

SUBCHAPTER 16Q - GENERAL ANESTHESIA AND SEDATION

SECTION .0100 – DEFINITIONS

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.

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 .0202 of this Section. 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 Rule .0202 of this Section 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.

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

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

- (1) The facility shall be equipped with the following:
 - (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
 - (B) a CPR board or dental chair without enhancements, suitable for providing emergency treatment;
 - (C) lighting as necessary for specific procedures and back-up lighting; and
 - (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
 - (E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients, and back-up E-cylinder portable oxygen tank apart from the central system;
 - (F) small, medium, and large oral and nasal airways;
 - (G) blood pressure monitoring device;
 - (H) EKG monitor; electrocardiograph;
 - (I) pulse oximeter;
 - (J) defibrillator;
 - (K) precordial stethoscope or capnograph;
 - (L) thermometer;
 - (M) vascular access as necessary for specific procedures, including hardware and fluids;
 - (N) laryngoscope with working batteries;
 - (O) intubation forceps and advanced airway devices;
 - (P) tonsillar suction with back-up suction;
 - (Q) syringes as necessary for specific procedures; and
 - (R) tourniquet and tape.
- (2) The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:
 - (A) Epinephrine;
 - (B) Atropine;
 - (C) antiarrhythmic;
 - (D) antihistamine;
 - (E) antihypertensive;
 - (F) bronchodilator;
 - (G) antihypoglycemic agent;
 - (H) vasopressor;
 - (I) corticosteroid;
 - (J) anticonvulsant;
 - (K) muscle relaxant;
 - (L) appropriate reversal agents;
 - (M) nitroglycerine; and
 - (N) antiemetic.
- (3) The permit holder shall maintain written emergency and patient discharge protocols and training to familiarize auxiliaries in the treatment of clinical emergencies shall be provided;
- (4) The permit holder shall maintain the following records for 10 years:
 - (A) Patient's current written medical history, including a record of known allergies and previous surgeries;
 - (B) Consent to general anesthesia, signed by the patient or guardian, identifying the risks and benefits, level of anesthesia, and date signed;
 - (C) Consent to the procedure, signed by the patient or guardian identifying the risks, benefits, and date signed; and
 - (D) Patient base line vital signs, including temperature, SPO2, blood pressure, and pulse;
- (5) The anesthesia record shall include:

- (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO₂ if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
 - (B) procedure start and end times;
 - (C) gauge of needle and location of IV on the patient, if used;
 - (D) status of patient upon discharge; and
 - (E) documentation of complications or morbidity; and
- (6) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other dental procedure.
- (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of anesthesia while the evaluator observes, and shall demonstrate competency in the following areas:
- (1) monitoring of blood pressure, pulse, ET CO₂ if capnography is utilized, and respiration;
 - (2) drug dosage and administration;
 - (3) treatment of untoward reactions including respiratory or cardiac depression;
 - (4) sterile technique;
 - (5) use of BLS certified auxiliaries;
 - (6) monitoring of patient during recovery; and
 - (7) sufficiency of patient recovery time.
- (c) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the treatment of the following clinical emergencies:
- (1) laryngospasm;
 - (2) bronchospasm;
 - (3) emesis and aspiration;
 - (4) respiratory depression and arrest;
 - (5) angina pectoris;
 - (6) myocardial infarction;
 - (7) hypertension and hypotension;
 - (8) syncope;
 - (9) allergic reactions;
 - (10) convulsions;
 - (11) bradycardia;
 - (12) hypoglycemia;
 - (13) cardiac arrest; and
 - (14) airway obstruction.
- (d) A general anesthesia permit holder shall evaluate a patient for health risks before starting any anesthesia procedure.
- (e) Post-operative monitoring and discharge shall include the following:
- (1) vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is recovered as defined by Subparagraph (e)(2) of this Rule and is ready for discharge from the office; and
 - (2) recovery from general anesthesia shall include documentation of the following:
 - (A) cardiovascular function stable;
 - (B) airway patency uncompromised;
 - (C) patient arousable and protective reflexes intact;
 - (D) state of hydration within normal limits;
 - (E) patient can talk, if applicable;
 - (F) patient can sit unaided, if applicable;
 - (G) patient can ambulate, if applicable, with minimal assistance; and
 - (H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved; and

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

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.

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 an evaluation or 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. 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.
- (b) An inspection fee of three hundred seventy five dollars (\$375.00) 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 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 general anesthesia. If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B-3(c). If a permit holder's facility fails an inspection, no further anesthesia procedures shall be performed at the facility until it passes a re-inspection by the Board.
- (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall notify the applicant in writing of the need for additional training.
- (h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed evaluation or inspection.

History Note: Authority G.S. 90-28; 90-30.1; 90-39;
Eff. February 1, 1990;
Amended Eff. April 1, 2016.; February 1, 2009; December 4, 2002; January 1, 1994.

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 (\$100.00) application fee. No mobile permit shall be required to administer general anesthesia in a hospital or credentialed surgery center.

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

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

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

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

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

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

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

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

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

(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.

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

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

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

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

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

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

- (1) six hours of continuing education each year in one or more of the following areas, which may 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 required in Subparagraph (e)(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 (e)(1) of this Rule.

(f) All permit holders applying for renewal of a general anesthesia 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(12); 90-48;
Eff. June 1, 2017.

SECTION .0300 - PARENTERAL 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 dollars (\$375.00) fee that includes the one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. The permit shall be renewed annually and shall be displayed with the current renewal at all times in the facility of the permit holder where it is visible to patients receiving treatment.

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

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

- (1) Training which may consist of either:
 - (A) Completion of 60 hours of Board approved didactic training in intravenous conscious sedation, and 30 hours of clinical training that shall include successful management of a minimum of 20 live patients, under supervision of the course instructor, using intravenous sedation. Training shall be provided by one or more individuals who meet the American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists that is hereby incorporated by reference, including subsequent amendments and editions. The guidelines may be found at www.ada.org/coda; or
 - (B) Completion of a pre-doctoral dental or postgraduate program that included intravenous conscious sedation training equivalent to that defined in Part (c)(1)(A) of this Rule;
- (2) Unexpired ACLS certification; and
- (3) That all auxiliaries involved in sedation procedures have unexpired BLS certification.

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

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

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

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

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

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

- (1) The facility shall be equipped with the following:
 - (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
 - (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
 - (C) lighting as necessary for specific procedures and back-up lighting; and
 - (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
 - (E) positive 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) EKG monitor;
 - (K) precordial stethoscope or capnograph;
 - (L) thermometer;
 - (M) vascular access set-up as necessary for specific procedures, including hardware and fluids;
 - (N) syringes as necessary for specific procedures;
 - (O) tourniquet and tape;
 - (P) advanced airway devices; and
 - (Q) tonsillar suction with back-up suction.
- (2) The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:
 - (A) injectable epinephrine;
 - (B) injectable Atropine;
 - (C) injectable appropriate reversal agents;
 - (D) injectable antihistamine;
 - (E) injectable corticosteroid;
 - (F) nitroglycerine;
 - (G) bronchodilator;
 - (H) injectable antiemetic;
 - (I) Dextrose; and
 - (J) injectable anti-arrhythmic.
- (3) The permit holder shall maintain written emergency and patient discharge protocols and training to familiarize auxiliaries in the treatment of clinical emergencies shall be provided; and
- (4) The dentist shall maintain the following records for at least 10 years:
 - (A) Patient's current written medical history and pre-operative assessment; and
 - (B) Drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration.
- (5) The sedation record shall include:
 - (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO₂ if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
 - (B) procedure start and end times;
 - (C) gauge of needle and location of IV on the patient, if used;
 - (D) status of patient upon discharge;
 - (E) documentation of complications or morbidity; and
 - (F) consent form, signed by the patient or guardian, identifying the procedure, risks and benefits, level of sedation, and date signed.
- (6) The following conditions shall be satisfied during a sedation procedure:

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

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

- (1) monitoring blood pressure, pulse, ET CO₂ if capnography is utilized, and respiration;
- (2) drug dosage and administration;
- (3) treatment of untoward reactions including respiratory or cardiac depression 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 verbally 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) A moderate conscious sedation permit holder shall evaluate a patient for health risks before starting any sedation procedure as follows:

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

(e) Post-operative monitoring and discharge:

- (1) vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is recovered as defined in Subparagraph (e)(2) of this Rule and is ready for discharge from the office.
- (2) recovery from moderate 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 special needs patients or patients 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) before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (e)(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 responsible adult at time of discharge; and
 - (C) a vested adult is available to transport the patient after discharge.

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.

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 OFF SITE USE OF MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION PERMITS

The holder of a moderate conscious sedation permit may travel to the office of a licensed dentist and provide moderate conscious sedation for the patients of that dentist who are undergoing dental procedures. The permit holder shall be responsible to ensure that the facility where the sedation is administered has passed inspection by the Board and meets the requirements set out in Rule .0302 of this Section. The permit holder shall be responsible to ensure that the facility is staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other dental procedure.

History Note: Authority G.S. 90-28; 90-30; 90-30.1; 90-48;
 Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013;
 Amended Eff. June 1, 2017.

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

- (a) Moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by paying a one hundred dollar (\$100.00) fee and completing the application requirements in this Rule.
- (b) If the completed permit renewal application and renewal fee are not received before January 31 of each year, a one hundred dollar (\$100.00) late fee shall be paid.
- (c) Any dentist who fails to renew a moderate conscious sedation permit before March 31 of each year shall complete a reinstatement application, pay the renewal fee, late fee, and comply with all conditions for renewal set out in this Rule. Dentists whose sedation permits have been lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process.
- (d) A dentist who administers moderate conscious sedation in violation of this Rule shall be subject to the penalties prescribed by Rule .0701 of this Subchapter.
- (e) As a condition for renewal of the moderate conscious sedation permit, the permit holder shall meet the clinical and equipment requirements of Rule .0302 of this Section and shall document the following:

- (1) six hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:
 - (A) sedation;
 - (B) medical emergencies;
 - (C) monitoring IV sedation and the use of monitoring equipment;
 - (D) pharmacology of drugs and agents used in IV sedation;
 - (E) physical evaluation, risk assessment, or behavioral management; or
 - (F) airway management;
- (2) unexpired ACLS certification, which shall not count towards the six hours of continuing education required in Subparagraph (e)(1) Rule;
- (3) that the permit holder and all auxiliaries involved in sedation procedures have practiced responding to dental emergencies as a team at least once every six months in the preceding year;
- (4) that the permit holder and all auxiliaries involved in sedation procedures have read the practice's emergency manual in the preceding year; and
- (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 (e)(1) of this Rule.

(f) All permit holders applying for renewal of a 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(12); 90-48;
Eff. June 1, 2017.

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

- (a) When an evaluation or on-site inspection is required, the Board shall designate one or more qualified persons to serve as evaluators each of whom has administered moderate conscious sedation for at least three years preceding the inspection. Training in moderate conscious sedation shall not be counted in the three years.
- (b) An inspection fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the dentist receives notice of the inspection of each additional location at which the dentist administers moderate conscious sedation.
- (c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.
- (d) The inspection team shall determine compliance with the requirements of the rules in this Subchapter, as applicable, by assigning a grade of "pass" or "fail."
- (e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The Committee shall determine whether the applicant has passed the evaluation or inspection and shall notify the applicant in writing of its decision.
- (f) An applicant who fails an inspection or evaluation shall not receive a permit to administer moderate conscious sedation. If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B-3(c). If a permit holder's facility fails an inspection, no further sedation procedures shall be performed at the facility until it passes a re-inspection by the Board.
- (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall notify the applicant in writing of the need for additional training.
- (h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed evaluation or inspection.

History Note: Authority G.S. 90-30.1; 90-39; 90-48;
Eff April 1, 2016.

SECTION .0400 - ENTERAL CONSCIOUS SEDATION

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

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

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

(c) Application:

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

(d) Evaluation:

- (1) Prior to issuance of a minimal conscious sedation permit the applicant shall undergo a facility inspection. The Board shall direct an evaluator qualified to administer minimal sedation to perform this inspection. The applicant shall be notified in writing that an inspection is required and provided with the name of the evaluator who shall perform the inspection. The applicant shall be responsible for successful completion of inspection of his or her facility within three months of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one.
- (2) During an inspection or evaluation, the applicant or permit holder shall demonstrate competency in the following areas:
 - (A) Monitoring of blood pressure, pulse, pulse oximetry and respiration;
 - (B) Drug dosage and administration (by verbal demonstration);
 - (C) Treatment of untoward reactions including respiratory or cardiac depression (by verbal demonstration);
 - (D) Sterilization;
 - (E) Use of CPR certified personnel;
 - (F) Monitoring of patient during recovery (by verbal demonstration); and
 - (G) Sufficiency of patient recovery time (by verbal demonstration).
- (3) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to the evaluator in the treatment of the following clinical emergencies:
 - (A) Laryngospasm;
 - (B) Bronchospasm;
 - (C) Emesis and aspiration;
 - (D) Respiratory depression and arrest;
 - (E) Angina pectoris;
 - (F) Myocardial infarction;
 - (G) Hypertension/Hypotension;
 - (H) Syncope;
 - (I) Allergic reactions;
 - (J) Convulsions;
 - (K) Bradycardia;
 - (L) Insulin shock; and
 - (M) Cardiac arrest.
- (4) The evaluator shall assign a grade of pass or fail and shall report his recommendation to the Board, setting out the basis for his conclusion. The Board is not bound by the evaluator's

recommendation and shall make a final determination regarding whether the applicant has passed the evaluation. The applicant shall be notified of the Board's decision in writing.

(e) Educational/Professional Requirements:

- (1) The dentist applying for a minimal conscious sedation permit shall meet one of the following criteria:
 - (A) successful completion of training consistent with that described in Part I or Part III of the American Dental Association (ADA) Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, and have documented administration of minimal conscious sedation in a minimum of five cases;
 - (B) successful completion of an ADA accredited post-doctoral training program which affords comprehensive training necessary to administer and manage minimal conscious sedation;
 - (C) successful completion of an 18-hour minimal conscious sedation course which must be approved by the Board based on whether it affords comprehensive training necessary to administer and manage minimal conscious sedation;
 - (D) successful completion of an ADA accredited postgraduate program in pediatric dentistry; or
 - (E) is a North Carolina licensed dentist in good standing who has been using minimal conscious sedation in a competent manner for at least one year immediately preceding October 1, 2007 and his or her office facility has passed an on-site inspection by a Board evaluator as required in Paragraph (d) of this Rule. Competency shall be determined by presentation of successful administration of minimal conscious sedation in a minimum of five clinical cases.
- (2) All applicants for a minimal sedation permit must document successful completion of a Basic Life Saving (BLS) course within the 12 months prior to the date of application.

*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. July 3, 2008.*

21 NCAC 16Q .0402 MINIMAL CONSCIOUS SEDATION PERMIT REQUIREMENTS, CLINICAL PROVISIONS AND EQUIPMENT

- (a) Minimal conscious sedation is indicated for use only as defined in Rule .0101(15) of this Subchapter (relating to Definitions). Minimal conscious sedation is not indicated for use to achieve deep sedation.
- (b) A minimal conscious sedation permit is not required for minor psychosedatives used for anxiolysis prescribed for administration outside of the dental office when pre-procedure instructions are likely to be followed. Medication administered for the purpose of minimal conscious sedation shall not exceed the maximum doses recommended by the drug manufacturer, sedation textbooks, or juried sedation journals. Except for nitrous inhalation, drugs in combination are not permitted for minimal conscious sedation. During longer periods of minimal conscious sedation, in which the amount of time of the procedures exceeds the effective duration of the sedative effect of the drug used, the incremental doses of the sedative shall not exceed total safe dosage levels based on the effective half-life of the drug used.
- (c) Each dentist shall:
 - (1) adhere to the clinical requirements as detailed in Paragraph (e) of this Rule;
 - (2) maintain under continuous direct supervision any auxiliary personnel, who shall be capable of assisting in procedures, problems, and emergencies incident to the use of minimal conscious sedation or secondary to an unexpected medical complication;
 - (3) utilize sufficient auxiliary personnel for each procedure performed who shall document annual successful completion of basic life support training; and
 - (4) not allow a minimal conscious sedation procedure to be performed in his or her office by a Certified Registered Nurse Anesthetist (CRNA) unless the dentist holds a permit issued by the Board for the procedure being performed. This provision addresses dentists and is not intended to address the scope of practice of persons licensed by any other agency.
- (d) Each dentist shall meet the following requirements:

- (1) Patient Evaluation. Patients who are administered minimal conscious sedation must be evaluated for medical health risks prior to the start of any sedative procedure. A patient receiving minimal conscious sedation must be healthy or medically stable (ASA I, or ASA II as defined by the American Society of Anesthesiologists). An evaluation is a review of the patient's current medical history and medication use. However, for individuals who are not medically stable or who have a significant health disability Physical Status III (ASA III, as defined by the American Society of Anesthesiologists) a consultation with their primary care physician or consulting medical specialist regarding potential procedure risk is required.
 - (2) Pre-procedure preparation, informed consent:
 - (A) The patient or guardian must be advised of the procedure associated with the delivery of the minimal conscious sedation.
 - (B) Equipment must be evaluated and maintained for proper operation.
 - (C) Baseline vital signs shall be obtained at the discretion of the operator depending on the medical status of the patient and the nature of the procedure to be performed.
 - (D) Dentists administering minimal conscious sedation shall use sedative agents that he/she is competent to administer and shall administer such agents in a manner that is within the standard of care.
- (e) Patient monitoring:
- (1) Patients who have been administered minimal conscious sedation shall be monitored during waiting periods prior to operative procedures. An adult who has accepted responsibility for the patient and been given written pre-procedural instruction may provide such monitoring. The patient shall be monitored for alertness, responsiveness, breathing and skin coloration.
 - (2) Dentists administering minimal conscious sedation shall maintain direct supervision of the patient during the operative procedure and for such a period of time necessary to establish pharmacologic and physiologic vital sign stability.
 - (A) Oxygenation. Color of mucosa, skin or blood shall be continually evaluated. Oxygen saturation shall be evaluated continuously by pulse oximetry, except as provided in Paragraph (e)(4) of this Rule.
 - (B) Ventilation. Observation of chest excursions or auscultation of breath sounds or both shall be performed.
 - (C) Circulation. Blood pressure and pulse shall be taken and recorded initially and thereafter as appropriate except as provided in Paragraph (e)(4) of this Rule.
 - (D) AED. Dentists administering minimal conscious sedation shall maintain a functioning automatic external defibrillator (AED).
 - (3) An appropriate time oriented anesthetic record of vital signs shall be maintained in the permanent record including documentation of individual(s) administering the drug and showing the name of drug, strength and dosage used.
 - (4) If the dentist responsible for administering minimal conscious sedation must deviate from the requirements set out in this Rule, he or she shall document the occurrence of such deviation and the reasons for such deviation.
- (f) Post-operative procedures:
- (1) Following the operative procedure, positive pressure oxygen and suction equipment shall be immediately available in the recovery area or operatory.
 - (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is sufficiently responsive for discharge from the office.
 - (3) Patients who have adverse reactions to minimal conscious sedation shall be assisted and monitored either in an operatory chair or recovery area until stable for discharge.
 - (4) Recovery from minimal conscious sedation shall include:
 - (A) cardiovascular function stable;
 - (B) airway patency uncompromised;
 - (C) patient easily arousable and protective reflexes intact;
 - (D) state of hydration within normal limits;
 - (E) patient can talk, if applicable;
 - (F) patient can sit unaided, if applicable;
 - (G) patient can ambulate, if applicable, with minimal assistance; and

- (H) for the patient who is disabled, or incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.
- (5) Prior to allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Paragraph (f)(4) of this Rule and the following discharge criteria:
 - (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and stable and have been documented;
 - (B) explanation and documentation of written postoperative instructions have been provided to the patient or a responsible adult at time of discharge;
 - (C) responsible individual is available for the patient to transport the patient after discharge;
 - (D) A vested adult must be available to transport patients for whom a motor vehicle restraint system is required and an additional responsible individual must be available to attend to the patients.
- (g) The dentist, personnel and facility shall be prepared to treat emergencies that may arise from the administration of minimal conscious sedation, and shall have the ability to provide positive pressure ventilation with 100% oxygen with an age appropriate device.

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

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 unexpired renewal at all times in the permit holder's facility where it is visible to patients receiving treatment.
- (b) A dentist applying for a permit to administer moderate pediatric conscious sedation shall meet at least one of the following criteria:
 - (1) completion of a postgraduate program that included pediatric intravenous conscious sedation training;
 - (2) completion of a Commission On Dental Accreditation (CODA) approved pediatric residency that included intravenous conscious sedation training; or
 - (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that includes training in the use and placement of IVs or intraosseous vascular access. A list of CODA approved institutions that is hereby incorporated by reference, including subsequent amendments and editions, appears at www.ada.org/coda and is available at no cost.
- (c) All applicants for moderate pediatric conscious sedation permits shall have completed the training required by Paragraph (b) of this Rule within the last two years or show evidence of moderate pediatric conscious sedation practice within the last two years in another state or U.S. Territory.
- (d) All applicants for moderate pediatric conscious sedation permits shall be in good standing with the Board.

History Note: Authority G.S. 90-30.1; 90-39; 90-48;
Eff. June 1, 2017.

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

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

- (1) The facility shall be equipped with the following:
 - (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
 - (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
 - (C) lighting as necessary for specific procedures and back-up lighting;
 - (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
 - (E) positive 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) oral and nasal airways of various sizes;
 - (G) blood pressure monitoring device;
 - (H) pulse oximeter;
 - (I) precordial stethoscope or capnograph;
 - (J) defibrillator;
 - (K) EKG monitor;
 - (L) thermometer;
 - (M) vascular access set-up as necessary for specific procedures, including hardware and fluids;
 - (N) syringes as necessary for specific procedures;
 - (O) advanced airways; and
 - (P) tourniquet and tape.
- (2) The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:
 - (A) epinephrine;
 - (B) Atropine;
 - (C) appropriate reversal agents;
 - (D) antihistamine;
 - (E) corticosteroid;
 - (F) nitroglycerine;
 - (G) bronchodilator;
 - (H) antiemetic; and
 - (I) Dextrose.
- (3) The permit holder shall maintain written emergency and patient discharge protocols and training to familiarize auxiliaries in the treatment of clinical emergencies shall be provided;
- (4) The following records are maintained for at least 10 years:
 - (A) patient's current written medical history and pre-operative assessment;
 - (B) drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration;
 - (C) a sedation record;
 - (D) a consent form, signed by the patient or a guardian, identifying the procedure, risks and benefits, level of sedation, and date signed.
- (5) The sedation record shall include:
 - (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO₂ if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
 - (B) procedure start and end times;
 - (C) gauge of needle and location of IV on the patient, if used;
 - (D) status of patient upon discharge; and
 - (E) documentation of complications or morbidity; and
- (6) The following conditions shall be satisfied during a sedation procedure:

- (A) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other dental procedure; and
- (B) when IV sedation is used, IV infusion shall be administered before the commencement of the procedure and maintained until the patient is ready for discharge.

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

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

- (1) monitoring blood pressure, pulse, 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.

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

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

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

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

(f) Patient monitoring:

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

- (A) cardiovascular function stable;
 - (B) airway patency uncompromised;
 - (C) patient arousable and protective reflexes intact;
 - (D) state of hydration within normal limits;
 - (E) patient can talk, if applicable;
 - (F) patient can sit unaided, if applicable;
 - (G) patient can ambulate, if applicable, with minimal assistance; and
 - (H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.
- (4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(3) of this Rule and the following discharge criteria:
- (A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient and stable, and have been documented;
 - (B) explanation and documentation of written postoperative instructions have been provided to a responsible adult at time of discharge;
 - (C) a vested adult is available to transport the patient after discharge; and
 - (D) a vested adult shall be available to transport patients for whom a motor vehicle restraint system is required and an additional responsible individual shall be available to attend to the patients.

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

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

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

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

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

- (a) Moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses by paying a one hundred (\$100.00) fee and completing the application requirements in this Rule.
- (b) If the completed renewal application and renewal fee are not received before January 31 of each year, a one hundred (\$100.00) late fee shall be paid.
- (c) Any dentist who fails to renew a moderate pediatric conscious sedation permit before March 31 of each year shall complete a reinstatement application, pay the renewal fee, late fee, and comply with all conditions for renewal set out in this Rule. Dentists whose sedation permits have been lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process.
- (d) A dentist who administers moderate pediatric conscious sedation in violation of this Rule shall be subject to the penalties prescribed by Rule .0701 of this Subchapter.
- (e) As a condition for renewal of the moderate pediatric conscious sedation permit, the permit holder shall meet the clinical and equipment requirements of Rule .0405 of this Section and shall document the following:
 - (1) six hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:
 - (A) sedation;
 - (B) medical emergencies;
 - (C) monitoring IV sedation and the use of monitoring equipment;
 - (D) pharmacology of drugs and agents used in IV sedation;

- (E) physical evaluation, risk assessment, or behavioral management; or
 - (F) airway management;
 - (2) unexpired PALS certification, which shall not count towards the six hours of continuing education required in Subparagraph (e)(1) of this rule;
 - (3) that the permit holder and all auxiliaries involved in sedation procedures have practiced responding to dental emergencies as a team at least once every six months in the preceding year.
 - (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 (e)(1) of this Rule.
- (f) All permit holders applying for renewal of a 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(12); 90-48;
Eff. June 1, 2017.

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

- (a) When an evaluation or on-site inspection is required, the Board shall designate one or more qualified persons to serve as evaluators, each of whom has administered moderate pediatric sedation for at least three years preceding the evaluation or inspection. Training in moderate pediatric sedation shall not count toward the three years.
- (b) An inspection fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the dentist receives notice of the inspection of each additional location at which the dentist administers moderate pediatric sedation.
- (c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.
- (d) The inspection team shall determine compliance with the requirements of the rules in this Subchapter, as applicable, by assigning a grade of "pass" or "fail."
- (e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The Committee shall determine whether the applicant has passed the evaluation or inspection and shall notify the applicant in writing of its decision.
- (f) An applicant who fails an inspection or evaluation shall not receive a permit to administer moderate pediatric sedation. If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B-3(c). If a permit holder's facility fails an inspection, no further sedation procedures shall be performed at the facility until it passes a re-inspection by the Board.
- (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall notify the applicant in writing of the need for additional training.
- (h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed evaluation or inspection.

History Note: Authority G.S. 90-30.1; 90-39; 90-48;
Eff. April 1, 2016.

SECTION .0500 - RENEWAL OF PERMITS

21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED

- (a) General anesthesia and all sedation permits shall be renewed by the Board annually. Such renewal shall be accomplished in conjunction with the license renewal process, and applications for permits shall be made at the same time as applications for renewal of licenses. A one hundred (\$100.00) annual renewal fee shall be paid at the time of renewal.
- (b) All sedation permits shall be subject to the same renewal deadlines as are dental practice licenses, in accordance with G.S. 90-31. If the permit renewal application is not received by the date specified in G.S. 90-31, continued

administration of general anesthesia or any level of conscious sedation shall be unlawful and shall subject the dentist to the penalties prescribed by Section .0700 of this Subchapter.

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

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

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

(e) moderate pediatric conscious sedation permit holders must have current PALS at all times.

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

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

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

*History Note: 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.*

21 NCAC 16Q .0502 PAYMENT OF FEES

A fee of fifty dollars (\$50.00) shall accompany the permit renewal application, such fee to be separate and apart from the annual license renewal fee imposed by the Board.

*History Note: Authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0402 to .0502.*

21 NCAC 16Q .0503 INSPECTION AUTHORIZED

Incident to the renewal of an anesthesia or sedation permit, for cause or routinely at reasonable time intervals in order to ensure compliance, the Board may require an on-site inspection of the dentist's facility, equipment, personnel and procedures. Such inspection shall be conducted in accordance with Rules .0204, .0205, .0303, and .0401 of this Subchapter.

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.

SECTION .0600 - REPORTING AND PENALTIES

21 NCAC 16Q .0601 REPORTS OF ADVERSE OCCURRENCES

21 NCAC 16Q .0602 FAILURE 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 - PENALTY FOR NON-COMPLIANCE

21 NCAC 16Q .0701 FAILURE TO COMPLY

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

History Note: Authority G.S. 90-28; 90-30.1; 90-41;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0601 to 16Q .0701.

21 NCAC 16Q .0703 REPORTS OF ADVERSE OCCURRENCES

(a) A dentist who holds a permit to administer general anesthesia or sedation shall report to the Board within 72 hours after each adverse occurrence related to the administration of general anesthesia or sedation that results in the death of a patient within 24 hours of the procedure. Sedation permit holders shall cease administration of sedation until the Board has investigated the death and approved resumption of permit privileges. General anesthesia permit holders shall cease administration of general anesthesia and sedation until the Board has reviewed the incident report and approved resumption of permit privileges.

(b) A dentist who holds a permit to administer general anesthesia or sedation shall report to the Board within 30 days after each adverse occurrence related to the administration of general anesthesia or sedation that results in permanent organic brain dysfunction of a patient occurring within 24 hours of the procedure or that results in physical injury or severe medical emergencies, causing hospitalization of a patient occurring within 24 hours of the procedure.

(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) anesthesia records.

(d) Upon receipt of any such report, 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 G.S. 90 or the Board's rules of this Chapter.

History Note: Authority G.S. 90-28; 90-30.1; 90-41; 90-48;
Eff. April 1, 2016.