

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
7. G.S. 90-48.

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.

....
(c) Review Process. - Each agency subject to this Article shall conduct a review of the agency's existing rules at least once every 10 years in accordance with the following process:

...
(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).

§ 150B-21.9. Standards and timetable for review by Commission.

(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

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

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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~~ 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 any 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 that allows for uninterrupted interactive ability in a totally an 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] shall be able to respond [normally] to tactile stimulation and verbal commands and walk, if applicable. [walk normally.] 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]~~ control, and have charge of all aspects of selection, dosage, ~~[timing]~~ timing, and method of delivery to the patient of any pharmacologic agent intended to reduce anxiety or depress consciousness.
- (17) ~~[(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)]~~ (6) "ASA" – American Society of Anesthesiologists.
- ~~[(8)]~~ (7) "Auxiliaries" – non-dentist staff members [directly] involved in general anesthesia or sedation procedures.
- ~~[(9)]~~ (8) "BLS" – Basic life support.
- (4) ~~[(10)]~~ (9) "Behavior control" – the use of pharmacological techniques to control behavior to a level [at which] that dental treatment can may be performed without injury to the patient or dentist. effectively and efficiently.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

SESSION LAW 2016-31
HOUSE BILL 1145

1 AN ACT TO DISAPPROVE THE GENERAL ANESTHESIA AND SEDATION DEFINITIONS
2 RULE AND CERTAIN RELATED RULES ADOPTED BY THE NORTH CAROLINA
3 BOARD OF DENTAL EXAMINERS AND TO DIRECT THE NORTH CAROLINA
4 BOARD OF DENTAL EXAMINERS NOT TO ENFORCE CERTAIN RULES.
5

6 The General Assembly of North Carolina enacts:
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8 **SECTION 1.** Pursuant to G.S. 150B-21.3(b1), 21 NCAC 16Q .0101 (General
9 Anesthesia and Sedation Definitions), as adopted by the North Carolina Board of Dental
10 Examiners on December 12, 2015, and approved by the Rules Review Commission on March 17,
11 2016, is disapproved.

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

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

21 21 NCAC 16Q .0204 (Procedure for General Anesthesia Evaluation or Inspection and
22 Re-inspection)

23 21 NCAC 16Q .0205 (Results of Site Evaluation and Reevaluation)

24 21 NCAC 16Q .0306 (Procedure for Moderate Conscious Sedation Evaluation or
25 Inspection and Re-Inspection)

26 21 NCAC 16Q .0408 (Procedure for Moderate Pediatric Conscious Sedation
27 Evaluation or Inspection and Re-Inspection)

28 21 NCAC 16Q .0703 (Reports of Adverse Occurrences)

29 21 NCAC 16Q .0601 (Reports of Adverse Occurrences)

30 21 NCAC 16Q .0602 (Failure to Report)

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

33 21 NCAC 16O .0301 (Nitrous Oxide Sedation)

34 21 NCAC 16O .0302 (Nitrous Oxide Monitoring)

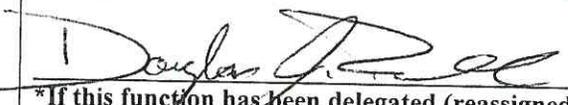
35 21 NCAC 16O .0401 (Non-Delegable Functions)

36 The Board shall continue to enforce these rules as they existed prior to the amendments which
37 became effective on April 1, 2016.



02

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: <input type="checkbox"/> ADOPTION <input checked="" type="checkbox"/> AMENDMENT <input type="checkbox"/> REPEAL <input type="checkbox"/> READOPTION	
4. Rule exempt from RRC review? <input type="checkbox"/> Yes. Cite authority: <input checked="" type="checkbox"/> No	5. Rule automatically subject to legislative review? <input type="checkbox"/> Yes. Cite authority: <input checked="" type="checkbox"/> No
6. Notice for Proposed Rule: <input checked="" type="checkbox"/> 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 <input type="checkbox"/> Notice not required under G.S.: Adoption by Agency on:	
7. Rule establishes or increases a fee? (See G.S. 12-3.1) <input type="checkbox"/> Yes Agency submitted request for consultation on: Consultation not required. Cite authority: <input checked="" type="checkbox"/> No	8. Fiscal impact (check all that apply): <input type="checkbox"/> State funds affected <input type="checkbox"/> Environmental permitting of DOT affected and analysis submitted to Board of Transportation <input type="checkbox"/> Local funds affected <input type="checkbox"/> Substantial economic impact (≥\$1,000,000) <input type="checkbox"/> Approved by OSBM <input checked="" type="checkbox"/> No fiscal note required
9. REASON FOR ACTION	
9A. What prompted this action? Check all that apply: <input checked="" type="checkbox"/> Agency <input type="checkbox"/> Court order / cite: <input type="checkbox"/> Federal statute / cite: <input type="checkbox"/> Federal regulation / cite: <input type="checkbox"/> Legislation enacted by the General Assembly Cite Session Law: <input type="checkbox"/> Petition for rule-making <input type="checkbox"/> 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.	
10. Rule-making Coordinator: Douglas Brocker, Esq. 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: <input type="checkbox"/> RRC extended period of review: <input type="checkbox"/> RRC determined substantial changes: <input type="checkbox"/> Withdrawn by agency <input type="checkbox"/> Subject to Legislative Review <input type="checkbox"/> Other:	

FILED
 2017 APR 20 PM 3:33
 OFFICE OF ADMIN HEARINGS

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

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

1 (25) "Itinerant general anesthesia provider"- a permittee who has complied with Rule .0206 of this
2 Subchapter and who administers general anesthesia at another practitioner's facility.

3 ~~(14)(26)~~ "Local anesthesia" – the elimination of sensations, especially including pain, in one part of the body
4 by the regional application or injection of a drug.

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

6 ~~(16)(27)~~ "Minimal conscious sedation" – conscious sedation characterized by a minimally depressed level of
7 consciousness, in which the patient retains the ability to independently and continuously maintain
8 an airway and respond normally to tactile stimulation and verbal command, provided to patients 13
9 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or
10 more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment,
11 possibly in combination with nitrous oxide. Minimal conscious sedation is may be provided for
12 behavioral management.

13 ~~(17)(28)~~ "Minor psychosedative/Minor tranquilizer" – pharmacological agents which that allow for
14 uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent
15 airway continuously and without assistance and carry a margin of safety wide enough to render
16 unintended loss of consciousness unlikely.

17 ~~(18)(29)~~ "Moderate conscious sedation" – conscious sedation characterized by a drug induced depression of
18 consciousness, during which patients ~~obey~~ respond purposefully to verbal commands, either alone
19 or accompanied by light tactile stimulation, provided to patients 13 years of age or older, by oral,
20 nasal, ~~rectal~~ rectal, or parenteral routes of administration of single or multiple pharmacological
21 agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly
22 in combination with nitrous oxide. Moderate conscious sedation ~~is may be~~ provided for behavior
23 ~~control.~~ control by licensed dentists who comply with the terms of Rule .0301 of this Subchapter. A
24 moderate conscious sedation provider shall not use the following:

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

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

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

35 ~~(20)(30)~~ "Moderate pediatric conscious sedation" - conscious sedation characterized by a drug induced
36 depression of consciousness, during which patients respond purposefully to ~~obey~~ verbal
37 commands, either alone or accompanied by light tactile stimulation, provided to patients up to 18

1 ~~under 13~~ years of age, or special needs patients, by oral, nasal, ~~rectal~~ rectal, or parenteral routes of
2 administration of single or multiple pharmacological agents, in single or multiple doses, within a 24
3 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate
4 pediatric conscious sedation ~~is~~ may be provided for behavior-~~control~~. control by licensed dentists
5 who comply with the terms of Rule .0404 of this Subchapter. A moderate pediatric conscious
6 sedation permit holder shall not use the following:

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

10 ~~(21)~~ ~~“Must” or “shall”~~ indicates an imperative need or duty or both; an essential or indispensable item;
11 ~~mandatory.~~

12 ~~(22)~~(31) “Parenteral” - the administration of pharmacological agents intravenously, intraosseously,
13 intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.

14 (32) “PALS” – Pediatric Advanced Life Support.

15 ~~(23)~~(33) “Protective reflexes” – includes the ability to swallow and cough.

16 (34) “RN” – Registered Nurse licensed by the North Carolina Board of Nursing.

17 (35) “Sedation Procedure” – **process** begins when any pharmacological agent is first administered to a
18 patient to induce general anesthesia or sedation and continues until the dentist permit holder
19 determines that the patient has met the **[applicable]** recovery and discharge criteria set forth in the
20 applicable Rules in this Subchapter.

21 (36) “Special needs patients” – patients with diminished mental and or physical capacity who are unable
22 to cooperate to receive ambulatory dental care without sedation or anesthesia.

23 ~~(24)~~(37) “Supplemental dosing” – the oral administration of a pharmacological agent that results in an
24 enhanced level of conscious sedation when added to the primary sedative agent administered for the
25 purpose of oral moderate conscious sedation, and ~~which~~, when added to the primary agent, does not
26 exceed the maximum safe dose of either agent, separately or synergistically.

27 ~~(25)~~(38) “Vested adult” – a responsible adult who is the legal parent or guardian, or designee of a legal parent
28 or guardian, entrusted with the care of a ~~minor~~ patient following the administration of general
29 anesthesia or conscious sedation.

30
31 *History Note: Authority G.S. ~~90-28; 90-30.1; 90-48;~~*
32 *Eff. February 1, 1990;*
33 *Temporary Amendment Eff. December 11, 2002;*
34 *Amended Eff. **June 1, 2017**; July 3, 2008; August 1, 2004.*

§ 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.

Further, the Rule imposes increased financial burden on dental patients. CRNAs, on average, charge \$125/hr. to \$140/hr. to administer Propofol. The average total costs to patients for two

hours of moderate sedation by a CRNA using Propofol is \$550.00. On the other hand, dental anesthesiologists on average charge a minimum of over \$2,000.00 to administer Propofol. Dental patients clearly suffer financially from the Rule.

In relation to the current Periodic Review of Existing Rules, based on the above Public Comment and Objection regarding 21 NCAC 16Q .0101(39), 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.

Sincerely,


Sheppard McKenzie DDS, MS

Bobby D. White
North Carolina State Board of Dental Examiners
2000 Perimeter Park Dr., Suite 160
Morrisville, NC 27560



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ANDI N. STAMPER, DNP, CRNA

A. Stamp CRNA

RICE ANESTHESIA, LLC
8 QUEENSLAND CT
DURHAM, NC 27712



Bobby D. White
North Carolina State Board of Dental Examiners
2000 Perimeter Park Dr., Suite 160
Morrisville, NC 27560



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Katy Chiggett 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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~~CRNA~~

Jacquelyn Carter, CRNA
Crescent City Anesthesia
1224 Timber Dr
Suite 123
Garner, NC 27495





Bobby D. White
North Carolina State Board of Dental Examiners
2000 Perimeter Park Dr., Suite 160
Morrisville, NC 27560

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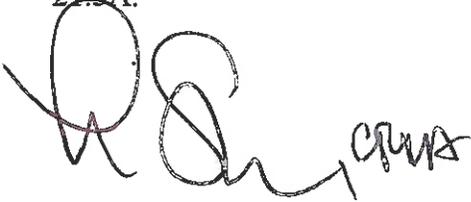
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Linda Shelton, CRNA

Anesthesia To Go

10521 Evergreen Spring Pl

Raleigh NC 27614

919.349.0144





Steven W. Hamrick, DMD
Sheppard A. McKenzie IV, DDS, MS
Travis J. Whitley, DDS, MS
*Diplomates of the American
Board of Periodontology*



Bobby D. White
North Carolina State Board of Dental Examiners
2000 Perimeter Park Dr., Suite 160
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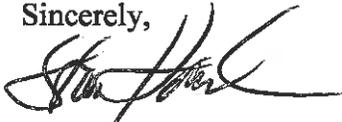
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Sincerely,

A handwritten signature in black ink, appearing to read "Steven W. Hamrick", written over a horizontal line.

Steven W. Hamrick, DMD



THE Brocker Law Firm P.A.

August 11, 2017

Dr. Steven Hamrick, DMD
Raleigh Periodontics
7501 Falls of Neuse Road, Suite 100
Raleigh, NC27615
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.

Douglas J. Brocker
Owner
direct 919.854.2460
doug@brockerlawfirm.com

Deanna S. Brocker
Owner
direct 919.854.2461
deanna@brockerlawfirm.com

Crystal S. Carlisle
Attorney
direct 919.353.4927
crystal@brockerlawfirm.com

Whitney Waldenberg
Attorney
direct 919.610.0573
whitney@brockerlawfirm.com

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,

A handwritten signature in black ink that reads "Douglas J. Brocker". The signature is written in a cursive style. Behind the signature is a faint, light gray watermark logo consisting of a shield with a stylized letter 'B' inside.

Douglas J. Brocker