

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16P .0105

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: *This request may extend to several pages. Please be sure you have reached the end of the document.*

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

Please remove all underlines, except for the language that you added post publication.

Assuming that the suggestion gets to the intent of your Rule, in order to make this Rule more clear and less duplicative, please consider reformatting with something the following:

- (b) It shall not be false or misleading for a dentist to hold himself or herself out to the public as a specialist, or any variation of the term, unless he or she has either:
 - (1) completed a qualifying postdoctoral educational program in the specialist area as set forth in Paragraph (c) of this Rule; or*
 - (2) holds current certification by a qualifying specialty board or organization approved by the Board as set forth in Paragraph (c) of this Rule.**
- (c) For purposes of this Rule, a "qualifying postdoctoral educational program" shall be a postdoctoral advanced dental educational program accredited by an agency recognized by the U.S. Department of Education (U.S. DOE.)*
- (d) In determining whether an organization is a qualifying specialty board or organization, the Board shall consider whether the organization meets the following criteria:
 - (1) requires completion of an educational training...*
 - (2) requires all dentists seeking organizational...*
 - (3)**

In (a) and (b), you have said "specialist, or use any variation of the term", but in (c), (d), and (f), you've said "specialist, certified specialist, or board-certified specialist." Is there a reason? If you feel like you need these terms spelled out, would it be appropriate to say in (a) something like "specialist, or use any variation of the term, such as certified specialist or board-certified specialist"?

I want to be sure that we have clear language that meets the intent of the Rule - is the intent of (c) to say something like "in order for an organization to be considered a qualifying specialty board or organization for purposes of this rule, it shall meet the following criteria:

- (1) require completion...*
- (2) Require all dentist...*

Amber May
Commission Counsel

Date submitted to agency: Thursday, January 3, 2018

In (c)(1), what is an “equivalent specialty board”? Equivalent to what? Using the language in this Subparagraph, do you mean something like “shall not be considered similar to a qualifying postdoctoral educational program”?

In (d), please change “subsection (c)” to “Paragraph (c) of this Rule”

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16P .0105 is readopted with changes as published in 33:5 NCR 503-04 as follows:

21 NCAC 16P .0105 ADVERTISING AS A SPECIALIST

~~Only dentists who have successfully completed a postdoctoral course approved by the American Dental Association Commission on Accreditation in a specialty area recognized by the ADA or have been approved by one of the specialty examining Boards recognized by the ADA may announce a specialty practice and advertise as a specialist.~~

(a) A dentist shall not advertise or otherwise hold himself or herself out to the public as a specialist, or use any variation of the term, in an area of practice if the communication is false or misleading under Rule.0101 of this Section.

(b) It shall not be false or misleading for a dentist to hold himself or herself out to the public as a specialist in a practice area provided the dentist has completed a qualifying postdoctoral educational program in that area. A qualifying postdoctoral educational program is a postdoctoral advanced dental educational program accredited by an agency recognized by the U.S. Department of Education (U.S. DOE).

(c) A dentist who has not completed a qualifying postdoctoral educational program shall not advertise or otherwise hold himself or herself out to the public as a specialist, certified specialist, or board-certified specialist, or use any variation of those terms, unless she or he holds current certification by a qualifying specialty board or organization.

The Board shall consider the following criteria in determining a qualifying specialty board or organization:

(1) the organization requires completion of ~~[a]~~ an educational ~~[training]~~ program with ~~[training, documentation, and]~~ didactic, ~~[clinical]~~ clinical, and experiential requirements appropriate for the specialty or subspecialty field of dentistry in which the dentist seeks certification, and the collective didactic, clinical and experiential requirements are similar in scope and complexity to a qualifying postdoctoral educational ~~[program in the specialty or subspecialty field of dentistry in which the dentist seeks certification.]~~ program.

Programs that require solely experiential training, continuing education classes, on-the-job training, or payment to the specialty board shall not constitute an equivalent specialty board;

(2) the organization requires all dentists seeking certification to pass a written or oral examination, or both, that tests the applicant's knowledge and skill in the specialty or subspecialty area of dentistry and includes a psychometric evaluation for validation;

(3) the organization has written rules on maintenance of certification and requires periodic recertification;

(4) the organization has written by-laws and a code of ethics to guide the practice of its members;

(5) the organization has staff to respond to consumer and regulatory inquiries; and

(6) the organization is recognized by another entity whose primary purpose is to evaluate and assess dental specialty boards and organizations.

(d) A dentist qualifying under Subsection (c) and advertising or otherwise holding himself or herself out to the public as a "specialist," "certified specialist," or "board-certified specialist" shall disclose in the advertisement or communication the specialty board by which the dentist was certified and provide information about the certification criteria or where the certification criteria may be located.

(e) A dentist shall maintain documentation of either completion of a qualifying postdoctoral educational program or of his or her current specialty certification and provide the documentation to the Board upon request. Dentists shall

1 maintain documentation demonstrating that the certifying board qualifies under the criteria in Subparagraphs (c)(1)
2 through (6) of this Rule and provide the documentation to the Board upon request.

3 (f) Nothing in this Section shall be construed to prohibit a dentist who does not qualify as a ~~specialist~~ “specialist,”
4 “certified specialist” or “board certified specialist” under the preceding paragraph Paragraphs (b) or (c) of this Rule
5 from restricting his or her practice to one or more specific areas of dentistry or from advertising the availability of his
6 or her ~~services.~~ services, provided that Such such advertisements may do not, not however, include the terms
7 “specialist,” “specialty,” or “specializing” “certified specialist,” or “board-certified specialist,” or any variation of
8 those terms, and must state that the services advertised are to be provided by a general dentist.

9 *History Note: Authority G.S. 90-41(a)(16),(17),(18); 90-48;*

10 *Eff. March 1, 1985;*

11 *Amended Eff. April 1, 2003; May 1, 1989.*

12 *Readopted with substantive changes February 1, 2019.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0202

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

Please remove the "and" at the end of (a)(1)(C).

For purposes of consistency, please end (a)(3), (a)(4)(D), (a)(5)(E) with a period. Please also delete the "and" at the end of (a)(5)(E).

Just out of curiosity, should (c) and (d) be in this Rule or is it addressed by .0204? This Rule appears to address procedures equipment and clinical requirements, then, it goes into evaluation, inspection, and testing requirements (which I assume need to happen before a dentist is even able to do general anesthesia?) Then, it goes back into post operative requirements.

In (d), please change "sections (b) and (c) of this Rule" to Paragraphs (b) and (c) of this Rule."

In (f)(1), please delete or define "continuously"

By (f)(1), do you mean something like "vital signs shall be monitored and patients supervised until oxygenation and circulation are stable and the patient is recovered and ready for discharge from the office in accordance with this Rule"?

In (f)(3), please delete or define "sufficient"

In (f)(3)(C), what is meant by "a vested adult"?

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0202 is amended as published in 33:6 NCR 584-86 as follows:

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

(a) A dentist administering general anesthesia shall 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;
- (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~~ protocols. ~~The permit holder shall also provide and training to familiarize auxiliaries in the treatment of clinical emergencies~~ 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) During the evaluation, the permit applicant shall take a written examination on the topics set forth in sections (b) and (c) of this Rule. The permit applicant must obtain a passing score on the written examination by answering eighty percent (80%) 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.

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

~~(e)-(f)~~ 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)-(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;

- 1 (C) patient arousable and protective reflexes intact;
2 (D) state of hydration within normal limits;
3 (E) patient can talk, if applicable;
4 (F) patient can sit unaided, if applicable;
5 (G) patient can ambulate, if applicable, with minimal assistance; and
6 (H) for the special needs patient or a patient incapable of the usually expected responses, the
7 pre-sedation level of responsiveness or the level as close as possible for that patient shall
8 be achieved; and
9 (3) before allowing the patient to leave the office, the dentist shall determine that the patient has met
10 the recovery criteria set out in Subparagraph ~~(e)~~(f)(2) of this Rule and the following discharge
11 criteria:
12 (A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient,
13 stable, and have been documented;
14 (B) explanation and documentation of written postoperative instructions have been provided
15 to the patient or a responsible adult at time of discharge; and
16 (C) vested adult is available to transport the patient after discharge.
17

18 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
19 *Eff. February 1, 1990;*
20 *Amended Eff. February 1, 2019; August 1, 2018; June 1, 2017; November 1, 2013; August 1, 2002;*
21 *August 1, 2000.*
22 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
23 *2018.*
24

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0204

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

In (h), please delete or define "successfully" in "successfully complete"

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0204 is amended as published in 33:6 NCR 586 as follows:

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

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

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

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

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

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

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

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

(h) A permit applicant who has failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who has failed the written portion of the examination three times shall successfully complete an additional Board approved course of study in the area(s) of deficiency and provide the Board evidence of the additional study before written reexamination.

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

1
2 (j) An applicant must complete all the requirements of Rule .0202, including passing the written examination,
3 evaluation and inspection, within twelve (12) months of submitting the application to the Board.
4

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

6 *Eff. February 1, 1990;*

7 *Amended Eff. February 1, 2019; August 1, 2018; April 1, 2016.; February 1, 2009; December 4,*
8 *2002; January 1, 1994.*

9 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
10 *2018.*
11

21 NCAC 16Q .0301 is amended as published in 33:6 NCR 586-87 as follows:

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

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

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

(1) Training that may consist of either:

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

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

(2) Unexpired ACLS certification; and

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

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

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

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

(g) A moderate conscious sedation permit holder may provide moderate conscious sedation at the office of another licensed dentist, regardless of the permit, if any held, by the hosting dentist. The permit holder shall ensure that the facility where the moderate conscious sedation is administered has been inspected and complies with the requirements

1 set out in Rule .0302 of this Section. The permit holder shall also obtain an itinerant moderate conscious sedation
2 permit and comply with the requirements of Rule .0304 of this Section.

3
4 *History Note: Authority G.S. 90-30.1; 90-39; 90-48;*
5 *Eff. February 1, 1990;*
6 *Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;*
7 *Temporary Amendment Eff. December 11, 2002;*
8 *Amended Eff. June 1, 2017; July 1, 2010, July 3, 2008; August 1, 2004;*
9 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
10 *2018;*
11 *Amended Eff. February 1, 2019; August 1, 2018.*
12
13

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0302

DEADLINE FOR RECEIPT: Friday, January 11, 2019

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

Please remove the "and" at the end of (a)(1)(C).

In (d), please change "sections (b) and (c) of this Rule" to Paragraphs (b) and (c) of this Rule."

In (f)(1), please delete or define "continuously"

In (f)(3)(A), please delete or define "responsible"

In (f)(3)(C), what is meant by "a vested adult"?

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0302 is amended as published in 33:6 NCR 587-89 as follows:

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

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

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

- (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
- (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
- (C) lighting as necessary for specific procedures and back-up lighting; and
- (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
- (E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from the central system;
- (F) small, medium, and large oral and nasal airways;
- (G) blood pressure monitoring device;
- (H) EKG monitor;
- (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~~ protocols. The permit holder shall also provide and training to familiarize auxiliaries in the treatment of clinical emergencies ~~emergencies; shall be provided;~~
- (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 ~~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) During the evaluation, the permit applicant shall take a written examination on the topics set forth in sections (b) and (c) of this Rule. The permit applicant must obtain a passing score on the written examination by answering eighty-percent (80%) 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.

~~(d)~~ (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;

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

28

29 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
30 *Eff. February 1, 1990;*
31 *Amended Eff. August 1, 2002; August 1, 2000;*
32 *Temporary Amendment Eff. December 11, 2002;*
33 *Amended Eff. February 1, 2019; August 1, 2018; June 1, 2017; November 1, 2013; July 1, 2010;*
34 *July 3, 2008; August 1, 2004.*
35 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
36 *2018.*

37

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0306

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

In (h), please delete or define "successfully" in "successfully complete"

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0306 is amended as published in 33:6 NCR 589 as follows:

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

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

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

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

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

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

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

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

(h) A permit applicant who has failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who has failed the written portion of the examination three times shall successfully complete an additional Board approved course of study in the area(s) of deficiency and provide the Board evidence of the additional study before written reexamination.

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

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

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

1 *Eff April 1, 2016.*
2 *Amended Eff. February 1, 2019; August 1, 2018.*
3 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
4 *2018.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0401

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: *This request may extend to several pages. Please be sure you have reached the end of the document.*

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

In (a), line 15, please delete or define "conspicuous"

In (a), are the substantive requirements of the form set forth elsewhere in rule or statute? If not, please provide them in Rule.

In (c)(2), please delete or define "completely" and "appropriate" Please note that providing the contents of the application form will address "completely" Also, I assume that by the "appropriate fees", you just mean the \$375? If so, please make that clear.

Do you need both sentences of (d)(1)? They appear to be saying the same thing.

In (d)(7), please delete or define "successfully"

In (e)(1)(A), (B), and (C), and (c)(2), please delete or define "successful"

Please add 90-39 to your History Note as authority for your fees.

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0401 is amended as published in 33:6 NCR 581-92 as follows:

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 three-hundred seventy-five dollars (\$375.00) that includes the ~~one hundred dollars~~ one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. 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 pass an evaluation and 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 passing the evaluation and inspection of his or her facility. 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 shall demonstrate the administration of minimal conscious sedation on a patient while the evaluator observes. During the observation, 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~~ administration; ~~(by verbal demonstration)~~;
- (C) Treatment of untoward reactions including respiratory or cardiac depression (by verbal demonstration);
- (D) ~~Sterilization~~ sterile technique;
- (E) ~~Use of CPR certified personnel~~; Use of BLS certified auxiliaries;
- (F) Monitoring of patient during ~~recovery~~ recovery; ~~(by verbal demonstration)~~; and
- (G) Sufficiency of patient recovery ~~time~~ 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~~ Hypoglycemia; and
- (M) Cardiac ~~arrest~~; arrest; and
- (N) Airway obstruction.
- ~~(4)~~ During the evaluation, the permit applicant shall take a written examination on the topics set forth in sections (d)(2) and (d)(3) of this Rule. The permit applicant must obtain a passing score on the written examination by answering eighty percent (80%) 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 Subparagraph (d)(7) of this Rule.
- ~~(4)(5)~~ The evaluator shall assign a recommended grade of pass or fail and shall report his or her 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.
- ~~(6)~~ An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of the grounds supporting the re-evaluation or re-inspection. Except as set forth in Subparagraph (d)(7) of this Rule, the Board shall require the applicant to

1 receive additional training prior to the re-evaluation to address the areas of deficiency determined
2 by the evaluation. The Board shall notify the applicant in writing of the need for additional training.

3 (7) A permit applicant who has failed the written examination portion of the evaluation but passed all
4 other aspects of the evaluation and inspection may retake the written examination two additional
5 times at the Board office. The applicant must wait a minimum of 72 hours before attempting to
6 retake a written examination. Any applicant who has failed the written portion of the examination
7 three times shall successfully complete an additional Board approved course of study in the area(s)
8 of deficiency and provide the Board evidence of the additional study before written reexamination.

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

11 (9) An applicant must complete all the requirements of this Rule, including passing the written
12 examination, evaluation and inspection, within twelve (12) months of submitting the application to
13 the Board.

14 (e) Educational/Professional Requirements:

15 (1) The dentist applying for a minimal conscious sedation permit shall meet one of the following
16 criteria:

17 ~~(A) — successful completion of training consistent with that described in Part I or Part III of the~~
18 ~~American Dental Association (ADA) Guidelines for Teaching the Comprehensive Control~~
19 ~~of Pain and Anxiety in Dentistry, and have documented administration of minimal~~
20 ~~conscious sedation in a minimum of five cases;~~

21 ~~(B)(A)~~ successful completion of an ADA accredited post-doctoral training program which affords
22 comprehensive training necessary to administer and manage minimal conscious sedation;

23 ~~(C)(B)~~ successful completion of an 18-hour minimal conscious sedation course which must be
24 approved by the Board based on whether it affords comprehensive training necessary to
25 administer and manage minimal conscious sedation; or

26 ~~(D)(C)~~ successful completion of an ADA accredited postgraduate program in pediatric dentistry;
27 or

28 ~~(E) — is a North Carolina licensed dentist in good standing who has been using minimal~~
29 ~~conscious sedation in a competent manner for at least one year immediately preceding~~
30 ~~October 1, 2007 and his or her office facility has passed an on site inspection by a Board~~
31 ~~evaluator as required in Paragraph (d) of this Rule. Competency shall be determined by~~
32 ~~presentation of successful administration of minimal conscious sedation in a minimum of~~
33 ~~five clinical cases.~~

34 (2) All applicants for a minimal sedation permit must document successful completion of an ACLS a
35 Basic Life Saving (BLS) course within the 12 months prior to the date of application;

36 (3) The permit holder shall maintain written emergency and patient discharge protocols. The permit
37 holder shall also provide training to familiarize auxiliaries in the treatment of clinical emergencies.

1 (f) Annual Permit Renewal:

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

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

11 (3) As a condition for renewal of the minimal conscious sedation permit, the permit holder shall meet
12 the requirements of Rule .0402 of this Subchapter and shall document unexpired ACLS certification
13 and obtain three hours of continuing education every year in one or more of the following areas,
14 which may be counted toward fulfillment of the continuing education required each calendar year
15 for license renewal:

16 (A) pediatric or adult sedation;

17 (B) medical emergencies;

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

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

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

21 (F) airway management.

22 (4) The minimal conscious sedation permit holder shall further document that the permit holder and all
23 auxiliaries involved in sedation procedures have read the practice's emergency manual in the
24 preceding year and that all auxiliaries involved in sedation procedures have completed BLS
25 certification and, within the past two years, completed three hours of continuing education in any of
26 the areas set forth in Subparagraphs (f)(3)(A)-(F) of this Rule.

27 (5) All permit holders applying for renewal of a minimal conscious sedation permit shall be in good
28 standing and their office shall be subject to inspection by the Board.

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

31
32 *History Note: Authority G.S. 90-28; 90-30.1;*

33 *Temporary Adoption Eff. March 13, 2003; December 11, 2002;*

34 *Eff. August 1, 2004;*

35 *Amended Eff. February 1, 2019; July 3, 2008;*

36 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
37 *2018.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0402

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

In (a), what is meant by "is not indicated"?

In (b), what is meant by "are likely to be followed"? By whom? How is this to be determined?

In (c)(2), please delete or define "continuous"

In (c)(3), please delete or define "sufficient"

In (c)(3), please delete or define "successful" in "successful completion."

In (d)(2)(B), please delete or define "proper"

In (d)(2)(C), please change "his/her" to "his or her"

In (e)(2), please provide some sort of introduction to the Parts (such as "as follows")

In (e)(2)(A), please delete or define "continually" and "continuously"

In (e)(3), delete or define "appropriate"

In (f)(1), please delete or define "immediately"

In (f)(2), delete or define "continuously", "continuous", and "sufficiently"

In (f)(4)(C), delete or define "easily"

In (f)(5)(B), please delete or define "responsible"

What's the difference between (f)(5)(C) and (D)?

In (f)(5)(D), what is meant by "a vested adult"?

Amber May

Commission Counsel

Date submitted to agency: Thursday, January 3, 2018

*What is the intent of (f)(5)(D)? Two adults are necessary? What is meant by "patients"
Do you mean "patient"*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road,
Raleigh, North Carolina 27609

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0402 is readopted as published in 33:6 NCR 592-93 as follows:

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 a ~~deep~~ deeper level of sedation.

(b) A minimal conscious sedation permit is not required for ~~minor psychosedatives~~ Schedule IV agents 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.

- 1 (4) Recovery from minimal conscious sedation shall include:
- 2 (A) cardiovascular function stable;
- 3 (B) airway patency uncompromised;
- 4 (C) patient easily arousable and protective reflexes intact;
- 5 (D) state of hydration within normal limits;
- 6 (E) patient can talk, if applicable;
- 7 (F) patient can sit unaided, if applicable;
- 8 (G) patient can ambulate, if applicable, with minimal assistance; and
- 9 (H) for the patient who is disabled, or incapable of the usually expected responses, the pre-
- 10 sedation level of responsiveness or the level as close as possible for that patient shall be
- 11 achieved.
- 12 (5) Prior to allowing the patient to leave the office, the dentist shall determine that the patient has met
- 13 the recovery criteria set out in Paragraph (f)(4) of this Rule and the following discharge criteria:
- 14 (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and
- 15 stable and have been documented;
- 16 (B) explanation and documentation of written postoperative instructions have been provided
- 17 to the patient or a responsible adult at time of discharge;
- 18 (C) responsible individual is available for the patient to transport the patient after discharge;
- 19 (D) A vested adult must be available to transport patients for whom a motor vehicle restraint
- 20 system is required and an additional responsible individual must be available to attend to
- 21 the patients.
- 22 (g) The dentist, personnel and facility shall be prepared to treat emergencies that may arise from the administration
- 23 of minimal conscious sedation, and shall have the ability to provide positive pressure ventilation with 100% oxygen
- 24 with an age appropriate device.
- 25
- 26 *History Note: Authority G.S. 90-28; 90-30.1;*
- 27 *Temporary Adoption Eff. December 11, 2002;*
- 28 *Eff. August 1, 2004;*
- 29 *Amended Eff. July 3, 2008;*
- 30 *Readopted with substantive changes February 1, 2019.*
- 31

21 NCAC 16Q .0404 is amended as published in 33:6 NCR 593-94 as follows:

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

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

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

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

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

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

(e) Prior to issuance of a moderate pediatric conscious sedation permit, the applicant shall pass an evaluation and a facility inspection. The applicant shall be responsible for passing the evaluation and inspection of his or her facility. ~~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 moderate pediatric conscious sedation permit holder may provide moderate pediatric conscious sedation at the office of another licensed dentist, regardless of the permit, if any held, by the hosting dentist. The permit holder shall ensure that the facility where the moderate pediatric conscious sedation is administered has been inspected and complies with the requirements set out in Rule .0405 of this Section. The permit holder shall also obtain an itinerant moderate pediatric conscious sedation permit and comply with the requirements of Rule .0406 of this Section.

History Note: Authority G.S. 90-30.1; 90-39; 90-48;
Eff. June 1, 2017.
Amended Eff. February 1, 2019; August 1, 2018.

1 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
2 *2018.*
3

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0405

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

In (e), please change "sections (b) and (c) of this Rule" to Paragraphs (b) and (c) of this Rule."

In (g)(2), please delete or define "continuously"

In (g)(4)(B), please delete or define "responsible"

In (g)(4)(C), what is meant by "a vested adult"?

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0405 is amended as published in 33:6 NCR 594-96 as follows:

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

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

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

- (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
- (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
- (C) lighting as necessary for specific procedures and back-up lighting;
- (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
- (E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from the central system;
- (F) small, medium, and large oral and nasal airways;
- (G) blood pressure monitoring device;
- (H) 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~~ protocols. The permit holder shall also provide ~~and~~ training to familiarize auxiliaries in the treatment of clinical ~~emergencies~~ emergencies; ~~shall be provided~~;
- (4) The following records are maintained for at least 10 years:
- (A) patient's current written medical history and pre-operative assessment;
 - (B) drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration;
 - (C) a sedation record; and
 - (D) a consent form, signed by the patient or a guardian, identifying the procedure, risks and benefits, level of sedation, and date signed;
- (5) The sedation record shall include:
- (A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO₂ if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
 - (B) procedure start and end times;
 - (C) gauge of needle and location of IV on the patient, if used;
 - (D) status of patient upon discharge; and
 - (E) documentation of complications or morbidity; and
- (6) The following conditions shall be satisfied during a sedation procedure:
- (A) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to 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 ~~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; and
- (14) airway obstruction.

(e) During the evaluation, the permit applicant shall take a written examination on the topics set forth in sections (c) and (d) of this Rule. The permit applicant must obtain a passing score on the written examination by answering eighty percent (80%) 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.

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

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

35
36 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
37 *Eff. June 1, 2017.*

1 *Amended Eff. February 1, 2019; August 1, 2018.*
2 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
3 *2018.*
4

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0408

DEADLINE FOR RECEIPT: Friday, January 11, 2019

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends that the following technical changes be made:

In (h), please delete or define "successfully" in "successfully complete"

Please move "Amended Eff. February 1, 2019" at the bottom, after "Pursuant to 150B..."

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber May
Commission Counsel
Date submitted to agency: Thursday, January 3, 2018

21 NCAC 16Q .0408 is amended as published in 33:6 NCR 596 as follows:

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

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

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

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

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

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

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

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

(h) A permit applicant who has failed the written examination portion of the evaluation but passed all other aspects of the evaluation and inspection may retake the written examination two additional times at the Board office. The applicant must wait a minimum of 72 hours before attempting to retake a written examination. Any applicant who has failed the written portion of the examination three times shall successfully complete an additional Board approved course of study in the area(s) of deficiency and provide the Board evidence of the additional study before written reexamination.

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

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

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

1 *Amended Eff. February 1, 2019; August 1, 2018.*
2 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
3 *2018.*
4

21 NCAC 16Q .0501 is repealed as published in 33:6 NCR 596 as follows:

21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED

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

Eff. February 1, 1990;

Amended Eff. August 1, 2002;

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

Temporary Amendment Eff. December 11, 2002;

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

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

Repealed Eff. February 1, 2019.