<p>| Subchapter | Rule Section | Rule Citation | Rule Name | Date and Last Agency Action on the Rule | Agency Determination - 21NCAC 16B [.130] | Implementations or Conflicts to Federal Regulation - 21NCAC 16B [.130] | Federal Regulation Citation | Public Comment Received - 21NCAC 16B [.130] | Agency Determination Following Public Comment - 21NCAC 16B [.130] | AHC Determination of Public Comments - 21NCAC 16B [.130] | Rule Final Determination of Status of Rule for Report to APO - 21NCAC 16B [.130] | CHA Next Steps |
|------------|--------------|---------------|----------|----------------------------------------|-----------------------------------------|---------------------------------------------|-------------------|---------------------|----------------------------------------|-----------------------------------------------|---------------------------------------------|---------------------------------------------|-----------------|
| Licensure  | 21 NCAC 16B .1001 | EXAMINATIONS | Section .0100 - ACTIVELY MILITARY PROVIDERS | Necessary without substantive public interest | No | No | Necessary without substantive public interest | No comments with merit | Necessary without substantive public interest and should remain in effect without further action | Keep in Code - Update History Note | | |
| Licensure  | 21 NCAC 16B .1001 | EXAMINATIONS | Section .0100 - ACTIVELY MILITARY PROVIDERS | Necessary without substantive public interest | No | No | Necessary without substantive public interest | No comments with merit | Necessary without substantive public interest and should remain in effect without further action | Keep in Code - Update History Note | | |
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### S.S. 150B-21.3A Report for 21 NCAC 16, BOARD OF DENTAL EXAMINERS

**Agency:** Board of Dental Examiners  
**Comment Period:** 03/05/2017 through 07/05/2017  
**Date Submitted to APO:** November 20, 2017

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<tr>
<td>21 NCAC 16Z</td>
<td>.0103</td>
<td>INSPECTIONS</td>
<td>Eff. February 1, 2008</td>
<td>Necessary without substantive public interest</td>
<td>No</td>
<td>No comments with merit</td>
<td>No comments with merit casting further action</td>
<td>Necessary without substantive public interest and should remain in effect without further action</td>
<td>Keep in Code - Update History Note</td>
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G.S. 150B-21.3A Report for 21 NCAC 16, BOARD OF DENTAL EXAMINERS

**Date Submitted to APO:** November 20, 2017

**Agency:** Board of Dental Examiners

**Comment Period:** 03/05/2017 through 07/05/2017

**Date Submitted to APO:** November 20, 2017

**Agency:** Board of Dental Examiners

**Comment Period:** 03/05/2017 through 07/05/2017

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**Date Submitted to APO:** November 20, 2017

**Agency:** Board of Dental Examiners

**Comment Period:** 03/05/2017 through 07/05/2017
Abby:

Attached is a message I just received from Drs. Hamrick and McKenzie withdrawing their previous objections to the categorization of amended 21NCAC 16Q.0101 (39). Drs. Hamrick and McKenzie were the 2 Dental Board licensees who previously had objected to the classification of that rule. There were several other objections submitted by non-licensees but were essentially identical in content and addressed the same issues. As explained in our periodic rule review report, the Board addressed these related objections and clarified that the procedure the dentists wanted to follow did not violate the Board's rules, including the one cited.

Please confirm receipt and let me know if you need us to bring copies of this communication to the Commission meeting on Thursday or require any additional information. Thank you.

Doug

This transmission is intended by the sender and proper recipient to be confidential, intended only for the proper recipient and may contain information that is privileged, attorney work product or exempt from disclosure under applicable law. If you are not the intended recipient, you are notified that the dissemination, distribution or copying of this message is strictly prohibited. If you receive this message in error, or are not the proper recipient, please notify the sender at either the e-mail address or telephone number above and delete this e-mail from your computer. Receipt by anyone other than the proper recipient is not a waiver of any attorney-client, work product, or other applicable privilege. Thank you.

From: Steve Hamrick [mailto:hamrick7501@gmail.com]
Sent: Monday, November 13, 2017 11:43 AM
To: Bobby White <bwhite@ncdentalboard.org>; Doug Brocker <doug@brockerlawfirm.com>; Sheppard McKenzie IV <sheppardmckenzie@gmail.com>
Subject: Withdrawal of Objection for RRC from Drs. Hamrick and McKenzie

Bobby, In light of the dental board's recent ruling regarding the utilization of our CRNAs to help administer certain drugs for Moderate IV Sedation, we are officially withdrawing our objection to the rules change under 21NCAC 16Q.0101 (39). Thank you and the board for clarification in this matter.

Sincerely, Steve Hamrick and Sheppard McKenzie

--

Steven W Hamrick, DMD

Raleigh Periodontics & Implant Dentistry
RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT REPORT. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: North Carolina Board of Dental Examiners

REPORT CITATION: 21 NCAC 16

RECOMMENDED ACTION:

X Approve

Change the agency determination following public comment

COMMENT:

This report is before the Rules Review Commission with the following determinations:

- Four rules as “necessary with substantive public interest;”
- 157 rules as “necessary without substantive public interest;” and
- Five rules as “unnecessary.”

The agency received public comments for Rule 21 NCAC 16Q .0101, which was published as “necessary without substantive public interest” and was approved as “necessary without substantive public interest” after review of the public comments by the agency.

For the Rules Review Commission’s consideration, here is the procedural history of this Rule:

1. Submission for Permanent Rule form, file stamped January 4, 2016;
2. Rule 21 NCAC 16Q .0101, approved by the Rules Review Commission on March 17, 2016 and legislative review was requested pursuant to G.S. 150B-21.3(b1);
3. Session Law 2016-31;
4. Submission for Permanent Rule form, file stamped April 20, 2017;
5. Rule 21 NCAC 16Q .0101, approved by the Rules Review Commission on May 18, 2017 and no legislative review was requested pursuant to G.S. 150B-21.3(b1);
6. G.S. 90-30.1; and

Please note that during the 2016 and 2017 review of this Rule by the Rules Review Commission, staff counsel made no recommendation for objection and the Rule was approved at both separate reviews. The Rule falls within the cited delegated authority; is clear and unambiguous; is reasonably necessary; and both rulemaking efforts of the agency complied with Part 2 of Article 2A of G.S. 150B.

Abigail M. Hammond
Commission Counsel
The agency received several verbatim public comments for 21 NCAC 16Q.0101, and a response was provided by counsel for the agency. Both items are attached for Commission review.

**Recommendation:**

Staff recommends finding that the public comments do not have merit, as the public comments do not address any of the standards for review by the Rules Review Commission set forth in G.S. 150B-21.9. The public comments address quality or efficacy of the Rule. The public comment focuses on the use of a drug for purposes of sedation that is not identified in the defined term, and requests to have the determination for only the defined term of “moderate conscious sedation” to be changed to “unnecessary,” which is only one term in a Rule containing 38 defined terms. Therefore, the public comments do not have merit and the determination should not be designated as “necessary with substantive public interest.” Staff recommends approving the report as submitted by the agency.

**Statutory standard for review:**

§ 150B-21.3A. Periodic review and expiration of existing rules.

(2) Step 2: The Commission shall review the reports received from the agencies pursuant to subdivision (1) of this subsection. If a public comment relates to a rule that the agency determined to be necessary and without substantive public interest or unnecessary, the Commission shall determine whether the public comment has merit and, if so, designate the rule as necessary with substantive public interest. For purposes of this subsection, a public comment has merit if it addresses the specific substance of the rule and relates to any of the standards for review by the Commission set forth in G.S. 150B-21.9(a).


(a) Standards. – The Commission must determine whether a rule meets all of the following criteria:

(1) It is within the authority delegated to the agency by the General Assembly.
(2) It is clear and unambiguous.
(3) It is reasonably necessary to implement or interpret an enactment of the General Assembly, or of Congress, or a regulation of a federal agency. The Commission shall consider the cumulative effect of all rules adopted by the agency related to the specific purpose for which the rule is proposed.
(4) It was adopted in accordance with Part 2 of this Article.

The Commission shall not consider questions relating to the quality or efficacy of the rule but shall restrict its review to determination of the standards set forth in this subsection
**SUBMISSION FOR PERMANENT RULE**

1. **Rule-Making Agency:** North Carolina State Board of Dental Examiners

2. **Rule citation & name (name not required for repeal):**
   21 NCAC 18Q_0101 General Anesthesia and Sedation Definitions

3. **Action:**
   - [X] ADOPTION
   - [ ] AMENDMENT
   - [ ] REPEAL
   - [ ] READOPATION

4. **Rule exempt from RRC review?**
   - [ ] Yes. Cite authority:
   - [X] No

5. **Rule automatically subject to legislative review?**
   - [ ] Yes. Cite authority:
   - [X] No

6. **Notice for Proposed Rule:**
   - [X] Notice Required
     - Notice of Text published on: July 1, 2015
     - Link to Agency notice: www.ncdentalboard.org
     - Hearing on: Aug. 6, 2015
     - Adoption by Agency on: December 12, 2015
   - [ ] Notice not required under G.S.
     - Adoption by Agency on:

7. **Rule establishes or increases a fee? (See G.S. 12-3.1)**
   - [ ] Yes
     - Agency submitted request for consultation on:
     - Consultation not required. Cite authority:
   - [X] No

8. **Fiscal impact (check all that apply):**
   - [ ] State funds affected
   - [ ] Environmental permitting of DOT affected and analysis submitted to Board of Transportation
   - [ ] Local funds affected
   - [ ] Substantial economic impact (> $1,000,000)
   - [X] Approved by OSBM
   - [ ] No fiscal note required

9. **REASON FOR ACTION**
   9A. **What prompted this action? Check all that apply:**
   - [X] Agency
   - [ ] Court order / cite:
   - [ ] Federal statute / cite:
   - [ ] Federal regulation / cite:
   - [ ] Legislation enacted by the General Assembly
     - Cite Session Law:
   - [ ] Petition for rule-making
   - [ ] Other:

   9B. **Explain:**
   21 NCAC 18Q_0101 was amended to to clarify and add to the definition of terms applicable to the administration of general anesthesia and sedation.

10. **Rule-making Coordinator:** Carolin Bakewell
    **Address:** 2000 Perimeter Parkway, Ste. 106, Morrisville NC 27560
    **Phone:** 919-306-0116
    **E-Mail:** carolin.bakewell@gmail.com
    **Agency Contact, if any:**
    **Phone:**
    **E-Mail:**

11. **Signature of Agency Head* or Rule-making Coordinator:**
    [Signature]

*If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

**Typed Name:** Carolin Bakewell
**Title:** Rule Making Coordinator

**RRC AND OAH USE ONLY**

**Action taken:**
- [ ] RRC extended period of review:
- [ ] RRC determined substantial changes:
- [ ] Withdrawn by agency
- [ ] Subject to Legislative Review
- [ ] Other:

Permanent Rule 0400 – 10/2015
21 NCAC 16Q .0101 is amended as published in 30:1 NCR 2 with changes as follows:

21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS
For the purpose of these Rules relative to the administration of minimal conscious sedation, moderate conscious sedation, moderate conscious sedation limited to oral routes or nitrous oxide inhalation, moderate pediatric conscious sedation, or general anesthesia by or under the direction of a dentist, the following definitions shall apply:

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

"Competent" – displaying special skill or knowledge derived from training and experience.

"Conscious sedation" – an induced state of a depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway without assistance and respond appropriately to physical stimulation and obey verbal commands, and that is produced by pharmacologic or non-pharmacologic agents, or a combination thereof. In accordance with this particular definition, the drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of consciousness unlikely. All dentists who perform conscious sedation shall have an unexpired sedation permit from the Dental Board.

"CRNA" – certified registered nurse anesthetist.

"Deep sedation" – an induced state of a depressed level of consciousness accompanied by partial loss of protective reflexes, including the ability to continually maintain an airway independently without assistance or respond purposefully to verbal command, and is produced by pharmacological agents. All dentists who perform deep sedation shall have an unexpired general anesthesia permit from the Dental Board.

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

"Direct supervision" – the dentist responsible for the sedation/anesthesia procedure shall be physically present in the facility immediately available and shall be continuously aware of the patient's physical status and well being at all times.

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

"ET CO2" — end tidal carbon dioxide.

"Facility" – the location where a permit holder practices dentistry and provides anesthesia/sedation services.

"Facility inspection" - an on-site inspection to determine if a facility where the applicant proposes to provide anesthesia/sedation is supplied, equipped, and maintained in a condition to support provision of anesthesia/sedation.
sedation services that meet the minimum standard of care, in compliance with the Dental Practice Act set forth in Article 2 of G.S. 90 and the Board’s rules of this Chapter.

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

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

(13) (24) (23) “Immediately available” – on-site in the facility and available for use without delay.

(25) (24) “Itinerant general anesthesia provider” - a permittee who has complied with Rule .0206 of this Subchapter and who administers general anesthesia at another practitioner’s facility.

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

(15) (27) “May” – indicates freedom or liberty to follow a reasonable alternative.

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

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

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

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

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

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

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

(21) "Must" or "shall"—indicates an imperative need or duty or both; an essential or indispensable item; mandatory.

(22) "Parenteral"—the administration of pharmacological agents intravenously, intraosseously, intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.

(23) "PALS"—Pediatric Advanced Life Support.

(24) "Protective reflexes"—includes the ability to swallow and cough.

(25) "RN"—Registered Nurse licensed by the North Carolina Board of Nursing.

(26) "Special needs patients"—patients with diminished mental and or physical capacity who are unable to cooperate sufficiently to receive ambulatory dental care without sedation or anesthesia.

(27) "Supplemental dosing"—the oral administration of a pharmacological agent that results in an enhanced level of conscious sedation when added to the primary sedative agent administered for the purpose of oral moderate conscious sedation, and which, when added to the primary agent, does not exceed the maximum safe dose of either agent, separately or synergistically.
"Vested adult" – a responsible adult who is the legal parent or guardian, or designee of a legal parent or guardian, entrusted with the care of a minor patient following the administration of general anesthesia or conscious sedation.

History Note: Authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Temporary Amendment Eff. December 11, 2002;
AN ACT TO DISAPPROVE THE GENERAL ANESTHESIA AND SEDATION DEFINITIONS RULE AND CERTAIN RELATED RULES ADOPTED BY THE NORTH CAROLINA BOARD OF DENTAL EXAMINERS AND TO DIRECT THE NORTH CAROLINA BOARD OF DENTAL EXAMINERS NOT TO ENFORCE CERTAIN RULES.

The General Assembly of North Carolina enacts:

SECTION 1. Pursuant to G.S. 150B-21.3(b1), 21 NCAC 16Q .0101 (General Anesthesia and Sedation Definitions), as adopted by the North Carolina Board of Dental Examiners on December 12, 2015, and approved by the Rules Review Commission on March 17, 2016, is disapproved.

SECTION 2. Pursuant to G.S. 150B-21.3(b2), the North Carolina Board of Dental Examiners caused the effective dates of a number of rules that were adopted as part of a group, including the rule disapproved by Section 1 of this act, to be delayed as provided in G.S. 150B-21.3(b1), by submitting a written statement to the Rules Review Commission on March 31, 2016. Except as provided in Section 3 of this act, the rules listed in the Board's written statement are disapproved to the same extent as 21 NCAC 16Q .0101.

SECTION 3. Notwithstanding G.S. 150B-21.3(b2) and the written statement of the North Carolina Board of Dental Examiners dated March 31, 2016, the following rules are effective April 1, 2016:

21 NCAC 16Q .0204 (Procedure for General Anesthesia Evaluation or Inspection and Re-inspection)
21 NCAC 16Q .0205 (Results of Site Evaluation and Reevaluation)
21 NCAC 16Q .0306 (Procedure for Moderate Conscious Sedation Evaluation or Inspection and Re-Inspection)
21 NCAC 16Q .0408 (Procedure for Moderate Pediatric Conscious Sedation Evaluation or Inspection and Re-Inspection)
21 NCAC 16Q .0703 (Reports of Adverse Occurrences)
21 NCAC 16Q .0601 (Reports of Adverse Occurrences)
21 NCAC 16Q .0602 (Failure to Report)

SECTION 4. Notwithstanding G.S. 150B-21.3(b), the North Carolina Board of Dental Examiners shall not enforce the following rules which became effective April 1, 2016:

21 NCAC 16O .0301 (Nitrous Oxide Sedation)
21 NCAC 16O .0302 (Nitrous Oxide Monitoring)
21 NCAC 16O .0401 (Non-Delegable Functions)

The Board shall continue to enforce these rules as they existed prior to the amendments which became effective on April 1, 2016.
SECTION 5. This act is effective when it becomes law.
In the General Assembly read three times and ratified this the 16th day of June, 2016.

s/ Daniel J. Forest
President of the Senate

s/ Tim Moore
Speaker of the House of Representatives

s/ Pat McCrory
Governor

Approved 4:03 p.m. this 22nd day of June, 2016
SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: The North Carolina State Board of Dental Examiners

2. Rule citation & name (name not required for repeal): 21 NCAC 16Q.0101 General Anesthesia and Sedation Definitions

3. Action:
☐ ADOPTION  ☒ AMENDMENT  ☐ REPEAL  ☐ READOPTION

4. Rule exempt from RRC review?
☐ Yes.
☒ No.

5. Rule automatically subject to legislative review?
☐ Yes. Cite authority:
☒ No.

6. Notice for Proposed Rule:
☒ Notice Required
Notice of Text published on: January 17, 2017
Link to Agency notice: www.ncdentalboard.org
Hearing on: February 9, 2017
Adoption by Agency on: April 7, 2017
☐ Notice not required under G.S.:
Adoption by Agency on:

7. Rule establishes or increases a fee? (See G.S. 12-3.1)
☐ Yes
☒ No
Agency submitted request for consultation on:
Consultation not required. Cite authority:

8. Fiscal impact (check all that apply):
☐ State funds affected
☐ Environmental permitting of DOT affected and analysis submitted to Board of Transportation
☐ Local funds affected
☐ Substantial economic impact ($1,000,000)
☐ Approved by OSBM
☒ No fiscal note required

9. REASON FOR ACTION

9A. What prompted this action? Check all that apply:
☒ Agency
☐ Court order / cite:
☐ Federal statute / cite:
☐ Federal regulation / cite:
☐ Legislation enacted by the General Assembly
☐ Cite Session Law:
☐ Petition for rule-making
☐ Other:

9B. Explain: 21 NCAC 16Q.0101 was amended to clarify and add to the definition of terms applicable to the administration of general anesthesia and sedation.

Address: 2000 Perimeter Park Drive, Suite 160,
Morrisville, North Carolina 27560

Phone: (919) 854-2460
E-Mail: doug@brockerlawfirm.com

Agency Contact, if any:
Phone:
E-Mail:

11. Signature of Agency Head* or Rule-making Coordinator:

*If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Douglas Brocker
Title: Rule Making Coordinator

Action taken:
☐ RRC extended period of review:
☐ RRC determined substantial changes:
☐ Withdrawn by agency
☐ Subject to Legislative Review
☐ Other:

Permanent Rule 0400 – 10/2015
21 NCAC 16Q .0101 is amended with changes as published in 31:14 NCR 1389-92 as follows:

21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS

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

1. “Analgesia” – the diminution or elimination of pain.
2. “Anti-anxiety sedative” – a sedative agent administered in a dosage intended to reduce anxiety without diminishing consciousness or protective reflexes.
3. “Anxiolysis” – pharmacological reduction of anxiety through the administration of a single dose of a minor psychosedative, possibly in combination with nitrous oxide, to children or adults prior to commencement of treatment on the day of the appointment which allows for uninterrupted interactive ability in a totally awake patient with no compromise in the ability to maintain a patent airway independently and continuously and without assistance. Nitrous oxide may be administered in addition to the minor psychosedative without constituting multiple dosing for purpose of these Rules.
4. “ACLS” – Advanced Cardiac Life Support.
5. “Administer” – to direct, manage, supervise, control, and have charge of all aspects of selection, dosage, timing, and method of delivery to the patient of any pharmacologic agent intended to reduce anxiety or depress consciousness.
7. “Auxiliaries” – non-dentist staff members involved in general anesthesia or sedation procedures.
9. “Behavior control” – the use of pharmacological techniques to control behavior to a level that dental treatment may be performed without injury to the patient or dentist, effectively and efficiently.
10. “Behavioral management” – the use of pharmacological or psychological techniques, singly or in combination, to modify behavior to a level that dental treatment may be performed effectively and efficiently, without injury to the patient or dentist.
11. “Competent” – displaying special skill or knowledge derived from training and experience.
12. “Conscious sedation” - an induced state of a depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway without assistance and respond appropriately to physical stimulation and verbal command, and that is produced by pharmacologic or non-pharmacologic agents, or a combination thereof. In accordance with this particular definition, the drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of consciousness unlikely. All dentists who perform conscious sedation shall have an unexpired sedation permit from the Dental Board.
“Deep sedation” – an induced state of a depressed level of consciousness accompanied by partial loss of protective reflexes, including the ability to continually maintain an airway independently without assistance or respond purposefully to verbal command, and is produced by pharmacological agents. All dentists who perform deep sedation shall have an unexpired general anesthesia permit from the Dental Board.

“Deliver” – to assist a permitted dentist in administering sedation or anesthesia drugs by providing the drugs to the patient pursuant to a direct order from the dentist and while under the dentist’s direct supervision.

“Direct supervision” – the dentist responsible for the sedation/anesthesia sedation or anesthesia procedure shall be physically present in the facility immediately available and shall be continuously aware of the patient's physical status and well being at all times.

“Emergencies manual” – a written manual that documents:

a) the location of all emergency equipment and medications in each facility;

b) each staff member’s role during medical emergencies; and

c) the appropriate treatment for laryngospasm, bronchospasm, emesis and aspiration, respiratory depression and arrest, angina pectoris, myocardial infarction, hypertension, hypotension, allergic reactions, convulsions, syncope, bradycardia, [insulin shock] hypoglycemia, cardiac arrest, and airway obstruction.

“Enteral” – the administration of pharmacological agents orally, intranasally, sublingually, or rectally.

“ET CO2” — end tidal carbon dioxide.

“Facility” – the location where a permit holder practices dentistry and provides anesthesia/sedation anesthesia or sedation services.

“Facility inspection” – an on-site inspection to determine if a facility where the applicant proposes to provide anesthesia/sedation anesthesia or sedation is supplied, equipped, staffed and maintained in a condition to support provision of anesthesia/sedation anesthesia or sedation services that meet the minimum standard of care in compliance with the Dental Practice Act set forth in Article 2 of G.S. 90 and the Board’s rules of this Chapter.

“General anesthesia” - the intended controlled state of a depressed level of consciousness that is produced by pharmacologic agents and accompanied by a partial or complete loss of protective reflexes, including the ability to maintain an airway and respond purposefully to physical stimulation and [obey] or verbal commands. All dentists who perform general anesthesia shall have an unexpired general anesthesia permit from the Dental Board.

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

“Immediately available” – on-site in the facility and available for immediate use, use without delay.
“Itinerant general anesthesia provider” - a permittee who has complied with Rule .0206 of this Subchapter and who administers general anesthesia at another practitioner’s facility.

"Local anesthesia" – the elimination of sensations, especially including pain, in one part of the body by the regional application or injection of a drug.

“May” – indicates freedom or liberty to follow a reasonable alternative.

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

"Minor psychosedative/Minor tranquilizer" – pharmacological agents which allow for uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent airway continuously and without assistance and carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

"Moderate conscious sedation" – conscious sedation characterized by a drug induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients 13 years of age or older, by oral, nasal, rectal, or parenteral routes of administration of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate conscious sedation is may be provided for behavior control. A moderate conscious sedation provider shall not use the following:

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

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

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

"Moderate pediatric conscious sedation" - conscious sedation characterized by a drug induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients up to 18
under 13 years of age, or special needs patients, by oral, nasal, rectal, or parenteral routes of administration of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate pediatric conscious sedation is may be provided for behavior control by licensed dentists who comply with the terms of Rule .0404 of this Subchapter. A moderate pediatric conscious sedation permit holder shall not use the following:

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

(21) "Must" or "shall" - indicates an imperative need or duty or both, an essential or indispensable item, mandatory.

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

(31) "PALS" - Pediatric Advanced Life Support.

"Protective reflexes" - includes the ability to swallow and cough.

(33) "RN" - Registered Nurse licensed by the North Carolina Board of Nursing.

(34) "Sedation Procedure" - process begins when any pharmacological agent is first administered to a patient to induce general anesthesia or sedation and continues until the dentist permit holder determines that the patient has met the [applicable] recovery and discharge criteria set forth in the applicable Rules in this Subchapter.

(36) "Special needs patients" - patients with diminished mental and or physical capacity who are unable to cooperate to receive ambulatory dental care without sedation or anesthesia.

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

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

History Note: Authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Temporary Amendment Eff. December 11, 2002;
§ 90-30.1. Standards for general anesthesia and enteral and parenteral sedation; fees authorized.

The North Carolina Board of Dental Examiners may establish by regulation reasonable education, training, and equipment standards for safe administration and monitoring of general anesthesia and enteral and parenteral sedation for outpatients in the dental setting. Regulatory standards may include a permit process for general anesthesia and enteral and parenteral sedation by dentists. The requirements of any permit process adopted under the authority of this section shall include provisions that will allow a dentist to qualify for continued use of enteral sedation, if he or she is licensed to practice dentistry in North Carolina and shows the Board that he or she has been utilizing enteral sedation in a competent manner for the five years preceding January 1, 2002, and his or her office facilities pass an on-site examination and inspection by qualified representatives of the Board. For purposes of this section, oral premedication administered for minimal sedation (anxiolysis) shall not be included in the definition of enteral sedation. In order to provide the means of regulating general anesthesia and enteral and parenteral sedation, including examination and inspection of dental offices involved, the Board may charge and collect fees established by its rules for each permit application, each annual permit renewal, and each office inspection in an amount not to exceed the maximum fee amounts set forth in G.S. 90-39. (1987 (Reg. Sess., 1988), c. 1073; 1989, c. 648; 1989 (Reg. Sess., 1990), c. 1066, s. 12(a); 1995 (Reg. Sess., 1996), c. 584, s. 2; 2001-511, s. 1.)
§ 90-48. Rules and regulations of Board; violation a misdemeanor.

The North Carolina State Board of Dental Examiners shall be and is hereby vested, as an agency of the State, with full power and authority to enact rules and regulations governing the practice of dentistry within the State, provided such rules and regulations are not inconsistent with the provisions of this Article. Such rules and regulations shall become effective 30 days after passage, and the same may be proven, as evidence, by the president and/or the secretary-treasurer of the Board, and/or by certified copy under the hand and official seal of the secretary-treasurer. A certified copy of any rule or regulation shall be receivable in all courts as prima facie evidence thereof if otherwise competent, and any person, firm, or corporation violating any such rule, regulation, or bylaw shall be guilty of a Class 2 misdemeanor, and each day that this section is violated shall be considered a separate offense.

The Board shall issue every two years to each licensed dentist a compilation or supplement of the Dental Practice Act and the Board rules and regulations, and upon written request therefor by such licensed dentist, a directory of dentists. (1935, c. 66, s. 19; 1957, c. 592, s. 6; 1971, c. 755, s. 12; 1993, c. 539, s. 620; 1994, Ex. Sess., c. 24, s. 14(c).)
Bobby D. White  
North Carolina State Board of Dental Examiners  
2000 Perimeter Park Dr., Suite 160  
Morrisville, NC 27560

Dear Mr. White:

In connection with the current Periodic Review of Existing Rules, on behalf of my practice, Raleigh Periodontics, please accept this as a "Public Comment" as defined by G.S. 150B-21.3A(a)(5), and objection to certain portions of Subchapter 16Q - General Anesthesia and Sedation Rules. This Public Comment and Objection specifically addresses the definition of Moderate Conscious Sedation as set forth in 21 NCAC 16Q .0101(39) (the “Rule”). The Rule, which became effective on June 1, 2017, states in part that a moderate conscious sedation provider shall not use drugs designed by the manufacturer for use in administering general anesthesia or deep sedation. Prior to June 1, 2017, no such restriction with respect to moderate sedation existed in the rules. This Public Comment and Objection references the Standards of Commission Review, as set forth in G.S. 150B-21.9(a), in that the Rule is not reasonably necessary to implement or interpret an enactment of the General Assembly, or of Congress, or a regulation of a federal agency, and the cumulative effect of the rule does not serve a specific purpose, it does not serve public interest, nor is it in the best interests of our patients. For the reasons set for below, the Rule should be classified by The North Carolina State Board of Dental Examiners as “Unnecessary” pursuant to N.C. Gen. Stat. 150B-21.3A.

The Rule arbitrarily and unnecessarily limits which drugs can be used for moderate sedation. As an example, under the Rule, practitioners who have a moderate sedation license can no longer use Propofol, even if it is administered by a highly trained CRNA and not by the person conducting the procedure. The Rule eviscerates a practitioner’s ability to use CRNAs to administer Propofol for moderate sedation. On the other hand, under the current rules, a practitioner licensed in general anesthesia may administer Propofol and conduct the procedure, as opposed to using a CRNA to administer the Propofol. Please note that the manufacturer of Propofol includes a warning on each box that it should only be administered by persons trained in the administration of general anesthesia and not by those involved in the conduct of the procedure. This illustrates a clear inconsistency in the Rule related to moderate sedation.

Propofol is a safe drug and serves the best interests of our patients. Propofol has been, and continues to be, the primary choice for CRNAs for moderate sedation. It has a very short half-life, quick recovery, a great safety profile, and results in a high level of patient satisfaction in connection with moderate sedation. Moreover, using a dedicated, highly trained anesthesia provider to administer Propofol is the best practice. The limits imposed by the Rule for moderate sedation are contrary to public interest, inconsistent with the rules related to administration of general anesthesia, and the cumulative effect of the Rule does not serve a specific purpose.

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Sincerely,

Sheppard McKenzie DDS, MS
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ANDI N. STAMPER, DNP, CRNA

RICE ANESTHESIA, LLC
8 QUEENSLAND CT
DURHAM, NC 27712
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21.3A.

Katy Choquette CRNA
Halcyon Anesthesia P.C.
228 William Drummond Way
Raleigh NC 27604
Bobby D. White  
North Carolina State Board of Dental Examiners  
2000 Perimeter Park Dr., Suite 160  
Morrisville, NC 27560

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Jacquelyn Carter, CRNA
Crescent City Anesthesia
1224 Timber Dr
Suite 123
Garnet, NC 27515
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Linda Sheldon
Anesthesia To Go
105th Evergreen Spring Pl.
Raleigh, NC 27604
919.349.0144
Bobby D. White  
North Carolina State Board of Dental Examiners  
2000 Perimeter Park Dr., Suite 160  
Morrisville, NC 27560

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Sincerely,

[Signature]

Steven W. Hamrick, DMD
August 11, 2017

Dr. Steven Hamrick, DMD
Raleigh Periodontics
7501 Falls of Neuse Road, Suite 100
Raleigh, NC 27615
hamrick7501@gmail.com

Re: Response to public comment concerning amended sedation definitions in 21 NCAC 16Q .0101(39)

Dear Dr. Hamrick:

I am counsel to the North Carolina Board of Dental Examiners and the Board has asked that I reply to your public comment, which the Board received on June 28, 2017. The Board wanted to respond and address the concerns that you expressed in that letter and your prior communications, including your appearance and presentation at the sedation advisory committee meeting on June 9. The primary concern you have expressed in your public comment and prior communications is your belief that the amended definition for moderate conscious sedation in 21 NCAC 16Q.0101(39) does not permit use of the drug Propofol or Diprivan by moderate conscious sedation permit holders, such as yourself, even when being administered by a Certified Registered Nurse Anesthetist (CRNA).

The following sets forth our understanding of the arrangement or proposed arrangement that prompted your communications and inquiry. You hold a moderate sedation permit and frequently have a North Carolina licensed CRNA administer sedation drugs to your patients during your dental surgery or other procedures. The CRNA working in your office would administer Propofol while you are performing surgery or other dental procedures. The CRNA is trained in the administration of general anesthesia. The CRNA’s primary responsibility is administering Propofol and is not involved in the surgery or dental procedure. According to your communications and representations, the CRNA would administer Propofol in a manner that placed the patient in a state not exceeding moderate conscious sedation and would not result in the patient entering a state of deep sedation or general anesthesia.
As you are aware, the applicable rules concerning general anesthesia and sedation are set forth in subchapter Q of the Board’s regulations. The Board’s regulations generally do not reference specific drugs, including Propofol, but reference them only by definition or classification. Accordingly, none of the Board’s regulations specifically reference Propofol.

The specific amended definition you reference that took effect on June 1, 2017 provides in pertinent part that:

A moderate conscious sedation provider shall not use the following:

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

21 NCAC 16Q .0101(39)

The Board’s regulations require a dentist with a moderate conscious sedation permit to supervise a CRNA employed to administer moderate sedation. 21 NCAC 16Q .0302(a). The Board’s amended regulations define "administer" as "to direct, manage, supervise, control, and have charge of all aspects of selection, dosage, timing, and method of delivery to the patient of any pharmacologic agent intended to reduce anxiety or depress consciousness." 21 NCAC 16Q .0101(5).

The Board’s regulations anticipate that its interpretation of the rules would require reference to other sources about the drugs at issue. Thus, the Board’s response to your comment is informed by information the drug manufacture of Propofol submitted to the Federal Drug Administration (FDA) and provided on its drug product label.

For example, the FDA-approved drug insert label for Propofol/Diprivan states under the Indications and Usage section: “DIPRIVAN is an IV general anesthetic and sedation drug.” One of the indications listed is for “Combined sedation and regional anesthesia,” in addition to general anesthesia uses. Additionally, use of Propofol for moderate conscious sedation is not listed in the Contraindication section of the drug label. Therefore, the FDA-approved drug insert label indicates that Propofol/Diprivan is not strictly limited to use for general anesthesia nor is it contraindicated for use in moderate sedation in all circumstances.
The FDA-approved drug insert label and the package warning label for Propofol, however, contain some essential conditions on its use and administration. For example, the package warning label on Propofol provides that it: “Should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.” The package warning label further provides: “Sedated patient should be continuously monitored, and facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation must be immediately available.” Therefore, the FDA-approved drug insert label and the drug package warning label for Propofol set forth critical restrictions and conditions for its use.

Based on the above stated facts and analysis, and assuming the above essential restrictions and conditions have been met, the Board does not believe that the administration of Propofol/Diprivan by a CRNA in the manner set forth by your comments and communications violates the Board’s amended rules, including 21 NCAC 16Q .0101(39). In responding to your public comment and related communications, the Board is relying upon its understanding of the above facts that you provided, as set forth in the second paragraph of this letter, and also that all the above essential conditions noted herein have been satisfied.

It is critical to note that different facts likely could result in a different conclusion. For example, it would violate the Board’s regulations if a patient being administered Propofol by a CRNA, under the supervision of a moderate sedation permit holder, was induced into deep sedation or general anesthesia because the dentist does not hold a permit for deep sedation or general anesthesia. See 21 NCAC 16Q .0201(a). The dentist permit holder is legally required to supervise the CRNA under the Dental Practice Act. N.C. Gen. Stat. § 90-29(b)(6). Accordingly, it is the responsibility of the dentist supervising a CRNA to ensure that the patient does not exceed a level of moderate conscious sedation and to be sufficiently trained to determine whether that level has been exceeded. 21 NCAC 16Q .0301(b). Failure to do so would violated the Board’s regulations.

Additionally, nothing in this response to your comment is intended to state or imply that a dentist holding a moderate conscious sedation permit is allowed by the Board’s rules to administer Propofol directly to a patient. Unlike a CRNA, the dentist moderate sedation permit holder has not been trained and qualified to administer general anesthesia. Therefore, a dentist moderate conscious sedation permit holder directly administering Propofol to a patient appears contrary to the package warning label against such use.
I hope that this response to your comment adequately addresses your concerns.

Sincerely,

[Signature]

Douglas J. Brocker