

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 - November 20, 2017												
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)]	RRC Determination of Public Comments [150B-21.3A(c)(2)]	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
SUBCHAPTER 16A – ORGANIZATION		21 NCAC 16A .0101	DEFINITIONS	Amended Eff. May 1, 2011	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16B - LICENSURE DENTISTS	SECTION .0100 - GENERAL PROVISIONS	21 NCAC 16B .0101	EXAMINATION REQUIRED; EXEMPTIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16B .0102	NO RECIPROCAL ARRANGEMENT	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary	No comments with merit	Unnecessary and should expire on the first day of the month following the consultation	Rule expired - remove from Code
	SECTION .0200 - QUALIFICATIONS	21 NCAC 16B .0201	IN GENERAL	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16B .0202	STUDENT MAY APPLY	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0300 - APPLICATION FOR LICENSURE	21 NCAC 16B .0301	APPLICATION FOR LICENSURE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16B .0303	BOARD APPROVED EXAMINATIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16B .0317	REEXAMINATION	Amended Eff. September 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0500 – LICENSURE BY CREDENTIALS	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0600 – LIMITED VOLUNTEER DENTAL LICENSE	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0700 – INSTRUCTOR'S LICENSE	21 NCAC 16B .0701	INSTRUCTOR'S LICENSE	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0800 – SPECIAL RESTRICTED LICENSES	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0900 – EXEMPTIONS FOR ACTIVE MILITARY	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16B .0902	EXEMPTIONS GRANTED	Eff. April 1, 2010	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .1000 - LICENSURE BY ENDORSEMENT BASED ON MILITARY SERVICE	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .1100 - REINSTATEMENT	21 NCAC 16B .1101	PROOF OF COMPETENCY	Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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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)]	RRC Determination of Public Comments [150B-21.3A(c)(2)]	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16C .0102	NO RECIPROCAL ARRANGEMENT	Amended Eff. May 1, 1989	Unnecessary	No		No	Unnecessary	No comments with merit	Unnecessary and should expire on the first day of the month following the consultation	Rule expired - remove from Code
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16C .0303	BOARD APPROVED EXAMINATIONS	Amended Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16C .0311	REEXAMINATION	Eff. September 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16D .0102	RESTRICTIONS ON PRACTICE	Amended Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16D .0104	APPLICATION	Amended Eff. December 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16D .0105	EXAMINATION	Amended Eff. August 1, 2002	Unnecessary	No		No	Unnecessary	No comments with merit	Unnecessary and should expire on the first day of the month following the consultation	Rule expired - remove from Code
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	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16E .0103	APPLICATION	Amended Eff. December 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16E .0104	EXAMINATION	Amended Eff. December 1, 2014	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16F - PROFESSIONAL CORPORATIONS	SECTION .0100 - SCOPE	21 NCAC 16F .0102	APPLICATION	Amended Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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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)]	RRC Determination of Public Comments [150B-21.3A(c)(2)]	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		21 NCAC 16F .0104	CERTIFICATE OF REGISTRATION	Amended Eff. August 1, 2009	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16F .0105	APPLICATION FOR RENEWAL	Amended Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16F .0108	EMPLOYMENT OF DENTAL HYGIENIST	Amended Eff. April 1, 1994	Unnecessary	No		No	Unnecessary	No comments with merit	Unnecessary and should expire on the first day of the month following the consultation	Rule expired - remove from Code
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0100 - DENTAL HYGIENISTS	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16G .0103	PROCEDURES PROHIBITED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16H - DENTAL ASSISTANTS	SECTION .0100 - CLASSIFICATION AND TRAINING	21 NCAC 16H .0101	CLASSIFICATION	Readopted Eff. September 26, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16H .0102	DENTAL ASSISTANT I	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16H .0103	DENTAL ASSISTANT II	Amended Eff. August 1, 2000	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0200 – PERMITTED FUNCTIONS OF DENTAL ASSISTANT	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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		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	No comments with merit	Necessary with substantive public interest and must be readopted	Agency must readopt
SUBCHAPTER 16I - ANNUAL RENEWAL OF DENTAL HYGIENIST LICENSE	SECTION .0100 - ANNUAL RENEWAL	21 NCAC 16I .0101	APPLICATIONS	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16I .0102	CONTINUING EDUCATION REQUIRED	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16I .0104	REPORTING CONTINUING EDUCATION	Amended Eff. November 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16I .0108	FORM OF CERTIFICATE	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16I .0109	CERTIFICATE DISPLAYED	Amended Eff. August 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16I .0111	EXEMPTIONS GRANTED	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16J - SANITATION		21 NCAC 16J .0101	PREMISES	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16J .0103	STERILIZATION	Amended Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16K - DENTAL SCHOOL EXTENSION FACILITIES		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16K .0106	REPORTS TO BOARD	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16L - BOARD OF DENTAL ELECTIONS		21 NCAC 16L .0101	BALLOTS	Readopted Eff. September 26, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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		21 NCAC 16L .0102	NOTICE TO NOMINEE	Readopted Eff. September 26, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16L .0104	SOLICITATIONS FOR VOTES	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16M - FEES PAYABLE	SECTION .0100 - FEES PAYABLE	21 NCAC 16M .0101	DENTISTS	Amended Eff. September 19, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16M .0102	DENTAL HYGIENISTS	Amended Eff. October 1, 2006	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in	Keep in Code - Update History Note
		21 NCAC 16M .0103	PRIMARY SOURCE VERIFICATION FEE	Eff. August 1, 1998	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0102	CONTENTS OF PETITION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0103	DISPOSITION OF PETITIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0203	ADDITIONAL INFORMATION	Amended Eff. March 1, 1985	Unnecessary	No		No	Unnecessary	No comments with merit	Unnecessary and should expire on the first day of the month following the consultation	Rule expired - remove from Code
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0304	WRITTEN SUBMISSIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0307	RECORD OF PROCEEDINGS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0403	DISPOSITION OF REQUESTS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0404	RECORD OF DECISION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0502	REQUEST FOR HEARING	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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												
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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)]	RRC Determination of Public Comments [150B-21.3A(c)(2)]	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0504	NOTICE OF HEARING	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0506	PETITION FOR INTERVENTION	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0507	TYPES OF INTERVENTION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0600 - ADMINISTRATIVE HEARINGS: DECISIONS: RELATED RIGHTS AND PROCEDURES	21 NCAC 16N .0602	SIMPLIFICATION OF ISSUES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0603	SUBPOENAS	Amended Eff. April 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0604	FINAL DECISION	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0605	PROPOSALS FOR DECISIONS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16N .0606	FAILURE TO APPEAR	Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16O – NITROUS-OXIDE-OXYGEN CONSCIOUS SEDATION	SECTION .0300 - DEFINITIONS	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0400 - QUALIFICATIONS TO PERFORM FUNCTIONS	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16O .0402	EDUCATIONAL REQUIREMENTS	Amended Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
SUBCHAPTER 16P - ADVERTISEMENT OF DENTAL SERVICES		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16P .0103	ADVERTISEMENT OF FEES	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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		21 NCAC 16P .0104	TESTIMONIALS AND ENDORSEMENTS	Amended Eff. May 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary with substantive public interest and must be readopted	Agency must readopt
SUBCHAPTER 16Q - GENERAL ANESTHESIA AND SEDATION	SECTION .0100 – DEFINITIONS	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0200 - GENERAL ANESTHESIA	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Q .0202	EQUIPMENT	Amended Eff. November 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0300 - PARENTERAL CONSCIOUS SEDATION	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0400 - ENTERAL CONSCIOUS SEDATION	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary with substantive public interest and must be readopted	Agency must readopt
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0500 - RENEWAL OF PERMITS	21 NCAC 16Q .0501	ANNUAL RENEWAL REQUIRED	Amended Eff. November 1, 2013	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in	Keep in Code - Update History Note
		21 NCAC 16Q .0503	INSPECTION AUTHORIZED	Amended Eff. August 1, 2004	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in	Keep in Code - Update History Note
	SECTION .0700 - PENALTY FOR NON-COMPLIANCE	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Q .0703	REPORTS OF ADVERSE OCCURRENCES	Eff. April 1, 2016	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16R .0202	APPROVED COURSES AND SPONSORS	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16R .0203	REPORTING CONTINUING EDUCATION	Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16S .0202	CONFIDENTIALITY	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16S .0203	INTERVENTION AND REFERRAL	Amended Eff. April 1, 2001	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16S .0204	MONITORING TREATMENT	Eff. April 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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		No	Necessary with substantive public interest	No comments with merit	Necessary with substantive public interest and must be readopted	Agency must readopt
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16U .0102	INVESTIGATIVE PANEL	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	SECTION .0200 - COMPLAINTS	21 NCAC 16U .0201	PROCESSING	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16U .0202	DISPOSITION	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16U .0203	PRE-HEARING CONFERENCES	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16U .0204	SETTLEMENT CONFERENCES	Eff. October 1, 1996	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
	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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Y .0102	APPLICATION	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Y .0103	EMPLOYMENT	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Y .0104	DIRECTION AND SUPERVISION	Amended Eff. July 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Y .0105	COMPLIANCE	Eff. August 1, 2002	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
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	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note
		21 NCAC 16Z .0102	RECORD KEEPING	Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

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 - November 20, 2017												
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)]	RRC Determination of Public Comments [150B-21.3A(c)(2)]	RRC Final Determination of Status of Rule for Report to APO [150B-21.3A(c)(2)]	OAH Next Steps
		21 NCAC 16Z .0103	INSPECTIONS	Eff. February 1, 2008	Necessary without substantive public interest	No		No	Necessary without substantive public interest	No comments with merit	Necessary without substantive public interest and should remain in effect without further action	Keep in Code - Update History Note

Hammond, Abigail M

From: Doug Bocker <doug@brockerlawfirm.com>
Sent: Monday, November 13, 2017 11:55 AM
To: Hammond, Abigail M
Cc: File; Bobby White
Subject: [External] FW: Withdrawal of Objection for RRC from Drs. Hamrick and McKenzie

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to report.spam@nc.gov.

Abby:

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

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

Doug

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

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

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

Sincerely, Steve Hamrick and Sheppard McKenzie

--

Steven W Hamrick, DMD

Raleigh Periodontics & Implant Dentistry

(919) 846-2480

(919) 846-2482 fax

www.raleighperio.com

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).

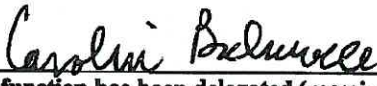
§ 150B-21.9. Standards and timetable for review by Commission.

(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

SUBMISSION FOR PERMANENT RULE

1. Rule-Making Agency: North Carolina State Board of Dental Examiners	
2. Rule citation & name (name not required for repeal): 21 NCAC 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: July 1, 2015 Link to Agency notice: www.ncdentalboard.org Hearing on: Aug. 6, 2015 Adoption by Agency on: December 12, 2015 <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 (\geq \$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 to clarify and add to the definition of terms applicable to the administration of general anesthesia and sedation.	
10. Rule-making Coordinator: Carolin Bakewell Address: 2000 Perimeter Parkway, Ste. 106, Morrisville NC 27560 Phone: 919 306 0116 E-Mail: caroln.bakewell@gmail.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: Carolin Bakewell Title: Rule Making Coordinator
RRC AND OAH USE ONLY	
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:	

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

21 NCAC 16Q .0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS

For the purpose of these Rules relative to the administration of ~~minimal conscious sedation~~, moderate conscious sedation, ~~moderate conscious sedation limited to oral routes or nitrous oxide inhalation~~, moderate pediatric conscious ~~sedation~~ 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.

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

- sedation services ~~that meet the minimum standard of care.~~ in compliance with the Dental Practice Act set forth in Article 2 of G.S. 90 and the Board's rules of this Chapter.
- (12) ~~[(22)]~~ (21) "General anesthesia" - the intended controlled state of a depressed level of consciousness that is produced by pharmacologic agents and accompanied by a partial or complete loss of protective reflexes, including the ability to maintain an airway and respond ~~purposefully~~ to physical stimulation ~~and obey~~ ~~or~~ verbal commands.
- ~~[(23)]~~ (22) "Good standing" – a licensee whose license is not suspended or revoked and who is not subject to a current disciplinary order imposing probationary terms.
- (13) ~~[(24)]~~ (23) "Immediately available" – on-site in the facility and available for ~~immediate use-~~ use without delay.
- ~~[(25)]~~ (24) ~~[(Itinerant)]~~ "Itinerant general ~~[dentist anesthesiologist]~~ anesthesia provider"- a ~~[licensee]~~ permittee who has complied with Rule .0206 of this ~~[Section]~~ Subchapter and who administers general anesthesia at another practitioner's facility.
- (14) ~~[(26)]~~ (25) "Local anesthesia" – the elimination of sensations, ~~especially including~~ pain, in one part of the body by the regional application or injection of a drug.
- (15) ~~[(27)]~~ "May" – indicates freedom or liberty to follow a reasonable alternative.
- (16) "Minimal conscious sedation" – conscious sedation characterized by a minimally depressed level of consciousness, in which patient retains the ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command, provided to patients 13 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment, possibly in combination with nitrous oxide. ~~Minimal conscious sedation is provided for behavioral management.~~
- (18) ~~[(28)]~~ (26) "Moderate conscious sedation" – conscious sedation characterized by a drug induced depression of consciousness, during which patients ~~obey~~ ~~respond purposefully to~~ verbal commands, either alone or accompanied by light tactile stimulation, provided to patients 13 years of age or older, by oral, nasal, ~~rectal~~ ~~rectal~~, or parenteral routes of administration of ~~single or~~ multiple pharmacological agents, in ~~single or~~ multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate conscious sedation ~~is~~ may be provided for behavior ~~control by licensed dentists who comply with the terms of Rule .0301 of this Subchapter. control.~~ ~~[Drugs designated by the manufacturer for use in administering general anesthesia or deep sedation and drugs contraindicated for use in moderate conscious sedation shall not be used by a moderate conscious sedation permit holder.]~~ A moderate conscious sedation provider shall not use the following:
- (a) drugs designed by the manufacturer for use in administering general anesthesia or deep sedation; or
- (b) drugs contraindicated for use in moderate conscious sedation.

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

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

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

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

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

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

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

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

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

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

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

1 ~~(37)~~ (34) (25) "Vested adult" – a responsible adult who is the legal parent or guardian, or designee of a
2 legal parent or guardian, entrusted with the care of a ~~minor~~ patient following the administration of
3 general anesthesia or conscious sedation.
4

5 *History Note: Authority G.S. ~~90-28~~; 90-30.1; 90-48;*
6 *Eff. February 1, 1990;*
7 *Temporary Amendment Eff. December 11, 2002;*
8 *Amended Eff. March 1, 2016; July 3, 2008; August 1, 2004.*
9
10

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:
7

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.



SECTION 5. This act is effective when it becomes law.
In the General Assembly read three times and ratified this the 16th day of June, 2016.

s/ Daniel J. Forest
President of the Senate

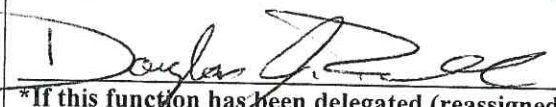
s/ Tim Moore
Speaker of the House of Representatives

s/ Pat McCrory
Governor

Approved 4:03 p.m. this 22nd day of June, 2016

SUBMISSION FOR PERMANENT RULE

Attachment 4 - 2017 Filing Form

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
<div style="text-align: center; font-weight: bold;">9. REASON FOR ACTION</div> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> 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: </div> <div style="width: 45%;"> <input type="checkbox"/> Legislation enacted by the General Assembly Cite Session Law: <input type="checkbox"/> Petition for rule-making <input type="checkbox"/> Other: </div> </div> 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: <div style="text-align: center;">  <hr/> </div> <div style="font-size: small;"> *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 </div>
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:	

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)~~ (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)~~ (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)~~ (11) “Competent” – displaying special skill or knowledge derived from training and experience.
- ~~(7)(12)~~ (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.

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

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

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

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

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

(17)(28) "Minor psychosedative/Minor tranquilizer" – pharmacological agents ~~which that~~ 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*History Note: Authority G.S. ~~90-28~~; 90-30.1; 90-48;
Eff. February 1, 1990;
Temporary Amendment Eff. December 11, 2002;
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. Stamper 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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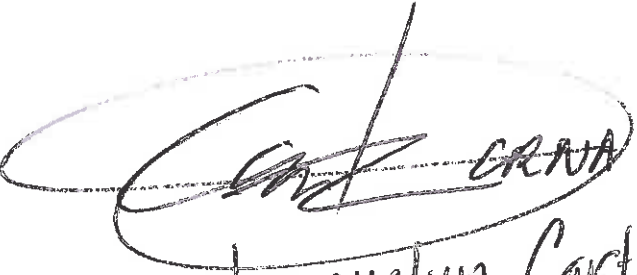
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Jacquelyn Carter, CRNA
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Bobby D. White
North Carolina State Board of Dental Examiners
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Morrisville, NC 27560



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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.

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.



Linda Shelton, CRNA

Anesthesia To Go

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



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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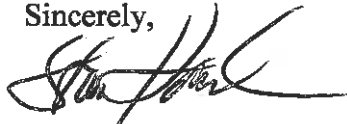
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Sincerely,

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.

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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 it's 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 over a faint, light gray circular seal or watermark that is partially visible in the background.

Douglas J. Brocker