

**G.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 - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
<b>SUBCHAPTER 16A – ORGANIZATION</b>		21 NCAC 16A .0101	DEFINITIONS	Amended Eff. May 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16B - LICENSURE DENTISTS</b>	<b>SECTION .0100 - GENERAL PROVISIONS</b>	21 NCAC 16B .0101	EXAMINATION REQUIRED; EXEMPTIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16B .0102	NO RECIPROCAL ARRANGEMENT	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary
	<b>SECTION .0200 - QUALIFICATIONS</b>	21 NCAC 16B .0201	IN GENERAL	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16B .0202	STUDENT MAY APPLY	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0300 - APPLICATION FOR LICENSURE</b>	21 NCAC 16B .0301	APPLICATION FOR LICENSURE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16B .0302	CONSENT FOR BOARD INVESTIGATION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16B .0303	BOARD APPROVED EXAMINATIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16B .0317	REEXAMINATION	Amended Eff. September 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0500 – LICENSURE BY CREDENTIALS</b>	21 ncac 16b .0501	DENTAL LICENSURE BY CREDENTIALS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0600 – LIMITED VOLUNTEER DENTAL LICENSE</b>	21 NCAC 16B .0601	LIMITED VOLUNTEER DENTAL LICENSE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0700 – INSTRUCTOR'S LICENSE</b>	21 NCAC 16B .0701	INSTRUCTOR'S LICENSE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0800 – SPECIAL RESTRICTED LICENSES</b>	21 NCAC 16B .0801	TEMPORARY VOLUNTEER DENTAL PERMIT	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0900 – EXEMPTIONS FOR ACTIVE MILITARY</b>	21 NCAC 16B .0901	DEFINITIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	26 U.S.C. 7508	No	Necessary without substantive public interest
		21 NCAC 16B .0902	EXEMPTIONS GRANTED	Eff. April 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .1000 - LICENSURE BY MILITARY ENDORSEMENT</b>	21 NCAC 16B .1001	DENTAL LICENSURE BY ENDORSEMENT BASED ON MILITARY SERVICE	Eff. September 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16B .1002	DENTAL LICENSURE BY ENDORSEMENT BASED ON STATUS AS MILITARY SPOUSE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .1100 - REINSTATEMENT</b>	21 NCAC 16B .1101	PROOF OF COMPETENCY	Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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SUBCHAPTER 16C - LICENSURE DENTAL HYGIENISTS	SECTION .0100 - GENERAL PROVISIONS	21 NCAC 16C .0101	LICENSURE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16C .0102	NO RECIPROCAL ARRANGEMENT	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary
	SECTION .0200 - QUALIFICATIONS	21 NCAC 16C .0202	STUDENT MAY APPLY	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0300 - APPLICATION	21 NCAC 16C .0301	APPLICATION FOR LICENSURE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16C .0302	CONSENT FOR BOARD INVESTIGATION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16C .0303	BOARD APPROVED EXAMINATIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16C .0311	REEXAMINATION	Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0500 - LICENSURE BY CREDENTIALS	21 NCAC 16C .0501	DENTAL HYGIENE LICENSURE BY CREDENTIALS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0600 - REINSTATEMENT OF DENTAL HYGIENE LICENSE	21 NCAC 16C .0601	PROOF OF COMPETENCY	Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SUBCHAPTER 16D - PROVISIONAL LICENSURE: DENTISTS	SECTION .0100 - GENERAL PROVISIONS	21 NCAC 16D .0101	ELIGIBILITY REQUIREMENTS	Amended Eff. January 1, 1994	Necessary without substantive public interest	No		No
		21 NCAC 16D .0102	RESTRICTIONS ON PRACTICE	Amended Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16D .0104	APPLICATION	Amended Eff. December 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16D .0105	EXAMINATION	Amended Eff. August 1, 2002	Unnecessary	No		No	Unnecessary
SUBCHAPTER 16E - PROVISIONAL LICENSURE: DENTAL HYGIENIST			21 NCAC 16E .0102	RESTRICTIONS ON PRACTICE	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No
		21 NCAC 16E .0103	APPLICATION	Amended Eff. December 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16E .0104	EXAMINATION	Amended Eff. December 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SUBCHAPTER 16F - PROFESSIONAL CORPORATIONS	SECTION .0100 - SCOPE	21 NCAC 16F .0102	APPLICATION	Amended Eff. April 1, 1994	Necessary without substantive public interest	No		No
		21 NCAC 16F .0103	CORPORATE OR LIMITED LIABILITY COMPANY NAME	Amended Eff. May 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16F .0104	CERTIFICATE OF REGISTRATION	Amended Eff. August 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16F .0105	APPLICATION FOR RENEWAL	Amended Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 16F .0107	AMENDMENTS TO ARTICLES OF INCORPORATION OR ORGANIZATION	Amended Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16F .0108	EMPLOYMENT OF DENTAL HYGIENIST	Amended Eff. April 1, 1994	Unnecessary	No		No	Unnecessary
		21 NCAC 16F .0110	CORPORATE OFFICERS OR MANAGERS MUST EXECUTE DOCUMENTS	Amended Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0100 - DENTAL HYGIENISTS</b>	21 NCAC 16G .0101	FUNCTIONS THAT MAY BE DELEGATED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16G .0103	PROCEDURES PROHIBITED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16G .0106	DENTAL HYGIENE SCHOOL EXTENSION FACILITIES AND OFF CAMPUS CLASSES	Eff. November 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16G .0107	DENTAL HYGIENE LICENSURE BY ENDORSEMENT BASED ON MILITARY SERVICE	Eff. September 19, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16G .0108	DENTAL HYGIENE LICENSURE BY ENDORSEMENT BASED ON STATUS AS MILITARY SPOUSE	Eff. September 19, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16H - DENTAL ASSISTANTS</b>	<b>SECTION .0100 - CLASSIFICATION AND TRAINING</b>	21 NCAC 16H .0101	CLASSIFICATION	Readopted Eff. September 26, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0102	DENTAL ASSISTANT I	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0103	DENTAL ASSISTANT II	Amended Eff. August 1, 2000	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0104	APPROVED EDUCATION AND TRAINING PROGRAMS	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0200 - PERMITTED FUNCTIONS OF DENTAL ASSISTANT</b>	21 NCAC 16H .0201	GENERAL PERMITTED FUNCTIONS OF DENTAL ASSISTANT I	Amended Eff. August 1, 2000	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0203	PERMITTED FUNCTIONS OF DENTAL ASSISTANT II	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0205	SPECIFIC PROHIBITED FUNCTIONS OF DENTAL ASSISTANTS I AND II	Amended Eff. August 1, 2000	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0206	DIRECT CONTROL AND SUPERVISION DEFINED	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16H .0207	LIMITED EXCEPTION FOR ASSISTING HYGIENISTS	Eff. December 1, 2016	Necessary with substantive public interest	No		No	Necessary with substantive public interest
<b>SUBCHAPTER 16I - ANNUAL RENEWAL OF DENTAL HYGIENIST LICENSE</b>	<b>SECTION .0100 - ANNUAL RENEWAL</b>	21 NCAC 16I .0101	APPLICATIONS	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 16I .0102	CONTINUING EDUCATION REQUIRED	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0103	APPROVED COURSES AND SPONSORS	Amended Eff. November 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0104	REPORTING CONTINUING EDUCATION	Amended Eff. November 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0105	PENALTY/NON-COMPLIANCE/CONTINUING EDUCATION REQUIREMENT	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0106	FEE FOR LATE FILING AND DUPLICATE LICENSE	Amended Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0107	LICENSE VOID UPON FAILURE TO RENEW	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0108	FORM OF CERTIFICATE	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0109	CERTIFICATE DISPLAYED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16I .0110	DEFINITIONS	Amended Eff. April 1, 2015	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	26 U.S.C. 7508	No	Necessary without substantive public interest
		21 NCAC 16I .0111	EXEMPTIONS GRANTED	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16J - SANITATION</b>		21 NCAC 16J .0101	PREMISES	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16J .0103	STERILIZATION	Amended Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16K - DENTAL SCHOOL EXTENSION FACILITIES</b>		21 NCAC 16K .0103	INSTRUCTORS TO BE APPROVED	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16K .0104	NO FEES FOR SERVICES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16K .0106	REPORTS TO BOARD	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16L - BOARD OF DENTAL ELECTIONS</b>		21 NCAC 16L .0101	BALLOTS	Readopted Eff. September 26, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16L .0102	NOTICE TO NOMINEE	Readopted Eff. September 26, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16L .0104	SOLICITATIONS FOR VOTES	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16M - FEES PAYABLE</b>	<b>SECTION .0100 - FEES PAYABLE</b>	21 NCAC 16M .0101	DENTISTS	Amended Eff. September 19, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16M .0102	DENTAL HYGIENISTS	Amended Eff. October 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16M .0103	PRIMARY SOURCE VERIFICATION FEE	Eff. August 1, 1998	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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SUBCHAPTER 16N - RULEMAKING AND ADMINISTRATIVE HEARING PROCEDURES	SECTION .0100 - PETITIONS FOR ADOPTION OF RULES	21 NCAC 16N .0101	PETITION FOR RULEMAKING HEARINGS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0102	CONTENTS OF PETITION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0103	DISPOSITION OF PETITIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0200 - NOTICE OF RULEMAKING HEARINGS	21 NCAC 16N .0202	NOTICE OF MAILING LIST	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0203	ADDITIONAL INFORMATION	Amended Eff. March 1, 1985	Unnecessary	No		No	Unnecessary
	SECTION .0300 - RULEMAKING HEARINGS	21 NCAC 16N .0302	CONTENT OF REQUEST: GENERAL TIME LIMITATIONS	Amended Eff. April 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0304	WRITTEN SUBMISSIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0305	BOARD PRESIDENT TO PRESIDE: POWERS AND DUTIES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0307	RECORD OF PROCEEDINGS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0400 - DECLARATORY RULINGS	21 NCAC 16N .0402	SUBMISSION OF REQUEST FOR RULING	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0403	DISPOSITION OF REQUESTS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0404	RECORD OF DECISION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0500 - ADMINISTRATIVE HEARING PROCEDURES	21 NCAC 16N .0501	RIGHT TO HEARING	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0502	REQUEST FOR HEARING	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0503	GRANTING OR DENYING HEARING REQUEST	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0504	NOTICE OF HEARING	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0505	WHO SHALL HEAR CONTESTED CASES	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0506	PETITION FOR INTERVENTION	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0507	TYPES OF INTERVENTION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0508	DISQUALIFICATION OF BOARD MEMBERS	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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	<b>SECTION .0600 - ADMINISTRATIVE HEARINGS: DECISIONS: RELATED RIGHTS AND PROCEDURES</b>	21 NCAC 16N .0602	SIMPLIFICATION OF ISSUES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0603	SUBPOENAS	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0604	FINAL DECISION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0605	PROPOSALS FOR DECISIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16N .0606	FAILURE TO APPEAR	Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16O - NITROUS-OXIDE-OXYGEN CONSCIOUS SEDATION</b>	<b>SECTION .0300 - DEFINITIONS</b>	21 NCAC 16O .0301	CONSCIOUS SEDATION	Amended Eff. April 1, 2016 (See S.L. 2016-31)	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16O .0302	MONITORING	Amended Eff. April 1, 2016 (See S.L. 2016-31)	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0400 - QUALIFICATIONS TO PERFORM FUNCTIONS</b>	21 NCAC 16O .0401	NON-DELEGABLE FUNCTIONS	Amended Eff. April 1, 2016 (See S.L. 2016-31)	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16O .0402	EDUCATIONAL REQUIREMENTS	Amended Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
<b>SUBCHAPTER 16P - ADVERTISEMENT OF DENTAL SERVICES</b>		21 NCAC 16P .0101	COMMUNICATIONS CONCERNING DENTAL SERVICES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16P .0102	ADS MUST INCLUDE DENTIST'S NAME AND AREA OF PRACTICE	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16P .0103	ADVERTISEMENT OF FEES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16P .0104	TESTIMONIALS AND ENDORSEMENTS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16P .0105	ADVERTISING AS A SPECIALIST	Amended Eff. April 1, 2003	Necessary with substantive public interest	No		No	Necessary with substantive public interest
<b>SUBCHAPTER 16Q - GENERAL ANESTHESIA AND SEDATION</b>	<b>SECTION .0100 - DEFINITIONS</b>	21 NCAC 16Q .0101	GENERAL ANESTHESIA AND SEDATION DEFINITIONS	Amended Eff. July 3, 2008	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	<b>SECTION .0200 - GENERAL ANESTHESIA</b>	21 NCAC 16Q .0201	GENERAL ANESTHESIA CREDENTIALS AND PERMIT	Amended Eff. February 5, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0202	EQUIPMENT	Amended Eff. November 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		21 NCAC 16Q .0204	PROCEDURE FOR GENERAL ANESTHESIA EVALUATION OR INSPECTION AND RE-INSPECTION	Amended Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0300 - PARENTERAL CONSCIOUS SEDATION</b>	21 NCAC 16Q .0301	CREDENTIALS AND PERMITS FOR MODERATE CONSCIOUS SEDATION, MODERATE PEDIATRIC CONSCIOUS SEDATION AND MODERATE CONSCIOUS SEDATION LIMITED TO ORAL ROUTES OF ADMINISTRATION AND NITROUS OXIDE	Amended Eff. July 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0302	CLINICAL REQUIREMENTS AND EQUIPMENT	Amended Eff. November 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0304	OFF SITE USE OF SEDATION PERMITS	Recodified from 21 NCAC 16Q .0302(e)(f), Eff. November 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0306	PROCEDURE FOR MODERATE CONSCIOUS SEDATION EVALUATION OR INSPECTION AND RE-INSPECTION	Eff April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0400 - ENTERAL CONSCIOUS SEDATION</b>	21 NCAC 16Q .0401	MINIMAL CONSCIOUS SEDATION CREDENTIALS, EVALUATION AND PERMIT	Amended Eff. July 3, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0402	MINIMAL CONSCIOUS SEDATION PERMIT REQUIREMENTS, CLINICAL PROVISIONS AND EQUIPMENT	Amended Eff. July 3, 2008	Necessary with substantive public interest	No		No	Necessary with substantive public interest
		21 NCAC 16Q .0408	PROCEDURE FOR MODERATE PEDIATRIC SEDATION EVALUATION OR INSPECTION AND RE-INSPECTION	Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0500 - RENEWAL OF PERMITS</b>	21 NCAC 16Q .0501	ANNUAL RENEWAL REQUIRED	Amended Eff. November 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0502	PAYMENT OF FEES	Transferred and Recodified from 16Q .0402 to .0502	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0503	INSPECTION AUTHORIZED	Amended Eff. August 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	<b>SECTION .0700 - PENALTY FOR NON-COMPLIANCE</b>	21 NCAC 16Q .0701	FAILURE TO COMPLY	Transferred and Recodified from 16Q .0601 to 16Q .0701	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Q .0703	REPORTS OF ADVERSE OCCURRENCES	Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest

**G.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 - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
SUBCHAPTER 16R - CONTINUING EDUCATION REQUIREMENTS: DENTISTS	SECTION .0100 - RENEWAL OF LICENSE	21 NCAC 16R .0101	APPLICATIONS	Amended Eff. July 1, 2015	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	26 U.S.C. 7508	No	Necessary without substantive public interest
		21 NCAC 16R .0102	FEE FOR LATE FILING AND DUPLICATE LICENSE	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16R .0108	LICENSE VOID UPON FAILURE TO TIMELY RENEW	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16R .0110	RENEWAL CERTIFICATE MUST BE DISPLAYED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0200 - CONTINUING EDUCATION	21 NCAC 16R .0201	CONTINUING EDUCATION REQUIRED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16R .0202	APPROVED COURSES AND SPONSORS	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16R .0203	REPORTING CONTINUING EDUCATION	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16R .0204	VARIANCES AND EXEMPTION FROM AND CREDIT FOR CONTINUING EDUCATION	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16R .0205	PENALTY/NON-COMPLIANCE/CONTINUING EDUCATION	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		SUBCHAPTER 16S - CARING DENTAL PROFESSIONALS PROGRAM	SECTION .0100 - GENERAL	21 NCAC 16S .0101	DEFINITIONS	Amended Eff. July 1, 2015	Necessary without substantive public interest	No	
21 NCAC 16S .0102	BOARD AGREEMENTS WITH PEER REVIEW ORGANIZATIONS			Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .0200 - GUIDELINES FOR PROGRAM ELEMENTS	21 NCAC 16S .0201		RECEIPT AND USE OF INFORMATION OF SUSPECTED IMPAIRMENT	Amended Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	21 NCAC 16S .0202		CONFIDENTIALITY	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	21 NCAC 16S .0203		INTERVENTION AND REFERRAL	Amended Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	21 NCAC 16S .0204		MONITORING TREATMENT	Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	21 NCAC 16S .0205		MONITORING REHABILITATION AND PERFORMANCE AFTER TREATMENT	Amended Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SUBCHAPTER 16T - PATIENT RECORDS		SECTION .0100 - PATIENT RECORDS	21 NCAC 16T .0101	RECORD CONTENT	Amended Eff. May 1, 2016	Necessary with substantive public interest	No	
21 NCAC 16T .0102		TRANSFER OF RECORDS UPON REQUEST		Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest

**G.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 - Filled in by RRC staff

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SUBCHAPTER 16U - INVESTIGATIONS	SECTION .0100 - PROCEDURES	21 NCAC 16U .0101	SECRETARY-TREASURER	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16U .0102	INVESTIGATIVE PANEL	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16U .0103	REPORTS FROM THE CONTROLLED SUBSTANCES REPORTING SYSTEM	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0200 - COMPLAINTS	21 NCAC 16U .0201	PROCESSING	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16U .0202	DISPOSITION	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16U .0203	PRE-HEARING CONFERENCES	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16U .0204	SETTLEMENT CONFERENCES	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SECTION .0100 - UNPROFESSIONAL CONDUCT	21 NCAC 16V .0101	DEFINITION: UNPROFESSIONAL CONDUCT BY A DENTIST	Amended Eff. August 1, 2016	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	45 CFR 160.103	No	Necessary without substantive public interest	
	21 NCAC 16V .0102	DEFINITION: UNPROFESSIONAL CONDUCT BY A DENTAL HYGIENIST	Amended Eff. August 1, 2016	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	45 CFR 160.103	No	Necessary without substantive public interest	
SUBCHAPTER 16W - PUBLIC HEALTH HYGIENISTS	SECTION .0100 - PUBLIC HEALTH HYGIENISTS	21 NCAC 16W .0101	DIRECTION DEFINED	Amended Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16W .0102	TRAINING FOR PUBLIC HEALTH HYGIENISTS	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16W .0103	TRAINING FOR PUBLIC HEALTH HYGIENISTS PERFORMING PREVENTIVE PROCEDURES	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SUBCHAPTER 16X - MANAGEMENT ARRANGEMENTS	SECTION .0100 - MANAGEMENT ARRANGEMENTS	21 NCAC 16X .0101	MANAGEMENT ARRANGEMENTS	Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SUBCHAPTER 16Y - INTERN PERMITTING: DENTISTS		21 NCAC 16Y .0101	ELIGIBILITY REQUIREMENTS	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Y .0102	APPLICATION	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Y .0103	EMPLOYMENT	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Y .0104	DIRECTION AND SUPERVISION	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Y .0105	COMPLIANCE	Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest
SUBCHAPTER 16Z - LIMITED SUPERVISION HYGIENISTS		21 NCAC 16Z .0101	ELIGIBILITY TO PRACTICE HYGIENE OUTSIDE DIRECT SUPERVISION	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest

**G.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 - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
		21 NCAC 16Z .0102	RECORD KEEPING	Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		21 NCAC 16Z .0103	INSPECTIONS	Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest



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  
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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



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.

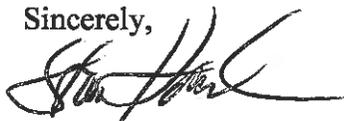
Propofol is a safe drug and serves the best interests of our patients. Propofol has been, and continues to be, the primary choice for CRNAs for moderate sedation. It has a very short half-life, quick recovery, a great safety profile, and results in a high level of patient satisfaction in connection with 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,

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Steven W. Hamrick, DMD

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



Dear Mr. White:

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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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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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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.

ANDI N. STAMPER, DNP, CRNA

*A. Stamp* CRNA

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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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~~CRNA~~

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Linda Shelton, CRNA

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