1	21 NCAC 16Q .020	)2 is a	mended as published in 32:16 NCR 1604 with changes as follows:
2			
3	21 NCAC 16Q .020		GENERAL ANESTHESIA EQUIPMENT AND CLINICAL REQUIREMENTS
4	(a) A dentist adm	iniste	ring general anesthesia shall be responsible to ensure that the facility where the general
5	anesthesia is admin	istere	d meets the following requirements:
6	(1) T	he fac	cility shall be equipped with the following:
7	(A	A)	an operatory of size and design to permit access of emergency equipment and personnel
8			and to permit emergency management;
9	(I	B)	a CPR board or <u>a</u> dental chair without enhancements, suitable for providing emergency
10			treatment;
11	(0	C)	lighting as necessary for specific procedures and back-up lighting; and
12	(I	D)	suction equipment as necessary for specific procedures, including non-electrical back-up
13			suction;
14	(I	Ε)	positive pressure oxygen delivery system, including full face masks for small, medium,
15			and large patients, and back-up E-cylinder portable oxygen tank apart from the central
16			system;
17	(I	F)	small, medium, and large oral and nasal airways;
18	(0	G)	blood pressure monitoring device;
19	(I	H)	EKG monitor; <del>electrocardiograph;</del>
20	(I	[)	pulse oximeter;
21	(J	J)	automatic external defibrillator (AED): defibrillator;
22	(H	K)	precordial stethoscope or capnograph;
23	(I	L)	thermometer;
24	(1	M)	vascular access <u>set-up</u> as necessary for specific procedures, including hardware and fluids;
25	1)	N)	laryngoscope with working batteries;
26	(0	O)	intubation forceps and advanced airway devices;
27	(F	P)	tonsillar suction with back-up suction;
28	(0	Q)	syringes as necessary for specific procedures; and
29	(F	R)	tourniquet and tape.
30	(2) T	he fol	lowing unexpired drugs shall be maintained in the facility and with access from the operatory
31	aı	nd rec	overy rooms:
32	(4	A)	Epinephrine;
33	(I	B)	Atropine;
34	(0	C)	antiarrhythmic;
35	(I	D)	antihistamine;
36	(I	E)	antihypertensive;
37	(F	F)	bronchodilator:

1		(G)	antihypoglycemic agent;
2		(H)	vasopressor;
3		(I)	corticosteroid;
4		(J)	anticonvulsant;
5		(K)	muscle relaxant;
6		(L)	appropriate reversal agents;
7		(M)	nitroglycerine; and
8		(N)	antiemetic. antiemetic; and
9		(O)	Dextrose.
10	(3)	The p	ermit holder shall maintain written emergency and patient discharge protocols and training to
11		famili	arize auxiliaries in the treatment of clinical emergencies shall be provided;
12	(4)	The p	ermit holder shall maintain the following records for 10 years:
13		(A)	Patient's current written medical history, including a record of known allergies and
14			previous surgeries;
15		(B)	Consent to general anesthesia, signed by the patient or guardian, identifying the risks and
16			benefits, level of anesthesia, and date signed;
17		(C)	Consent to the procedure, signed by the patient or guardian identifying the risks, benefits,
18			and date signed; and
19		(D)	Patient base line vital signs, including temperature, SPO2, blood pressure, and pulse;
20	(5)	The ar	nesthesia record shall include:
21		(A)	base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen
22			saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient
23			recorded in real time at 15 minute intervals;
24		(B)	procedure start and end times;
25		(C)	gauge of needle and location of IV on the patient, if used;
26		(D)	status of patient upon discharge; and
27		(E)	documentation of complications or morbidity; and
28	(6)	The fa	acility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be
29		dedica	ated to patient monitoring and recording general anesthesia or sedation data throughout the
30		sedati	on procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to
31		patien	t care and monitoring regarding general anesthesia or sedation throughout the sedation
32		procee	dure and is not performing the surgery or other dental procedure.
33	(b) During an	inspect	ion or evaluation, the applicant or permit holder shall demonstrate the administration of
34	anesthesia while	e the eva	luator observes, and shall demonstrate competency in the following areas:
35	(1)	monit	oring of blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
36	(2)	drug d	losage and administration;
37	(3)	treatm	nent of untoward reactions including respiratory or cardiac depression;

1	(4)	sterile technique;		
2	(5)	use of BLS certified auxiliaries;		
3	(6)	monitoring of patient during recovery; and		
4	(7)	sufficiency of patient recovery time.		
5	(c) During an ir	aspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the		
6	treatment of the	following clinical emergencies:		
7	(1)	laryngospasm;		
8	(2)	bronchospasm;		
9	(3)	emesis and aspiration;		
10	(4)	respiratory depression and arrest;		
11	(5)	angina pectoris;		
12	(6)	myocardial infarction;		
13	(7)	hypertension and hypotension;		
14	(8)	syncope;		
15	(9)	allergic reactions;		
16	(10)	convulsions;		
17	(11)	bradycardia;		
18	(12)	hypoglycemia;		
19	(13)	cardiac arrest; and		
20	(14)	airway obstruction.		
21	(d) A general and	esthesia permit holder shall evaluate a patient for health risks before starting any anesthesia procedure.		
22	(e) Post-operativ	ve monitoring and discharge shall include the following:		
23	(1)	vital signs shall be continuously monitored when the sedation is no longer being administered and		
24		the patient shall have direct continuous supervision until oxygenation and circulation are stable and		
25		the patient is recovered as defined by Subparagraph (e)(2) of this Rule and is ready for discharge		
26		from the office; and		
27	(2)	recovery from general anesthesia shall include documentation of the following:		
28		(A) cardiovascular function stable;		
29		(B) airway patency uncompromised;		
30		(C) patient arousable and protective reflexes intact;		
31		(D) state of hydration within normal limits;		
32		(E) patient can talk, if applicable;		
33		(F) patient can sit unaided, if applicable;		
34		(G) patient can ambulate, if applicable, with minimal assistance; and		
35		(H) for the special needs patient or a patient incapable of the usually expected responses, the		
36		pre-sedation level of responsiveness or the level as close as possible for that patient shall		
37		be achieved; and		

1	(3)	before allowing the patient to leave the office, the dentist shall determine that the patient has met
2		the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:
3		(A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient,
4		stable, and have been documented;
5		(B) explanation and documentation of written postoperative instructions have been provided
6		to the patient or a responsible adult at time of discharge; and
7		(C) vested adult is available to transport the patient after discharge.
8		
9	History Note:	Authority G.S. 90-28; 90-30.1; 90-48;
10		Eff. February 1, 1990;
11		Amended Eff. August 1, 2018; June 1, 2017; November 1, 2013; August 1, 2002; August 1, 2000.

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21 NCAC 16Q .0204 is amended as published in 32:16 NCR 1605 with changes as follows:

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

- 5 (a) When both an evaluation or and on-site inspection is required, the Board shall designate two or more qualified
- 6 persons to serve as evaluators, each of whom has administered general anesthesia for at least three years preceding
- 7 the inspection. Training in general anesthesia shall not be counted in the three years. The fee for an evaluation and
- 8 on-site inspection shall be three-hundred seventy-five dollars (\$375.00). When an on-site inspection involves only a
- 9 facility and equipment check and not an evaluation of the dentist, the inspection may be accomplished by one
- evaluator. evaluator, and the fee for the on-site inspection shall be two-hundred seventy-five dollars (\$275.00).
- 11 (b) An inspection fee of three hundred two-hundred seventy-five dollars (\$375.00) (\$275.00) shall be due 10 days
- 12 after the dentist receives notice of the inspection of each additional location at which the dentist administers general
- 13 anesthesia.
- 14 (c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.
- 15 (d) The inspection team shall determine compliance with the requirements of the Rules rules in this Subchapter, as
- applicable, by assigning a grade of "pass" or "fail."
- 17 (e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting
- forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The
- Committee shall determine whether the applicant has passed the evaluation of and inspection and shall notify the
- applicant in writing of its decision.
- 21 (f) An applicant who fails an inspection or evaluation shall not receive a permit to administer general anesthesia.
- 22 a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B 3(c). If a
- 23 permit holder's facility fails an inspection, no further general anesthesia procedures shall be performed at the facility
- 24 until it passes a re-inspection by the Board.
- 25 (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of
- 26 receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of
- 27 the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional
- 28 training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall
- 29 notify the applicant in writing of the need for additional training.
- 30 (h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed
- 31 evaluation or inspection.

32

- 33 *History Note: Authority G.S.* 90-28; 90-30.1; 90-39;
- 34 Eff. February 1, 1990;
- 35 Amended Eff. <u>August 1, 2018</u>; April 1, 2016.; February 1, 2009; December 4, 2002; January 1,
- 36 1994.

1 of 1 5

1	21 NCAC 16Q .0206 is amended as published in 32:16 NCR 1606 with changes as follows:	
2		
3	21 NCAC 16Q .0206 ITINERANT (MOBILE) GENERAL ANESTHESIA PERMIT, EQUIPMENT	ΓAND
4	EVALUATION (A) A LA STATE AND A LA S	
5	(a) A dentist who holds a general anesthesia permit from the Board and who wishes to provide general anesth	
6	other sedation services in the office of another practitioner shall obtain a mobile general anesthesia permit fi	
7	Board by completing the application requirements of this Rule and paying a one hundred <u>dollar</u> (\$100.00) app	
8	fee. fee and a two-hundred seventy-five dollar (\$275.00) inspection fee. No mobile permit shall be requ	iired to
9	administer general anesthesia in a hospital or credentialed surgery center.	
10	(b) Before a mobile general anesthesia permit may be issued, a general anesthesia permit holder appointed	•
11	Board shall inspect the applicant's equipment and medications to ensure that they comply with Paragraphs (c)	and (d)
12	of this Rule.	
13	(c) The permit holder shall maintain the following equipment: in good working order the equipment required	<u>y Rule</u>
14	.0202(a)(1) of this Section.	
15	(1) positive pressure ventilation system and back up E cylinder portable oxygen tank;	
16	(2) standard ASA monitors with back up power;	
17	(3) EKG monitor;	
18	(4) precordial stethoscope or capnograph;	
19	(5) small, medium, and large oral airways and nasal trumpets;	
20	(6) small, medium, and large laryngoscope blades and back up laryngoscope;	
21	(7) small, medium, and large nasal and oral endotracheal tubes;	
22	(8) Magill forceps;	
23	(9) small, medium, and large supraglottic airway devices;	
24	(10) back up suction;	
25	(11) defibrillator with pediatric capability;	
26	(12) small, medium, and large anesthesia circuits;	
27	(13) back up lighting;	
28	(14) gastric suction device;	
29	(15) endotracheal tube and pulmonary suction device;	
30	(16) equipment for performing emergency cricothyrotomies and delivering positive pressure vent	ilation;
31	(17) back up ventilation measurement;	
32	(18) rebreathing device;	
33	(19) scavenging system;	
34	(20) intermittent compression devices;	
35	(21) CPR board or dental chair without enhancements suitable for providing emergency treatment	<del>ıt;</del>
36	(22) laryngoscope with working batteries; and	

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(23) tourniquet and tape.

37

1	(d) The unexp	oired medications required by Rule .0202(a)(2) of this Section shall be [immediately] on site and
2	available to the	permit holder. The following unexpired medications shall be immediately available to the permit
3	<del>holder:</del>	
4	(1)	—Epinephrine;
5	(2)	— Atropine;
6	(3)	— antiarrhythic;
7	(4)	<del>antihistamine;</del>
8	(5)	— antihypertensive;
9	(6)	— bronchodilator;
10	(7)	antihypoglycemic agent;
11	(8)	<del>vasopressor;</del>
12	(9)	<del>corticosteroid;</del>
13	(10)	— anticonvulsant;
14	(11)	— muscle relaxant;
15	(12)	appropriate reversal agents;
16	(13)	— nitroglycerine;
17	(14)	—antiemetic;
18	(15)	neuromuscular blocking agent; and
19	(16)	anti malignant hyperthermia agent.
20	(e) The evalua	tion and on-site inspection shall be conducted as set out in Rule .0204 of this Section.
21	(f) Before Prio	r to administering general anesthesia or sedation at another provider's office, the mobile permit holder
22	shall inspect the	e host facility within 24 business hours before each procedure and shall to ensure that:
23	(1)	the operatory's size and design permit emergency management and access of emergency equipment
24		and personnel;
25	(2)	there is a CPR board or dental chair without enhancements suitable for providing emergency
26		treatment;
27	(3)	there is lighting to permit performance of all procedures planned for the facility;
28	(4)	there is suction equipment, including non-electrical back-up suction; and
29	(5)	the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be
30		dedicated to patient monitoring and recording general anesthesia or sedation data throughout the
31		sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to
32		patient care and monitoring regarding general anesthesia or sedation throughout the sedation
33		procedure and is not performing the surgery or other dental procedure.
34	(g) At least 24	hours before the procedure is scheduled to begin, the mobile permit holder shall send written notice to
35	the Board office	e confirming that the facility where the general anesthesia or sedation will be performed meets the
36	requirements o	f Paragraph (f) of this Rule and documenting when the inspection was conducted. The permit holder

shall retain a copy of the written notice for 10 years following the procedure. No procedure shall be performed until

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- the report required by this Paragraph is filed. Upon inspection, the permit holder shall document that the facility where
- 2 the general anesthesia or sedation procedure will be performed was inspected and that it met the requirements of
- 3 Paragraph (f) of this Rule. The permit holder shall retain the inspection and compliance record required by this
- 4 Paragraph for 10 years following the procedure and provide these records to the Board upon request.
- 5 (h) The mobile general anesthesia permit shall be displayed in the host facility where it is visible to patients receiving
- 6 treatment.
- 7 (i) All applicants for mobile general anesthesia permit shall be in good standing with the Board.

8

- 9 History Note: Authority G.S. 90-28; 90-30.1; 90-39; 90-48;
- 10 Eff. June 1, 2017.
- 11 <u>Amended Eff. August 1, 2018.</u>

8 3 of 3

1	21 NCAC 16Q .0	2207 is amended as published in 32:16 NCR 1607 with changes as follows:		
2				
3	21 NCAC 16Q .	0207 ANNUAL RENEWAL OF GENERAL ANESTHESIA AND ITINERAN		
4		(MOBILE) GENERAL ANESTHESIA PERMIT REQUIRED		
5	(a) General anes	thesia <u>and itinerant general anesthesia</u> permits shall be renewed by the Board annually at the sam		
6	time as dental lic	censes by <u>the dentist</u> paying a <u>one hundred one-hundred</u> dollar (\$100.00) fee and completing the		
7	application requi	rements of this Rule. If the completed general anesthesia and itinerant general anesthesia perm		
8	renewal applicati	on and renewal fee are not received before January 31 of each year, a one hundred-fifty dollar		
9	<del>(\$100.00)</del> <u>(\$50.0</u>	<u>0</u> ) late fee shall be paid.		
10	(b) Itinerant gene	eral anesthesia permits shall be renewed by the Board annually at the same time as dental licenses b		
11	paying a one hu	indred dollar (\$100.00) fee and completing the application requirements of this Rule. and Th		
12	application <u>is</u> av	ailable from on the Board's website: www.ncdentalboard.org. If the completed itinerant genera		
13	sedation permit <u>a</u>	pplication and renewal fee are not received before January 31 of each year, a <del>one hundred <u>fifty</u> d</del> olla		
14	<del>(\$100.00)</del> <u>(\$50.0</u>	0) late fee shall be paid.		
15	(c) Any dentist v	who fails to renew a general anesthesia permit or itinerant general anesthesia permit before March 3		
16	of each year shal	l complete a reinstatement application, pay the renewal fee, late fee, and comply with all condition		
17	for renewal set of	ut in this Rule. Dentists whose anesthesia permits or itinerant general anesthesia permits have bee		
18	lapsed for more th	nan 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement process		
19	(d) A dentist wh	o administers general anesthesia in violation of this Rule shall be subject to the penalties prescribe		
20	by Rule .0701 of	this Subchapter.		
21	(e) As a condition for renewal of the general anesthesia and itinerant general anesthesia permit, the general anesthesia			
22	permit holder sha	ıll <del>maintain</del> <u>meet</u> the clinical equipment and requirements set out in <del>Rules</del> <u>Rule</u> .0202 <u>of this Sectio</u>		
23	and the itinerant	general anesthesia permit holder shall maintain the clinical equipment and requirements set out i		
24	<u>Rule</u> .0206 of thi	s Section and shall document the following:		
25	(1)	six hours of continuing education each year in one or more of the following areas, which may sha		
26		be counted toward fulfillment of the continuing education required each calendar year for licens		
27		renewal:		
28		(A) sedation;		
29		(B) medical emergencies;		
30		(C) monitoring IV sedation and the use of monitoring equipment;		
31		(D) pharmacology of drugs and agents used in general anesthesia and IV sedation;		
32		(E) physical evaluation, risk assessment, or behavioral management; or		
33		(F) airway management;		
34	(2)	unexpired ACLS certification, which shall not count towards the six hours of continuing education		
35		required in Subparagraph (e)(1) of this Rule;		

1	(3)	that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have
2		practiced responding to dental emergencies as a team at least once every six months in the preceding
3		year;
4	(4)	that the permit holder and all auxiliaries involved in anesthesia or sedation procedures have read the
5		practice's emergency manual in the preceding year; and
6	(5)	that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
7		of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this Rule.
8	(f) All permit l	nolders applying for renewal of a general anesthesia or itinerant general anesthesia permit shall be in
9	good standing a	and their office shall be subject to inspection by the Board.
10		
11	History Note:	Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
12		Eff. June 1, 2017.
13		Amended Eff. August 1, 2018.

21 NCAC 16Q .0301 is amended as published in 32:16 NCR 1607 with changes as follows:

## 21 NCAC 16Q .0301 CREDENTIALS AND PERMITS FOR MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION

- (a) Before a dentist licensed to practice in North Carolina may administer or supervise a CRNA employed to administer or RN employed to deliver moderate conscious sedation, the dentist shall obtain a permit from the Board by completing the application requirements in this Rule and paying a fee of three hundred seventy-five dollar seventy five dollars (\$375.00) fee that includes the one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. The permit shall be renewed annually and shall be displayed with the current renewal at all times in the facility of the permit holder where it is visible to patients receiving treatment.
- (b) The permit holder shall provide supervision to any CRNA employed to administer or RN employed to deliver sedation, and shall ensure that the level and duration of the sedation does not exceed the level of the sedation allowed by the permit holder's permit.
- (c) A dentist applying for a permit to administer moderate conscious sedation shall document the following:
  - (1) Training which that may consist of either:
    - (A) Completion of 60 hours of Board approved didactic training in intravenous conscious sedation, and 30 hours of clinical training that shall include successful management of a minimum of 20 live patients, under supervision of the course instructor, using intravenous sedation. Training shall be provided by one or more individuals who meet the American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists that is hereby incorporated by reference, including subsequent amendments and editions. The guidelines may be found at www.ada.org/coda; or
    - (B) Completion of a pre-doctoral dental or postgraduate program that included intravenous conscious sedation training equivalent to that defined in Part (c)(1)(A) of this Rule;
  - (2) Unexpired ACLS certification; and
  - (3) That all auxiliaries involved in sedation procedures have unexpired BLS certification.
- (d) All applicants for a moderate conscious sedation permit shall be in good standing with the Board.
- (e) Prior to issuance of a moderate conscious sedation permit, the applicant shall pass an evaluation and a facility inspection. The applicant shall be responsible for passing the evaluation and inspection of his or her facility within 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one by contacting the Board in writing.
- 32 (f) A dentist who holds a moderate conscious sedation permit shall not intentionally administer deep sedation.
- 33 (g) A moderate conscious sedation permit holder may provide moderate conscious sedation at the office of another
- 34 licensed dentist, regardless of the permit, if any held, by the hosting dentist. The permit holder shall ensure that the
- 35 facility where the moderate conscious sedation is administered has been inspected and complies with the requirements
- 36 set out in Rule .0302 of this Section. The permit holder shall also obtain an itinerant moderate conscious sedation
- permit and comply with the requirements of Rule .0304 of this Section.

1		
2	History Note:	Authority G.S. 90-30.1; 90-39; 90-48;
3		Eff. February 1, 1990;
4		Amended Eff. April 1, 2001; August 1, 2000; January 1, 1994;
5		Temporary Amendment Eff. December 11, 2002;
6		Amended Eff. August 1, 2018; June 1, 2017; July 1, 2010, July 3, 2008; August 1, 2004

1	21 NCAC 16Q .0	0302 is a	mended as publish	ed in 32:16 NCR 1	608 <u>wit</u>	<u>h changes</u> as f	ollows:	
2								
3	21 NCAC 16Q.	0302	MODERATE	PARENTERAL	AND	ENTERAL	CONSCIOUS	SEDATION
4			CLINICAL RE	QUIREMENTS A	ND EQ	QUIPMENT		
5	(a) A dentist ad	ministeri	ng moderate cons	cious sedation or s	upervisi	ng any CRNA	employed to adr	ninister or RN
6	employed to deli	ver mode	erate conscious sec	lation shall <del>be resp</del>	<del>onsible</del>	to-ensure that	the facility where	the sedation is
7	administered me	ets the fo	llowing requireme	ents:				
8	(1)	The fac	ility shall be equip	pped with the follow	ving:			
9		(A)	an operatory of	size and design to	permit a	access of emer	gency equipment	and personnel
10			and to permit em	ergency managem	ent;			
11		(B)	a CPR board or	a dental chair with	nout enl	nancements, su	itable for providi	ng emergency
12			treatment;					
13		(C)	lighting as neces	sary for specific pr	ocedure	s and back-up	lighting; and	
14		(D)	suction equipme	nt as necessary for	specific	e procedures, i	ncluding non-elec	etrical back-up
15			suction;					
16		(E)	positive pressure	oxygen delivery	system,	including full	face masks for s	mall, medium,
17			and large patien	ts and back-up E-	cylinder	portable oxy	gen tank apart fro	om the central
18			system;					
19		(F)	small, medium, a	and large oral and r	asal air	ways;		
20		(G)	blood pressure m	nonitoring device;				
21		<u>(H)</u>	EKG monitor; [e	<del>lectrocardiograph;</del>	<del>]</del>			
22		(H)(I)	pulse oximeter;					
23		( <u>I)(J)</u>	automatic extern	al defibrillator (AE	(D);			
24		<del>(J)</del>	EKG monitor;					
25		(K)	precordial stetho	scope or capnograp	oh;			
26		(L)	thermometer;					
27		(M)	vascular access s	et-up as necessary	for spec	ific procedures	s, including hardw	are and fluids;
28		(N)	laryngoscope wi	th working batterie	<u>s;</u>			
29		(O)	intubation forcep	s and advanced air	way dev	vices;		
30		<u>(P)</u>	tonsillar suction	with back-up suction	on;			
31		(N)(Q)	syringes as neces	ssary for specific p	cocedure	es; and		
32		<del>(O)</del> (R)	tourniquet and ta	<del>pe;</del> <u>tape.</u>				
33		<del>(P)</del>	advanced airway	devices; and				
34		<del>(Q)</del>	tonsillar suction	with back up suction	<del>on</del> .			
35	(2)	The foll	lowing unexpired of	drugs shall be main	tained ir	the facility an	d with access from	n the operatory
36		and reco	overy rooms:					
37		(A)	iniectable eniner	<del>brine</del> Eninenhrine:				

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1		(B) injectable-Atropine;
2		(C) antiarrhythmic;
3		(C) injectable appropriate reversal agents;
4		(D) injectable antihistamine;
5		(E) antihypertensive;
6		(F) bronchodilator;
7		(G) antihypoglycemic agent;
8		(H) vasopressor;
9		(E)(I) injectable corticosteroid;
10		(J) anticonvulsant;
11		(K) muscle relaxant;
12		(L) appropriate reversal agents;
13		(F)(M) nitroglycerine;
14		(G) bronchodilator;
15		(H)(N) injectable antiemetic; and
16		(I)(O) <u>Dextrose</u> . Dextrose; and
17		(J) injectable anti-arrhythmic.
18	(3)	The permit holder shall maintain written emergency and patient discharge protocols and training to
19		familiarize auxiliaries in the treatment of clinical emergencies shall be provided; and
20	(4)	The dentist shall maintain the following records for at least 10 years:
21		(A) Patient's patient's current written medical history and pre-operative assessment; and
22		(B) Drugs drugs administered during the procedure, including route of administration, dosage,
23		strength, time, and sequence of administration administration; and
24		(C) a sedation record;
25	(5)	The sedation record shall include:
26		(A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen
27		saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient
28		recorded in real time at 15 minute intervals;
29		(B) procedure start and end times;
30		(C) gauge of needle and location of IV on the patient, if used;
31		(D) status of patient upon discharge;
32		(E) documentation of complications or morbidity; and
33		(F) consent form, signed by the patient or guardian, identifying the procedure, risks and
34		benefits, level of sedation, and date signed.signed; and
35	(6)	The following conditions shall be satisfied during a sedation procedure:
36		(A) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall
37		be dedicated to patient monitoring and recording sedation data throughout the sedation

1		procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to
2		patient care and monitoring regarding general anesthesia or sedation throughout the
3		sedation procedure and is not performing the surgery or other dental procedure. procedure:
4		<mark>and</mark>
5		(B) If IV sedation is used, IV infusion shall be administered before the start of the procedure
6		and maintained until the patient is ready for discharge.
7	(b) During an in	aspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate
8	conscious seda	tion on a patient, including the deployment of an intravenous delivery system, while the evaluator
9	observes. Durin	ng the demonstration, the applicant or permit holder shall demonstrate competency in the following
10	areas:	
11	(1)	monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
12	(2)	drug dosage and administration;
13	(3)	treatment of untoward reactions including respiratory or cardiac depression if applicable;
14	(4)	sterile technique;
15	(5)	use of BLS certified auxiliaries;
16	(6)	monitoring of patient during recovery; and
17	(7)	sufficiency of patient recovery time.
18	(c) During an i	inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency to the
19	evaluator in the	treatment of the following clinical emergencies:
20	(1)	laryngospasm;
21	(2)	bronchospasm;
22	(3)	emesis and aspiration;
23	(4)	respiratory depression and arrest;
24	(5)	angina pectoris;
25	(6)	myocardial infarction;
26	(7)	hypertension and hypotension;
27	(8)	allergic reactions;
28	(9)	convulsions;
29	(10)	syncope;
30	(11)	bradycardia;
31	(12)	hypoglycemia;
32	(13)	cardiac arrest; and
33	(14)	airway obstruction.
34	(d) A moderate	e conscious sedation permit holder shall evaluate a patient for health risks before starting any sedation
35	procedure as fo	llows:
36	(1)	a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's
37		current medical history and medication use or;

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I	(2)	a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation
2		with the patient's primary care physician or consulting medical specialist regarding the potential
3		risks posed by the procedure.
4	(e) Post-operat	ive monitoring and discharge:
5	(1)	vital signs shall be continuously monitored when the sedation is no longer being administered and
6		the patient shall have direct continuous supervision until oxygenation and circulation are stable and
7		the patient is recovered as defined in Subparagraph (e)(2) of this Rule and is ready for discharge
8		from the office.
9	(2)	recovery from moderate conscious sedation shall include documentation of the following:
10		(A) cardiovascular function stable;
11		(B) airway patency uncompromised;
12		(C) patient arousable and protective reflexes intact;
13		(D) state of hydration within normal limits;
14		(E) patient can talk, if applicable;
15		(F) patient can sit unaided, if applicable;
16		(G) patient can ambulate, if applicable, with minimal assistance; and
17		(H) for the special needs patients patient or patients patient incapable of the usually expected
18		responses, the pre-sedation level of responsiveness or the level as close as possible for that
19		patient shall be achieved.
20	(3)	before allowing the patient to leave the office, the dentist shall determine that the patient has met
21		the recovery criteria set out in Subparagraph (e)(2) of this Rule and the following discharge criteria:
22		(A) oxygenation, circulation, activity, skin color, and level of consciousness are stable, and
23		have been documented;
24		(B) explanation and documentation of written postoperative instructions have been provided
25		to the patient or a responsible adult at time of discharge; and
26		(C) a vested adult is available to transport the patient after discharge.
27		
28	History Note:	Authority G.S. 90-28; 90-30.1; 90-48;
29		Eff. February 1, 1990;
30		Amended Eff. August 1, 2002; August 1, 2000;
31		Temporary Amendment Eff. December 11, 2002;
32		Amended Eff. August 1, 2018; June 1, 2017; November 1, 2013; July 1, 2010; July 3, 2008; August
33		1, 2004.
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35		
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1	21 NCAC 16Q .0304 is a	mended as published in 3	32:16 NCR 1610 <u>with</u>	changes as foll	ows:	
2						
3	21 NCAC 16Q .0304	OFF SITE USE OF N	MODERATE PARE	NTERAL AN	D ENTERAL CO	<del>ONSCIOUS</del>
4		SEDATION PERM	ITS— <u>ITINERANT</u>	(MOBILE)	MODERATE	PERMIT,
5		EQUIPMENT AND E	<u>CVALUATION</u>			
6	The holder of a moderate	conscious sedation permi	t may travel to the off	ice of a licensed	l dentist and provi	<del>de moderate</del>
7	conscious sedation for the	e patients of that dentist	who are undergoing o	lental procedur	es. The permit ho	<del>lder shall be</del>
8	responsible to ensure that	the facility where the sec	lation is administered	has passed insp	ection by the Boa	rd and meets
9	the requirements set out in	1 Rule .0302 of this Secti	on. The permit holder	shall be respon	sible to ensure the	t the facility
10	is staffed with at least to	wo BLS certified auxilia	aries, one of whom s	shall be dedicat	ed to patient mo	nitoring and
11	recording general anesthe	sia or sedation data throu	ighout the sedation pr	ocedure. This S	ubparagraph shall	not apply if
12	the dentist permit holde	r is dedicated to patien	t care and monitorir	ng regarding go	eneral anesthesia	or sedation
13	throughout the sedation p	rocedure and is not perfe	rming the surgery or	other dental pro	ecedure.	
14	(a) A dentist who holds	a moderate conscious sec	lation permit from the	e Board and wh	o wishes to provi	de moderate
15	conscious sedation or otl	ner sedation services in	the office of another	practitioner sh	all obtain a mobi	ile moderate
16	conscious sedation permi	t from the Board by com	pleting the application	n requirements	of this Rule and p	aying a one-
17	hundred dollar (\$100.00)	application fee and a tw	o-hundred seventy-fiv	ve dollar (\$275.	00) inspection fee	. No mobile
18	permit shall be required to	o administer moderate co	nscious sedation in a	hospital or cred	lentialed surgery of	enter.
19	(b) The permit holder sha	<u>ll maintain in good worki</u>	ng order the equipmer	nt required by R	ule .0302(a)(1) of	this Section.
20	(c) The unexpired medica	tions required by Rule .0	302(a)(2) of this Section	on shall be [ <mark>imn</mark>	<mark>nediately</mark> ] <mark>on site a</mark>	<mark>ınd</mark> available
21	to the permit holder.					
22	(d) Before a mobile mod	lerate sedation permit ma	ay be issued, a permit	t holder appoint	ted by the Board	shall inspect
23	the applicant's equipment	and medications to ensu	re that they comply	with Paragraphs	s (b) and (c) of th	is Rule. The
24	evaluation and inspection	shall be conducted as se	t out in Rule .0306 of	this Section.		
25	(e) Prior to administering	g moderate conscious se	dation or other sedat	ion services at	another provider	s office, the
26	mobile permit holder sha	ll inspect the host facility	within 24 business l	hours before ea	ch procedure and	shall ensure
27	that:					
28	(1) the ope	ratory's size and design p	ermit emergency man	nagement and ac	ccess of emergenc	y equipment
29	and per	sonnel;				
30	(2) there is	s a CPR board or denta	l chair without enha	ncements suita	ble for providing	emergency
31	treatme	<u>nt;</u>				
32	(3) there is	lighting to permit perfor	mance of all procedur	res planned for	the facility;	
33	(4) there is	suction equipment, inclu	ding non-electrical ba	ack-up suction;	<u>and</u>	
34	(5) the fac	ility shall be staffed wi	th at least two BLS	certified auxili	aries, one of wh	om shall be
35	dedicat	ed to patient monitoring	g and recording mod	derate consciou	s sedation or oth	ner sedation
36	services	s data throughout the sec	lation procedure. Thi	s Subparagraph	shall not apply i	f the dentist

1	]	permit holder is dedicated to patient care and monitoring regarding sedation throughout the sedation
2	1	procedure and is not performing the surgery or other dental procedure.
3	(f) Upon inspects	ion, the permit holder shall document that the facility where the general anesthesia or sedation
4	procedure will be	performed was inspected and that it met the requirements of Paragraph (e) of this Rule. The permit
5	holder shall retain	the inspection and compliance record required by this Paragraph for 10 years following the
6	procedure and pro-	vide these records to the Board upon request.
7	(g) The mobile mo	oderate conscious sedation permit shall be displayed in the host facility where it is visible to patients
8	receiving treatmen	<u>ıt.</u>
9	(i) All applicants	for mobile moderate conscious sedation permit shall be in good standing with the Board.
10		
11	History Note:	Authority G.S. 90-28; 90-30; 90-30.1; <u>90-39;</u> 90-48;
12	i	Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013;
13	1	Amended Eff. <u>August 1, 2018</u> ; June 1, 2017.

1	21 NCAC 16Q .030	05 is amended as published in 32:16 NCR 1611 with changes as follows:
2		
3	21 NCAC 16Q .030	05 ANNUAL RENEWAL OF MODERATE PARENTERAL AND ENTERAL
4		CONSCIOUS SEDATION PERMIT REQUIRED
5	(a) Moderate consc	cious sedation permits shall be renewed by the Board annually at the same time as dental licenses
6	by <u>the dentist</u> payin	g a one hundred one-hundred dollar (\$100.00) fee and completing the application requirements in
7	this Rule. If the con	mpleted permit renewal application and renewal fee are not received before January 31 of each
8	year, a fifty dollar (	\$50.00) late fee shall be paid.
9	(b) <u>Itinerant moder</u>	rate conscious sedation permits shall be renewed by the Board annually at the same time as dental
10	licenses by paying	a one-hundred dollar (\$100.00) fee and completing the application requirements in this Rule. If
11	the completed pern	nit renewal application and renewal fee are not received before January 31 of each year, a one
12	hundred fifty dollar	(\$100.00) (\$50.00) late fee shall be paid.
13	(c) Any dentist wh	no fails to renew a moderate conscious sedation permit or itinerate moderate conscious sedation
14	permit before Marc	ch 31 of each year shall complete a reinstatement application, pay the renewal fee, late fee, and
15	comply with all con	ditions for renewal set out in this Rule. Dentists whose sedation permits have been lapsed for more
16	than 12 calendar mo	onths shall pass an inspection and an evaluation as part of the reinstatement process.
17	(d) A dentist who a	administers moderate conscious sedation in violation of this Rule shall be subject to the penalties
18	prescribed by Rule	.0701 of this Subchapter.
19	(e) As a condition	for renewal of the moderate conscious sedation permit, permit and itinerate moderate conscious
20	sedation permit, the	e permit holder shall meet the clinical and equipment requirements of Rule Rules .0302 and .0304
21	of this Section and	shall document the following:
22	(1) si	ix hours of continuing education each year in one or more of the following areas, which may shall
23	bo	e counted toward fulfillment of the continuing education required each calendar year for license
24	re	enewal:
25	(4	A) sedation;
26	(H	B) medical emergencies;
27	(0	c) monitoring IV sedation and the use of monitoring equipment;
28	(I	D) pharmacology of drugs and agents used in IV sedation;
29	(I	E) physical evaluation, risk assessment, or behavioral management; or
30	(I	F) airway management;
31	(2) un	nexpired ACLS certification, which shall not count towards the six hours of continuing education
32	re	equired in Subparagraph (e)(1) Rule;
33	(3) th	nat the permit holder and all auxiliaries involved in sedation procedures have practiced responding
34	to	dental emergencies as a team at least once every six months in the preceding year;
35	(4) th	nat the permit holder and all auxiliaries involved in sedation procedures have read the practice's
36	eı	mergency manual in the preceding year; and

1	(5)	that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
2		of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this Rule.
3	(f) All permit h	nolders applying for renewal of a moderate conscious sedation permit or itinerate moderate conscious
4	sedation permit	shall be in good standing and their office shall be subject to inspection by the Board.
5		
6	History Note:	Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
7		Eff. June 1, 2017.
8		Amended Eff. August 1, 2018.

21 NCAC 16Q .0306 is amended as published in 32:16 NCR 1611 with changes as follows:

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

- 5 (a) When an evaluation or on-site inspection is required, the Board shall designate one or more qualified persons to
- 6 serve as evaluators each of whom has administered moderate conscious sedation for at least three years preceding the
- 7 inspection. Training in moderate conscious sedation shall not be counted in the three years.
- 8 (b) An inspection fee of three hundred two-hundred seventy-five dollars (\$375.00) (\$275.00) shall be due 10 days
- 9 after the dentist receives notice of the inspection of each additional location at which the dentist administers moderate
- 10 conscious sedation.
- 11 (c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.
- 12 (d) The inspection team shall determine compliance with the requirements of the rules in this Subchapter, as
- applicable, by assigning a grade of "pass" or "fail."
- 14 (e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting
- 15 forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The
- 16 Committee shall determine whether the applicant has passed the evaluation or inspection and shall notify the applicant
- in writing of its decision.
- 18 (f) An applicant who fails an inspection or evaluation shall not receive a permit to administer moderate conscious
- 19 sedation. If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B-
- 20 3(e). If a permit holder's facility fails an inspection, no further moderate sedation procedures shall be performed at the
- 21 facility until it passes a re-inspection by the Board.
- 22 (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of
- 23 receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of
- the grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional
- training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall
- 26 notify the applicant in writing of the need for additional training.
- 27 (h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed
- 28 evaluation or inspection.

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- 30 *History Note:* Authority G.S. 90-30.1; 90-39; 90-48;
- 31 *Eff April 1, 2016*.
- 32 <u>Amended Eff. August 1, 2018.</u>

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21 NCAC 16Q .0404 is amended as published in 32:16 NCR 1612 with changes as follows:

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

- (a) Before a dentist licensed to practice in North Carolina may administer moderate pediatric conscious sedation, the dentist shall obtain a general anesthesia or moderate pediatric conscious sedation permit from the Board by completing
- 7 the application requirements of this Rule and paying a fee of three hundred seventy-five dollars (\$375.00) that includes
- 8 the one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee.
- 9 The permit shall be renewed annually and shall be displayed with the unexpired current renewal at all times in the 10 permit holder's facility where it is visible to patients receiving treatment.
  - (b) A dentist applying for a permit to administer moderate pediatric conscious sedation shall meet at least one of the following criteria:
    - (1) completion of a postgraduate program that included pediatric intravenous conscious sedation training;
    - (2) completion of a Commission On Dental Accreditation (CODA) approved pediatric residency that included intravenous conscious sedation training; or
    - (3) completion of a pediatric degree or pediatric residency at a CODA approved institution that includes training in the use and placement of IVs or intraosseous vascular access. A list of CODA approved institutions that is hereby incorporated by reference, including subsequent amendments and editions, appears at www.ada.org/coda and is available at no cost.
    - (c) All applicants for moderate pediatric conscious sedation permits shall have completed the training required by Paragraph (b) of this Rule within the last two years or show evidence of moderate pediatric conscious sedation practice within the last two years in another state or U.S. Territory.
- 24 (d) All applicants for moderate pediatric conscious sedation permits shall be in good standing with the Board.
- 25 (e) Prior to issuance of a moderate pediatric conscious sedation permit, the applicant shall pass an evaluation and a
- 26 facility inspection. The applicant shall be responsible for passing the evaluation and inspection of his or her facility
- 27 within 90 days of notification. An extension of no more than 90 days shall be granted if the designated evaluator or
- 28 applicant requests one by contacting the Board in writing.
- 29 (e) (f) A moderate pediatric conscious sedation permit holder may provide moderate pediatric conscious sedation at
- 30 the office of another licensed dentist, regardless of the permit, if any held, by the hosting dentist. The permit holder
- 31 shall ensure that the facility where the moderate pediatric conscious sedation is administered has been inspected and
- 32 complies with the requirements set out in Rule .0405 of this Section. The permit holder shall also obtain an itinerant
- 33 moderate pediatric conscious sedation permit and comply with the requirements of Rule .0406 of this Section.

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

36 Eff. June 1, 2017.

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37 Amended Eff. August 1, 2018.

1	21 NCAC 16Q .0405 is	s amended as publishe	ed in 32:16 NCR <u>1</u>	612	ges as follows:	
2						
3	21 NCAC 16Q .0405	MODERATE	PEDIATRIC	CONSCIOUS	SEDATION	CLINICAL
4		_	TS AND EQUIPM			
5	(a) A dentist administe	ring moderate pediatr	ric conscious sedati	on shall <del>be responsil</del>	<mark>le to</mark> ensure that th	e facility where
6	the sedation is adminis	tered meets the follow	ving requirements:			
7	(1)   The	facility shall be equip	ped with the follow	ving:		
8	(A)	-		permit access of emo	ergency equipmen	t and personnel
9		-	ergency manageme			
10	(B)	a CPR board or	a dental chair with	nout enhancements,	suitable for provid	ling emergency
11		treatment;				
12	(C)			ocedures and back-u		
13	(D)		nt as necessary for	specific procedures,	including non-ele	ectrical back-up
14		suction;				
15	(E)			system, including fu		
16		and large patient	s and back-up E-c	cylinder portable ox	ygen tank apart fi	rom the central
17		system;				
18	(F)			asal <del>airways <u>airway</u>s</del>	s; of various sizes;	
19	(G)	blood pressure m				
20	<u>(H)</u>		l <mark>ectrocardiograph;</mark> ]			
21	<del>(H)</del> ( <u>I</u>	-				
22	<del>(I)</del> —	•	scope or capnograp			
23	(J)		al defibrillator (AE	<u>D); defibrillator;</u>		
24	<del>(K)</del>	EKG monitor;				
25	<u>(K)</u>	*	scope or capnograp	<u>h;</u>		
26	(L)	thermometer;				
27	(M)		-	for specific procedur	es, including hard	ware and fluids;
28	<u>(N)</u>		h working batteries			
29	<u>(O)</u>	intubation forcep	s and advanced air	way devices;		
30	<u>(P)</u>	tonsillar suction v	with back-up suction	on;		
31	<del>(N)</del> (0	-, -, -, -, -, -, -, -, -, -, -, -, -, -	sary for specific pr	ocedures; and		
32	<del>(O)</del>	advanced airways				
33	<del>(P)</del> ( <u>F</u>		•			
34	(2)   The t	following unexpired d	rugs shall be maint	ained in the facility a	and with access fro	m the operatory
35	and r	recovery rooms:				
36	(A)	epinephrine Epin	ephrine;			
37	(B)	Atropine;				

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1		<del>(C)</del>	<del>appropriate reversal agents;</del>
2		(C)	antiarrhythmic;
3		(D)	antihistamine;
4		<u>(E)</u>	antihypertensive;
5		<u>(F)</u>	bronchodilator;
6		(G)	antihypoglycemic agent:
7		(H)	vasopressor;
8		<del>(E)</del> (I)	corticosteroid;
9		<u>(J)</u>	anticonvulsant;
10		(K)	muscle relaxant;
11		<u>(L)</u>	appropriate reversal agents:
12		<del>(F)</del> (M)	nitroglycerine;
13		<del>(G)</del>	
14		<del>(H)</del> (N	antiemetic; and
15		( <u>I)(O)</u>	Dextrose.
16	(3)	The pe	ermit holder shall maintain written emergency and patient discharge protocols and training to
17		familia	arize auxiliaries in the treatment of clinical emergencies shall be provided;
18	(4)	The fo	ollowing records are maintained for at least 10 years:
19		(A)	patient's current written medical history and pre-operative assessment;
20		(B)	drugs administered during the procedure, including route of administration, dosage,
21			strength, time, and sequence of administration;
22		(C)	a sedation record; and
23		(D)	a consent form, signed by the patient or a guardian, identifying the procedure, risks and
24			benefits, level of sedation, and date signed-:
25	(5)	The se	edation record shall include:
26		(A)	base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen
27			saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient
28			recorded in real time at 15 minute intervals;
29		(B)	procedure start and end times;
30		(C)	gauge of needle and location of IV on the patient, if used;
31		(D)	status of patient upon discharge; and
32		(E)	documentation of complications or morbidity; and
33	(6)	The fo	ollowing conditions shall be satisfied during a sedation procedure:
34		(A)	the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall
35			be dedicated to patient monitoring and recording sedation data throughout the sedation
36			procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to

1		patient care and monitoring regarding general anesthesia or sedation throughout the
2		sedation procedure and is not performing the surgery or other dental procedure; and
3		(B) when IV sedation is used, IV infusion shall be administered before the commencement of
4		the procedure and maintained until the patient is ready for discharge.
5	(b) During an i	nspection or evaluation, applicants and permit holders who use intravenous sedation shall demonstrate
6	the administrat	tion of moderate pediatric conscious sedation on a live patient, including the deployment of an
7	intravenous del	ivery system, while the evaluator observes. Applicants and permit holders who do not use IV sedation
8	shall describe	the proper deployment of an intravascular intravenous delivery system to the evaluator and shall
9	demonstrate the	e administration of moderate pediatric conscious sedation on a live patient while the evaluator observes.
10	(c) During the	demonstration, all applicants and permit holders shall demonstrate competency in the following areas:
11	(1)	monitoring blood pressure, pulse, and respiration;
12	(2)	drug dosage and administration;
13	(3)	treatment of untoward reactions including respiratory or cardiac depression if applicable;
14	(4)	sterile technique;
15	(5)	use of BLS certified auxiliaries;
16	(6)	monitoring of patient during recovery; and
17	(7)	sufficiency of patient recovery time.
18	(d) During an	inspection or evaluation, the applicant or permit holder shall verbally demonstrate competency in the
19	treatment of the	e following clinical emergencies:
20	(1)	laryngospasm;
21	(2)	bronchospasm;
22	(3)	emesis and aspiration;
23	(4)	respiratory depression and arrest;
24	(5)	angina pectoris;
25	(6)	myocardial infarction;
26	(7)	hypertension and hypotension;
27	(8)	allergic reactions;
28	(9)	convulsions;
29	(10)	syncope;
30	(11)	bradycardia;
31	(12)	hypoglycemia;
32	(13)	cardiac arrest; and
33	(14)	airway obstruction. obstruction; and
34	(15)	vascular access.
35	(e) A moderate	e pediatric conscious sedation permit holder shall evaluate patients for health risks before starting any

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sedation procedure as follows:

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1	(1)	a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's
2		current medical history and medication use; or
3	(2)	a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation
4		with the patient's primary care physician or consulting medical specialist regarding the potentia
5		risks posed by the procedure.
6	(f) Patient mor	nitoring:
7	(1)	Patients who have been administered moderate pediatric conscious sedation shall be monitored for
8		alertness, responsiveness, breathing, and skin coloration during waiting periods before operative
9		procedures.
10	(2)	Vital signs shall be continuously monitored when the sedation is no longer being administered and
11		the patient shall have direct continuous supervision until oxygenation and circulation are stable and
12		the patient is recovered as defined in Subparagraph (f)(3) of this Rule and is ready for discharge
13		from the office.
14	(3)	Recovery from moderate pediatric conscious sedation shall include documentation of the following
15		(A) cardiovascular function stable;
16		(B) airway patency uncompromised;
17		(C) patient arousable and protective reflexes intact;
18		(D) state of hydration within normal limits;
19		(E) patient can talk, if applicable;
20		(F) patient can sit unaided, if applicable;
21		(G) patient can ambulate, if applicable, with minimal assistance; and
22		(H) for the special needs patient or a patient incapable of the usually expected responses, the
23		pre-sedation level of responsiveness or the level as close as possible for that patient shal
24		be achieved.
25	(4)	Before allowing the patient to leave the office, the dentist shall determine that the patient has me
26		the recovery criteria set out in Subparagraph (f)(3) of this Rule and the following discharge criteria
27		(A) oxygenation, circulation, activity, skin color, and level of consciousness are sufficient and
28		stable, and have been documented;
29		(B) explanation and documentation of written postoperative instructions have been provided
30		to a responsible adult at time of discharge; and
31		(C) a vested adult is available to transport the patient after <u>discharge</u> , <u>discharge</u> ; and <u>for the</u>
32		patient for whom a motor vehicle restraint system is required, an additional responsible
33		individual is available to attend to the patient.
34		(D) a vested adult shall be available to transport patients for whom a motor vehicle restrain
35		system is required and an additional responsible individual shall be available to attend to
36		the <u>patient</u> .
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1 History Note: Authority G.S. 90-28; 90-30.1; 90-48;

2 Eff. June 1, 2017.

3 <u>Amended Eff. August 1, 2018</u>.

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1	21 NCAC 16Q .0406 is amended as published in 32:16 NCR 1614 with changes as follows:	
2		
3	21 NCAC 16Q .0406 OFF SITE USE OF MODERATE PEDIATRIC CONSCIOUS SEDATION	N
4	PERMITS ITINERANT (MOBILE) MODERATE PEDIATRIC CONSCIOU	J <b>S</b>
5	SEDATION PERMITS	
6	The holder of a moderate pediatric conscious sedation permit may travel to the office of a licensed dentist and provi	<del>de</del>
7	moderate pediatric conscious sedation. The permit holder shall be responsible to ensure that the facility where t	he
8	sedation is administered has been inspected by the Board as required by Rule .0404 of this Section, and that t	he
9	equipment, facility, and auxiliaries meet the requirements of Rule .0405 of this Section.	
10	a) A dentist who holds a moderate pediatric conscious sedation permit from the Board and who wishes to provi	<u>de</u>
11	moderate pediatric conscious sedation or other sedation services in the office of another practitioner shall obtain	<u>1 a</u>
12	mobile moderate pediatric conscious sedation permit from the Board by completing the application requirements	<u>of</u>
13	this Rule and paying a one hundred dollar (\$100.00) application fee and a two-hundred seventy-five dollar (\$275.0	<u>(0)</u>
14	inspection fee. No mobile permit shall be required to administer moderate pediatric conscious sedation in a hospit	<u>tal</u>
15	or credentialed surgery center.	
16	(b) The permit holder shall maintain in good working order the equipment required by Rule 0405(a)(1) of this Section	<u>)n.</u>
17	(c) The unexpired medications required by Rule .0405(a)(2) of this Section shall be [immediately]-on site a	<u>nd</u>
18	available to the permit holder.	
19	(d) Before a mobile moderate pediatric sedation permit may be issued, a permit holder appointed by the Board sha	<u>all</u>
20	inspect the applicant's equipment and medications to ensure that they comply with Paragraphs (b) and (c) of this Ru	le.
21	The evaluation and on-site inspection shall be conducted as set out in Rule .0405 of this Section.	
22	(e) Prior to administering moderate pediatric conscious sedation or other sedation services at another provider's office	<u>ce,</u>
23	the mobile permit holder shall inspect the host facility within 24 business hours before each procedure and shall ensu	<u>ıre</u>
24	<u>that:</u>	
25	(1) the operatory's size and design permit emergency management and access of emergency equipme	nt
26	and personnel;	
27	(2) there is a CPR board or dental chair without enhancements suitable for providing emergen	су
28	treatment;	
29	(3) there is lighting to permit performance of all procedures planned for the facility;	
30	(4) there is suction equipment, including non-electrical back-up suction; and	
31	(5) the facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall	be
32	dedicated to patient monitoring and recording moderate pediatric conscious sedation or other	ıer
33	sedation services data throughout the sedation procedure. This Subparagraph shall not apply if t	he
34	dentist permit holder is dedicated to patient care and monitoring regarding sedation throughout t	he
35	sedation procedure and is not performing the surgery or other dental procedure.	
36	(f) Upon inspection, the permit holder shall document that the facility where the sedation procedure will be perform	<u>ed</u>
37	was inspected and that it met the requirements of Paragraph (e) of this Rule. The permit holder shall retain t	he

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- inspection and compliance record required by this Paragraph for 10 years following the procedure and provide these
- 2 records to the Board upon request.
- 3 (g) The mobile moderate pediatric conscious sedation permit shall be displayed in the host facility where it is visible
- 4 <u>to patients receiving treatment.</u>
- 5 (h) All applicants for a mobile moderate pediatric conscious sedation permit shall be in good standing with the Board.

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- 7 History Note: Authority G.S. 90-28; 90-30.1; 90-48;
- 8 Eff. June 1, 2017.
- 9 <u>Amended Eff. August 1, 2018</u>.

1 21 NCAC 16Q .0407 is amended as published in 32:16 NCR 1615 with changes as follows: 2 3 21 NCAC 16Q .0407 ANNUAL RENEWAL OF MODERATE PEDIATRIC CONSCIOUS SEDATION 4 PERMIT REQUIRED 5 (a) Moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time as dental 6 licenses by the dentist paying a one-one-hundred dollar (\$100.00) fee and completing the application requirements in 7 this Rule. 8 (b)—If the completed renewal application and renewal fee are not received before January 31 of each year, a one 9 hundred (\$100.00) fifty (\$50.00) dollar late fee shall be paid. 10 (b) Itinerant moderate pediatric conscious sedation permits shall be renewed by the Board annually at the same time 11 as dental licenses by paying a one-one-hundred dollar (\$100.00) fee and completing the application requirements in 12 this Rule. If the completed permit renewal application and renewal fee are not received before January 31 of each 13 year, a fifty dollar (\$50.00) late fee shall be paid. 14 (c) Any dentist who fails to renew a moderate pediatric conscious sedation permit or itinerant moderate pediatric 15 conscious sedation permit before March 31 of each year shall complete a reinstatement application, pay the renewal 16 fee, late fee, and comply with all conditions for renewal set out in this Rule. Dentists whose sedation permits have 17 been lapsed for more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement 18 process. 19 (d) A dentist who administers moderate pediatric conscious sedation in violation of this Rule shall be subject to the 20 penalties prescribed by Rule .0701 of this Subchapter. 21 (e) As a condition for renewal of the moderate pediatric conscious sedation permit, permit and itinerant moderate 22 pediatric conscious sedation permit, the permit holder shall meet the clinical and equipment requirements of Rule 23 .0405 of this Section and shall document the following: 24 (1) six hours of continuing education each year in one or more of the following areas, which-may shall 25 be counted toward fulfillment of the continuing education required each calendar year for license 26 renewal: 27 (A) sedation; 28 (B) medical emergencies; 29 (C) monitoring IV sedation and the use of monitoring equipment; 30 (D) pharmacology of drugs and agents used in IV sedation; 31 (E) physical evaluation, risk assessment, or behavioral management; or 32 (F) airway management; 33 (2) unexpired PALS certification, which shall not count towards the six hours of continuing education 34 required in Subparagraph (e)(1) of this rule; 35 (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, year;

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1	(4)	that the permit holder and all auxiliaries involved in sedation procedures have read the practice's
2		emergency manual in the preceding year; and
3	(5)	that all auxiliaries involved in sedation procedures have completed BLS certification and three hours
4		of continuing education annually in any of the areas set forth in Subparagraph (e)(1) of this Rule.
5	(f) All permit l	holders applying for renewal of a moderate pediatric conscious sedation permit or itinerant moderate
6	pediatric consc	ious sedation permit shall be in good standing and their office shall be subject to inspection by the
7	Board.	
8		
9	History Note:	Authority G.S. 90-28; 90-30.1; 90-31; 90-39(12); 90-48;
10		Eff. June 1, 2017.
11		Amended Eff. August 1, 2018.

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21 NCAC 16Q .0408 is amended as published in 32:16 NCR 1615 with changes as follows:

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

- 5 (a) When an evaluation or on-site inspection is required, the Board shall designate one or more qualified persons to
- 6 serve as evaluators, each of whom has administered moderate pediatric sedation for at least three years preceding the
- 7 evaluation or inspection. Training in moderate pediatric sedation shall not count toward the three years.
- 8 (b) An inspection fee of three hundred two-hundred seventy-five dollars (\$375.00) (\$275.00) shall be due 10 days
- 9 after the dentist receives notice of the inspection of each additional location at which the dentist administers moderate
- 10 pediatric sedation.
- 11 (c) Any dentist-member of the Board may observe or consult in any evaluation or inspection.
- 12 (d) The inspection team shall determine compliance with the requirements of the rules in this Subchapter, as
- applicable, by assigning a grade of "pass" or "fail."
- 14 (e) Each evaluator shall report his or her recommendation to the Board's Anesthesia and Sedation Committee, setting
- 15 forth the details supporting his or her conclusion. The Committee shall not be bound by these recommendations. The
- 16 Committee shall determine whether the applicant has passed the evaluation or inspection and shall notify the applicant
- in writing of its decision.
- 18 (f) An applicant who fails an inspection or evaluation shall not receive a permit to administer moderate pediatric
- 19 sedation. If a permit holder fails an evaluation, the permit shall be summarily suspended as provided by G.S. 150B
- 20 <del>3(e).</del> If a permit holder's facility fails an inspection, no further <u>moderate pediatric</u> sedation procedures shall be
- 21 performed at the facility until it passes a re-inspection by the Board.
- 22 (g) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of
- 23 receiving the notice of failure. The request shall be directed to the Board in writing and include a statement of the
- 24 grounds supporting the re-evaluation or re-inspection. The Board shall require the applicant to receive additional
- training prior to the re-evaluation to address the areas of deficiency determined by the evaluation. The Board shall
- 26 notify the applicant in writing of the need for additional training.
- 27 (h) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved in the failed
- 28 evaluation or inspection.

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- 30 *History Note:* Authority G.S. 90-30.1; 90-39; 90-48;
- 31 Eff. April 1, 2016.
- 32 <u>Amended Eff. August 1, 2018.</u>

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1	21 NCAC 16Q .0501 is amended as published in 32:16 NCR 1616 with changes as follows:
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3	21 NCAC 16Q .0501 ANNUAL RENEWAL REQUIRED
4	(a) General anesthesia and all sedation permits shall must be renewed by the Board annually. Such renewal shall be
5	accomplished in conjunction with the license renewal process, and applications for permits shall be made by the permit
6	holder at the same time as applications for renewal of licenses. A one one-hundred dollar (\$100.00) annual permit
7	renewal fee shall be paid by the permit holder at the time of renewal. renewal and is in addition to the annual license
8	renewal fee.
9	(b) All sedation permits shall be subject to the same renewal deadlines as are dental practice licenses, in accordance
10	with G.S. 90-31. If the permit renewal application is not received by the date specified in G.S. 90-31, continued
11	administration of general anesthesia or any level of conscious sedation shall be unlawful and shall subject the dentist
12	to the penalties prescribed by Section .0700 of this Subchapter.
13	(c) As a condition for renewal of the general anesthesia permit, permit or itinerate general anesthesia permit, the
14	permit holder shall meet the requirements of 21 NCAC 16Q .0202 Rule .0207 of this Subchapter. and document
15	current, successful completion of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other
16	equivalent course, and auxiliary personnel shall document annual, successful completion of basic life support (BLS)
17	training.
18	(d) As a condition for renewal of the moderate conscious sedation permit or itinerate moderate pediatric-conscious
19	sedation permit, the permit holder shall meet the requirements of 21 NCAC 16Q .0302 and: Rule .0305 of this
20	Subchapter.
21	(1) document annual, successful completion of BLS training and obtain three hours of continuing
22	education each year in one or more of the following areas, which may be counted toward fulfillment
23	of the continuing education required each calendar year for license renewal:
24	(A) sedation;
25	(B) medical emergencies;
26	(C) monitoring IV sedation and the use of monitoring equipment;
27	(D) pharmacology of drugs and agents used in IV sedation;
28	(E) physical evaluation, risk assessment, or behavioral management;
29	(F) audit ACLS/Pediatric Advanced Life Support (PALS) courses; and
30	(G) airway management; or
31	(2) document current, successful completion of ACLS training or its age specific equivalent, or other
32	equivalent course and annual successful completion of BLS.
33	(e) As a condition for renewal of the moderate pediatric conscious sedation permit holders or itinerate moderate
34	pediatric conscious sedation permit, the permit holder shall meet the requirements of Rule .0407 of this Subchapter.
35	must have current PALS at all times.
36	(f) As a condition for renewal of the minimal conscious sedation permit and the moderate conscious sedation permit

limited to oral routes and nitrous oxide inhalation, the permit holder shall meet the requirements of 16Q .0402 Rule

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1 .0402 of this Subchapter and shall document annual, successful completion of BLS training and obtain six hours of 2 continuing education every two years in one or more of the following areas, which may be counted toward fulfillment 3 of the continuing education required each calendar year for license renewal: 4 pediatric or adult sedation; (1) 5 (2) medical emergencies; 6 (3) monitoring sedation and the use of monitoring equipment; 7 **(4)** pharmacology of drugs and agents used in sedation; 8 (5) physical evaluation, risk assessment, or behavioral management; or 9 (6)audit ACLS/PALS courses; and 10 (7) airway management. 11 (g) Any dentist who fails to renew a general anesthesia or sedation permit on or before March 31 of each year must 12 complete a reinstatement application, pay the one hundred dollar (\$100.00) renewal fee and a one hundred fifty dollar 13 (\$100.00) (\$50.00) penalty and comply with all conditions for renewal set out in this Rule for the permit sought. 14 Dentists whose anesthesia or sedation permits have been lapsed for more than 12 calendar months must pass a an 15 evaluation and facilities inspection and must pay the application evaluation and inspection fee set forth in the applicable rules of this Subchapter as part of the reinstatement process. 16 17 18 Authority G.S. 90-28; 90-30.1; 90-48; History Note: 19 Eff. February 1, 1990; 20 Amended Eff. August 1, 2002;

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

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

Temporary Amendment Eff. December 11, 2002;

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1	21 NCAC 16Q .0502 is repealed as published in 32:16 NCR 1616 as follows:
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3	21 NCAC 16Q .0502 PAYMENT OF FEES
4	
5	History Note: Authority G.S. 90-28; 90-30.1;
6	Eff. February 1, 1990;
7	Transferred and Recodified from 16Q .0402 to .0502;
8	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,
9	<u>2018.</u>
10	Repealed Eff. August 1, 2018.

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