

21 NCAC 16Q .0202 is amended as published in 32:16 NCR 1604 with changes as follows:

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

(a) A dentist administering general anesthesia shall **be responsible to** ensure that the facility where the general anesthesia is administered meets the following requirements:

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

- (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
- (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
- (C) lighting as necessary for specific procedures and back-up lighting; and
- (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
- (E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients, and back-up E-cylinder portable oxygen tank apart from the central system;
- (F) small, medium, and large oral and nasal airways;
- (G) blood pressure monitoring device;
- (H) EKG monitor; **electrocardiograph;**
- (I) pulse oximeter;
- (J) automatic external defibrillator (AED); ~~defibrillator;~~
- (K) precordial stethoscope or capnograph;
- (L) thermometer;
- (M) vascular access set-up as necessary for specific procedures, including hardware and fluids;
- (N) laryngoscope with working batteries;
- (O) intubation forceps and advanced airway devices;
- (P) tonsillar suction with back-up suction;
- (Q) syringes as necessary for specific procedures; and
- (R) tourniquet and tape.

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

- (A) Epinephrine;
- (B) Atropine;
- (C) antiarrhythmic;
- (D) antihistamine;
- (E) antihypertensive;
- (F) bronchodilator;

- (G) antihypoglycemic agent;
- (H) vasopressor;
- (I) corticosteroid;
- (J) anticonvulsant;
- (K) muscle relaxant;
- (L) appropriate reversal agents;
- (M) nitroglycerine; ~~and~~
- (N) ~~antiemetic~~ antiemetic; and
- (O) Dextrose.
- (3) The permit holder shall maintain written emergency and patient discharge protocols and training to familiarize auxiliaries in the treatment of clinical emergencies shall be provided;
- (4) The permit holder shall maintain the following records for 10 years:
- (A) Patient's current written medical history, including a record of known allergies and previous surgeries;
- (B) Consent to general anesthesia, signed by the patient or guardian, identifying the risks and benefits, level of anesthesia, and date signed;
- (C) Consent to the procedure, signed by the patient or guardian identifying the risks, benefits, and date signed; and
- (D) Patient base line vital signs, including temperature, SPO2, blood pressure, and pulse;
- (5) The anesthesia record shall include:
- (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
- (B) procedure start and end times;
- (C) gauge of needle and location of IV on the patient, if used;
- (D) status of patient upon discharge; and
- (E) documentation of complications or morbidity; and
- (6) The facility shall be 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 Subparagraph 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) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of anesthesia while the evaluator observes, and shall demonstrate competency in the following areas:
- (1) monitoring of blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
- (2) drug dosage and administration;
- (3) treatment of untoward reactions including respiratory or cardiac depression;

- (4) sterile technique;
- (5) use of BLS certified auxiliaries;
- (6) monitoring of patient during recovery; and
- (7) sufficiency of patient recovery time.

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

- (1) laryngospasm;
- (2) bronchospasm;
- (3) emesis and aspiration;
- (4) respiratory depression and arrest;
- (5) angina pectoris;
- (6) myocardial infarction;
- (7) hypertension and hypotension;
- (8) syncope;
- (9) allergic reactions;
- (10) convulsions;
- (11) bradycardia;
- (12) hypoglycemia;
- (13) cardiac arrest; and
- (14) airway obstruction.

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

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

- (1) vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is recovered as defined by Subparagraph (e)(2) of this Rule and is ready for discharge from the office; and
- (2) recovery from general anesthesia shall include documentation of the following:
 - (A) cardiovascular function stable;
 - (B) airway patency uncompromised;
 - (C) patient arousable and protective reflexes intact;
 - (D) state of hydration within normal limits;
 - (E) patient can talk, if applicable;
 - (F) patient can sit unaided, if applicable;
 - (G) patient can ambulate, if applicable, with minimal assistance; and
 - (H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved; and

- 1 (3) before allowing the patient to leave the office, the dentist shall determine that the patient has met
2 the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:
3 (A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient,
4 stable, and have been documented;
5 (B) explanation and documentation of written postoperative instructions have been provided
6 to the patient or a responsible adult at time of discharge; and
7 (C) vested adult is available to transport the patient after discharge.

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

10 *Eff. February 1, 1990;*

11 *Amended Eff. August 1, 2018; June 1, 2017; November 1, 2013; August 1, 2002; August 1, 2000.*

21 NCAC 16Q .0204 is amended as published in 32:16 NCR 1605 with changes as follows:

**21 NCAC 16Q .0204 PROCEDURE FOR GENERAL ANESTHESIA EVALUATION OR INSPECTION
AND RE-INSPECTION**

(a) When both an evaluation ~~or~~ and on-site inspection is required, the Board shall designate two or more qualified persons to serve as evaluators, each of whom has administered general anesthesia for at least three years preceding the inspection. Training in general anesthesia shall not be counted in the three years. The fee for an evaluation and on-site inspection shall be three-hundred seventy-five dollars (\$375.00). When an on-site inspection involves only a facility and equipment check and not an evaluation of the dentist, the inspection may be accomplished by one ~~evaluator. evaluator, and the fee for the on-site inspection shall be two-hundred seventy-five dollars (\$275.00).~~

(b) An inspection fee of ~~three hundred~~ two-hundred seventy-five dollars ~~(\$375.00)~~ (\$275.00) shall be due 10 days after the dentist receives notice of the inspection of each additional location at which the dentist administers general anesthesia.

(c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.

(d) The inspection team shall determine compliance with the requirements of the ~~Rules~~ rules in this Subchapter, as applicable, by assigning a grade of "pass" or "fail."

(e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The Committee shall determine whether the applicant has passed the evaluation ~~or~~ and inspection and shall notify the applicant in writing of its decision.

(f) An applicant who fails an inspection or evaluation shall not receive a permit to administer general anesthesia. If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B 3(e). If a permit holder's facility fails an inspection, no further general anesthesia procedures shall be performed at the facility until it passes a re-inspection by the Board.

(g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall notify the applicant in writing of the need for additional training.

(h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed evaluation or inspection.

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

Eff. February 1, 1990;

Amended Eff. August 1, 2018; April 1, 2016.; February 1, 2009; December 4, 2002; January 1, 1994.

21 NCAC 16Q .0206 is amended as published in 32:16 NCR 1606 with changes as follows:

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

(a) A dentist who holds a general anesthesia permit from the Board and who wishes to provide general anesthesia or other sedation services in the office of another practitioner shall obtain a mobile general anesthesia permit from the Board by completing the application requirements of this Rule and paying a one hundred dollar (\$100.00) application ~~fee. fee and a two-hundred seventy-five dollar (\$275.00) inspection fee.~~ No mobile permit shall be required to administer general anesthesia in a hospital or credentialed surgery center.

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

(c) The permit holder shall maintain ~~the following equipment:~~ in good working order the equipment required by Rule .0202(a)(1) of this Section.

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

(d) The unexpired medications required by Rule .0202(a)(2) of this Section shall be [immediately] on site and available to the permit holder. ~~The following unexpired medications shall be immediately available to the permit holder:~~

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

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

(f) ~~Before~~ Prior to administering general anesthesia or sedation at another provider's office, the mobile permit holder shall inspect the host facility within 24 business hours before each procedure and shall to ensure that:

- (1) the operator's size and design permit emergency management and access of emergency equipment and personnel;
- (2) there is a CPR board or dental chair without enhancements suitable for providing emergency treatment;
- (3) there is lighting to permit performance of all procedures planned for the facility;
- (4) there is suction equipment, including non-electrical back-up suction; and
- (5) the facility shall be 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 Subparagraph 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.

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

1 ~~the report required by this Paragraph is filed. Upon inspection, the permit holder shall document that the facility where~~
2 ~~the general anesthesia or sedation procedure will be performed was inspected and that it met the requirements of~~
3 ~~Paragraph (f) of this Rule. The permit holder shall retain the inspection and compliance record required by this~~
4 ~~Paragraph for 10 years following the procedure and provide these records to the Board upon request.~~

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

7 (i) All applicants for mobile general anesthesia permit shall be in good standing with the Board.
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9 *History Note: Authority G.S. 90-28; 90-30.1; 90-39; 90-48;*

10 *Eff. June 1, 2017.*

11 *Amended Eff. August 1, 2018.*

21 NCAC 16Q .0207 is amended as published in 32:16 NCR 1607 with changes as follows:

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

(a) General anesthesia and itinerant general anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by the dentist paying a ~~one hundred~~ one-hundred dollar (\$100.00) fee and completing the application requirements of this Rule. If the completed general anesthesia and itinerant general anesthesia permit renewal application and renewal fee are not received before January 31 of each year, a ~~one hundred-fifty~~ dollar ~~(\$100.00)~~ (\$50.00) late fee shall be paid.

(b) Itinerant general anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by paying a one hundred dollar (\$100.00) fee and completing the application requirements of this Rule. ~~an~~ The application is available ~~from~~ on the Board's website: www.ncdentalboard.org. If the completed itinerant general sedation permit application and renewal fee are not received before January 31 of each year, a ~~one hundred-fifty~~ dollar ~~(\$100.00)~~ (\$50.00) late fee shall be paid.

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

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

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

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

(A) sedation;

(B) medical emergencies;

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

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

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

(F) airway management;

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

- 1 (3) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have
2 practiced responding to dental emergencies as a team at least once every six months in the preceding
3 year;
4 (4) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have read the
5 practice's emergency manual in the preceding year; and
6 (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
7 of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this Rule.
8 (f) All permit holders applying for renewal of a general anesthesia or itinerant general anesthesia permit shall be in
9 good standing and their office shall be subject to inspection by the Board.

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11 *History Note:* *Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;*
12 *Eff. June 1, 2017.*
13 *Amended Eff. August 1, 2018.*

21 NCAC 16Q .0301 is amended as published in 32:16 NCR 1607 with changes as follows:

**21 NCAC 16Q .0301 CREDENTIALS AND PERMITS FOR MODERATE PARENTERAL AND
ENTERAL CONSCIOUS SEDATION**

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a CRNA employed to administer or RN employed to deliver moderate conscious sedation, the dentist shall obtain a permit from the Board by completing the application requirements in this Rule and paying a fee of three hundred ~~seventy-five dollar seventy five dollars~~ (\$375.00) ~~fee~~ that includes the one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. The permit shall be renewed annually and shall be displayed with the current renewal at all times in the facility of the permit holder where it is visible to patients receiving treatment.

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

(c) A dentist applying for a permit to administer moderate conscious sedation shall document the following:

(1) Training ~~which~~ that may consist of either:

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

(B) Completion of a pre-doctoral dental or postgraduate program that included intravenous conscious sedation training equivalent to that defined in Part (c)(1)(A) of this Rule;

(2) Unexpired ACLS certification; and

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

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

(e) Prior to issuance of a moderate conscious sedation permit, the applicant shall pass an evaluation and a facility inspection. The applicant shall be responsible for passing the evaluation and inspection of his or her facility within 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one by contacting the Board in writing.

(f) A dentist who holds a moderate conscious sedation permit shall not intentionally administer deep sedation.

(g) A moderate conscious sedation permit holder may provide moderate conscious sedation at the office of another licensed dentist, regardless of the permit, if any held, by the hosting dentist. The permit holder shall ensure that the facility where the moderate conscious sedation is administered has been inspected and complies with the requirements set out in Rule .0302 of this Section. The permit holder shall also obtain an itinerant moderate conscious sedation permit and comply with the requirements of Rule .0304 of this Section.

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History Note: Authority G.S. 90-30.1; 90-39; 90-48;
Eff. February 1, 1990;
Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;
Temporary Amendment Eff. December 11, 2002;
Amended Eff. August 1, 2018; June 1, 2017; July 1, 2010, July 3, 2008; August 1, 2004.

21 NCAC 16Q .0302 is amended as published in 32:16 NCR 1608 with changes as follows:

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

(a) A dentist administering moderate conscious sedation or supervising any CRNA employed to administer or RN employed to deliver moderate conscious sedation shall ~~be responsible to~~ ensure that the facility where the sedation is administered meets the following requirements:

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

- (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
- (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
- (C) lighting as necessary for specific procedures and back-up lighting; and
- (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
- (E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from the central system;
- (F) small, medium, and large oral and nasal airways;
- (G) blood pressure monitoring device;
- (H) EKG monitor; ~~electrocardiograph;~~
- ~~(H)~~(I) pulse oximeter;
- ~~(H)~~(J) automatic external defibrillator (AED);
- ~~(J)~~ EKG monitor;
- (K) precordial stethoscope or capnograph;
- (L) thermometer;
- (M) vascular access set-up as necessary for specific procedures, including hardware and fluids;
- ~~(N)~~ laryngoscope with working batteries;
- ~~(O)~~ intubation forceps and advanced airway devices;
- ~~(P)~~ tonsillar suction with back-up suction;
- ~~(N)~~(Q) syringes as necessary for specific procedures; and
- ~~(O)~~(R) tourniquet and ~~tape~~; tape.
- ~~(P)~~ advanced airway devices; and
- ~~(Q)~~ tonsillar suction with back-up suction.

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

- (A) ~~injectable epinephrine~~ Epinephrine;

- (B) ~~injectable~~ Atropine;
- (C) ~~antiarrhythmic~~;
- (C) ~~injectable appropriate reversal agents~~;
- (D) ~~injectable~~ antihistamine;
- (E) ~~antihypertensive~~;
- (F) ~~bronchodilator~~;
- (G) ~~antihypoglycemic agent~~;
- (H) ~~vasopressor~~;
- (E)(I) ~~injectable~~ corticosteroid;
- (J) ~~anticonvulsant~~;
- (K) ~~muscle relaxant~~;
- (L) ~~appropriate reversal agents~~;
- (F)(M) ~~nitroglycerine~~;
- (G) ~~bronchodilator~~;
- (H)(N) ~~injectable~~ antiemetic; and
- (H)(O) ~~Dextrose. Dextrose; and~~
- (J) ~~injectable anti arrhythmic~~.
- (3) The permit holder shall maintain written emergency and patient discharge protocols and training to familiarize auxiliaries in the treatment of clinical emergencies shall be provided; ~~and~~
- (4) The dentist shall maintain the following records for at least 10 years:
- (A) ~~Patient's~~ patient's current written medical history and pre-operative assessment; and
- (B) ~~Drugs~~ drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration. administration; and
- (C) a sedation record;
- (5) The sedation record shall include:
- (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
- (B) procedure start and end times;
- (C) gauge of needle and location of IV on the patient, if used;
- (D) status of patient upon discharge;
- (E) documentation of complications or morbidity; and
- (F) consent form, signed by the patient or guardian, identifying the procedure, risks and benefits, level of sedation, and date signed. signed; and
- (6) The following conditions shall be satisfied during a sedation procedure:
- (A) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording sedation data throughout the sedation

1 procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to
2 patient care and monitoring regarding ~~general anesthesia or~~ sedation throughout the
3 sedation procedure and is not performing the surgery or other dental ~~procedure, procedure;~~
4 and

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

7 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate
8 conscious sedation on a patient, including the deployment of an intravenous delivery system, while the evaluator
9 observes. During the demonstration, the applicant or permit holder shall demonstrate competency in the following
10 areas:

- 11 (1) monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
- 12 (2) drug dosage and administration;
- 13 (3) treatment of untoward reactions including respiratory or cardiac depression if applicable;
- 14 (4) sterile technique;
- 15 (5) use of BLS certified auxiliaries;
- 16 (6) monitoring of patient during recovery; and
- 17 (7) sufficiency of patient recovery time.

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

- 20 (1) laryngospasm;
- 21 (2) bronchospasm;
- 22 (3) emesis and aspiration;
- 23 (4) respiratory depression and arrest;
- 24 (5) angina pectoris;
- 25 (6) myocardial infarction;
- 26 (7) hypertension and hypotension;
- 27 (8) allergic reactions;
- 28 (9) convulsions;
- 29 (10) syncope;
- 30 (11) bradycardia;
- 31 (12) hypoglycemia;
- 32 (13) cardiac arrest; and
- 33 (14) airway obstruction.

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

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

- 1 (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation
2 with the patient's primary care physician or consulting medical specialist regarding the potential
3 risks posed by the procedure.
- 4 (e) Post-operative monitoring and discharge:
- 5 (1) vital signs shall be continuously monitored when the sedation is no longer being administered and
6 the patient shall have direct continuous supervision until oxygenation and circulation are stable and
7 the patient is recovered as defined in Subparagraph (e)(2) of this Rule and is ready for discharge
8 from the office.
- 9 (2) recovery from moderate conscious sedation shall include documentation of the following:
- 10 (A) cardiovascular function stable;
11 (B) airway patency uncompromised;
12 (C) patient arousable and protective reflexes intact;
13 (D) state of hydration within normal limits;
14 (E) patient can talk, if applicable;
15 (F) patient can sit unaided, if applicable;
16 (G) patient can ambulate, if applicable, with minimal assistance; and
17 (H) for the special needs ~~patients~~ ~~patient~~ or ~~patients~~ ~~patient~~ incapable of the usually expected
18 responses, the pre-sedation level of responsiveness or the level as close as possible for that
19 patient shall be achieved.
- 20 (3) before allowing the patient to leave the office, the dentist shall determine that the patient has met
21 the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:
- 22 (A) oxygenation, circulation, activity, skin color, and level of consciousness are stable, and
23 have been documented;
24 (B) explanation and documentation of written postoperative instructions have been provided
25 to the patient or a responsible adult at time of discharge; and
26 (C) a vested adult is available to transport the patient after discharge.

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28 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
29 *Eff. February 1, 1990;*
30 *Amended Eff. August 1, 2002; August 1, 2000;*
31 *Temporary Amendment Eff. December 11, 2002;*
32 *Amended Eff. August 1, 2018; June 1, 2017; November 1, 2013; July 1, 2010; July 3, 2008; August*
33 *1, 2004.*
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21 NCAC 16Q .0304 is amended as published in 32:16 NCR 1610 with changes as follows:

21 NCAC 16Q .0304 ~~OFF SITE USE OF MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION PERMITS ITINERANT (MOBILE) MODERATE PERMIT, EQUIPMENT AND EVALUATION~~

~~The holder of a moderate conscious sedation permit may travel to the office of a licensed dentist and provide moderate conscious sedation for the patients of that dentist who are undergoing dental procedures. The permit holder shall be responsible to ensure that the facility where the sedation is administered 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 Subparagraph 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.~~

(a) A dentist who holds a moderate conscious sedation permit from the Board and who wishes to provide moderate conscious sedation or other sedation services in the office of another practitioner shall obtain a mobile moderate conscious sedation permit from the Board by completing the application requirements of this Rule and paying a one-hundred dollar (\$100.00) application fee and a two-hundred seventy-five dollar (\$275.00) inspection fee. No mobile permit shall be required to administer moderate conscious sedation in a hospital or credentialed surgery center.

(b) The permit holder shall maintain in good working order the equipment required by Rule .0302(a)(1) of this Section.

(c) The unexpired medications required by Rule .0302(a)(2) of this Section shall be **immediately** **on site and** available to the permit holder.

(d) Before a mobile moderate sedation permit may be issued, a permit holder appointed by the Board shall inspect the applicant's equipment and medications to ensure that they comply with Paragraphs (b) and (c) of this Rule. The evaluation and inspection shall be conducted as set out in Rule .0306 of this Section.

(e) Prior to administering moderate conscious sedation or other sedation services at another provider's office, the mobile permit holder shall inspect the host facility within 24 business hours before each procedure and shall ensure that:

- (1) the operator's size and design permit emergency management and access of emergency equipment and personnel;
- (2) there is a CPR board or dental chair without enhancements suitable for providing emergency treatment;
- (3) there is lighting to permit performance of all procedures planned for the facility;
- (4) there is suction equipment, including non-electrical back-up suction; and
- (5) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording moderate conscious sedation or other sedation services data throughout the sedation procedure. This Subparagraph shall not apply if the dentist

1 permit holder is dedicated to patient care and monitoring regarding sedation throughout the sedation
2 procedure and is not performing the surgery or other dental procedure.

3 (f) Upon inspection, the permit holder shall document that the facility where the general anesthesia or sedation
4 procedure will be performed was inspected and that it met the requirements of Paragraph (e) of this Rule. The permit
5 holder shall retain the inspection and compliance record required by this Paragraph for 10 years following the
6 procedure and provide these records to the Board upon request.

7 (g) The mobile moderate conscious sedation permit shall be displayed in the host facility where it is visible to patients
8 receiving treatment.

9 (i) All applicants for mobile moderate conscious sedation permit shall be in good standing with the Board.

10
11 *History Note: Authority G.S. 90-28; 90-30; 90-30.1; ~~90-39~~; 90-48;*
12 *Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013;*
13 *Amended Eff. August 1, 2018; June 1, 2017.*

21 NCAC 16Q .0305 is amended as published in 32:16 NCR 1611 with changes as follows:

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

(a) Moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by the dentist paying a ~~one hundred~~ one-hundred dollar (\$100.00) fee and completing the application requirements in this Rule. If the completed permit renewal application and renewal fee are not received before January 31 of each year, a fifty dollar (\$50.00) late fee shall be paid.

(b) Itinerant moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by paying a one-hundred dollar (\$100.00) fee and completing the application requirements in this Rule. If the completed permit renewal application and renewal fee are not received before January 31 of each year, a ~~one hundred~~ fifty dollar (~~\$100.00~~) (\$50.00) late fee shall be paid.

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

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

(e) As a condition for renewal of the moderate conscious sedation ~~permit, permit and itinerate moderate conscious sedation permit~~, the permit holder shall meet the clinical and equipment requirements of ~~Rule Rules~~ Rules .0302 and .0304 of this Section and shall document the following:

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

(A) sedation;

(B) medical emergencies;

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

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

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

(F) airway management;

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

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

(4) that the permit holder and all auxiliaries involved in sedation procedures have read the 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 moderate conscious sedation permit or itinerate moderate conscious
4 sedation permit shall be in good standing and their office shall be subject to inspection by the Board.

5

6 *History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;*
7 *Eff. June 1, 2017.*
8 *Amended Eff. August 1, 2018.*

21 NCAC 16Q .0306 is amended as published in 32:16 NCR 1611 with changes as follows:

**21 NCAC 16Q .0306 PROCEDURE FOR MODERATE CONSCIOUS SEDATION EVALUATION OR
INSPECTION AND RE-INSPECTION**

(a) When an evaluation or on-site inspection is required, the Board shall designate one or more qualified persons to serve as evaluators each of whom has administered moderate conscious sedation for at least three years preceding the inspection. Training in moderate conscious sedation shall not be counted in the three years.

(b) An inspection fee of ~~three hundred two hundred~~ seventy-five dollars (~~\$375.00~~) (\$275.00) shall be due 10 days after the dentist receives notice of the inspection of each additional location at which the dentist administers moderate conscious sedation.

(c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.

(d) The inspection team shall determine compliance with the requirements of the rules in this Subchapter, as applicable, by assigning a grade of "pass" or "fail."

(e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The Committee shall determine whether the applicant has passed the evaluation or inspection and shall notify the applicant in writing of its decision.

(f) An applicant who fails an inspection or evaluation shall not receive a permit to administer moderate conscious sedation. ~~If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B-3(e).~~ If a permit holder's facility fails an inspection, no further moderate sedation procedures shall be performed at the facility until it passes a re-inspection by the Board.

(g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall notify the applicant in writing of the need for additional training.

(h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed evaluation or inspection.

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

Eff April 1, 2016.

Amended Eff. August 1, 2018.

21 NCAC 16Q .0404 is amended as published in 32:16 NCR 1612 with changes as follows:

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

(a) Before a dentist licensed to practice in North Carolina may administer moderate pediatric conscious sedation, the dentist shall obtain a general anesthesia or moderate pediatric conscious sedation permit from the Board by completing the application requirements of this Rule and paying a fee of three hundred seventy-five dollars (\$375.00) that includes the one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. The permit shall be renewed annually and shall be displayed with the ~~unexpired~~ current renewal at all times in the permit holder's facility where it is visible to patients receiving treatment.

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

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

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

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

(e) Prior to issuance of a moderate pediatric conscious sedation permit, the applicant shall pass an evaluation and a facility inspection. The applicant shall be responsible for passing the evaluation and inspection of his or her facility within 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one by contacting the Board in writing.

[(e)] (f) A moderate pediatric conscious sedation permit holder may provide moderate pediatric conscious sedation at the office of another licensed dentist, regardless of the permit, if any held, by the hosting dentist. The permit holder shall ensure that the facility where the moderate pediatric conscious sedation is administered has been inspected and complies with the requirements set out in Rule .0405 of this Section. The permit holder shall also obtain an itinerant moderate pediatric conscious sedation permit and comply with the requirements of Rule .0406 of this Section.

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

Eff. June 1, 2017.

Amended Eff. August 1, 2018.

21 NCAC 16Q .0405 is amended as published in 32:16 NCR ~~1612~~ ~~1412~~ with changes as follows:

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

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

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

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

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

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

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

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

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

(G) blood pressure monitoring device;

~~(H)~~ EKG monitor; [electrocardiograph;]

~~(H)(I)~~ pulse oximeter;

~~(I)~~ precordial stethoscope or capnograph;

(J) automatic external defibrillator (AED); ~~defibrillator;~~

~~(K)~~ EKG monitor;

~~(K)~~ precordial stethoscope or capnograph;

(L) thermometer;

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

~~(N)~~ laryngoscope with working batteries;

~~(O)~~ intubation forceps and advanced airway devices;

~~(P)~~ tonsillar suction with back-up suction;

~~(N)(Q)~~ syringes as necessary for specific procedures; and

~~(O)~~ advanced airways; and

~~(P)(R)~~ tourniquet and tape.

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

(A) ~~epinephrine~~ Epinephrine;

(B) Atropine;

- ~~(C)~~ ~~appropriate reversal agents;~~
(C) antiarrhythmic;
(D) antihistamine;
(E) antihypertensive;
(F) bronchodilator;
(G) antihypoglycemic agent;
(H) vasopressor;
~~(E)~~(I) corticosteroid;
(J) anticonvulsant;
(K) muscle relaxant;
(L) appropriate reversal agents;
~~(F)~~(M) nitroglycerine;
~~(G)~~ ~~bronchodilator;~~
~~(H)~~(N) antiemetic; and
~~(H)~~(O) Dextrose.
- (3) The permit holder shall maintain written emergency and patient discharge protocols and training to familiarize auxiliaries in the treatment of clinical emergencies shall be provided;
- (4) The following records are maintained for at least 10 years:
- (A) patient's current written medical history and pre-operative assessment;
- (B) drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration;
- (C) a sedation record; and
- (D) a consent form, signed by the patient or a guardian, identifying the procedure, risks and benefits, level of sedation, and date signed;
- (5) The sedation record shall include:
- (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
- (B) procedure start and end times;
- (C) gauge of needle and location of IV on the patient, if used;
- (D) status of patient upon discharge; and
- (E) documentation of complications or morbidity; and
- (6) The following conditions shall be satisfied during a sedation procedure:
- (A) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to

1 patient care and monitoring regarding ~~general anesthesia or~~ sedation throughout the
2 sedation procedure and is not performing the surgery or other dental procedure; and

3 (B) when IV sedation is used, IV infusion shall be administered before the commencement of
4 the procedure and maintained until the patient is ready for discharge.

5 (b) During an inspection or evaluation, applicants and permit holders who use intravenous sedation shall demonstrate
6 the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an
7 intravenous delivery system, while the evaluator observes. Applicants and permit holders who do not use IV sedation
8 shall describe the proper deployment of an intravascular ~~intravenous~~ delivery system to the evaluator and shall
9 demonstrate the administration of moderate pediatric conscious sedation on a live patient while the evaluator observes.

10 (c) During the demonstration, all applicants and permit holders shall demonstrate competency in the following areas:

- 11 (1) monitoring blood pressure, pulse, and respiration;
- 12 (2) drug dosage and administration;
- 13 (3) treatment of untoward reactions including respiratory or cardiac depression if applicable;
- 14 (4) sterile technique;
- 15 (5) use of BLS certified auxiliaries;
- 16 (6) monitoring of patient during recovery; and
- 17 (7) sufficiency of patient recovery time.

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

- 20 (1) laryngospasm;
- 21 (2) bronchospasm;
- 22 (3) emesis and aspiration;
- 23 (4) respiratory depression and arrest;
- 24 (5) angina pectoris;
- 25 (6) myocardial infarction;
- 26 (7) hypertension and hypotension;
- 27 (8) allergic reactions;
- 28 (9) convulsions;
- 29 (10) syncope;
- 30 (11) bradycardia;
- 31 (12) hypoglycemia;
- 32 (13) cardiac arrest; and
- 33 (14) airway obstruction. ~~obstruction; and~~
- 34 ~~(15) vascular access.~~

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

- (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or
- (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure.
- (f) Patient monitoring:
- (1) Patients who have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures.
- (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge from the office.
- (3) Recovery from moderate pediatric conscious sedation shall include documentation of the following:
- (A) cardiovascular function stable;
 - (B) airway patency uncompromised;
 - (C) patient arousable and protective reflexes intact;
 - (D) state of hydration within normal limits;
 - (E) patient can talk, if applicable;
 - (F) patient can sit unaided, if applicable;
 - (G) patient can ambulate, if applicable, with minimal assistance; and
 - (H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.
- (4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(3) of this Rule and the following discharge criteria:
- (A) oxygenation, circulation, activity, skin color, and level of consciousness are ~~sufficient and~~ stable, and have been documented;
 - (B) explanation and documentation of written postoperative instructions have been provided to a responsible adult at time of discharge; and
 - (C) a vested adult is available to transport the patient after ~~discharge, discharge,~~ and for the patient for whom a motor vehicle restraint system is required, an additional responsible individual is available to attend to the patient.
 - ~~(D) a vested adult shall be available to transport patients for whom a motor vehicle restraint system is required and an additional responsible individual shall be available to attend to the patient.~~

- 1 *History Note:* *Authority G.S. 90-28; 90-30.1; 90-48;*
- 2 *Eff. June 1, 2017.*
- 3 *Amended Eff. August 1, 2018.*

21 NCAC 16Q .0406 is amended as published in 32:16 NCR 1614 with changes as follows:

**21 NCAC 16Q .0406 OFF SITE USE OF MODERATE PEDIATRIC CONSCIOUS SEDATION
PERMITS ITINERANT (MOBILE) MODERATE PEDIATRIC CONSCIOUS
SEDATION PERMITS**

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

a) A dentist who holds a moderate pediatric conscious sedation permit from the Board and who wishes to provide moderate pediatric conscious sedation or other sedation services in the office of another practitioner shall obtain a mobile moderate pediatric conscious sedation permit from the Board by completing the application requirements of this Rule and paying a one hundred dollar (\$100.00) application fee and a two-hundred seventy-five dollar (\$275.00) inspection fee. No mobile permit shall be required to administer moderate pediatric conscious sedation in a hospital or credentialed surgery center.

(b) The permit holder shall maintain in good working order the equipment required by Rule 0405(a)(1) of this Section.

(c) The unexpired medications required by Rule .0405(a)(2) of this Section shall be immediately on site and available to the permit holder.

(d) Before a mobile moderate pediatric sedation permit may be issued, a permit holder appointed by the Board shall inspect the applicant's equipment and medications to ensure that they comply with Paragraphs (b) and (c) of this Rule. The evaluation and on-site inspection shall be conducted as set out in Rule .0405 of this Section.

(e) Prior to administering moderate pediatric conscious sedation or other sedation services at another provider's office, the mobile permit holder shall inspect the host facility within 24 business hours before each procedure and shall ensure that:

(1) the operator's size and design permit emergency management and access of emergency equipment and personnel;

(2) there is a CPR board or dental chair without enhancements suitable for providing emergency treatment;

(3) there is lighting to permit performance of all procedures planned for the facility;

(4) there is suction equipment, including non-electrical back-up suction; and

(5) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording moderate pediatric conscious sedation or other sedation services data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding sedation throughout the sedation procedure and is not performing the surgery or other dental procedure.

(f) Upon inspection, the permit holder shall document that the facility where the sedation procedure will be performed was inspected and that it met the requirements of Paragraph (e) of this Rule. The permit holder shall retain the

1 inspection and compliance record required by this Paragraph for 10 years following the procedure and provide these
2 records to the Board upon request.

3 (g) The mobile moderate pediatric conscious sedation permit shall be displayed in the host facility where it is visible
4 to patients receiving treatment.

5 (h) All applicants for a mobile moderate pediatric conscious sedation permit shall be in good standing with the Board.

6
7 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*

8 *Eff. June 1, 2017.*

9 *Amended Eff. August 1, 2018.*

21 NCAC 16Q .0407 is amended as published in 32:16 NCR 1615 with changes as follows:

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

(a) Moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by the dentist paying a ~~one one-hundred~~ dollar (\$100.00) fee and completing the application requirements in this Rule.

~~(b) If the completed renewal application and renewal fee are not received before January 31 of each year, a one hundred (\$100.00) fifty (\$50.00) dollar late fee shall be paid.~~

(b) Itinerant moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by paying a one one-hundred dollar (\$100.00) fee and completing the application requirements in this Rule. If the completed permit renewal application and renewal fee are not received before January 31 of each year, a fifty dollar (\$50.00) late fee shall be paid.

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

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

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

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

(A) sedation;

(B) medical emergencies;

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

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

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

(F) airway management;

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

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

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

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

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

8
9 *History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;*

10 *Eff. June 1, 2017.*

11 *Amended Eff. August 1, 2018.*

21 NCAC 16Q .0408 is amended as published in 32:16 NCR 1615 with changes as follows:

**21 NCAC 16Q .0408 PROCEDURE FOR MODERATE PEDIATRIC SEDATION EVALUATION OR
INSPECTION AND RE-INSPECTION**

(a) When an evaluation or on-site inspection is required, the Board shall designate one or more qualified persons to serve as evaluators, each of whom has administered moderate pediatric sedation for at least three years preceding the evaluation or inspection. Training in moderate pediatric sedation shall not count toward the three years.

(b) An inspection fee of ~~three hundred two hundred~~ seventy-five dollars (~~\$375.00~~) (\$275.00) shall be due 10 days after the dentist receives notice of the inspection of each additional location at which the dentist administers moderate pediatric sedation.

(c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.

(d) The inspection team shall determine compliance with the requirements of the rules in this Subchapter, as applicable, by assigning a grade of "pass" or "fail."

(e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The Committee shall determine whether the applicant has passed the evaluation or inspection and shall notify the applicant in writing of its decision.

(f) An applicant who fails an inspection or evaluation shall not receive a permit to administer moderate pediatric sedation. ~~If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B-3(e).~~ If a permit holder's facility fails an inspection, no further moderate pediatric sedation procedures shall be performed at the facility until it passes a re-inspection by the Board.

(g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall notify the applicant in writing of the need for additional training.

(h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed evaluation or inspection.

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

Eff. April 1, 2016.

Amended Eff. August 1, 2018.

21 NCAC 16Q .0501 is amended as published in 32:16 NCR 1616 with changes as follows:

21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED

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

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

(c) As a condition for renewal of the general anesthesia ~~permit, permit or itinerate general anesthesia permit,~~ the permit holder shall meet the requirements of ~~21 NCAC 16Q .0202- Rule .0207 of this Subchapter, and document current, successful completion of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other equivalent course, and auxiliary personnel shall document annual, successful completion of basic life support (BLS) training.~~

(d) As a condition for renewal of the moderate conscious sedation permit or ~~itinerate moderate pediatric-conscious sedation permit,~~ the permit holder shall meet the requirements of ~~21 NCAC 16Q .0302 and- Rule .0305 of this Subchapter.~~

(1) ~~document annual, successful completion of BLS training and obtain three hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:~~

(A) ~~sedation;~~

(B) ~~medical emergencies;~~

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

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

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

(F) ~~audit ACLS/Pediatric Advanced Life Support (PALS) courses; and~~

(G) ~~airway management; or~~

(2) ~~document current, successful completion of ACLS training or its age-specific equivalent, or other equivalent course and annual successful completion of BLS.~~

(e) ~~As a condition for renewal of the moderate pediatric conscious sedation permit holders or itinerate moderate pediatric conscious sedation permit, the permit holder shall meet the requirements of Rule .0407 of this Subchapter. must have current PALS at all times.~~

(f) As a condition for renewal of the minimal conscious sedation permit ~~and the moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation,~~ the permit holder shall meet the requirements of ~~16Q .0402- Rule~~

1 .0402 of this Subchapter and shall document annual, successful completion of BLS training and obtain six hours of
2 continuing education every two years in one or more of the following areas, which may be counted toward fulfillment
3 of the continuing education required each calendar year for license renewal:

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

11 (g) Any dentist who fails to renew a general anesthesia or sedation permit on or before March 31 of each year must
12 complete a reinstatement application, pay the one hundred dollar (\$100.00) renewal fee and a ~~one hundred-fifty~~ dollar
13 ~~(\$100.00) (\$50.00)~~ penalty and comply with all conditions for renewal set out in this Rule for the permit sought.
14 Dentists whose anesthesia or sedation permits have been lapsed for more than 12 calendar months must pass ~~a~~ an
15 evaluation and facilities inspection and must pay the application evaluation and inspection fee set forth in the
16 applicable rules of this Subchapter as part of the reinstatement process.

17
18 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*

19 *Eff. February 1, 1990;*

20 *Amended Eff. August 1, 2002;*

21 *Transferred and Recodified from 16Q .0401 to 16Q .0501;*

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

23 *Amended Eff. August 1, 2018; November 1, 2013; July 3, 2008; August 1, 2004.*

21 NCAC 16Q .0502 is repealed as published in 32:16 NCR 1616 as follows:

21 NCAC 16Q .0502 PAYMENT OF FEES

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

Eff. February 1, 1990:

Transferred and Recodified from 16Q .0402 to .0502:

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

Repealed Eff. August 1, 2018.