NOTICE OF TEXT
[Authority G.S. 150B-21.2(c)]

OAH USE ONLY

VOLUME:

ISSUE:

CHECK APPROPRIATE BOX:

[X] **Notice with a scheduled hearing**

[ ] **Notice without a scheduled hearing**

[ ] **Republication of text. Complete the following cite for the volume and issue of previous publication, as well as blocks 1 - 4 and 7 - 14. If a hearing is scheduled, complete block 5.**
Previous publication of text was published in Volume: Issue:

1. Rule-Making Agency: Board of Dental Examiners

2. Link to agency website pursuant to G.S. 150B-19.1(c): www.ncdentalboard.org

3. Proposed Action -- Check the appropriate box(es) and list rule citation(s) beside proposed action:

[X] **ADOPTION:** 21 NCAC 16Q .0103-.0105, .0702

[X] **AMENDMENT:** 21 NCAC 16Q .0202, .0302, .0405, .0703

[ ] **REPEAL:**

[ ] **READOPTION with substantive changes:**

[ ] **READOPTION without substantive changes:**

[ ] **REPEAL through READOPTION:**

4. Proposed effective date: 05/01/2022

5. Is a public hearing planned? Yes

If yes:

Date	Time	Location
02/03/2022	6:30 p.m.	2000 Perimeter Park Drive, Suite 160, Morrisville, NC 27560

6. If no public hearing is scheduled, provide instructions on how to demand a public hearing:

7. Explain Reason For Proposed Rule(s):

21 NCAC 16Q .0103 is proposed to address the practice requirements for a permit holder to administer general anesthesia, moderate conscious sedation, and moderate pediatric conscious sedation.
21 NCAC 16Q .0104 is proposed to address requirements for facility inspections and evaluations.
21 NCAC 16Q .0105 is proposed to set out requirements related to dedicated sedation monitoring and sedation providers.
21 NCAC 16Q .0202 is proposed for amendment to set out modified requirements for a general anesthesia permit applicant or holder.
21 NCAC 16Q .0302 is proposed for amendment to set out modified requirements for a moderate conscious sedation permit applicant or holder.
21 NCAC 16Q .0405 is proposed for amendment to set out modified requirements for a moderate pediatric conscious sedation permit applicant or holder.
21 NCAC 16Q .0702 is proposed to address adverse event tracking.
21 NCAC 16Q .0703 is proposed for amendment to change requirements for adverse occurrence reporting.

8. Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or email. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Rule(s) is automatically subject to legislative review. Cite statutory reference:

9. The person to whom written comments may be submitted on the proposed rule(s):

Name: Bobby White
Address: 2000 Perimeter Park Drive, Suite 160
Morrisville, NC 27560
Phone (optional):
Fax (optional):
EMail (optional)

10. Comment Period Ends: 03/04/2022

11. Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

No fiscal note required

12. Rule-making Coordinator:

Name: Dauna L. Bartley
919-283-1390
dauna@brockerlawfirm.com

Agency contact, if any:

Name:
Phone:
Email:

13. The Agency formally proposed the text of this rule(s) on

Date: 11/12/2021

21 NCAC 16Q .0103 is proposed for adoption as follows:

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 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.

(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 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;

(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) a blood pressure monitoring device;

(H) an EKG monitor;

(I) a pulse oximeter;

(J) an automatic external defibrillator (AED);

(K) a capnograph;

(L) a thermometer;

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

(N) a 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 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 maintained in the facility 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;

(M) an antiemetic; and

(N) dextrose.

(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 those set out in Rule .0702(d) of this Subchapter, and shall review and practice responding to clinical emergencies with all auxiliaries as a team and in person every six months.

(2) All auxiliaries in the facility shall be BLS certified.

(3) Unless the permit holder 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 permit holder shall ensure that an auxiliary meeting the education and training requirements of this Subchapter is dedicated to patient monitoring and recording anesthesia or sedation data throughout the sedation procedure.

(4) The permit holder and any auxiliary dedicated to patient monitoring shall complete a training course every two years offered by a Board-approved continuing education course sponsor as set out in 21 NCAC 16R .0202, which the permit holder may apply toward fulfillment of the continuing education required each calendar year for license renewal, that includes the following topics:

(A) patient assessment and selection;

(B) appropriate medications and dosages, including those for moderate conscious sedation;

(C) proper patient monitoring;

(D) effective airway management; and

(E) recognizing, diagnosing, and effectively managing medical emergencies.

(5) The permit holder shall complete one hour of continuing education on substance abuse issues each calendar year, which the permit holder may apply toward fulfillment of the continuing education required for license renewal.

(6) 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:

(1) evaluate the patient for health risks as follows:

(A) 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

(B) 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;

(2) evaluate 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) perform a "time out" immediately prior to starting the sedation procedure, including verifying:

(A) correct patient;

(B) correct procedure;

(C) correct site;

(D) correct medication and dosage based on the patient's pertinent health history, medical conditions, and body mass index;

(E) availability of special equipment that may be needed; and

(F) necessary documentation in the treatment record as set out in Subparagraphs (h)(2) and (3) of this Rule.

(f) During the sedation procedure:

(1) The permit holder shall not administer or cause to be administered anesthetic or sedative agents in amounts exceeding the manufacturers' maximum recommended dosages.

(2) Prescriptions intended to accomplish procedural sedation, including enteral dosages, shall be administered only under the direct supervision of the permit holder.

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

(4) Capnography shall be used to monitor patients. The permit holder shall ensure the patient's base line vital signs are taken and recorded, including temperature, SPO2, blood pressure, and pulse. The permit holder shall ensure the patient's blood pressure, oxygen saturation, ET CO2, pulse, and respiration rates are monitored continuously and are recorded in intervals of five minutes or less during the procedure. All vital sign information monitored and recorded shall be printed, downloaded, or otherwise retained as part of the sedation record. A permit holder's failure to maintain the vital sign documentation produced by capnograph shall be deemed a failure to monitor the patient as required pursuant to the rules of this Subchapter.

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

(A) the device is applied to avoid airway obstruction or chest restriction;

(B) the patient's head position and respiratory excursions are checked frequently to ensure airway patency;

(C) a hand or foot is kept exposed; and

(D) the patient is attended at all times.

(6) The permit holder shall satisfy any additional requirements 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 signs 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, and for a patient for whom a motor vehicle restraint system is required, an additional responsible individual is available to attend to the patient.

(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 Subparagraphs (e)(1) and (2) 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) a copy or description of any prescription used for sedation, including medication administered enterally, along with the instructions given to the patient or person responsible for the patient;

(5) the anesthesia or sedation record that shall include:

(A) the patient's base line vital signs, including temperature, SPO2, blood pressure, and pulse;

(B) real-time documentation, in intervals of five minutes or less, of the patient's vital signs including capnography documentation pursuant to Subparagraph (f)(4) of this Rule;

(C) documentation of a "time out" as set out in Subparagraph (e)(3) of this Rule;

(D) procedure start and end times;

(E) gauge of needle and location of IV on the patient, if used;

(F) 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 the individualized patient effect of administered drugs and the patient's level of consciousness and responsiveness;

(H) documentation of complications, morbidity, or adverse events and clinical responses as set out in Rule .0702(d) of this Subchapter, and their treatment; and

(I) status of patient upon discharge, including documentation of satisfying the requirements set out in Paragraph (g) of this Rule; and

(6) 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. _____.

21 NCAC 16Q .0104 is proposed for adoption as follows:

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 including but not limited to 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 .0702(d) of this Subchapter.

(c) During the evaluation, the applicant shall take a written examination on the topics set forth in Paragraph (b) 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. _____.

21 NCAC 16Q .0105 is proposed for adoption as follows:

21 NCAC 16Q .0105 REQUIREMENTS FOR DEDICATED ANESTHESIA AND SEDATION MONITORING

(a) During a sedation procedure involving the administration of general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the permit holder performing the surgical or other dental treatment shall utilize either a dedicated sedation provider or a dedicated sedation auxiliary as set out in this Rule. The dedicated sedation provider or dedicated sedation auxiliary shall not perform the surgical or dental treatment or any other dental assisting tasks during the sedation procedure.

(b) The permit holder shall utilize a dedicated sedation provider to administer any medication that is contraindicated for administration by the person performing the surgical or other dental treatment, as indicated by either the U.S. Food and Drug Administration or the manufacturer.

(c) For purposes of this Rule, a "dedicated sedation provider" shall mean a practitioner who is dedicated to administering the anesthesia or sedation and monitoring the patient's well-being throughout the sedation procedure. The dedicated sedation provider shall be:

(1) a dentist holding an itinerant (mobile) permit in accordance with Rules .0206, .0304, or .0406 of this Subchapter;

(2) a dentist holding a permit in accordance with Rules .0201, .0301, or .0404 of this Subchapter, and who has satisfied the requirements of Rule .0103(b) of this Section to administer the anesthesia or sedation level at the facility where the sedation procedure is performed;

(3) an anesthesiologist licensed and practicing in accordance with the rules of the North Carolina Medical Board; or

(4) 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 sedation administered does not exceed the level of the sedation allowed by the permit holder's permit.

(d) For purposes of this Rule, a "dedicated sedation auxiliary" shall mean an auxiliary with an unexpired ACLS certification who is dedicated to patient monitoring and recording anesthesia or sedation data throughout the sedation procedure. The dedicated sedation auxiliary shall be:

(1) an RN licensed and practicing in accordance with the rules of the North Carolina Board of Nursing; or

(2) a dental assistant with proof of an unexpired dental anesthesia assistant certification from the Dental Anesthesia Assistant National Certification Examination program offered by the American Association of Oral and Maxillofacial Surgeons, or from another Board-approved dental anesthesia assistant certification program. A list of approved programs is available on the Board's website at www.ncdentalboard.org.

(e) The permit holder shall ensure that each dedicated sedation auxiliary completes the training course set out in Rule .0103 of this Section every two years in addition to the training set out in this Rule.

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

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

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer general anesthesia shall ~~ensure that the facility where the general anesthesia is administered meets the following requirements:~~ 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 maintained in the facility and be accessible from the operatory and recovery rooms.

~~(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;~~

~~(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;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

(D) antihistamine;

(E) antihypertensive;

(F) bronchodilator;

(G) antihypoglycemic agent;

(H) vasopressor;

(I) corticosteroid;

(J) anticonvulsant;

(K) muscle relaxant;

(L) appropriate reversal agents;

(M) nitroglycerine;

(N) antiemetic; and

(O) Dextrose.

(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 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.

(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 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) During the evaluation, the permit applicant shall take a written examination on the topics set forth in Paragraphs (b) and (c) of this Rule. The permit applicant must obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the permit applicant fails to obtain a passing score on the written examination that is administered during the evaluation, he or she may be re-examined in accordance with Rule .0204(h) of this Section.

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

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

(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 by Subparagraph (f)(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 (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 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; 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. _____; February 1, 2019; August 1, 2018.

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

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

(a) A dentist ~~administering~~ 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 ~~ensure that the facility where the sedation is administered meets the following requirements:~~ 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 maintained in the facility and be accessible from the operatory and recovery rooms.

(c) A moderate conscious sedation permit holder shall not use:

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

(2) drugs contraindicated for use in moderate conscious sedation.

~~(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) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

~~(D) antihistamine;~~

~~(E) antihypertensive;~~

~~(F) bronchodilator;~~

~~(G) antihypoglycemic agent;~~

~~(H) vasopressor;~~

~~(I) corticosteroid;~~

~~(J) anticonvulsant;~~

~~(K) muscle relaxant;~~

~~(L) appropriate reversal agents;~~

~~(M) nitroglycerine;~~

~~(N) antiemetic; and~~

~~(O) Dextrose.~~

~~(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 dentist 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, 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; 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 sedation throughout the sedation procedure and is not performing the surgery or other dental procedure; and

(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 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 permit applicant shall take a written examination on the topics set forth in Paragraphs (b) and (c) of this Rule. The permit applicant must obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the permit applicant fails to obtain a passing score on the written examination that is administered during the evaluation, he or she may be re-examined in accordance with Rule .0306(h) of this Section.

~~(e) 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.~~

~~(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 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 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) 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)(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; 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. _____; February 1, 2019; August 1, 2018.

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

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer moderate pediatric conscious sedation shall ~~ensure that the facility where the sedation is administered meets the following requirements:~~ 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 maintained in the facility 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 with PALS or comparable training.

(d) In addition to the requirements set out in Rule .0103(e) and (f) of this Subchapter, 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) In addition to the requirements set out in Rule .0103(h) of this Subchapter, 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 person responsible for a patient transported in a car 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.

(f) A moderate pediatric conscious sedation permit holder shall not use:

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

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

~~(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) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

~~(D) antihistamine;~~

~~(E) antihypertensive;~~

~~(F) bronchodilator;~~

~~(G) antihypoglycemic agent;~~

~~(H) vasopressor;~~

~~(I) corticosteroid;~~

~~(J) anticonvulsant;~~

~~(K) muscle relaxant;~~

~~(L) appropriate reversal agents;~~

~~(M) nitroglycerine;~~

~~(N) antiemetic; and~~

~~(O) Dextrose.~~

~~(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 following records are maintained for at least 10 years:~~

~~(A) patient's current written medical history and pre-operative assessment;~~

(B) drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration;

(C) a sedation record; and

(D) a consent form, signed by the patient or a guardian, identifying the procedure, risks and benefits, level of sedation, and date signed;

(5) The sedation record shall include:

(A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;

(B) procedure start and end times;

(C) gauge of needle and location of IV on the patient, if used;

(D) status of patient upon discharge; and

(E) documentation of complications or morbidity; and

(6) The following conditions shall be satisfied during a sedation procedure:

(A) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding 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 intravascular 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 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; and

(14) airway obstruction.

(e) During the evaluation, the permit applicant shall take a written examination on the topics set forth in Paragraphs (c) and (d) of this Rule. The permit applicant must obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the permit applicant fails to obtain a passing score on the written examination that is administered during the evaluation, he or she may be re-examined in accordance with Rule .0408(h) of this Section.

(f) 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.

(g) 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) 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 (g)(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 (g)(3) 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 a person responsible for the patient at time of discharge; and~~

~~(C) a person responsible for the patient is available to transport the patient after discharge, and for the patient for whom a motor vehicle restraint system is required, an additional responsible individual is available to attend to the patient.~~

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. _____; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0702 is proposed for adoption as follows:

21 NCAC 16Q .0702 TRACKING OF ADVERSE EVENTS

(a) A dentist who holds a permit to administer general anesthesia or sedation shall maintain an adverse event record, separate from patient treatment records, in which the permit holder tracks all adverse events during sedation procedures, including the permit holder's interventions to respond to each adverse event.

(b) On a quarterly basis, the permit holder shall examine all adverse events for assessment of risk reduction, including modification of procedures or equipment, or completion of relevant training or continuing education by the permit holder and all auxiliaries involved in sedation procedures.

(c) Each adverse event and risk reduction assessment shall be documented and maintained in the permit holder's adverse event record for 10 years. The permit holder's adverse event record shall be made available during a Board conducted facility inspection or evaluation.

(d) For purposes of this Rule, the term "adverse event" shall include the following clinical emergencies:

(1) airway obstruction;

(2) allergic reactions;

(3) angina pectoris;

(4) apnea;

(5) bradycardia;

(6) bronchospasm;

(7) cardiac arrest;

(8) convulsions;

(9) emesis and aspiration;

(10) hypertensive crisis, including rise in blood pressure to 180/120 mm Hg or higher;

(11) hypoglycemia;

(12) hypotension, including drop in blood pressure to 90/60 mm Hg or lower;

(13) hypoventilation and respiratory arrest;

(14) hypoxemia and hypoxia;

(15) laryngospasm;

(16) myocardial infarction; and

(17) syncope.

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

21 NCAC 16Q .0703 is proposed for amendment as follows:

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~~ if the patient dies or has permanent organic brain dysfunction within 24 hours ~~of~~ after the ~~procedure.~~ administration of general anesthesia or sedation. ~~Sedation permit~~ Permit holders shall cease administration of general anesthesia or 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 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~~ if the patient is admitted to a hospital for a medical emergency or physical injury within 24 hours after the administration of general anesthesia or sedation.~~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,~~ 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 ~~G.S.~~ Chapter 90 of the General Statutes 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;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, ~~2018.~~2018;
Amended Eff. _____.