
32 supervision of the course instructor, using intravenous sedation; sedation. Training shall be provided
33 by one or more individuals who meet the American Dental Association Guidelines for Teaching
34 Pain Control and Sedation to Dentists that is hereby incorporated by reference, including subsequent
35 amendments and editions. The guidelines may be found at www.ada.org/coda; or

1 ~~(2)(B)~~ Satisfactory completion Completion of a pre-doctoral dental or postgraduate program ~~which~~
2 ~~that~~ included intravenous conscious sedation training equivalent to that defined in Subparagraph
3 (c)(1)(~~a~~)(A) of this Rule; ~~or~~

4 (2) Unexpired ACLS certification; and

5 (3) That all auxiliaries involved in sedation procedures have unexpired BLS certification.

6 ~~(3) Satisfactory completion of an internship or residency which included intravenous conscious~~
7 ~~sedation training equivalent to that defined in Subparagraph (c)(1) of this Rule.~~

8 ~~(d) Notwithstanding the foregoing, a dentist may also qualify for a permit to administer moderate pediatric conscious~~
9 ~~sedation by documenting, with patient names and dates of completion, at least 100 cases of moderate pediatric sedation~~
10 ~~procedures successfully completed between July 3, 2006 and July 3, 2009. A dentist who obtains a pediatric conscious~~
11 ~~sedation permit pursuant to this Paragraph may not administer sedation intravenously and such limitation shall be~~
12 ~~noted on the dentist's permit.~~

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

18 ~~(f) To be eligible for a moderate conscious sedation permit, moderate conscious sedation limited to oral routes and~~
19 ~~nitrous oxide inhalation permit or moderate pediatric conscious sedation permit, a dentist must operate within a facility~~
20 ~~which includes the capability of delivering positive pressure oxygen, and is staffed with supervised auxiliary personnel~~
21 ~~for each procedure performed. The dentist shall ensure that auxiliary personnel document annual, successful~~
22 ~~completion of basic life support (BLS) training and are capable of assisting with procedures, problems and~~
23 ~~emergencies incident thereto.~~

24 (d) All applicants for a moderate conscious sedation permit shall be in good standing with the Board.

25 ~~(e)(g)~~ Prior to issuance of a moderate conscious sedation permit, moderate conscious pediatric sedation permit or
26 moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation permit, the applicant shall
27 undergo pass an evaluation which includes and a facility inspection. The Board shall direct an evaluator to perform
28 this evaluation. The applicant shall be notified in writing that an evaluation and facility inspection is required and
29 provided with the name of the evaluator who shall perform the evaluation and facility inspection. The applicant shall
30 be responsible for successful completion of passing the evaluation and inspection of his or her facility within three
31 months-90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or
32 applicant requests ~~one~~ one by contacting the Board in writing.

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

1 ~~(f)~~ A dentist who holds a moderate conscious sedation, sedation moderate conscious sedation limited to oral routes
2 ~~and nitrous oxide inhalation or moderate pediatric conscious sedation~~ permit shall not intentionally administer deep
3 ~~sedation sedation, although deep sedation may occur briefly and unintentionally.~~

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

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

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

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

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

22
23 *History Note: Authority G.S. ~~90-28; 90-30.1; 90-39~~(12); 90-48;*
24 *Eff. February 1, 1990;*
25 *Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;*
26 *Temporary Amendment Eff. December 11, 2002;*
27 *Amended Eff. June 1, 2017; July 1, 2010, July 3, 2008; August 1, 2004.*

21 NCAC 16Q .0302 is amended with changes as published in 31:14 NCR 1397-99 as follows:

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

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

- (1) The facility ~~is~~ shall be equipped with the following: ~~with:~~
 - (A) ~~An~~ an operatory of size and design to permit access of emergency equipment and personnel and to permit ~~effective~~ emergency management;
 - (B) ~~A~~ a CPR ~~Board~~ board or a dental chair without enhancements, suitable for providing emergency treatment;
 - (C) ~~Lighting~~ lighting as necessary for specific ~~procedures;~~ procedures and back-up lighting; and
 - (D) ~~Suction~~ suction equipment as necessary for specific procedures, including non-electrical back-up suction.
- ~~(2) The following equipment is maintained:~~
 - ~~(A)~~ (E) Positive positive oxygen delivery system, including full face masks for ~~adults and pediatric~~ small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from the central system;
 - ~~(B)~~ (F) small, medium, and large ~~Oral~~ oral and nasal ~~airways of various sizes;~~ airways;
 - ~~(C)~~ (G) ~~Blood~~ blood pressure monitoring device;
 - ~~(D)~~ (H) ~~Pulse~~ pulse oximeter; ~~and~~
 - ~~(E)~~ (I) ~~Automatic External Defibrillator (AED);~~ automatic external defibrillator (AED);
 - (J) EKG monitor;
 - (K) precordial stethoscope or capnograph;
 - (L) thermometer;
- ~~(3) The following emergency equipment is maintained:~~
 - ~~(A)~~ (M) I.V. vascular access set-up as necessary for specific procedures, including hardware and fluids, if anesthesia is intravenous; fluids;
 - ~~(B)~~ (N) Syringes syringes as necessary for specific procedures; ~~and~~
 - ~~(C)~~ (O) ~~tourniquet~~ Tourniquet ~~and tape;~~ tape;
 - (P) advanced airway devices; and
 - (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 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~~ auxiliaries, one of
5 whom shall be dedicated to patient monitoring and recording sedation data throughout the
6 sedation procedure. This [~~requirement~~ Subparagraph shall not apply if the dentist permit
7 holder is dedicated to patient care and monitoring regarding general anesthesia or sedation
8 throughout the sedation procedure and is not performing the surgery or other dental
9 procedure.

10 (B) If IV sedation is used, IV infusion shall be administered before the
11 start of the procedure and maintained until the patient is ready for discharge.

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

- 18 (1) ~~Monitoring~~ monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
19 (2) ~~Drug drug~~ dosage and administration;
20 (3) ~~Treatment~~ treatment of untoward reactions including respiratory or cardiac depression if applicable;
21 (4) ~~Sterile~~ sterile technique;
22 (5) ~~Use use of CPR~~ BLS certified personnel; auxiliaries;
23 (6) ~~Monitoring~~ monitoring of patient during recovery; and
24 (7) ~~Sufficiency~~ sufficiency of patient recovery time.

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

- 27 (1) ~~Laryngospasm;~~ laryngospasm;
28 (2) ~~Bronchospasm;~~ bronchospasm;
29 (3) ~~Emesis~~ emesis and aspiration;
30 (4) ~~Respiratory~~ respiratory depression and arrest;
31 (5) ~~Angina~~ angina pectoris;
32 (6) ~~Myocardial~~ myocardial infarction;
33 (7) ~~Hypertension/Hypotension;~~ hypertension and hypotension;
34 (8) ~~Allergie~~ allergic reactions;
35 (9) ~~Convulsions;~~ convulsions;
36 (10) ~~Syneope;~~ syncope;
37 (11) ~~Bradycardia;~~ bradycardia

1 (12) ~~Insulin [insulin] shock hypoglycemia; and~~

2 (13) ~~Cardiac arrest. cardiac arrest; and~~

3 (14) ~~airway obstruction.~~

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

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

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

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

15 (e) Post-operative monitoring and discharge:

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

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

21 (A) cardiovascular function stable;

22 (B) airway patency uncompromised;

23 (C) patient arousable and protective reflexes intact;

24 (D) state of hydration within normal limits;

25 (E) patient can talk, if applicable;

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

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

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

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

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

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

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

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History Note: Authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Amended Eff. August 1, 2002; August 1, 2000;
Temporary Amendment Eff. December 11, 2002;
*Amended Eff. **June 17, 2017**; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004.*

1 21 NCAC 16Q .0304 is amended with changes as published in 31:14 NCR 1399-1400 as follows:

2
3 **21 NCAC 16Q .0304 OFF SITE USE OF MODERATE PARENTERAL AND ENTERAL CONSCIOUS**
4 **SEDATION PERMITS**

5 ~~(a) Upon request, the~~ The holder of a ~~moderate pediatric conscious sedation or moderate conscious sedation permit~~
6 ~~may travel to the office of a licensed dentist who does not hold such a permit and provide moderate conscious sedation~~
7 ~~services at the level for which the traveling dentist holds a valid permit, as well as minimal sedation or moderate~~
8 ~~conscious sedation limited to oral routes for the patients of that dentist who are undergoing dental procedures. The~~
9 ~~permit holder is solely responsible for providing~~ shall be responsible to ensure that the facility ~~in which~~ where the
10 sedation is administered ~~meets the requirements established by the Board, that the required drugs and equipment are~~
11 ~~present, and that the permit holder utilizes sufficient auxiliary personnel for each procedure performed based on the~~
12 ~~standard of care who shall document annual successful completion of basic life support training and be capable of~~
13 ~~assisting with procedures, problems, and emergency incidents that may occur as a result of the sedation or secondary~~
14 ~~to an unexpected medical complication.~~ has passed inspection by the Board and meets the requirements set out in Rule
15 .0302 of this Section. The permit holder shall be responsible to ensure that the facility is staffed with at least two BLS
16 certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation
17 data throughout the sedation procedure. This ~~requirement~~ **Subparagraph** shall not apply if the dentist permit holder
18 is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure
19 and is not performing the surgery or other dental procedure.

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

22
23 *History Note: Authority G.S. 90-28; 90-30; 90-30.1; 90-48;*

24 *Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013.*

25 *Amended Eff. **June 1, 2017.***

1 21 NCAC 16Q .0305 is adopted with changes as published in 31:14 NCR 1400 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~~ the application requirements in this Rule. ~~available~~
7 ~~from the Board's website: 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 holders applying for renewal of a moderate conscious sedation permit shall be in good standing and
37 their office shall be subject to inspection by the Board.

1

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

3 *Eff. June 1, 2017.*

1 21 NCAC 16Q .0404 is adopted with changes as published in 31:14 NCR 1400-01 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~~ the application form requirements of this Rule and paying a fee of three hundred seventy-five dollars (\$375.00)
8 that includes the one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00)
9 inspection fee. ~~The application form is available on the Board's website: www.ncdentalboard.org.~~ The permit shall
10 be renewed annually and shall be displayed with the unexpired renewal at all times in the permit holder's facility
11 where it is visible to patients receiving treatment.

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

- 14 (1) completion of a postgraduate program that included pediatric intravenous conscious sedation
15 training;
- 16 (2) completion of a ~~Council~~ Commission On Dental Accreditation (CODA) approved pediatric
17 residency that included intravenous conscious sedation training; or
- 18 (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that includes
19 training in the use and placement of IVs or intraosseous vascular access. A list of CODA approved
20 institutions that is hereby incorporated by reference, including subsequent amendments and editions,
21 appears at www.ada.org/coda and is available at no cost.

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

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

26

27

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

29 *Eff. June 1, 2017.*

1 21 NCAC 16Q .0405 is adopted with changes as published in 31:14 NCR 1401-02 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~~ 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~~ sedation, and date signed.
- 11 (5) The sedation record shall include:
- 12 (A) base line vital signs, blood pressure (unless patient behavior prevents ~~recording~~);
13 recording), oxygen saturation, ET CO₂ if capnography is utilized, pulse and respiration
14 rates of the patient 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~~ the facility shall be staffed with at least two BLS certified auxiliaries, one of whom
21 shall be dedicated to patient monitoring and recording sedation data throughout the
22 sedation procedure. This ~~requirement~~ Subparagraph shall not apply if the dentist permit
23 holder is dedicated to patient care and monitoring regarding general anesthesia or sedation
24 throughout the sedation procedure and is not performing the surgery or other dental
25 procedure; and
- 26 (B) when IV sedation is used, IV infusion shall be administered before the commencement of
27 the procedure and maintained until the patient is ready for discharge.
- 28 (b) During an inspection or evaluation, applicants and permit holders who use intravenous sedation shall demonstrate
29 the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an
30 intravenous delivery system, while the evaluator observes. Applicants and permit holders who do not use IV sedation
31 shall describe the proper deployment of an intravenous delivery system to the evaluator and shall demonstrate the
32 administration of moderate pediatric conscious sedation on a live patient while the evaluator observes.
- 33 (c) During the demonstration, all applicants and permit holders shall demonstrate competency in the following areas:
- 34 (1) monitoring blood pressure, pulse, and respiration;
- 35 (2) drug dosage and administration;
- 36 (3) treatment of untoward reactions including respiratory or cardiac depression if applicable;
- 37 (4) sterile technique;

- 1 (5) use of BLS certified auxiliaries;
- 2 (6) monitoring of patient during recovery; and
- 3 (7) sufficiency of patient recovery time.

4 (d) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the
5 treatment of the following clinical emergencies:

- 6 (1) laryngospasm;
- 7 (2) bronchospasm;
- 8 (3) emesis and aspiration;
- 9 (4) respiratory depression and arrest;
- 10 (5) angina pectoris;
- 11 (6) myocardial infarction;
- 12 (7) hypertension and hypotension;
- 13 (8) allergic reactions;
- 14 (9) convulsions;
- 15 (10) syncope;
- 16 (11) bradycardia;
- 17 (12) ~~insulin shock~~ hypoglycemia;
- 18 (13) cardiac arrest;
- 19 (14) airway obstruction; and
- 20 (15) vascular access.

21 (e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any
22 sedation procedure as follows:

- 23 (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's
24 current medical history and medication use; or
- 25 (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation
26 with the patient's primary care physician or consulting medical specialist regarding the potential
27 risks posed by the procedure.

28 (f) Patient monitoring:

- 29 (1) Patients who have been administered moderate pediatric conscious sedation shall be monitored for
30 alertness, responsiveness, breathing, and skin coloration during waiting periods before operative
31 procedures.
- 32 (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and
33 the patient shall have direct continuous supervision until oxygenation and circulation are stable and
34 the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge
35 from the office.
- 36 (3) Recovery from moderate pediatric conscious sedation shall include documentation of the following:
37 (A) cardiovascular function stable;

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

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

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

20

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

22 *Eff. June 1, 2017.*

1 21 NCAC 16Q .0406 is adopted with changes as published in 31:14 NCR 1402 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. June 1, 2017.*

1 21 NCAC 16Q .0407 is adopted with changes as published in 31:14 NCR 1403 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~~ the application requirements in this Rule. available
7 ~~from the Board's website: 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~~ certification, which shall not count towards the six hours of continuing
28 education 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. June 1, 2017.*