SUBCHAPTER 16Q - GENERAL ANESTHESIA AND SEDATION

SECTION .0100 – GENERAL

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 pediatric conscious 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 that allows for uninterrupted interactive ability in an awake patient with no compromise in the ability to maintain a patent airway independently and continuously. 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.
- (9) "Behavior control" the use of pharmacological techniques to control behavior to a level that dental treatment may be performed without injury to the patient or dentist.
- (10) "Behavioral management" the use of pharmacological or psychological techniques, singly or in combination, to modify behavior to a level that dental treatment may be performed without injury to the patient or dentist.
- (11) "Competent" displaying special skill or knowledge derived from training and experience.
- (12) "Conscious sedation" an induced state of a depressed level of consciousness that retains the patient's ability to maintain an airway without assistance and respond to physical stimulation and verbal commands, and that is produced by pharmacologic or non-pharmacologic agents, or a combination thereof. All dentists who perform conscious sedation shall have an unexpired sedation permit from the Dental Board.
- (13) "CRNA" Certified Registered Nurse Anesthetist.
- (14) "Deep sedation" an induced state of a depressed level of consciousness accompanied by partial loss of protective reflexes, including the ability to maintain an airway without assistance or respond to verbal command, produced by pharmacological agents. All dentists who perform deep sedation shall have an unexpired general anesthesia permit from the Dental Board.
- (15) "Deliver" to assist a permitted dentist in administering sedation or anesthesia drugs by providing the drugs to the patient pursuant to a direct order from the dentist and while under the dentist's direct supervision.
- (16) "Direct supervision" the dentist responsible for the sedation or anesthesia procedure shall be immediately available and shall be aware of the patient's physical status and well being at all times.
- (17) "Emergencies manual" a written manual that documents:
 - (a) the location of all emergency equipment and medications in each facility;
 - (b) each staff member's role during medical emergencies; and
 - (c) the appropriate treatment for laryngospasm, bronchospasm, emesis and aspiration, respiratory depression and arrest, angina pectoris, myocardial infarction, hypertension, hypotension, allergic reactions, convulsions, syncope, bradycardia, hypoglycemia, cardiac arrest, and airway obstruction.
- (18) "Enteral" the administration of pharmacological agents orally, intranasally, sublingually, or rectally.
- (19) "ET CO2" —end tidal carbon dioxide.

- (20) "Facility" the location where a permit holder practices dentistry and provides anesthesia or sedation services.
- (21) "Facility inspection" an on-site inspection to determine if a facility where the applicant proposes to provide anesthesia or sedation is supplied, equipped, staffed, and maintained in a condition to support provision of anesthesia or sedation services in compliance with the Dental Practice Act set forth in Article 2 of G.S. 90 and the Board's rules of this Chapter.
- (22) "General anesthesia" the intended controlled state of a depressed level of consciousness that is produced by pharmacologic agents and accompanied by a partial or complete loss of protective reflexes, including the ability to maintain an airway and respond to physical stimulation and verbal commands. All dentists who perform general anesthesia shall have an unexpired general anesthesia permit from the Dental Board.
- (23) "Good standing" a licensee whose license is not suspended or revoked and who is not subject to a current disciplinary order imposing probationary terms.
- (24) "Immediately available" on-site in the facility and available for use without delay.
- (25) "Itinerant general anesthesia provider"- a permittee who has complied with Rule .0206 of this Subchapter and who administers general anesthesia at another practitioner's facility.
- (26) "Local anesthesia" the elimination of sensations, including pain, in one part of the body by the regional application or injection of a drug.
- (27) "Minimal conscious sedation" conscious sedation characterized by a minimally depressed level of consciousness, in which the patient retains the ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command, provided to patients 13 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment, possibly in combination with nitrous oxide. Minimal conscious sedation may be provided for behavioral management.
- (28) "Minor psychosedative/Minor tranquilizer" pharmacological agents that allow for uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent airway continuously and without assistance and carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
- (29) "Moderate conscious sedation" conscious sedation characterized by a drug induced depression of consciousness, during which patients respond to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients 13 years of age or older, by oral, nasal, rectal, or parenteral routes of administration of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate conscious sedation may be provided for behavior control by licensed dentists who comply with the terms of Rule .0301 of this Subchapter. A moderate conscious sedation provider shall not use the following:
 - (a) drugs designed by the manufacturer for use in administering general anesthesia or deep sedation; or
 - (b) drugs contraindicated for use in moderate conscious sedation.
- (30) "Moderate pediatric conscious sedation" conscious sedation characterized by a drug induced depression of consciousness, during which patients respond to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients up to 18 years of age, or special needs patients, by oral, nasal, rectal, or parenteral routes of administration of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate pediatric conscious sedation may be provided for behavior control by licensed dentists who comply with the terms of Rule .0404 of this Subchapter. A moderate pediatric conscious sedation permit holder shall not use the following:
 - (a) drugs designed by the manufacturer for use in administering general anesthesia or deep sedation; or
 - (b) drugs contraindicated for use in moderate pediatric conscious sedation.
- (31) "Parenteral" the administration of pharmacological agents intravenously, intraosseously, intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.
- (32) "PALS" Pediatric Advanced Life Support.
- (33) "Protective reflexes" includes the ability to swallow and cough.

- (34) "RN" Registered Nurse licensed by the North Carolina Board of Nursing.
- (35) "Sedation Procedure" process begins when any pharmacological agent is first administered to a patient to induce general anesthesia or sedation and continues until the dentist permit holder determines that the patient has met the recovery and discharge criteria set forth in the applicable rules in this Subchapter.
- (36) "Special needs patients" patients with diminished mental and or physical capacity who are unable to cooperate to receive ambulatory dental care without sedation or anesthesia.
- (37) "Supplemental dosing" the oral administration of a pharmacological agent that results in an enhanced level of conscious sedation when added to the primary sedative agent administered for the purpose of oral moderate conscious sedation, and when added to the primary agent, does not exceed the maximum safe dose of either agent, separately or synergistically.
- (38) "Vested adult" a responsible adult who is the legal parent or guardian, or designee of a legal parent or guardian, entrusted with the care of a patient following the administration of general anesthesia or conscious sedation.

History Note: Authority G.S. 90-30.1; 90-48; Eff. February 1, 1990; Temporary Amendment Eff. December 11, 2002; Amended Eff. June 1, 2017; July 3, 2008; August 1, 2004; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.

21 NCAC 16Q .0102 APPLICATION FOR GENERAL ANESTHESIA OR SEDATION PERMIT, PERMIT RENEWAL, AND PERMIT REINSTATEMENT

(a) An applicant for a general anesthesia or sedation permit shall be licensed and in good standing with the Board.(b) All permit applications shall be made on the forms furnished by the Board at www.ncdentalboard.org and shall include:

- (1) the full name;
- (2) the mailing address;
- (3) the North Carolina dental license number;
- (4) a telephone number; and
- (5) an email address.

(c) In addition to the information in Paragraph (b) of this Rule, all applications for a general anesthesia, moderate conscious sedation, moderate pediatric conscious sedation, or minimal conscious sedation permit shall include:

- (1) the addresses of all dental offices where the applicant intends to use general anesthesia or sedation;
- (2) dental education, including dental school name, dates attended, degree received, and any other dental post-graduate education or specialty degrees received;
- (3) a resume or curriculum vitae;
- (4) the names of and copies of unexpired BLS certifications for any auxiliaries that will assist the applicant with general anesthesia or sedation;
- (5) a statement disclosing and explaining any instances of patient mortality or morbidity in connection with applicant's prior use of general anesthesia or sedation; and
- (6) documentation of the required qualifications for the permit for which the applicant is applying, as set out in Rule .0201, .0301, .0404, or .0504 of this Subchapter.
- (d) In addition to the information in Paragraph (b) of this Rule, all applications for an itinerant permit shall include:
 - (1) North Carolina general anesthesia or sedation permit number; and
 - (2) a statement of compliance with the requirements for the itinerant permit for which the applicant is applying, as set out in Rule .0206, .0304, or .0406 of this Subchapter.

(e) All applications for renewal of a general anesthesia or sedation permit shall be submitted electronically through the Board's website, www.ncdentalboard.org, and shall include:

- (1) the full name;
- (2) the permit number and expiration date;
- (3) the addresses of all dental offices where the permit holder uses general anesthesia or sedation; and

(4) a statement disclosing and explaining any instances of patient mortality or morbidity in connection with use of general anesthesia or sedation that occurred during the calendar year preceding the application and that were not previously disclosed to the Board.

(f) All applications for reinstatement of a general anesthesia or sedation permit shall be made on forms furnished by the Board at www.ncdentalboard.org and shall include:

- (1) the full name;
- (2) the permit number and date of issuance;
- (3) the mailing address;
- (4) the North Carolina dental license number;
- (5) the addresses of all dental offices where the applicant intends to use general anesthesia or sedation; and
- (6) a statement disclosing and explaining any instances of patient mortality or morbidity in connection with use of general anesthesia or sedation that occurred during the calendar year preceding the application.
- (g) Any permit obtained through fraud or by any false representation shall be revoked.

History Note: Authority G.S. 90-28; 90-30.1; Eff. August 1, 2021.

21 NCAC 16Q .0103 EQUIPMENT, PERSONNEL, AND CLINICAL REQUIREMENTS TO ADMINISTER ANESTHESIA OR MODERATE SEDATION

(a) Before administering general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation ("anesthesia or moderate sedation"), or supervising a CRNA to administer or an RN employed to deliver anesthesia or moderate sedation, a dentist shall hold an unexpired permit issued by the Board in accordance with this Subchapter permitting the dentist to administer that level of sedation.

(b) Before performing sedation procedures in a facility other than a hospital or credentialed surgery center, the permit holder shall ensure that the Board has been notified that the permit holder intends to administer anesthesia or moderate sedation at the facility and shall ensure that the facility has passed a facility inspection by the Board in accordance with this Subchapter. For purposes of these Rules, "credentialed surgery center" means a surgical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities.

(c) The permit holder shall ensure that the facility where the sedation procedure is to be performed meets the following requirements at the time of the procedure:

- (1) The permit holder shall ensure the facility is equipped as follows and that the following listed equipment is immediately available and accessible from the operatory and recovery rooms:
 - (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 dental chair suitable for providing emergency treatment;
 - (C) lighting as necessary for the procedure to be performed, and back-up lighting;
 - (D) suction equipment as necessary for the procedure to be performed, including nonelectrical 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) a blood pressure monitoring device;
 - (H) an EKG monitor;
 - (I) a pulse oximeter;
 - (J) an automatic external defibrillator (AED);
 - (K) a capnograph;
 - (L) a precordial or pretracheal stethoscope;
 - (M) a thermometer;
 - (N) vascular access set-up as necessary for the procedure to be performed, including hardware and fluids;
 - (O) a laryngoscope with working batteries;
 - (P) intubation forceps and advanced airway devices;

- (Q) tonsillar suction with back-up suction;
- (R) syringes as necessary for the procedure to be performed; and
- (S) tourniquet and tape.
- (2) The permit holder shall ensure all monitoring and other equipment in the facility receives preventive maintenance no less frequently than once per year, including safety and function checks per the manufacturers' recommendations. The permit holder shall maintain documentation of all preventive maintenance performed, and shall ensure equipment is replaced upon its expiration or as clinically required.
- (3) The permit holder shall ensure the following unexpired drugs are immediately available and are accessible from the operatory and recovery rooms:
 - (A) epinephrine;
 - (B) atropine;
 - (C) an antiarrhythmic;
 - (D) an antihistamine;
 - (E) an antihypertensive;
 - (F) a bronchodilator;
 - (G) an antihypoglycemic agent;
 - (H) a vasopressor;
 - (I) a corticosteroid;
 - (J) an anticonvulsant;
 - (K) appropriate reversal agents;
 - (L) nitroglycerine; and
 - (M) an antiemetic.
- (4) The permit holder shall maintain written emergency and patient discharge protocols accessible from the operatory and recovery rooms. The written emergency manual shall include a protocol for activation of emergency management services for life-threatening complications along with the information set out in Rule .0101(17) of this Section.
- (5) The permit holder shall satisfy any additional facility requirements applicable to the level of the permit, as set out in Rule .0202, .0206, .0302, or .0405 of this Subchapter.

(d) The permit holder shall ensure that the following staffing, education, and training requirements are met prior to performing a sedation procedure:

- (1) The permit holder shall provide training to familiarize all auxiliaries in the treatment of clinical emergencies including the following, and shall review and practice responding to clinical emergencies with all auxiliaries as a team and in person every six months;
 - (A) airway obstruction;
 - (B) allergic reactions;
 - (C) angina pectoris;
 - (D) apnea;
 - (E) bradycardia;
 - (F) bronchospasm;
 - (G) cardiac arrest;
 - (H) convulsions;
 - (I) emesis and aspiration;
 - (J) hypertension;
 - (K) hypoglycemia;
 - (L) hypotension;
 - (M) hypoventilation and respiratory arrest;
 - (N) hypoxemia and hypoxia;
 - (O) laryngospasm;
 - (P) myocardial infarction; and
 - (Q) syncope.
- (2) All auxiliaries in the facility shall be BLS certified.
- (3) Except as set out in Subparagraph (d)(4) of this Rule, the permit holder performing the surgery or other dental procedure shall ensure that an RN or a BLS-certified auxiliary is dedicated to patient monitoring and recording anesthesia or sedation data throughout the sedation procedure.

- (4) The requirement set out in Subparagraph (d)(3) of this Rule shall not apply if the permit holder or an additional sedation provider is dedicated to patient care and monitoring regarding anesthesia or moderate sedation throughout the sedation procedure and is not performing the surgery or other dental procedure. The additional sedation provider shall be:
 - (A) a dentist holding a permit or mobile permit in satisfaction of this Subchapter to administer the anesthesia or sedation level at the facility where the sedation procedure is performed;
 - (B) an anesthesiologist licensed and practicing in accordance with the rules of the North Carolina Medical Board; or
 - (C) a CRNA licensed and practicing in accordance with the rules of the North Carolina Board of Nursing, under the supervision and direction of the permit holder who shall ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit.
- (5) The permit holder shall satisfy any additional staffing, education, and training requirements applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(e) Before starting any sedation procedure, the permit holder shall conduct a pre-operative patient evaluation which shall include the following:

- (1) evaluating the patient for health risks relevant to the potential sedation procedure;
- (2) evaluating the patient's food and fluid intake following the ASA guidelines for pre-operative fasting applicable to elective procedures involving the administration of anesthesia or moderate sedation. The ASA guidelines are incorporated by reference, including subsequent amendments and editions, and may be accessed at https://www.asahq.org at no cost; and
- (3) satisfying any additional requirements for pre-operative patient evaluation and procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(f) During the sedation procedure:

- (1) Prescriptions intended to accomplish procedural sedation, including enteral dosages, shall be administered only under the direct supervision of the permit holder.
- (2) If IV sedation is used, IV infusion shall be administered before the start of the procedure and maintained until the patient is ready for discharge.
- (3) Capnography shall be used to monitor patients unless an individual patient's behavior or condition prevents use of capnography. In that event, the permit holder shall document in the sedation record the clinical reason capnography could not be used.
- (4) The permit holder shall ensure the patient's baseline vital signs are taken and recorded, including temperature, SPO2, blood pressure, and pulse.
- (5) The permit holder shall ensure the patient's blood pressure, oxygen saturation, ET CO2 (unless capnography cannot be used), pulse, and respiration rates ("vital sign information") are monitored continuously in a manner that enables the permit holder to view vital sign trends throughout the procedure.
- (6) The permit holder shall ensure the intraoperative vital sign information is recorded on the anesthesia or sedation record contemporaneously throughout the procedure in intervals of five minutes or less for patients over twelve years old, and in intervals of ten minutes or less for pediatric patients twelve years old or younger.
- (7) The permit holder shall satisfy any additional requirements for operative procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.
- (g) Post-operative monitoring and discharge shall include the following:
 - (1) The permit holder or an auxiliary under his or her direct supervision shall monitor the patient's post-operative vital sign information until the patient is recovered and is ready for discharge from the office. Recovery from anesthesia or moderate sedation shall include documentation of the following:
 - (A) stable cardiovascular function;
 - (B) uncompromised airway patency;
 - (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 with minimal assistance, if applicable; and

- (H) for a special needs patient, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.
- (2) Before allowing the patient to leave the office, the permit holder shall determine that the patient has met the recovery criteria set out in Subparagraph (g)(1) of this Rule and the following discharge criteria:
 - (A) oxygenation, circulation, activity, skin color, and level of consciousness are stable and have been documented;
 - (B) explanation and documentation of written post-operative instructions have been provided to the patient or a person responsible for the patient at time of discharge; and
 - (C) a person authorized by or responsible for the patient is available to transport the patient after discharge.
- (h) The permit holder shall maintain the following in the patient treatment records for 10 years:
 - (1) the patient's current written medical history, including known allergies and previous surgeries;
 - (2) a pre-operative assessment as set out in Paragraph (e) of this Rule;
 - (3) consent to the procedure and to the anesthesia or sedation, signed by the patient or guardian, identifying the procedure and its risks and benefits, the level of anesthesia or sedation and its risks and benefits, and the date signed;
 - (4) the anesthesia or sedation record that shall include:
 - (A) the patient's baseline vital signs and intraoperative vital sign information as set out in Subparagraphs (f)(4)-(6) of this Rule;
 - (B) the printed or downloaded vital sign information from the capnograph. A permit holder's failure to maintain capnograph documentation, except as set out in Subparagraph (f)(3) of this Rule, shall be deemed a failure to monitor the patient as required pursuant to this Subchapter;
 - (C) procedure start and end times;
 - (D) gauge of needle and location of IV on the patient, if used;
 - (E) the total amount of any local anesthetic administered during the procedure;
 - (F) any analgesic, sedative, pharmacological, or reversal agent, or other drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration, with separate entries for each increment of medication that is titrated to effect;
 - (G) documentation of complications or morbidity, and clinical responses; and
 - (H) status of patient upon discharge, including documentation of satisfying the requirements set out in Paragraph (g) of this Rule; and
 - (5) any additional documentation applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

History Note: Authority G.S. 90-28; 90-30.1; 90-31.1; 90-48; Eff. June 17, 2024.

21 NCAC 16Q .0104 REQUIREMENTS FOR INSPECTIONS AND EVALUATIONS

(a) During a facility inspection pursuant to the rules of this Subchapter, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or permit holder shall demonstrate satisfaction of the requirements set forth in Rule .0103(c) and (d) of this Section.

(b) During an evaluation, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or permit holder shall demonstrate the administration of anesthesia or sedation in accordance with the level of the permit, and shall demonstrate competency in the following areas:

- (1) pre-operative patient evaluation and procedures, including the requirements set forth in Rule .0103(e) of this Section;
- (2) operative procedures, including the deployment of an intravenous delivery system and the requirements set forth in Rule .0103(f) of this Section;
- (3) post-operative patient monitoring and discharge, including the requirements set forth in Rule .0103(g) of this Section; and
- (4) treatment of the clinical emergencies set out in Rule .0103(d)(1) of this Section.

(c) During the evaluation, the applicant shall take a written examination on the topics set forth in Subparagraphs (b)(1)-(4) of this Rule. The applicant shall obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the applicant fails to obtain a passing score on the written examination, he or she may be re-examined in accordance with Rule .0204(h), .0306(h), or .0408(h) of this Subchapter.

(d) The permit holder shall be subject to re-evaluation every five years. Each facility where the permit holder administers anesthesia or sedation shall be subject to a facility inspection upon annual renewal of the permit.

History Note: Authority G.S. 90-28; 90-30.1; 90-48; Eff. June 17, 2024.

SECTION .0200 - GENERAL ANESTHESIA

21 NCAC 16Q .0201 GENERAL ANESTHESIA CREDENTIALS AND PERMIT

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a CRNA to administer general anesthesia or perform deep sedation, the dentist shall obtain a general anesthesia permit from the Board by completing the application requirements of this Rule and paying a four hundred seventy-five dollar (\$475.00) fee that includes the one-hundred dollar (\$100.00) application fee and the three-hundred seventy-five dollar (\$375.00) inspection fee. The permit shall be renewed annually and shall be displayed with the 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 general anesthesia permit shall be in good standing with the Board, has an unexpired ACLS certification, and demonstrates that he or she has one of the following qualifications:

- (1) has completed a minimum of two years of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level;
- (2) has graduated from a program certified by the American Dental Association in Oral and Maxillofacial Surgery;
- (3) is a Diplomate of or eligible for examination by the American Board of Oral and Maxillofacial Surgery; or
- (4) is a Fellow of the American Dental Society of Anesthesiology.

(c) Before receiving a general anesthesia permit, all applicants shall pass an evaluation and inspection as set out in Rule .0104 of this Subchapter. Every location other than a hospital or credentialed surgery center where a general anesthesia permit holder administers general anesthesia shall pass an inspection as set out in Rule .0204 of this Section.

(d) A dentist who holds a general anesthesia permit may administer any level of sedation without obtaining a separate sedation permit.

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

(f) A general anesthesia permit holder may provide general anesthesia 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 general anesthesia is administered has been inspected and complies with the requirements set out in Rules .0103 and .0202 of this Subchapter, and shall obtain an itinerant general anesthesia permit and comply with the requirements of Rule .0206 of this Section.

History Note: Authority G.S. 90-28; 90-30.1; 90-39; Eff. February 1, 1990; Amended Eff. April 1, 2001; August 1, 2000; Temporary Amendment Eff. December 11, 2002; Amended Eff. June 1, 2017; February 5, 2008; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. August 1, 2024.

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

(a) A dentist holding or applying for a permit to administer general anesthesia shall be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired neuromuscular blocking agent shall be immediately available and be accessible from the operatory and recovery rooms.

History Note: Authority G.S. 90-28; 90-30.1; 90-48; Eff. February 1, 1990; Amended Eff. June 1, 2017; November 1, 2013; August 1, 2002; August 1, 2000; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. June 17, 2024; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0203 TEMPORARY APPROVAL PRIOR TO SITE EVALUATION

History Note: Authority G.S. 90-28; 90-30.1; Eff. February 1, 1990; Amended Eff. August 1, 2002; Repealed Eff. April 1, 2016.

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

(a) When both an evaluation 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, and the fee for the on-site inspection shall be two-hundred seventy-five dollars (\$275.00).

(b) An inspection fee of two-hundred seventy-five dollars (\$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 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 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'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. Except as set forth in Paragraph (h) of this Rule, 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) A permit applicant who has failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who has failed the written portion of the examination three times shall complete an additional Board approved course of study in the area(s) of deficiency and provide the Board evidence of the additional study before written reexamination.

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

(j) An applicant must complete all the requirements of Rules .0103, .0104, and .0202 of this Subchapter, including passing the written examination, evaluation and inspection, within 12 months of submitting the application to the Board.

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

Eff. February 1, 1990; Amended April 1, 2016; February 1, 2009; December 4, 2002; January 1, 1994; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;

Amended Eff. August 1, 2024; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0205 RESULTS OF SITE EVALUATION AND REEVALUATION

History Note:

Authority G.S. 90-28; 90-30.1; Eff. February 1, 1990; Amended Eff. August 1, 2002; Repealed Eff. April 1, 2016.

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 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 in good working order the following equipment:

- (1) small, medium, and large supraglottic airways devices;
- (2) small, medium, and large anesthesia circuits;
- (3) rebreathing device;
- (4) scavenging system;
- (5) intermittent compression devices;
- (6) gastric suction device;
- (7) endotracheal tube and pulmonary suction device;
- (8) equipment for performing emergency cricothyrotomies and delivering positive pressure ventilation; and
- (9) the equipment required by Rule .0103 of this Subchapter.

(d) A neuromuscular blocking agent, an anti-malignant hyperthermia agent, and the medications required by Rules .0103 and .0202 of this Subchapter shall be on site, unexpired, and available to the permit holder.

(e) The evaluation and on-site inspection shall be conducted as set out in Rules .0104 and .0204 of this Subchapter.

(f) 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 ensure that:

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

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

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

History Note: Authority G.S. 90-28; 90-30.1; 90-39; 90-48; Eff. June 1, 2017; Amended Eff. August 1, 2024; August 1, 2021; August 1, 2018.

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

(a) General anesthesia permits and itinerant general anesthesia permits shall be renewed by the Board annually at the same time as dental licenses. For each permit to be renewed, the permit holder shall pay a one-hundred dollar (\$100.00) fee and complete the renewal application requirements of this Rule. If the completed permit renewal application and renewal fee are not received before midnight on January 31 of each year, a fifty dollar (\$50.00) late fee shall be charged. The renewal application shall be submitted electronically through the Board's website, www.ncdentalboard.org, and shall include the information required by Rule .0102(e) of this Subchapter and a report of compliance with the conditions for renewal in Paragraph (d) of this Rule.

(b) Any permit holder 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 and late fee set out in Paragraph (a) of this Rule, and comply with all conditions for renewal set out in this Rule. Dentists whose general 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 in accordance with Rules. 0104 and .0204 of this Subchapter. All applicants for reinstatement of a permit shall be in good standing. All applications for reinstatement of a permit shall be submitted on forms furnished by the Board at www.ncdentalboard.org and shall include the information required by Rule .0102(f) of this Subchapter and a report of compliance with the conditions for renewal set out in Paragraph (d) of this Rule.

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

(d) As a condition for renewal of the general anesthesia permit and itinerant general anesthesia permit, the permit holder shall meet the clinical equipment and requirements set out in Rules .0103 and .0202 of this Subchapter, the itinerant general anesthesia permit holder shall also meet the clinical equipment and requirements set out in Rule .0206 of this Section, and the permit holder shall document the following:

- (1) six hours of continuing education each year in one or more of the following areas, which 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 (d)(1) of this Rule;
- (3) that the permit holder and all auxiliaries involved in anesthesia or 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 anesthesia or sedation procedures have read the practice's emergency manual in the preceding year; and
- (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours of continuing education annually in any of the areas set forth in Subparagraph (d)(1) of this Rule.

(e) Absent a Board order stating otherwise, all permit holders applying for renewal of a general anesthesia permit or itinerant general anesthesia permit shall be in good standing and their office shall be subject to inspection by the Board.

History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39; 90-48; Eff. June 1, 2017; Amended Eff. August 1, 2024; August 1, 2021; August 1, 2018.

SECTION .0300 - MODERATE CONSCIOUS SEDATION

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 (\$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 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 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:

- Training that may consist of either: (1)
 - (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
 - Completion of a pre-doctoral dental or postgraduate program that included intravenous **(B)** conscious sedation training equivalent to that defined in Part (c)(1)(A) of this Rule:
- (2) Unexpired ACLS certification; and
- That all auxiliaries involved in sedation procedures have unexpired BLS certification. (3)

(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.

(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 Rules .0103 and .0302 of this Subchapter. The permit holder shall also obtain an itinerant moderate conscious sedation permit and comply with the requirements of Rule .0304 of this Section.

Authority G.S. 90-30.1; 90-39; 90-48; History Note: *Eff. February 1. 1990:* Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994; Temporary Amendment Eff. December 11, 2002; Amended Eff. June 1, 2017; July 1, 2010, July 3, 2008; August 1, 2004; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;

Amended Eff. August 1, 2024; February 1, 2019; August 1, 2018.

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

(a) A dentist holding or applying for a permit to administer moderate conscious sedation or supervising any CRNA employed to administer or RN employed to deliver moderate conscious sedation shall be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) As part of the pre-operative assessment required by Rule .0103(e) of this Subchapter, the permit holder shall evaluate the patient for health risks 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 the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

(d) During the sedation procedure, a moderate conscious sedation permit holder shall not administer anesthetic or sedative agents:

- (1) designed by the manufacturer for use in administering general anesthesia or deep sedation;
- (2) determined by the manufacturer to be contraindicated for use in moderate conscious sedation; or
- (3) in amounts exceeding the manufacturers' maximum recommended dosages, unless the permit holder documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

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 1, 2017; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. June 17, 2024; February 1, 2019; August 1, 2018.

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

History Note: Authority G.S. 90-28; 90-30.1; Eff. February 1, 1990; Amended Eff. August 1, 2002; January 1, 1994; Temporary Amendment Eff. December 11, 2002; Amended Eff. September 1, 2014; February 1, 2009; July 3, 2008; August 1, 2004; Repealed Eff. April 1, 2016.

21 NCAC 16Q .0304 ITINERANT (MOBILE) MODERATE PERMIT, EQUIPMENT AND EVALUATION

(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 .0103 of this Subchapter.

(c) The unexpired medications required by Rules .0103 and .0302 of this Subchapter shall be 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 Rules .0104 and .0306 of this Subchapter.

(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 operatory'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 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 general anesthesia or 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 inspection and compliance record required by this Paragraph for 10 years following the procedure and provide these records to the Board upon request.

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

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

History Note: Authority G.S. 90-28; 90-30; 90-30.1; 90-39; 90-48; Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013; Amended Eff. June 1, 2017; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. August 1, 2024; August 1, 2018.

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

(a) Moderate conscious sedation permits and itinerant moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses. For each permit to be renewed, the permit holder shall pay a one-hundred dollar (\$100.00) fee and complete the renewal application requirements in this Rule. If the completed permit renewal application and renewal fee are not received before midnight on January 31 of each year, a fifty dollar (\$50.00) late fee shall be charged. The renewal application shall be submitted electronically through the Board's website, www.ncdentalboard.org, and shall include the information required by Rule .0102(e) of this Subchapter and a report of compliance with the conditions for renewal in Paragraph (d) of this Rule.

(b) Any permit holder who fails to renew a moderate conscious sedation permit or itinerant moderate conscious sedation permit before March 31 of each year shall complete a reinstatement application, pay the renewal fee and late fee set out in Paragraph (a) of this Rule, and comply with all conditions for renewal set out in this Rule. Dentists whose moderate conscious sedation permits or itinerant moderate conscious sedation permits have been lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process in accordance with Rules .0104 and .0306 of this Subchapter. All applicants for reinstatement of a permit shall be in good standing. All applications for reinstatement of a permit shall be submitted on forms furnished by the Board at www.ncdentalboard.org and shall include the information required by Rule .0102(f) of this Subchapter and a report of compliance with the conditions for renewal set out in Paragraph (d) of this Rule.

(c) 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.

(d) As a condition for renewal of the moderate conscious sedation permit and itinerant moderate conscious sedation permit, the permit holder shall meet the clinical and equipment requirements set out in Rules .0103 and .0302 of this Subchapter, the itinerant moderate conscious sedation permit holder shall also meet the clinical and equipment requirements set out in Rule .0304 of this Section, and the permit holder shall document the following:

- (1) six hours of continuing education each year in one or more of the following areas, which 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 (d)(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;

- (4) that the permit holder and all auxiliaries involved in sedation procedures have read the practice's emergency manual in the preceding year; and
- (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours of continuing education annually in any of the areas set forth in Subparagraph (d)(1) of this Rule.

(e) Absent a Board order stating otherwise, all permit holders applying for renewal of a moderate conscious sedation permit or itinerant moderate conscious sedation permit shall be in good standing and their office shall be subject to inspection by the Board.

History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39; 90-48; Eff. June 1, 2017; Amended Eff. August 1, 2024; August 1, 2021; August 1, 2018.

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 two-hundred seventy-five dollars (\$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'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. Except as set forth in subsection (h) of this Rule, 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) A permit applicant who has failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who has failed the written portion of the examination three times shall complete an additional Board approved course of study in the area(s) of deficiency and provide the Board evidence of the additional study before written reexamination.

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

(j) An applicant must complete all the requirements of Rules .0103, .0104, and .0302 of this Subchapter, including passing the written examination, evaluation and inspection, within 12 months of submitting the application to the Board.

History Note: Authority G.S. 90-30.1; 90-39; 90-48; Eff. April 1, 2016; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. August 1, 2024; February 1, 2019; August 1, 2018.

SECTION .0400 - PEDIATRIC MODERATE CONSCIOUS SEDATION

21 NCAC 16Q .0401 MINIMAL CONSCIOUS SEDATION CREDENTIALS, EVALUATION AND PERMIT (RECODIFIED TO 21 NCAC 16Q .0504 EFF. NOVEMBER 9, 2020)

21 NCAC 16Q .0402 MINIMAL CONSCIOUS SEDATION PERMIT REQUIREMENTS, CLINICAL PROVISIONS AND EQUIPMENT (RECODIFIED TO 21 NCAC 16Q .0505 EFF. NOVEMBER 9, 2020)

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

History Note: Authority G.S. 90-28; 90-30.1. Temporary Adoption Eff. March 13, 2003; December 11, 2002; Eff. August 1, 2004; Amended Eff. February 1, 2009; July 3, 2008; Repealed Eff. April 1, 2016.

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 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 hold an unexpired PALS certification and 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.

(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 Rules .0103 and .0405 of this Subchapter. 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, 2024; February 1, 2019; August 1, 2018.

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

(a) A dentist holding or applying for a permit to administer moderate pediatric conscious sedation shall be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) In addition to the requirements set out in Rule .0103(c)(4) of this Subchapter, the permit holder's emergency manual shall include assignments to be performed in the event of emergency by a BLS-certified auxiliary dedicated to patient monitoring.

(d) In addition to the requirements set out in Rule .0103(e) of this Subchapter concerning pre-operative procedures, the permit holder shall ensure that patients who have been administered moderate pediatric conscious sedation are monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures by the permit holder or an auxiliary dedicated to patient monitoring.

(e) As part of the pre-operative assessment required by Rule .0103(e) of this Subchapter, the permit holder shall evaluate the patient for health risks 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 the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

(f) If a patient immobilization device is used, the permit holder shall ensure that:

- (1) the device is applied to avoid airway obstruction or chest restriction;
- (2) the patient's head position and respiratory excursions are checked frequently to ensure airway patency;
- (3) a hand or foot is kept exposed; and
- (4) the patient is under observation by the permit holder or a BLS-certified auxiliary at all times.

(g) During the sedation procedure, a moderate pediatric conscious sedation permit holder shall not administer anesthetic or sedative agents:

- (1) designed by the manufacturer for use in administering general anesthesia or deep sedation;
- (2) determined by the manufacturer to be contraindicated for use in moderate pediatric conscious sedation; or
- (3) in amounts exceeding the manufacturers' maximum recommended dosages, unless the permit holder documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

(h) In addition to the requirements set out in Rule .0103(h) of this Subchapter concerning the patient treatment record, the permit holder shall maintain documentation of pre-sedation instructions and information provided to the patient or person responsible for the patient, which shall include:

- (1) objectives of the sedation;
- (2) anticipated changes in patient behavior during and after sedation;
- (3) instructions to the person responsible for a patient transported in a child safety seat regarding patient head position to avoid airway obstruction;
- (4) a 24-hour telephone number for the permit holder or his or her BLS-certified auxiliaries; and
- (5) instructions on limitations of activities and dietary precautions.

(i) For purposes of Rule .0104(b)(2) of this Subchapter, during an evaluation, a moderate pediatric conscious sedation permit holder or applicant shall demonstrate competency in the deployment of an intravenous delivery system as follows:

- (1) a permit holder or applicant who uses intravenous sedation shall demonstrate the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an intravenous delivery system; and
- (2) a permit holder or applicant who does not use intravenous sedation shall describe the proper deployment of an intravenous delivery system and shall demonstrate the administration of moderate pediatric conscious sedation on a live patient.

History Note: Authority G.S. 90-28; 90-30.1; 90-48; Eff. June 1, 2017; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. June 17, 2024; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0406 ITINERANT (MOBILE) MODERATE PEDIATRIC CONSCIOUS SEDATION PERMITS

(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 .0103 of this Subchapter.

(c) The unexpired medications required by Rules .0103 and .0405 of this Subchapter shall be 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 Rules .0104 and .0408 of this Subchapter.

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

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

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

History Note: Authority G.S. 90-28; 90-30.1; 90-48; Eff. June 1, 2017; Amended Eff. August 1, 2024; August 1, 2018.

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

(a) Moderate pediatric conscious sedation permits and itinerant moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses. For each permit to be renewed, the permit holder shall pay a one-hundred dollar (\$100.00) fee and complete the renewal application requirements in this Rule. If the completed renewal application and renewal fee are not received before midnight on January 31 of each year, a fifty dollar (\$50.00) late fee shall be charged. The renewal application shall be submitted electronically through the Board's website, www.ncdentalboard.org, and shall include the information required by Rule .0102(e) of this Subchapter and a report of compliance with the conditions for renewal in Paragraph (d) of this Rule.

(b) Any permit holder 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 and late fee set out in Paragraph (a) of this Rule, and comply with all conditions for renewal set out in Paragraphs (d) and (e) of this Rule. Dentists whose moderate pediatric conscious sedation permits or itinerant moderate pediatric conscious sedation permits have been lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process in accordance with Rules .0104 and .0408 of this

Subchapter. All applicants for reinstatement of a permit shall be in good standing. All applications for reinstatement of a permit shall be submitted on forms furnished by the Board at www.ncdentalboard.org and shall include the information required by Rule .0102(f) of this Subchapter and a report of compliance with the conditions for renewal set out in Paragraph (d) of this Rule.

(c) 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.

(d) As a condition for renewal of the moderate pediatric conscious sedation permit and itinerant moderate pediatric conscious sedation permit, the permit holder shall meet the clinical and equipment requirements of Rules .0103 and .0405 of this Subchapter, the itinerant moderate pediatric conscious sedation permit holder shall also meet the clinical and equipment requirements of Rule .0406 of this Section, and the permit holder shall document the following:

- (1) six hours of continuing education each year in one or more of the following areas, which 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 (d)(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;
- (4) that the permit holder and all auxiliaries involved in sedation procedures have read the practice's emergency manual in the preceding year; and
- (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours of continuing education annually in any of the areas set forth in Subparagraph (d)(1) of this Rule.

(e) Absent a Board order stating otherwise, all permit holders applying for renewal of a moderate pediatric conscious sedation permit or itinerant moderate pediatric conscious sedation permit shall be in good standing and their office shall be subject to inspection by the Board.

History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39; 90-48; Eff. June 1, 2017; Amended Eff. August 1, 2024; August 1, 2021; August 1, 2018.

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 two-hundred seventy-five dollars (\$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'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. Except as set forth in subsection (h) of this Rule, 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) A permit applicant who has failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who has failed the written portion of the examination three times shall complete an additional Board approved course of study in the area(s) of deficiency and provide the Board evidence of the additional study before written reexamination.

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

(j) An applicant must complete all the requirements of Rules .0103, .0104, and .0405 of this Subchapter, including passing the written examination, evaluation and inspection, within 12 months of submitting the application to the Board.

History Note: Authority G.S. 90-30.1; 90-39; 90-48; Eff. April 1, 2016; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. August 1, 2024; February 1, 2019; August 1, 2018.

SECTION .0500 - ENTERAL MINIMAL CONSCIOUS SEDATION

21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED

History Note: Authority G.S. 90-28; 90-30.1; 90-48; Eff. February 1, 1990; Amended Eff. August 1, 2002; Transferred and Recodified from 16Q .0401 to 16Q .0501; Temporary Amendment Eff. December 11, 2002; Amended Eff. November 1, 2013; July 3, 2008; August 1, 2004; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. August 1, 2018; Repealed Eff. February 1, 2019.

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.

21 NCAC 16Q .0503 INSPECTION AUTHORIZED (RECODIFIED TO 21 NCAC 16Q .0704 EFF. NOVEMBER 9, 2020)

21 NCAC 16Q .0504 MINIMAL CONSCIOUS SEDATION CREDENTIALS AND PERMIT

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a CRNA employed to administer or an RN employed to deliver minimal conscious sedation, the dentist shall obtain a Board-issued permit for minimal conscious sedation, moderate pediatric conscious sedation, moderate conscious sedation, or general anesthesia. A dentist may obtain a minimal 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 current renewal at all times in the facility of the permit holder where it is visible to patients receiving treatment.

(b) The minimal conscious sedation permit holder shall ensure the level of the sedation administered does not exceed minimal conscious sedation as defined in Rule .0101(27) of this Subchapter.

(c) An applicant for a minimal conscious sedation permit shall submit to the Board:

- (1) a completed application form provided by the Board at www.ncdentalboard.org that includes the information and materials required by Rule .0102(b) and (c) of this Subchapter;
- (2) a copy of an unexpired ACLS certification; and
- (3) documentation showing completion of one of the following:
 - (A) an 18-hour minimal conscious sedation course from the list, available on the Board's website, of sedation courses reviewed at any public Board meeting and approved by a majority of the Board based on its collective experience; or
 - (B) a post-doctoral program accredited by the Commission on Dental Accreditation (CODA) that provides training in administering and managing minimal conscious sedation. A list of CODA-accredited programs is available at no cost at www.ada.org/coda and is incorporated by reference, including subsequent amendments and editions.

(d) Prior to issuance of a minimal conscious sedation permit, the applicant shall pass an evaluation and facility inspection in accordance with Rules .0505 and .0507 of this Section.

(e) An applicant shall submit the fee set out in Paragraph (a) and satisfy all requirements in Paragraphs (c) and (d) of this Rule for the application to be complete. Applications that are not completed within one year of being submitted to the Board shall be disregarded without a refund of the fee.

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

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

Temporary Adoption Eff. March 13, 2003; December 11, 2002; Eff. August 1, 2004; Amended Eff. July 3, 2008; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. February 1, 2019; Recodified from 21 NCAC 16Q .0401 Eff. November 9, 2020; Amended Eff. August 1, 2021.

21 NCAC 16Q .0505 MINIMAL CONSCIOUS SEDATION CLINICAL REQUIREMENTS AND EQUIPMENT

(a) A permit holder administering minimal conscious sedation or supervising a CRNA employed to administer or RN employed to deliver minimal conscious sedation shall 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;
- (G) blood pressure monitoring device;
- (H) pulse oximeter;
- (I) automatic external defibrillator (AED);
- (J) thermometer;
- (K) tonsillar suction with back-up suction; and

- (L) syringes as necessary for specific procedures.
- (2) The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:
 - (A) epinephrine;
 - (B) oral antihistamine;
 - (C) bronchodilator;
 - (D) antihypoglycemic agent;
 - (E) appropriate reversal agents; and
 - (F) nitroglycerine.
- (3) The permit holder shall maintain written emergency and patient discharge protocols. The permit holder shall also provide training to familiarize auxiliaries in the treatment of clinical emergencies.
- (4) The permit holder shall maintain the following records 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; 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, pulse and respiration rates of the patient recorded in real time at 15-minute intervals;
 - (B) procedure start and end times;
 - (C) status of patient upon discharge;
 - (D) documentation of complications or morbidity; and
 - (E) a consent form, signed by the patient or guardian, identifying the procedure, risks and benefits, level of sedation, and date signed.
- (6) During a sedation procedure, the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be involved in patient monitoring. This Subparagraph shall not apply if the 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.

(b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of minimal sedation on a patient while the evaluator observes. During the demonstration, the applicant or permit holder shall demonstrate competency in the following areas:

- (1) monitoring blood pressure, pulse, pulse oximetry, and respiration;
- (2) drug dosage and administration;
- (3) treatment of untoward reactions, including respiratory or cardiac depression if applicable;
- (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 demonstrate competency to the evaluator 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) allergic reactions;
- (9) convulsions;
- (10) syncope;
- (11) bradycardia;
- (12) hypoglycemia;
- (13) cardiac arrest; and
- (14) airway obstruction.

(d) During the evaluation, the applicant shall take a written examination on the topics set forth in Paragraphs (b) and (c) of this Rule. The applicant must obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the applicant fails to obtain a passing score on the written examination that is administered during the evaluation, he or she may be reexamined in accordance with Rule .0507(h) of this Section.

(e) A minimal conscious sedation permit holder shall evaluate each patient for health risks before starting any sedation procedure as follows:

- (1) The permit holder shall review the patient's current medical history and medication use and, if the permit holder considers it clinically necessary, the permit holder shall consult with the patient's treating medical provider.
- (2) A patient who is not medically stable or who is ASA III or higher shall be evaluated further by the permit holder's consultation with the patient's treating primary care physician or medical specialist regarding the potential risks posed by the procedure the permit holder plans to perform.
- (f) Post-operative monitoring and discharge:
 - (1) The permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined in Subparagraph (f)(2) of this Rule and is ready for discharge from the office.
 - (2) Recovery from minimal 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 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.
 - (3) Prior to allowing the patient to leave the office, the permit holder shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(2) of this Rule and the following discharge criteria:
 - (A) oxygenation, circulation, activity, skin color, and level of consciousness are stable and have been documented;
 - (B) explanation and documentation of written postoperative instructions have been provided to the patient or a person responsible for the patient at the time of discharge; and
 - (C) a person authorized by the patient is available to transport the patient after discharge.

History Note: Authority G.S. 90-28; 90-30.1; Temporary Adoption Eff. December 11, 2002; Eff. August 1, 2004; Amended Eff. July 3, 2008; Readopted Eff. February 1, 2019; Recodified from 21 NCAC 16Q .0402 Eff. November 9, 2020; Amended Eff. August 1, 2021.

21 NCAC 16Q .0506 ANNUAL RENEWAL OF MINIMAL CONSCIOUS SEDATION PERMIT REQUIRED

(a) Minimal conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by the permit holder paying a renewal fee of one hundred dollars (\$100.00) and completing the renewal application requirements of this Rule. If the completed permit renewal application and renewal fee are not received in the Board's office before midnight on January 31 of each year, a fifty dollar (\$50.00) late fee shall be charged. The renewal application shall be submitted electronically through the Board's website, www.ncdentalboard.org, and shall include the information required by Rule .0102(e) of this Subchapter and a report of compliance with the conditions for renewal in Paragraph (d) of this Rule.

(b) Any permit holder who fails to renew a minimal conscious sedation permit before midnight on March 31 of each year shall complete a reinstatement application, pay the renewal fee and late fee set out in Paragraph (a), and comply with all conditions for renewal set out 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 in accordance with Rules .0505 and .0507 of this Section. All applicants for reinstatement of a permit shall be in good standing. All applications for reinstatement of a permit shall be submitted on forms furnished by the Board at www.ncdentalboard.org and shall include the information required by Rule .0102(f) of this Subchapter and a report of compliance with the conditions for renewal set out in Paragraph (d) of this Rule.

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

(d) As a condition for renewal of the minimal conscious sedation permit, the permit holder shall meet the clinical and equipment requirements of Rule .0505 of this Section and shall document the following:

- (1) three hours of continuing education each year in one or more of the following areas, which shall be counted toward fulfillment of the continuing education required each calendar year for license renewal:
 - (A) sedation;
 - (B) medical emergencies;
 - (C) monitoring sedation and the use of monitoring equipment;
 - (D) pharmacology of drugs and agents used in sedation;
 - (E) physical evaluation, risk assessment, or behavioral management; or
 - (F) airway management;
- (2) unexpired ACLS certification, which shall not count towards the three hours of continuing education required in Subparagraph (d)(1) of this Rule;
- (3) that the permit holder and all auxiliaries involved in sedation procedures have read the practice's emergency manual in the preceding year; and
- (4) that all auxiliaries involved in sedation procedures have completed BLS certification and, within the past two years, completed three hours of continuing education in any of the areas set forth in Subparagraph (d)(1) of this Rule.

(e) Absent a Board order stating otherwise, all permit holders applying for renewal of a minimal conscious sedation permit shall be in good standing and their office shall be subject to inspection as set out in Rule .0507 of this Section.

History Note: Authority G.S. 90-30.1; 90-31; 90-39; Eff. August 1, 2021.

21 NCAC 16Q .0507 PROCEDURE FOR MINIMAL 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 persons to serve as evaluators, each of whom has administered sedation or general anesthesia in accordance with this Subchapter for at least three years preceding the inspection. Training in minimal conscious sedation or other levels of sedation shall not be counted in the three years.

(b) The inspection fee set out in Rule .0504(a) of this Section shall be paid no later than 10 days after the applicant or permit holder receives notice of the inspection for each additional location at which the applicant or permit holder administers minimal conscious sedation.

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

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

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

(f) An applicant who fails an inspection or evaluation shall not receive a permit to administer minimal conscious sedation. If a permit holder's facility fails an inspection, no further minimal conscious sedation procedures shall be performed at the facility until it passes a re-inspection by the Board.

(g) An applicant or permit holder 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. Except as set forth in Paragraph (h) of this Rule, the Board shall require the applicant or permit holder 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) An applicant who failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who failed the written portion of the examination three times shall complete an additional Board-approved course of study in the areas of deficiency and provide the Board evidence of the additional study before written reexamination.

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

(j) An applicant must satisfy all the requirements of Rule .0505 of this Section, including passing the written examination, evaluation, and inspection, within 12 months of submitting the application to the Board.

History Note: Authority G.S. 90-30.1; 90-39; Eff. August 1, 2021.

SECTION .0600 - REPORTING AND PENALTIES

21 NCAC 16Q .0601REPORTS OF ADVERSE OCCURRENCES21 NCAC 16Q .0602FAILURE TO REPORT

History Note: Authority G.S. 90-28; 90-30.1; 90-41; Eff. February 1, 1990; Transferred and Recodified from 16Q .0501 to 16Q .0601; Transferred and Recodified from 16Q .0502 to 16Q .0602; Temporary Amendment Eff. December 11, 2002; Amended Eff. August 1, 2004; Repealed Eff. April 1, 2016.

SECTION .0700 - COMPLIANCE AND REPORTING

21 NCAC 16Q .0701 FAILURE TO COMPLY

(a) Failure to comply with the provisions of this Subchapter may result in suspension or revocation of the general anesthesia or sedation permit and the dentist's license to practice dentistry in accordance with G.S. 90-41.

- (b) Absent a Board order stating otherwise, a dentist whose permit has been revoked shall not be eligible to:
 - (1) apply for reinstatement of the permit for a period of one year after the effective date of the revocation; or
 - (2) re-apply for reinstatement of the permit for a period of one year after the Board's denial of the applicant's previous application for reinstatement.

(c) An application for permit reinstatement that is received before the applicant is eligible to apply pursuant to Paragraph (b) of this Rule shall be disregarded without a refund of the application fees.

History Note: Authority G.S. 90-28; 90-30.1; 90-41; 90-48; Eff. February 1, 1990; Transferred and Recodified from 16Q .0601 to 16Q .0701; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. June 1, 2025.

21 NCAC 16Q .0703 REPORTS OF ADVERSE OCCURRENCES

(a) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board within 72 hours after each adverse occurrence if the patient dies or has permanent organic brain dysfunction within 24 hours after the administration of general anesthesia or sedation. Sedation permit holders shall cease administration of sedation until the Board has investigated the death or permanent organic brain dysfunction and approved resumption of permit privileges. General anesthesia permit holders shall cease administration of general anesthesia and sedation until the Board has reviewed the adverse occurrence report and approved resumption of permit privileges.

(b) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board within 30 days after each adverse occurrence if the patient is admitted to a hospital on inpatient status for a medical emergency or physical injury within 24 hours after the administration of general anesthesia or sedation.

(c) The adverse occurrence report shall be in writing and shall include the following:

- (1) dentist's name, license number and permit number;
- (2) date and time of the occurrence;
- (3) facility where the occurrence took place;
- (4) name and address of the patient;
- (5) surgical procedure involved;
- (6) type and dosage of sedation or anesthesia utilized in the procedure;
- (7) circumstances involved in the occurrence; and
- (8) the entire patient treatment record including anesthesia records.

(d) Upon receipt of any report submitted pursuant to this Rule, the Board shall investigate and shall take disciplinary action if the evidence demonstrates that a licensee has violated the Dental Practice Act set forth in Article 2 of Chapter 90 of the General Statutes or the rules of this Chapter.

History Note: Authority G.S. 90-28; 90-30.1; 90-41; 90-48; Eff. April 1, 2016; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. June 17, 2024.

21 NCAC 16Q .0704 INSPECTION AUTHORIZED

Incident to the renewal of an anesthesia or sedation permit or any itinerant permit, or incident to an investigation pursuant to 21 NCAC 16U, the Board may require an on-site inspection of the dentist's facility, equipment, personnel, and procedures. The inspection shall be conducted in accordance with the rules and requirements of this Subchapter applicable to the type of permit.

History Note: Authority G.S. 90-28; 90-30.1; Eff. February 1, 1990; Amended Eff. January 1, 1994; Transferred and Recodified from 16Q .0403 to 16Q .0503; Temporary Amendment Eff. December 11, 2002; Amended Eff. August 1, 2004; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018; Amended Eff. August 1, 2018; Recodified from 21 NCAC 16Q .0503 Eff. November 9, 2020; Amended Eff. July 1, 2022.