

G.S. 150B-21.3A Report for 10A NCAC 13C, LICENSING OF AMBULATORY SURGICAL FACILITIES									
Agency - Medical Care Commission									
Comment Period - 2/24/17 - 4/25/17									
Date Submitted to APO - Filled in by RRC staff									
Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
	SECTION .0100 – GENERAL	10A NCAC 13C .0103	DEFINITIONS	Amended Eff. September 30, 2015	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.2 Subpart A	Yes	Necessary without substantive public interest
	SECTION .0200 - LICENSING PROCEDURES	10A NCAC 13C .0201	APPLICATION	Amended Eff. November 1, 1989	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.2 Subpart A	No	Necessary without substantive public interest
		10A NCAC 13C .0202	REQUIREMENTS FOR ISSUANCE OF LICENSE	Amended Eff. November 1, 2014	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.2 Subpart A	No	Necessary with substantive public interest
		10A NCAC 13C .0203	SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY	Amended Eff. November 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 13C .0204	TYPE OF FACILITY DEEMED TO BE LICENSED	Amended Eff. November 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 13C .0205	ITEMIZED CHARGES	Amended Eff. November 1, 2014	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.50	No	Necessary without substantive public interest
	SECTION .0300 – GOVERNING AUTHORITY MANAGEMENT	10A NCAC 13C .0301	GOVERNING AUTHORITY	Amended Eff. November 1, 2014	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary with substantive public interest
		10A NCAC 13C .0302	CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary without substantive public interest
		10A NCAC 13C .0303	ADMINISTRATIVE RECORDS	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary without substantive public interest
		10A NCAC 13C .0304	SURGICAL PROCEDURES PERFORMED	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary without substantive public interest
		10A NCAC 13C .0305	PERSONNEL	Amended Eff. November 1, 1989	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41	No	Necessary without substantive public interest
		10A NCAC 13C .0306	QUALITY ASSURANCE	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41 42 CFR Part §416.43	No	Necessary without substantive public interest

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	SECTION .0400 - MEDICAL AND SURGICAL SERVICES	10A NCAC 13C .0401	MEDICAL SERVICES	Amended Eff. November 1, 1985	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.42 42 CFR Part §416.45 42 CFR Part §416.52	No	Necessary without substantive public interest
		10A NCAC 13C .0402	SURGICAL SERVICES	Amended Eff. April 1, 2003	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.42 42 CFR Part §416.45	No	Necessary without substantive public interest
		10A NCAC 13C .0403	EMERGENCY CASES	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41(b)	No	Necessary without substantive public interest
	SECTION .0500 - ANESTHESIA SERVICES	10A NCAC 13C .0501	PROVIDING ANESTHESIA SERVICES	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.42	Yes	Necessary with substantive public interest
		10A NCAC 13C .0502	EQUIPMENT	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.42 42 CFR Part §416.51	No	Necessary without substantive public interest
		10A NCAC 13C .0503	POST ANESTHESIA NOTE	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.42	No	Necessary without substantive public interest
		10A NCAC 13C .0504	REQUIREMENT OF PERSON TRAINED IN CPR	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44(d)	No	Necessary without substantive public interest
	SECTION .0600 - PATHOLOGY SERVICES	10A NCAC 13C .0601	PROVISION FOR LABORATORY TESTS	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.49	No	Necessary without substantive public interest
		10A NCAC 13C .0602	DISPOSAL OF WASTE	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary without substantive public interest
	SECTION .0700 - RADIOLOGY SERVICES	10A NCAC 13C .0701	PROVISION FOR RADIOLOGY SERVICES	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.49 42 CFR Part §482.26(b)	No	Necessary without substantive public interest
		10A NCAC 13C .0702	REGULATIONS FOR PERFORMED SERVICES	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.49	No	Necessary without substantive public interest

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	SECTION .0800 - PHARMACEUTICAL SERVICES	10A NCAC 13C .0801	DRUG DISPENSING	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.48	No	Necessary without substantive public interest
		10A NCAC 13C .0802	REGULATIONS FOR DISPENSING	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.48	No	Necessary without substantive public interest
	SECTION .0900 - NURSING SERVICES	10A NCAC 13C .0901	NURSING ADMINISTRATION	Amended Eff. December 24, 1979	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.46	No	Necessary without substantive public interest
		10A NCAC 13C .0902	NURSING PERSONNEL	Eff. October 14, 1978	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.46	No	Necessary with substantive public interest
	SECTION .1000 - MEDICAL RECORDS SERVICES	10A NCAC 13C .1001	MEDICAL RECORD SYSTEM	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.47	No	Necessary without substantive public interest
		10A NCAC 13C .1002	INDIVIDUAL PATIENT RECORDS	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.47	No	Necessary without substantive public interest
	SECTION .1100 - SURGICAL FACILITIES AND EQUIPMENT	10A NCAC 13C .1101	OPERATING SUITE	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44	No	Necessary without substantive public interest
		10A NCAC 13C .1102	CARE OF OPERATING SUITE	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary without substantive public interest
	SECTION .1200 - FUNCTIONAL SAFETY	10A NCAC 13C .1201	GENERAL	Amended Eff. December 24, 1979	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.41 42 CFR Part §416.44	No	Necessary without substantive public interest
		10A NCAC 13C .1202	PREVENTIVE MAINTENANCE	Amended Eff. April 1, 2003	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.43 42 CFR Part §416.44	No	Necessary without substantive public interest
	SECTION .1300 - CONTROL AND SANITATION	10A NCAC 13C .1301	GENERAL	Amended Eff. November 1, 1989	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.43 42 CFR Part §416.51	No	Necessary without substantive public interest

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		10A NCAC 13C .1302	STERILIZATION PROCEDURES	Amended Eff. November 1, 1989	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary without substantive public interest
		10A NCAC 13C .1303	HOUSEKEEPING	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary without substantive public interest
		10A NCAC 13C .1304	LINEN AND LAUNDRY	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary without substantive public interest
		10A NCAC 13C .1305	SANITATION	Eff. October 14, 1978	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.44 42 CFR Part §416.51	No	Necessary without substantive public interest
	SECTION .1400 - PHYSICAL PLANT CONSTRUCTION	10A NCAC 13C .1401	OPERATING SUITE	Amended Eff. December 24, 1979	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary without substantive public interest
		10A NCAC 13C .1402	RECOVERY AREA	Amended Eff. December 24, 1979	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary without substantive public interest
		10A NCAC 13C .1403	SUPPORTING ELEMENTS	Amended Eff. April 1, 2003	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary without substantive public interest
		10A NCAC 13C .1404	DETAILS AND FINISHES	Amended Eff. November 1, 1989	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary with substantive public interest
		10A NCAC 13C .1405	MECHANICAL REQUIREMENTS	Amended Eff. April 1, 2003	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary with substantive public interest
		10A NCAC 13C .1406	PLUMBING AND OTHER PIPING SYSTEMS	Amended Eff. April 1, 2003	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary with substantive public interest
		10A NCAC 13C .1407	ELECTRICAL REQUIREMENTS	Amended Eff. April 1, 2003	Necessary with substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary with substantive public interest
		10A NCAC 13C .1408	GENERAL	Eff. April 1, 2003	Necessary without substantive public interest	Yes If yes, include the citation to the federal law	42 CFR Part §416.40 42 CFR Part §416.44	No	Necessary without substantive public interest

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		10A NCAC 13C .1409	LIST OF REFERENCED CODES AND STANDARDS	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 13C .1410	APPLICATION OF PHYSICAL PLANT REQUIREMENTS	Eff. April 1, 2003	Necessary with substantive public interest	No		No	Necessary with substantive public interest
		10A NCAC 13C .1411	ACCESS AND SAFETY	Eff. April 1, 2003	Necessary without substantive public interest	No		No	Necessary without substantive public interest

Periodic Rules Review and Expiration of Existing Rules
Subchapter 13C – Licensing of Ambulatory Surgical Facilities
Public Comments and Agency Response to Comments

Rule Citation & Title	Date	Commenter	Comment	Agency Response
1) 10A NCAC 13C .0103 – Definitions	2/23/17	Erin Glendening, DHSR erin.glendening@dhhs.nc.gov	This is a test of the system to verify that everything is working properly.	<p>This rule was determined as necessary without substantive public interest.</p> <p>The comment is about the test of the electronic comment reporting system.</p> <p>The Agency will not change the determination of this rule.</p>
2) 10A NCAC 13C .0501 – Providing Anesthesia Services	3/20/17	Dana Simpson, Smith Anderson, et al. dsimpson@smithlaw.com	Dear Medical Care Commission Members: On behalf of our client the North Carolina Society of Anesthesiologists ('NCSA'), we would like to provide comment as part of the Commission's review of existing rules pursuant to the requirements under N.C.Gen.Stat. § 150B-21.3A. Specifically, the Commission is in the process of receiving public comment regarding the current rule governing the provision of anesthesia services in ambulatory surgery centers—10A NCAC 13C.0501 ('Anesthesia Rule'). The Anesthesia Rule in question reads as follows: 'Only a physician, dentist, or qualified anesthesiologist shall administer anesthetic agents (general and regional).' The NCSA believes this rule should be revised to make clear that a qualified anesthesiologist may only administer anesthesia 'under the supervision of a physician or dentist,' as required by North Carolina law. It is well-established law that nurse anesthetists may only practice under physician or dentist supervision in North Carolina. This has been repeatedly confirmed by the North Carolina Court of Appeals, Attorney General and Medical Board. In 2005, the North Carolina Court of Appeals	<p>This rule was determined as necessary without substantive public interest.</p> <p>The comment indicates several situations that warrant a thoughtful review and the potential need for a revision to the existing rule. We have noted the comment and it will be taken into consideration when the rule is reviewed.</p> <p>The Agency will change the determination of this rule to necessary with substantive public interest</p>

			<p>noted that 'physician supervision of nurse anesthetists providing anesthesia care...is a fundamental patient safety standard required by North Carolina law.' (See N.C. Medical Society, et al. vs. N.C. Board of Nursing, 169 N.C. App. 1; 610 S.E.2d 722.) Similarly, an Attorney General Opinion from 1998 concluded that '...the anesthesia care of a patient [must] be under the supervision of a physician.' (See 1998 N.C.A.G. 58 (12/31/98).) Similarly in its position statement governing the standard of care for office-based surgery, the North Carolina Medical Board expressly requires physician supervision of nurse anesthetists. Finally, the Dental Practice Act requires that any nurse anesthetist providing a dental anesthetic be 'under the supervision and direction of a licensed dentist or physician.' (See N.C.Gen.Stat. § 90-29(b)(6).) As clearly demonstrated above, physician and dentist supervision of nurse anesthetists is the law in North Carolina. This patient safety standard, therefore, should be reflected in the Anesthesia Rule governing ambulatory surgery centers. To this end, the NCSA would request the Commission to consider clarifying the Anesthesia Rule as follows: 'Only a physician, dentist, or qualified anesthetist under the supervision of a physician or dentist shall administer anesthetic agents (general and regional).' Physician and dentist supervision of nurse anesthetists is a fundamental standard of patient safety in North Carolina, and this legal requirement should be clearly identified for operators of ambulatory surgery centers. Thank you for your consideration of our comments. We would be glad to provide additional information, if needed. With best regards. Sincerely, Dana E. Simpson</p>	
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