

G.S. 150B-21.3A Report for 10A NCAC 14E, CERTIFICATIONS OF CLINICS FOR ABORTION									
Agency - HHS - Division of Health Service Regulation									
Comment Period - 4/09/18 - 6/08/18									
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 - CERTIFICATION PROCEDURE	10A NCAC 14E .0101	DEFINITIONS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14E .0102	CONFERENCE	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14E .0103	CHANGES	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0104	PLANS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0105	APPROVAL	Amended Eff. December 1, 1989	Necessary with substantive public interest	No		Yes	Necessary with substantive public interest
		10A NCAC 14E .0106	APPLICATION	Amended Eff. July 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0107	ISSUANCE OF CERTIFICATE	Amended Eff. July 1, 1994	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14E .0108	POSTING	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0109	RENEWAL	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0110	REVOCATION	Amended Eff. December 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0111	INSPECTIONS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		10A NCAC 14E .0112	ALTERATIONS	Amended Eff. December 1, 1989	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0200 - MINIMUM STANDARDS FOR CONSTRUCTION AND EQUIPMENT	10A NCAC 14E .0201	BUILDING CODE REQUIREMENTS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14E .0202	SANITATION	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0203	ELEVATOR	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0204	CORRIDORS	Amended Eff. July 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0205	DOORS	Amended Eff. July 1, 1994	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0206	ELEMENTS AND EQUIPMENT	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0207	AREA REQUIREMENTS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0208	SHARED SERVICES	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
	SECTION .0300 – GOVERNING AUTHORITY	10A NCAC 14E .0301	OWNERSHIP	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0302	GOVERNING AUTHORITY	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		10A NCAC 14E .0303	POLICIES AND PROCEDURES AND ADMINISTRATIVE RECORDS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0304	ADMISSION AND DISCHARGE	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0305	MEDICAL RECORDS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0306	PERSONNEL RECORDS	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0307	NURSING SERVICE	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0309	LABORATORY SERVICES	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0310	EMERGENCY BACK-UP SERVICES	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0311	SURGICAL SERVICES	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0312	MEDICATIONS AND ANESTHESIA	Readopted Eff. December 19, 1977	Necessary with substantive public interest	No		No	Necessary with substantive public interest
		10A NCAC 14E .0313	POST-OPERATIVE CARE	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0314	CLEANING OF MATERIALS AND EQUIPMENT	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest

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		10A NCAC 14E .0315	HOUSEKEEPING	Amended Eff. October 1, 2015	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0316	FOOD SERVICE	Amended Eff. January 1, 1990	Necessary with substantive public interest	No		No	Necessary with substantive public interest
	SECTION .0400 - MEDICAL STAFF	10A NCAC 14E .0401	QUALIFICATIONS	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest
		10A NCAC 14E .0402	FILE	Readopted Eff. December 19, 1977	Necessary without substantive public interest	No		No	Necessary without substantive public interest

Periodic Rules Review and Expiration of Existing Rules  
Subchapter 14E – Certifications of Clinics for Abortion  
Public Comments and Agency Response to Comments

Rule Citation & Title	Date	Commenter	Comment	Agency Response
1) 10A NCAC 14E .0101 – Definitions	4/4/18	1a) Erin Glendening, DHSR erin.glendening@dhhs.nc.gov	This is a test to verify that everything is working properly.	This rule was determined as Necessary Without Substantive Public Interest.  The comment is about the test of the electronic comment reporting system.  The Agency will not change the determination of this rule.
	4/17/18	1b) Erin Glendening, DHSR erin.glendening@dhhs.nc.gov	This is a test comment on Google Chrome	This rule was determined as Necessary Without Substantive Public Interest.  The comment is about the test of the electronic comment reporting system through Google Chrome.  The Agency will not change the determination of this rule.
2) 10A NCAC 14E .0102 – Conference	4/9/18	Joel Luper	Which Section(s) of the Division of Health Service Regulation are to be consulted? (eg. Acute & Home Care Licensure and Certification? Construction?) does this need clarification?	This rule was determined as Necessary Without Substantive Public Interest.  It is not necessary to identify within this Rule which Section of DHSR a potential sponsor or owner needs to meet with for a conference. Staff of the Division of Health Service Regulation means both the Acute and Home Care Licensure and Certification Section (operational plans) and the Construction Section (construction plans). A potential sponsor or owner may need to meet with either one or both of these Sections.  The Agency will not change the determination of this rule.
3) 10A NCAC 14E .0105 – Approval	4/9/18	joel luper	Should is not a regulatory term - change to 'shall' or 'must'	This rule was determined as Necessary With Substantive Public Interest.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				<p>This comment will be evaluated and taken into consideration when this rule is revised.</p> <p>The Agency will not change the determination of this rule.</p>
4) 10A NCAC 14E .0107 – Issuance of Certificate	04/9/18		.0107(d) seems to indicate that only incidents of vandalism are to be reported. Shouldn't all incidents that affect the operation of the clinic be reported, whether natural, accidental, or by vandalism?	<p>This rule was determined as Necessary Without Substantive Public Interest.</p> <p>The rule comment does not indicate the rule language is unclear or ambiguous. Current rule language addresses disruptions to services.</p> <p>The Agency will not change the determination of this rule.</p>
5) 10A NCAC 14E .0201 – Building Code Requirements	4/9/18	joel Luper	The current building code also has an applicable section '422. Ambulatory Health Care Facilities' that should be referenced. Due to CMS certification, listing the current NFPA 101 Life Safety Code might be appropriate.	<p>This rule was determined as Necessary Without Substantive Public Interest.</p> <p>The North Carolina State Building Code (NCSBC) has been incorporated in this Rule with subsequent amendments and editions. As a result, any changes to the NCSBC will be applicable to these clinics. Abortion clinics are not certified by the Centers for Medicare and Medicaid Services and it would be inappropriate to incorporate and require compliance with a federal standard such as NFPA 101.</p> <p>The Agency will not change the determination of this rule.</p>

Comments Submitted for Periodic Review  
10A NCAC 14E, Certification of Clinics for Abortion

Rule Title	Rule Citation	Date	First Name	Last Name	Company	Email	Zip	Comment
DEFINITIONS	10A NCAC 14E .0101	04-Apr-18	Erin	Glendening	DHSR	erin.glendening@dhhs.nc.gov		This is a test to verify that everything is working properly.
DEFINITIONS	10A NCAC 14E .0101	17-Apr-18	Erin	Glendening	DHSR	erin.glendening@dhhs.nc.gov		This is a test comment on Google Chrome
CONFERENCE	10A NCAC 14E .0102	09-Apr-18	Joel	Luper				Which Section(s) of the Division of Health Service Regulation are to be consulted? (eg. Acute & Home Care Licensure and Certification? Construction?) does this need clarification?
APPROVAL	10A NCAC 14E .0105	09-Apr-18	joel	luper				Should is not a regulatory term - change to 'shall' or 'must'
ISSUANCE OF CERTIFICATE	10A NCAC 14E .0107	09-Apr-18						.0107(d) seems to indicate that only incidents of vandalism are to be reported. Shouldn't all incidents that affect the operation of the clinic be reported, whether natural, accidental, or by vandalism?
BUILDING CODE REQUIREMENTS	10A NCAC 14E .0201	09-Apr-18	joel	Luper				The current building code also has an applicable section '422. Ambulatory Health Care Facilities' that should be referenced.  Due to CMS certification, listing the current NFPA 101 Life Safety Code might be appropriate.