

1 21 NCAC 16O .0301 is amended as published in 30:1 NCR 2 with changes, as follows:

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3 **21 NCAC 16O .0301 NITROUS OXIDE CONSCIOUS SEDATION**

4 "~~Conscious Nitrous~~ **"Nitrous** oxide sedation" means the use of ~~drugs~~ nitrous oxide for controlling pain or
5 apprehension without rendering the patient unconscious. A sedation permit ~~is not~~ shall not be required to
6 administer nitrous oxide, without any other drugs, for the purpose of anxiolysis. A sedation permit ~~is~~ shall be
7 required if nitrous oxide is administered in combination with other sedative agents.

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9 *History Note:* *Authority G.S. 90-29(b)(6); 90-48; 90-223;*

10 *Eff. July 16, 1980;*

11 *Amended Eff. March 1, 2016; May 1, 1989.*

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1 21 NCAC 16O .0302 is amended as published in 30:1 NCR 2 with changes as follows:

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3 **21 NCAC 16O .0302 NITROUS OXIDE MONITORING**

4 "Monitoring" means observation of the patient during the flow of nitrous oxide ~~sedation agents~~ and includes
5 reducing the flow of nitrous oxide ~~sedation~~ or shutting off equipment controlling such flow. Monitoring does not
6 include starting or increasing the flow of ~~sedation agents~~, nitrous oxide.

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8 *History Note:* *Authority G.S. 90-29(b)(6); 90-48; 90-223;*

9 *Eff. July 16, 1980;*

10 *Amended Eff. March 1, 2016; May 1, 1989.*

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1 21 NCAC 160 .0401 is amended as published in 30:1 NCR 2 as follows:

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3 **21 NCAC 160 .0401 NON-DELEGABLE FUNCTIONS**

4 ~~Conscious Nitrous oxide~~ sedation shall not be induced by anyone other than a dentist or a lawfully qualified nurse ~~or~~
5 ~~anesthetist [anesthesiologist]~~ who does so under the supervision and direction of a ~~dentist or physician.~~ dentist.

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7 *History Note: Authority G.S. 90-29(b)(6); 90-48; 90-223;*

8 *Eff. July 16, 1980;*

9 *Amended Eff. March 1, 2016; May 1, 1989.*

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1 21 NCAC 160 .0402 is amended as published in 30:1 NCR 2 with changes as follows:

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3 **21 NCAC 160 .0402 EDUCATIONAL REQUIREMENTS**

4 A Dental Assistant ~~For a Dental Assistant~~ ~~if not otherwise qualified under G.S. 90-29(c)(13)~~ may aid and assist a
5 licensed dentist in the ~~administration~~ monitoring of nitrous oxide-oxygen inhalant ~~conscious~~ sedation ~~after~~
6 ~~completion of a~~ by completing a Board-approved course totaling at least seven hours ~~and directed by an individual~~
7 ~~or individuals approved by the Board. Such course shall include:~~ that covers the following topics:

- 8 (1) ~~Definitions~~ definitions and descriptions of physiological and psychological aspects of pain and
9 anxiety;
- 10 (2) ~~The~~ the states of drug-induced central nervous system depression through all levels of
11 consciousness and unconsciousness, with special emphasis on the distinction between the
12 conscious and unconscious state;
- 13 (3) ~~Respiratory~~ respiratory and circulatory ~~physiology~~ physiology, and related anatomy;
- 14 (4) ~~Pharmacology~~ pharmacology of agents used in the ~~conscious nitrous oxide sedation~~ techniques
15 being taught, including drug interaction and incompatibility;
- 16 (5) ~~Patient~~ patient monitoring, with particular attention to vital signs and reflexes related to
17 consciousness;
- 18 (6) ~~Prevention,~~ prevention, ~~recognition~~ recognition, and management of complications and life
19 threatening situations that may occur during the use of the ~~conscious sedation~~ nitrous oxide
20 techniques, including cardio pulmonary resuscitation;
- 21 (7) ~~Description~~ description and use of ventilation sedation equipment; and
- 22 (8) ~~Potential~~ potential health hazards of trace anesthetics, and proposed techniques for elimination of
23 these potential health hazards.

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25 *History Note:* Authority G.S. 90-29(b)(6); 90-29(c)(13); 90-48; 90-223;

26 *Eff. July 16, 1980;*

27 *Amended Eff. March 1, 2016; May 1, 1989.*

28

1 21 NCAC 16Q .0101 is amended as published in 30:1 NCR 2 with changes as follows:

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3 **21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS**

4 For the purpose of these Rules relative to the administration of ~~minimal conscious sedation~~, moderate conscious
5 sedation, ~~moderate conscious sedation limited to oral routes or nitrous oxide inhalation~~, moderate pediatric
6 conscious ~~sedation~~ sedation, or general anesthesia by or under the direction of a dentist, the following definitions
7 shall apply:

- 8 (1) "Analgesia" – the diminution or elimination of pain.
- 9 (2) "Anti-anxiety sedative" – a sedative agent administered in a dosage intended to reduce anxiety
10 without diminishing consciousness or protective reflexes.
- 11 (3) "Anxiolysis" – pharmacological reduction of anxiety through the administration of a single dose of
12 a any minor anti-anxiety drug psychosedative, within a 24 hour period, or nitrous oxide ~~possibly in~~
13 ~~combination with nitrous oxide~~, to children or adults prior to commencement of treatment on the
14 day of the appointment which that allows for uninterrupted interactive ability in a totally an awake
15 patient with no compromise in the ability to maintain a patent airway continuously and without
16 assistance. ~~Nitrous oxide may be administered in addition to the minor psychosedative without~~
17 ~~constituting multiple dosing for purpose of these Rules.~~ The patient [must]-shall be able to
18 respond [normally] to tactile stimulation and verbal commands and walk, if applicable. [walk
19 normally.] A dentist may perform anxiolysis without obtaining a permit from the Dental Board.
- 20 (4) "ACLS" – Advanced cardiac life support.
- 21 (5) "Administer"—to direct, manage, supervise, ~~[control]~~ control, and have charge of all aspects of
22 selection, dosage, [timing] timing, and method of delivery to the patient of any pharmacologic
23 agent intended to reduce anxiety or depress consciousness.
- 24 (17) ~~[(6) "Anti Anxiety Drug"]~~ Minor psychosedative/Minor tranquilizer" – pharmacological agents which
25 allow for uninterrupted interactive ability in a patient with no compromise in the ability to
26 maintain a patent airway continuously and without assistance and carry a margin of safety wide
27 enough to render unintended loss of consciousness unlikely. [The patient must be able to respond
28 normally to tactile stimulation and verbal commands and walk normally.]
- 29 ~~[(7)]~~ (6) "ASA" – American Society of Anesthesiologists.
- 30 ~~[(8)]~~ (7) "Auxiliaries" – non-dentist staff members [directly] involved in general anesthesia or sedation
31 procedures.
- 32 ~~[(9)]~~ (8) "BLS" – Basic life support.
- 33 (4) ~~[(10)]~~ (9) "Behavior control" – the use of pharmacological techniques to control behavior to a level [at
34 which] that dental treatment can may be performed without injury to the patient or dentist.
35 effectively and efficiently.

- 1 (5) ~~[(14)]~~ (10) "Behavioral management" – the use of pharmacological or psychological techniques,
2 singly or in combination, to modify behavior to a level that [at which] dental treatment can may be
3 performed effectively and efficiently, without injury to the patient or dentist.
- 4 (6) ~~[(12)]~~ (11) "Competent" – displaying special skill or knowledge derived from training and experience.
- 5 (7) ~~[(13)]~~ (12) "Conscious sedation" - an induced state of a depressed level of consciousness that retains the
6 patient's ability to independently and continuously maintain an airway without assistance and
7 respond appropriately to physical stimulation and obey verbal command, commands, and that is
8 produced by pharmacologic or non-pharmacologic agents, or a combination thereof. ~~In~~
9 accordance with this particular definition, the drugs or techniques used shall carry a margin of
10 safety wide enough to render unintended loss of consciousness unlikely. All dentists who
11 perform conscious sedation shall have an unexpired [a current] sedation permit from the Dental
12 Board.
- 13 ~~[(14)]~~ (13) "CRNA" – certified registered nurse anesthetist.
- 14 (8) ~~[(15)]~~ (14) "Deep sedation" – an induced state of a depressed level of consciousness accompanied by
15 partial loss of protective reflexes, including the ability to continually maintain an airway
16 independently without assistance or respond purposefully to verbal command, ~~and is~~ produced by
17 pharmacological agents. All dentists who perform deep sedation shall have an unexpired [a
18 current] general anesthesia permit from the Dental Board.
- 19 ~~[(16)]~~ (15) "Deliver" – to assist a [properly qualified] permitted dentist in administering sedation or
20 anesthesia drugs by providing the drugs [directly] to the patient pursuant to a direct order from the
21 dentist and while under the dentist's direct supervision.
- 22 (9) ~~[(17)]~~ (16) "Direct supervision" – the dentist responsible for the ~~sedation/anesthesia~~ sedation or
23 anesthesia procedure shall be physically present in the facility immediately available and shall be
24 continuously aware of the patient's physical status and well being, being at all times.
- 25 ~~[(18)]~~ (17) "Emergencies manual" – a written [or digital] manual that documents 1) the location of all
26 emergency equipment and medications in each facility; [dental office,] 2) each staff member's role
27 during medical [emergencies] emergencies; and 3) the appropriate treatment for laryngospasm,
28 bronchospasm, emesis and aspiration, respiratory depression and arrest, angina pectoris,
29 myocardial infarction, hypertension, hypotension, allergic reactions, convulsions, syncope,
30 bradycardia, insulin shock, cardiac [arrest] arrest, and airway obstruction.
- 31 ~~[(19)]~~ (18) "ET CO2" —end tidal carbon dioxide.
- 32 (10) ~~[(20)]~~ (19) "Facility" – the location where a permit holder practices dentistry and provides
33 ~~anesthesia/sedation~~ anesthesia or sedation services.
- 34 (11) ~~[(21)]~~ (20) "Facility inspection" - an on-site inspection to determine if a facility where the applicant
35 proposes to provide ~~anesthesia/sedation~~ anesthesia or sedation is supplied, equipped, staffed
36 staffed, and maintained in a condition to support provision of ~~anesthesia/sedation~~ anesthesia or

1 sedation services ~~that meet the minimum standard of care.~~ in compliance with the Dental Practice
2 Act set forth in Article 2 of G.S. 90 and the Board's rules of this Chapter.

3 (12) ~~[(22)]~~ (21) "General anesthesia" - the intended controlled state of a depressed level of consciousness
4 that is produced by pharmacologic agents and accompanied by a partial or complete loss of
5 protective reflexes, including the ability to maintain an airway and respond purposefully to
6 physical stimulation and obey ~~or~~ verbal commands.

7 ~~[(23)]~~ (22) "Good standing" – a licensee whose license is not suspended or revoked and who is not subject
8 to a current disciplinary order imposing probationary terms.

9 (13) ~~[(24)]~~ (23) "Immediately available" – on-site in the facility and available for immediate use- use
10 without delay.

11 ~~[(25)]~~ (24) ~~[Itinerant]~~ "Itinerant general ~~[dentist anesthesiologist]~~ anesthesia provider"- a ~~[licensee]~~
12 permittee who has complied with Rule .0206 of this ~~[Section]~~ Subchapter and who administers
13 general anesthesia at another practitioner's facility.

14 (14) ~~[(26)]~~ (25) "Local anesthesia" – the elimination of sensations, especially including pain, in one part of
15 the body by the regional application or injection of a drug.

16 (15) ~~[(27)]~~ "May" – indicates freedom or liberty to follow a reasonable alternative.

17 (16) "Minimal conscious sedation" – ~~conscious sedation characterized by a minimally depressed level of~~
18 ~~consciousness, in which patient retains the ability to independently and continuously maintain an~~
19 ~~airway and respond normally to tactile stimulation and verbal command, provided to patients 13~~
20 ~~years or older, by oral or rectal routes of administration of a single pharmacological agent, in one~~
21 ~~or more doses, not to exceed the manufacturer's maximum recommended dose, at the time of~~
22 ~~treatment, possibly in combination with nitrous oxide. Minimal conscious sedation is provided for~~
23 ~~behavioral management.~~

24 (18) ~~[(28)]~~ (26) "Moderate conscious sedation" – conscious sedation characterized by a drug induced
25 depression of consciousness, during which patients obey ~~respond purposefully to~~ verbal
26 commands, either alone or accompanied by light tactile stimulation, provided to patients 13 years
27 of age or older, by oral, nasal, ~~rectal~~ rectal, or parenteral routes of administration of single or
28 multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including
29 the time of treatment, possibly in combination with nitrous oxide. Moderate conscious sedation is
30 may be provided for behavior control by licensed dentists who comply with the terms of Rule
31 .0301 of this Subchapter. control. ~~[Drugs designated by the manufacturer for use in administering~~
32 ~~general anesthesia or deep sedation and drugs contraindicated for use in moderate conscious~~
33 ~~sedation shall not be used by a moderate conscious sedation permit holder.]~~ A moderate
34 conscious sedation provider shall not use the following:

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

37 (b) drugs contraindicated for use in moderate conscious sedation.

1 ~~(19)~~ "Moderate conscious sedation limited to oral routes and nitrous oxide inhalation" — conscious
2 sedation characterized by a drug-induced depression of consciousness during which patients
3 respond purposefully to verbal commands, either alone or accompanied by light tactile
4 stimulation, provided to patients 13 years or older, by oral routes of administration and nitrous
5 oxide inhalation, of single or multiple pharmacological agents, in single or multiple doses, within
6 a 24-hour period. Moderate conscious sedation limited to oral routes and nitrous oxide inhalation
7 is provided for behavior control.

8 ~~[(29)]~~ (27) (20) "Moderate pediatric conscious sedation" - conscious sedation characterized by a drug
9 induced depression of consciousness, during which patients ~~respond purposefully to obey~~ verbal
10 commands, either alone or accompanied by light tactile stimulation, provided to patients ~~up to~~
11 ~~under 18~~ 13 years of age, ~~or special needs patients~~, by oral, nasal, ~~rectal~~ rectal, or parenteral routes
12 of administration of single or multiple pharmacological agents, in single or multiple doses, within
13 a 24-hour period, including the time of treatment, possibly in combination with nitrous oxide.
14 Moderate pediatric conscious sedation ~~is~~ may be provided for behavior ~~control by licensed~~
15 ~~dentists who comply with the terms of Rule .0404 of this Subchapter. control.~~ ~~[Drugs designated~~
16 ~~by the manufacturer for use in administering general anesthesia or deep sedation and drugs~~
17 ~~contraindicated for use in moderate pediatric conscious sedation shall not be used by a moderate~~
18 ~~pediatric conscious sedation permit holder.] A moderate pediatric conscious sedation permit~~
19 ~~holder shall not use the following:~~

20 (a) ~~drugs designed by the manufacturer for use in administering general anesthesia~~
21 ~~or deep sedation; or~~

22 (b) ~~drugs contraindicated for use in moderate pediatric conscious sedation.~~

23 ~~[(30)]~~ (21) "Must" or "shall" — indicates an imperative need or duty or both; an essential or indispensable
24 ~~item; mandatory.~~

25 ~~[(31)]~~ (28) (22) "Parenteral" - the administration of pharmacological agents intravenously, intraosseously,
26 intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.

27 ~~[(32)]~~ (29) "PALS" – Pediatric Advanced Life Support.

28 ~~[(33)]~~ (30) (23) "Protective reflexes" – includes the ability to swallow and cough.

29 ~~[(34)]~~ (31) [RN] "RN" – Registered Nurse licensed by the North Carolina Board of Nursing.

30 ~~[(35)]~~ (32) ~~[Special]~~ "Special needs ~~[patients]~~ patients" – patients with diminished mental and or physical
31 capacity who are unable to cooperate ~~[sufficiently]~~ to receive ambulatory dental care without
32 sedation or anesthesia.

33 ~~[(36)]~~ (33) (24) "Supplemental dosing" – the oral administration of a pharmacological agent that results in
34 an enhanced level of conscious sedation when added to the primary sedative agent administered
35 for the purpose of oral moderate conscious sedation, and ~~which~~, when added to the primary agent,
36 does not exceed the maximum safe dose of either agent, separately or synergistically.

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~~(37)~~ (34) (25) "Vested adult" – a responsible adult who is the legal parent or guardian, or designee of a legal parent or guardian, entrusted with the care of a ~~minor~~ patient following the administration of general anesthesia or conscious sedation.

*History Note: Authority G.S. ~~90-28~~; 90-30.1; 90-48;
Eff. February 1, 1990;
Temporary Amendment Eff. December 11, 2002;
Amended Eff. March 1, 2016; July 3, 2008; August 1, 2004.*

1 21 NCAC 16Q .0202 is amended as published in 30:1 NCR 2 with changes as follows:

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3 **21 NCAC 16Q .0202 GENERAL ANESTHESIA EQUIPMENT AND CLINICAL REQUIREMENTS**

4 (a) A dentist administering general anesthesia shall be responsible to ensure is solely responsible for providing that
5 the facility environment in which where the general anesthesia is ~~to be~~ administered meets the following
6 requirements:

7 (1) The facility is shall be equipped ~~with;~~ with the following:

8 (A) ~~An an~~ An an operator of size and design to permit access of emergency equipment and
9 personnel and to permit effective emergency management;

10 (B) ~~A chair or table for emergency treatment, including chair suitable for CPR or CPR Board;~~
11 ~~[A] a~~ a CPR board or dental chair without ~~[enhancements]~~ enhancements, suitable for
12 providing emergency treatment;

13 (C) ~~Lighting~~ lighting as necessary for specific ~~[procedures]~~ procedures, procedures; and
14 back-up lighting; and

15 (D) ~~Suction~~ suction equipment as necessary for specific ~~procedures; procedures,~~
16 non-electrical back-up ~~suction; [suction.]~~ suction;

17 ~~(2) The following equipment is maintained:~~

18 ~~(A)-(E)~~ (A)-(E) Positive positive pressure oxygen delivery system, including full face masks for small,
19 medium, and large adults and pediatric patients, ~~patients;~~ and back-up E-cylinder
20 portable oxygen tank apart from the central system;

21 ~~(B)-(F)~~ (B)-(F) [Small,] small, [medium] medium, and large oral ~~Oral~~ and nasal airways; airways of
22 various sizes;

23 ~~(C)-(G)~~ (G) Blood blood pressure monitoring device;

24 ~~(D)-(H)~~ (H) EKG ~~[Monitor; Electrocardiograph;]~~ monitor; electrocardiograph;

25 ~~(E)-(I)~~ (I) Pulse pulse oximeter; ~~and~~

26 ~~(F)-(J)~~ (J) Defibrillator; defibrillator;

27 ~~(G)-(K)~~ (K) Capnograph; capnograph;

28 ~~(H)-(L)~~ (L) [Thermometer;] thermometer;

29 ~~(3) The following emergency equipment is maintained:~~

30 (A) ~~(D)~~ (M) I.V. set up [Vascular] vascular access as necessary for specific procedures,
31 including hardware and fluids;

32 (B) ~~(J)~~ (N) Laryngoscope laryngoscope with current- working batteries;

33 (C) ~~(K)~~ (O) Intubation intubation forceps and ~~endotracheal tubes;~~ advanced airway devices;

34 (D) ~~(L)~~ (P) Tonsillar tonsillar-suction with back-up suction;

35 (E) ~~(M)~~ (Q) Syringes syringes as necessary for specific procedures; and

36 (F) ~~(N)~~ (R) Tourniquet tourniquet & tape; and and tape.

37 (G) ~~—~~ Blood pressure monitoring device;

1 (4) (3) The following drugs are maintained with a current shelf life and with access from the operator
2 and recovery room: The following unexpired drugs shall be maintained in the facility and with
3 access from the operator and recovery rooms:

- 4 (A) Ephinephrine; ephinephrine;
- 5 (B) Atropine;
- 6 (C) Lidocaine; [Antiarrhythmic;] antiarrhythmic;
- 7 (D) Antihistamine; antihistamine;
- 8 (E) Antihypertensive; antihypertensive;
- 9 (F) Bronchial dilator; [Bronchodilator;] bronchodilator;
- 10 (G) Antihypoglycemic antihypoglycemic agent;
- 11 (H) Vasopressor; vasopressor;
- 12 (I) Corticosteroid; corticosteroid;
- 13 (J) Anticonvulsant; anticonvulsant;
- 14 (K) Muscle muscle relaxant;
- 15 (L) Appropriate appropriate reversal agents;
- 16 (M) Appropriate anti arrhythmic medication;
- 17 (M) (N) Nitroglycerine; nitroglycerine; and
- 18 (N) (O) Antiemetic; [Antiemetic;] antiemetic.

19 (5) (4) The permit holder shall maintain written Written emergency and patient discharge protocols and
20 training to familiarize office personnel auxiliaries in the treatment of clinical emergencies are
21 shall be provided; and

22 (6) (5) The permit holder shall maintain the following records for 10 years: are maintained: [maintained
23 for 10 years;]

- 24 (A) Patient's current written medical history, including a record of known allergies and
25 previous surgeries; surgery;
- 26 (B) [Signed consent] Consent to general [anesthesia form;] anesthesia, signed by the patient
27 or guardian, identifying the risks and benefits, level of [anesthesia] anesthesia, and date
28 signed;
- 29 (C) [Signed consent] Consent to the procedure, signed by the patient or guardian identifying
30 the [procedure, risks] risks, [and] [benefits] benefits, and date signed; and
- 31 (D) (B) Patient Base base line vital signs, including temperature, SPO2, blood pressure and pulse;
32 [(E)] (C) An anesthesia [record] record which shall include:
 - 33 (i) Periodic vital signs taken at intervals during the procedure;
 - 34 (ii) Drugs administered during the procedure, including route of administration,
35 dosage, time and sequence of administration;
 - 36 (iii) Duration of the procedure;
 - 37 (iv) Documentation of complications or morbidity; and

(v) ~~_____~~ Status of patient upon discharge.

(6) The ~~_____~~ sedation anesthesia record shall include:

(A) ~~_____~~ base line vital signs, blood pressure (unless patient behavior prevents recording);
oxygen saturation, ET CO₂, 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; morbidity; and

~~(d) _____~~ (7) A dentist administering general anesthesia shall ensure that the ~~The~~ facility ~~shall be~~ is staffed with
at least two BLS certified ~~auxiliary personnel~~ auxiliaries who shall be present at all times during
the procedure and at least one of whom shall be dedicated to patient monitoring and recording
general anesthesia or sedation data. ~~document annual successful completion of basic life support~~
~~training and be capable of assisting with procedures, problems, and emergency incidents that may~~
~~occur as a result of the general anesthetic or secondary to an unexpected medical complication.~~

(b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of
anesthesia while the evaluator ~~observes~~. ~~During the demonstration, the applicant or permit holder observes, and~~
shall demonstrate competency in the following areas:

(1) Monitoring monitoring of blood pressure, pulse, ET CO₂, and respiration;

(2) Drug drug dosage and administration;

(3) Treatment treatment of untoward reactions including respiratory or cardiac depression;

(4) Sterilization; sterile technique;

(5) Use use of BLS CPR certified auxiliaries; personnel;

(6) Monitoring monitoring of patient during recovery; and

(7) Sufficiency 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; laryngospasm;

(2) Bronchospasm; bronchospasm;

(3) Emesis emesis and aspiration;

(4) Respiratory respiratory depression and arrest;

(5) Angina angina-pectoris;

(6) Myocardial myocardial infarction;

(7) Hypertension/Hypotension; [Hypertension and Hypotension;] hypertension and hypotension;

(8) Syncope; syncope;

(9) Allergic allergic reactions;

(10) Convulsions; convulsions;

- 1 (11) ~~Bradycardia;~~ bradycardia;
- 2 (12) ~~Insulin~~ insulin shock; ~~and~~
- 3 (13) ~~Cardiac~~ cardiac arrest; ~~and~~
- 4 (14) ~~[Airway]~~ airway obstruction.

5 (d) A general anesthesia permit holder shall evaluate ~~[patients-]~~ a patient for health risks before starting any
6 anesthesia procedure.

7 (e) Post-operative monitoring and ~~[discharge-]~~ discharge shall include the following:

8 (1) ~~[Vital]~~ vital signs shall be continuously monitored when the sedation is no longer being
9 administered and the patient shall have direct continuous supervision until oxygenation and
10 circulation are stable and the patient is ~~[sufficiently responsive]~~ recovered as defined by
11 ~~[Paragraph]~~ Subparagraph (e)(2) of this Rule and is ready for discharge from the office.

12 (2) ~~[Recovery]~~ recovery from general anesthesia shall include documentation of the following:

- 13 (A) cardiovascular function stable;
- 14 (B) airway patency uncompromised;
- 15 (C) patient ~~[easily]~~ arousable and protective reflexes intact;
- 16 (D) state of hydration within normal limits;
- 17 (E) patient can talk, if applicable;
- 18 (F) patient can sit unaided, if applicable;
- 19 (G) patient can ambulate, if applicable, with minimal assistance; and
- 20 (H) for the ~~special needs~~ patient or a patient ~~[who is disabled, or]~~ incapable of the usually
21 expected responses, the pre-sedation level of responsiveness or the level as close as
22 possible for that patient shall be achieved.

23 (3) ~~[Before]~~ before allowing the patient to leave the office, the dentist shall determine that the patient
24 has met the recovery criteria set out in Subparagraph ~~[Paragraph]~~ (e)(2) of this Rule and the
25 following discharge criteria:

- 26 (A) oxygenation, circulation, activity, skin ~~color~~ color, and level of consciousness are
27 sufficient, ~~[sufficient and stable]~~ stable, and have been documented;
- 28 (B) explanation and documentation of written postoperative instructions have been provided
29 to the patient or a responsible adult at time of discharge; and
- 30 (C) ~~[responsible individual]~~ a vested adult is available ~~[for the patient]~~ to transport the
31 patient after discharge.

32
33 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
34 *Effective February 1, 1990;*
35 *Amended Eff. March 1, 2016; November 1, 2013; August 1, 2002; August 1, 2000.*

1 21 NCAC 16Q .0203 is repealed as published in 30:1 NCR 2 as follows:

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3 **21 NCAC 16Q .0203 TEMPORARY APPROVAL PRIOR TO SITE EVALUATION**

4

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

6 *Eff. February 1, 1990;*

7 *Amended Eff. August 1, 2002*

8 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0204 is amended as published in 30:1 NCR 2 as follows:

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3 **21 NCAC 16Q .0204 PROCEDURE FOR GENERAL ANESTHESIA EVALUATION OR INSPECTION**
4 **AND RE-INSPECTION**

5 (a) When an evaluation or on-site inspection is required, the Board ~~will~~ **shall** designate two or more qualified
6 ~~persons,~~ **persons to serve as evaluators,** each of ~~which~~ **whom** has administered general anesthesia for at least three
7 years preceding the ~~inspection, exclusive of his [or her] training in general anesthesia,~~ **inspection. Training in**
8 **general anesthesia shall not be counted in the three years.** When an on-site inspection involves only a facility and
9 equipment check and not an evaluation of the dentist, the inspection may be accomplished by one ~~or more~~
10 **evaluators,** **evaluator.**

11 ~~(b)~~ **(e)** ~~At least a 15 day notice shall be given prior to an evaluation or inspection. The entire evaluation fee of three~~
12 ~~hundred seventy five dollars (\$375.00) shall be due 10 days after the date of receipt of such notice. An inspection~~
13 ~~fee of two hundred seventy five dollars (\$275.00) three hundred seventy five dollars (\$375.00) shall be due 10 days~~
14 ~~after the dentist receives notice of the inspection of each additional location at which the dentist administers general~~
15 ~~anesthesia.~~

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

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

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

23 **(f)** ~~An applicant who fails an inspection or evaluation shall not receive a permit to administer general anesthesia. If~~
24 ~~a permit holder fails an evaluation, the permit shall be summarily~~ **suspended,** **suspended as provided by G.S. 150B-**
25 **3(c).** ~~If a permit holder's facility fails an inspection, no further anesthesia procedures [may] shall be performed at~~
26 ~~the facility until it passes a re-inspection by the Board.~~

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

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

34
35 *History Note: Authority G.S. 90-28; 90-30.1; 90-39;*

36 *Eff. February 1, 1990;*

37 *Amended Eff. March 1, 2016; February 1, 2009; December 4, 2002; January 1, 1994.*

1 21 NCAC 16Q .0205 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0205 RESULTS OF SITE EVALUATION AND REEVALUATION**

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

5 *Eff. February 1, 1990;*

6 *Amended Eff. August 1, 2002.*

7 *Repealed Eff. March 1, 2016.*

8

1 21 NCAC 16Q .0206 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0206 ITINERANT (MOBILE) GENERAL ANESTHESIA PERMIT, EQUIPMENT**
4 **AND EVALUATION**

5 (a) A dentist who holds a general anesthesia permit from the Board and who wishes to provide general anesthesia or
6 other sedation services in the office of another practitioner shall obtain a mobile general anesthesia permit from the
7 Board. The application form may be obtained on the Board's website: www.ncdentalboard.org. and shall be
8 accompanied by a one hundred (\$100.00) fee. No mobile permit ~~is~~ shall be required to administer general
9 anesthesia in a hospital or credentialed surgery center.

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

13 (c) ~~The following equipment shall be maintained;~~ permit holder shall maintain the following equipment:

- 14 (1) ~~Positive~~ positive pressure ventilation system and back-up E cylinder portable oxygen tank;
- 15 (2) ~~Standard~~ standard ASA monitors with back-up power;
- 16 (3) ~~EKG monitor;~~ EKG Monitor;
- 17 (4) ~~capnograph;~~ Capnograph;
- 18 (5) ~~Small,~~ small, ~~medium~~ medium, and large oral airways and nasal trumpets;
- 19 (6) ~~Small,~~ small, ~~medium~~ medium, and large laryngoscope blades and back-up laryngoscope;
- 20 (7) ~~Small,~~ small, ~~medium~~ medium, and large nasal and oral endotracheal tubes;
- 21 (8) Magill forceps;
- 22 (9) ~~Small,~~ small, ~~medium~~ medium, and large supraglottic airway devices;
- 23 (10) ~~Back-up~~ back-up suction;
- 24 (11) ~~Defibrillator~~ defibrillator with pediatric capability;
- 25 (12) ~~Small,~~ small, ~~medium~~ medium, and large anesthesia circuits;
- 26 (13) ~~Back-up~~ back-up lighting;
- 27 (14) ~~Gastric~~ gastric suction device;
- 28 (15) ~~Endotracheal~~ endotracheal tube and pulmonary suction device;
- 29 (16) ~~Equipment~~ equipment for performing emergency cricothyrotomies and delivering positive
30 pressure ventilation;
- 31 (17) ~~Back-up~~ back-up ventilation measurement;
- 32 (18) ~~Rebreathing~~ rebreathing device;
- 33 (19) ~~Scavenging~~ scavenging system;
- 34 (20) ~~Intermittent~~ intermittent compression devices;
- 35 (21) CPR board or dental chair without enhancements suitable for providing emergency treatment;
- 36 (22) ~~Laryngoscope~~ laryngoscope with working ~~current~~ batteries; and
- 37 (23) ~~Tourniquet~~ tourniquet and tape.

- 1 (d) The following ~~current~~ unexpired medications shall be immediately accessible ~~accessible~~ to the permit holder:
- 2 (1) ~~Epinephrine; ephinephrine;~~
- 3 (2) Atropine;
- 4 (3) ~~Antiarrhythmic~~ antiarrhythmic;
- 5 (4) ~~Antihistamine;~~ antihistamine;
- 6 (5) ~~Antihypertensive;~~ antihypertensive;
- 7 (6) ~~Bronchodilator;~~ bronchodilator;
- 8 (7) ~~Antihypoglycemic agent;~~ antihypoglycemic agent;
- 9 (8) ~~Vasopressor;~~ vasopressor;
- 10 (9) ~~Corticosteroid;~~ corticosteroid;
- 11 (10) ~~Anticonvulsant;~~ anticonvulsant;
- 12 (11) ~~Muscle relaxant;~~ muscle relaxant;
- 13 (12) ~~Appropriate~~ appropriate reversal agents;
- 14 (13) ~~Nitroglycerine;~~ nitroglycerine;
- 15 (14) ~~Antiemetic;~~ antiemetic;
- 16 (15) ~~Neuromuscular~~ neuromuscular blocking agent; and
- 17 (16) ~~Anti-malignant~~ anti-malignant hyperthermia agent.
- 18 (e) The evaluation and on-site inspection shall be conducted as set out in Rule .0204 of this Section.
- 19 (f) Before administering general anesthesia or sedation at another provider's office, the mobile permit holder shall
- 20 inspect the host facility to ensure that:
- 21 (1) ~~The the operator is of sufficient~~ operator's size and design ~~to permit effective~~
- 22 emergency management and access of emergency equipment and
- 23 personnel;
- 24 (2) ~~There there~~ is a CPR board or dental chair without enhancements suitable for
- 25 providing emergency treatment;
- 26 (3) ~~There there is sufficient lighting;~~ lighting to permit performance of all procedures planned for the
- 27 facility;
- 28 (4) ~~There there~~ is suction equipment, including non-electrical back-up suction; and
- 29 (5) ~~At at~~ at least two BLS certified auxiliaries ~~[shall be]~~ are present during all procedures.
- 30 (g) At least 24 hours before the procedure is scheduled to begin, the mobile permit holder shall send written notice
- 31 to the Board office confirming that the facility where the general anesthesia or sedation will be performed meets the
- 32 requirements of Paragraph (f) of this Rule and documenting when the inspection was conducted. The permit holder
- 33 shall retain a copy of the written notice for 10 years following the procedure. No procedure ~~may~~ shall be performed
- 34 until if the report is ~~not filed~~ as required by this Paragraph. Paragraph is filed.
- 35 (h) The mobile general anesthesia permit shall be displayed in the host facility where it is visible to patients
- 36 receiving treatment.
- 37 (i) All applicants for mobile general anesthesia permit shall be in good standing with the Board.

1 21 NCAC 16Q .0207 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0207 ANNUAL RENEWAL OF GENERAL ANESTHESIA AND ITINERANT**
4 **(MOBILE) GENERAL ANESTHESIA PERMIT REQUIRED**

5 (a) General anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by paying
6 a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:

7 www.ncdentalboard.org. If the completed renewal application and renewal fee are not received before January 31
8 of each year, a one hundred dollar (\$100.00) late fee shall be paid.

9 (b) Itinerant general anesthesia permits shall be renewed by the Board annually at the same time as dental licenses
10 by paying a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:

11 www.ncdentalboard.org. If the completed itinerant general sedation permit and renewal fee are not received before
12 January 31 of each year, a one hundred dollar (\$100.00) late fee shall be paid.

13 (c) Any dentist who fails to renew a general anesthesia permit or itinerant general anesthesia permit before March
14 31 of each year shall complete a reinstatement application, pay the renewal ~~fee and fee~~, late ~~fee fee~~, and comply with
15 all conditions for renewal set out in this Rule. Dentists whose anesthesia permits or itinerant general anesthesia
16 permits have been lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the
17 reinstatement process.

18 (d) A dentist who ~~continues to administer~~ administers general anesthesia ~~or any level of sedation~~ in violation of this
19 Rule shall be subject to the penalties prescribed by Rule .0701 of this Subchapter.

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

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

26 (A) sedation;

27 (B) medical emergencies;

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

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

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

31 (F) airway management; ~~management and~~

32 (2) unexpired current ACLS, ACLS certification, which shall not count towards the six hours required
33 in ~~Subparagraph Paragraph [(e);] (e)(1) of this Rule; and~~

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

- 1 (4) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have read
2 the practice's emergency manual in the preceding year; and
3 (5) that all [~~permit holder~~] auxiliaries involved in sedation procedures have completed BLS
4 certification and six hours of continuing education in medical emergencies annually.
5

6 *History Note:* Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
7 Eff. March 1, 2016.
8
9
10

1 21 NCAC 16Q .0301 is amended as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0301 CREDENTIALS AND PERMITS FOR MODERATE CONSCIOUS SEDATION**
4 **SEDATION, MODERATE PEDIATRIC CONSCIOUS SEDATION AND**
5 **MODERATE CONSCIOUS SEDATION LIMITED TO ORAL ROUTES OF**
6 **ADMINISTRATION AND NITROUS OXIDE**

7 (a) Before a dentist licensed to practice in North Carolina may administer or supervise a ~~certified registered nurse~~
8 ~~anesthetist (CRNA)~~ CRNA ~~[or RN]~~ employed to administer or RN employed to deliver moderate conscious
9 sedation, ~~moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes of~~
10 ~~administration and nitrous oxide to dental patients on an outpatient basis~~, the dentist shall obtain a permit from the
11 Board by completing an application form ~~provided by the Board~~ and paying a fee of ~~one hundred dollars (\$100.00).~~
12 three hundred seventy five dollars (\$375.00). The application form is available on the Board's website:

13 www.ncdentalboard.org. ~~The~~ Such permit shall be renewed annually and shall be displayed with the current
14 renewal at all times ~~in a conspicuous place in the facility of the permit holder.~~ holder where it is visible to patients
15 receiving treatment.

16 (b) The permit holder shall ~~[directly supervise]~~ provide direct supervision to any CRNA ~~[or RN]~~ employed to
17 administer or RN employed to deliver [sedation] sedation, and shall ensure that the level and duration of the
18 sedation does not exceed the permit holder's permit.

19 (b) ~~For a dentist to employ a certified registered nurse anesthetist to administer moderate conscious sedation,~~
20 ~~moderate conscious sedation limited to oral routes and nitrous oxide or moderate pediatric conscious sedation,~~ the
21 dentist must demonstrate through the permitting process that he or she is capable of performing all duties and
22 procedures to be delegated to the CRNA ~~The dentist must not delegate said CRNA perform procedures outside of~~
23 ~~the scope of the technique and purpose of moderate conscious sedation, moderate pediatric conscious sedation or~~
24 ~~moderate conscious sedation limited to oral routes and nitrous oxide as defined in Rule .0101 of this Subchapter.~~

25 (c) A dentist applying for a permit to administer moderate conscious sedation ~~or moderate pediatric conscious~~
26 ~~sedation shall~~ must meet at least one of the following criteria: ~~[document:]~~ document the following:

- 27 (1) ~~Satisfactory completion~~ Completion of a minimum of [90] 60 hours of Board approved didactic
28 training training, including PALS (Pediatric Advanced Life Support), and instruction in
29 intravenous conscious sedation, sedation and 30 hours of clinical training, ~~[which]~~ that shall
30 include satisfactory successful management of a minimum of ~~40~~ 20 live patients, under
31 ~~[supervision,]~~ supervision of the course instructor, using intravenous sedation. Training shall be
32 provided by one or more individuals who meet the American Dental Association Guidelines For
33 Teaching Pain Control and Sedation to [Dentists or:] Dentists that is hereby incorporated by
34 reference, including subsequent amendments and editions. The guidelines may be found at
35 www.ada.org/coda.

1 (2) ~~Satisfactory completion~~ Completion of a pre-doctoral dental or postgraduate program ~~which that~~
2 included intravenous conscious sedation training equivalent to that defined in Subparagraph (c)(1)
3 of this Rule; ~~or [and;]~~

4 (3) ~~[Current] Unexpired ACLS certification [ACLS;]~~ and

5 (4) ~~That all auxiliaries involved in sedation procedures have [current] unexpired BLS certification.~~

6 (3) ~~Satisfactory completion of a pre-doctoral dental or postgraduate program which included~~
7 ~~intravenous conscious sedation training equivalent to that defined in Subparagraph (c)(1) of this~~
8 ~~Rule.~~

9 ~~(d) Notwithstanding the foregoing, a dentist may also qualify for a permit to administer moderate pediatric~~
10 ~~conscious sedation by documenting, with patient names and dates of completion, at least 100 cases of moderate~~
11 ~~pediatric sedation procedures successfully completed between July 3, 2006 and July 3, 2009. A dentist who obtains~~
12 ~~a pediatric conscious sedation permit pursuant to this Paragraph may not administer sedation intravenously and such~~
13 ~~limitation shall be noted on the dentist's permit.~~

14 ~~(e) A dentist may modify his or her moderate conscious sedation permit to include the privilege of moderate~~
15 ~~pediatric conscious sedation by completing a Board approved pediatric dental degree or pediatric dental residency~~
16 ~~program or obtaining the equivalent hours of continuing education program in pediatric dental anesthesia. If said~~
17 ~~qualifications are satisfied, it shall be so designated on the dentist's moderate conscious sedation permit and will be~~
18 ~~subject to the renewal requirements stated in Rule .0501(d) of this Subchapter.~~

19 ~~(f) To be eligible for a moderate conscious sedation permit, moderate conscious sedation limited to oral routes and~~
20 ~~nitrous oxide inhalation permit or moderate pediatric conscious sedation permit, a dentist must operate within a~~
21 ~~facility which includes the capability of delivering positive pressure oxygen, and is staffed with supervised auxiliary~~
22 ~~personnel for each procedure performed. The dentist shall ensure that auxiliary personnel document annual,~~
23 ~~successful completion of basic life support (BLS) training and are capable of assisting with procedures, problems~~
24 ~~and emergencies incident thereto.~~

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

26 ~~(e)(g) Prior to issuance of a moderate conscious sedation permit, moderate conscious pediatric sedation permit or~~
27 ~~moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation permit, the applicant shall~~
28 ~~undergo pass an evaluation which includes and a facility inspection. The Board shall direct an evaluator to perform~~
29 ~~this evaluation. The applicant shall be notified in writing that an evaluation and facility inspection is required and~~
30 ~~provided with the name of the evaluator who shall perform the evaluation and facility inspection. The applicant shall~~
31 ~~be responsible for successful completion of passing the evaluation and inspection of his or her facility within three~~
32 ~~months 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or~~
33 ~~applicant requests one, one by contacting the Board in writing.~~

34 ~~[(f) The entire fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the applicant receives~~
35 ~~notice of the inspection of each additional location at which the dentist administers sedation.]~~

36 ~~(h) [(g) The evaluator shall assign a grade of pass or fail and shall report his [or her] recommendation to the Board,~~
37 ~~setting out the basis for his [or her] conclusion. The Board, [Board's Anesthesia and Sedation Committee] is not~~

1 bound by the evaluator's recommendation and shall make a final determination regarding whether the applicant has
2 passed the evaluation. The applicant shall be notified of the ~~[Committee's]~~Board's decision in writing.

3 ~~[(h) An applicant who fails an inspection or evaluation shall not receive a sedation permit.]~~

4 ~~[(i) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days
5 of receiving the notice of failure. The request shall state specific grounds supporting it. The Board shall
6 require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency
7 determined by the evaluation.]~~

8 ~~[(j) Re-inspections and re-evaluations shall be conducted by evaluators not involved in the failed inspection or
9 evaluation.]~~

10 ~~[(k) An applicant who does not pass the evaluation and inspection within the time allowed by Paragraph (e) of this
11 Rule shall reapply and pay an additional three hundred seventy five dollar (\$375.00) fee.]~~

12 ~~(i) ~~[(4)]~~ (f) A dentist who holds a moderate conscious sedation, sedation, sedation moderate conscious sedation limited to oral
13 routes and nitrous oxide inhalation or moderate pediatric conscious sedation permit shall not intentionally administer
14 deep sedation sedation. although deep sedation may occur briefly and unintentionally.~~

15 ~~(j) A dentist may obtain a moderate conscious sedation permit limited to oral routes of administration and nitrous
16 oxide inhalation, including the ability to add supplemental dosing to the techniques set out in Rule .0101(23) of this
17 Subchapter upon compliance with the following requirements:~~

18 (1) — successfully complete 24 hours of didactic training and manage at least 10 adult case experiences,
19 including at least three live clinical dental experiences. The live clinical cases shall not be handled
20 by groups with more than five student participants. The remaining cases may include simulations,
21 video presentations or both, but must include one experience in returning/rescuing a patient from
22 deep to moderate sedation; or

23 (2) — document, with patient names and dates of completion, at least 100 cases of oral moderate
24 conscious sedation procedures successfully completed within one year preceding June 3, 2008;
25 and fulfill all the requirements listed in Rule .0401 of this Subchapter for minimal conscious
26 sedation.

27 ~~(k) A dentist who is qualified to administer general anesthesia, moderate conscious sedation or moderate pediatric
28 conscious sedation and holds a general anesthesia, moderate conscious sedation permit or a moderate pediatric
29 conscious sedation permit may administer minimal conscious sedation or moderate conscious sedation limited to
30 oral routes without obtaining an additional a separate minimal conscious sedation permit.~~

31 ~~(l) Any dentist who holds an active parenteral conscious sedation permit as of October 1, 2007 shall be deemed to
32 hold an active moderate conscious sedation permit. Such permits shall be subject to the renewal requirements set
33 out in Rule .0501 of this Subchapter.~~

34
35 *History Note: Authority G.S. 90-28; 90-30.1; 90-39(12); 90-48;*
36 *Eff. February 1, 1990;*
37 *Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;*

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Temporary Amendment Eff. December 11, 2002;
Amended Eff. March 1, 2016; July 1, 2010, July 3, 2008; August 1, 2004.

1 21 NCAC 16Q .0302 is amended as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0302 MODERATE CONSCIOUS SEDATION CLINICAL REQUIREMENTS AND**
4 **EQUIPMENT**

5 (a) A dentist administering moderate conscious sedation ~~or moderate pediatric conscious sedation~~ or supervising the
6 administration delivery of moderate conscious sedation ~~or moderate pediatric conscious sedation~~ by a certified
7 ~~registered nurse anesthetist~~ by a CRNA or RN shall be responsible to ensure that the facility in which where the
8 sedation is ~~to be~~ administered meets the following requirements:

- 9 (1) The facility shall be is equipped with the following: with:
- 10 (A) an An operatory of size and design to permit access of emergency equipment and
11 personnel and to permit effective emergency management;
- 12 (B) a A CPR ~~Board~~ board or a dental chair without enhancements, suitable for providing
13 emergency treatment;
- 14 (C) lighting Lighting as necessary for specific ~~procedures;~~ procedures and back-up lighting;
15 and
- 16 (D) suction Suction equipment as necessary for specific procedures, including non-electrical
17 back-up suction.

18 ~~(2) The following equipment is maintained:~~

- 19 ~~(A) (E) Positive positive~~ oxygen delivery system, including full face masks for ~~adults and~~
20 ~~pediatric~~ small, [medium] medium, and large patients and back-up E-cylinder portable
21 oxygen tank apart from the central system;
- 22 ~~(B) (F) Small, [medium] medium, and large Oral oral~~ and nasal airways; airways of various
23 sizes;
- 24 ~~(C) (G) Blood blood~~ pressure monitoring device;
- 25 ~~(D) (H) Pulse pulse~~ oximeter; and
- 26 ~~(E) (I) Automatic External Defibrillator automatic external defibrillator (AED); AED;~~
- 27 ~~(F) (J) EKG Monitor; monitor;~~
- 28 ~~[(G) (K)] [Capnograph; and] capnograph;~~
- 29 ~~(H) (L) [Thermometer.] thermometer;~~

30 ~~(3) The following emergency equipment is maintained:~~

- 31 (A) ~~[(D) (M)] L.V. [Vascular] vascular~~ access set-up as necessary for specific procedures, including
32 hardware and fluids; fluids, if anesthesia is intravenous;
- 33 ~~(B) [(J) (N)] Syringes syringes~~ as necessary for specific procedures; ~~and~~
- 34 ~~(C) [(K) (O)] tourniquet Tourniquet and tape- tape;~~
- 35 ~~[(L) (P)] [Advanced] advanced~~ airway devices; and
- 36 ~~[(M) (Q)] [Tonsillar] tonsillar~~ suction with back-up suction.

1 (4) ~~[(2)]~~ (3) The following drugs are maintained with a current shelf life and with access from the operator
2 and recovery area. The following unexpired drugs shall be maintained in the facility and with
3 access from the operator and recovery rooms:

- 4 (A) Epinephrine; ~~[Injectable]~~ injectable epinephrine;
- 5 (B) Atropine; ~~[Injectable]~~ injectable Atropine;
- 6 (C) Appropriate ~~[Injectable]~~ injectable appropriate reversal agents;
- 7 (D) Antihistamine; ~~[Injectable]~~ injectable antihistamine;
- 8 (E) Corticosteroid; ~~[Injectable]~~ injectable corticosteroid;
- 9 (F) Nitroglycerine; ~~nitroglycerine~~;
- 10 (G) Bronchial dilator; ~~[Bronchodilator;]~~ bronchodilator;
- 11 (H) Antiemetic; ~~[Injectable]~~ injectable antiemetic;
- 12 (I) ~~[Injectable]~~ injectable 50% Dextrose; and
- 13 (J) Anti-arrhythmic; ~~[Injectable]~~ injectable anti-arrhythmic.

14 (5) ~~[(3)]~~ (4) The permit holder shall maintain written ~~Written~~ emergency and patient discharge protocols
15 are maintained and training to familiarize office personnel auxiliaries in the treatment of clinical
16 emergencies is shall be provided; and

17 (6) ~~[(4)]~~ (5) The dentist shall maintain the following records are maintained for at least 10 years:

- 18 (A) Patient's current written medical history, history and pre-operative assessment; including
19 known allergies and previous surgery; and
- 20 (B) Drugs administered during the procedure, including route of administration, dosage,
21 strength, time and sequence of administration;
- 22 (C) A sedation record which shall include: ~~[record; and]~~
 - 23 (i) blood pressure;
 - 24 (ii) pulse rate;
 - 25 (iii) respiration;
 - 26 (iv) duration of procedure;
 - 27 (v) documentations of complications or morbidity; and
 - 28 (vi) status of patient upon discharge.

29 ~~[(D) Signed consent form, identifying the procedure, risks and benefits,
30 level of sedation and date signed.]~~

31 (5) (6) The sedation record shall include:

- 32 (A) base line vital signs, blood pressure (unless patient behavior prevents recording);
33 oxygen saturation, ET CO₂, pulse and respiration rates of the patient recorded in real
34 time at 15 minute intervals;
- 35 (B) procedure start and end times;
- 36 (C) gauge of needle and location of ~~[IV;]~~ IV on the patient, if used;
- 37 (D) status of patient upon discharge; ~~[and]~~

1 (E) ~~documentation of complications or morbidity;~~ morbidity; and

2 (F) ~~Consent form, signed by the patient or guardian, identifying the procedure, risks and~~
3 ~~benefits, level of sedation, and date signed.~~

4 ~~(6)~~ (7) The following conditions shall be satisfied during a sedation procedure:

5 (A) ~~Two~~ two BLS certified auxiliaries shall be present at all times during the
6 procedure, one of whom shall be dedicated to continuous patient
7 monitoring and recording sedation ~~data;~~ data; and

8 (B) ~~If~~ if IV sedation is used, IV infusion shall be administered before the
9 start of the procedure and maintained until the patient is ready for
10 ~~dismissal;~~ discharge.

11 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of
12 moderate conscious sedation on a patient, ~~or where applicable, moderate pediatric conscious sedation on a patient,~~
13 including the deployment of an intravenous delivery system, while the evaluator observes. ~~Practices limited to~~
14 ~~pediatric dentistry will not be required to demonstrate the deployment of an intravenous delivery system. Instead,~~
15 ~~they will orally describe to the evaluator the technique of their training in intravenous and intraosseous deployment.~~

16 During the demonstration, the applicant or permit holder shall demonstrate competency in the following areas:

- 17 (1) ~~Monitoring~~ monitoring blood pressure, pulse, ET ~~CO₂~~ CO₂, and respiration;
- 18 (2) ~~Drug~~ drug dosage and administration;
- 19 (3) ~~Treatment~~ treatment of untoward reactions including respiratory or cardiac depression if
20 applicable;
- 21 (4) ~~Sterile~~ sterile technique;
- 22 (5) ~~Use~~ use of BLS CPR certified ~~personnel;~~ auxiliaries;
- 23 (6) ~~Monitoring~~ monitoring of patient during recovery; and
- 24 (7) ~~Sufficiency~~ sufficiency of patient recovery time.

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

- 27 (1) ~~Laryngospasm;~~ laryngospasm;
- 28 (2) ~~bronchospasm;~~ Bronchospasm;
- 29 (3) ~~Emesis~~ emesis and aspiration;
- 30 (4) ~~Respiratory~~ respiratory depression and arrest;
- 31 (5) ~~Angina~~ angina pectoris;
- 32 (6) ~~Myocardial~~ myocardial infarction;
- 33 (7) ~~Hypertension/Hypotension;~~ ~~[Hypertension and Hypotension;]~~ hypertension and hypotension;
- 34 (8) ~~Syncope;~~ syncope;
- 35 (9) ~~Allergie~~ allergic reactions;
- 36 (10) ~~Convulsions;~~ convulsions;
- 37 (11) ~~Bradycardia;~~ bradycardia

- 1 (12) ~~Insulin~~ insulin shock; ~~and~~
- 2 (13) ~~Cardiac~~ arrest. cardiac arrest; and
- 3 (14) ~~[Airway]~~ airway obstruction.

4 ~~(d) A dentist administering moderate conscious sedation or moderate pediatric conscious sedation shall ensure that~~
5 ~~the facility is staffed with sufficient auxiliary personnel for each procedure performed who shall document annual~~
6 ~~successful completion of basic life support training and be capable of assisting with procedures, problems, and~~
7 ~~emergency incidents that may occur as a result of the sedation or secondary to an unexpected medical complication.~~

8 (d) A moderate conscious sedation permit holder shall evaluate [patients] a patient for health risks before starting
9 any sedation procedure as follows:

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

15 (e) Post-operative monitoring and discharge:

- 16 (1) [Vital] vital signs shall be continuously monitored when the sedation is no longer being
17 administered and the patient shall have direct continuous supervision until oxygenation and
18 circulation are stable and the patient is [sufficiently responsive] recovered as defined in
19 [Paragraph] Subparagraph (e)(2) of this Rule and is ready for discharge from the office.
- 20 (2) [Recovery] recovery from moderate conscious sedation shall [include:] include documentation of
21 the following:
 - 22 (A) cardiovascular function stable;
 - 23 (B) airway patency uncompromised;
 - 24 (C) patient [easily] arousable and protective reflexes intact;
 - 25 (D) state of hydration within normal limits;
 - 26 (E) patient can talk, if applicable;
 - 27 (F) patient can sit unaided, if applicable;
 - 28 (G) patient can ambulate, if applicable, with minimal assistance; and
 - 29 (H) for special needs patients [the patient who is disabled, or] or patients incapable of the
30 usually expected responses, the pre-sedation level of responsiveness or the level as close
31 as possible for that patient shall be achieved.
- 32 (3) [Before] before allowing the patient to leave the office, the dentist shall determine that the patient
33 has met the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following
34 discharge criteria:
 - 35 (A) oxygenation, circulation, activity, skin [color] color, and level of consciousness are
36 [sufficient and stable] stable, and have been documented;

- 1 (B) explanation and documentation of written postoperative instructions have been provided
2 to the patient or a responsible adult at time of discharge; and
3 (C) ~~responsible individual~~ a vested adult is available ~~for the patient~~ to transport the patient
4 after discharge.

5
6 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
7 *Eff. February 1, 1990;*
8 *Amended Eff. August 1, 2002; August 1, 2000;*
9 *Temporary Amendment Eff. December 11, 2002;*
10 *Amended Eff. March 1, 2016; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004.*

1 21 NCAC 16Q .0303 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0303 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION**

4

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

6 *Eff. February 1, 1990;*

7 *Amended Eff. August 1, 2002; January 1, 1994;*

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

9 *Amended Eff. September 1, 2014; February 1, 2009; July 3, 2008; August 1, 2004.*

10 *Repealed Eff. March 1, 2016.*

11

12

1 21 NCAC 16Q .0304 is amended as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0304 OFF SITE USE OF MODERATE CONSCIOUS SEDATION PERMITS**

4 ~~(a) Upon request, the~~ The holder of a ~~moderate pediatric conscious sedation or moderate conscious sedation permit~~
5 may travel to the office of a licensed dentist ~~who does not hold such a permit~~ and provide moderate conscious
6 ~~sedation services at the level for which the traveling dentist holds a valid permit, as well as minimal sedation or~~
7 ~~moderate conscious sedation limited to oral routes~~ for the patients of that dentist who are undergoing dental
8 procedures. The permit holder shall be responsible to ensure ~~is solely responsible for providing~~ that the facility ~~in~~
9 ~~which~~ where the sedation is administered has passed inspection by the Board and meets the requirements set out in
10 Rule .0302 of this Section. ~~established by the Board, that the required drugs and equipment are present, and~~ The
11 ~~that the permit holder shall~~ be responsible to ensure that utilizes sufficient auxiliary personnel for each procedure
12 ~~performed based on the standard of care who shall document annual successful completion of basic life support~~
13 ~~training- two BLS certified auxiliaries are available for each procedure. and be capable of assisting with procedures,~~
14 ~~problems, and emergency incidents that may occur as a result of the sedation or secondary to an unexpected medical~~
15 ~~complication.~~

16 ~~(b) Holders of moderate conscious sedation permits limited to oral routes and nitrous oxide inhalation may not~~
17 ~~provide sedation at the office of a licensed dentist who does not hold an appropriate sedation permit.~~

18

19 *History Note: Authority G.S. 90-28; 90-30; 90-30.1; 90-48;*

20 *Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013.*

21 *Amended Eff. March 1, 2016.*

22

23

24

1 21 NCAC 16Q .0305 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0305 ANNUAL RENEWAL OF MODERATE CONSCIOUS SEDATION PERMIT**
4 **REQUIRED**

5 (a) Moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses
6 by paying a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:
7 www.ncdentalboard.org.

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

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

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

16 (e) As a condition for renewal of the moderate conscious sedation ~~permit-permit~~, the ~~applicant-permit holder~~ shall
17 meet the clinical and equipment requirements of Rule .0302 of this Section and shall ~~document-~~ document the
18 following:

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

22 (A) sedation;

23 (B) medical emergencies;

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

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

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

27 (F) airway management; ~~and~~

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

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

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

34 (5) that all auxiliaries involved in sedation procedures have completed BLS certification and six hours
35 of continuing education in medical emergencies annually.

36 (f) All ~~applicants-permit holders applying-~~ for renewal of a moderate conscious sedation permit shall be in good
37 standing with the Board.

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History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
Eff. March 1, 2016.

1 21 NCAC 16Q .0306 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0306 PROCEDURE FOR MODERATE CONSCIOUS SEDATION EVALUATION OR**
4 **INSPECTION AND RE-INSPECTION**

5 (a) When an evaluation or on-site inspection is required, the Board ~~will~~ shall designate one or more qualified
6 ~~persons,~~ persons to serve as evaluators [or inspectors,] each of whom has administered moderate conscious sedation
7 for at least three years preceding the ~~inspection,~~ inspection. ~~exclusive of his or her training~~ Training in moderate
8 conscious ~~sedation.~~ sedation shall not be counted in the three years.

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

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

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

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

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

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

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

29
30 *History Note: Authority G.S. ~~90-28;~~ 90-30.1; 90-39;*90-48;
31 *Eff. March 1, 2016.*
32

1 21 NCAC 16Q .0401 - .0403 are repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0401 MINIMAL CONSCIOUS SEDATION CREDENTIALS, EVALUATION AND**
4 **PERMIT**

5 **21 NCAC 16Q .0402 MINIMAL CONSCIOUS SEDATION PERMIT REQUIREMENTS, CLINICAL**
6 **PROVISIONS AND EQUIPMENT**

7 **21 NCAC 16Q .0403 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION**

8

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

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

11 *Eff. August 1, 2004;*

12 *Amended Eff. February 1, 2009; July 3, 2008;*

13 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0404 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0404 CREDENTIALS AND PERMITS FOR MODERATE PEDIATRIC CONSCIOUS**
4 **SEDATION**

5 (a) Before a dentist licensed to practice in North Carolina may administer moderate pediatric conscious sedation,
6 the dentist shall obtain a general anesthesia or moderate pediatric conscious sedation permit from the Board by
7 completing an application form and paying a fee of three hundred seventy-five dollars (\$375.00). The application
8 form is available on the Board's website: www.ncdentalboard.org. The permit shall be renewed annually and shall
9 be displayed with the ~~current~~ unexpired renewal at all times in the permit holder's facility where it is visible to
10 patients receiving treatment.

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

- 13 (1) completion of a postgraduate program ~~which that~~ included pediatric intravenous conscious
14 sedation training;
- 15 (2) completion of a Council On Dental Accreditation (CODA) approved pediatric residency ~~which~~
16 that included intravenous conscious sedation training; or
- 17 (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that
18 includes training in the use and placement of IVs or intraosseous vascular access. A list of CODA
19 approved institutions that is hereby incorporated by reference, including subsequent amendments
20 and editions, appears at www.ada.org/coda.

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

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

25 ~~(e) Before receiving a moderate pediatric sedation permit, the applicant shall pass an evaluation and a facility~~
26 ~~inspection. The Board shall direct an evaluator to perform this evaluation and inspection. The Board shall notify~~
27 ~~the applicant in writing that an evaluation and facility inspection is required and [provided with the name of] the~~
28 ~~evaluator who shall perform the evaluation and facility inspection at least 15 days before the inspection and~~
29 ~~evaluation. The applicant shall be responsible for successful completion of the evaluation and inspection of his or~~
30 ~~her facility within 90 days of notification. An extension of no more than 90 days shall be granted if the designated~~
31 ~~evaluator or applicant requests one.~~

32 ~~(f) An additional fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the applicant~~
33 ~~receives notice of the inspection of each additional location at which the dentist administers sedation.~~

34 ~~(g) The evaluator shall assign a grade of pass or fail and shall report his or her recommendation to the Board, setting~~
35 ~~out the basis for his or her conclusion. The Board's Anesthesia and Sedation Committee is not bound by the~~
36 ~~evaluator's recommendation and shall make a final determination regarding whether the applicant has passed the~~
37 ~~evaluation. The applicant shall be notified of the Committee's decision in writing.~~

- 1 ~~(h) An applicant who fails an inspection or an evaluation shall not receive a sedation permit.~~
2 ~~(i) An applicant who fails an inspection or evaluation may request a re-evaluation within 15 days of receiving the~~
3 ~~notice of failure. The request shall state specific grounds supporting it. The Board shall require the applicant~~
4 ~~to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the~~
5 ~~evaluation.~~
6 ~~(j) Re-inspections shall be conducted by evaluators not involved in the failed inspection or evaluation.~~
7 ~~(k) An applicant who does not pass the evaluation and inspection within the time allowed by Paragraph [(g)]~~
8 ~~of this Rule shall reapply and pay an additional three hundred seventy five dollar (\$375.00) fee.~~
9 ~~(l) (e) A dentist who holds a moderate pediatric conscious sedation permit shall not intentionally administer deep~~
10 ~~sedation.~~

11

12

13 *History Note: Authority G.S. ~~90-28~~; 90-30.1; 90-39(12); 90-48;*

14 *Eff. March 1, 2016.*

15

1 21 NCAC 16Q .0405 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0405 MODERATE PEDIATRIC CONSCIOUS SEDATION CLINICAL**
4 **REQUIREMENTS AND EQUIPMENT**

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

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

8 (A) ~~An~~ an operatory of size and design to permit access of emergency equipment and
9 personnel and to permit ~~effective~~ emergency management;

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

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

13 (D) ~~Suction~~ suction equipment as necessary for specific procedures, including non-electrical
14 back-up ~~{suction.}~~ suction;

15 ~~{(2) The following equipment is maintained:}~~

16 ~~{(A) (E) Positive positive oxygen delivery system, including full face masks for small, medium,~~
17 ~~and large adults and pediatric patients—patients, and back-up E-cylinder portable oxygen~~
18 ~~tank apart from the central system;~~

19 ~~{(B) (F) Oral oral and nasal airways of various sizes;~~

20 ~~{(C) (G) Blood blood pressure monitoring device;~~

21 ~~{(D) (H) Pulse pulse oximeter;~~

22 ~~{(E) (I) Capnograph; capnograph;~~

23 ~~{(F) (J) Defibrillator; defibrillator;~~

24 ~~{(G) (K) EKG Monitor; monitor;~~

25 ~~{(H) (L) Thermometer; thermometer;~~

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

28 ~~{(J) (N) Syringes syringes as necessary for specific procedures;~~

29 ~~{(K) (O) Advanced-advanced-airways; and~~

30 ~~{(L) (P) Tourniquet tourniquet and tape.~~

31 ~~{(3) (2) The following drugs are maintained with a current shelf life and with access from the operatory~~
32 ~~and recovery area: The following unexpired drugs shall be maintained in the facility and with~~
33 ~~access from the operatory and recovery rooms:~~

34 (A) ~~Epinephrine; epinephrine;~~

35 (B) ~~Atropine;~~

36 (C) ~~Appropriate-appropriate reversal agents;~~

37 (D) ~~Antihistamine; antihistamine;~~

- 1 (E) ~~Corticosteroid;~~ corticosteroid;
- 2 (F) ~~Nitroglycerine;~~ nitroglycerine;
- 3 (G) ~~Bronchodilator;~~ bronchodilator;
- 4 (H) ~~Antiemetic;~~ antiemetic; and
- 5 (I) 50% Dextrose.

6 ~~[(4)] (3) The permit holder shall maintain written~~ Written emergency and patient discharge protocols ~~are~~
 7 ~~maintained~~ and training to familiarize auxiliaries in the treatment of clinical emergencies is shall
 8 ~~be provided; and~~

9 ~~[(5)] (4) The following records are maintained for at least 10 years:~~

- 10 (A) ~~patient's~~ Patient's current written medical history and pre-operative assessment;
- 11 (B) ~~drugs~~ Drugs administered during the procedure, including route of administration,
 12 dosage, strength, time and sequence of administration;
- 13 (C) ~~A~~ a sedation record;
- 14 (D) ~~a~~ Signed consent form, signed by the patient or a guardian, identifying the procedure,
 15 risks and benefits, level of sedation and date signed.

16 ~~[(6)] (5) The sedation record shall include:~~

- 17 (A) base line vital signs, blood pressure (unless patient behavior prevents recording); oxygen
 18 saturation, ET CO2, pulse and respiration rates of the patient recorded in real time at 15
 19 minute intervals;
- 20 (B) procedure start and end times;
- 21 (C) gauge of needle and location of ~~IV,~~ IV on the patient, if used;
- 22 (D) status of patient upon discharge; and
- 23 (E) documentation of complications or ~~morbidity.~~ morbidity; and

24 ~~[(7)] (6) The following conditions shall be satisfied during a sedation procedure:~~

- 25 (A) ~~Two~~ two BLS certified auxiliaries shall be present at all times during the
 26 procedure, one of whom shall be dedicated to patient monitoring and
 27 recording sedation data.
- 28 (B) ~~When~~ when IV sedation is used, IV infusion shall be administered before the
 29 commencement of the procedure and maintained until the patient is ready for ~~dismissal.~~
 30 discharge.

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

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

- 1 (1) ~~Monitoring~~ monitoring blood pressure, pulse, and respiration;
- 2 (2) ~~Drug-drug~~ dosage and administration;
- 3 (3) ~~Treatment~~ treatment of untoward reactions including respiratory or cardiac depression if
- 4 applicable;
- 5 (4) ~~Sterile~~ sterile technique;
- 6 (5) ~~Use~~ use of BLS certified auxiliaries;
- 7 (6) ~~Monitoring~~ monitoring of patient during recovery; and
- 8 (7) ~~Sufficiency~~ sufficiency of patient recovery time.

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

- 11 (1) ~~Laryngospasm;~~ laryngospasm;
- 12 (2) ~~bronchospasm;~~ bronchospasm;
- 13 (3) ~~Emesis~~ emesis and aspiration;
- 14 (4) ~~Respiratory~~ respiratory depression and arrest;
- 15 (5) ~~Angina~~ angina pectoris;
- 16 (6) ~~Myocardial~~ myocardial infarction;
- 17 (7) ~~Hypertension/Hypotension;~~ [~~Hypertension and Hypotension;~~] hypertension and hypotension;
- 18 (8) ~~Allergie~~ allergic reactions;
- 19 (9) ~~Convulsions;~~ convulsions;
- 20 (10) ~~Syneope;~~ syncope;
- 21 (11) ~~Bradycardia;~~ bradycardia;
- 22 (12) ~~Insulin~~ insulin shock;
- 23 (13) ~~Cardiac~~ cardiac arrest;
- 24 (14) ~~Airway~~ airway obstruction; and
- 25 (15) ~~Vascular~~ vascular access.

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

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

33 (f) Patient monitoring:

- 34 (1) Patients who have been administered moderate pediatric conscious sedation shall be monitored for
 35 alertness, responsiveness, ~~breathing~~ breathing, and skin coloration during waiting periods before
 36 operative procedures.

- 1 (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and
2 the patient shall have direct continuous supervision until oxygenation and circulation are stable
3 and the patient is [~~sufficiently responsive~~] recovered as defined in Subparagraph (f)(3) of this Rule
4 and is ready for discharge from the office.
- 5 (3) Recovery from moderate pediatric conscious sedation shall ~~include:~~ include documentation of the
6 following:
- 7 (A) cardiovascular function stable;
 - 8 (B) airway patency uncompromised;
 - 9 (C) patient [~~easily~~] arousable and protective reflexes intact;
 - 10 (D) state of hydration within normal limits;
 - 11 (E) patient can talk, if applicable;
 - 12 (F) patient can sit unaided, if applicable;
 - 13 (G) patient can ambulate, if applicable, with minimal assistance; and
 - 14 (H) for the special needs patient who is disabled, or a patient incapable of the usually
15 expected responses, the pre-sedation level of responsiveness or the level as close as
16 possible for that patient shall be achieved.
- 17 (4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met
18 the recovery criteria set out in Subparagraph (f)(3) of this Rule and the following discharge
19 criteria:
- 20 (A) oxygenation, circulation, activity, skin ~~color~~ color, and level of consciousness are
21 sufficient and ~~stable~~ stable, and have been documented;
 - 22 (B) explanation and documentation of written postoperative instructions have been provided
23 to a responsible adult at time of discharge;
 - 24 ~~(C) a vested adult [responsible individual] is available [for the patient] to transport the patient~~
25 after discharge; and
 - 26 (D) ~~A~~ a vested adult shall be available to transport patients for whom a motor vehicle
27 restraint system is required and an additional responsible individual shall be available to
28 attend to the patients.

29
30 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
31 *Eff. March 1, 2016.*
32

1 21 NCAC 16Q .0406 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0406 OFF SITE USE OF MODERATE PEDIATRIC CONSCIOUS SEDATION**

4

PERMITS

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

9

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

11 *Eff. March 1, 2016.*

1 21 NCAC 16Q .0407 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0407 ANNUAL RENEWAL OF MODERATE PEDIATRIC CONSCIOUS SEDATION**
4 **PERMIT REQUIRED**

5 (a) Moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as
6 dental licenses by paying a one hundred (\$100.00) fee and completing an application available from the Board's
7 website: www.ncdentalboard.org.

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

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

14 (d) A dentist who administers ~~Continued administration of moderate pediatric conscious level of~~ sedation in
15 violation of this Rule ~~shall be unlawful and shall be~~ subject ~~the dentist~~ to the penalties prescribed by Rule .0701 of
16 this Subchapter.

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

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

22 (A) sedation;

23 (B) medical emergencies;

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

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

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

27 (F) airway management; ~~and~~

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

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

32 (4) ~~document~~ that the permit holder and all auxiliaries involved in sedation procedures have read the
33 practice's emergency manual in the preceding year.

34 (5) ~~document~~ that all auxiliaries involved in sedation procedures have completed BLS certification
35 and six hours of continuing education in medical emergencies annually.

36 (f) All ~~applicants~~ permit holders applying for renewal of a moderate pediatric conscious sedation permit shall be in
37 good standing with the Board.

1

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

3

Eff. March 1, 2016.

4

5

1 21 NCAC 16Q .0408 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0408 PROCEDURE FOR MODERATE PEDIATRIC SEDATION EVALUATION OR**
4 **INSPECTION AND RE-INSPECTION**

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

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

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

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

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

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

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

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

29
30 *History Note: Authority G.S. ~~90-28; 90-30.1; 90-39; 90-48;~~*
31 *Eff. March 1, 2016.*
32
33
34

1 21 NCAC 16Q .0501 - .0503 are repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED**

4 **21 NCAC 16Q .0502 PAYMENT OF FEES**

5 **21 NCAC 16Q .0503 INSPECTION AUTHORIZED**

6

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

8 *Eff. February 1, 1990;*

9 *Amended Eff. August 1, 2002; January 1, 1994;*

10 *Transferred and Recodified from 16Q .0403 to 16Q .0503;*

11 *Transferred and Recodified from 16Q .0403 to 16Q .0501*

12 *Transferred and Recodified from 16Q .0402 to 16Q .0502;*

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

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

15 *Repealed Eff. March 1, 2016.*

16

1 21 NCAC 16Q .0601 - .0602 are repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0601 REPORTS OF ADVERSE OCCURRENCES**

4 **21 NCAC 16Q .0602 FAILURE TO REPORT**

5

6 *History Note: Authority G.S. 90-28; 90-30.1; 90-41;*

7 *Eff. February 1, 1990;*

8 *Transferred and Recodified from 16Q .0502 to 16Q .0602;*

9 *Transferred and Recodified from 16Q .0501 to 16Q .0601;*

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

11 *Amended Eff. August 1, 2004;*

12 *Repealed Eff. March 1, 2016.*

13

14

1 21 NCAC 16Q .0703 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0703 REPORTS OF ADVERSE OCCURRENCES**

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

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

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

- 16 (1) ~~The~~ dentist's name, license number and permit number;
- 17 (2) ~~The~~ date and time of the occurrence;
- 18 (3) ~~The~~ facility where the occurrence took place;
- 19 (4) ~~The~~ name and address of the patient;
- 20 (5) ~~The~~ surgical procedure involved;
- 21 (6) ~~The~~ type and dosage of sedation or anesthesia utilized in the procedure;
- 22 (7) ~~The~~ circumstances involved in the occurrence; and
- 23 (8) ~~The~~ anesthesia records.

24 (d) Upon receipt of any such report, the Board shall investigate and shall take disciplinary action if the evidence
25 demonstrates that a licensee has violated the Dental Practice Act set forth in Article 2 of G.S. 90 Act ~~or the Board's~~
26 rules of this Chapter .

27

28 *History Note: Authority G.S. 90-28; 90-30.1; 90-41; 90-48;*

29 *Eff. March 1, 2016.*

30

31

32



STATE OF NORTH CAROLINA
OFFICE OF ADMINISTRATIVE HEARINGS

Mailing address:
6714 Mail Service Center
Raleigh, NC 27699-6714

Street address:
1711 New Hope Church Rd
Raleigh, NC 27609-6285

February 18, 2016

Sent via email to carolin.bakewell@gmail.com:

Carolin Bakewell
North Carolina State Board of Dental Examiners
2000 Perimeter Parkway, Suite 106
Morrisville, North Carolina 27560

Re: 21 NCAC 16O .0301, .0302, .0401, .0402
21 NCAC 16Q .0101, .0202, .0203, .0204, .0205, .0206, .0207, .0301, .0302,
.0303, .0304, .0305, .0306, .0401, .0402, .0403, .0404, .0405, .0406, .0407, .0408,
.0501, .0502, .0503, .0601, .0602, .0703

Dear Ms. Bakewell:

At its February 18, 2016 meeting, the Rules Review Commission extended the period of review on the above-identified rules in accordance with G.S. 150B-21.10 and G.S. 150B-21.13. The Commission extended the period of review to allow the North Carolina Board of Dental Examiners additional time to revise the rules in response to the technical change requests.

If you have any questions regarding the Commission's action, please do not hesitate to contact me directly at (919) 431-3076.

Sincerely,

Abigail M. Hammond
Commission Counsel

Administration
919/431-3000
fax: 919/431-3100

Rules Division
919/431-3000
fax: 919/431-3104

Judges and
Assistants
919/431-3000
fax: 919/431-3100

Clerk's Office
919/431-3000
fax: 919/431-3100

Rules Review
Commission
919/431-3000
fax: 919/431-3104

Civil Rights
Division
919/431-3036
fax: 919/431-3103

Hammond, Abigail M

From: Carolin Bakewell <carolin.bakewell@gmail.com>
Sent: Friday, February 05, 2016 8:39 AM
To: Hammond, Abigail M
Cc: Casie Goode; Bobby White; Doug Brocker
Subject: Dental Board Technical Changes Request

Dear Ms. Hammond:

Please accept this message as the Dental Board's request pursuant to G.S. 150B-21.10(3) for an extension of review of the proposed changes to 21 NCAC 16O and 16Q. The Board wishes to carefully review the technical change requests and does not meet until after the Feb. 10 deadline.

Thanks very much.

Carolin Bakewell
Board Counsel

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16O .0301

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 4, the term "Nitrous" is both struckthrough and underlined. Please remove underlining.

Line 5, replace "is not" with "shall not be"

Line 6, replace "is" with "shall be"

Line 11, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 160 .0301 is amended as published in 30:1 NCR 2 with changes, as follows:

2

3 **21 NCAC 160 .0301 NITROUS OXIDE CONSCIOUS SEDATION**

4 "~~Conscious Nitrous~~ "Nitrous oxide sedation" means the use of ~~drugs~~ nitrous oxide for controlling pain or
5 apprehension without rendering the patient unconscious. A sedation permit is not required to administer nitrous
6 oxide, without any other drugs, for the purpose of anxiolysis. A sedation permit is required if nitrous oxide is
7 administered in combination with other sedative agents.

8

9 *History Note:* *Authority G.S. 90-29(b)(6); 90-48; 90-223;*

10 *Eff. July 16, 1980;*

11 *Amended Eff. March 1, 2016; May 1, 1989.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16O .0302

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Please identify the changes to the rule name on the Submission for Permanent Rule form in Box 2

Line 10, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16O .0302 is amended as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16O .0302 NITROUS OXIDE MONITORING**

4 "Monitoring" means observation of the patient during the flow of nitrous oxide ~~sedation agents~~ and includes
5 reducing the flow of nitrous oxide ~~sedation~~ or shutting off equipment controlling such flow. Monitoring does not
6 include starting or increasing the flow of ~~sedation agents~~, nitrous oxide.

7

8 *History Note:* *Authority G.S. 90-29(b)(6); 90-48; 90-223;*

9 *Eff. July 16, 1980;*

10 *Amended Eff. March 1, 2016; May 1, 1989.*

11

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16O .0401

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 5, what is the purpose of the clause "or physician." as that seems outside the authority of Article 2 of G.S. 90. Is there a purpose for that clause in this Rule? In light of the last clause of G.S. 90-29(b)(6), is this Rule necessary? It seems to restate the statute with a minor change to the clause "lawfully qualified nurse anesthetist" Please clarify.

Line 9, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16O .0401 is amended as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16O .0401 NON-DELEGABLE FUNCTIONS**

4 ~~Conscious Nitrous oxide~~ sedation shall not be induced by anyone other than a dentist or a lawfully qualified nurse or
5 ~~anesthetist~~ anesthesiologist who does so under the supervision and direction of a dentist or physician.

6

7 *History Note: Authority G.S. 90-29(b)(6); 90-48; 90-223;*

8 *Eff. July 16, 1980;*

9 *Amended Eff. March 1, 2016; May 1, 1989.*

10

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16O .0402

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Lines 4 thru 7, please clarify what this sentence is stating. The statement seems to indicate that if a dental assistant is not qualified or authorized under G.S. 90-29(c)(13), the dental assistant could still participate in the type of work described, if the dental assistant has completed seven hours of training. How is that statement different than the second sentence of the statutory requirements of G.S. 90-29(c)(13)? This seems like a restatement of the statute and unnecessary. Consider simplifying the statement by stating the following:

“A Dental Assistant may comply with G.S. 90-29(c)(13) by completing at least seven hours of training in courses that cover the following topics:”

Lines 8 thru 20, begin the clauses with lowercase letters as they are part of a list

Line 12, add a comma after “physiology”

Line 16, add a comma after “recognition”

Line 25, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16O .0402 is amended as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16O .0402 EDUCATIONAL REQUIREMENTS**

4 A Dental Assistant ~~I or a Dental Assistant II~~ not otherwise qualified under G.S. 90-29(c)(13) may aid and assist a
5 licensed dentist in the ~~administration~~ monitoring of nitrous oxide-oxygen inhalant ~~conscious~~ sedation after
6 completion of a Board-approved course totaling at least seven hours and directed by an individual or individuals
7 approved by the Board. Such course shall include:

- 8 (1) Definitions and descriptions of physiological and psychological aspects of pain and anxiety;
- 9 (2) The states of drug-induced central nervous system depression through all levels of consciousness
10 and unconsciousness, with special emphasis on the distinction between the conscious and
11 unconscious state;
- 12 (3) Respiratory and circulatory physiology and related anatomy;
- 13 (4) Pharmacology of agents used in the ~~conscious~~ nitrous oxide sedation techniques being taught,
14 including drug interaction and incompatibility;
- 15 (5) Patient monitoring, with particular attention to vital signs and reflexes related to consciousness;
- 16 (6) Prevention, recognition and management of complications and life threatening situations that may
17 occur during the use of the ~~conscious sedation~~ nitrous oxide techniques, including cardio
18 pulmonary resuscitation;
- 19 (7) Description and use of ventilation sedation equipment; and
- 20 (8) Potential health hazards of trace anesthetics, and proposed techniques for elimination of these
21 potential health hazards.

22

23 *History Note: Authority G.S. 90-29(b)(6); 90-29(c)(13); 90-48; 90-223;*

24 *Eff. July 16, 1980;*

25 *Amended Eff. March 1, 2016; May 1, 1989.*

26

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0101

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 6, add a comma after "sedation"

Lines 13 and 24, replace "which" with "that"

Line 13, define or delete "totally"

Lines 14 and 25, define or delete "continuously"

Line 16, replace "must" with "shall"

Lines 16, 17, and 27, define or delete "normally"

Line 17 thru 18, based upon the following sentence in G.S. 90-30.1, what is the purpose of the language in these lines:

For purposes of this section, oral premedication administered for minimal sedation (anxiolysis) shall not be included in the definition of enteral sedation.

Please clarify the need to restate the statute

Line 20, add a comma after "control"

Line 21, add a comma after "timing"

Lines 25 thru 26, and page 2, lines 5 thru 6, please clarify what is meant by the following clause:

"carry a margin of safety wide enough to render unintended loss of consciousness unlikely."

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Please clarify if that is a known medical standard.

Line 29, define or delete “directly” Alternatively, consider replacing “directly” with “under the direct supervision”

Lines 32 and 35, replace “at which” with “that”

Lines 33 and 35, replace “can” with “may”

Lines 33 and 36, define or delete “effectively and efficiently”

Page 2, lines 2 and 10, define or delete “independently”

Page 2, lines 2 and 18, define or delete “continuously”

Page 2, line 2, define or delete “appropriately”

Page 2, lines 6 and 12, delete “current”

Page 2, lines 6 thru 7, and 11 thru 13, please consider adding a cross-reference to the applicable permitting rule

Page 2, line 10, define or delete “continually”

Page 2, lines 11 and 35, define or delete “purposefully”

Page 2, line 14, replace “properly qualified” with “permitted”

Page 2, line 15, define or delete “directly”

Page 2, line 18, replace “physically present in the facility” with the defined clause “immediately available”

Page 2, line 20, are the digital manuals available for review?

Page 2, line 21, replace “dental office” with the defined term “facility”

Page 2, line 21, replace the comma after “office” with a semicolon

Page 2, line 22, add a semicolon after “emergencies”

Page 2, line 25, add a comma after “arrest”

Page 2, line 30, add a comma after “staffed”

Page 2, line 32, please clarify what is meant by “the minimum standard of care.” Consider incorporating an outside standard in compliance with G.S. 150B-21.6 to clarify this language.

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

Page 3, line 3, define “immediate”

Page 3, line 4, is the proper term “licensee” or “permittee”? Please use consistent terms.

Page 3, line 7, replace “especially” with “including”

Page 3, line 9, please clarify the necessity or basis of this definition

Page 3, lines 18 and 34, define or delete “purposefully”

Page 3, line 19, add “of age” after “years”

Page 3, line 19 references 13 and line 35 references 18. Should these numbers be consistent? Please clarify.

Page 3, line 20, add a comma after “rectal”

Page 3, line 22, replace “is” with “may be”

Page 3, lines 22 thru 25, consider the following rewrite the clarify this sentence:

A moderate conscious sedation permit holder shall not use the following:

- (a) drugs designed by the manufacturer for use in administering general anesthesia or deep sedation; or
- (b) drugs contraindicated for use in moderate conscious sedation.

Please note the suggested change of the conjunction from “and” to “or” on line 23.

Page 3, line 36, add a comma after “rectal”

Page 3, line 37 uses the term “single” twice, whereas the term “moderate conscious sedation” does not use the term “single” once. Is this distinction intentional? Please clarify.

Page 4, line 2, replace “is” with “may be”

Page 4, lines 2 thru 5, consider the following rewrite the clarify this sentence:

A moderate pediatric conscious sedation permit holder shall not use the following:

- (a) drugs designed by the manufacturer for use in administering general anesthesia or deep sedation; or
- (b) drugs contraindicated for use in moderate pediatric conscious sedation.

Please note the suggested change of the conjunction from “and” to “or” on line 3.

Page 4, lines 6 thru 7, please clarify the necessity or basis of this definition

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

Page 4, lines 8 thru 9, please clarify that all the terms in this definition are known to the regulated public

Page 4, line 14, define or delete "sufficiently"

Page 4, line 18, delete "which,"

Page 4, line 24, consider replacing 90-28 with 90-48

Page 4, line 27, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0101 is amended as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS**

4 For the purpose of these Rules relative to the administration of ~~minimal conscious sedation,~~ moderate conscious
5 sedation, ~~moderate conscious sedation limited to oral routes or nitrous oxide inhalation,~~ moderate pediatric
6 conscious sedation or general anesthesia by or under the direction of a dentist, the following definitions shall apply:

7 (1) "Analgesia" – the diminution or elimination of pain.

8 (2) "Anti-anxiety sedative" – a sedative agent administered in a dosage intended to reduce anxiety
9 without diminishing consciousness or protective reflexes.

10 (3) "Anxiolysis" – pharmacological reduction of anxiety through the administration of a single dose of
11 ~~a any minor anti-anxiety drug psychosedative, within a 24 hour period, or nitrous oxide possibly in~~
12 ~~combination with nitrous oxide,~~ to children or adults prior to commencement of treatment on the
13 day of the appointment which allows for uninterrupted interactive ability in a totally awake patient
14 with no compromise in the ability to maintain a patent airway continuously and without assistance.
15 ~~Nitrous oxide may be administered in addition to the minor psychosedative without constituting~~
16 ~~multiple dosing for purpose of these Rules. The patient must be able to respond normally to~~
17 ~~tactile stimulation and verbal commands and walk normally. A dentist may perform anxiolysis~~
18 ~~without obtaining a permit from the Dental Board.~~

19 (4) "ACLS" – Advanced cardiac life support.

20 (5) "Administer"—to direct, manage, supervise, control and have charge of all aspects of selection,
21 dosage, timing and method of delivery to the patient of any pharmacologic agent intended to
22 reduce anxiety or depress consciousness.

23 ~~(17)(6)~~ (6) "Anti-Anxiety [Drug]Drug" ~~Minor psychosedative/Minor tranquilizer~~ – pharmacological agents
24 which allow for uninterrupted interactive ability in a patient with no compromise in the ability to
25 maintain a patent airway continuously and without assistance and carry a margin of safety wide
26 enough to render unintended loss of consciousness unlikely. The patient must be able to respond
27 normally to tactile stimulation and verbal commands and walk normally.

28 (7) "ASA" – American Society of Anesthesiologists.

29 (8) "Auxiliaries" – non-dentist staff members directly involved in general anesthesia or sedation
30 procedures.

31 (9) "BLS" – Basic life support.

32 ~~(4)(10)~~ (10) "Behavior control" – the use of pharmacological techniques to control behavior to a level at which
33 ~~that~~ dental treatment can be performed effectively and efficiently.

34 ~~(5)(11)~~ (11) "Behavioral management" – the use of pharmacological or psychological techniques, singly or in
35 combination, to modify behavior to a level that at which dental treatment can be performed
36 effectively and efficiently.

37 ~~(6)~~ (12) "Competent" – displaying special skill or knowledge derived from training and experience.

1 ~~(7)~~ (13) "Conscious sedation" - an induced state of a depressed level of consciousness that retains the
2 patient's ability to independently and continuously maintain an airway and respond appropriately
3 to physical stimulation and verbal command, and that is produced by pharmacologic or non-
4 pharmacologic agents, or a combination thereof. In accordance with this particular definition, the
5 drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of
6 consciousness unlikely. All dentists who perform conscious sedation shall have a current
7 sedation permit from the Dental Board.

8 (14) "CRNA" – certified registered nurse anesthetist.

9 ~~(8)~~(15) "Deep sedation" – an induced state of a depressed level of consciousness accompanied by partial
10 loss of protective reflexes, including the ability to continually maintain an airway independently or
11 respond purposefully to verbal command, ~~and is~~ produced by pharmacological agents. All
12 dentists who perform deep sedation shall have a current general anesthesia permit from the Dental
13 Board.

14 (16) "Deliver" – to assist a properly qualified dentist in administering sedation or anesthesia drugs by
15 providing the drugs directly to the patient pursuant to a direct order from the dentist and while
16 under the dentist's direct supervision.

17 ~~(9)~~(17) "Direct supervision" – the dentist responsible for the ~~sedation/anesthesia~~ sedation or anesthesia
18 procedure shall be physically present in the facility and shall be continuously aware of the patient's
19 physical status and well being.

20 (18) "Emergencies manual" – a written or digital manual that documents 1) the location of all
21 emergency equipment and medications in each dental office, 2) each staff member's role during
22 medical emergencies and 3) the appropriate treatment for laryngospasm, bronchospasm, emesis
23 and aspiration, respiratory depression and arrest, angina pectoris, myocardial infarction,
24 hypertension, hypotension, allergic reactions, convulsions, syncope, bradycardia, insulin shock,
25 cardiac arrest and airway obstruction.

26 (19) "ET CO2" —end tidal carbon dioxide.

27 ~~(10)~~ (20) "Facility" – the location where a permit holder practices dentistry and provides
28 ~~anesthesia/sedation~~ anesthesia or sedation services.

29 ~~(11)~~ (21) "Facility inspection" - an on-site inspection to determine if a facility where the applicant proposes
30 to provide ~~anesthesia/sedation~~ anesthesia or sedation is supplied, equipped, staffed and maintained
31 in a condition to support provision of ~~anesthesia/sedation~~ anesthesia or sedation services that meet
32 the minimum standard of care.

33 ~~(12)~~ (22) "General anesthesia" - the intended controlled state of a depressed level of consciousness that is
34 produced by pharmacologic agents and accompanied by a partial or complete loss of protective
35 reflexes, including the ability to maintain an airway and respond purposefully to physical
36 stimulation or verbal commands.

1 (23) “Good standing” – a licensee whose license is not suspended or revoked and who is not subject to
2 a current disciplinary order imposing probationary terms.

3 ~~(13)~~ (24) "Immediately available" – on-site in the facility and available for immediate use.

4 (25) [Itinerant]-[Itinerant] general [dentist anesthesiologist]- anesthesiology provider"- a licensee who has
5 complied with Rule .0206 of this [Section] Subchapter and who administers general anesthesia at
6 another practitioner’s facility.

7 (14) (26) "Local anesthesia" – the elimination of sensations, especially pain, in one part of the body by the
8 regional application or injection of a drug.

9 ~~(15)~~ (27) "May" – indicates freedom or liberty to follow a reasonable alternative.

10 ~~(16)~~ "Minimal conscious sedation"—conscious sedation characterized by a minimally depressed level of
11 consciousness, in which patient retains the ability to independently and continuously maintain an
12 airway and respond normally to tactile stimulation and verbal command, provided to patients 13
13 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one
14 or more doses, not to exceed the manufacturer's maximum recommended dose, at the time of
15 treatment, possibly in combination with nitrous oxide. Minimal conscious sedation is provided for
16 behavioral management.

17 ~~(18)~~ (28) "Moderate conscious sedation" – conscious sedation characterized by a drug induced depression of
18 consciousness, during which patients respond purposefully to verbal commands, either alone or
19 accompanied by light tactile stimulation, provided to patients 13 years or older, by oral, nasal,
20 rectal or parenteral routes of administration of multiple pharmacological agents, in multiple doses,
21 within a 24 hour period, including the time of treatment, possibly in combination with nitrous
22 oxide. Moderate conscious sedation is provided for behavior control. Drugs designated by the
23 manufacturer for use in administering general anesthesia or deep sedation and drugs
24 contraindicated for use in moderate conscious sedation shall not be used by a moderate conscious
25 sedation permit holder.

26 ~~(19)~~ "Moderate conscious sedation limited to oral routes and nitrous oxide inhalation"—conscious
27 sedation characterized by a drug induced depression of consciousness during which patients
28 respond purposefully to verbal commands, either alone or accompanied by light tactile
29 stimulation, provided to patients 13 years or older, by oral routes of administration and nitrous
30 oxide inhalation, of single or multiple pharmacological agents, in single or multiple doses, within
31 a 24 hour period. Moderate conscious sedation limited to oral routes and nitrous oxide inhalation
32 is provided for behavior control.

33 (29) (20) "Moderate pediatric conscious sedation" - conscious sedation characterized by a drug induced
34 depression of consciousness, during which patients respond purposefully to verbal commands,
35 either alone or accompanied by light tactile stimulation, provided to patients up to under 18 ~~13~~
36 years of age, or special needs patients, by oral, nasal, rectal or parenteral routes of administration
37 of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period,

1 including the time of treatment, possibly in combination with nitrous oxide. Moderate pediatric
2 conscious sedation is provided for behavior control. Drugs designated by the manufacturer for
3 use in administering general anesthesia or deep sedation and drugs contraindicated for use in
4 moderate pediatric conscious sedation shall not be used by a moderate pediatric conscious
5 sedation permit holder.

6 (30) ~~(24)~~ "Must" or "shall" – indicates an imperative need or duty or both; an essential or indispensable
7 item; mandatory.

8 (31) ~~(22)~~ "Parenteral" - the administration of pharmacological agents intravenously, intraosseously,
9 intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.

10 (32) "PALS" – Pediatric Advanced Life Support.

11 (33) ~~(23)~~ "Protective reflexes" – includes the ability to swallow and cough.

12 (34) ~~[RN]~~ "RN" – Registered Nurse licensed by the North Carolina Board of Nursing.

13 (35) ~~[Special]~~ "Special needs [patients] patients" – patients with diminished mental and or physical
14 capacity who are unable to cooperate sufficiently to receive ambulatory dental care without
15 sedation or anesthesia.

16 (36) ~~(24)~~ "Supplemental dosing" – the oral administration of a pharmacological agent that results in an
17 enhanced level of conscious sedation when added to the primary sedative agent administered for
18 the purpose of oral moderate conscious sedation, and which, when added to the primary agent,
19 does not exceed the maximum safe dose of either agent, separately or synergistically.

20 (37) ~~(25)~~ "Vested adult" – a responsible adult who is the legal parent or guardian, or designee of a legal
21 parent or guardian, entrusted with the care of a minor patient following the administration of
22 general anesthesia or conscious sedation.

23
24 *History Note: Authority G.S. 90-28; 90-30.1;*
25 *Eff. February 1, 1990;*
26 *Temporary Amendment Eff. December 11, 2002;*
27 *Amended Eff. March 1, 2016; July 3, 2008; August 1, 2004.*
28

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0202

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0206, .0302, .0405. Many of the following technical change requests will be duplicative across these four rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

Please identify the changes to the rule name on the Submission for Permanent Rule form in Box 2

Line 4, add "be responsible to" before "ensure"

Lines 6 and 15, replace "is" with "shall be"

Line 6, add "the following" after "with"

Lines 7 thru 13, lines 16 thru 33, and line 37, begin the clauses with lowercase letters as they are part of a list

Line 8, define or delete "effective"

Line 10, add a comma after "enhancements"

Line 12, this clause appears to be missing a conjuncture. Please clarify.

Line 13, replace the semicolon after "procedures" with a comma

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

Line 15, either add the clause “in the facility” after “maintained” or match to line 6 and state “The facility shall be equipped with the following:” Alternatively, as done in 21 NCAC 16Q .0206 and 21 NCAC 16Q .0405, is a heading necessary or is this a continuing list?

Lines 16 thru 33, should the list of equipment be the same as Rules .0206, .0302, and .0405? If so, please verify content.

Lines 16 and 17 references “full face masks for adults and pediatric” Rule .0302 says “small, medium, and large.” Is there a distinction? Please clarify. Please use consistent terms throughout the rules.

Line 17, add a comma after “patients”

Line 19, add a comma after “medium”

Line 29, delete “current” Consider using the term “working” or “operable”

Lines 35 thru 36, consider the following rewrite:

“The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:”

Page 1, line 37 thru page 2, line 14, should the list of drugs be the same as Rules .0206, .0302, and .0405? If so, please verify content.

Page 2, lines 15 thru 16, who is the clause referencing? Please clarify what is occurring in this requirement, as the clause does not identify parties.

Page 2, lines 16 and 17, replace “are” with “shall be”

Page 2, line 16, delete the “and” at the end of the clause

Page 2, line 17, are there any requirements for maintenance of these records, such as format? If so, please clarify in this Rule.

Page 2, lines 20 thru 21 seem to repeat the content of line 22. Please reorganize these clauses and delete redundant language. Consider deleting the term “form” on line 20. Add a comma after “anesthesia” on line 21. Add a comma after “risks” on line 22. For the remaining language, clarify who is doing this and what is the format. Please clarify.

Page 2, line 23, clarify whose information

Page 2, line 23, add an “and” at the end of the clause

Page 2, line 33, add “of the patient” after “rates”

Page 2, line 36, add “on patient” after “IV”

Page 3, line 1, replace the period at the end of the clause with a semicolon

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

Page 3, line 1, add an “and” at the end of the clause

Page 3, lines 3 thru 7, indent the language to clarify the content of the subparagraph

Page 3, lines 11 thru 17, and lines 20 thru 33, begin the clauses with lowercase letters as they are part of a list

Page 3, line 36, add “shall include the following” after “discharge”

Page 4, lines 1, 4, and 15, begin the clauses with lowercase letters as they are part of a list

Page 4, line 3, define or delete “sufficiently”

Page 4, line 7, define or delete “easily”

Page 4, line 12, replace “disabled” with the defined term “special needs”

Page 4, line 16, the correct term was “Subparagraph” Please correct

Page 4, line 18 add a comma after “color”

Page 4, line 18, add a comma after “sufficient”

Page 4, line 18, delete “and” after “sufficient”

Page 4, line 19, add a comma after “stable”

Page 4, line 27, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0202 is amended as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0202 GENERAL ANESTHESIA EQUIPMENT AND CLINICAL REQUIREMENTS**

4 (a) A dentist administering general anesthesia shall ensure ~~is solely responsible for providing that the facility~~
5 ~~environment in which~~ where the general anesthesia is ~~to be~~ administered meets the following requirements:

6 (1) The facility is equipped with:

7 (A) An operatory of size and design to permit access of emergency equipment and personnel
8 and to permit effective emergency management;

9 (B) ~~A chair or table for emergency treatment, including chair suitable for CPR or CPR Board;~~
10 A CPR board or dental chair without enhancements suitable for providing emergency
11 treatment;

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

13 (D) Suction equipment as necessary for specific procedures; including non-electrical back-up
14 ~~suction~~; suction.

15 (2) The following equipment is maintained:

16 (A) Positive pressure oxygen delivery system, including full face masks for adults and
17 pediatric ~~patients~~ patients; and back-up E-cylinder portable oxygen tank apart from the
18 central system;

19 (B) Small, medium and large oral ~~Oral and nasal~~ airways; ~~airways of various sizes~~;

20 (C) Blood pressure monitoring device;

21 (D) EKG Monitor; ~~Electrocardiograph~~;

22 (E) Pulse oximeter; and

23 (F) Defibrillator;

24 (G) Capnograph;

25 (H) Thermometer;

26 (3) ~~The following emergency equipment is maintained:~~

27 ~~(A)~~(I) ~~I.V. set up~~ Vascular access as necessary for specific procedures, including hardware and
28 fluids;

29 ~~(B)~~(J) Laryngoscope with current batteries;

30 ~~(C)~~(K) Intubation forceps and ~~endotracheal tubes~~; advanced airway devices;

31 ~~(D)~~(L) Tonsillar suction with back-up suction;

32 ~~(E)~~(M) Syringes as necessary for specific procedures; and

33 ~~(F)~~(N) Tourniquet ~~& tape~~; and ~~and tape~~.

34 (G) ~~Blood pressure monitoring device~~;

35 (4) (3) The following drugs are maintained with a current shelf life and with access from the operatory
36 and recovery room:

37 (A) Epinephrine;

- 1 (B) Atropine;
- 2 (C) ~~Lidocaine;~~ Antiarrhythmic;
- 3 (D) Antihistamine;
- 4 (E) Antihypertensive;
- 5 (F) ~~Bronchial dilator;~~ Bronchodilator;
- 6 (G) Antihypoglycemic agent;
- 7 (H) Vasopressor;
- 8 (I) Corticosteroid;
- 9 (J) Anticonvulsant;
- 10 (K) Muscle relaxant;
- 11 (L) Appropriate reversal agents;
- 12 ~~(M) Appropriate anti arrhythmic medication;~~
- 13 ~~(M) (N) Nitroglycerine; and~~
- 14 ~~(N) (O) Antiemetic; Antiemetic.~~
- 15 ~~(5)~~ (4) Written emergency and patient discharge protocols and training to familiarize ~~office personnel~~
- 16 auxiliaries in the treatment of clinical emergencies are provided; and
- 17 ~~(6)~~ (5) The following records are ~~maintained;~~ maintained for 10 years:
- 18 (A) Patient's current written medical history, including a record of known allergies and
- 19 previous ~~surgeries; surgery;~~
- 20 (B) Signed consent to general anesthesia form identifying the risks and benefits, level of
- 21 anesthesia and date signed;
- 22 (C) Signed consent identifying the procedure, risks and benefits and date signed;
- 23 ~~(D) (B)~~ Base line vital signs, including temperature, SPO2, blood pressure and pulse;
- 24 ~~(E) (C)~~ An anesthesia record; record which shall include:
- 25 (i) ~~Periodic vital signs taken at intervals during the procedure;~~
- 26 (ii) ~~Drugs administered during the procedure, including route of administration,~~
- 27 ~~dosage, time and sequence of administration;~~
- 28 (iii) ~~Duration of the procedure;~~
- 29 (iv) ~~Documentation of complications or morbidity; and~~
- 30 (v) ~~Status of patient upon discharge.~~
- 31 (6) The ~~sedation~~ anesthesia record shall include:
- 32 (A) base line vital signs, blood pressure (unless patient behavior prevents recording);
- 33 oxygen saturation, ET CO2, pulse and respiration rates recorded in real time
- 34 at 15 minute intervals;
- 35 (B) procedure start and end times;
- 36 (C) gauge of needle and location of IV, if used;
- 37 (D) status of patient upon discharge; and

1 (E) documentation of complications or morbidity.

2 ~~(d) — (7) A dentist administering general anesthesia shall ensure that the~~ The facility shall be is-staffed with at
3 least two BLS certified auxiliary personnel auxiliaries who shall be present at all times during the procedure and at
4 least one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation data.
5 ~~document annual successful completion of basic life support training and be capable of assisting with procedures,~~
6 ~~problems, and emergency incidents that may occur as a result of the general anesthetic or secondary to an~~
7 ~~unexpected medical complication.~~

8 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of
9 anesthesia while the evaluator ~~observes.~~ During the demonstration, the applicant or permit holder observes, and
10 shall demonstrate competency in the following areas:

- 11 (1) Monitoring of blood pressure, pulse, ET CO₂, and respiration;
- 12 (2) Drug dosage and administration;
- 13 (3) Treatment of untoward reactions including respiratory or cardiac depression;
- 14 (4) Sterilization;
- 15 (5) Use of BLS CPR certified ~~auxiliaries; personnel;~~
- 16 (6) Monitoring of patient during recovery; and
- 17 (7) Sufficiency of patient recovery time.

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

- 20 (1) Laryngospasm;
- 21 (2) Bronchospasm;
- 22 (3) Emesis and aspiration;
- 23 (4) Respiratory depression and arrest;
- 24 (5) Angina pectoris;
- 25 (6) Myocardial infarction;
- 26 (7) ~~Hypertension/Hypotension;~~ Hypertension and Hypotension;
- 27 (8) Syncope;
- 28 (9) Allergic reactions;
- 29 (10) Convulsions;
- 30 (11) Bradycardia;
- 31 (12) Insulin shock; ~~and~~
- 32 (13) Cardiac arrest; and
- 33 (14) Airway obstruction.

34 (d) A general anesthesia permit holder shall evaluate patients for health risks before starting any anesthesia
35 procedure.

36 (e) Post-operative monitoring and discharge:

1 (1) Vital signs shall be continuously monitored when the sedation is no longer being administered and
2 the patient shall have direct continuous supervision until oxygenation and circulation are stable
3 and the patient is sufficiently responsive for discharge from the office.

4 (2) Recovery from general anesthesia shall include documentation of the following:

5 (A) cardiovascular function stable;

6 (B) airway patency uncompromised;

7 (C) patient easily arousable and protective reflexes intact;

8 (D) state of hydration within normal limits;

9 (E) patient can talk, if applicable;

10 (F) patient can sit unaided, if applicable;

11 (G) patient can ambulate, if applicable, with minimal assistance; and

12 (H) for the patient who is disabled, or incapable of the usually expected responses, the pre-
13 sedation level of responsiveness or the level as close as possible for that patient shall be
14 achieved.

15 (3) Before allowing the patient to leave the office, the dentist shall determine that the patient has met
16 the recovery criteria set out in [Subparagraph] Paragraph (e)(2) of this Rule and the following
17 discharge criteria:

18 (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and
19 stable and have been documented;

20 (B) explanation and documentation of written postoperative instructions have been provided
21 to the patient or a responsible adult at time of discharge; and

22 (C) [responsible individual] a vested adult is available [- for the patient] to transport the
23 patient after discharge.

24
25 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*

26 *Effective February 1, 1990;*

27 *Amended Eff. March 1, 2016; November 1, 2013; August 1, 2002; August 1, 2000.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0203, .0205, .0303, .0401-.0403, .0501-.0602

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

For the repeals, please review this [example](#). There should be no text in the body of the rule. The history note should reflect all information pertaining to the identified rule. The repeal date should be underlined.

Please note that [26 NCAC 02C .0406](#) requires consecutive repeals to be combined. Please review this [example](#). The history note for the combine rules reflects all information in all of the individual history notes. Please combine the following sets:

21 NCAC 16Q .0401, .0402, .0403

21 NCAC 16Q .0501, .0502, .0503

21 NCAC 16Q .0601, .0602

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0203 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0203 TEMPORARY APPROVAL PRIOR TO SITE EVALUATION**

4 ~~(a) If a dentist meets the requirements of Rule .0201 of this Section, he shall be granted temporary approval to~~
5 ~~continue to administer general anesthesia until a permit can be issued. Temporary approval may be granted based~~
6 ~~solely on credentials until all processing and investigation has been completed. Temporary approval may not exceed~~
7 ~~three months. An on site evaluation of the facilities, equipment, procedures, records and personnel shall be required~~
8 ~~prior to the issuance of a permit.~~

9 ~~(b) An evaluation may be made any time it is deemed necessary by the Board.~~

10 ~~(c) Temporary approval shall not be granted to a provisional licensee.~~

11

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

13 *Eff. February 1, 1990;*

14 *Amended Eff. August 1, 2002*

15 *Repealed Eff. March 1, 2016.*

16

1 21 NCAC 16Q .0205 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0205 RESULTS OF SITE EVALUATION AND REEVALUATION**

4 ~~(a) An applicant who fails an inspection or evaluation shall not receive a permit to administer general anesthesia, or~~
5 ~~if the holder of a permit, shall not have it renewed. An applicant who has obtained temporary approval from the~~
6 ~~Board and fails an inspection or evaluation shall no longer be approved.~~

7 ~~(b) An applicant who receives notification of failure of an inspection may, within 15 days after receiving the notice,~~
8 ~~request a reevaluation. Such request must state specific grounds supporting it. The Board shall require the applicant~~
9 ~~to receive additional training prior to the reevaluation. The additional training shall consist of, but not be limited to,~~
10 ~~areas of deficiency as determined by the evaluation.~~

11 ~~(c) If the reevaluation is granted, it shall be conducted by different persons, qualified as evaluators, in the manner~~
12 ~~prescribed in Rule .0204 of this Section.~~

13 ~~(d) No applicant who has received a failing notice from the Board may request more than one reevaluation within~~
14 ~~any 12 month period.~~

15

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

17 *Eff. February 1, 1990;*

18 *Amended Eff. August 1, 2002.*

19 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0303 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0303 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION**

4 ~~(a) If a dentist meets the requirements of Paragraphs (a)–(e) of Rule .0301 of this Subchapter, he/she shall be~~
5 ~~granted temporary approval to administer moderate conscious sedation, or moderate pediatric conscious sedation~~
6 ~~until a permit can be issued. If a dentist meets the requirements of Paragraph (j) of Rule .0301 of this Subchapter,~~
7 ~~he/she shall be granted temporary approval to administer moderate conscious sedation limited to oral routes and~~
8 ~~nitrous oxide inhalation. Temporary approval may be granted based solely on credentials until all processing and~~
9 ~~investigation has been completed. The temporary approval will expire after 90 days. In its discretion and for good~~
10 ~~cause, the Board may extend the temporary approval for an additional 90 days. No other extensions will be granted.~~
11 ~~An applicant who fails to complete the live patient practice requirements within the time allowed by this Rule must~~
12 ~~re-apply for a permit and will not be eligible for temporary approval. An on-site evaluation of the facilities,~~
13 ~~equipment, procedures, and personnel shall be required prior to issuance of a permanent permit. The evaluation~~
14 ~~shall be conducted in accordance with Rules .0204–.0205 of this Subchapter, except that evaluations of dentists~~
15 ~~applying for moderate conscious sedation permits may be conducted by dentists who have been issued moderate~~
16 ~~conscious sedation permits by the Board and who have been approved by the Board, as set out in these Rules. A~~
17 ~~two hundred seventy five dollar (\$275.00) inspection fee shall be collected for each site inspected pursuant to this~~
18 ~~Rule.~~

19 ~~(b) An inspection may be made upon renewal of the permit or for cause.~~

20 ~~(c) Temporary approval shall not be granted to a provisional licensee or applicants who are subject of a pending~~
21 ~~Board disciplinary investigation or whose licenses have been revoked, suspended or are subject to an order of stayed~~
22 ~~suspension or probation.~~

23

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

25 *Eff. February 1, 1990;*

26 *Amended Eff. August 1, 2002; January 1, 1994;*

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

28 *Amended Eff. February 1, 2009; July 3, 2008; August 1, 2004.*

29 *Repealed Eff. March 1, 2016.*

30

1 21 NCAC 16Q .0401 is repealed as published in 30:1 NCR 2 as follows:

2
3 **21 NCAC 16Q .0401 MINIMAL CONSCIOUS SEDATION CREDENTIALS, EVALUATION AND**
4 **PERMIT**

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

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

14 ~~(c) Application:~~

15 ~~(1) A minimal conscious sedation permit may be obtained by completing an application form~~
16 ~~provided by Board, a copy of which may be obtained from the Board office, and meeting the~~
17 ~~requirements of Section .0400 of this Subchapter.~~

18 ~~(2) The application form must be filled out completely and appropriate fees paid.~~

19 ~~(3) An applicant for a minimal conscious sedation permit shall be licensed and in good standing with~~
20 ~~the Board in order to be approved. For purposes of these Rules "good standing" means that the~~
21 ~~applicant is not subject to a disciplinary investigation and his or her licensee has not been revoked~~
22 ~~or suspended and is not subject to a probation or stayed suspension order.~~

23 ~~(d) Evaluation:~~

24 ~~(1) Prior to issuance of a minimal conscious sedation permit the applicant shall undergo a facility~~
25 ~~inspection. The Board shall direct an evaluator qualified to administer minimal sedation to~~
26 ~~perform this inspection. The applicant shall be notified in writing that an inspection is required~~
27 ~~and provided with the name of the evaluator who shall perform the inspection. The applicant shall~~
28 ~~be responsible for successful completion of inspection of his or her facility within three months of~~
29 ~~notification. An extension of no more than 90 days shall be granted if the designated evaluator or~~
30 ~~applicant requests one.~~

31 ~~(2) During an inspection or evaluation, the applicant or permit holder shall demonstrate competency~~
32 ~~in the following areas:~~

33 ~~(A) Monitoring of blood pressure, pulse, pulse oximetry and respiration;~~

34 ~~(B) Drug dosage and administration (by verbal demonstration);~~

35 ~~(C) Treatment of untoward reactions including respiratory or cardiac depression (by verbal~~
36 ~~demonstration);~~

37 ~~(D) Sterilization;~~

- ~~(E) — Use of CPR certified personnel;~~
- ~~(F) — Monitoring of patient during recovery (by verbal demonstration); and~~
- ~~(G) — Sufficiency of patient recovery time (by verbal demonstration).~~
- ~~(3) — During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to the evaluator in the treatment of the following clinical emergencies:~~
 - ~~(A) — Laryngospasm;~~
 - ~~(B) — Bronchospasm;~~
 - ~~(C) — Emesis and aspiration;~~
 - ~~(D) — Respiratory depression and arrest;~~
 - ~~(E) — Angina pectoris;~~
 - ~~(F) — Myocardial infarction;~~
 - ~~(G) — Hypertension/Hypotension;~~
 - ~~(H) — Syncope;~~
 - ~~(I) — Allergic reactions;~~
 - ~~(J) — Convulsions;~~
 - ~~(K) — Bradycardia;~~
 - ~~(L) — Insulin shock; and~~
 - ~~(M) — Cardiac arrest.~~
- ~~(4) — The evaluator shall assign a grade of pass or fail and shall report his recommendation to the Board, setting out the basis for his conclusion. The Board is not bound by the evaluator's recommendation and shall make a final determination regarding whether the applicant has passed the evaluation. The applicant shall be notified of the Board's decision in writing.~~

~~(e) Educational/Professional Requirements:~~

- ~~(1) — The dentist applying for a minimal conscious sedation permit shall meet one of the following criteria:~~
 - ~~(A) — successful completion of training consistent with that described in Part I or Part III of the American Dental Association (ADA) Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, and have documented administration of minimal conscious sedation in a minimum of five cases;~~
 - ~~(B) — successful completion of an ADA accredited post doctoral training program which affords comprehensive training necessary to administer and manage minimal conscious sedation;~~
 - ~~(C) — successful completion of an 18 hour minimal conscious sedation course which must be approved by the Board based on whether it affords comprehensive training necessary to administer and manage minimal conscious sedation;~~
 - ~~(D) — successful completion of an ADA accredited postgraduate program in pediatric dentistry;~~
- ~~or~~

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

7 ~~(2) — All applicants for a minimal sedation permit must document successful completion of a Basic Life~~
8 ~~Saving (BLS) course within the 12 months prior to the date of application.~~

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

11 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0402 is repealed as published in 30:1 NCR 2 as follows:

2
3 **21 NCAC 16Q .0402 MINIMAL CONSCIOUS SEDATION PERMIT REQUIREMENTS, CLINICAL**
4 **PROVISIONS AND EQUIPMENT**

5 ~~(a) Minimal conscious sedation is indicated for use only as defined in Rule .0101(15) of this Subchapter (relating to~~
6 ~~Definitions). Minimal conscious sedation is not indicated for use to achieve deep sedation.~~

7 ~~(b) A minimal conscious sedation permit is not required for minor psychosedatives used for anxiolysis prescribed~~
8 ~~for administration outside of the dental office when pre-procedure instructions are likely to be followed. Medication~~
9 ~~administered for the purpose of minimal conscious sedation shall not exceed the maximum doses recommended by~~
10 ~~the drug manufacturer, sedation textbooks, or juried sedation journals. Except for nitrous inhalation, drugs in~~
11 ~~combination are not permitted for minimal conscious sedation. During longer periods of minimal conscious~~
12 ~~sedation, in which the amount of time of the procedures exceeds the effective duration of the sedative effect of the~~
13 ~~drug used, the incremental doses of the sedative shall not exceed total safe dosage levels based on the effective half~~
14 ~~life of the drug used.~~

15 ~~(c) Each dentist shall:~~

16 ~~(1) — adhere to the clinical requirements as detailed in Paragraph (c) of this Rule;~~

17 ~~(2) — maintain under continuous direct supervision any auxiliary personnel, who shall be capable of~~
18 ~~assisting in procedures, problems, and emergencies incident to the use of minimal conscious~~
19 ~~sedation or secondary to an unexpected medical complication;~~

20 ~~(3) — utilize sufficient auxiliary personnel for each procedure performed who shall document annual~~
21 ~~successful completion of basic life support training; and~~

22 ~~(4) — not allow a minimal conscious sedation procedure to be performed in his or her office by a~~
23 ~~Certified Registered Nurse Anesthetist (CRNA) unless the dentist holds a permit issued by the~~
24 ~~Board for the procedure being performed. This provision addresses dentists and is not intended to~~
25 ~~address the scope of practice of persons licensed by any other agency.~~

26 ~~(d) Each dentist shall meet the following requirements:~~

27 ~~(1) — Patient Evaluation. Patients who are administered minimal conscious sedation must be evaluated~~
28 ~~for medical health risks prior to the start of any sedative procedure. A patient receiving minimal~~
29 ~~conscious sedation must be healthy or medically stable (ASA I, or ASA II as defined by the~~
30 ~~American Society of Anesthesiologists). An evaluation is a review of the patient's current medical~~
31 ~~history and medication use. However, for individuals who are not medically stable or who have a~~
32 ~~significant health disability Physical Status III (ASA III, as defined by the American Society of~~
33 ~~Anesthesiologists) a consultation with their primary care physician or consulting medical~~
34 ~~specialist regarding potential procedure risk is required.~~

35 ~~(2) — Pre-procedure preparation, informed consent:~~

36 ~~(A) — The patient or guardian must be advised of the procedure associated with the delivery of~~
37 ~~the minimal conscious sedation.~~

1 ~~(B) — Equipment must be evaluated and maintained for proper operation.~~

2 ~~(C) — Baseline vital signs shall be obtained at the discretion of the operator depending on the~~
3 ~~medical status of the patient and the nature of the procedure to be performed.~~

4 ~~(D) — Dentists administering minimal conscious sedation shall use sedative agents that he/she is~~
5 ~~competent to administer and shall administer such agents in a manner that is within the~~
6 ~~standard of care.~~

7 ~~(e) Patient monitoring:~~

8 ~~(1) — Patients who have been administered minimal conscious sedation shall be monitored during~~
9 ~~waiting periods prior to operative procedures. An adult who has accepted responsibility for the~~
10 ~~patient and been given written pre-procedural instruction may provide such monitoring. The~~
11 ~~patient shall be monitored for alertness, responsiveness, breathing and skin coloration.~~

12 ~~(2) — Dentists administering minimal conscious sedation shall maintain direct supervision of the patient~~
13 ~~during the operative procedure and for such a period of time necessary to establish pharmacologic~~
14 ~~and physiologic vital sign stability.~~

15 ~~(A) — Oxygenation. Color of mucosa, skin or blood shall be continually evaluated. Oxygen~~
16 ~~saturation shall be evaluated continuously by pulse oximetry, except as provided in~~
17 ~~Paragraph (e)(4) of this Rule.~~

18 ~~(B) — Ventilation. Observation of chest excursions or auscultation of breath sounds or both~~
19 ~~shall be performed.~~

20 ~~(C) — Circulation. Blood pressure and pulse shall be taken and recorded initially and thereafter~~
21 ~~as appropriate except as provided in Paragraph (e)(4) of this Rule.~~

22 ~~(D) — AED. Dentists administering minimal conscious sedation shall maintain a functioning~~
23 ~~automatic external defibrillator (AED).~~

24 ~~(3) — An appropriate time-oriented anesthetic record of vital signs shall be maintained in the permanent~~
25 ~~record including documentation of individual(s) administering the drug and showing the name of~~
26 ~~drug, strength and dosage used.~~

27 ~~(4) — If the dentist responsible for administering minimal conscious sedation must deviate from the~~
28 ~~requirements set out in this Rule, he or she shall document the occurrence of such deviation and~~
29 ~~the reasons for such deviation.~~

30 ~~(f) Post-operative procedures:~~

31 ~~(1) — Following the operative procedure, positive pressure oxygen and suction equipment shall be~~
32 ~~immediately available in the recovery area or operator.~~

33 ~~(2) — Vital signs shall be continuously monitored when the sedation is no longer being administered and~~
34 ~~the patient shall have direct continuous supervision until oxygenation and circulation are stable~~
35 ~~and the patient is sufficiently responsive for discharge from the office.~~

36 ~~(3) — Patients who have adverse reactions to minimal conscious sedation shall be assisted and monitored~~
37 ~~either in an operator 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 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0403 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0403 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION**

4 ~~(a) A dentist whose facility has not been inspected but who has otherwise met the requirements of Rule .0401 of~~
5 ~~this Section may seek temporary approval to administer minimal conscious sedation until a permit can be issued.~~

6 ~~Temporary approval may be granted based solely on credentials until all processing and investigation has been~~
7 ~~completed. Temporary approval may not exceed three months.~~

8 ~~(b) Temporary approval shall not be granted to a provisional licensee or to an applicant who is not in good standing.~~

9 ~~he subject of a disciplinary investigation or whose license has been revoked or suspended or is the subject of a~~
10 ~~probation or stayed suspension order.~~

11 ~~(c) A two hundred seventy five dollar (\$275.00) fee shall be collected for each site inspected pursuant to Rule .0401~~
12 ~~of this Section.~~

13

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

15 *Temporary Adoption Eff. December 11, 2002;*

16 *Eff. August 1, 2004;*

17 *Amended Eff. February 1, 2009; July 3, 2008.*

18 *Repealed Eff. March 1, 2016;*

19

1 21 NCAC 16Q .0501 is repealed as published in 30:1 NCR 2 as follows:

2
3 **21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED**

4 ~~(a) General anesthesia and all sedation permits shall be renewed by the Board annually. Such renewal shall be~~
5 ~~accomplished in conjunction with the license renewal process, and applications for permits shall be made at the~~
6 ~~same time as applications for renewal of licenses. A one hundred (\$100.00) annual renewal fee shall be paid at the~~
7 ~~time of renewal.~~

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

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

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

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

21 (A) — sedation;

22 (B) — medical emergencies;

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

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

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

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

27 (G) — airway management; or

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

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

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

36 (1) — pediatric or adult sedation;

37 (2) — medical emergencies;

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

6 ~~(g) Any dentist who fails to renew a general anesthesia or sedation permit on or before March 31 of each year must~~
7 ~~complete a reinstatement application, pay the one hundred dollar (\$100.00) renewal fee and a one hundred dollar~~
8 ~~(\$100.00) penalty and comply with all conditions for renewal set out in this Rule for the permit sought. Dentists~~
9 ~~whose anesthesia or sedation permits have been lapsed for more than 12 calendar months must pass a facilities~~
10 ~~inspection as part of the reinstatement process.~~

11
12 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
13 *Eff. February 1, 1990;*
14 *Amended Eff. August 1, 2002;*
15 *Transferred and Recodified from 16Q .0401 to 16Q .0501;*
16 *Temporary Amendment Eff. December 11, 2002;*
17 *Amended Eff. November 1, 2013; July 3, 2008; August 1, 2004.*
18 *Repealed Eff. March 1, 2016.*

19

1 21 NCAC 16Q .0502 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0502 PAYMENT OF FEES**

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

6

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

8 *Eff. February 1, 1990;*

9 *Transferred and Recodified from 16Q .0402 to .0502.*

10 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0503 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0503 INSPECTION AUTHORIZED**

4 ~~Incident to the renewal of an anesthesia or sedation permit, for cause or routinely at reasonable time intervals in~~
5 ~~order to ensure compliance, the Board may require an on-site inspection of the dentist's facility, equipment,~~
6 ~~personnel and procedures. Such inspection shall be conducted in accordance with Rules .0204, .0205, .0303, and~~
7 ~~.0401 of this Subchapter.~~

8

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

10 *Eff. February 1, 1990;*

11 *Amended Eff. January 1, 1994;*

12 *Transferred and Recodified from 16Q .0403 to 16Q .0503;*

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

14 *Amended Eff. August 1, 2004.*

15 *Repealed Eff. March 1, 2016.*

1 21 NCAC 16Q .0601 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0601 REPORTS OF ADVERSE OCCURRENCES**

4 ~~(a) A dentist who holds a permit to administer general anesthesia or sedation shall submit a report to the Board~~
5 ~~within 72 hours after each adverse occurrence related to the administration of general anesthesia or sedation which~~
6 ~~results in the death of a patient within 24 hours of the procedure.~~

7 ~~(b) A dentist who holds a permit to administer general anesthesia or sedation shall report to the Board, within 30~~
8 ~~days after each adverse occurrence related to the administration of general anesthesia or sedation, any situation~~
9 ~~which results in permanent organic brain dysfunction of a patient within 24 hours of the procedure or which results~~
10 ~~in physical injury causing hospitalization of a patient within 24 hours of the procedure.~~

11 ~~(c) The adverse occurrence report shall be in writing and shall include:~~

- 12 ~~(1) The dentist's name, license number and permit number;~~
- 13 ~~(2) The date and time of the occurrence;~~
- 14 ~~(3) The facility where the occurrence took place;~~
- 15 ~~(4) The name and address of the patient;~~
- 16 ~~(5) The surgical procedure involved;~~
- 17 ~~(6) The type and dosage of sedation or anesthesia utilized in the procedure; and~~
- 18 ~~(7) The circumstances involved in the occurrence.~~

19 ~~(d) Upon receipt of any such report, the Board shall make such investigation as it deems appropriate and shall take~~
20 ~~such action as it deems necessary.~~

21

22 *History Note: Authority G.S. 90-28; 90-30.1; 90-41;*

23 *Repealed Eff. March 1, 2016.*

24

1 21 NCAC 16Q .0602 is repealed as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0602 FAILURE TO REPORT**

4 ~~If a dentist fails to report any incident as required by these Rules, the dentist shall be subject to discipline in~~
5 ~~accordance with Section .0700 of this Subchapter.~~

6

7 *History Note: Authority G.S. 90-28; 90-30.1; 90-41;*

8

Repealed Eff. March 1, 2016.

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REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0204

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0306, .0408. Many of the following technical change requests will be duplicative across these three rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

Please identify the changes to the rule name on the Submission for Permanent Rule form in Box 2

Line 5, replace "will" with "may" or "shall"

Line 5, add "to serve as evaluators" after "persons"

Line 6, change the comma after "inspection" to a period.

Lines 6 thru 7, replace "exclusive of his or her training in general anesthesia" with "Training in general anesthesia shall not be counted in the three years."

Line 8, replace "one or more inspectors." with "one inspector."

Line 12, the inspection fee is for an additional office? So a dentist with only one office does not get charged an inspection fee, but a dentist with multiple offices gets charged an inspection fee for every office location over the one office? Please clarify.

Line 14, can the dentist-member also be part of the on-side inspection? Or is the member limited to the evaluation? Please clarify.

Line 16, move the punctuation within the quotation marks of "fail"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Line 18, replace “is not” with “shall not be”

Line 22, define or delete “summarily”

Line 23, replace “may” with “shall”

Line 26, how is the request made by the applicant? Is there a time limit on this request? Please clarify the process for a re-evaluation or re-inspection.

Lines 27 thru 28, if the Board requires additional training, how is this information conveyed to the applicant? Does this retraining requirement only apply for the evaluation and not the inspection? Please clarify the process.

Line 34, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0204 is amended as published in 30:1 NCR 2 as follows:

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

(a) When an evaluation or on-site inspection is required, the Board will designate two or more qualified persons, each of ~~which~~ whom has administered general anesthesia for at least three years preceding the inspection, exclusive of his or her training in general anesthesia. 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 or more evaluators.

~~(b) (e) At least a 15 day notice shall be given prior to an evaluation or inspection. The entire evaluation fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the date of receipt of such notice.~~ An inspection fee of ~~two hundred seventy five dollars (\$275.00)~~ three hundred seventy five dollars (\$375.00) shall be due 10 days after the dentist receives notice of the inspection of each additional location at which the dentist administers general anesthesia.

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

~~(e) (d)~~ (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".

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

~~(f) An applicant who fails an inspection or evaluation shall not receive a permit to administer general anesthesia. If a permit holder fails an evaluation, the permit shall be summarily suspended. If a permit holder's facility fails an inspection, no further anesthesia procedures may 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 include a statement of the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation.~~

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

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

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0206

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0202, .0302, .0405. Many of the following technical change requests will be duplicative across these four rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Line 7 references a form. G.S. 150B-2(8a)d does not require a form to be a rule if "the contents or substantive requirements of which are prescribed by rule or statute." Is there a rule or statute that provides the information required in the application? Could it be cross-referenced? Please clarify.

Line 8 references a fee. However, the history note does not cite an authority for this fee. Please clarify the statutory authority for the fee and update the history note accordingly.

Line 8, replace "is" with "shall be"

Line 10, replace "is" with "may be"

Paragraph (b) requires an inspection but only has one inspector. The prior inspection rule had two inspectors. Was the limitation to one inspector in this Rule intentional? Please clarify.

Line 13, please clarify who is maintaining this equipment.

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Lines 14 thru 37, should the list of equipment be the same as Rules .0202, .0302, and .0405? If so, please verify content.

Lines 14 thru 37, begin the clauses with lowercase letters as they are part of a list

Lines 18, 19, 20, and 25, add a comma after "medium"

Line 35, consider adding the clause "without enhancements" to be consistent with Rules .0202, .0302, and .0405

Line 36, delete "current" Consider using the term "working" or "operable"

Page 2, line 1, please clarify who needs to be able to "immediately access" the medications

Page 2, lines 2 thru 17, should the list of drugs be the same as Rules .0202, .0302, and .0405? If so, please verify content.

Page 2, lines 2 thru 17, begin the clauses with lowercase letters as they are part of a list

Page 2, line 18, insert "on-site" before "inspection" to be consistent with other rules

Page 2, lines 21 through 28, begin the clauses with lowercase letters as they are part of a list

Page 2, lines 21 and 26, define or delete "sufficient"

Page 2, line 21, define or delete "effective"

Page 2, line 32, are there any requirements for maintenance of these records, such as format? If so, please clarify in this Rule.

Page 2, line 32, replace "The" with "No"

Page 2, line 32, replace "may" with "shall not"

Page 3, line 1, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0206 is adopted as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0206 ITINERANT (MOBILE) GENERAL ANESTHESIA PERMIT, EQUIPMENT**
4 **AND EVALUATION**

5 (a) A dentist who holds a general anesthesia permit from the Board and who wishes to provide general anesthesia or
6 other sedation services in the office of another practitioner shall obtain a mobile general anesthesia permit from the
7 Board. The application form may be obtained on the Board’s website: www.ncdentalboard.org, and shall be
8 accompanied by a one hundred (\$100.00) fee. No mobile permit is required to administer general anesthesia in a
9 hospital or credentialed surgery center.

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

13 (c) The following equipment shall be maintained:

- 14 (1) Positive pressure ventilation system and back- up E cylinder portable oxygen tank;
- 15 (2) Standard ASA monitors with back- up power;
- 16 (3) EKG Monitor;
- 17 (4) Capnograph;
- 18 (5) Small, medium and large oral airways and nasal trumpets;
- 19 (6) Small, medium and large laryngoscope blades and back-up laryngoscope;
- 20 (7) Small, medium and large nasal and oral endotracheal tubes;
- 21 (8) Magill forceps;
- 22 (9) Small, medium and large supraglottic airway devices;
- 23 (10) Back-up suction;
- 24 (11) Defibrillator with pediatric capability;
- 25 (12) Small, medium and large anesthesia circuits;
- 26 (13) Back-up lighting;
- 27 (14) Gastric suction device;
- 28 (15) Endotracheal tube and pulmonary suction device;
- 29 (16) Equipment for performing emergency cricothyrotomies and delivering positive pressure
30 ventilation;
- 31 (17) Back-up ventilation measurement;
- 32 (18) Rebreathing device;
- 33 (19) Scavenging system;
- 34 (20) Intermittent compression devices;
- 35 (21) CPR board or dental chair suitable for providing emergency treatment;
- 36 (22) Laryngoscope with current batteries; and
- 37 (23) Tourniquet and tape.

1 (d) The following current medications shall be immediately accessible:

- 2 (1) Epinephrine;
- 3 (2) Atropine;
- 4 (3) Antiarrhythmic
- 5 (4) Antihistamine;
- 6 (5) Antihypertensive;
- 7 (6) Bronchodilator;
- 8 (7) Antihypoglycemic agent;
- 9 (8) Vasopressor;
- 10 (9) Corticosteroid;
- 11 (10) Anticonvulsant;
- 12 (11) Muscle relaxant;
- 13 (12) Appropriate reversal agents;
- 14 (13) Nitroglycerine;
- 15 (14) Antiemetic;
- 16 (15) Neuromuscular blocking agent; and
- 17 (16) Anti-malignant hyperthermia agent.

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

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

- 21 (1) The operatory is of sufficient size and design to permit effective
22 emergency management and access of emergency equipment and
23 personnel;
- 24 (2) There is a CPR board or dental chair without enhancements suitable for
25 providing emergency treatment;
- 26 (3) There is sufficient lighting;
- 27 (4) There is suction equipment, including non-electrical back-up suction; and
- 28 (5) At least two BLS certified auxiliaries ~~shall be~~ are present during all procedures.

29 (g) At least 24 hours before the procedure is scheduled to begin, the mobile permit holder shall send written notice
30 to the Board office confirming that the facility where the general anesthesia or sedation will be performed meets the
31 requirements of Paragraph (f) of this Rule and documenting when the inspection was conducted. The permit holder
32 shall retain a copy of the written notice for 10 years following the procedure. No procedure may be performed if the
33 report is not filed as required by this Paragraph.

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

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

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

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2

Eff. March 1, 2016.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0207

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0305, .0407. Many of the following technical change requests will be duplicative across these three rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Lines 6 and 10 references a fee. However, the history note does not cite an authority for this fee. Please clarify the statutory authority for the fee and update the history note accordingly.

Lines 7 and 10 references a form. G.S. 150B-2(8a)d does not require a form to be a rule if "the contents or substantive requirements of which are prescribed by rule or statute." Is there a rule or statute that provides the information required in the application? Could it be cross-referenced? Please clarify.

Lines 7 and 12 references a renewal deadline. Is this based on G.S. 90-31? If so, please add that statute to the history note.

Line 14, add a comma after "renewal fee" and delete the "and"

Line 14, add a comma after "late fee"

Line 18, replace "continues to administer" with "administers"

Line 18, delete "or any level of sedation" as this Rule specifies "general anesthesia"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Line 20, add a comma after “anesthesia permit”

Line 22, replace “document” with “shall document the following:”

Lines 31, 33, and 36, delete the “and” at the end of the clauses

Line 31, add a semicolon after “management”

Line 32, delete “current”

Line 32, consider adding “certification” to ACLS to clarify what is required

Line 32, replace “Paragraph” with “Subparagraph”

Lines 35 thru 36, so an inspection is done annually, but the practice required by this language must be done twice before the annual inspection? If that is not the intent, please clarify.

Page 2, line 3, add “certification” after “BLS”

Page 2, line 4, is the intent of this last line to limit the six hours to only “medical emergencies” in (e)(1)(B)? Or should the language refer to any of the topics in (e)(1)(A) thru (e)(1)(F)? Please clarify.

Page 2, line 7, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

21 NCAC 16Q .0207 is adopted as published in 30:1 NCR 2 with changes as follows:

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

(a) General anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by paying a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:

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

(b) Itinerant general anesthesia permits shall be renewed by the Board annually at the same time as dental licenses by paying a one hundred dollar (\$100.00) fee and completing an application available from the Board's website:

www.ncdentalboard.org. If the completed itinerant general sedation permit and renewal fee are not received before January 31 of each year, a one hundred dollar (\$100.00) late fee shall be paid.

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

(d) A dentist who continues to administer general anesthesia or any level of sedation in violation of this Rule shall be subject to the penalties prescribed by Rule .0701 of this Subchapter.

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

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

(A) sedation;

(B) medical emergencies;

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

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

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

(F) airway management and

(2) current ACLS, which shall not count towards the six hours required in Paragraph ~~(e);~~ (e)(1) of this Rule; and

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

- 1 (4) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have read
2 the practice's emergency manual in the preceding year; and
3 (5) that all permit holder auxiliaries involved in sedation procedures have completed BLS and six
4 hours of continuing education in medical emergencies annually.

5

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

7 *Eff. March 1, 2016.*

8

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0301

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rule 21 NCAC 16Q .0404. Many of the following technical change requests will be duplicative across these two rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

Please identify the changes to the rule name on the Submission for Permanent Rule form in Box 2

Line 11 references a fee. However, the history note does not cite an authority for this fee. Is the fee for the application or the inspection? Please specify. Please clarify the statutory authority for the fee and update the history note accordingly.

Line 12 references a form. G.S. 150B-2(8a)d does not require a form to be a rule if "the contents or substantive requirements of which are prescribed by rule or statute." Is there a rule or statute that provides the information required in the application? Could it be cross-referenced? Please clarify.

Line 15, replace "directly supervise" with "provide direct supervision to"

Lines 15 and 27, add a comma after "sedation"

Line 24, add "the following" after "document"

Line 27, delete the comma after "training"

Line 27, replace "which" with "that"

Lines 27, define or delete "satisfactory"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Line 28, please clarify who is providing the supervision for the “under supervision” requirement

Lines 29 thru 30 reference outside material. Please incorporate in accordance with [G.S. 150B-21.6](#).

Line 33, delete the “and” at the end of the clause”

Lines 34 and 35, delete “current”

Line 34, consider adding “certification” to ACLS to clarify what is required

Page 2, lines 23 thru 24, refers to an evaluator performing an evaluation. Is it only one evaluator? Other evaluations and inspections refers two or more evaluators.

Page 2, line 26, what is a “successful completion”? Please clarify.

Page 2, lines 27 thru 28, how is the extension requested? Please clarify the process.

Page 2, lines 29 thru 30, the inspection fee is for an additional office? So a dentist with only one office does not get charged an inspection fee, but a dentist with multiple offices gets charged an inspection fee for every office location over the one office? Please clarify.

Please note that the content of this Rule from Paragraphs (e)-(j) is duplicative of Paragraphs (d)-(h) of 21 NCAC 16Q .0306. Is the repetition necessary? Please clarify.

Page 2, lines 31 thru 34 is similar to 21 NCAC 16Q .0204(e), but the language is not consistent. Please clarify the intent. Consider moving the Board’s full name from line 32 to line 31, and insert “Committee” on line 32. Also on line 32, replace “is not” with “shall not be”

Page 2, line 35, delete “an” before “evaluation”

Page 2, line 36, how is the request made by the applicant? Is there a time limit on this request? Please clarify the process for a re-evaluation or re-inspection.

Page 2, line 35, add “moderate conscious” before sedation to help clarify the application of this Rule among the types of sedation addressed in these Rules

Page 2, line 37, please clarify what is meant by “it”

Page 2, line 37 thru page 3, line 2, if the Board requires additional training, how is this information conveyed to the applicant? Does this retraining requirement only apply for the evaluation and not the inspection? Please clarify the process.

Page 3, line 3, for consistency, please consider ordering the terms the same as they are set forth in 21 NCAC 16Q .0204(h). The clause should read “Re-evaluations and re-inspections...”

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

Page 3, line 3, should the phrase "Board-appointed" be placed before "evaluators" to be consistent with 21 NCAC 16Q .0204(h)? Please clarify.

Page 3, line 6 references a fee. However, the history note does not cite an authority for this fee. Please clarify the statutory authority for the fee and update the history note accordingly.

Page 3, line 30, consider replacing 90-28 with 90-48

Page 3, line 34, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

21 NCAC 16Q .0301 is amended as published in 30:1 NCR 2 with changes as follows:

**21 NCAC 16Q .0301 CREDENTIALS AND PERMITS FOR MODERATE CONSCIOUS SEDATION
~~SEDATION, MODERATE PEDIATRIC CONSCIOUS SEDATION AND~~
~~MODERATE CONSCIOUS SEDATION LIMITED TO ORAL ROUTES OF~~
~~ADMINISTRATION AND NITROUS OXIDE~~**

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a ~~certified registered nurse anesthetist (CRNA)~~ CRNA or RN to ~~administer~~ deliver moderate conscious sedation, ~~moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes of administration and nitrous oxide to dental patients on an outpatient basis,~~ the dentist shall obtain a permit from the Board by completing an application form ~~provided by the Board~~ and paying a fee of ~~one hundred dollars (\$100.00).~~ three hundred seventy five dollars (\$375.00). ~~The application form is available on the Board’s website: www.ncdentalboard.org.~~ The ~~Such~~ permit shall be renewed annually and shall be displayed with the current renewal at all times ~~in a conspicuous place in the facility of the permit holder.~~ holder where it is visible to patients receiving treatment.

(b) The permit holder shall directly supervise any CRNA or RN employed to ~~administer~~ deliver sedation and shall ensure that the level and duration of the sedation does not exceed the permit holder’s permit.

~~(b) For a dentist to employ a certified registered nurse anesthetist to administer moderate conscious sedation, moderate conscious sedation limited to oral routes and nitrous oxide or moderate pediatric conscious sedation, the dentist must demonstrate through the permitting process that he or she is capable of performing all duties and procedures to be delegated to the CRNA. The dentist must not delegate said CRNA perform procedures outside of the scope of the technique and purpose of moderate conscious sedation, moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes and nitrous oxide as defined in Rule .0101 of this Subchapter.~~

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

- (1) ~~Satisfactory completion~~ Completion of ~~a minimum of [90]~~ 60 hours of Board approved didactic training ~~training,~~ including PALS (Pediatric Advanced Life Support), and instruction in intravenous conscious sedation and 30 hours of clinical training, which shall include satisfactory management of a minimum of ~~40~~ 20 live patients, under supervision, 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; or
- (2) ~~Satisfactory completion~~ Completion of a pre-doctoral dental or postgraduate program which included intravenous conscious sedation training equivalent to that defined in Subparagraph (c)(1) of this Rule; ~~or and;~~
- (3) Current ACLS; and
- (4) That all auxiliaries involved in sedation procedures have current BLS certification.

1 (3) ~~Satisfactory completion of a pre-doctoral dental or postgraduate program which included~~
2 ~~intravenous conscious sedation training equivalent to that defined in Subparagraph (c)(1) of this~~
3 ~~Rule.~~

4 ~~(d) Notwithstanding the foregoing, a dentist may also qualify for a permit to administer moderate pediatric~~
5 ~~conscious sedation by documenting, with patient names and dates of completion, at least 100 cases of moderate~~
6 ~~pediatric sedation procedures successfully completed between July 3, 2006 and July 3, 2009. A dentist who obtains~~
7 ~~a pediatric conscious sedation permit pursuant to this Paragraph may not administer sedation intravenously and such~~
8 ~~limitation shall be noted on the dentist's permit.~~

9 ~~(e) A dentist may modify his or her moderate conscious sedation permit to include the privilege of moderate~~
10 ~~pediatric conscious sedation by completing a Board approved pediatric dental degree or pediatric dental residency~~
11 ~~program or obtaining the equivalent hours of continuing education program in pediatric dental anesthesia. If said~~
12 ~~qualifications are satisfied, it shall be so designated on the dentist's moderate conscious sedation permit and will be~~
13 ~~subject to the renewal requirements stated in Rule .0501(d) of this Subchapter.~~

14 ~~(f) To be eligible for a moderate conscious sedation permit, moderate conscious sedation limited to oral routes and~~
15 ~~nitrous oxide inhalation permit or moderate pediatric conscious sedation permit, a dentist must operate within a~~
16 ~~facility which includes the capability of delivering positive pressure oxygen, and is staffed with supervised auxiliary~~
17 ~~personnel for each procedure performed. The dentist shall ensure that auxiliary personnel document annual,~~
18 ~~successful completion of basic life support (BLS) training and are capable of assisting with procedures, problems~~
19 ~~and emergencies incident thereto.~~

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

21 ~~(e) (g) Prior to issuance of a moderate conscious sedation permit, moderate conscious pediatric sedation permit or~~
22 ~~moderate conscious sedation permit limited to oral routes and nitrous oxide inhalation permit, the applicant shall~~
23 ~~undergo pass an evaluation which includes and a facility inspection. The Board shall direct an evaluator to perform~~
24 ~~this evaluation. The applicant shall be notified in writing that an evaluation and facility inspection is required and~~
25 ~~provided with the name of the evaluator who shall perform the evaluation and facility inspection. The applicant shall~~
26 ~~be responsible for successful completion of the evaluation and inspection of his or her facility within three months~~
27 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or
28 applicant requests one.

29 (f) The entire fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the applicant receives
30 notice of the inspection of each additional location at which the dentist administers sedation.

31 ~~(h) (g)~~ (g) The evaluator shall assign a grade of pass or fail and shall report his or her recommendation to the Board,
32 setting out the basis for his or her conclusion. ~~The Board,~~ Board's Anesthesia and Sedation Committee is not bound
33 by the evaluator's recommendation and shall make a final determination regarding whether the applicant has passed
34 the evaluation. The applicant shall be notified of the Committee's ~~Board's~~ decision in writing.

35 (h) An applicant who fails an inspection or an evaluation shall not receive a sedation permit.

36 (i) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of
37 receiving the notice of failure. The request shall state specific grounds supporting it. The Board shall require the

1 applicant to receive additional training prior to the re-evaluation to address the areas of deficiency determined by the
2 evaluation.

3 (j) Re-inspections and re-evaluations shall be conducted by evaluators not involved in the failed inspection or
4 evaluation.

5 (k) An applicant who does not pass the evaluation and inspection within the time allowed by Paragraph (e) of this
6 Rule shall reapply and pay an additional three hundred seventy five dollar (\$375.00) fee.

7 ~~(i) (l) A dentist who holds a moderate conscious sedation, moderate conscious sedation limited to oral routes and~~
8 ~~nitrous oxide inhalation or moderate pediatric conscious sedation permit shall not intentionally administer deep~~
9 ~~sedation sedation, although deep sedation may occur briefly and unintentionally.~~

10 ~~(j) A dentist may obtain a moderate conscious sedation permit limited to oral routes of administration and nitrous~~
11 ~~oxide inhalation, including the ability to add supplemental dosing to the techniques set out in Rule .0101(23) of this~~
12 ~~Subchapter upon compliance with the following requirements:~~

13 (1) ~~successfully complete 24 hours of didactic training and manage at least 10 adult case experiences,~~
14 ~~including at least three live clinical dental experiences. The live clinical cases shall not be handled~~
15 ~~by groups with more than five student participants. The remaining cases may include simulations,~~
16 ~~video presentations or both, but must include one experience in returning/rescuing a patient from~~
17 ~~deep to moderate sedation; or~~

18 (2) ~~document, with patient names and dates of completion, at least 100 cases of oral moderate~~
19 ~~conscious sedation procedures successfully completed within one year preceding June 3, 2008;~~
20 ~~and fulfill all the requirements listed in Rule .0401 of this Subchapter for minimal conscious~~
21 ~~sedation.~~

22 ~~(k) A dentist who is qualified to administer general anesthesia, moderate conscious sedation or moderate pediatric~~
23 ~~conscious sedation and holds a general anesthesia, moderate conscious sedation permit or a moderate pediatric~~
24 ~~conscious sedation permit may administer minimal conscious sedation or moderate conscious sedation limited to~~
25 ~~oral routes without obtaining an additional a separate minimal conscious sedation permit.~~

26 ~~(l) Any dentist who holds an active parenteral conscious sedation permit as of October 1, 2007 shall be deemed to~~
27 ~~hold an active moderate conscious sedation permit. Such permits shall be subject to the renewal requirements set~~
28 ~~out in Rule .0501 of this Subchapter.~~

29
30 *History Note: Authority G.S. 90-28; 90-30.1;*
31 *Eff. February 1, 1990;*
32 *Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;*
33 *Temporary Amendment Eff. December 11, 2002;*
34 *Amended Eff. March 1, 2016; July 1, 2010, July 3, 2008; August 1, 2004.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0302

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0202, .0206, .0405. Many of the following technical change requests will be duplicative across these four rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

Please identify the changes to the rule name on the Submission for Permanent Rule form in Box 2

Line 7, add "be responsible to" before "ensure"

Lines 9 and 17, replace "is" with "shall be"

Line 9, add "the following" after "with"

Lines 10 thru 15, lines 18 thru 34, and line 37, begin the clauses with lowercase letters as they are part of a list

Line 11, define or delete "effective"

Line 17, either add the clause "in the facility" after "maintained" or match to line 9 and state "The facility shall be equipped with the following:" Alternatively, as done in 21 NCAC 16Q .0206 and 21 NCAC 16Q .0405, is a heading necessary or is this a continuing list?

Lines 18 thru 34, should the list of equipment be the same as Rules .0202, .0206, and .0405? If so, please verify content.

Lines 19 and 21, add a comma after "medium"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Lines 35 thru 36, consider the following rewrite:

“The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:”

Page 1, line 37 thru page 2, line 9, should the list of drugs be the same as Rules .0202, .0206, and .0405? If so, please verify content.

Page 2, lines 10 thru 11, who is the clause referencing? Please clarify what is occurring in this requirement, as the clause does not identify parties.

Page 2, line 11, replace “is” with “shall be”

Page 2, line 12, replace “are” with “shall be”

Page 2, line 12, are there any requirements for maintenance of these records, such as format? If so, please clarify in this Rule.

Page 2, lines 13 thru 14, please note that this language is not consistent the amendments to 21 NCAC 16Q .0202(a)(5)(A). Please use consistent language in rules. Please clarify.

Page 2, line 15 thru 16, this information is redundant of lines 30 thru 31. Please clarify and delete redundant language

Page 2, line 24, who is providing the signature? Please clarify.

Page 2, line 28, add “of the patient” after “rates”

Page 2, line 31, add “on patient” after “IV”

Page 2, line 37, replace the period at the end of the clause with a semicolon

Page 2, line 37, add an “and” at the end of the clause

Page 3, line 3, should the term be “dismissal” or “discharge”? Please clarify.

Page 3, lines 10 thru 16, and lines 19 thru 32, begin the clauses with lowercase letter as they are part of a list

Page 3, line 12, is the clause “if applicable” necessary? Consider deleting

Page 3, line 13, the term used in this Rule and 21 NCAC 16Q .0405 is “sterile technique.” However, 21 NCAC 16Q .0202 uses the term “sterilization.” Is there a distinction among these rules? Please use consistent terms throughout the rules.

Page 3, line 14, please clarify the change to the text. “CPR” has been struckthrough in other rules, but it is not clear in this Rule.

Page 4, line 3, uncapitalize “A”

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Page 4, lines 3 and 5 references “ASA” classifications. Are these terms defined in another rule or statute? How is this information known? Please clarify. If necessary, please incorporate the outside authority in accordance with [G.S. 150B-21.6](#).

Page 4, line 4, replace the period at the end of the clause with a semicolon

Page 4, line 4, add an “or” at the end of the clause

Page 4, line 5, replace “Patients” with “a patient”

Page 4, line 11, define or delete “sufficiently”

Page 4, line 12, add “documentation of the following” after “include”

Page 4, line 15, define or delete “easily”

Page 4, line 20, replace “disabled” with the defined term “special needs”

Page 4, line 24, the correct term was “Subparagraph” Please correct

Page 4, line 26, add a comma after “color”

Page 4, line 27, add a comma after “stable”

Page 4, line 37, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0302 is amended as published in 30:1 NCR 2 with changes as follows:

2

3 **21 NCAC 16Q .0302 MODERATE CONSCIOUS SEDATION CLINICAL REQUIREMENTS AND**
4 **EQUIPMENT**

5 (a) A dentist administering moderate conscious sedation ~~or moderate pediatric conscious sedation~~ or supervising the
6 administration delivery of moderate conscious sedation ~~or moderate pediatric conscious sedation~~ by a certified
7 ~~registered nurse anesthetist~~ by a CRNA or RN shall ensure that the facility in which the sedation is ~~to be~~
8 administered meets the following requirements:

9 (1) The facility is equipped with:

10 (A) An operatory of size and design to permit access of emergency equipment and personnel
11 and to permit effective emergency management;

12 (B) A CPR ~~Board~~ board or a dental chair without enhancements, suitable for providing
13 emergency treatment;

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

15 (D) Suction equipment as necessary for specific procedures, including non-electrical back-up
16 suction.

17 (2) The following equipment is maintained:

18 (A) Positive oxygen delivery system, including full face masks for ~~adults and pediatric~~ small,
19 medium and large patients and back-up E-cylinder portable oxygen tank apart from the
20 central system;

21 (B) Small, medium and large Oral oral and nasal airways; ~~airways of various sizes~~;

22 (C) Blood pressure monitoring device;

23 (D) Pulse oximeter; ~~and~~

24 (E) ~~Automatic External Defibrillator (AED)~~; Defibrillator;

25 (F) EKG Monitor;

26 (G) Capnograph; ~~and~~

27 (H) Thermometer.

28 ~~(3) The following emergency equipment is maintained:~~

29 ~~(A)(I) I.V. Vascular access~~ set-up as necessary for specific procedures, including hardware and
30 fluids; ~~fluids, if anesthesia is intravenous~~;

31 ~~(B)(J) Syringes~~ as necessary for specific procedures; ~~and~~

32 ~~(C)(K) Tourniquet and tape~~; tape;

33 ~~(L) Advanced airway devices~~; and

34 ~~(M) Tonsillar suction~~ with back-up suction.

35 ~~(4) [(2)] (3)~~ The following drugs are maintained with a current shelf life and with access from the operatory
36 and recovery area:

37 (A) ~~Epinephrine~~; Injectable epinephrine;

- 1 (B) ~~Atropine;~~ Injectable atropine;
2 (C) ~~Appropriate~~ Injectable appropriate reversal agents;
3 (D) ~~Antihistamine;~~ Injectable antihistamine;
4 (E) ~~Corticosteroid;~~ Injectable corticosteroid;
5 (F) Nitroglycerine;
6 (G) ~~Bronchial dilator;~~ Bronchodilator;
7 (H) ~~Antiemetic;~~ Injectable antiemetic;
8 (I) Injectable 50% Dextrose; and
9 (J) ~~Anti-arrythmic;~~ Injectable anti-arrythmic.
- 10 (5) ~~(3)~~ (4) Written emergency and patient discharge protocols are maintained and training to familiarize
11 office personnel-auxiliaries in the treatment of clinical emergencies is provided; and
- 12 (6) ~~(4)~~ (5) The following records are maintained for at least 10 years:
- 13 (A) Patient's current written medical ~~history;~~ history and pre-operative assessment; including
14 known allergies and previous surgery;
- 15 (B) Drugs administered during the procedure, including route of administration, dosage,
16 strength, time and sequence of administration;
- 17 (C) A sedation ~~record which shall include;~~ record; and
- 18 (i) ~~blood pressure;~~
19 (ii) ~~pulse rate;~~
20 (iii) ~~respiration;~~
21 (iv) ~~duration of procedure;~~
22 (v) ~~documentations of complications or morbidity; and~~
23 (vi) ~~status of patient upon discharge.~~
- 24 (D) Signed consent form, identifying the procedure, risks and benefits,
25 level of sedation and date signed.
- 26 ~~(5)~~ (6) The sedation record shall include:
- 27 (A) base line vital signs, blood pressure (unless patient behavior prevents recording);
28 oxygen saturation, ET CO2, pulse and respiration rates recorded in real time at
29 15 minute intervals;
- 30 (B) procedure start and end times;
31 (C) gauge of needle and location of IV, if used;
32 (D) status of patient upon discharge; and
33 (E) documentation of complications or morbidity.
- 34 ~~(6)~~ (7) The following conditions shall be satisfied during a sedation procedure:
- 35 (A) Two BLS certified auxiliaries shall be present at all times during the
36 procedure, one of whom shall be dedicated to continuous patient
37 monitoring and recording sedation data.

1 (B) If IV sedation is used, IV infusion shall be administered before the
2 start of the procedure and maintained until the patient is ready for
3 dismissal.

4 (b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of
5 moderate conscious sedation on a patient, ~~or where applicable, moderate pediatric conscious sedation on a patient,~~
6 including the deployment of an intravenous delivery system, while the evaluator observes. ~~Practices limited to~~
7 ~~pediatric dentistry will not be required to demonstrate the deployment of an intravenous delivery system. Instead,~~
8 ~~they will orally describe to the evaluator the technique of their training in intravenous and intraosseous deployment.~~

9 During the demonstration, the applicant or permit holder shall demonstrate competency in the following areas:

- 10 (1) Monitoring blood pressure, pulse, ET CO2 and respiration;
- 11 (2) Drug dosage and administration;
- 12 (3) Treatment of untoward reactions including respiratory or cardiac depression if applicable;
- 13 (4) Sterile technique;
- 14 (5) Use of BLS CPR certified ~~personnel;~~ auxiliaries;
- 15 (6) Monitoring of patient during recovery; and
- 16 (7) Sufficiency of patient recovery time.

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

- 19 (1) Laryngospasm;
- 20 (2) Bronchospasm;
- 21 (3) Emesis and aspiration;
- 22 (4) Respiratory depression and arrest;
- 23 (5) Angina pectoris;
- 24 (6) Myocardial infarction;
- 25 (7) ~~Hypertension/Hypotension;~~ Hypertension and Hypotension;
- 26 (8) Syncope;
- 27 (9) Allergic reactions;
- 28 (10) Convulsions;
- 29 (11) Bradycardia;
- 30 (12) Insulin shock; ~~and~~
- 31 (13) Cardiac ~~arrest.~~ arrest; and
- 32 (14) Airway obstruction.

33 ~~(d) A dentist administering moderate conscious sedation or moderate pediatric conscious sedation shall ensure that~~
34 ~~the facility is staffed with sufficient auxiliary personnel for each procedure performed who shall document annual~~
35 ~~successful completion of basic life support training and be capable of assisting with procedures, problems, and~~
36 ~~emergency incidents that may occur as a result of the sedation or secondary to an unexpected medical complication.~~

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

3 (1) A patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the
4 patient's current medical history and medication use.

5 (2) Patients who are not medically stable or who are ASA III or higher shall be evaluated by a
6 consultation with the patient's primary care physician or consulting medical specialist regarding
7 the potential risks posed by the procedure.

8 (e) Post-operative monitoring and discharge:

9 (1) Vital signs shall be continuously monitored when the sedation is no longer being administered and
10 the patient shall have direct continuous supervision until oxygenation and circulation are stable
11 and the patient is sufficiently responsive for discharge from the office.

12 (2) Recovery from moderate conscious sedation shall include:

13 (A) cardiovascular function stable;

14 (B) airway patency uncompromised;

15 (C) patient easily arousable and protective reflexes intact;

16 (D) state of hydration within normal limits;

17 (E) patient can talk, if applicable;

18 (F) patient can sit unaided, if applicable;

19 (G) patient can ambulate, if applicable, with minimal assistance; and

20 (H) for the patient who is disabled, or incapable of the usually expected responses, the pre-
21 sedation level of responsiveness or the level as close as possible for that patient shall be
22 achieved.

23 (3) Before allowing the patient to leave the office, the dentist shall determine that the patient has met
24 the recovery criteria set out in [Subparagraph] Paragraph (e)(2) of this Rule and the following
25 discharge criteria:

26 (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and
27 stable and have been documented;

28 (B) explanation and documentation of written postoperative instructions have been provided
29 to the patient or a responsible adult at time of discharge; and

30 (C) [responsible individual] a vested adult is available [for the patient] to transport the patient
31 after discharge.

32
33 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*

34 *Eff. February 1, 1990;*

35 *Amended Eff. August 1, 2002; August 1, 2000;*

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

37 *Amended Eff. March 1, 2016; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0304

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Please identify the changes to the rule name on the Submission for Permanent Rule form in Box 2

Based on content, please compare to 21 NCAC 16Q .0406 for consistency

Line 5, consider deleting unnecessary language of "who does not hold such a permit and"

Line 8, add "be responsible to" before "ensure"

Line 8, replace "which" with "where"

Lines 10 thru 13 are not necessary and should be deleted, as this requirement is set forth in 21 NCAC 16Q .0302(a)(7)

Line 18, consider adding 90-30.1

Line 20, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0304 is amended as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0304 OFF SITE USE OF MODERATE CONSCIOUS SEDATION PERMITS**

4 (a) ~~Upon request, the~~ The holder of a ~~moderate pediatric conscious sedation or moderate conscious sedation permit~~
5 may travel to the office of a licensed dentist who does not hold such a permit and provide moderate conscious
6 ~~sedation services at the level for which the traveling dentist holds a valid permit, as well as minimal sedation or~~
7 ~~moderate conscious sedation limited to oral routes~~ for the patients of that dentist who are undergoing dental
8 procedures. The permit holder shall ensure ~~is solely responsible for providing~~ that the facility in which the sedation
9 is administered has passed inspection by the Board and meets the requirements set out in Rule .0302 of this Section.
10 ~~established by the Board, that the required drugs and equipment are present, and~~ The ~~that the permit holder~~ shall
11 ensure that ~~utilizes sufficient auxiliary personnel for each procedure performed based on the standard of care who~~
12 ~~shall document annual successful completion of basic life support training- two BLS certified auxiliaries are~~
13 available for each procedure. ~~and be capable of assisting with procedures, problems, and emergency incidents that~~
14 ~~may occur as a result of the sedation or secondary to an unexpected medical complication.~~

15 (b) ~~Holders of moderate conscious sedation permits limited to oral routes and nitrous oxide inhalation may not~~
16 ~~provide sedation at the office of a licensed dentist who does not hold an appropriate sedation permit.~~

17

18 *History Note: Authority G.S. 90-28; 90-30; 90-48;*

19 *Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013.*

20 *Amended Eff. March 1, 2016.*

21

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0305

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0207, .0407. Many of the following technical change requests will be duplicative across these three rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Lines 6 and 9 references a fee. However, the history note does not cite an authority for this fee. Please clarify the statutory authority for the fee and update the history note accordingly.

Line 6 references a form. G.S. 150B-2(8a)d does not require a form to be a rule if "the contents or substantive requirements of which are prescribed by rule or statute." Is there a rule or statute that provides the information required in the application? Could it be cross-referenced? Please clarify.

Line 8 references a renewal deadline. Is this based on G.S. 90-31? If so, please add that statute to the history note.

Line 11, add a comma after "late fee"

Lines 12 thru 13, delete "a facilities" and replace it with "an" to be consistent with 21 NCAC 16Q .0207

Line 16, add a comma after "sedation permit"

Line 16, replace "applicant" with "permit holder"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Line 17, add an “and” between “equipment” and “requirements” to be consistent with 21 NCAC 16Q .0207

Line 17, add “the following” after “document”

Line 26, delete the “and” at the end of the clauses

Line 27, delete “current”

Line 27, consider adding “certification” to ACLS to clarify what is required

Line 28, replace “Paragraph” with “Subparagraph”

Line 28, replace the period at the end of the clause with a semicolon

Lines 29, 31, and 33, add “moderate conscious” before “sedation” to help clarify the application of this Rule among the types of sedation addressed in these Rules

Lines 29 thru 30, so an inspection is done annual, but the practice required by this language must be done twice before the annual inspection? If that is not the intent, please clarify.

Line 33, add “certification” after “BLS”

Line 34, is the intent of this last line to limit the six hours to only “medical emergencies” in (e)(1)(B)? Or should the language refer to any of the topics in (e)(1)(A) thru (e)(1)(F)? Please clarify.

Line 35, replace “applicants” with “permit holders” Please note that this sentence is not in 21 NCAC 16O .0207.

Page 2, line 1, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0305 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0305 ANNUAL RENEWAL OF MODERATE CONSCIOUS SEDATION PERMIT**
4 **REQUIRED**

5 (a) Moderate conscious sedation permits shall be renewed by the Board annually at the same time as dental licenses
6 by paying a one hundred dollar (\$100.00) fee and completing an application available from the Board’s website:
7 www.ncdentalboard.org.

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

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

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

16 (e) As a condition for renewal of the moderate conscious sedation permit the applicant shall meet the clinical
17 equipment requirements of Rule .0302 of this Section and shall document:

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

21 (A) sedation;

22 (B) medical emergencies;

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

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

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

26 (F) airway management; and

27 (2) current ACLS, which shall not count towards the six hours of continuing education required in
28 [Subparagraph] Paragraph (e)(1) of this Rule.

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

31 (4) that the permit holder and all auxiliaries **involved in sedation procedures** have read the practice’s
32 emergency manual in the preceding year; and

33 (5) that all auxiliaries **involved in sedation procedures** have completed BLS and six hours of
34 continuing education in medical emergencies annually.

35 (f) All applicants for renewal of a moderate conscious sedation permit shall be in good standing with the Board.
36

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

1
2

Eff. March 1, 2016.

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0306

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0204, .0408. Many of the following technical change requests will be duplicative across these three rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Line 5, replace "will" with "may" or "shall"

Line 5, add "to serve as evaluators" after "persons"

Lines 8 thru 9, the inspection fee is for an additional office? So a dentist with only one office does not get charged an inspection fee, but a dentist with multiple offices gets charged an inspection fee for every office location over the one office? Please clarify.

Line 10, can the dentist-member also be part of the on-side inspection? Or is the member limited to the evaluation? Please clarify.

Please note that the content of this Rule from Paragraphs (d)-(h) is duplicative of Paragraphs (e)-(j) of 21 NCAC 16Q .0301. Is the repetition necessary? Please clarify.

Line 14, replace "is not" with "shall not be"

Line 18, replace "will" with "shall"

Line 18, define or delete "summarily"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Line 19, replace “may” with “shall”

Line 22, how is the request made by the applicant? Is there a time limit on this request? Please clarify the process for a re-evaluation or re-inspection.

Lines 23 thru 24, if the Board requires additional training, how is this information conveyed to the applicant? Does this retraining requirement only apply for the evaluation and not the inspection? Please clarify the process.

Line 28, consider replacing 90-28 with 90-48

Line 29, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0306 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0306 PROCEDURE FOR MODERATE CONSCIOUS SEDATION EVALUATION OR**
4 **INSPECTION AND RE-INSPECTION**

5 (a) When an evaluation or on-site inspection is required, the Board will designate one or more qualified persons,
6 each of whom has administered moderate conscious sedation for at least three years preceding the inspection,
7 exclusive of his or her training in moderate conscious sedation.

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

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

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

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

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

21 (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days
22 of receiving the notice of failure. The request shall include a statement of the grounds supporting the re-evaluation
23 or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to
24 address the areas of deficiency determined by the evaluation.

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

27
28 *History Note: Authority G.S. 90-28; 90-30.1; 90-39;*
29 *Eff. March 1, 2016.*
30

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0404

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rule 21 NCAC 16Q .0301. Many of the following technical change requests will be duplicative across these two rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Line 6, delete the clause "general anesthesia or" as this is unnecessary language and covered in 21 NCAC 16Q .0204

Line 7 references a fee. However, the history note does not cite an authority for this fee. Is the fee for the application or the inspection? Please specify. Please clarify the statutory authority for the fee and update the history note accordingly.

Line 8 references a form. G.S. 150B-2(8a)d does not require a form to be a rule if "the contents or substantive requirements of which are prescribed by rule or statute." Is there a rule or statute that provides the information required in the application? Could it be cross-referenced? Please clarify.

Lines 13 and 15, replace "which" with "that"

Lines 15 and 17 refers to a list of residencies or institutions. How is this information known? Please clarify. If necessary, please incorporate the outside authority in accordance with [G.S. 150B-21.6](#).

Line 16, add "or" at the end of the clause

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Please note that the content of this Rule from Paragraphs (e)-(j) is duplicative of Paragraphs (d)-(h) of 21 NCAC 16Q .0408. Is the repetition necessary? Please clarify.

Line 23, please note that this language is not consistent with line 21 of 21 NCAC 16Q .0301.

Line 24, refers to an evaluator performing an evaluation. Is it only one evaluator? Other evaluations and inspections refers two or more evaluators. Please clarify the process.

Line 27, what is a “successful completion”? Please clarify.

Line 28, how is the extension requested? Please clarify the process.

Lines 30 thru 31, the inspection fee is for an additional office? So a dentist with only one office does not get charged an inspection fee, but a dentist with multiple offices gets charged an inspection fee for every office location over the one office? Please clarify.

Lines 32 thru 35 is similar to 21 NCAC 16Q .0204(e), but the language is not consistent. Please clarify the intent. Consider moving the Board’s full name from line 33 to line 32, and insert “Committee” on line 33. Also on line 33, replace “is not” with “shall not be”

Line 36, add “moderate pediatric conscious” before “sedation” to help clarify the application of this Rule among the types of sedation addressed in these Rules

Page 2, line 2, how is the request made by the applicant? Is there a time limit on this request? Please clarify the process for a re-evaluation or re-inspection.

Page 2, lines 2 thru 3, if the Board requires additional training, how is this information conveyed to the applicant? Does this retraining requirement only apply for the evaluation and not the inspection? Please clarify the process.

Page 2, line 4, should this sentence also reference “re-evaluations” to be consistent with 21 NCAC 16Q .0204(h)? Please clarify.

Page 2, line 4, should the phrase “Board-appointed” be placed before “evaluators” to be consistent with 21 NCAC 16Q .0204(h)? Please clarify.

Page 2, line 6 references a fee. However, the history note does not cite an authority for this fee. Please clarify the statutory authority for the fee and update the history note accordingly.

Page 2, line 10, consider replacing 90-28 with 90-48

Page 2, line 11, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0404 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0404** **CREDENTIALS AND PERMITS FOR MODERATE PEDIATRIC CONSCIOUS**
4 **SEDATION**

5 (a) Before a dentist licensed to practice in North Carolina may administer moderate pediatric conscious sedation,
6 the dentist shall obtain a general anesthesia or moderate pediatric conscious sedation permit from the Board by
7 completing an application form and paying a fee of three hundred seventy-five dollars (\$375.00). The application
8 form is available on the Board’s website: www.ncdentalboard.org. The permit shall be renewed annually and shall
9 be displayed with the current renewal at all times in the permit holder’s facility where it is visible to patients
10 receiving treatment.

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

13 (1) completion of a postgraduate program which included pediatric intravenous conscious sedation
14 training;

15 (2) completion of a Council On Dental Accreditation (CODA) approved pediatric residency which
16 included intravenous conscious sedation training;

17 (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that
18 includes training in the use and placement of IVs or intraosseous vascular access.

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

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

23 (e) Before receiving a moderate pediatric sedation permit, the applicant shall pass an evaluation and a facility
24 inspection. The Board shall direct an evaluator to perform this evaluation and inspection. The Board shall notify
25 the applicant in writing that an evaluation and facility inspection is required and identify [provided with the name of
26] the evaluator who shall perform the evaluation and facility inspection at least 15 days before the inspection and
27 evaluation. The applicant shall be responsible for successful completion of the evaluation and inspection of his or
28 her facility within 90 days of notification. An extension of no more than 90 days shall be granted if the designated
29 evaluator or applicant requests one.

30 (f) An additional fee of three hundred seventy five dollars (\$375.00) shall be due 10 days after the applicant
31 receives notice of the inspection of each additional location at which the dentist administers sedation.

32 (g) The evaluator shall assign a grade of pass or fail and shall report his or her recommendation to the Board, setting
33 out the basis for his or her conclusion. The Board’s Anesthesia and Sedation Committee is not bound by the
34 evaluator's recommendation and shall make a final determination regarding whether the applicant has passed the
35 evaluation. The applicant shall be notified of the Committee’s decision in writing.

36 (h) An applicant who fails an inspection or an evaluation shall not receive a sedation permit.

- 1 (i) An applicant who fails an inspection or evaluation may request a re-evaluation within 15 days of receiving the
2 notice of failure. The request shall state specific grounds supporting it. The Board shall require the applicant to
3 receive additional training prior to the re-evaluation to address the areas of deficiency determined by the evaluation.
4 (j) Re-inspections shall be conducted by evaluators not involved in the failed inspection or evaluation.
5 (k) An applicant who does not pass the evaluation and inspection within the time allowed by Paragraph ~~(g)~~ (e) of
6 this Rule shall reapply and pay an additional three hundred seventy five dollar (\$375.00) fee.
7 (l) A dentist who holds a moderate pediatric conscious sedation permit shall not intentionally administer deep
8 sedation.

9
10 *History Note: Authority G.S. 90-28; 90-30.1;*
11 *Eff. March 1, 2016.*

12

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0405

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0202, .0206, .0302. Many of the following technical change requests will be duplicative across these four rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Line 5, add "be responsible to" before "ensure"

Lines 7, replace "is" with "shall be"

Line 7, add "the following" after "with"

Lines 8 thru 29, lines 32 thru page 2, line 3, begin the clauses with lowercase letters as they are part of a list

Line 9, define or delete "effective"

Line 15, in 21 NCAC 16Q .0202 and 21 NCAC 16Q .0302, another list began before these items. Please clarify why the distinction is made in this Rule. Please be consistent in formatting of similar ideas throughout these rules.

Line 16 references "full face masks for adults and pediatric" Rule .0302 says "small, medium, and large." Is there a distinction? Please clarify. Please use consistent terms throughout the rules.

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Lines 16 thru 29, should the list of equipment requirements be the same as Rules .0202, .0206, and .0302? If so, please verify content.

Line 17, add a comma after “patients”

Line 18, in 21 NCAC 16Q .0202 and 21 NCAC 16Q .0302, there was a listing of “small, medium, and large” that is not in this Rule. Is there a distinction? Please clarify. Please use consistent terms throughout the rules.

Lines 30 thru 31, consider the following rewrite:

“The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:”

Page 1, line 32 thru page 2, line 3, should the list of drugs be the same as Rules .0202, .0206, and .0302? If so, please verify content.

Page 2, lines 4 thru 5, who is the clause referencing? Please clarify what is occurring in this requirement, as the clause does not identify parties.

Page 2, line 6, replace “are” with “shall be”

Page 2, line 6, are there any requirements for maintenance of these records, such as format? If so, please clarify in this Rule.

Page 2, line 10, add an “and” at the end of the clause

Page 2, line 11, who is providing the signature? Please clarify.

Page 2, line 17, add “of the patient” after “rates”

Page 2, line 18, add “on patient” after “IV”

Page 2, line 26, should the term be “dismissal” or “discharge”? Please clarify.

Page 2, lines 34 thru page 2, lines 3, and page 3, lines 6 thru 20, begin the clauses with lowercase letters as they are part of a list

Page 3, line 5, replace “treating” with “the treatment of”

Page 3, line 23, uncapitalize “A”

Page 3, lines 23 and 25 references “ASA” classifications. Are these terms defined in another rule or statute? How is this information known? Please clarify. If necessary, please incorporate the outside authority in accordance with [G.S. 150B-21.6](#).

Page 3, line 24, replace the period at the end of the clause with a semicolon

Page 3, line 24, add an “or” at the end of the clause

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Page 3, line 25, replace “Patients” with “a patient”

Page 3, line 30, add a comma after “breathing”

Page 3, line 34, define or delete “sufficiently”

Page 3, line 35, add “documentation of the following” after “include”

Page 4, line 1, define or delete “easily”

Page 4, line 6, replace “disabled” with the defined term “special needs”

Page 4, line 10, the correct term was “Subparagraph” Please correct

Page 4, line 12 add a comma after “color”

Page 4, line 13, add a comma after “stable”

Page 4, line 26, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0405 is adopted as published in 30:1 NCR 2 with changes as follows:

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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 in which the sedation is to be administered meets the following requirements:

- (1) The facility is equipped with:
 - (A) An operatory of size and design to permit access of emergency equipment and personnel and to permit effective 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.~~ suction;

~~(2) The following equipment is maintained:~~

- ~~(A)~~ (E) Positive oxygen delivery system, including full face masks for adults and pediatric patients and back-up E-cylinder portable oxygen tank apart from the central system;
- ~~(B)~~ (F) Oral and nasal airways of various sizes;
- ~~(C)~~ (G) Blood pressure monitoring device;
- ~~(D)~~ (H) Pulse oximeter;
- ~~(E)~~ (I) Capnograph;
- ~~(F)~~ (J) Defibrillator;
- ~~(G)~~ (K) EKG Monitor;
- ~~(H)~~ (L) Thermometer;
- ~~(I)~~ (M) Vascular access set-up as necessary for specific procedures, including hardware and fluids;
- ~~(J)~~ (N) Syringes as necessary for specific procedures;
- ~~(K)~~ (O) Advanced airways; and
- ~~(L)~~ (P) Tourniquet and tape.

~~(3)~~ (2) The following drugs are maintained with a current shelf life and with access from the operatory and recovery area:

- (A) Epinephrine;
- (B) Atropine;
- (C) Appropriate reversal agents;
- (D) Antihistamine;
- (E) Corticosteroid;
- (F) Nitroglycerine;

1 (G) Bronchodilator;

2 (H) Antiemetic; and

3 (I) 50% Dextrose.

4 ~~(4)~~ (3) Written emergency and patient discharge protocols are maintained and training to familiarize
5 auxiliaries in the treatment of clinical emergencies is provided; and

6 ~~(5)~~ (4) The following records are maintained for at least 10 years:

7 (A) Patient's current written medical history and pre-operative assessment;

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

10 (C) A sedation record;

11 (D) Signed consent form, identifying the procedure, risks and benefits,
12 level of sedation and date signed.

13 ~~(6)~~ (5) The sedation record shall include:

14 (A) base line vital signs, blood pressure (unless patient behavior prevents recording);
15 oxygen saturation, ET CO2, pulse and respiration rates recorded in real time at
16 15 minute intervals;

17 (B) procedure start and end times;

18 (C) gauge of needle and location of IV, if used;

19 (D) status of patient upon discharge; and

20 (E) documentation of complications or morbidity.

21 ~~(7)~~ (6) The following conditions shall be satisfied during a sedation procedure:

22 (A) Two BLS certified auxiliaries shall be present at all times during the
23 procedure, one of whom shall be dedicated to patient monitoring and
24 recording sedation data.

25 (B) When IV sedation is used, IV infusion shall be administered before the commencement
26 of the procedure and maintained until the patient is ready for dismissal.

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

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

34 (1) Monitoring blood pressure, temperature, pulse, and respiration;

35 (2) Drug dosage and administration;

36 (3) Treatment of any untoward reactions including respiratory or cardiac depression;

37 (4) Sterile technique;

- 1 (5) Use of BLS certified auxiliaries;
- 2 (6) Monitoring of patient during recovery; and
- 3 (7) Sufficiency of patient recovery time.

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

- 6 (1) Laryngospasm;
- 7 (2) Bronchospasm;
- 8 (3) Emesis and aspiration;
- 9 (4) Respiratory depression and arrest;
- 10 (5) Angina pectoris;
- 11 (6) Myocardial infarction;
- 12 (7) Hypertension and Hypotension;
- 13 (8) Allergic reactions;
- 14 (9) Convulsions;
- 15 (10) Syncope;
- 16 (11) Bradycardia;
- 17 (12) Insulin shock;
- 18 (13) Cardiac arrest;
- 19 (14) Airway obstruction; and
- 20 (15) Vascular access.

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

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

28 (f) Patient monitoring:

- 29 (1) Patients who have been administered moderate pediatric conscious sedation shall be monitored for
30 alertness, responsiveness, breathing and skin coloration during waiting periods before operative
31 procedures.
- 32 (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and
33 the patient shall have direct continuous supervision until oxygenation and circulation are stable
34 and the patient is sufficiently responsive for discharge from the office.
- 35 (3) Recovery from moderate pediatric conscious sedation shall include:
 - 36 (A) cardiovascular function stable;
 - 37 (B) airway patency uncompromised;

- 1 (C) patient easily 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 patient who is disabled, or incapable of the usually expected responses, the pre-
- 7 sedation level of responsiveness or the level as close as possible for that patient shall be
- 8 achieved.

9 (4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met
10 the recovery criteria set out in Paragraph [Subparagraph] (f)(3) of this Rule and the following
11 discharge criteria:

- 12 (A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and
- 13 stable and have been documented;
- 14 (B) explanation and documentation of written postoperative instructions have been provided
- 15 to a responsible adult at time of discharge;
- 16 (C) a vested adult [responsible individual] is available [for the patient] to transport the patient
- 17 after discharge; and
- 18 (D) A vested adult shall be available to transport patients for whom a motor vehicle restraint
- 19 system is required and an additional responsible individual shall be available to attend to
- 20 the patients.

21
22 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
23 *Eff. February 1, 1990;*
24 *Amended Eff. August 1, 2002; August 1, 2000;*
25 *Temporary Amendment Eff. December 11, 2002;*
26 *Amended Eff. March 1, 2016; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0406

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Based on content, please compare to 21 NCAC 16Q .0304 for consistency

Line 6, add "be responsible to" before "ensure"

Line 7, add a comma after "Section"

Line 8, add a comma after "facility"

Line 10, consider adding 90-30.1

Line 11, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0406 is adopted as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0406 OFF SITE USE OF MODERATE PEDIATRIC CONSCIOUS SEDATION**

4

PERMITS

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

9

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

11 *Eff. March 1, 2016.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0407

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0207, .0305. Many of the following technical change requests will be duplicative across these three rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Lines 6 and 9 references a fee. However, the history note does not cite an authority for this fee. Please clarify the statutory authority for the fee and update the history note accordingly.

Line 6 references a form. G.S. 150B-2(8a)d does not require a form to be a rule if "the contents or substantive requirements of which are prescribed by rule or statute." Is there a rule or statute that provides the information required in the application? Could it be cross-referenced? Please clarify.

Line 8 references a renewal deadline. Is this based on G.S. 90-31? If so, please add that statute to the history note.

Line 11, add a comma after "late fee"

Line 13, delete "a facilities" and replace it with "an" to be consistent with 21 NCAC 16Q .0207

Line 14, replace "Continued administration of level of sedation" with "A dentist who administers moderate pediatric conscious sedation"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Lines 17, add “shall document the following:” after “and”

Line 18, 27, 29, 31, and 33, delete “document”

Line 26, delete the “and” at the end of the clause

Line 27, delete “current”

Line 27, consider adding “certification” to PALS to clarify what is required

Line 28, replace “Paragraph” with “Subparagraph”

Lines 29, 31, and 33, add “moderate pediatric conscious” before “sedation” to help clarify the application of this Rule among the types of sedation addressed in these Rules

Lines 29 thru 30, so an inspection is done annual, but the practice required by this language must be done twice before the annual inspection? If that is not the intent, please clarify.

Line 33, add “certification” after “BLS”

Lines 33 thru 34, is the intent of this last line to limit the six hours to only “medical emergencies” in (e)(1)(B)? Or should the language refer to any of the topics in (e)(1)(A) thru (e)(1)(F)? Please clarify.

Line 35, replace “applicants” with “permit holders” Please not that this sentence is not in 21 NCAC 16O .0207.

Page 2, line 2, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0407 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0407 ANNUAL RENEWAL OF MODERATE PEDIATRIC CONSCIOUS SEDATION**
4 **PERMIT REQUIRED**

5 (a) Moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as
6 dental licenses by paying a one hundred (\$100.00) fee and completing an application available from the Board's
7 website: www.ncdentalboard.org.

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

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

14 (d) Continued administration of level of sedation in violation of this Rule shall be unlawful and shall subject the
15 dentist to the penalties prescribed by Rule .0701 of this Subchapter.

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

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

21 (A) sedation;

22 (B) medical emergencies;

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

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

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

26 (F) airway management; and

27 (2) document current PALS, which shall not count towards the six hours of continuing education
28 required in [Subparagraph] Paragraph (e)(1) of this rule;

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

31 (4) document that the permit holder and all auxiliaries **involved in sedation procedures** have read the
32 practice's emergency manual in the preceding year.

33 (5) document that all auxiliaries **involved in sedation procedures** have completed BLS and six hours
34 of continuing education in medical emergencies annually.

35 (f) All applicants for renewal of a moderate pediatric conscious sedation permit shall be in good standing with the
36 Board.

37

1 *History Note: Authority G.S. 90-28; 90-30.1; 90-48;*
2 *Eff. March 1, 2016.*
3

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0408

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Upon review of the packet of rules, it appears as though this Rule has content similar to Rules 21 NCAC 16Q .0204, .0306. Many of the following technical change requests will be duplicative across these three rules. If upon the agency's review, additional changes should be made to provide consistency and uniformity in the content, please provide those changes to me in a separate document upon submission of the revised rules.

For an adoption, the only language that should be underlined is changes made since publication. Please see this [example](#).

Line 5, replace "will" with "may" or "shall"

Line 5, add "to serve as evaluators" after "persons"

Lines 8 thru 9, the inspection fee is for an additional office? So a dentist with only one office does not get charged an inspection fee, but a dentist with multiple offices gets charged an inspection fee for every office location over the one office? Please clarify.

Line 10, can the dentist-member also be part of the on-side inspection? Or is the member limited to the evaluation? Please clarify.

Please note that the content of this Rule from Paragraphs (d)-(h) is duplicative of Paragraphs (e)-(j) of 21 NCAC 16Q .0404. Is the repetition necessary? Please clarify.

Line 14, replace "is not" with "shall not be"

Line 17, add "moderate" after "administer"

Line 18, replace "will" with "shall"

Line 18, define or delete "summarily"

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

Line 19, replace “may” with “shall”

Line 22, how is the request made by the applicant? Is there a time limit on this request? Please clarify the process for a re-evaluation or re-inspection.

Lines 23 thru 24, if the Board requires additional training, how is this information conveyed to the applicant? Does this retraining requirement only apply for the evaluation and not the inspection? Please clarify the process.

Line 29, underline the effective date of March 1, 2016 to reflect the addition to the history note

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0408 is adopted as published in 30:1 NCR 2 with changes as follows:

2
3 **21 NCAC 16Q .0408 PROCEDURE FOR MODERATE PEDIATRIC SEDATION EVALUATION OR**
4 **INSPECTION AND RE-INSPECTION**

5 (a) When an evaluation or on-site inspection is required, the Board will designate one or more qualified persons,
6 each of whom has administered moderate pediatric sedation for at least three years preceding the inspection,
7 exclusive of his or her training in moderate pediatric sedation.

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

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

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

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

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

21 (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days
22 of receiving the notice of failure. The request shall include a statement of the grounds supporting the re-evaluation
23 or re-inspection. The Board shall require the applicant to receive additional training prior to the re-evaluation to
24 address the areas of deficiency determined by the evaluation.

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

27
28 *History Note: Authority G.S. 90-28; 90-30.1; 90-39;90-48l*
29 *Eff. March 1, 2016.*
30

REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0703

DEADLINE FOR RECEIPT: Wednesday, February 10, 2016

NOTE WELL: This request when viewed on computer extends 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 this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Lines 4 and 10 have reporting requirements. What triggers the time clock running on these reporting requirements? Please clarify.

Lines 5, 11, and 12, replace "which" with "that"

Line 7 investigates the death and line 9 reviews the incident report. Is this distinction intentional? Line 7 only speaks to "sedation" and line 8 speaks to ceasing "general anesthesia and sedation." Again, is this distinction intentional? Could these two sentences be combined into one sentence? Please clarify.

Line 15, add "the following" after "include"

Lines 16 through 23, delete the "The" and that will being each clause of the list of with a lower case letter

Line 25, is the investigation limited to the practice act? Should it also include "and the Rules of this Subchapter"? Please clarify.

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

Abigail M. Hammond
Commission Counsel

Date submitted to agency: Wednesday, January 27, 2016

1 21 NCAC 16Q .0703 is adopted as published in 30:1 NCR 2 as follows:

2

3 **21 NCAC 16Q .0703 REPORTS OF ADVERSE OCCURRENCES**

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

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

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

- 16 (1) The dentist's name, license number and permit number;
- 17 (2) The date and time of the occurrence;
- 18 (3) The facility where the occurrence took place;
- 19 (4) The name and address of the patient;
- 20 (5) The surgical procedure involved;
- 21 (6) The type and dosage of sedation or anesthesia utilized in the procedure;
- 22 (7) The circumstances involved in the occurrence; and
- 23 (8) The anesthesia records.

24 (d) Upon receipt of any such report, the Board shall investigate and shall take disciplinary action if the evidence
25 demonstrates that a licensee has violated the Dental Practice Act.

26

27 *History Note: Authority G.S. 90-28; 90-30.1; 90-41;90-48;*

28 *Eff. March 1, 2016.*