Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)
Attachments: 21 NCAC 16Q .0103.docx; 21 NCAC 16Q .0104.docx; 21 NCAC 16Q .0703.docx; 01.2023 - Dental Examiners - 21 NCAC 16Q_Responses.docx; 21 NCAC 16Q .0302.docx; 21 NCAC 16Q .0405.docx; 21 NCAC 16Q .0202.docx

From: Dauna Bartley <dauna@brockerlawfirm.com>
Sent: Monday, January 16, 2023 9:15 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Doug Brocker <doug@brockerlawfirm.com>; File <file@brockerlawfirm.com>; Rules, Oah <oah.rules@oah.nc.gov>
Subject: RE: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)

Good morning Brian,

I hope you had a good weekend!

I am attaching rewritten Rules 21 NCAC 16Q .0103, .0104, and .0703, per your notes below and our conversation on Friday afternoon. The specific changes are noted below in response to your comments in bold. For your convenience, I am also resending our original response, rewritten 16Q .0302 and .0405, and 16Q .0202 (no changes), so that you have everything in one place.

Thank you again for your assistance! Please let me know if you need anything else.

Dauna

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0103

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (a), line 6, would it change the meaning to revise as follows: "… or supervising a CRNA or an RN employed to administer…" This seems simpler. The suggested language would change the meaning and cannot be used. "Administer" and "deliver" are defined terms, and RNs are not authorized to "administer" medications. CRNAs may administer, and RNs may only deliver medications.

Either way, in (a), please add "an" prior to "RN". Done.

In (b), line 9, what is a "credentialed surgery center"? Credentialed how? Clarified to define a "credentialed surgery center."

In (c)(1)(B), line 19, what are the "enhancements" discussed here? Please define. Omitted the term "without enhancements."

In (C), line 12, (D), line 22, (N), line 35, and (R), p.2, line 2, what does "necessary for specific procedures" mean? This seems rather vague. Clarified to "necessary for the procedure to be performed" in each instance.

In (d)(2), line 15, and (3), line 17, what does it mean to be "BLS certified"? I see in 16Q .0101 that BLS means Basic Life Support, but I'm unclear on the certification process. BLS certification is a term familiar to the Board's regulated public. It is clear and unambiguous, and adding a definition or explanation of the certification process is unnecessary. It would be negligent at best for a dentist not to know what it means to be BLS certified. In addition, the terms "BLS certified" and "BLS certification" currently appear 21 times across 13 different rules in Subchapter 16Q, including rules reviewed and approved by the Rules Review Commission as recently as 2021. Adding verbiage to this rule to explain "BLS certified" would create confusion and ambiguity with respect to whether it means something new and different in this rule than in all the other rules where it appears.

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

In (d)(4)(C), line 28, add a comma following "holder." A comma after "holder" and before "who" would change the meaning of this sentence in a way contrary to the intention of the Rule. In the phrase "under the supervision and direction of the permit holder who shall ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit," the word "who" refers to the permit holder in accordance with the intention of the Rule to impose the obligation on the permit holder to ensure the level of sedation does not exceed the level of his or her permit.

However, adding a comma after "holder" would result in the phrase "under the supervision and direction of the permit holder" being set off as a nonrestrictive (nonessential) clause, and the word "who" would refer back to the CRNA who is the subject of the main sentence. That would not reflect the intention of the Rule, and at the very least it would create ambiguity in the Rule regarding exactly who is supposed to "ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit."

Also on line 29, add "of" between "level" and "sedation." Done.

On line 30, is there a better way to phrase "allowed by the permit holder's permit"? Maybe just "allowed by the permit"? It is phrased "allowed by the permit holder's permit" to ensure that is no ambiguity regarding which/whose permit sets the sedation level limitation.

In (5), line 32, "Rule" should be plural. Please check throughout these Rules, as I saw this multiple times. I believe "Rule" should be singular in all of these instances. Each one is a list of alternatives using "or". For example, this line says, "The permit holder shall satisfy any additional facility requirements applicable to the level of the permit, as set out in Rule .0202, .0206, .0302, or .0405 of this Subchapter." Because these are alternatives ("or") and not cumulative ("and"), each must be able to stand alone. It would be incorrect to say, "as set out in Rules .0405 of this Subchapter." The correct approach is to say, "as set out in Rule .0405 of this Subchapter." Therefore, "Rule" is the proper form.

In (e), line 33-34, it isn't necessary to say "but not limited to", "include" is fine on it's own. However, "include" has an open-ended connotation, so what else, beyond (1)-(3) must the permit holder evaluate? Done - omitted "but not limited to". Subparagraphs (1)-(3) are the requirements that "must" be included as part of the mandatory pre-op evaluation. There are no other specific mandatory items. The permit holder should evaluate other factors as needed based on the patient and the procedure.

In (e)(1)-(3), the first word of each item should be in a different tense for grammatical consistency. Consider "evaluating" or "evaluation of" instead of "evaluate". Done.

In (e)(2), line 37, are all sedation dentistry procedures elective? If not, is a different standard applicable to non-elective dental procedures? This standard applies to both elective and nonelective sedation procedures. The permit holder must evaluate food and fluid intake following the ASA's pre-operative fasting guidelines for elective procedures.

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

In (e)(3), p.4, line 4, "Rule" should be plural. Please see response above. "Rule" is properly written as singular here.

In (f)(4), line 13, I think "base line" should be one word. Done.

In (f)(7), line 24, "Rule" should be plural. Please see response above. "Rule" is properly written as singular here.

In (g)(1), line 27, does the term "vital signs" mean the same thing as "vital sign information" in (f)(5)? If not, what are the differences? It means the same thing.

In (h), p.5, line 11, add a comma after "history." Done.

In (h)(5), line 33, "Rule" should be plural. Please see response above. "Rule" is properly written as singular here.

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0104

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (b), line 10, please delete "but not limited to". However, as "including" has an open-ended connotation, what beyond the 4 things listed in (b) must the dentist demonstrate competency in? Done – changed to "including in the following areas". Subparagraphs (1)-(4) are the specific areas that "must" be covered as part of the required demonstration of competency administering anesthesia or sedation in accordance with the level of the permit.

In (c), line 18, are the "topics set forth in Paragraph (b)" "general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation"? Please clarify. Clarified to "Subparagraphs (b)(1)-(4)."

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0302

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (a), line 6, would it change the meaning to revise as follows: "… or supervising a CRNA or an RN employed to administer…" This seems simpler. The suggested language would change the meaning and cannot be used. "Administer" and "deliver" are defined terms, and RNs are not authorized to "administer" medications. CRNAs may administer, and RNs may only deliver medications.

Either way, in (a), please add "an" prior to "RN". This provision is phrased "supervising any CRNA employed to administer or RN employed to deliver…" Grammatically, "any" refers to both CRNA and RN. Adding "an" prior to "RN" would be incorrect.

In (c)(2), line 15, is there a better way to phrase "evaluated by … consultation"? Not one that is apparent. The phrase conveys the intended meaning in a clear, unambiguous fashion.

In (c)(2), line 16, is "consulting" a noun or adjective? i.e. does this mean a "consulting medical specialist" as written, or was this supposed to mean that the permit holder should "consult with" the patient's medical specialist. Just checking. "Consulting" is an adjective – a "consulting medical specialist."

In (d), line 21, "contraindicated" by whom? The manufacturer? Yes. Clarified to "determined by the manufacturer to be contraindicated for use…"

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0405

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (c), line 11, what is "BLS-certified"? Same question as in Rule .0103. Same response as in Rule .0103. BLS certification is a term familiar to the Board's regulated public. It is clear and unambiguous, and adding a definition or explanation of the certification process is unnecessary. It would be negligent at best for a dentist not to know what it means to be BLS certified. In addition, the terms "BLS certified" and "BLS certification" currently appear 21 times across 13 different rules in Subchapter 16Q, including rules reviewed and approved by the Rules Review Commission as recently as 2021. Adding verbiage to this rule to explain "BLS-certified" would create confusion and ambiguity with respect to whether it means something new and different in this rule than in all the other rules where it appears.

In (e)(2), line 21, is there a better way to phrase "evaluated by … consultation"? Not one that is apparent. The phrase conveys the intended meaning in a clear, unambiguous fashion.

In (e)(2), line 22, is "consulting" a noun or adjective? i.e. does this mean a "consulting medical specialist" as written, or was this supposed to mean that the permit holder should "consult with" the patient's medical specialist. Just checking. "Consulting" is an adjective – a "consulting medical specialist."

In (f)(3), line 28, mostly out of curiosity, but why must a hand or foot be left exposed? For patient monitoring and safety.

In (f)(4), line 29, what does "attended" mean? Clarified to "under observation by the permit holder or a BLS-certified auxiliary."

In (g)(2), line 33, "contraindicated" by whom? The manufacturer? Yes. Clarified to "determined by the manufacturer to be contraindicated for use…"

In (h)(3), line 6, add "the" between "to" and "person." Done.

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

Also, what do you mean by "car seat"? It seems to me this means something other than a seat in a car. Clarified to "child safety seat."

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0703

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (a), line 4, I assume "sedation" refers to both moderate conscious sedation and moderate pediatric conscious sedation? I haven't seen where one term was used to capture all kinds of sedation elsewhere in these rules. The term "sedation" is used to refer to all conscious sedation permit levels (moderate, pediatric, and minimal) in Sections .0100 and .0700 (see 16Q .0101, .0102, .0703, and .0704).

In (a), line 10, the paragraph reads as if only general anesthesia permit holders have to file the adverse occurrence report. Please clarify and revise as necessary. The first sentence of Paragraph (a), line 4-7, sets out the requirement that a dentist holding a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board as specified. The Board's regulated public is familiar with this requirement. The second and third sentences, lines 7-10, set out the requirement that permit holders shall cease administration of general anesthesia or sedation until the Board has taken the specified action. Line 10 does not repeat the requirement to file an adverse occurrence report, as that is unnecessary. Please let us know if you have further questions.

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

15A NCAC 10B .0201 is readopted as published in 37:06 NCR 449 as follows:

15A NCAC 10B .0201 PROHIBITED TAKING AND MANNER OF TAKE

(a) ~~It is unlawful for any~~ No person ~~to~~ shall take, or have in their possession, any wild animal or wild bird listed in this Section except during the open seasons and in accordance with the limits herein prescribed, or as prescribed by 15A NCAC 10B .0300 pertaining to trapping or 15A NCAC 10D applicable to game lands managed by the Wildlife Resources Commission, unless otherwise permitted by law. ~~Lawful seasons and bag limits for each species apply beginning with the first day of the listed season and continue through the last day of the listed season, with all dates being included. When any hunting season ends on a January 1 that falls on a Sunday, that season shall be extended to Monday, January 2.~~

(b) Lawful seasons and bag limits for each species apply beginning with the first day of the [~~listed~~] established season and continue through the last day of the listed season, with all dates being included.

(c) When any hunting season ends on a January 1 that falls on a Sunday, that season shall be extended to Monday, January 2.

~~(b)~~ (d) On Sundays, the following manners of take shall be allowed subject to the restrictions in G.S. 103-2: [~~hunting on private lands shall be allowed under the following conditions:~~]

(1) archery equipment as described in 15A NCAC ~~10B .0116, falconry, and~~ 10B .0116;

(2) falconry; and

(3) dogs where and when allowed the other days of the ~~week are lawful methods of take, except as prohibited in G.S. 103-2:~~ week.

~~(2) firearms are lawful methods of take when used as described in G.S. 103-2; and~~

~~(3) migratory game birds may not be taken.~~

(e) Migratory game birds shall not be taken on Sundays.

~~(c) On Sundays, hunting on public lands is allowed with the following restrictions:~~

~~(1) only falconry and dogs used in conjunction with falconry are lawful methods of take; and~~

~~(2) migratory game birds may not be taken~~.

~~These restrictions do not apply to military installations under the exclusive jurisdiction of the federal government.~~

~~(e) On Sundays, the following shall be prohibited on public game lands:~~

~~(1) hunting with a firearm between 9:30 AM and 12:30 PM;~~

~~(2) the use of a firearm to take deer that are run or chased by dogs;~~

~~(3) hunting with a firearm within 500 yards of a place of religious worship, as defined by G.S. 32 54.1(b), or any accessory structure thereof; and~~

~~(4) hunting migratory game birds~~

(f) Sunday hunting restrictions in paragraph (d) of this Rule shall not apply to military reservations. ~~installations under the exclusive jurisdiction of the federal government.~~

~~(d)~~ ~~(f)~~ (g) Those animals not classified as game animals in G.S. 113-129(7c), and for which a season is set under this Section, may be taken during the hours and methods authorized for taking game animals.

~~(g)~~ (h) No person shall possess or use any substance or material that contains or is labeled as containing any excretion collected from a cervid, including feces, urine, blood, gland oil, or other bodily fluid for the purposes of taking or attempting to take, attracting, or scouting wildlife. This prohibition shall not apply to the following substances:

(1) Products containing synthetic analogs of cervid excretions and labeled as such.

(2) Products consisting of or containing natural substances collected by a hunter from a legally harvested cervid in North Carolina.

(3) Natural substances collected from facilities within North Carolina that have a valid Farmed Cervid License from the North Carolina Department of Agriculture and Consumer Services and are labeled as such.

(4) Natural deer urine products containing excretions from facilities within North Carolina that have a valid Farmed Cervid License from the North Carolina Department of Agriculture and Consumer Services and are labeled as such.

(5) Natural deer urine products containing excretions from facilities that meet all the following requirements and are labeled as such:

(A) Determined to be free of chronic wasting disease (CWD) based on testing by an independent laboratory using a method that may help detect the presence of CWD prions.

(B) Complies with a federally approved CWD herd certification program and any federal CWD protocols.

(C) Participates in additional herd management requirements as specified by the Wildlife Resources Commission.

~~(e)~~ ~~(h)~~ (i) Where ~~local~~ laws with local effect govern hunting, or ~~are in~~ conflict with this Subchapter, ~~the local~~ that law shall prevail.

History Note: *Authority S.L 2021-176; G.S. 103-2; 113-291.1(a); 113-134; 113-291.2; 113-291.3;*
Eff. February 1, 1976;
Amended Eff. February 1, 2023; May 1, 2016; August 1, 2012; July 10, 2010; July 1, 1996; July 1, 1987;

15A NCAC 10F .0361 is amended as published in 37:06 NCR 458-459 as follows:

15A NCAC 10F .0361 WILKES COUNTY

(a) Regulated Areas. This Rule shall apply to ~~those waters within 50 yards of any marked boat launching area, bridge, dock, pier, marina, boat storage structure, or boat service area located~~ the following waters on W. Kerr Scott Reservoir in Wilkes ~~County.~~ County:

(1) the waters of Dam Site Park Cove at Dam Site Shelter, 499 Reservoir Road, Wilkesboro, south of a line at the mouth of the cove from a point on the east shore at 36.13090 N, 81.22955 W to a point on the west shore at 36.13040 N, 81.23122;

(2) the waters of the cove at Skyline Marina, 4008 W. N.C. Hwy 268, Wilkesboro, south of a line at the mouth of the cove from a point on the east shore at 36.12738 N, 81.23530 W to a point on the west shore at 36.12608 N, 81.23847 W;

(3) the waters of the cove north and west of Berry Mountain Park, 4732 W. N.C. Hwy 268, Wilkesboro, south of a line at the mouth of the cove from a point on the east shore at 36.12558 N, 81.24025 W to a point on the west shore at 36.12545 N, 81.24245 W, surrounding the Berry Mountain swim beach, and to the southwest to the end of the cove;

(4) within 50 yards of the Boomer Park boat ramp, 400 Boomer Road, Boomer;

(5) within 50 yards of the Keowee boat ramp, 7659 N.C. Hwy 268, Boomer;

(6) the waters of the cove where Smithey's Creek boat ramp and Fort Hamby boat ramp are located, northwest of a line at the mouth of the cove from a point on the east shore at 36.12612 N, 81.26129 W to a point on the west shore at 36.12361 N, 81.26404 W;

(7) the waters within 50 yards north and 50 yards south of the N.C. Hwy 268 Bridge, at 36.09902 N, 81.28070 W;

(8) the waters within 50 yards surrounding the Boomer Park Beach Swim Area located at 400 Boomer Road, Boomer;

(9) the waters within 50 yards surrounding the Fort Hamby Swim Area located at 36.12314 N, 81.26870 W, near 1534 S. Recreation Road, Wilkesboro; and

(10) the waters of the cove where the Warrior Creek Swim Area is located, southwest of a line at the mouth of the cove from a point on the south shore at 36.10494 N, 81.28304 W to a point on the north shore at 36.10591 N, 81.28412 W.

(b) Swimming Areas. No person operating or responsible for the operation of a vessel shall permit it to enter the waters of the following swim areas:

(1) the waters of the Fort Hamby Swim Area located at 36.12314 N, 81.26870 W, [~~at~~] near 1534 S. Recreation Road, Wilkesboro;

(2) the waters of Warrior Creek Swim Area located at 36.10367 N, 81.28664 W, at 7659 W. Hwy 268, Boomer;

(3) the waters of Boomer Park Beach Swim Area located at 36.09271 N, 81.27967 W, 400 Boomer Road, Boomer;

(4) the waters of the Berry Mountain Park Swim Beach located at 36.12498 N, 81.24010 W, 4732 W. N.C. Hwy 268, Wilkesboro; and

(5) the waters of the Bandit's Roost Park Swim Area located at 36.12425 N, 81.25172 W, 667 Jess Walsh Road, Wilkesboro.

(c) Safety Zone. Except for authorized persons and vessels, no entry shall be allowed in the waters 50 yards downstream from the W. Kerr Scott Dam and Intake Tower.

(d) Speed Limit. No person shall operate a vessel at greater than no wake speed within the regulated areas described in Paragraph (a) of this Rule.

(e) Placement of Markers. The Wilkes County Board of Commissioners and the U.S. Army Corps of Engineers shall be the designated agencies for placement and maintenance of the markers implementing this Rule, subject to the authority of the U.S. Army Corps of Engineers.

~~(b) Speed Limit. No person shall operate a vessel at greater than no wake speed within any of the regulated area described in Paragraph (a) of this Rule.~~

~~(c) Placement of Markers. The Wilkes County Board of Commissioners shall be the designated agency for placement of the markers implementing this Rule.~~

History Note: *Authority G.S. 75A-3; 75A-15;*
Eff. September 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 6, 2016;
Amended Eff. February 1, 2023; October 1, 2018.

15A NCAC 10I .0104 is amended as published in 37:6 NCR 451-452 as follows:

15A NCAC 10I .0104 THREATENED SPECIES LISTED

(a) The following species of resident wildlife shall be designated as federally-listed threatened species:

(1) Amphibians: ~~None Listed At This Time.~~ Neuse River waterdog (Necturus lewisi).

(2) Birds:

(A) Eastern black rail (Laterallus jamaicensis jamaicensis);

(B) Piping plover (Charadrius melodus melodus);

(C) Red knot (Calidris canutus rufa); and

(D) Wood stork (Mycteria americana).

(3) Crustacea: None ~~Listed At This Time.~~ listed.

(4) Fish:

(A) Spotfin chub (Erimonax monachus); and

(B) Waccamaw silverside (Menidia extensa).

(5) Mammals: Northern long-eared bat (Myotis septentrionalis)

(6) Mollusks:

(A) Atlantic pigtoe (Fusconaia masoni);

~~(A)~~(B) Noonday globe (Patera clarki nantahala); and

~~(B)~~(C) Yellow lance (Elliptio lanceolata).

(7) Reptiles:

(A) Bog turtle (Glyptemys muhlenbergii);

(B) American alligator (Alligator mississipiensis);

(C) Green ~~seaturtle~~ sea turtle (Chelonia mydas); and

(D) Loggerhead ~~seaturtle~~ sea turtle (Caretta caretta).

(b) The following species of resident wildlife are designated as State-listed threatened species:

(1) Amphibians:

(A) Eastern tiger salamander (Ambystoma tigrinum tigrinum);

(B) Green salamander (Aneides aeneus);

(C) Junaluska salamander (Eurycea junaluska);

(D) Long-tailed salamander (Eurycea ~~longicauda~~ longicauda);

(E) Mabee's salamander (Ambystoma mabeei);

(F) Pine Barrens tree frog (Hyla andersonii); and

(G) Wehrle's salamander (Plethodon wehrlei).

(2) Birds:

(A) Bald eagle (Haliaeetus leucocephalus);

(B) Caspian tern (Hydroprogne caspia);

(C) Gull-billed tern (Gelochelidon nilotica aranea); and

(D) Northern saw-whet owl (Aegolius acadicus).

(3) Crustacea:

(A) Broad River spiny crayfish (Cambarus spicatus);

(B) French Broad crayfish (Cambarus reburrus);

(C) Pamlico crayfish (Procambarus medialis);

(D) Sandhills crayfish (Procambarus pearsei); and

(E) South Mountains crayfish (Cambarus franklini).

(4) Fish:

(A) Bigeye jumprock (Moxostoma ariommum);

(B) Blotched chub (Erimystax insignis)

~~(B) Carolina madtom (Noturus furiosus);~~

(C) Carolina pygmy sunfish (Elassoma boehlkei);

(D) Carolina redhorse (Moxostoma sp.);

(E) Ironcolor shiner (Notropis chalybaeus)

~~(E)~~(F) Least brook lamprey (Lampetra aepyptera);

~~(F)~~(G) Logperch (Percina caprodes);

~~(G)~~(H) Mimic shiner (Notropis volucellus);

~~(H)~~(I) Rosyface chub (Hybopsis rubrifrons);

~~(I)~~(J) Sharphead darter (Etheostoma acuticeps);

(K) Santee chub (Cyprinella zanema)

~~(J)~~(L) Sicklefin redhorse (Moxostoma sp.);

(M) Thicklip chub (Cyprinella labrosa)

~~(K)~~(N) Turquoise darter (Etheostoma inscriptum); and

~~(L)~~(O) Waccamaw darter (Etheostoma perlongum).

(5) Mammals:

(A) Eastern woodrat (Neotoma floridana floridana);

(B) Rafinesque's big-eared bat (Corynorhinus rafinesquii rafinesquii); and

(C) Red wolf (Canis rufus).

(6) Mollusks:

(A) Alewife floater ~~(Utterbackiana~~ (Utterbackiana implicata);

(B) Big-tooth covert (Fumonelix jonesiana);

(C) Cape Fear threetooth (Triodopsis soelneri);

(D) Eastern lampmussel (Lampsilis radiata);

(E) Eastern pondmussel (Ligumia nasuta);

(F) Engraved covert (Fumonelix orestes);

(G) Mountain creekshell (Villosa vanuxemensis);

(H) Notched rainbow (Villosa constricta);

(I) Rainbow (Villosa iris);

(J) Roan supercoil (Paravitrea varidens);

(K) Sculpted supercoil (Paravitrea ternaria);

(L) Smoky Mountain covert (Inflectarius ferrissi);

(M) Creeper (Strophitus undulatus);

(N) Tidewater mucket (Leptodea ochracea);

(O) Triangle floater (Alasmidonta undulata); and

(P) Waccamaw ambersnail (Catinella waccamawensis).

(7) Reptiles:

(A) Northern pine snake (Pituophis melanoleucus melanoleucus); and

(B) Southern hognose snake (Heterodon simus).

History Note: *Authority G.S. 113-134; ~~113-291.2; 113-292;~~ 113-333;*
Eff. March 17, 1978;
Amended Eff. June 1, 2008; April 1, 2001; November 1, 1991; April 1, 1991; June 1, 1990; September 1, 1989;
Temporary Amendment Eff. February 27, 2015;
Amended Eff. October 1, 2017; July 1, 2016; August 1, 2016;
Readopted Eff. October 1, 2021.
Amended Eff February 1, 2023.

21 NCAC 16Q .0103 is adopted with changes as published in 37:07 NCR 543-45 as follows:

21 NCAC 16Q .0103 EQUIPMENT, PERSONNEL, AND CLINICAL REQUIREMENTS TO ADMINISTER ANESTHESIA OR MODERATE SEDATION

(a) Before administering general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation ("anesthesia or moderate sedation"), or supervising a CRNA to administer or an RN employed to deliver anesthesia or moderate sedation, a dentist shall hold an unexpired permit issued by the Board in accordance with this Subchapter permitting the dentist to administer that level of sedation.

(b) Before performing sedation procedures in a facility other than a hospital or credentialed surgery center, the permit holder shall ensure that the Board has been notified that the permit holder intends to administer anesthesia or moderate sedation at the facility and shall ensure that the facility has passed a facility inspection by the Board in accordance with this Subchapter. For purposes of these Rules, "credentialed surgery center" means a surgical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities.

(c) The permit holder shall ensure that the facility where the sedation procedure is to be performed meets the following requirements at the time of the procedure:

(1) The permit holder shall ensure the facility is equipped as follows and that the following listed equipment is immediately available and accessible from the operatory and recovery rooms:

(A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;

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

(C) lighting as necessary for the procedure to be performed, ~~specific procedures~~ and back-up lighting;

(D) suction equipment as necessary for the procedure to be performed, ~~specific procedures,~~ including non-electrical back-up suction;

(E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients, and back-up E-cylinder portable oxygen tank apart from the central system;

(F) small, medium, and large oral and nasal airways;

(G) a blood pressure monitoring device;

(H) an EKG monitor;

(I) a pulse oximeter;

(J) an automatic external defibrillator (AED);

(K) a capnograph;

(L) a precordial or pretracheal stethoscope;

(M) a thermometer;

(N) vascular access set-up as necessary for the procedure to be performed, ~~specific procedures,~~ including hardware and fluids;

(O) a laryngoscope with working batteries;

(P) intubation forceps and advanced airway devices;

(Q) tonsillar suction with back-up suction;

(R) syringes as necessary for the procedure to be performed; ~~specific procedures;~~ and

(S) tourniquet and tape.

(2) The permit holder shall ensure all monitoring and other equipment in the facility receives preventive maintenance no less frequently than once per year, including safety and function checks per the manufacturers' recommendations. The permit holder shall maintain documentation of all preventive maintenance performed, and shall ensure equipment is replaced upon its expiration or as clinically required.

(3) The permit holder shall ensure the following unexpired drugs are immediately available and are accessible from the operatory and recovery rooms:

(A) epinephrine;

(B) atropine;

(C) an antiarrhythmic;

(D) an antihistamine;

(E) an antihypertensive;

(F) a bronchodilator;

(G) an antihypoglycemic agent;

(H) a vasopressor;

(I) a corticosteroid;

(J) an anticonvulsant;

(K) appropriate reversal agents;

(L) nitroglycerine; and

(M) an antiemetic.

(4) The permit holder shall maintain written emergency and patient discharge protocols accessible from the operatory and recovery rooms. The written emergency manual shall include a protocol for activation of emergency management services for life-threatening complications along with the information set out in Rule .0101(17) of this Section.

(5) The permit holder shall satisfy any additional facility requirements applicable to the level of the permit, as set out in Rule .0202, .0206, .0302, or .0405 of this Subchapter.

(d) The permit holder shall ensure that the following staffing, education, and training requirements are met prior to performing a sedation procedure:

(1) The permit holder shall provide training to familiarize all auxiliaries in the treatment of clinical emergencies including the following, and shall review and practice responding to clinical emergencies with all auxiliaries as a team and in person every six months;

(A) airway obstruction;

(B) allergic reactions;

(C) angina pectoris;

(D) apnea;

(E) bradycardia;

(F) bronchospasm;

(G) cardiac arrest;

(H) convulsions;

(I) emesis and aspiration;

(J) hypertension;

(K) hypoglycemia;

(L) hypotension;

(M) hypoventilation and respiratory arrest;

(N) hypoxemia and hypoxia;

(O) laryngospasm;

(P) myocardial infarction; and

(Q) syncope.

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

(3) Except as set out in Subparagraph (d)(4) of this Rule, the permit holder performing the surgery or other dental procedure shall ensure that an RN or a BLS-certified auxiliary is dedicated to patient monitoring and recording anesthesia or sedation data throughout the sedation procedure.

(4) The requirement set out in Subparagraph (d)(3) of this Rule shall not apply if the permit holder or an additional sedation provider is dedicated to patient care and monitoring regarding anesthesia or moderate sedation throughout the sedation procedure and is not performing the surgery or other dental procedure. The additional sedation provider shall be:

(A) a dentist holding a permit or mobile permit in satisfaction of this Subchapter to administer the anesthesia or sedation level at the facility where the sedation procedure is performed;

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

(C) a CRNA licensed and practicing in accordance with the rules of the North Carolina Board of Nursing, under the supervision and direction of the permit holder who shall ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit.

(5) The permit holder shall satisfy any additional staffing, education, and training requirements applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(e) Before starting any sedation procedure, the permit holder shall conduct a pre-operative patient evaluation which shall ~~include, but is not limited to,~~ include the following:

(1) ~~evaluate~~ evaluating the patient for health risks relevant to the potential sedation procedure;

(2) ~~evaluate~~ evaluating the patient's food and fluid intake following the ASA guidelines for pre-operative fasting applicable to elective procedures involving the administration of anesthesia or moderate sedation. The ASA guidelines are incorporated by reference, including subsequent amendments and editions, and may be accessed at https://www.asahq.org at no cost; and

(3) ~~satisfy~~ satisfying any additional requirements for pre-operative patient evaluation and procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(f) During the sedation procedure:

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

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

(3) Capnography shall be used to monitor patients unless an individual patient's behavior or condition prevents use of capnography. In that event, the permit holder shall document in the sedation record the clinical reason capnography could not be used.

(4) The permit holder shall ensure the patient's ~~base-line~~ baseline vital signs are taken and recorded, including temperature, SPO2, blood pressure, and pulse.

(5) The permit holder shall ensure the patient's blood pressure, oxygen saturation, ET CO2 (unless capnography cannot be used), pulse, and respiration rates ("vital sign information") are monitored continuously in a manner that enables the permit holder to view vital sign trends throughout the procedure.

(6) The permit holder shall ensure the intraoperative vital sign information is recorded on the anesthesia or sedation record contemporaneously throughout the procedure in intervals of five minutes or less for patients over twelve years old, and in intervals of ten minutes or less for pediatric patients twelve years old or younger.

(7) The permit holder shall satisfy any additional requirements for operative procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

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

(1) The permit holder or an auxiliary under his or her direct supervision shall monitor the patient's post-operative vital ~~signs~~ sign information until the patient is recovered and is ready for discharge from the office. Recovery from anesthesia or moderate sedation shall include documentation of the following:

(A) stable cardiovascular function;

(B) uncompromised airway patency;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

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

(H) for a special needs patient, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

(2) Before allowing the patient to leave the office, the permit holder shall determine that the patient has met the recovery criteria set out in Subparagraph (g)(1) of this Rule and the following discharge criteria:

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

(B) explanation and documentation of written post-operative instructions have been provided to the patient or a person responsible for the patient at time of discharge; and

(C) a person authorized by or responsible for the patient is available to transport the patient after discharge.

(h) The permit holder shall maintain the following in the patient treatment records for 10 years:

(1) the patient's current written medical ~~history~~ history, including known allergies and previous surgeries;

(2) a pre-operative assessment as set out in Paragraph (e) of this Rule;

(3) consent to the procedure and to the anesthesia or sedation, signed by the patient or guardian, identifying the procedure and its risks and benefits, the level of anesthesia or sedation and its risks and benefits, and the date signed;

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

(A) the patient's ~~base line~~ baseline vital signs and intraoperative vital sign information as set out in Subparagraphs (f)(4)-(6) of this Rule;

(B) the printed or downloaded vital sign information from the capnograph. A permit holder's failure to maintain capnograph documentation, except as set out in Subparagraph (f)(3) of this Rule, shall be deemed a failure to monitor the patient as required pursuant to this Subchapter;

(C) procedure start and end times;

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

(E) the total amount of any local anesthetic administered during the procedure;

(F) any analgesic, sedative, pharmacological, or reversal agent, or other drugs administered during the procedure, including route of administration, dosage, strength, time, and

sequence of administration, with separate entries for each increment of medication that is titrated to effect;

(G) documentation of complications or morbidity, and clinical responses; and

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

(5) any additional documentation applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

History Note: *Authority G.S. 90-28; 90-30.1; 90-31.1; 90-48;*
Eff. February 1, 2023.

21 NCAC 16Q .0104 is adopted with changes as published in 37:07 NCR 545 as follows:

21 NCAC 16Q .0104 REQUIREMENTS FOR INSPECTIONS AND EVALUATIONS

(a) During a facility inspection pursuant to the rules of this Subchapter, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or permit holder shall demonstrate satisfaction of the requirements set forth in Rule .0103(c) and (d) of this Section.

(b) During an evaluation, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or permit holder shall demonstrate the administration of anesthesia or sedation in accordance with the level of the permit, and shall demonstrate competency ~~including but not limited to~~ in the following areas:

(1) pre-operative patient evaluation and procedures, including the requirements set forth in Rule .0103(e) of this Section;

(2) operative procedures, including the deployment of an intravenous delivery system and the requirements set forth in Rule .0103(f) of this Section;

(3) post-operative patient monitoring and discharge, including the requirements set forth in Rule .0103(g) of this Section; and

(4) treatment of the clinical emergencies set out in Rule .0103(d)(1) of this Section.

(c) During the evaluation, the applicant shall take a written examination on the topics set forth in ~~Paragraph (b)~~ Subparagraphs (b)(1)-(4) of this Rule. The applicant shall obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the applicant fails to obtain a passing score on the written examination, he or she may be re-examined in accordance with Rule .0204(h), .0306(h), or .0408(h) of this Subchapter.

(d) The permit holder shall be subject to re-evaluation every five years. Each facility where the permit holder administers anesthesia or sedation shall be subject to a facility inspection upon annual renewal of the permit.

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. February 1, 2023.

21 NCAC 16Q .0202 is amended as published in 37:07 NCR 546-48 as follows:

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer general anesthesia shall ~~ensure that the facility where the general anesthesia is administered meets the following requirements:~~ be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired neuromuscular blocking agent shall be immediately available and be accessible from the operatory and recovery rooms.

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

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

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

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

~~(D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;~~

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

~~(F) small, medium, and large oral and nasal airways;~~

~~(G) blood pressure monitoring device;~~

~~(H) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

(D) antihistamine;

(E) antihypertensive;

(F) bronchodilator;

(G) antihypoglycemic agent;

(H) vasopressor;

(I) corticosteroid;

(J) anticonvulsant;

(K) muscle relaxant;

(L) appropriate reversal agents;

(M) nitroglycerine;

(N) antiemetic; and

(O) Dextrose.

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

(4) The permit holder shall maintain the following records for 10 years:

(A) Patient's current written medical history, including a record of known allergies and previous surgeries;

(B) Consent to general anesthesia, signed by the patient or guardian, identifying the risks and benefits, level of anesthesia, and date signed;

(C) Consent to the procedure, signed by the patient or guardian identifying the risks, benefits, and date signed; and

(D) Patient base line vital signs, including temperature, SPO2, blood pressure, and pulse.

(5) The anesthesia record shall include:

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

(B) procedure start and end times;

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

(D) status of patient upon discharge; and

(E) documentation of complications or morbidity.

(6) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording general anesthesia or sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding general anesthesia or sedation throughout the sedation procedure and is not performing the surgery or other dental procedure.

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

(1) monitoring of blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;

(2) drug dosage and administration;

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

(4) sterile technique;

(5) use of BLS certified auxiliaries;

(6) monitoring of patient during recovery; and

(7) sufficiency of patient recovery time.

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

(1) laryngospasm;

(2) bronchospasm;

(3) emesis and aspiration;

(4) respiratory depression and arrest;

(5) angina pectoris;

(6) myocardial infarction;

(7) hypertension and hypotension;

(8) syncope;

(9) allergic reactions;

(10) convulsions;

(11) bradycardia;

(12) hypoglycemia;

(13) cardiac arrest; and

(14) airway obstruction.

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

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

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

(1) the permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined by Subparagraph (f)(2) of this Rule and is ready for discharge from the office; and

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

(A) cardiovascular function stable;

(B) airway patency uncompromised;

(C) patient arousable and protective reflexes intact;

~~(D) state of hydration within normal limits;~~

~~(E) patient can talk, if applicable;~~

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

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

~~(H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved; and~~

~~(3) before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(2) of this Rule and the following discharge criteria:~~

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

~~(B) explanation and documentation of written postoperative instructions have been provided to the patient or a person responsible for the patient at time of discharge; and~~

~~(C) a person authorized by the patient is available to transport the patient after discharge.~~

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. February 1, 1990;
Amended Eff. June 1, 2017; November 1, 2013; August 1, 2002; August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Amended Eff. February 1, 2023; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0302 is amended with changes as published in 37:07 NCR 548-50 as follows:

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer moderate conscious sedation or supervising any CRNA employed to administer or RN employed to deliver moderate conscious sedation shall ~~ensure that the facility where the sedation is administered meets the following requirements:~~ be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) As part of the pre-operative assessment required by Rule .0103(e) of this Subchapter, the permit holder shall evaluate the patient for health risks as follows:

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

(d) During the sedation procedure, a moderate conscious sedation permit holder shall not administer anesthetic or sedative agents:

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

(2) determined by the manufacturer to be contraindicated for use in moderate conscious sedation; or

(3) in amounts exceeding the manufacturers' maximum recommended dosages, unless the permit holder documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

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

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

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

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

~~(D) suction equipment as necessary for specific procedures, including non-electrical back up suction;~~

~~(E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back up E cylinder portable oxygen tank apart from the central system;~~

~~(F) small, medium, and large oral and nasal airways;~~

~~(G) blood pressure monitoring device;~~

~~(H) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

~~(D) antihistamine;~~

~~(E) antihypertensive;~~

~~(F) bronchodilator;~~

~~(G) antihypoglycemic agent;~~

~~(H) vasopressor;~~

~~(I) corticosteroid;~~

~~(J) anticonvulsant;~~

~~(K) muscle relaxant;~~

~~(L) appropriate reversal agents;~~

~~(M) nitroglycerine;~~

~~(N) antiemetic; and~~

~~(O) Dextrose.~~

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

~~(4) The dentist shall maintain the following records for at least 10 years:~~

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

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

~~(C) a sedation record;~~

~~(5) The sedation record shall include:~~

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

~~(B) procedure start and end times;~~

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

~~(D) status of patient upon discharge;~~

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

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

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

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

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

~~(b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate conscious sedation on a patient, including the deployment of an intravenous delivery system, while the evaluator observes. During the demonstration, the applicant or permit holder shall demonstrate competency in the following areas:~~

~~(1) monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;~~

~~(2) drug dosage and administration;~~

~~(3) treatment of untoward reactions including respiratory or cardiac depression if applicable;~~

~~(4) sterile technique;~~

~~(5) use of BLS certified auxiliaries;~~

~~(6) monitoring of patient during recovery; and~~

~~(7) sufficiency of patient recovery time.~~

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

~~(1) laryngospasm;~~

~~(2) bronchospasm;~~

~~(3) emesis and aspiration;~~

~~(4) respiratory depression and arrest;~~

~~(5) angina pectoris;~~

~~(6) myocardial infarction;~~

~~(7) hypertension and hypotension;~~

(8) allergic reactions;

(9) convulsions;

(10) syncope;

(11) bradycardia;

(12) hypoglycemia;

(13) cardiac arrest; and

(14) airway obstruction.

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

(e) A moderate conscious sedation permit holder shall evaluate a patient for health risks before starting any sedation procedure as follows:

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use or;

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure.

(f) Post-operative monitoring and discharge:

(1) the permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined in Subparagraph (f)(2) of this Rule and is ready for discharge from the office.

(2) recovery from moderate conscious sedation shall include documentation of the following:

(A) cardiovascular function stable;

(B) airway patency uncompromised;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

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

(H) for the special needs patient or patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

(3) before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(2) of this Rule and the following discharge criteria:

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

~~(B) explanation and documentation of written postoperative instructions have been provided to the patient or a person responsible for the patient at the time of discharge; and~~

~~(C) a person authorized by the patient is available to transport the patient after discharge.~~

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. February 1, 1990;
Amended Eff. August 1, 2002; August 1, 2000;
Temporary Amendment Eff. December 11, 2002;
Amended Eff. June 1, 2017; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Amended Eff. February 1, 2023; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0405 is amended with changes as published in 37:07 NCR 550-52 as follows:

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer moderate pediatric conscious sedation shall ~~ensure that the facility where the sedation is administered meets the following requirements:~~ be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) In addition to the requirements set out in Rule .0103(c)(4) of this Subchapter, the permit holder's emergency manual shall include assignments to be performed in the event of emergency by a BLS-certified auxiliary dedicated to patient monitoring.

(d) In addition to the requirements set out in Rule .0103(e) of this Subchapter concerning pre-operative procedures, the permit holder shall ensure that patients who have been administered moderate pediatric conscious sedation are monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures by the permit holder or an auxiliary dedicated to patient monitoring.

(e) As part of the pre-operative assessment required by Rule .0103(e) of this Subchapter, the permit holder shall evaluate the patient for health risks as follows:

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

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

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

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

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

(4) the patient is [~~attended~~] under observation by the permit holder or a BLS-certified auxiliary at all times.

(g) During the sedation procedure, a moderate pediatric conscious sedation permit holder shall not administer anesthetic or sedative agents:

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

(2) determined by the manufacturer to be contraindicated for use in moderate pediatric conscious sedation; or

(3) in amounts exceeding the manufacturers' maximum recommended dosages, unless the permit holder documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

(h) In addition to the requirements set out in Rule .0103(h) of this Subchapter concerning the patient treatment record, the permit holder shall maintain documentation of pre-sedation instructions and information provided to the patient or person responsible for the patient, which shall include:

(1) objectives of the sedation;

(2) anticipated changes in patient behavior during and after sedation;

(3) instructions to the person responsible for a patient transported in a [~~car~~] child safety seat regarding patient head position to avoid airway obstruction;

(4) a 24-hour telephone number for the permit holder or his or her BLS-certified auxiliaries; and

(5) instructions on limitations of activities and dietary precautions.

(i) For purposes of Rule .0104(b)(2) of this Subchapter, during an evaluation, a moderate pediatric conscious sedation permit holder or applicant shall demonstrate competency in the deployment of an intravenous delivery system as follows:

(1) a permit holder or applicant who uses intravenous sedation shall demonstrate the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an intravenous delivery system; and

(2) a permit holder or applicant who does not use intravenous sedation shall describe the proper deployment of an intravenous delivery system and shall demonstrate the administration of moderate pediatric conscious sedation on a live patient.

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

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

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

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

~~(D) suction equipment as necessary for specific procedures, including non electrical back up suction;~~

~~(E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back up E cylinder portable oxygen tank apart from the central system;~~

~~(F) small, medium, and large oral and nasal airways;~~

~~(G) blood pressure monitoring device;~~

~~(H) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

~~(D) antihistamine;~~

~~(E) antihypertensive;~~

~~(F) bronchodilator;~~

~~(G) antihypoglycemic agent;~~

~~(H) vasopressor;~~

~~(I) corticosteroid;~~

~~(J) anticonvulsant;~~

~~(K) muscle relaxant;~~

~~(L) appropriate reversal agents;~~

~~(M) nitroglycerine;~~

~~(N) antiemetic; and~~

~~(O) Dextrose.~~

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

~~(4) The following records are maintained for at least 10 years:~~

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

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

~~(C) a sedation record; and~~

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

~~(5) The sedation record shall include:~~

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

(B) procedure start and end times;

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

(D) status of patient upon discharge; and

(E) documentation of complications or morbidity; and

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

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

(B) when IV sedation is used, IV infusion shall be administered before the commencement of the procedure and maintained until the patient is ready for discharge.

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

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

(1) monitoring blood pressure, pulse, and respiration;

(2) drug dosage and administration;

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

(4) sterile technique;

(5) use of BLS certified auxiliaries;

(6) monitoring of patient during recovery; and

(7) sufficiency of patient recovery time.

(d) During an inspection or evaluation, the applicant or permit holder shall demonstrate competency in the treatment of the following clinical emergencies:

(1) laryngospasm;

(2) bronchospasm;

(3) emesis and aspiration;

(4) respiratory depression and arrest;

(5) angina pectoris;

(6) myocardial infarction;

(7) hypertension and hypotension;

(8) allergic reactions;

(9) convulsions;

(10) syncope;

(11) bradycardia;

(12) hypoglycemia;

(13) cardiac arrest; and

(14) airway obstruction.

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

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

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure.

(g) Patient monitoring:

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

(2) The permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined in Subparagraph (g)(3) of this Rule and is ready for discharge from the office.

(3) Recovery from moderate pediatric conscious sedation shall include documentation of the following:

(A) cardiovascular function stable;

(B) airway patency uncompromised;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

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

(H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

~~(4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (g)(3) of this Rule and the following discharge criteria:~~

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

~~(B) explanation and documentation of written postoperative instructions have been provided to a person responsible for the patient at time of discharge; and~~

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

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. June 1, 2017;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Amended Eff. February 1, 2023; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0703 is amended with changes as published in 37:07 NCR 552-53 as follows:

21 NCAC 16Q .0703 REPORTS OF ADVERSE OCCURRENCES

(a) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board within 72 hours after each adverse occurrence ~~related to the administration of general anesthesia or sedation that results in the death of a patient~~ if the patient dies or has permanent organic brain dysfunction within 24 hours ~~of~~ after the ~~procedure.~~ administration of general anesthesia or sedation. Sedation permit holders shall cease administration of sedation until the Board has investigated the death or permanent organic brain dysfunction and approved resumption of permit privileges. General anesthesia permit holders shall cease administration of general anesthesia and sedation until the Board has reviewed the ~~incident~~ adverse occurrence report and approved resumption of permit privileges.

(b) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board within 30 days after each adverse occurrence ~~related to~~ if the patient is admitted to a hospital on inpatient status for a medical emergency or physical injury within 24 hours after the administration of general anesthesia or sedation.~~sedation that results in permanent organic brain dysfunction of a patient occurring within 24 hours of the procedure or that results in physical injury or severe medical emergencies, causing hospitalization of a patient occurring within 24 hours of the procedure.~~

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

(1) dentist's name, license number and permit number;

(2) date and time of the occurrence;

(3) facility where the occurrence took place;

(4) name and address of the patient;

(5) surgical procedure involved;

(6) type and dosage of sedation or anesthesia utilized in the procedure;

(7) circumstances involved in the occurrence; and

(8) the entire patient treatment record including anesthesia records.

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

History Note: *Authority G.S. 90-28; 90-30.1; 90-41; 90-48;*
Eff. April 1, 2016;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, ~~2018.~~2018;
Amended Eff. February 1, 2023.

Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)

From: Dauna Bartley <dauna@brockerlawfirm.com>
Sent: Friday, January 13, 2023 4:45 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Doug Brocker <doug@brockerlawfirm.com>; File <file@brockerlawfirm.com>
Subject: RE: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)

Thanks Brian. Can I get back to you with the necessary changes on Tuesday? I won't be able to address these by 5pm today.

Dauna

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, January 13, 2023 4:12 PM
To: Dauna Bartley <dauna@brockerlawfirm.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Doug Brocker <doug@brockerlawfirm.com>; File <file@brockerlawfirm.com>
Subject: RE: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)

Hi Dauna,

Sorry for the tight timing. I've reviewed your responses, and have a few minor issues to come back to you with:

.0103

> *In (g)(1), line 27, does the term "vital signs" mean the same thing as "vital sign information" in (f)(5)? If not, what are the differences?* It means the same thing.
>
> **If the meaning is the same, I think the terms should be identical then. The only reason I'm being this picky is that you've designated certain vital signs as "vital sign information" in (f), so I think it's confusing that you go to the trouble to specify "these things are 'vital sign information'" and then don't use that term again.**

.0104

In (b), line 10, please delete "but not limited to". However, as "including" has an open-ended connotation, what beyond the 4 things listed in (b) must the dentist demonstrate competency in? Done – changed to "including in the following areas". Subparagraphs (1)-(4) are the specific areas that "must" be covered as part of the required demonstration of competency administering anesthesia or sedation in accordance with the level of the permit.

If you're only looking for (1)-(4), then I would amend the language on lines 9-10 to omit "…including in…" and just say "shall demonstrate competency in the following areas:" If there are other areas of competency that will be examined, then they need to be spelled out and included here.

.0703

In (a), line 10, the paragraph reads as if only general anesthesia permit holders have to file the adverse occurrence report. Please clarify and revise as necessary. The first sentence of Paragraph (a), line 4-7, sets out the requirement that a dentist holding a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board as specified. The Board's regulated public is familiar with this requirement. The second and third sentences, lines 7-10, set out the requirement that permit holders shall cease administration of general anesthesia or sedation until the Board has taken the specified action. Line 10 does not repeat the requirement to file an adverse occurrence report, as that is unnecessary. Please let us know if you have further questions.

I think the issue here is on line 4, and the language "shall report". Not trying to be nitpicky, but it doesn't actually *say* "submit an adverse occurrence report". One may report an adverse occurrence by making a phone call or sending an email.

Further, there is a difference here in how sedation and general anesthesia permit holders are handled:

Lines 7-9: "Sedation permit holders shall cease administration of sedation until the Board has investigated the death or permanent organic brain dysfunction and approved resumption of permit privileges."

Lines 9-10: "General anesthesia permit holders shall cease administration of general anesthesia and sedation until the Board has reviewed the adverse occurrence report and approved resumption of permit privileges."

As you can see, there's a difference between "investigating the death" and "reviewing the report." Given that line 4 doesn't actually say that anyone shall submit this particular report, the "adverse occurrence report" is omitted from the sentence related to "sedation permit holders", and then appears for the first time in the sentence related to "general anesthesia permit holders," I think it does give the impression that this particular report is only filed by general anesthesia permit holders.

Other than these three rules—which I think are easily fixed—I think the 16Q rules are fine and will be recommending approval.

Please let me know if you have further questions.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948

brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)
Attachments: 01.2023 - Dental Examiners - 21 NCAC 16Q_Responses.docx; 21 NCAC 16Q .0103.docx; 21 NCAC 16Q .0104.docx; 21 NCAC 16Q .0302.docx; 21 NCAC 16Q .0405.docx

From: Dauna Bartley <dauna@brockerlawfirm.com>
Sent: Friday, January 13, 2023 2:44 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Doug Brocker <doug@brockerlawfirm.com>; File <file@brockerlawfirm.com>
Subject: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC (OAH Comm)

Brian,

I am attaching our responses to your questions and requests, along with the rules that have been rewritten. The timing on this one was a bit tight, and I hope we have answered your questions sufficiently. Please let me know if you need additional information. If not, please let me know what you will recommend.

I plan to attend the meeting next week in person.

Best regards,
Dauna

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0103

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (a), line 6, would it change the meaning to revise as follows: "… or supervising a CRNA or an RN employed to administer…" This seems simpler. The suggested language would change the meaning and cannot be used. "Administer" and "deliver" are defined terms, and RNs are not authorized to "administer" medications. CRNAs may administer, and RNs may only deliver medications.

Either way, in (a), please add "an" prior to "RN". Done.

In (b), line 9, what is a "credentialed surgery center"? Credentialed how? Clarified to define a "credentialed surgery center."

In (c)(1)(B), line 19, what are the "enhancements" discussed here? Please define. Omitted the term "without enhancements."

In (C), line 12, (D), line 22, (N), line 35, and (R), p.2, line 2, what does "necessary for specific procedures" mean? This seems rather vague. Clarified to "necessary for the procedure to be performed" in each instance.

In (d)(2), line 15, and (3), line 17, what does it mean to be "BLS certified"? I see in 16Q .0101 that BLS means Basic Life Support, but I'm unclear on the certification process. BLS certification is a term familiar to the Board's regulated public. It is clear and unambiguous, and adding a definition or explanation of the certification process is unnecessary. It would be negligent at best for a dentist not to know what it means to be BLS certified. In addition, the terms "BLS certified" and "BLS certification" currently appear 21 times across 13 different rules in Subchapter 16Q, including rules reviewed and approved by the Rules Review Commission as recently as 2021. Adding verbiage to this rule to explain "BLS certified" would create confusion and ambiguity with respect to whether it means something new and different in this rule than in all the other rules where it appears.

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

In (d)(4)(C), line 28, add a comma following "holder." A comma after "holder" and before "who" would change the meaning of this sentence in a way contrary to the intention of the Rule. In the phrase "under the supervision and direction of the permit holder who shall ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit," the word "who" refers to the permit holder in accordance with the intention of the Rule to impose the obligation on the permit holder to ensure the level of sedation does not exceed the level of his or her permit.

However, adding a comma after "holder" would result in the phrase "under the supervision and direction of the permit holder" being set off as a nonrestrictive (nonessential) clause, and the word "who" would refer back to the CRNA who is the subject of the main sentence. That would not reflect the intention of the Rule, and at the very least it would create ambiguity in the Rule regarding exactly who is supposed to "ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit."

Also on line 29, add "of" between "level" and "sedation." Done.

On line 30, is there a better way to phrase "allowed by the permit holder's permit"? Maybe just "allowed by the permit"? It is phrased "allowed by the permit holder's permit" to ensure that is no ambiguity regarding which/whose permit sets the sedation level limitation.

In (5), line 32, "Rule" should be plural. Please check throughout these Rules, as I saw this multiple times. I believe "Rule" should be singular in all of these instances. Each one is a list of alternatives using "or". For example, this line says, "The permit holder shall satisfy any additional facility requirements applicable to the level of the permit, as set out in Rule .0202, .0206, .0302, or .0405 of this Subchapter." Because these are alternatives ("or") and not cumulative ("and"), each must be able to stand alone. It would be incorrect to say, "as set out in Rules .0405 of this Subchapter." The correct approach is to say, "as set out in Rule .0405 of this Subchapter." Therefore, "Rule" is the proper form.

In (e), line 33-34, it isn't necessary to say "but not limited to", "include" is fine on it's own. However, "include" has an open-ended connotation, so what else, beyond (1)-(3) must the permit holder evaluate? Done - omitted "but not limited to". Subparagraphs (1)-(3) are the requirements that "must" be included as part of the mandatory pre-op evaluation. There are no other specific mandatory items. The permit holder should evaluate other factors as needed based on the patient and the procedure.

In (e)(1)-(3), the first word of each item should be in a different tense for grammatical consistency. Consider "evaluating" or "evaluation of" instead of "evaluate". Done.

In (e)(2), line 37, are all sedation dentistry procedures elective? If not, is a different standard applicable to non-elective dental procedures? This standard applies to both elective and nonelective sedation procedures. The permit holder must evaluate food and fluid intake following the ASA's pre-operative fasting guidelines for elective procedures.

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

In (e)(3), p.4, line 4, "Rule" should be plural. Please see response above. "Rule" is properly written as singular here.

In (f)(4), line 13, I think "base line" should be one word. Done.

In (f)(7), line 24, "Rule" should be plural. Please see response above. "Rule" is properly written as singular here.

In (g)(1), line 27, does the term "vital signs" mean the same thing as "vital sign information" in (f)(5)? If not, what are the differences? It means the same thing.

In (h), p.5, line 11, add a comma after "history." Done.

In (h)(5), line 33, "Rule" should be plural. Please see response above. "Rule" is properly written as singular here.

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0104

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (b), line 10, please delete "but not limited to". However, as "including" has an open-ended connotation, what beyond the 4 things listed in (b) must the dentist demonstrate competency in? Done – changed to "including in the following areas". Subparagraphs (1)-(4) are the specific areas that "must" be covered as part of the required demonstration of competency administering anesthesia or sedation in accordance with the level of the permit.

In (c), line 18, are the "topics set forth in Paragraph (b)" "general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation"? Please clarify. Clarified to "Subparagraphs (b)(1)-(4)."

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0302

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (a), line 6, would it change the meaning to revise as follows: "… or supervising a CRNA or an RN employed to administer…" This seems simpler. The suggested language would change the meaning and cannot be used. "Administer" and "deliver" are defined terms, and RNs are not authorized to "administer" medications. CRNAs may administer, and RNs may only deliver medications.

Either way, in (a), please add "an" prior to "RN". This provision is phrased "supervising any CRNA employed to administer or RN employed to deliver…" Grammatically, "any" refers to both CRNA and RN. Adding "an" prior to "RN" would be incorrect.

In (c)(2), line 15, is there a better way to phrase "evaluated by … consultation"? Not one that is apparent. The phrase conveys the intended meaning in a clear, unambiguous fashion.

In (c)(2), line 16, is "consulting" a noun or adjective? i.e. does this mean a "consulting medical specialist" as written, or was this supposed to mean that the permit holder should "consult with" the patient's medical specialist. Just checking. "Consulting" is an adjective – a "consulting medical specialist."

In (d), line 21, "contraindicated" by whom? The manufacturer? Yes. Clarified to "determined by the manufacturer to be contraindicated for use…"

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0405

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (c), line 11, what is "BLS-certified"? Same question as in Rule .0103. Same response as in Rule .0103. BLS certification is a term familiar to the Board's regulated public. It is clear and unambiguous, and adding a definition or explanation of the certification process is unnecessary. It would be negligent at best for a dentist not to know what it means to be BLS certified. In addition, the terms "BLS certified" and "BLS certification" currently appear 21 times across 13 different rules in Subchapter 16Q, including rules reviewed and approved by the Rules Review Commission as recently as 2021. Adding verbiage to this rule to explain "BLS-certified" would create confusion and ambiguity with respect to whether it means something new and different in this rule than in all the other rules where it appears.

In (e)(2), line 21, is there a better way to phrase "evaluated by … consultation"? Not one that is apparent. The phrase conveys the intended meaning in a clear, unambiguous fashion.

In (e)(2), line 22, is "consulting" a noun or adjective? i.e. does this mean a "consulting medical specialist" as written, or was this supposed to mean that the permit holder should "consult with" the patient's medical specialist. Just checking. "Consulting" is an adjective – a "consulting medical specialist."

In (f)(3), line 28, mostly out of curiosity, but why must a hand or foot be left exposed? For patient monitoring and safety.

In (f)(4), line 29, what does "attended" mean? Clarified to "under observation by the permit holder or a BLS-certified auxiliary."

In (g)(2), line 33, "contraindicated" by whom? The manufacturer? Yes. Clarified to "determined by the manufacturer to be contraindicated for use…"

In (h)(3), line 6, add "the" between "to" and "person." Done.

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

Also, what do you mean by "car seat"? It seems to me this means something other than a seat in a car. Clarified to "child safety seat."

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Board of Dental Examiners

RULE CITATION: 21 NCAC 16Q .0703

DEADLINE FOR RECEIPT: Friday, January 13, 2023.

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

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

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

In (a), line 4, I assume "sedation" refers to both moderate conscious sedation and moderate pediatric conscious sedation? I haven't seen where one term was used to capture all kinds of sedation elsewhere in these rules. The term "sedation" is used to refer to all conscious sedation permit levels (moderate, pediatric, and minimal) in Sections .0100 and .0700 (see 16Q .0101, .0102, .0703, and .0704).

In (a), line 10, the paragraph reads as if only general anesthesia permit holders have to file the adverse occurrence report. Please clarify and revise as necessary. The first sentence of Paragraph (a), line 4-7, sets out the requirement that a dentist holding a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board as specified. The Board's regulated public is familiar with this requirement. The second and third sentences, lines 7-10, set out the requirement that permit holders shall cease administration of general anesthesia or sedation until the Board has taken the specified action. Line 10 does not repeat the requirement to file an adverse occurrence report, as that is unnecessary. Please let us know if you have further questions.

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

Brian Liebman
Commission Counsel
Date submitted to agency: January 6, 2023

21 NCAC 16Q .0103 is adopted with changes as published in 37:07 NCR 543-45 as follows:

21 NCAC 16Q .0103 EQUIPMENT, PERSONNEL, AND CLINICAL REQUIREMENTS TO ADMINISTER ANESTHESIA OR MODERATE SEDATION

(a) Before administering general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation ("anesthesia or moderate sedation"), or supervising a CRNA to administer or an RN employed to deliver anesthesia or moderate sedation, a dentist shall hold an unexpired permit issued by the Board in accordance with this Subchapter permitting the dentist to administer that level of sedation.

(b) Before performing sedation procedures in a facility other than a hospital or credentialed surgery center, the permit holder shall ensure that the Board has been notified that the permit holder intends to administer anesthesia or moderate sedation at the facility and shall ensure that the facility has passed a facility inspection by the Board in accordance with this Subchapter. For purposes of these Rules, "credentialed surgery center" means a surgical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities.

(c) The permit holder shall ensure that the facility where the sedation procedure is to be performed meets the following requirements at the time of the procedure:

(1) The permit holder shall ensure the facility is equipped as follows and that the following listed equipment is immediately available and accessible from the operatory and recovery rooms:

(A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;

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

(C) lighting as necessary for the procedure to be performed, ~~specific procedures~~ and back-up lighting;

(D) suction equipment as necessary for the procedure to be performed, ~~specific procedures,~~ including non-electrical back-up suction;

(E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients, and back-up E-cylinder portable oxygen tank apart from the central system;

(F) small, medium, and large oral and nasal airways;

(G) a blood pressure monitoring device;

(H) an EKG monitor;

(I) a pulse oximeter;

(J) an automatic external defibrillator (AED);

(K) a capnograph;

(L) a precordial or pretracheal stethoscope;

(M) a thermometer;

(N) vascular access set-up as necessary for the procedure to be performed, ~~specific procedures,~~ including hardware and fluids;

(O) a laryngoscope with working batteries;

(P) intubation forceps and advanced airway devices;

(Q) tonsillar suction with back-up suction;

(R) syringes as necessary for the procedure to be performed; ~~specific procedures;~~ and

(S) tourniquet and tape.

(2) The permit holder shall ensure all monitoring and other equipment in the facility receives preventive maintenance no less frequently than once per year, including safety and function checks per the manufacturers' recommendations. The permit holder shall maintain documentation of all preventive maintenance performed, and shall ensure equipment is replaced upon its expiration or as clinically required.

(3) The permit holder shall ensure the following unexpired drugs are immediately available and are accessible from the operatory and recovery rooms:

(A) epinephrine;

(B) atropine;

(C) an antiarrhythmic;

(D) an antihistamine;

(E) an antihypertensive;

(F) a bronchodilator;

(G) an antihypoglycemic agent;

(H) a vasopressor;

(I) a corticosteroid;

(J) an anticonvulsant;

(K) appropriate reversal agents;

(L) nitroglycerine; and

(M) an antiemetic.

(4) The permit holder shall maintain written emergency and patient discharge protocols accessible from the operatory and recovery rooms. The written emergency manual shall include a protocol for activation of emergency management services for life-threatening complications along with the information set out in Rule .0101(17) of this Section.

(5) The permit holder shall satisfy any additional facility requirements applicable to the level of the permit, as set out in Rule .0202, .0206, .0302, or .0405 of this Subchapter.

(d) The permit holder shall ensure that the following staffing, education, and training requirements are met prior to performing a sedation procedure:

(1) The permit holder shall provide training to familiarize all auxiliaries in the treatment of clinical emergencies including the following, and shall review and practice responding to clinical emergencies with all auxiliaries as a team and in person every six months;

(A) airway obstruction;

(B) allergic reactions;

(C) angina pectoris;

(D) apnea;

(E) bradycardia;

(F) bronchospasm;

(G) cardiac arrest;

(H) convulsions;

(I) emesis and aspiration;

(J) hypertension;

(K) hypoglycemia;

(L) hypotension;

(M) hypoventilation and respiratory arrest;

(N) hypoxemia and hypoxia;

(O) laryngospasm;

(P) myocardial infarction; and

(Q) syncope.

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

(3) Except as set out in Subparagraph (d)(4) of this Rule, the permit holder performing the surgery or other dental procedure shall ensure that an RN or a BLS-certified auxiliary is dedicated to patient monitoring and recording anesthesia or sedation data throughout the sedation procedure.

(4) The requirement set out in Subparagraph (d)(3) of this Rule shall not apply if the permit holder or an additional sedation provider is dedicated to patient care and monitoring regarding anesthesia or moderate sedation throughout the sedation procedure and is not performing the surgery or other dental procedure. The additional sedation provider shall be:

(A) a dentist holding a permit or mobile permit in satisfaction of this Subchapter to administer the anesthesia or sedation level at the facility where the sedation procedure is performed;

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

(C) a CRNA licensed and practicing in accordance with the rules of the North Carolina Board of Nursing, under the supervision and direction of the permit holder who shall ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit.

(5) The permit holder shall satisfy any additional staffing, education, and training requirements applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(e) Before starting any sedation procedure, the permit holder shall conduct a pre-operative patient evaluation which shall ~~include, but is not limited to,~~ include the following:

(1) ~~evaluate~~ evaluating the patient for health risks relevant to the potential sedation procedure;

(2) ~~evaluate~~ evaluating the patient's food and fluid intake following the ASA guidelines for pre-operative fasting applicable to elective procedures involving the administration of anesthesia or moderate sedation. The ASA guidelines are incorporated by reference, including subsequent amendments and editions, and may be accessed at https://www.asahq.org at no cost; and

(3) ~~satisfy~~ satisfying any additional requirements for pre-operative patient evaluation and procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(f) During the sedation procedure:

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

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

(3) Capnography shall be used to monitor patients unless an individual patient's behavior or condition prevents use of capnography. In that event, the permit holder shall document in the sedation record the clinical reason capnography could not be used.

(4) The permit holder shall ensure the patient's ~~base-line~~ baseline vital signs are taken and recorded, including temperature, SPO2, blood pressure, and pulse.

(5) The permit holder shall ensure the patient's blood pressure, oxygen saturation, ET CO2 (unless capnography cannot be used), pulse, and respiration rates ("vital sign information") are monitored continuously in a manner that enables the permit holder to view vital sign trends throughout the procedure.

(6) The permit holder shall ensure the intraoperative vital sign information is recorded on the anesthesia or sedation record contemporaneously throughout the procedure in intervals of five minutes or less for patients over twelve years old, and in intervals of ten minutes or less for pediatric patients twelve years old or younger.

(7) The permit holder shall satisfy any additional requirements for operative procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

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

(1) The permit holder or an auxiliary under his or her direct supervision shall monitor the patient's post-operative vital signs until the patient is recovered and is ready for discharge from the office. Recovery from anesthesia or moderate sedation shall include documentation of the following:

(A) stable cardiovascular function;

(B) uncompromised airway patency;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

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

(H) for a special needs patient, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

(2) Before allowing the patient to leave the office, the permit holder shall determine that the patient has met the recovery criteria set out in Subparagraph (g)(1) of this Rule and the following discharge criteria:

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

(B) explanation and documentation of written post-operative instructions have been provided to the patient or a person responsible for the patient at time of discharge; and

(C) a person authorized by or responsible for the patient is available to transport the patient after discharge.

(h) The permit holder shall maintain the following in the patient treatment records for 10 years:

(1) the patient's current written medical ~~history~~ history, including known allergies and previous surgeries;

(2) a pre-operative assessment as set out in Paragraph (e) of this Rule;

(3) consent to the procedure and to the anesthesia or sedation, signed by the patient or guardian, identifying the procedure and its risks and benefits, the level of anesthesia or sedation and its risks and benefits, and the date signed;

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

(A) the patient's ~~base line~~ baseline vital signs and intraoperative vital sign information as set out in Subparagraphs (f)(4)-(6) of this Rule;

(B) the printed or downloaded vital sign information from the capnograph. A permit holder's failure to maintain capnograph documentation, except as set out in Subparagraph (f)(3) of this Rule, shall be deemed a failure to monitor the patient as required pursuant to this Subchapter;

(C) procedure start and end times;

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

(E) the total amount of any local anesthetic administered during the procedure;

(F) any analgesic, sedative, pharmacological, or reversal agent, or other drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration, with separate entries for each increment of medication that is titrated to effect;

(G) documentation of complications or morbidity, and clinical responses; and

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

(5) any additional documentation applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

History Note: *Authority G.S. 90-28; 90-30.1; 90-31.1; 90-48;*
Eff. February 1, 2023.

21 NCAC 16Q .0104 is adopted with changes as published in 37:07 NCR 545 as follows:

21 NCAC 16Q .0104 REQUIREMENTS FOR INSPECTIONS AND EVALUATIONS

(a) During a facility inspection pursuant to the rules of this Subchapter, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or permit holder shall demonstrate satisfaction of the requirements set forth in Rule .0103(c) and (d) of this Section.

(b) During an evaluation, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or permit holder shall demonstrate the administration of anesthesia or sedation in accordance with the level of the permit, and shall demonstrate competency including ~~but not limited to~~ in the following areas:

(1) pre-operative patient evaluation and procedures, including the requirements set forth in Rule .0103(e) of this Section;

(2) operative procedures, including the deployment of an intravenous delivery system and the requirements set forth in Rule .0103(f) of this Section;

(3) post-operative patient monitoring and discharge, including the requirements set forth in Rule .0103(g) of this Section; and

(4) treatment of the clinical emergencies set out in Rule .0103(d)(1) of this Section.

(c) During the evaluation, the applicant shall take a written examination on the topics set forth in ~~Paragraph (b)~~ Subparagraphs (b)(1)-(4) of this Rule. The applicant shall obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the applicant fails to obtain a passing score on the written examination, he or she may be re-examined in accordance with Rule .0204(h), .0306(h), or .0408(h) of this Subchapter.

(d) The permit holder shall be subject to re-evaluation every five years. Each facility where the permit holder administers anesthesia or sedation shall be subject to a facility inspection upon annual renewal of the permit.

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. February 1, 2023.

21 NCAC 16Q .0302 is amended with changes as published in 37:07 NCR 548-50 as follows:

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer moderate conscious sedation or supervising any CRNA employed to administer or RN employed to deliver moderate conscious sedation shall ~~ensure that the facility where the sedation is administered meets the following requirements:~~ be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) As part of the pre-operative assessment required by Rule .0103(e) of this Subchapter, the permit holder shall evaluate the patient for health risks as follows:

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

(d) During the sedation procedure, a moderate conscious sedation permit holder shall not administer anesthetic or sedative agents:

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

(2) determined by the manufacturer to be contraindicated for use in moderate conscious sedation; or

(3) in amounts exceeding the manufacturers' maximum recommended dosages, unless the permit holder documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

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

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

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

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

~~(D) suction equipment as necessary for specific procedures, including non-electrical back up suction;~~

~~(E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back up E cylinder portable oxygen tank apart from the central system;~~

~~(F) small, medium, and large oral and nasal airways;~~

~~(G) blood pressure monitoring device;~~

~~(H) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

~~(D) antihistamine;~~

~~(E) antihypertensive;~~

~~(F) bronchodilator;~~

~~(G) antihypoglycemic agent;~~

~~(H) vasopressor;~~

~~(I) corticosteroid;~~

~~(J) anticonvulsant;~~

~~(K) muscle relaxant;~~

~~(L) appropriate reversal agents;~~

~~(M) nitroglycerine;~~

~~(N) antiemetic; and~~

~~(O) Dextrose.~~

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

~~(4) The dentist shall maintain the following records for at least 10 years:~~

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

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

~~(C) a sedation record;~~

~~(5) The sedation record shall include:~~

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

~~(B) procedure start and end times;~~

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

~~(D) status of patient upon discharge;~~

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

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

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

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

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

~~(b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate conscious sedation on a patient, including the deployment of an intravenous delivery system, while the evaluator observes. During the demonstration, the applicant or permit holder shall demonstrate competency in the following areas:~~

~~(1) monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;~~

~~(2) drug dosage and administration;~~

~~(3) treatment of untoward reactions including respiratory or cardiac depression if applicable;~~

~~(4) sterile technique;~~

~~(5) use of BLS certified auxiliaries;~~

~~(6) monitoring of patient during recovery; and~~

~~(7) sufficiency of patient recovery time.~~

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

~~(1) laryngospasm;~~

~~(2) bronchospasm;~~

~~(3) emesis and aspiration;~~

~~(4) respiratory depression and arrest;~~

~~(5) angina pectoris;~~

~~(6) myocardial infarction;~~

~~(7) hypertension and hypotension;~~

(8) allergic reactions;

(9) convulsions;

(10) syncope;

(11) bradycardia;

(12) hypoglycemia;

(13) cardiac arrest; and

(14) airway obstruction.

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

(e) A moderate conscious sedation permit holder shall evaluate a patient for health risks before starting any sedation procedure as follows:

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use or;

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure.

(f) Post-operative monitoring and discharge:

(1) the permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined in Subparagraph (f)(2) of this Rule and is ready for discharge from the office.

(2) recovery from moderate conscious sedation shall include documentation of the following:

(A) cardiovascular function stable;

(B) airway patency uncompromised;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

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

(H) for the special needs patient or patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

(3) before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(2) of this Rule and the following discharge criteria:

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

~~(B) explanation and documentation of written postoperative instructions have been provided to the patient or a person responsible for the patient at the time of discharge; and~~

~~(C) a person authorized by the patient is available to transport the patient after discharge.~~

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. February 1, 1990;
Amended Eff. August 1, 2002; August 1, 2000;
Temporary Amendment Eff. December 11, 2002;
Amended Eff. June 1, 2017; November 1, 2013; July 1, 2010; July 3, 2008; August 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Amended Eff. February 1, 2023; February 1, 2019; August 1, 2018.

21 NCAC 16Q .0405 is amended with changes as published in 37:07 NCR 550-52 as follows:

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

(a) A dentist ~~administering~~ holding or applying for a permit to administer moderate pediatric conscious sedation shall ~~ensure that the facility where the sedation is administered meets the following requirements:~~ be subject to the requirements set out in Section .0100 of this Subchapter.

(b) In addition to the drugs listed in Rule .0103(c)(3) of this Subchapter, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) In addition to the requirements set out in Rule .0103(c)(4) of this Subchapter, the permit holder's emergency manual shall include assignments to be performed in the event of emergency by a BLS-certified auxiliary dedicated to patient monitoring.

(d) In addition to the requirements set out in Rule .0103(e) of this Subchapter concerning pre-operative procedures, the permit holder shall ensure that patients who have been administered moderate pediatric conscious sedation are monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures by the permit holder or an auxiliary dedicated to patient monitoring.

(e) As part of the pre-operative assessment required by Rule .0103(e) of this Subchapter, the permit holder shall evaluate the patient for health risks as follows:

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

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

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

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

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

(4) the patient is [~~attended~~] under observation by the permit holder or a BLS-certified auxiliary at all times.

(g) During the sedation procedure, a moderate pediatric conscious sedation permit holder shall not administer anesthetic or sedative agents:

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

(2) determined by the manufacturer to be contraindicated for use in moderate pediatric conscious sedation; or

(3) in amounts exceeding the manufacturers' maximum recommended dosages, unless the permit holder documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

(h) In addition to the requirements set out in Rule .0103(h) of this Subchapter concerning the patient treatment record, the permit holder shall maintain documentation of pre-sedation instructions and information provided to the patient or person responsible for the patient, which shall include:

(1) objectives of the sedation;

(2) anticipated changes in patient behavior during and after sedation;

(3) instructions to the person responsible for a patient transported in a [~~car~~] child safety seat regarding patient head position to avoid airway obstruction;

(4) a 24-hour telephone number for the permit holder or his or her BLS-certified auxiliaries; and

(5) instructions on limitations of activities and dietary precautions.

(i) For purposes of Rule .0104(b)(2) of this Subchapter, during an evaluation, a moderate pediatric conscious sedation permit holder or applicant shall demonstrate competency in the deployment of an intravenous delivery system as follows:

(1) a permit holder or applicant who uses intravenous sedation shall demonstrate the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an intravenous delivery system; and

(2) a permit holder or applicant who does not use intravenous sedation shall describe the proper deployment of an intravenous delivery system and shall demonstrate the administration of moderate pediatric conscious sedation on a live patient.

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

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

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

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

~~(D) suction equipment as necessary for specific procedures, including non electrical back up suction;~~

~~(E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back up E cylinder portable oxygen tank apart from the central system;~~

~~(F) small, medium, and large oral and nasal airways;~~

~~(G) blood pressure monitoring device;~~

~~(H) EKG monitor;~~

~~(I) pulse oximeter;~~

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

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

~~(L) thermometer;~~

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

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

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

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

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

~~(R) tourniquet and tape.~~

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

~~(A) Epinephrine;~~

~~(B) Atropine;~~

~~(C) antiarrhythmic;~~

~~(D) antihistamine;~~

~~(E) antihypertensive;~~

~~(F) bronchodilator;~~

~~(G) antihypoglycemic agent;~~

~~(H) vasopressor;~~

~~(I) corticosteroid;~~

~~(J) anticonvulsant;~~

~~(K) muscle relaxant;~~

~~(L) appropriate reversal agents;~~

~~(M) nitroglycerine;~~

~~(N) antiemetic; and~~

~~(O) Dextrose.~~

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

~~(4) The following records are maintained for at least 10 years:~~

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

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

~~(C) a sedation record; and~~

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

~~(5) The sedation record shall include:~~

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

(B) procedure start and end times;

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

(D) status of patient upon discharge; and

(E) documentation of complications or morbidity; and

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

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

(B) when IV sedation is used, IV infusion shall be administered before the commencement of the procedure and maintained until the patient is ready for discharge.

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

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

(1) monitoring blood pressure, pulse, and respiration;

(2) drug dosage and administration;

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

(4) sterile technique;

(5) use of BLS certified auxiliaries;

(6) monitoring of patient during recovery; and

(7) sufficiency of patient recovery time.

(d) During an inspection or evaluation, the applicant or permit holder shall demonstrate competency in the treatment of the following clinical emergencies:

(1) laryngospasm;

(2) bronchospasm;

(3) emesis and aspiration;

(4) respiratory depression and arrest;

(5) angina pectoris;

(6) myocardial infarction;

(7) hypertension and hypotension;

(8) allergic reactions;

(9) convulsions;

(10) syncope;

(11) bradycardia;

(12) hypoglycemia;

(13) cardiac arrest; and

(14) airway obstruction.

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

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

(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use; or

(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure.

(g) Patient monitoring:

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

(2) The permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined in Subparagraph (g)(3) of this Rule and is ready for discharge from the office.

(3) Recovery from moderate pediatric conscious sedation shall include documentation of the following:

(A) cardiovascular function stable;

(B) airway patency uncompromised;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

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

(H) for the special needs patient or a patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

~~(4) Before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (g)(3) of this Rule and the following discharge criteria:~~

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

~~(B) explanation and documentation of written postoperative instructions have been provided to a person responsible for the patient at time of discharge; and~~

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

History Note: *Authority G.S. 90-28; 90-30.1; 90-48;*
Eff. June 1, 2017;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018;
Amended Eff. February 1, 2023; February 1, 2019; August 1, 2018.

Burgos, Alexander N

From: Dauna Bartley <dauna@brockerlawfirm.com>
Sent: Friday, January 6, 2023 4:27 PM
To: Liebman, Brian R
Cc: Burgos, Alexander N
Subject: [External] RE: 21 NCAC 16Q Requests for Changes - January 2023 RRC

Hi Brian!

We'll work through the requests and let you know if we have any questions.

Have a good weekend,
Dauna

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, January 6, 2023 3:53 PM
To: Dauna Bartley <dauna@brockerlawfirm.com>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 21 NCAC 16Q Requests for Changes - January 2023 RRC

Hi Dauna,

I'm the attorney who reviewed the Rules submitted by the Board for the January 2023 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, January 19, 2023, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than 5 p.m. on Friday, January 13, 2023.

In the meantime, please do not hesitate to reach out via email with any questions or concerns.

Please note, there were no requests for changes for Rule .0202.

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov
