AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0101

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Amendment%20with%20c hanges%20for%20Publication%20in%20the%20NCAC.pdf

- Line 12, replace "which" with "that"
- Line 13, define or delete "totally"
- Line 14, define or delete "continuously"
- Line 31, remove underlining from "obey"
- Page 2, line 18, remove underlining from "insulin shock"
- Page 2, line 33, remove underlining from "obey"
- Page 2, line 37, remove underlining from "immediate use."
- Page 3, line 6, define or delete "minimally"
- Page 3, line 7, define or delete "independently and continuously"
- Page 3, line 8, add "without assistance" between "airway and"
- Page 3, line, 8, define or delete "normally"

Page 3, line 11, replace "is" with "shall be" or "may be" Consider "may be" to be consistent with page 3, line 22

Page 3, line 13, replace "which" with "that"

Page 3, line 15, define or delete "continuously"

Page 3, lines 15 thru 16, please clarify what is meant by the following clause:

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

Please clarify if that is a known medical standard.

Page 3, line 18, remove underlining from "obey"

Page 3, line 36, remove underlining from "obey"

Page 4, line 17, consider adding "process" before "begins"

Page 4, line 19, delete "applicable" before "recovery"

Page 4, line 34, add the date of "June 1, 2017" to the history note to reflective the effective date

1 2 21 NCAC 16Q .0101 is proposed for amendment as follows:

D 21 NUAU 100 .0101 GENERAL ANEST MESIA AND SEDATION DEFINITI	3	21 NCAC 16Q .0101	GENERAL ANEST	HESIA AND SEDATION DEF	FINITION
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For the purpose of these Rules relative to the administration of minimal conscious sedation, moderate conscious sedation, moderate conscious sedation limited to oral routes or nitrous oxide inhalation, moderate pediatric 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.
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- 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 minor psychosedative, possibly in combination with nitrous oxide, to children or adults prior to 12 commencement of treatment on the day of the appointment which allows for uninterrupted 13 interactive ability in a totally awake patient with no compromise in the ability to maintain a patent 14 airway continuously and without assistance. Nitrous oxide may be administered in addition to the 15 minor psychosedative without constituting multiple dosing for purpose of these Rules.
- 16 <u>(4)</u> "ACLS" Advanced Cardiac Life Support.
- 17 (5) "Administer" to direct, manage, supervise, control, and have charge of all aspects of selection,
 18 dosage, timing, and method of delivery to the patient of any pharmacologic agent intended to reduce
 19 anxiety or depress consciousness.

20 (6) "ASA" – American Society of Anesthesiologists.

21 (7) "Auxiliaries" – non-dentist staff members involved in general anesthesia or sedation procedures.

22 (8) "BLS" – Basic Life Support.

- (4)(9) "Behavior control" the use of pharmacological techniques to control behavior to a level that dental
 treatment can may be performed without injury to the patient or dentist. effectively and efficiently.
- (5)(10) "Behavioral management" the use of pharmacological or psychological techniques, singly or in
 combination, to modify behavior to a level that dental treatment can-may be performed effectively
 and efficiently. without injury to the patient or dentist.
- 28 (6)(11) "Competent" displaying special skill or knowledge derived from training and experience.
- (7)(12) "Conscious sedation" an induced state of a depressed level of consciousness that retains the patient's
 ability to independently and continuously maintain an airway without assistance and respond
 appropriately to physical stimulation and [obey] verbal command, commands, and that is produced
 by pharmacologic or non-pharmacologic agents, or a combination thereof. In accordance with this
 particular definition, the drugs or techniques used shall carry a margin of safety wide enough to
 render unintended loss of consciousness unlikely. All dentists who perform conscious sedation
 shall have an unexpired sedation permit from the Dental Board.
- 36 (13) "CRNA" Certified Registered Nurse Anesthetist.

1	(8)(14) "Deep sedation" – an induced state of a depressed level of consciousness accompanied by partial
2	loss of protective reflexes, including the ability to continually maintain an airway independently
3	without assistance or respond purposefully to verbal command, and is produced by pharmacological
4	agents. All dentists who perform deep sedation shall have an unexpired general anesthesia permit
5	from the Dental Board.
6	(15) "Deliver" – to assist a permitted dentist in administering sedation or anesthesia drugs by providing
7	the drugs to the patient pursuant to a direct order from the dentist and while under the dentist's direct
8	supervision.
9	(9)(16) "Direct supervision" - the dentist responsible for the sedation/anesthesia sedation or anesthesia
10	procedure shall be physically present in the facility immediately available and shall be continuously
11	aware of the patient's physical status and well being. being at all times.
12	(17) "Emergencies manual" – a written manual that documents:
13	a) the location of all emergency equipment and medications in each facility;
14	b) each staff member's role during medical emergencies; and
15	c) the appropriate treatment for laryngospasm, bronchospasm, emesis and
16	aspiration, respiratory depression and arrest, angina pectoris, myocardial
17	infarction, hypertension, hypotension, allergic reactions, convulsions, syncope,
18	bradycardia, [insulin shock] hypoglycemia, cardiac arrest, and airway
19	obstruction.
20	(18) "Enteral" - the administration of pharmacological agents orally, intranasally, sublingually, or
21	rectally.
22	(19) "ET CO2" —end tidal carbon dioxide.
23	(10)(20) "Facility" – the location where a permit holder practices dentistry and provides anesthesia/sedation
24	anesthesia or sedation services.
25	(11)(21) "Facility inspection" – an on-site inspection to determine if a facility where the applicant proposes
26	to provide anesthesia/sedation anesthesia or sedation is supplied, equipped, staffed staffed, and
27	maintained in a condition to support provision of anesthesia/sedation anesthesia or sedation services
28	that meet the minimum standard of care. in compliance with the Dental Practice Act set forth in
29	Article 2 of G.S. 90 and the Board's rules of this Chapter.
30	(12)(22) "General anesthesia" - the intended controlled state of a depressed level of consciousness that is
31	produced by pharmacologic agents and accompanied by a partial or complete loss of protective
32	reflexes, including the ability to maintain an airway and respond purposefully to physical
33	stimulation and [obey] or verbal commands. All dentists who perform general anesthesia shall have
34	an unexpired general anesthesia permit from the Dental Board.
35	(23) "Good standing" – a licensee whose license is not suspended or revoked and who is not subject to a
36	current disciplinary order imposing probationary terms.
37	(13)(24) "Immediately available" – on-site in the facility and available for immediate use. use without delay.

1	(25)	"Itinerant general anesthesia provider"- a permittee who has complied with Rule .0206 of this
2		Subchapter and who administers general anesthesia at another practitioner's facility.
3	(14)<u>(</u>26)	"Local anesthesia" - the elimination of sensations, especially including pain, in one part of the body
4		by the regional application or injection of a drug.
5	(15)	"May" indicates freedom or liberty to follow a reasonable alternative.
6	(16) (27)	"Minimal conscious sedation" - conscious sedation characterized by a minimally depressed level of
7		consciousness, in which the patient retains the ability to independently and continuously maintain
8		an airway and respond normally to tactile stimulation and verbal command, provided to patients 13
9		years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or
10		more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment,
11		possibly in combination with nitrous oxide. Minimal conscious sedation is provided for behavioral
12		management.
13	(17)<u>(28)</u>	"Minor psychosedative/Minor tranquilizer" - pharmacological agents which allow for uninterrupted
14		interactive ability in a patient with no compromise in the ability to maintain a patent airway
15		continuously and without assistance and carry a margin of safety wide enough to render unintended
16		loss of consciousness unlikely.
17	(18) (29)	_"Moderate conscious sedation" - conscious sedation characterized by a drug induced depression of
18		consciousness, during which patients [obey] respond-purposefully to verbal commands, either alone
19		or accompanied by light tactile stimulation, provided to patients 13 years of age or older, by oral,
20		nasal, rectal rectal, or parenteral routes of administration of single or multiple pharmacological
21		agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly
22		in combination with nitrous oxide. Moderate conscious sedation is may be provided for behavior
23		control. control by licensed dentists who comply with the terms of Rule .0301 of this Subchapter. A
24		moderate conscious sedation provider shall not use the following:
25		(a) drugs designed by the manufacturer for use in administering general anesthesia or
26		deep sedation; or
27		(b) drugs contraindicated for use in moderate conscious sedation.
28	-(19) " N	Aoderate conscious sedation limited to oral routes and nitrous oxide inhalation" conscious sedation
29		characterized by a drug induced depression of consciousness during which patients respond
30		purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided
31		to patients 13 years or older, by oral routes of administration and nitrous oxide inhalation, of single
32		or multiple pharmacological agents, in single or multiple doses, within a 24 hour period. Moderate
33		conscious sedation limited to oral routes and nitrous oxide inhalation is provided for behavior
34		control.
35	(20) (30	"Moderate pediatric conscious sedation" - conscious sedation characterized by a drug induced
36		depression of consciousness, during which patients respond purposefully to [obey] verbal
37		commands, either alone or accompanied by light tactile stimulation, provided to patients up to 18

1		under13 years of age, or special needs patients, by oral, nasal, rectal rectal, or parenteral routes of
2		administration of single or multiple pharmacological agents, in single or multiple doses, within a 24
3		hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate
4		pediatric conscious sedation is may be provided for behavior-control. control by licensed dentists
5		who comply with the terms of Rule .0404 of this Subchapter. A moderate pediatric conscious
6		sedation permit holder shall not use the following:
7		(a) drugs designed by the manufacturer for use in administering general anesthesia or
8		deep sedation; or
9		(b) drugs contraindicated for use in moderate pediatric conscious sedation.
10	(21)	-Must" or "shall" indicates an imperative need or duty or both; an essential or indispensable item;
11		mandatory.
12	(22) <u>(3</u>]	1)"Parenteral" - the administration of pharmacological agents intravenously, intraosseously,
13		intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.
14	(32)	"PALS" – Pediatric Advanced Life Support.
15	(23)<u>(</u>33) "Protective reflexes" – includes the ability to swallow and cough.
16	<u>(34)</u>	"RN" - Registered Nurse licensed by the North Carolina Board of Nursing.
17	<u>(35)</u>	"Sedation Procedure" - begins when any pharmacological agent is first administered to a patient to
18		induce general anesthesia or sedation and continues until the dentist permit holder determines that
19		the patient has met the applicable recovery and discharge criteria set forth in the applicable Rules in
20		this Subchapter.
21	(36)	"Special needs patients" - patients with diminished mental and or physical capacity who are unable
22		to cooperate to receive ambulatory dental care without sedation or anesthesia.
23	(24)<u>(</u>37) "Supplemental dosing" - the oral administration of a pharmacological agent that results in an
24		enhanced level of conscious sedation when added to the primary sedative agent administered for the
25		purpose of oral moderate conscious sedation, and which, when added to the primary agent, does not
26		exceed the maximum safe dose of either agent, separately or synergistically.
27	(25) <u>(38</u>) "Vested adult" – a responsible adult who is the legal parent or guardian, or designee of a legal parent
28		or guardian, entrusted with the care of a minor patient following the administration of general
29		anesthesia or conscious sedation.
30		
31	History Note:	Authority G.S. 90-28; 90-30.1; <u>90-48;</u>
32		Eff. February 1, 1990;
33		Temporary Amendment Eff. December 11, 2002;
34		Amended Eff; July 3, 2008; August 1, 2004.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0201

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

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Line 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

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Line 11 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 11 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 18 thru 26 appears to be a list. Consider beginning the clauses with lowercase letters. Also, please clarify what are the alternative options. Is it any one of the items one through four, and then everyone must also comply with five? It is unclear. If five is a mandatory requirement and items one through four are alternatives, consider moving the clause "has an unexpired ACLS certification" to line 16, and re-writing as follows:

"good standing with the Board, has an unexpired ACLS certification, and demonstrates that he or she has one of the following qualifications:"

Please review and clarify this list.

Page 2, line 2, replace "permit" with "employ" as the Dental Board is issuing permits and the dentist merely employs

Page 2, line 3, remove the underlining from "direct"

Page 2, line 7, remove the underlining from "or"

Page 2, line 7, replace "provisions" with "requirements"

Page 2, line 14, add the date of "June 1, 2017" to the history note to reflective the effective date

 21 NCAC 16Q .0201 is proposed for amendment as follows:

2		
3	21 NCAC 16Q	.0201 GENERAL ANESTHESIA CREDENTIALS AND PERMIT
4	(a) No dentist	shall employ or use general anesthesia on an outpatient basis for dental patients unless the dentist
5	possesses a perr	nit issued by the Board. A dentist holding a permit shall be subject to review and shall only employ or
6	use general ane	sthesia at a facility located in the State of North Carolina in accordance with 21 NCAC 16Q .0202.
7	Such permit mu	st be renewed annually and shall be displayed with the current renewal at all times in a conspicuous
8	place in the offi	ce of the permit holder.
9	(a) Before a der	ntist licensed to practice in North Carolina may administer or supervise a CRNA to administer general
10	anesthesia or pe	rform deep sedation, the dentist shall obtain a general anesthesia permit from the Board by completing
11	an application f	form and paying a four hundred seventy-five dollar (\$475.00) fee. The application form is available
12	on the Board's	website: www.ncdentalboard.org. The permit shall be renewed annually and shall be displayed with
13	the current rene	wal at all times in the permit holder's facility where it is visible to patients receiving treatment.
14	(b) Any dentis	t who wishes to administer general anesthesia to patients must apply to the Board for the required
15	permit on a pre	scribed application form, submit an application fee of one hundred dollars (\$100.00) and produce
16	evidence showi	ng A dentist applying for a general anesthesia permit shall be in good standing with the Board and
17	demonstrate that	t he or she:
18	(1)	Has completed a minimum of one year two years of advanced training in anesthesiology and related
19		academic subjects (or its equivalent) beyond the undergraduate dental school level; or
20	(2)	Has graduated from a program certified by the American Dental Association in Oral and
21		Maxillofacial Surgery; or
22	(3)	Is a Diplomate of or eligible for examination by the American Board of Oral and Maxillofacial
23		Surgery; or
24	(4)	Is a Fellow of the American Dental Society of Anesthesiology; or and
25	(5)	Is a dentist who has been administering general anesthetics in a competent manner for the five years
26		preceding the effective date of this Rule. Has an unexpired ACLS certification.
27	(c) Before rece	eiving a general anesthesia permit, all applicants shall pass an evaluation and inspection as set out in
28	Rule .0202 of t	this Section. Every location other than a hospital or credentialed surgery center where a general
29	anesthesia perm	it holder administers general anesthesia shall pass an inspection as set out in Rule .0204 of this Section.
30	-(c)(d) A dentist	who is qualified to administer general anesthesia in accordance with this Section and holds a general
31	anesthesia perm	nit may is also authorized to administer any level of sedation without obtaining a separate sedation
32	permit.	
33	(d) The dentist	involved with the administration of general anesthesia shall document current, successful completion
34	of advanced car	diac life support (ACLS) training, or its age specific equivalent or other Board approved equivalent
35	course and auxi	liary personnel shall document annual, successful completion of basic life support (BLS) training.

1	(e) A dentist where the second	no does not hold a general anesthesia permit may not employ a CRNA to administer general anesthesia
2	services. A de	ntist who holds a general anesthesia permit may permit a CRNA to administer general anesthesia
3	services under [direct supervision of the dentist.
4	(f) A general	anesthesia permit holder may provide general anesthesia at the office of another licensed dentist,
5	regardless of the	e permit, if any held, by the hosting dentist. The permit holder shall ensure that the facility where the
6	general anesthes	sia is administered has been inspected and complies with the requirements set out in Rule .0202 of this
7	Section [or] and	shall obtain an itinerant general anesthesia permit and comply with the provisions of Rule .0206 of
8	this Section.	
9		
10	History Note:	Authority G.S. 90-28; 90-30.1;
11		Eff. February 1, 1990;
12		Amended Eff. April 1, 2001; August 1, 2000;
13		Temporary Amendment Eff. December 11, 2002;
14		Amended Eff; February 5, 2008.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0202

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Page 3, line 8, replace the period at the end of the clause with a semicolon

Page 3, line 8, add an "and" at the end of the clause

Page 3, lines 11 thru 13, this text is confusing. Please consider the following re-write:

This requirement shall not apply if the following applies:

- (A) the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure; and
- (B) the dentist permit holder is not performing the surgery or other dental procedure.

Page 3, line 37, remove the underlining from "insulin"

Page 4, line 9, define or delete "continuously"

Page 4, line 34, add the date of "June 1, 2017" to the history note to reflective the effective date

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

1	21 NCAC 16Q .0	0202 is pr	oposed for amendment as follows:
2			
3	21 NCAC 16Q.	0202	GENERAL ANESTHESIA EQUIPMENT AND CLINICAL REQUIREMENTS
4	(a) A dentist adu	ninisterir	ng general anesthesia is solely responsible for providing shall be responsible to ensure that
5	the environment	in which	facility where the general anesthesia is to be administered meets the following requirements:
6	(1)	The faci	lity is shall be equipped with: with the following:
7		(A)	An 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 lighting as necessary for specific procedures procedures; and back-up lighting;
13			and
14		(D)	Suction suction equipment as necessary for specific procedures, including non-electrical
15			back-up suction;
16	(2)	The foll	owing equipment is maintained:
17		(A)<u>(E)</u>	Positive positive pressure oxygen delivery system, including full face masks for small,
18			medium, and large [adults and pediatric] patients, patients; and back-up E-cylinder portable
19			oxygen tank apart from the central system;
20		(B) (F)	Oral small, medium, and large oral and nasal airways of various sizes; airways;
21		(<u>C)(G)</u>	<u>Blood</u> <u>blood</u> pressure monitoring device;
22		(D)<u>(H)</u>	Electrocardiograph; EKG monitor; electrocardiograph;
23		(E) (I)	Pulse pulse oximeter; and
24		(F)(J)	Defibrillator; <u>defibrillator;</u>
25		<u>(K)</u>	precordial stethoscope or capnograph;
26		<u>(L)</u>	thermometer;
27	(3)	The foll	owing emergency equipment is maintained:
28		(A)(<u>M)</u>	I.V. set up vascular access as necessary for specific procedures, including hardware and
29			fluids;
30		(<u>B)(N)</u> I	Laryngoscope laryngoscope with current working batteries;
31		(C)<u>(</u>0) I	ntubation intubation forceps and endotracheal tubes; advanced airway devices;
32		(D)(P) 7	Consillar tonsillar suction with back-up suction;
33		(E)(Q) 	Syringes syringes as necessary for specific procedures; and
34		(F)<u>(R)</u> T	Courniquet & tape; tourniquet and tape.
35		(G)	Blood pressure monitoring device;

1	<u>(4) (2)</u>	The follo	owing drugs are maintained with a current shelf life and with access from the operatory and
2		recovery	room: The following unexpired drugs shall be maintained in the facility and with access
3		from the	operatory and recovery rooms:
4		(A)	Epinephrine; Epinephrine;
5		(B)	Atropine;
6		(C)	Lidocaine; antiarrhythmic;
7		(D)	Antihistamine; antihistamine;
8		(E)	Antihypertensive; antihypertensive;
9		(F)	Bronchial dilator; 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		<u>(M)</u> (N)	Nitroglycerine; nitroglycerine; and
18		<u>(N)</u> (O)	Antiemetic; antiemetic.
19	(5) <u>(3)</u>	Written	The permit holder shall maintain written emergency and patient discharge protocols and
20		training	to familiarize office personnel auxiliaries in the treatment of clinical emergencies are shall
21		<u>be</u> provi	ded; and
22	(6) <u>(</u>4)	The perr	nit holder shall maintain the following records are maintained: for 10 years:
23		(A)	Patient's current written medical history, including a record of known allergies and
24			previous surgery; surgeries;
25		<u>(B)</u>	Consent to general anesthesia, signed by the patient or guardian, identifying the risks and
26			benefits, level of anesthesia, and date signed;
27		(C)	Consent to the procedure, signed by the patient or guardian identifying the risks, benefits,
28			and date signed; and
29		<u>(D</u>) (B)	Patient Base base line vital signs, including temperature, SPO2, blood pressure pressure,
30			and pulse;
31		-(C)	An anesthesia record which shall include:
32			(i) Periodic vital signs taken at intervals during the procedure;
33			(ii) Drugs administered during the procedure, including route of administration,
34			dosage, time and sequence of administration;
35			(iii) Duration of the procedure;
36			(iv) Documentation of complications or morbidity; and
37			(v) Status of patient upon discharge.

1		(5)	The anesthesia record shall include:
2			(A) base line vital signs, blood pressure (unless patient behavior prevents recording),
3			oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the
4			patient recorded in real time at 15 minute intervals;
5			(B) procedure start and end times;
6			(C) gauge of needle and location of IV on the patient, if used;
7			(D) status of patient upon discharge; and
8			(E) documentation of complications or morbidity.
9		(6) <u>The</u>	facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to
10		patient r	nonitoring and recording general anesthesia or sedation data throughout the sedation procedure. This
11		requiren	nent shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding
12		general	anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other
13		<u>dental p</u>	rocedure.
14	(b)	During	an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of
15		anesthes	sia while the evaluator observes. During the demonstration, the applicant or permit holder observes,
16		and shal	l demonstrate competency in the following areas:
17		(1)	Monitoring monitoring of blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
18		(2)	Drug-drug dosage and administration;
19		(3)	Treatment treatment of untoward reactions including respiratory or cardiac depression;
20		(4)	Sterilization; sterile technique;
21		(5)	Use use of CPR BLS certified personnel; auxiliaries;
22		(6)	Monitoring monitoring of patient during recovery; and
23		(7)	Sufficiency sufficiency of patient recovery time.
24	(c)	During	an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency ω
25		the eval	uator in the treatment of the following clinical emergencies:
26		(1)	Laryngospasm; <u>l</u>aryngospasm;
27		(2)	Bronchospasm; bronchospasm;
28		(3)	Emesis emesis and aspiration;
29		(4)	Respiratory respiratory depression and arrest;
30		(5)	Angina angina pectoris;
31		(6)	Myocardial myocardial infarction;
32		(7)	Hypertension/Hypotension; hypertension and hypotension;
33		(8)	Syncope; syncope;
34		(9)	Allergic allergic reactions;
35		(10)	Convulsions; convulsions;
36		(11)	Bradycardia; bradycardia;
37		(12)	Insulin [<mark>insulin] shock</mark> hypoglycemia; and

1	(13)	Cardiac cardiac arrest; and
2	(14)	airway obstruction.
3	(d) A dentist ad	Iministering general anesthesia shall ensure that the facility is staffed with auxiliary personnel who
4	shall de	ocument annual successful completion of basic life support training and be capable of assisting with
5	procedu	ares, problems, and emergency incidents that may occur as a result of the general anesthetic or
6	seconda	ary to an unexpected medical complication.
7	(d) A general an	esthesia permit holder shall evaluate a patient for health risks before starting any anesthesia procedure.
8	(e) Post-operativ	ve monitoring and discharge shall include the following:
9	<u>(1)</u>	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 and
11		the patient is recovered as defined by Subparagraph (e)(2) of this Rule and is ready for discharge
12		from the office; and
13	(2)	recovery from general anesthesia shall include documentation of the following:
14		(A) cardiovascular function stable;
15		(B) airway patency uncompromised:
16		(C) patient arousable and protective reflexes intact;
17		(D) state of hydration within normal limits;
18		(E) patient can talk, if applicable;
19		(F) patient can sit unaided, if applicable;
20		(G) patient can ambulate, if applicable, with minimal assistance; and
21		(H) for the special needs patient or a patient incapable of the usually expected responses, the
22		pre-sedation level of responsiveness or the level as close as possible for that patient shall
23		be achieved; and
24	(3)	before allowing the patient to leave the office, the dentist shall determine that the patient has met
25		the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:
26		(A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient,
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) vested adult is available to transport the patient after discharge.
31		
32	History Note:	Authority G.S. 90-28; 90-30.1; 90-48;
33		Effective February 1, 1990;
34		Amended Eff; November 1, 2013; August 1, 2002; August 1, 2000.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0206

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

For an adoption, the only language that should be underlined is changes made since publication. Based upon the technical changes requested in this document, the formatting example is the following:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

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 37, replace "accessible" with "available" to track the term as defined in 21 NCAC 16Q .0101(24)

Page 2, line 26, add a comma after "auxiliaries"

Page 2, lines 28 thru 30, this text is confusing. Please consider the following re-write:

This requirement shall not apply if the following applies:

(A) the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure; and

(B) the dentist permit holder is not performing the surgery or other dental procedure.

Page 3, line 3, add the date of "June 1, 2017" to the history note to reflective the effective date

1

21 NCAC 16Q .0206 is proposed for adoption 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 s	vervices in the office of another practitioner shall obtain a mobile general anesthesia permit from the		
7	Board. The a	pplication form may be obtained on the Board's website: www.ncdentalboard.org and shall be		
8	accompanied by	y a one hundred (\$100.00) fee. No mobile permit shall be required to administer general anesthesia		
9	in a hospital or	credentialed surgery center.		
10	(b) Before a m	obile general anesthesia permit may be issued, a general anesthesia permit holder appointed by the		
11	Board shall insp	bect the applicant's equipment and medications to ensure that they comply with Paragraphs (c) and (d)		
12	of this Rule.			
13	(c) The permit h	nolder shall maintain the following equipment:		
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)	precordial stethoscope or 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 ventilation;		
30	(17)	back-up ventilation measurement;		
31	(18)	rebreathing device;		
32	(19)	scavenging system;		
33	(20)	intermittent compression devices;		
34	(21)	CPR board or dental chair without enhancements suitable for providing emergency treatment;		
35	(22)	laryngoscope with working batteries; and		
36	(23)	tourniquet and tape.		
37	(d) The follow	ving unexpired medications shall be immediately accessible to the permit holder:		

1	(1)	Epinephrine;
2	(2)	Atropine;
3	(3)	antiarrhythic;
4	(4)	antihistamine;
5	(5)	antihypertensive;
6	(6)	bronchodilator;
7	(7)	antihypoglycemic agent;
8	(8)	vasopressor;
9	(9)	corticosteroid;
10	(10)	anticonvulsant;
11	(11)	muscle relaxant;
12	(12)	appropriate reversal agents;
13	(13)	nitroglycerine;
14	(14)	antiemetic;
15	(15)	neuromuscular blocking agent; and
16	(16)	anti-malignant hyperthermia agent.
17	(e) The evaluation and on-site inspection shall be conducted as set out in Rule .0204 of this Section.	
18	(f) Before administering general anesthesia or sedation at another provider's office, the mobile permit holder shall	
19	inspect the host facility to ensure that:	
20	(1)	the operatory's size and design permit emergency management and access of emergency equipment
21		and personnel;
22	(2)	there is a CPR board or dental chair without enhancements suitable for providing emergency
23		treatment;
24	(3)	there is lighting to permit performance of all procedures planned for the facility;
25	(4)	there is suction equipment, including non-electrical back-up suction; and
26	(5)	the facility shall be staffed with at least two BLS certified auxiliaries one of whom shall be dedicated
27		to patient monitoring and recording general anesthesia or sedation data throughout the sedation
28		procedure. This requirement shall not apply if the dentist permit holder is dedicated to patient care
29		and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is
30		not performing the surgery or other dental procedure.
31	(g) At least 24 hours before the procedure is scheduled to begin, the mobile permit holder shall send written notice to	
32	the Board office confirming that the facility where the general anesthesia or sedation will be performed meets the	
33	requirements of Paragraph (f) of this Rule and documenting when the inspection was conducted. The permit holder	
34	shall retain a copy of the written notice for 10 years following the procedure. No procedure shall be performed until	
35	the report required by this Paragraph is filed.	
36	(h) The mobile general anesthesia permit shall be displayed in the host facility where it is visible to patients receiving	
27	4	

37 treatment.

- 1 (i) All applicants for mobile general anesthesia permit shall be in good standing with the Board.
- 2 History Note: Authority G.S. 90-28; 90-30.1; 90-39; 90-48;

3 *Eff.*_____.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0207

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

For an adoption, the only language that should be underlined is changes made since publication. Please see this <u>example</u>.

Lines 6 and 10 references an "application" available on the Board's website. 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.

Page 2, line 1, is the use of "three hours" correct considering the "six hours" on page 1, line 22? Please verify and change if necessary.

Page 2, line 6, add the date of "June 1, 2017" to the history note to reflective the effective date

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 of 8 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 by 10 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 31 14 of each year shall complete a reinstatement application, pay the renewal fee, late fee, and comply with all conditions 15 for renewal set out in this Rule. Dentists whose anesthesia permits or itinerant general anesthesia permits have been 16 lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process. 17 (d) A dentist who administers general anesthesia in violation of this Rule shall be subject to the penalties prescribed 18 by Rule .0701 of this Subchapter. 19 (e) As a condition for renewal of the general anesthesia and itinerant general anesthesia permit, the permit holder 20 shall maintain the clinical equipment and requirements set out in Rules .0202 and .0206 of this Section and shall

21 document the following:

26

27

29

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2

- (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:
- 25 (A) sedation;
 - (B) medical emergencies;
 - (C) monitoring IV sedation and the use of monitoring equipment;
- 28 (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;
- 31 (2) unexpired ACLS certification, which shall not count towards the six hours required in Subparagraph
 32 (e)(1) of this Rule;
- 33 (3) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have
 34 practiced responding to dental emergencies as a team at least once every six months in the preceding
 35 year;
- 36 (4) that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have read the
 37 practice's emergency manual in the preceding year; and

- (5) that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
 of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this rule.
- 3 (f) All permit holders applying for renewal of a general anesthesia or itinerant general anesthesia permit shall be in
- 4 good standing and their office shall be subject to inspection by the Board.
- 5 History Note: Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
 - *Eff.* _____.

6

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0301

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Amendment%20with%20c hanges%20for%20Publication%20in%20the%20NCAC.pdf

Line 12 references a fee. However, the history note cites a fee that is capped at \$100. Please verify the authority for the fee and update the fee or 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 21, remove underlining from "direct"

Line 28, is the comma after "training" necessary"? Please review

Line 36, the "(a)" should be capitalized if referring to "(A)" on line 26

Page 3, line 24, add the date of "June 1, 2017" to the history note to reflective the effective date

1 21 NCAC 16Q .0301 is proposed for amendment as follows:

2

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

7 (a) Before a dentist licensed to practice in North Carolina may administer or supervise a certified registered nurse 8 anesthetist (CRNA) CRNA employed to administer or RN employed to deliver moderate conscious sedation, 9 moderate pediatric conscious sedation or moderate conscious sedation limited to oral routes of administration and 10 nitrous oxide to dental patients on an outpatient basis, the dentist shall obtain a permit from the Board by completing 11 an application form provided by the Board and paying a fee of one hundred dollars (\$100.00). three hundred seventy 12 five dollars (\$375.00). The application form is available on the Board's website: www.ncdentalboard.org. Such The 13 permit shall be renewed annually and shall be displayed with the current renewal at all times in a conspicuous place 14 in the facility of the permit holder. holder where it is visible to patients receiving treatment. 15 (b) For a dentist to employ a certified registered nurse anesthetist to administer moderate conscious sedation, moderate 16 conscious sedation limited to oral routes and nitrous oxide or moderate pediatric conscious sedation, the dentist must 17 demonstrate through the permitting process that he or she is capable of performing all duties and procedures to be

18 delegated to the CRNA The dentist must not delegate said CRNA perform procedures outside of the scope of the

19 technique and purpose of moderate conscious sedation, moderate pediatric conscious sedation or moderate conscious

20 sedation limited to oral routes and nitrous oxide as defined in Rule .0101 of this Subchapter.

21 (b) The permit holder shall provide [direct] supervision to any CRNA employed to administer or RN employed to

22 <u>deliver sedation, and shall ensure that the level and duration of the sedation does not exceed the permit holder's permit.</u>

23 (c) A dentist applying for a permit to administer moderate conscious sedation or moderate pediatric conscious sedation

24 must meet at least one of the following criteria: <u>shall</u> document the following:

25	(1)	Training which may consist of either:
26		(A) Satisfactory completion of a minimum Completion of 60 hours of Board approved didactic
27		_training, including PALS-(Pediatric Advanced Life Support), and instruction training in intravenous
28		conscious sedation sedation, and satisfactory 30 hours of clinical training, that shall include
29		successful management of a minimum of 40 20 live patients, under supervision, supervision of the
30		course instructor, using intravenous sedation; sedation. Training shall be provided by one or more
31		individuals who meet the American Dental Association Guidelines for Teaching Pain Control and
32		Sedation to Dentists that is hereby incorporated by reference, including subsequent amendments and
33		editions. The guidelines may be found at www.ada.org/coda; or
34		(2)(B) Satisfactory completion Completion of a pre-doctoral dental or postgraduate program which
35		that included intravenous conscious sedation training equivalent to that defined in Subparagraph
36		(c)(1)(a) of this Rule; or

37 (2) Unexpired ACLS certification; and

1 That all auxiliaries involved in sedation procedures have unexpired BLS certification. (3) 2 Satisfactory completion of an internship or residency which included intravenous conscious (3)3 sedation training equivalent to that defined in Subparagraph (c)(1) of this Rule. 4 (d) Notwithstanding the foregoing, a dentist may also qualify for a permit to administer moderate pediatric conscious 5 sedation by documenting, with patient names and dates of completion, at least 100 cases of moderate pediatric sedation 6 procedures successfully completed between July 3, 2006 and July 3, 2009. A dentist who obtains a pediatric conscious 7 sedation permit pursuant to this Paragraph may not administer sedation intravenously and such limitation shall be 8 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 pediatric 10 conscious sedation by completing a Board approved pediatric dental degree or pediatric dental residency program or 11 obtaining the equivalent hours of continuing education program in pediatric dental anesthesia. If said qualifications 12 are satisfied, it shall be so designated on the dentist's moderate conscious sedation permit and will be subject to the 13 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 facility 16 which includes the capability of delivering positive pressure oxygen, and is staffed with supervised auxiliary personnel 17 for each procedure performed. The dentist shall ensure that auxiliary personnel document annual, successful 18 completion of basic life support (BLS) training and are capable of assisting with procedures, problems and 19 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 passing the evaluation and inspection of his or her facility within three 27 months 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or 28 applicant requests one. one by contacting the Board in writing. 29 (h)The evaluator shall assign a grade of pass or fail and shall report his recommendation to the Board, setting out the 30 basis for his conclusion. The Board is not bound by the evaluator's recommendation and shall make a final 31 determination regarding whether the applicant has passed the evaluation. The applicant shall be notified of the Board's 32 decision in writing. 33 -(i)(f) A dentist who holds a moderate conscious sedation, sedation moderate conscious sedation limited to oral routes 34 and nitrous oxide inhalation or moderate pediatric conscious sedation permit shall not intentionally administer deep 35 sedation sedation. although deep sedation may occur briefly and unintentionally.

(j) A dentist may obtain a moderate conscious sedation permit limited to oral routes of administration and nitrous
 oxide inhalation, including the ability to add supplemental dosing to the techniques set out in Rule .0101(23) of this

3 Subchapter upon compliance with the following requirements:

- 4 successfully complete 24 hours of didactic training and manage at least 10 adult case experiences, (1)5 including at least three live clinical dental experiences. The live clinical cases shall not be handled 6 by groups with more than five student participants. The remaining cases may include simulations, 7 video presentations or both, but must include one experience in returning/rescuing a patient from 8 deep to moderate sedation; or 9 document, with patient names and dates of completion, at least 100 cases of oral moderate conscious (2)10 sedation procedures successfully completed within one year preceding June 3, 2008; and fulfill all 11 the requirements listed in Rule .0401 of this Subchapter for minimal conscious sedation. 12 (k) A dentist who is qualified to administer general anesthesia, moderate conscious sedation or moderate pediatric 13 conscious sedation and holds a general anesthesia, moderate conscious sedation permit or a moderate pediatric 14 conscious sedation permit may administer minimal conscious sedation without obtaining a separate minimal conscious 15 sedation permit. 16 (1) Any dentist who holds an active parenteral conscious sedation permit as of October 1, 2007 shall be deemed to 17 hold an active moderate conscious sedation permit. Such permits shall be subject to the renewal requirements set out
- 18 in Rule .0501 of this Subchapter.
- 19

20 <i>History Note:</i> Authority G.S. 90-28; 90-30.1; <u>90-39(12); 90-48;</u>
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- 21 *Eff. February 1, 1990;*
- 22 Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;
- 23 Temporary Amendment Eff. December 11, 2002;
- 24 Amended Eff. ; July 1, 2010, July 3, 2008; August 1, 2004.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0302

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Amendment%20with%20c hanges%20for%20Publication%20in%20the%20NCAC.pdf

- Line 6, remove underlining from "delivery"
- Line 7, remove underlining from "by a CRNA or RN"

Page 2, line 21, add a comma after "time"

- Page 3, line 4, add a comma after "auxiliaries"
- Page 3, lines 6 thru 8, this text is confusing. Please consider the following re-write:

This requirement shall not apply if the following applies:

- (A) the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure; and
- (B) the dentist permit holder is not performing the surgery or other dental procedure.

Page 3, line 36, delete this blank line of text

Page 4, line 1, remove the underlining from "insulin"

Page 4, line 16, define or delete "continuously"

Page 4, lines 35 and 36, correct the text spacing

Page 5, line 6, add the date of "June 1, 2017" to the history note to reflective the effective date

1	21 NCAC 16Q .0302 is	proposed for amendment as follows:
2		
3	21 NCAC 16Q .0302	MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION
4		CLINICAL REQUIREMENTS AND EQUIPMENT
5	(a) A dentist administer	ing moderate conscious sedation or moderate pediatric conscious sedation or supervising any
6	CRNA employed to ad	minister or RN employed to deliver the administration [delivery] of moderate conscious
7	sedation or moderate per	liatric conscious sedation by a certified registered nurse anesthetist [by a CRNA or RN] shall
8	be responsible to ensure	e that the facility-in which where the sedation is to be administered meets the following
9	requirements:	
10	(1) The fa	cility-is shall be equipped with the following: with:
11	(A)	An an operatory of size and design to permit access of emergency equipment and personnel
12		and to permit effective emergency management;
13	(B)	A a CPR Board board or a dental chair without enhancements, suitable for providing
14		emergency treatment;
15	(C)	Lighting lighting as necessary for specific procedures; procedures and back-up lighting;
16		and
17	(D)	Suction-suction equipment as necessary for specific procedures, including non-electrical
18		back-up suction.
19	(2) The fo	llowing equipment is maintained:
20	(A)<u>(E)</u>	Positive positive oxygen delivery system, including full face masks for adults and pediatric
21		small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from
22		the central system;
23	(B) <u>(F</u>) small, medium, and large Oral oral and nasal airways of various sizes; airways;
24	(C) (<u>G</u>)	<u>Blood</u> pressure monitoring device;
25	(D)(H) Pulse-pulse_oximeter; and
26	(E) (I)	Automatic External Defibrillator (AED). automatic external defibrillator (AED);
27	<u>(J)</u>	EKG monitor:
28	<u>(K)</u>	precordial stethoscope or capnograph;
29	<u>(L)</u>	thermometer;
30	(3) The fo	llowing emergency equipment is maintained:
31	(A)<u>(</u>M) I.V. vascular access set-up as necessary for specific procedures, including hardware and
32		fluids, if anesthesia is intravenous; fluids;
33	(B) <u>(N</u>) Syringes syringes as necessary for specific procedures; and
34	(C) (O) tourniquet Tourniquet and tape. tape;
35	<u>(P) adv</u>	vanced airway devices; and

36 (Q) tonsillar suction with back-up suction.

1	(4)(2) The following drugs are maintained with a current shelf life and with access from the operatory and
2	recovery area: The following unexpired drugs shall be maintained in the facility and with access
3	from the operatory and recovery rooms:
4	(A) Epinephrine; injectable epinephrine;
5	(B) Atropine; injectable Atropine;
6	(C) Appropriate injectable appropriate reversal agents;
7	(D) Antihistamine; injectable antihistamine;
8	(E) Corticosteroid; injectable corticosteroid;
9	(F) Nitroglycerine; nitroglycerine;
10	(G) Bronchial dilator; bronchodilator;
11	(H) Antiemetic; and injectable antiemetic;
12	(I) <u>injectable_50% Dextrose</u> Dextrose; and
13	(J) injectable anti-arrhythmic.
14	(5)(3) Written The permit holder shall maintain written emergency and patient discharge protocols are
15	maintained and training to familiarize office personnel auxiliaries in the treatment of clinical
16	emergencies is shall be provided; and
17	(6)(4) 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;-and
19	including known allergies and previous surgery;
20	(B) Drugs administered during the procedure, including route of administration, dosage,
21	strength, time and sequence of administration; administration.
22	(C) A sedation record which shall include:
23	(i) blood pressure;
24	(ii) pulse rate;
25	(iii) respiration;
26	(iv) duration of procedure;
27	(v) documentation of complications or morbidity; and
28	(vi) status of patient upon discharge.
29	(5) The sedation record shall include:
30	(A) base line vital signs, blood pressure (unless patient behavior prevents recording),
31	oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the
32	patient recorded in real time at 15 minute intervals;
33	(B) procedure start and end times:
34	(C) gauge of needle and location of IV on the patient, if used;
35	(D) status of patient upon discharge;
36	(E) documentation of complications or morbidity; and

1		(F) consent form, signed by the patient or guardian, identifying the procedure, risks and
2		benefits, level of sedation, and date signed.
3	(6)	The following conditions shall be satisfied during a sedation procedure:
4		(A) The facility shall be staffed with at least two BLS certified auxiliaries one of whom shall
5		be dedicated to patient monitoring and recording sedation data throughout the sedation
6		procedure. This requirement shall not apply if the dentist permit holder is dedicated to
7		patient care and monitoring regarding general anesthesia or sedation throughout the
8		sedation procedure and is not performing the surgery or other dental procedure.
9		(B) If IV sedation is used, IV infusion shall be administered before the
10		start of the procedure and maintained until the patient is ready for discharge.
11	(b) During an in	nspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate
12	conscious sedat	ion on a patient, or where applicable, moderate pediatric conscious sedation on a patient, including the
13	deployment of	an intravenous delivery system, while the evaluator observes. Practices limited to pediatric dentistry
14	will not be req	uired to demonstrate the deployment of an intravenous delivery system. Instead, they will orally
15	describe to the	evaluator the technique of their training in intravenous and intraosseous deployment. During the
16	demonstration,	the applicant or permit holder shall demonstrate competency in the following areas:
17	(1)	Monitoring monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
18	(2)	Drug drug dosage and administration;
19	(3)	Treatment treatment of untoward reactions including respiratory or cardiac depression if applicable;
20	(4)	Sterile sterile technique;
21	(5)	Use use of CPR BLS certified personnel; auxiliaries;
22	(6)	Monitoring monitoring of patient during recovery; and
23	(7)	Sufficiency sufficiency of patient recovery time.
24	(c) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to the	
25	evaluator in the	treatment of the following clinical emergencies:
26	(1)	Laryngospasm; laryngospasm;
27	(2)	Bronchospasm; bronchospasm;
28	(3)	Emesis emesis and aspiration;
29	(4)	Respiratory respiratory depression and arrest;
30	(5)	Angina angina pectoris;
31	(6)	Myocardial myocardial infarction;
32	(7)	Hypertension/Hypotension; hypertension and hypotension;
33	(8)	Allergie allergic reactions;
34	(9)	Convulsions; convulsions;
35	(10)	Syncope; syncope;
36		
37	(11)	Bradycardia; bradycardia

1	(12)	Insulin [<mark>insulin] shock</mark> hypoglycemia; and
2	(13)	Cardiac arrest. cardiac arrest; and
3	(14)	airway obstruction.
4	(d) A dentist ac	dministering moderate conscious sedation or moderate pediatric conscious sedation shall ensure that
5	the facility is st	affed with sufficient auxiliary personnel for each procedure performed who shall document annual
6	successful com	pletion of basic life support training and be capable of assisting with procedures, problems, and
7	emergency incid	lents 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 a patient for health risks before starting any sedation
9	procedure as fol	lows:
10	(1)	a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's
11		current medical history and medication use or:
12	(2)	a patient who-is not medically stable or who is ASA III or higher shall be evaluated by a consultation
13		with the patient's primary care physician or consulting medical specialist regarding the potential
14		risks posed by the procedure.
15	(e) Post-operati	ve monitoring and discharge:
16	<u>(1)</u>	vital signs shall be continuously monitored when the sedation is no longer being administered and
17		the patient shall have direct continuous supervision until oxygenation and circulation are stable and
18		the patient is recovered as defined in Subparagraph (e)(2) of this Rule and is ready for discharge
19		from the office.
20	(2)	recovery from moderate conscious sedation shall include documentation of the following:
21		(A) cardiovascular function stable;
22		(B) airway patency uncompromised;
23		(C) patient arousable and protective reflexes intact;
24		(D) state of hydration within normal limits;
25		(E) patient can talk, if applicable;
26		(F) patient can sit unaided, if applicable;
27		(G) patient can ambulate, if applicable, with minimal assistance; and
28		(H) for special needs patients or patients incapable of the usually expected responses, the pre-
29		sedation level of responsiveness or the level as close as possible for that patient shall be
30		achieved.
31	(3)	before allowing the patient to leave the office, the dentist shall determine that the patient has met
32		the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:
33		(A) oxygenation, circulation, activity, skin color, and level of consciousness are stable, and
34		have been documented;
35		(B) explanation and documentation of written postoperative instructions have been
36		provided to the patient or a responsible adult at time of discharge; and
37		(C) a vested adult is available to transport the patient after discharge.

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

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0304

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Amendment%20with%20c hanges%20for%20Publication%20in%20the%20NCAC.pdf

Line 11, delete "<u>The</u>" as this term was not published in the Register

Line 11, delete "<u>shall be responsible to ensure that</u>" as this text was not published in the Register

Line 13, delete "<u>two BLS certified auxiliaries are available for each procedure</u>." as this text was not published in the Register

Lines 18 thru 20, this text is confusing. Please consider the following re-write:

This requirement shall not apply if the following applies:

- (A) the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure; and
- (B) the dentist permit holder is not performing the surgery or other dental procedure.

Line 26, add the date of "June 1, 2017" to the history note to reflective the effective date

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.
2

3 21 NCAC 16Q .0304 OFF SITE USE OF <u>MODERATE PARENTERAL AND ENTERAL CONSCIOUS</u> 4 SEDATION PERMITS

5 (a) Upon request, the The holder of a moderate pediatric conscious sedation or moderate conscious sedation permit 6 may travel to the office of a licensed dentist who does not hold such a permit and provide moderate conscious sedation 7 services at the level for which the traveling dentist holds a valid permit, as well as minimal sedation or moderate 8 conscious sedation limited to oral routes for the patients of that dentist who are undergoing dental procedures. The 9 permit holder is solely responsible for providing shall be responsible to ensure that the facility in which where the 10 sedation is administered meets the requirements established by the Board, that the required drugs and equipment are 11 present, and The that the permit holder shall be responsible to ensure that utilizes sufficient auxiliary personnel for 12 each procedure performed based on the standard of care who shall document annual successful completion of basic 13 life support training two BLS certified auxiliaries are available for each procedure. and be capable of assisting with 14 procedures, problems, and emergency incidents that may occur as a result of the sedation or secondary to an 15 unexpected medical complication. has passed inspection by the Board and meets the requirements set out in Rule 16 .0302 of this Section. The permit holder shall be responsible to ensure that the facility is staffed with at least two BLS 17 certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation 18 data throughout the sedation procedure. This requirement shall not apply if the dentist permit holder is dedicated to 19 patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not 20 performing the surgery or other dental procedure. 21 (b) Holders of moderate conscious sedation permits limited to oral routes and nitrous oxide inhalation may not provide 22 sedation at the office of a licensed dentist who does not hold an appropriate sedation permit. 23 24 *History Note:* Authority G.S. 90-28; 90-30; 90-30.1; 90-48; 25 Recodified from 21 NCAC 16Q.0302(e)(f), Eff. November 1, 2013.

26 *Amended Eff.* _____.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0305

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

For an adoption, the only language that should be underlined is changes made since publication. Based upon the technical changes requested in this document, the formatting example is the following:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

Line 6 references an "application" available on the Board's website. 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 33, is the use of "three hours" correct considering the "six hours" on line 18? Please verify and change if necessary.

Line 36, the text was published in the Register as "All permit holders" Please correct to reflect the text as it was published in the Register.

Please note that if no changes are made to the text of this rule since publication in the Register, even considering these technical change suggestions, then the formatting should follow this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20for%20Public ation%20in%20the%20NCAC.pdf

Page 2, line 3, add the date of "June 1, 2017" to the history note to reflective the effective date

3 21 NCAC 16Q .0305 ANNUAL RENEWAL OF MODERATE PARENTERAL AND ENTERAL 4 CONSCIOUS SEDATION PERMIT 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.

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- 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
- 12 out in this Rule. Dentists whose sedation permits have been lapsed for more than 12 calendar months shall pass an
- 13 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 penalties

- 15 prescribed by Rule .0701 of this Subchapter.
- 16 (e) As a condition for renewal of the moderate conscious sedation permit, the permit holder shall meet the clinical
- 17 and equipment requirements of Rule .0302 of this Section and shall document the following:
- 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;
 - (D) pharmacology of drugs and agents used in IV sedation;
 - (E) physical evaluation, risk assessment, or behavioral management; or
 - (F) airway management;
- 27 (2) unexpired ACLS certification, which shall not count towards the six hours of continuing education
 28 required in Subparagraph (e)(1) Rule;
- (3) that the permit holder and all auxiliaries involved in sedation procedures have practiced
 responding to dental emergencies as a team at least once every six months in the preceding year;
- 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 certification and three
 34 hours of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this
 35 rule.

36 (f) <u>All Permit permit holders applying for renewal of a moderate conscious sedation permit shall be in good standing</u>

and their office shall be subject to inspection by the Board.

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

Eff. _____.

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AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0404

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL</u>: 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

For an adoption, the only language that should be underlined is changes made since publication. Based upon the technical changes requested in this document, the formatting example is the following:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

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 7 references a fee. However, the history note cites a fee that is capped at \$100. Please verify the authority for the fee and update the fee or history note accordingly.

Line 27, add the date of "June 1, 2017" to the history note to reflective the effective date

1 21 NCAC 16Q .0404 is proposed for adoption 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, the 6 dentist shall obtain a general anesthesia or moderate pediatric conscious sedation permit from the Board by completing 7 an application form and paying a fee of three hundred seventy-five dollars (\$375.00). The application form is available 8 on the Board's website: www.ncdentalboard.org. The permit shall be renewed annually and shall be displayed with 9 the unexpired renewal at all times in the permit holder's facility where it is visible to patients receiving treatment. 10 (b) A dentist applying for a permit to administer moderate pediatric conscious sedation shall meet at least one of the 11 following criteria: 12 (1)completion of a postgraduate program that included pediatric intravenous conscious sedation 13 training; 14 completion of a Council-Commission On Dental Accreditation (CODA) approved pediatric (2) 15 residency that included intravenous conscious sedation training; or 16 (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that includes 17 training in the use and placement of IVs or intraosseous vascular access. A list of CODA approved 18 institutions that is hereby incorporated by reference, including subsequent amendments and editions, 19 appears at www.ada.org/coda and is available at no cost. 20 (c) All applicants for moderate pediatric conscious sedation permits shall have completed the training required by 21 Paragraph (b) of this Rule within the last two years or show evidence of moderate pediatric conscious sedation practice 22 within the last two years in another state or U.S. Territory. 23 (d) All applicants for moderate pediatric conscious sedation permits shall be in good standing with the Board. 24 25

- 26 History Note: Authority G.S. 90-30.1; 90-39(12); 90-48;
- 27

Eff._____.

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0405

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL</u>: 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

For an adoption, the only language that should be underlined is changes made since publication. Based upon the technical changes requested in this document, the formatting example is the following:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

Page 2, line 7, add a comma after "time"

Page 2, line 10, add a comma after "sedation"

Page 2, line 12, replace the semicolon after "recording" with a comma

Page 2, line 20, uncapitalize "The"

Page 2, lines 22 thru 24, this text is confusing. Please consider the following re-write:

This requirement shall not apply if the following applies:

- (A) the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure; and
- (B) the dentist permit holder is not performing the surgery or other dental procedure.

Abigail M. Hammond Commission Counsel Date submitted to agency: Wednesday, April 26, 2017 Page 3, line 31, define or delete "continuously"

Page 4, line 21, add the date of "June 1, 2017" to the history note to reflective the effective date

1	21 NCAC 16Q .	0405 is j	proposed for adoptic	on as follows:			
2							
3	21 NCAC 16Q .	.0405	MODERATE	PEDIATRIC	CONSCIOUS	SEDATION	CLINICAL
4 5	(a) A dontist adr	ninistari	ng moderate pediatr	TS AND EQUIPN		le to oncure that th	a facility where
6			red meets the follow		on shan be responsib	le to ensure that th	le facility where
7			cility shall be equip	•	ing:		
8	(1)	(A)		-	ermit access of eme	ergency equipmen	t and nersonnel
9		(11)	1	ergency manageme		igency equipment	t and personner
10		(B)	-		out enhancements, s	suitable for provid	ling emergency
11		(-)	treatment;		,	r	
12		(C)		ary for specific pro	cedures and back-up	o lighting;	
13		(D)	suction equipmen	it as necessary for	specific procedures,	including non-ele	ectrical back-up
14			suction;	-		-	-
15		(E)	positive oxygen d	lelivery system, ind	cluding full face ma	sks for small, me	dium, and large
16			and back-up E-cy	linder portable oxy	gen tank apart from	the central system	1;
17		(F)	oral and nasal airv	ways of various siz	es;		
18		(G)	blood pressure me	onitoring device;			
19		(H)	pulse oximeter;				
20		(I)	precordial stethos	cope or capnograp	1;		
21		(J)	defibrillator;				
22		(K)	EKG monitor;				
23		(L)	thermometer;				
24		(M)	vascular access se	et-up as necessary f	or specific procedure	es, including hardv	ware and fluids;
25		(N)	syringes as n	ecessary for specifi	c procedures;		
26		(0)	advanced-airways	; and			
27		(P)	tourniquet and tap	pe.			
28	(2)	The following unexpired drugs shall be maintained in the facility and with access from the operatory					
29		and recovery rooms:					
30		(A)	epinephrine;				
31		(B)	Atropine;				
32		(C)	appropriate revers	sal agents;			
33		(D)	antihistamine;				
34		(E)	corticosteroid;				
35		(F)	nitroglycerine;				
36		(G)	bronchodilator;				
37		(H)	antiemetic; and				

1		(I)	Dextrose.	
2	(3)	The pe	rmit holder shall maintain written emergency and patient discharge protocols and training to	
3		familiarize auxiliaries in the treatment of clinical emergencies is shall be provided;		
4	(4)	The fo	llowing records are maintained for at least 10 years:	
5		(A)	patient's current written medical history and pre-operative assessment;	
6		(B)	drugs administered during the procedure, including route of administration, dosage,	
7			strength, time and sequence of administration;	
8		(C)	a sedation record;	
9		(D)	a consent form, signed by the patient or a guardian, identifying the procedure,	
10			risks and benefits, level of sedation and date signed.	
11	(5)	The se	dation record shall include:	
12		(A)	base line vital signs, blood pressure (unless patient behavior prevents recording); oxygen	
13			saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient	
14			recorded in real time at 15 minute intervals;	
15		(B)	procedure start and end times;	
16		(C)	gauge of needle and location of IV on the patient, if used;	
17		(D)	status of patient upon discharge; and	
18		(E)	documentation of complications or morbidity; and	
19	(6)	The fo	llowing conditions shall be satisfied during a sedation procedure:	
20		(A)	The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall	
21			be dedicated to patient monitoring and recording sedation data throughout the sedation	
22			procedure. This requirement shall not apply if the dentist permit holder is dedicated to	
23			patient care and monitoring regarding general anesthesia or sedation throughout the	
24			sedation procedure and is not performing the surgery or other dental procedure; and	
25		(B)	when IV sedation is used, IV infusion shall be administered before the commencement of	
26			the procedure and maintained until the patient is ready for discharge.	
27	(b) During an ir	spection	or evaluation, applicants and permit holders who use intravenous sedation shall demonstrate	
28	the administrati	on of m	oderate pediatric conscious sedation on a live patient, including the deployment of an	
29	intravenous deli	very syst	em, while the evaluator observes. Applicants and permit holders who do not use IV sedation	
30	shall describe th	ne proper	e deployment of an intravenous delivery system to the evaluator and shall demonstrate the	
31	administration o	f modera	te pediatric conscious sedation on a live patient while the evaluator observes.	
32	(c) During the d	emonstra	tion, all applicants and permit holders shall demonstrate competency in the following areas:	
33	(1)	monitoring blood pressure, pulse, and respiration;		
34	(2)	drug dosage and administration;		
35	(3)	treatment of untoward reactions including respiratory or cardiac depression if applicable;		
36	(4)	sterile technique;		
37	(5)	use of	BLS certified auxiliaries;	
36	(4)	sterile	technique;	

2(7)sufficiency of patient recovery time.3(d) During an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the treatment of the Following clinical energencies:5(1)laryngospasm;6(2)bronchospasm;7(3)emesis and aspiration;8(4)respiratory depression and arrest;9(5)angina pectoris;10(6)myocardial infarction;11(7)hypertension and hypotension;12(8)allergic reactions;13(9)convulsions;14(10)syncope;15(11)bradycardia;16(12)insulin shock hypoglycemia;17(13)cardiac arrest;18(14)airway obstruction; and19cit)vacular access.20(c) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any21secdation procedure:22(1)a patient who is medically stable and who is ASA I or II shall be evaluated by a consultation23(c) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any23secdation procedure:24(2)a patient who is medically stable and who is ASA I or II shall be evaluated by a consultation24(f) Patient modically stable or who is ASA II or II shall be evaluated by a consultation25with the patient's primary care physician or consulting medical speciali	1	(6)	monitoring of patient during recovery; and		
 treatment of the following clinical emergencies: (1) laryngospasm; (2) bronchospasm; (3) emesis and aspiration; (4) respiratory depression and arrest; (5) angina pectoris; (6) myocardial infarction; (1) (6) myocardial infarction; (1) (7) hypertension and hypotension; (2) (8) allergic reactions; (3) (9) convulsions; (4) (10) syncope; (5) (11) bradycardia; (6) (12) insulia shock hypoglycemia; (7) (13) cardiac arrest; (8) (4) airway obstruction; and (14) airway obstruction; and (15) vascular access. (c) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any sedation procedure as follows: (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or (1) a patient who is not medically stable or who is ASA II or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure. (f) Patient monitoring: (g) Patient synoh have been administered moderate pediatric conscious sedation shall be monitored for alcitness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures. (g) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is recovered as defined in Subparagraph (0)(3) of this Rule and is ready for discharge from the office. 	2	(7)	sufficiency of patient recovery time.		
 I) laryngospasm; () laryngospasm; (2) bronchospasm; (3) emesis and aspiration; (4) respiratory depression and arrest; (9) (5) angina pectoris; (0) (6) myocardia infarction; (11) (7) hypertension and hypotension; (2) (8) allergic reactions; (3) (6) envolusions; (4) (10) syncope; (11) bradycardia; (10) bradycardia; (11) bradycardia; (12) insulia shock hypoglycemia; (13) cardiac arrest; (14) airway obstruction; and (15) vascular access. (e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any sedation procedure as follows: (current medical history and medication use; or (2) a patient who is not medically stable or who is ASA I or II shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure. (f) Patient monitoring: (f) Patient monitoring: (f) Patient shol have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative advitation during waiting periods before operative procedures. (f) Patient monitoring: (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge (a) the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge 	3	(d) During an in	an inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the		
6 (2) bronchospasm; 7 (3) emesis and aspiration; 8 (4) respiratory depression and arrest; 9 (5) angina pectoris; 10 (6) myocardial infarction; 11 (7) hypertension and hypotension; 12 (8) allergic reactions; 13 (9) convulsions; 14 (10) syncope; 15 (11) bradycardia; 16 (12) insulin shock hypoglycemia; 17 (13) cardiac arrest; 18 (14) airway obstruction; and 19 (15) vascular access. 20 (c) A moderate pediatric conscious selation permit holder shall evaluate patients for health risks before starting any selation procedure as follows: 21 (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or 24 (2) a patient who is not medically stable or who is ASA II or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure. 27	4	treatment of the	following clinical emergencies:		
7(3)emesia and aspiration;8(4)respiratory depression and arrest;9(5)angina pectoris;10(6)myocardial infarction;11(7)hypertension and hypotension;12(8)allergic reactions;13(9)convulsions;14(10)syncope;15(11)bradycardia;16(12)insulin shock hypoglycemia;17(13)cardiac arrest;18(14)airvay obstruction; and19(15)vascular access.20(e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any21sedation procedure as follows:22(1)a patient who is medically stable and who is ASA I or II shall be evaluated by a consultation23current medical history and medication use; or24(2)a patient who is not medically stable or who is ASA I I or higher shall be evaluated by a consultation24(f) Patient monitring:25(f) Patient monitring:26(f) Patient monitring:27(f) Patient monitring:28(l)Patients who have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures.39(2)Vital signs shall be continuously monitored when the sedation is no longer being administered and	5	(1)	laryngospasm;		
8(4)respiratory depression and arrest;9(5)angina pectoris;10(6)myocardial infarction;11(7)hypertension and hypotension;12(8)allergic reactions;13(9)convulsions;14(10)syncope;15(11)bradycardia;16(12)insulin shock hypoglycemia;17(13)cardia carrest;18(14)airway obstruction; and19(15)vascular access.20(e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any21sedation procedure as follows:22(1)a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or24(2)a patient who is not medically stable or who is ASA I I or higher shall be evaluated by a consultation2526(1)Patients who have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative26(1)Patientness, responsiveness, breathing, and skin coloration during waiting periods before operative27(1)Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge28(1)Vital signs shall be continuously supervision until oxygenation and cir	6	(2)	bronchospasm;		
 9 (5) angina pectoris; 10 (6) myocardial infarction; 11 (7) hypertension and hypotension; 12 (8) allergic reactions; 13 (9) convulsions; 14 (10) syncope; 15 (11) bradycardia; 16 (12) insulin shock hypoglycemia; 17 (13) cardiac arrest; 18 (14) airway obstruction; and 19 (15) vascular access. 20 (e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any sedation procedure as follows: 22 (1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or 24 (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure. 27 (f) Patient monitoring: 28 (1) Patients who have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures. 31 (2) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge 34 (b) of the office. 	7	(3)	emesis and aspiration;		
 myocardial infarction; myocardial infarction; (7) hypertension and hypotension; (8) allergic reactions; (9) convulsions; (10) syncope; (11) bradycardia; (12) insulin shock hypoglycemia; (12) insulin shock hypoglycemia; (13) cardiac arrest; (14) airway obstruction; and (15) vascular access. (c) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any sedation proceture as follows: (a) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or (2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure. (f) Patient monitoring: (1) Patient swho have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures. (1) Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge 34 	8	(4)	respiratory depression and arrest;		
11(7)hypertension and hypotension;12(8)allergic reactions;13(9)convulsions;14(10)syncope;15(11)bradycardia;16(12)insulin shock hypoglycemia;17(13)cardiac arrest;18(14)airway obstruction; and19(15)vascular access.20(e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any21sedation procedure as follows:22(1)a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's23current medical history and medication use; or24(2)a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation25with the patient's primary care physician or consulting medical specialist regarding the potential26risks posed by the procedure.27(f) Patient monitoring:28(1)Patients who have been administered moderate pediatric conscious sedation shall be monitored for30alertness, responsiveness, breathing, and skin coloration during waiting periods before operative30procedures.31(2)Vital signs shall be continuously monitored when the sedation is no longer being administered and32the patient shall have direct continuous supervision until oxygenation and circulation are stable and33the patient shall have direct continuous supervision until oxygenation and circulation are stable and </th <td>9</td> <td>(5)</td> <td>angina pectoris;</td>	9	(5)	angina pectoris;		
12(8)allergic reactions;13(9)convulsions;14(10)syncope;15(11)bradycardia;16(12)insulin shock hypoglycemia;17(13)cardiac arrest;18(14)airway obstruction; and19(15)vascular access.20(e) A moderate pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any21sedation procedure as follows:22(1)a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's23current medical history and medication use; or24(2)a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation25isks posed by the procedure.27(f) Patient monitoring:28(1)Patients who have been administered moderate pediatric conscious sedation shall be monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures.30procedures.31(2)Vital signs shall be continuously monitored when the sedation is no longer being administered and the patient shall have direct continuous supervision until oxygenation and circulation are stable and the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge from the office.	10	(6)	myocardial infarction;		
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30procedures.31(2)Vital signs shall be continuously monitored when the sedation is no longer being administered and32the patient shall have direct continuous supervision until oxygenation and circulation are stable and33the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge34from the office.	28	(1)	Patients who have been administered moderate pediatric conscious sedation shall be monitored for		
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 33 the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge 34 from the office. 	31	(2)	Vital signs shall be continuously monitored when the sedation is no longer being administered and		
34 from the office.	32		the patient shall have direct continuous supervision until oxygenation and circulation are stable and		
	33				
	34				
35 (3) Recovery from moderate pediatric conscious sedation shall include documentation of the following:	35	(3)	Recovery from moderate pediatric conscious sedation shall include documentation of the following:		
36 (A) cardiovascular function stable;			(A) cardiovascular function stable;		
	37		(B) airway patency uncompromised;		
	3/		(B) airway patency uncompromised;		

1		(C)	patient arousable and protective reflexes intact;
2		(D)	state of hydration within normal limits;
3		(E)	patient can talk, if applicable;
4		(F)	patient can sit unaided, if applicable;
5		(G)	patient can ambulate, if applicable, with minimal assistance; and
6		(H)	for the special needs patient or a patient incapable of the usually expected responses, the
7			pre-sedation level of responsiveness or the level as close as possible for that patient shall
8			be achieved.
9	(4)	Before	e allowing the patient to leave the office, the dentist shall determine that the patient has met
10		the rec	covery criteria set out in Subparagraph $(f)(3)$ of this Rule and the following discharge criteria:
11		(A)	oxygenation, circulation, activity, skin color, and level of consciousness are sufficient and
12			stable, and have been documented;
13		(B)	explanation and documentation of written postoperative instructions have been provided
14			to a responsible adult at time of discharge;
15		(C)	a vested adult is available to transport the patient after discharge; and
16		(D)	a vested adult shall be available to transport patients for whom a motor vehicle restraint
17			system is required and an additional responsible individual shall be available to attend to
18			the patients.
19			
20	History Note:	Author	rity G.S. 90-28; 90-30.1; 90-48;
21		<i>Eff</i>	

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0406

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL:</u> 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20for%20Public ation%20in%20the%20NCAC.pdf

Please note that if no changes are made to the text of an adoption since publication in the Register, then the formatting should follow this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20for%20Public ation%20in%20the%20NCAC.pdf

Line 11, add the date of "June 1, 2017" to the history note to reflective the effective date

1	21 NCAC 16Q .0406 is prop	osed for adoption as follows:
2		
3	21 NCAC 16Q .0406 0	FF SITE USE OF MODERATE PEDIATRIC CONSCIOUS SEDATION
4	Pl	ERMITS
5	The holder of a moderate ped	iatric conscious sedation permit may travel to the office of a licensed dentist and provide
6	moderate pediatric conscious	s sedation. The permit holder shall be responsible to ensure that the facility where the
7	sedation is administered has	been inspected by the Board as required by Rule .0404 of this Section, and that the
8	equipment, facility, and auxil	liaries meet the requirements of Rule .0405 of this Section.
9		
10	History Note: Authority C	G.S. 90-28; 90-30.1; 90-48;
11	<i>Eff.</i>	·

AGENCY: North Carolina State Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0407

DEADLINE FOR RECEIPT: Thursday, May 11, 2017

<u>NOTE WELL</u>: 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 1, please update this line in compliance with <u>26 NCAC 02C .0404</u>. For purposes of this Rule, please review this example:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

For an adoption, the only language that should be underlined is changes made since publication. Based upon the technical changes requested in this document, the formatting example is the following:

http://www.ncoah.com/rules/examples/Permanent%20Adoption%20with%20chan ges%20for%20Publication%20in%20the%20NCAC.pdf

Line 6 references an "application" 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 27, add a comma after "certification"

Line 33, is the use of "three hours" correct considering the "six hours" on line 18? Please verify and change if necessary.

Page 2, line 2, add the date of "June 1, 2017" to the history note to reflective the effective date

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, April 26, 2017

2		
3	21 NCAC 16Q.	0407 ANNUAL RENEWAL OF MODERATE PEDIATRIC CONSCIOUS SEDATION
4		PERMIT REQUIRED
5	(a) Moderate pe	diatric conscious sedation permits shall be renewed by the Board annually at the same time as dental
6	licenses by payin	ng a one hundred (\$100.00) fee and completing an application available from the Board's website:
7	www.ncdentalbo	ard.org.
8	(b) If the complete	ted renewal application and renewal fee are not received before January 31 of each year, a one hundred
9	(\$100.00) late fe	e shall be paid.
10	(c) Any dentist w	who fails to renew a moderate pediatric conscious sedation permit before March 31 of each year shall
11	complete a reinst	atement application, pay the renewal fee, late fee, and comply with all conditions for renewal set out
12	in this Rule. D	entists whose sedation permits have been lapsed for more than 12 calendar months shall pass an
13	inspection and an	n evaluation as part of the reinstatement process.
14	(d) A dentist wh	to administers moderate pediatric conscious sedation in violation of this Rule shall be subject to the
15	penalties prescril	bed by Rule .0701 of this Subchapter.
16	(e) As a condition	on for renewal of the moderate pediatric conscious sedation permit, the permit holder shall meet the
17	clinical and equi	pment requirements of Rule .0405 of this Section and shall document the following:
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;
27	(2)	unexpired PALS certification which shall not count towards the six hours of continuing education
28		required in Subparagraph (e)(1) of this rule;
29	(3)	that the permit holder and all auxiliaries involved in sedation procedures have practiced responding
30		to dental emergencies as a team at least once every six months in the preceding year.
21	(A)	that the normit holder and all auxiliaries involved in codation precedures have read the practice's

- 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
- that all auxiliaries involved in sedation procedures have completed BLS certification and three_hours
 of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this rule.
- 35 (f) All permit holders applying for renewal of a moderate pediatric conscious sedation permit shall be in good standing

36 and their office shall be subject to inspection by the Board.

21 NCAC 16Q .0407 is proposed for adoption as follows:

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

*Eff.*____.