SUBCHAPTER 14C - CERTIFICATE OF NEED REGULATIONS

SECTION .0100 - GENERAL

10A NCAC 14C .0101 DEFINITIONS

History Note: Authority G.S. 131E-177; Eff. January 1, 1990; Amended Eff. November 1, 1996; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .0102 LOCATION OF THE AGENCY

As used in this Subchapter, the agency is the Healthcare Planning and Certificate of Need Section in the Division of Health Service Regulation, North Carolina Department of Health and Human Services. The location of the agency is 809 Ruggles Drive, Raleigh, North Carolina, 27603. The mailing address of the agency is Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation, 2704 Mail Service Center, Raleigh, NC 27699-2704. The telephone number of the agency is 919-855-3873.

History Note: Authority G.S. 131E-177; Eff. November 1, 1996; Amended Eff. January 1, 2013; January 1, 2000. Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 19, 2019; Amended Eff. February 1, 2022.

10A NCAC 14C .0103 STATE MEDICAL FACILITIES PLAN

History Note: Authority G.S. 131E-176(25); 131E-177(1); 131E-183(1); 42 U.S.C. 300K-2; Eff. June 19, 1979; Temporary Amendment Eff. January 1, 1983 for a Period of 120 Days to Expire on May 1, 1983; Amended Eff. November 1, 1989; January 1, 1989; February 1, 1988; January 1, 1987; Repealed Eff. October 1, 2016.

SECTION .0200 - APPLICATION AND REVIEW PROCESS

10A NCAC 14C .0201 LETTER OF INTENT

History Note: Authority G.S. 131E-177; Eff. October 1, 1981; Amended Eff. November 1, 1996; January 1, 1990; November 1, 1989; Repealed Eff. October 1, 2016.

10A NCAC 14C .0202 DEFINITIONS

The following definitions shall apply throughout this Subchapter:

- (1) "Applicant" means each person identified in Section A of the application forms listed in 10A NCAC 14C .0203(a).
- (2) "Application deadline" means no later than 5:00 p.m. on the 15th day of the month preceding the month that the review period begins. If the 15th day of the month falls on a weekend or a State holiday as set forth in 25 NCAC 01E .0901, which is hereby incorporated by reference including subsequent amendments, the application deadline is the next business day.
- (3) "Competitive review" means two or more applications submitted to begin review in the same review period proposing the same new institutional health service in the same service area and the CON Section determines that approval of one application may require denial of another application included in the same review period.
- (4) "CON Section" means the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation.

- (5) "Full fiscal year" means the 12-month period used by the applicant to track and report revenues and operating expenses for the services proposed in the application.
- (6) "Health service" shall have the same meaning as defined in G.S. 131E-176(9a).
- (7) "New institutional health service" shall have same meaning as defined in G.S. 131E-176(16).
- (8) "Person" shall have the same meaning as defined in G.S. 131E-176(19).
- (9) "Proposal" means a new institutional health service that requires a certificate of need.
- (10) "Related entity" means a person that:
 - (a) shares the same parent corporation or holding company with the applicant;
 - (b) is a subsidiary of the same parent corporation or holding company as the applicant; or
 - (c) participates with the applicant in a joint venture that provides the same type of health services proposed in the application.
- (11) "Review category" means the categories described in Chapter 3 of the annual State Medical Facilities Plan.
- (12) "Review period" means the 90 to 150 days that the CON Section has to review a certificate of need application and issue a decision pursuant to G.S. 131E-185 and G.S. 131E-186. There are eleven review periods each calendar year. Each review period starts on the first day of the month and the first review period starts on February 1. There is no review period beginning January 1.
- (13) "State Medical Facilities Plan" shall have the same meaning as defined in G.S. 131E-176(25). For purposes of this Subchapter, the annual State Medical Facilities Plan is hereby incorporated by reference, including subsequent amendments and editions. This document is available at no cost at https://info.ncdhhs.gov/dhsr/ncsmfp/index.html.
- (14) "USB flash drive" means a device used for data storage that includes a flash memory and an integrated universal serial bus interface.
- History Note: Authority G.S. 131E-177;

Eff. October 1, 1981;

Amended Eff. January 1, 1990; January 1, 1987; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. November 1, 1996; January 4, 1994; Temporary Amendment Eff. January 1, 2000; Amended Eff. April 1, 2001; Readopted Eff. January 1, 2021.

10A NCAC 14C .0203 FILING APPLICATIONS

- (a) "Application form" refers to one of the following:
 - (1) the Certificate of Need Application form; or
 - (2) the Dialysis or End Stage Renal Disease Services Application form.
- (b) An application form may be obtained from the CON Section by:
 - (1) sending an email to DHSR.CON.Applications@dhhs.nc.gov; or
 - (2) calling (919) 855-3873.
- (c) An email request for an application form shall:
 - (1) describe the proposal;
 - (2) identify the city or county where the proposal would be located; and
 - (3) include the estimated capital cost for the proposal.
- (d) For each proposal, the CON Section shall determine based on Chapter 3 of the annual State Medical Facilities Plan in effect at the time the review begins the:
 - (1) review category; and
 - (2) review period.

(e) An application is complete for inclusion in the review period if the CON Section determines that all of the following are true:

- (1) the original application is printed, placed between a front and back cover, and bound using metal paper fasteners;
- (2) the original and one copy of the application were received by the CON Section on or before the application deadline for the review period;
- (3) the entire application fee required by G.S. 131E-182(c) was received by the CON Section; and

(4) each applicant identified in Section A of the application form signed the certification page that asks the applicant to certify that the information in the application is correct and they intend to develop and offer the project as described in the application.

(f) The copy of the application shall be printed and bound consistent with Subparagraph (e)(1) of this Rule or in an electronic format saved on a USB flash drive. The files on the USB flash drive shall not be encrypted or password protected.

(g) No later than the fifth business day following the application deadline, the CON Section shall notify the contact individual identified in Section A of the application if the application is complete.

(h) If the application is not complete pursuant to Paragraph (e) of this Rule, the CON Section shall notify the contact individual identified in Section A of the application of what is missing or incorrect. The applicant shall only provide the items listed below in order to complete the application after the application deadline:

- (1) a signed certification page; or
- (2) the copy of the application.

(i) Signed certification pages or the copy of the application shall be received by the CON Section no later than 5:00 p.m. on the last business day of the month preceding the first day of the review period.

(j) The CON Section shall not include the application in the review period if it is not complete pursuant to Paragraph (e) of this Rule by 5:00 p.m. on the last business day of the month preceding the first day of the review period.

History Note: Authority G.S. 131E-177; 131E-182;

Eff. October 1, 1981;

Amended Eff. January 1, 1982;

Temporary Amendment Eff. July 15, 1983, for a Period of 118 Days, to Expire on November 10, 1983;

Amended Eff. November 1, 1990: January 1, 1990; December 1, 1989; January 1, 1987; October 1, 1984; November 10, 1983;

Temporary Amendment Eff. August 11, 1993, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. January 4, 1994;

Temporary Amendment Eff. August 12, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. December 1, 1994;

Temporary Amendment Eff. January 1, 2000;

Amended Eff. April 1, 2001;

Temporary Amendment Eff. February 16, 2004;

Amended Eff. August 1, 2004;

Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006;

Temporary Amendment Eff. January 1, 2008; Amended Eff. July 1, 2008; Readopted Eff. January 1, 2021.

10A NCAC 14C .0204 AMENDMENTS TO APPLICATIONS

An applicant may not amend an application. Responding to a request for additional information made by the agency after the review has commenced is not an amendment.

History Note: Authority G.S. 131E-177; 131E-182; Eff. October 1, 1981; Amended Eff. January 1, 1990; January 1, 1987; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 19, 2019.

10A NCAC 14C .0205 EXTENSION OF REVIEW PERIOD

(a) If the review is not expedited, the review may be extended for the following reasons:

(1) the total number of applications, including those in other review periods, prevents the CON Section from completing the review in 90 days;

- (2) the applicant has not submitted a response to a request from the CON Section for clarifying information; or
- (3) the CON Section received clarifying information from the applicant but is not able to complete the review in 90 days.

(b) The CON Section shall notify the contact individual identified in Section A of the application if the review period is extended. Failure to receive such notice prior to the last day of the review period does not entitle the applicant to a certificate of need nor authorize the applicant to proceed with the proposal in the application without a certificate of need.

History Note: Authority G.S. 131E-177; 131E-185; Eff. October 1, 1981; Amended Eff. January 1, 1990; January 1, 1982; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. January 4, 1994; Readopted Eff. January 1, 2021.

10A NCAC 14C .0206 EXPEDITED REVIEW

History Note: Authority G.S. 131E-177(1); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .0207AGENCY DECISION10A NCAC 14C .0208ISSUANCE OF A CERTIFICATE OF NEED10A NCAC 14C .0209PROGRESS REPORTS

History Note: Authority G.S. 131E-177; 131E-189; Eff. October 1, 1981; Amended Eff. January 1, 1990; February 1, 1986; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

SECTION .0300 - EXEMPTIONS

10A NCAC 14C .0301 RESEARCH ACTIVITY

History Note: Authority G.S. 131E-177; 131E-179; Eff. January 1, 1982; Amended Eff. February 1, 2000; January 1, 1990; November 1, 1989; February 1, 1986; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .0302 HEALTH MAINTENANCE ORGANIZATIONS

History Note: Authority G.S. 131E-177; 131E-180; Eff. January 1, 1982; Amended Eff. November 1, 1996; January 1, 1990; November 1, 1989; February 1, 1986; Temporary Amendment Eff. January 1, 2000; Amended Eff. April 1, 2001; Repealed Eff. January 1, 2013.

10A NCAC 14C .0303 REPLACEMENT EQUIPMENT

(a) This Rule defines the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).

(b) "Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.

(c) Replacement equipment is not "comparable" if:

- (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or
- (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

History Note: Authority G.S. 131E-177(1); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. April 1, 1999; November 1, 1996; Temporary Amendment Eff. June 3, 2002; Amended Eff. April 1, 2003; Readopted Eff. January 1, 2021.

10A NCAC 14C .0304 PSYCHIATRIC BED CONVERSIONS

History Note: Authority G.S. 131E-177; Eff. November 1, 1996; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

SECTION .0400 - CERTIFICATE OF NEED APPEAL PROCESS

10A NCAC 14C .0401 PETITION FOR A HEARING

History Note: Authority G.S. 131E-177; 131E-188; Eff. October 1, 1981; Amended Eff. January 1, 1990; November 1, 1989; February 1, 1986; Repealed Eff. October 1, 2016.

10A NCAC 14C .0402 ISSUES

The correctness, adequacy, or appropriateness of criteria, plans, and standards shall not be an issue in a contested case hearing.

History Note: Authority G.S. 131E-177; 131E-188; Eff. October 1, 1981; Amended Eff. February 1, 1986; October 1, 1984; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 19, 2019.

10A NCAC 14C .0403 CONTESTED CASE HEARINGS

History Note: Authority G.S. 131E-177; 131E-188; Eff. January 1, 1990; Repealed Eff. October 1, 2016.

SECTION .0500 - ENFORCEMENT AND SANCTIONS

10A NCAC 14C .0501 ASSESSMENT OF CIVIL PENALTY

History Note: Authority G.S. 131E-177(1); 131E-190(f); Eff. November 1, 1996; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .0502 WITHDRAWAL OF A CERTIFICATE

History Note: Authority G.S. 131E-177; 131E-189; Eff. October 1, 1981; Amended Eff. January 1, 1990; Temporary Amendment Eff. October 10, 1990, for a Period of 142 Days to Expire on February 28, 1991; Amended Eff. November 1, 1996; March 1, 1991; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

SECTION .0600 - RESERVED FOR FUTURE CODIFICATION

SECTION .0700 – RESERVED FOR FUTURE CODIFICATION

SECTION .0800 – RESERVED FOR FUTURE CODIFICATION

SECTION .0900 – RESERVED FOR FUTURE CODIFICATION

SECTION .1000 - RESERVED FOR FUTURE CODIFICATION

SECTION .1100 – CRITERIA AND STANDARDS FOR NURSING FACILITY OR ADULT CARE HOME SERVICES

10A NCAC 14C .1101 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-175; 131E-176; 131E-177(1); 131E-183(b); S.L. 2001, c. 234; Eff. November 1, 1996; Temporary Amendment Eff. January 1, 2003; January 1, 2002; Amended Eff. August 1, 2004; April 1, 2003; Repealed Eff. February 1, 2016.

10A NCAC 14C .1102 PERFORMANCE STANDARDS

(a) For the purposes of this Rule the following definitions shall apply:

- (1) "Approved beds" means nursing home or adult care home beds that were issued a certificate of need but are not being used to provide services as of the application deadline for the review period.
- (2) "Existing beds" means nursing home or adult care home beds that are being used to provide services as of the application deadline for the review period.
- (3) "Maximum capacity" means the total number of existing, approved, and proposed nursing home or adult care home beds times 365 days.
- (4) "Occupancy rate" means the total number of patient days of care provided in the nursing home or adult care home beds during a full fiscal year of operation divided by maximum capacity expressed as a percentage.
- (5) "Proposed beds" means the nursing home or adult care home beds proposed in the application under review.

(b) An applicant proposing to develop nursing home beds pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization of the existing, approved, and proposed beds during each of the first three full fiscal years of operation following completion of the project;
- (2) project an occupancy rate for the existing, approved, and proposed beds of at least 90 percent of maximum capacity during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used to project the utilization and occupancy rate required by Subparagraphs (1) and (2) of this Paragraph.

(c) An applicant proposing to develop adult care home beds pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization of the existing, approved, and proposed beds during each of the first three full fiscal years of operation following completion of the project;
- (2) project an occupancy rate for the existing, approved, and proposed beds of at least 85 percent of maximum capacity during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used to project the utilization and occupancy rate required by Subparagraphs (1) and (2) of this Paragraph.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. November 1, 1996; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Readopted Eff. January 1, 2023.

SECTION .1200 - CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

10A NCAC 14C .1201 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .1202 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Repealed Eff. February 1, 2016.

10A NCAC 14C .1203 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .1204SUPPORT SERVICES10A NCAC 14C .1205STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; 131E-183(b); Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

SECTION .1300 - CRITERIA AND STANDARDS FOR PEDIATRIC INTENSIVE CARE SERVICES

10A NCAC 14C .1301 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .1302 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

10A NCAC 14C .1303 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. January 4, 1994; Amended Eff. November 1, 1996; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .1304SUPPORT SERVICES10A NCAC 14C .1305STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

SECTION .1400 – CRITERIA AND STANDARDS FOR LEVEL IV NEONATAL INTENSIVE CARE SERVICES

10A NCAC 14C .1401 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Approved neonatal intensive care unit (NICU) beds" means acute care beds in a hospital that were issued a certificate of need to provide Level IV neonatal intensive care services but are not providing those services as of the application deadline for the review period.
- (2) "Average daily census (ADC)" means the total number of existing, approved, and proposed NICU days of care provided during a full fiscal year of operation divided by 365 days.
- (3) "Existing NICU beds" means acute care beds in a hospital that are providing Level IV neonatal intensive care services as of the application deadline for the review period.
- (4) "Level IV neonatal intensive care services" means services provided to high-risk medically unstable or critically ill neonates less than 32 weeks of gestational age, or infants requiring constant nursing care or supervision in NICU beds.
- (5) "Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed NICU beds expressed as a percentage.
- (6) "Proposed NICU beds" means the acute care beds proposed to provide Level IV neonatal intensive care services in a hospital in the application under review.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003; Readopted Eff. January 1, 2024.

10A NCAC 14C .1402 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Repealed Eff. February 1, 2016.

10A NCAC 14C .1403 PERFORMANCE STANDARDS

(a) An applicant proposing to develop a new Level IV neonatal intensive care service without increasing the total number of acute care beds on the hospital license shall:

- (1) provide projected utilization of the proposed NICU beds during each of the first three full fiscal years of operation following completion of the project;
- (2) document that the occupancy rate for the proposed NICU beds shall be at least 65 percent during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used for the projected utilization and occupancy rate required by Subparagraphs (1) and (2) of this Paragraph.

(b) An applicant proposing to develop a new Level IV neonatal intensive care service or increase the number of NICU beds on the hospital license shall:

- (1) provide projected utilization of all existing, approved, and proposed NICU beds on the hospital license during each of the first three full fiscal years of operation following completion of the project;
- (2) document that the occupancy rate for all existing, approved, and proposed NICU beds on the hospital license shall be at least 65 percent during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used for the projected utilization and occupancy rate required by Subparagraphs (1) and (2) of this Paragraph.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Temporary Amendment Eff. January 27, 2023; Readopted Eff. January 1, 2024.

10A NCAC 14C .1404SUPPORT SERVICES10A NCAC 14C .1405STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. March 15, 2002; Amended Eff. April 1, 2003; Repealed Eff. February 1, 2016.

SECTION .1500 - CRITERIA AND STANDARDS FOR HOSPICES

10A NCAC 14C .1501 DEFINITIONS

History Note: Authority G.S. 131E-177(1);

Eff. July 1, 1994; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .1502 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. July 1, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

10A NCAC 14C .1503 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); Eff. July 1, 1994; Temporary Amendment Eff. January 1, 1999; Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. April 1, 2001; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .1504SUPPORT SERVICES10A NCAC 14C .1505STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. July 1, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

SECTION .1600 - CRITERIA AND STANDARDS FOR CARDIAC CATHETERIZATION EQUIPMENT

10A NCAC 14C .1601 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Angiography procedures" means procedures performed using cardiac catheterization equipment that are not cardiac catheterization services.
- (2) "Approved cardiac catheterization equipment" means cardiac catheterization equipment that was issued a certificate of need but is not being used to provide cardiac catheterization services as of the application deadline for the review period.
- (3) "Cardiac catheterization equipment" shall have the same meaning as defined in G.S. 131E-176(2f).
- (4) "Cardiac catheterization services" shall have the same meaning as defined in G.S. 131E-176(2g).

- (5) "Diagnostic-equivalent cardiac catheterization procedures" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (6) "Existing cardiac catheterization equipment" means cardiac catheterization equipment that is being used to offer cardiac catheterization services as of the application deadline for the review period.
- (7) "Fixed cardiac catheterization equipment" means cardiac catheterization equipment that is not mobile or shared fixed cardiac catheterization equipment.
- (8) "Fixed cardiac catheterization equipment service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (9) "Host site" means the location where the mobile cardiac catheterization equipment provides cardiac catheterization services.
- (10) "Mobile cardiac catherization equipment" means cardiac catheterization equipment that is moved weekly to provide cardiac catheterization services at two or more host sites.
- (11) "Mobile cardiac catheterization equipment service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (12) "Proposed cardiac catheterization equipment" means the cardiac catheterization equipment proposed in the certificate of need application.
- (13) "Shared fixed cardiac catheterization equipment" means fixed cardiac catheterization equipment that is used to perform cardiac catheterization procedures and angiography procedures.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 1, 1987; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. November 1, 1996; February 1, 1994; Temporary Amendment Eff. January 1, 1999; Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 1, 2000; Temporary Amendment Eff. January 1, 2001; Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001; Amended Eff. August 1, 2002; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Readopted Eff. January 1, 2022.

10A NCAC 14C .1602 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183;

Eff. January 1, 1987; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. November 1, 1996; February 1, 1994; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(1) identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;

- (2) identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;
- (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used to project the utilization required by Subparagraph
 (3) of this Paragraph; and
- (5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.

(b) An applicant proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;
- (2) provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and
- (3) project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of the project.

(c) An applicant proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in the State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that provides cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;
- (2) identify the approved mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that will provide cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;
- (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs
 (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used to project the utilization required by Subparagraph
 (3) of this Paragraph; and
- (5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Eff. January 1, 1987;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. November 1, 1996; February 1, 1994;

Temporary Amendment Eff. January 1, 1999;

Temporary Eff. January 1, 1999 Expired on October 12, 1999;

Temporary Amendment Eff. January 1, 2000;

Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;

Temporary Amendment Eff. January 1, 2001;

Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001;

Temporary Amendment Eff. January 1, 2002;

Amended Eff. August 1, 2002;

Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;

Amended Eff. April 1, 2003;

Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Readopted Eff. January 1, 2022.

10A NCAC 14C .1604SUPPORT SERVICES10A NCAC 14C .1605STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); *Eff. January 1, 1987;* Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. February 1, 1994; Temporary Amendment Eff. February 2, 2001; Temporary Amendment Eff. January 1, 2002; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

SECTION .1700 - CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND HEART-LUNG BYPASS MACHINES

10A NCAC 14C .1701 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Approved heart-lung bypass machine" means a heart-lung bypass machine that was issued a certificate of need but is not being used as of the application deadline for the review period.
- (2) "Existing heart-lung bypass machine" means a heart-lung bypass machine that is being used as of the application deadline for the review period.
- (3) "Health service facility" shall have the same meaning as defined in G.S. 131E-176(9b).
- (4) "Heart-lung bypass machine" shall have the same meaning as defined in G.S. 131E-176(10a).
- (5) "Open-heart surgical procedure" means one visit by a patient to an operating room for open heart surgery services.
- (6) "Open-heart surgery services" shall have the same meaning as defined in G.S. 131E-176(18b).
- (7) "Proposed heart-lung bypass machine" means the heart-lung bypass machine proposed in the application under review.

Authority G.S. 131E-177(1); 131E-183(b); History Note: Eff. January 1, 1987; Amended Eff. November 1, 1989; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. November 1, 1996; January 4, 1994; Temporary Amendment Eff. January 1, 1999: Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Amendment Eff. January 1, 2000 and shall expire on the date on which the permanent amendment to this Rule, approved by the Rules Review Commission on November 17, 1999, becomes effective; Amended Eff. July 1, 2000; Temporary Amendment Eff. March 1, 2010; Amended Eff. January 1, 2013; November 1, 2010; Readopted Eff. January 1, 2022.

10A NCAC 14C .1702 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183;

Eff. January 1, 1987; Amended Eff. November 1, 1989; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. November 1, 1996; January 4, 1994; Temporary Amendment January 1, 1999; Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. January 1, 2013; April 1, 2001; Repealed Eff. February 1, 2016.

10A NCAC 14C .1703 PERFORMANCE STANDARDS

(a) A health service facility that proposes to develop a new open-heart surgery service shall:

- (1) provide the projected number of open-heart surgical procedures to be performed during each of the first three full fiscal years of operation following completion of the project;
 - (2) provide the assumptions and methodology used to project the utilization required by Subparagraph (a)(1) of this Paragraph; and
 - (3) project to perform 150 or more open-heart surgical procedures in the third full fiscal year of operation following completion of the project.

(b) A health service facility that proposes to acquire a heart-lung bypass machine, excluding a heart-lung bypass machine proposed to be acquired pursuant to Policy AC-6 in the annual State Medical Facilities Plan in effect as of the first day of the review period, shall:

- (1) provide the number of existing heart-lung bypass machines owned or operated by the health service facility;
- (2) provide the number of approved heart-lung bypass machines that will be owned or operated by the health service facility;
- (3) provide projected utilization of the existing and approved heart-lung bypass machines identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed heart-lung bypass machine during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(3) of this Paragraph; and
- (5) project that the existing and approved heart-lung bypass machines identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed heart-lung bypass machine will be used during the third full fiscal year of operation following completion of the project:
 - (A) to perform 200 or more open-heart surgical procedures per heart-lung bypass machine; or
 - (B) for 900 hours or more per heart-lung bypass machine, including time in use and time spent on standby, for all types of procedures.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Eff. January 1, 1987;

Amended Eff. November 1, 1989;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. January 4, 1994;

Temporary Amendment January 1, 1999;

Temporary Eff. January 1, 1999 expired October 12, 1999;

Temporary Amendment Eff. January 1, 2000 and shall expire on the date the permanent amendment to this rule, approved by the Rules Review Commission on November 17, 1999, becomes effective;

Amended Eff. July 1, 2000;

Temporary Amendment Eff. January 1, 2002;

Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2010; Amended Eff. January 1, 2013; November 1, 2010; Readopted Eff. February 1, 2022.

10A NCAC 14C .1704SUPPORT SERVICES10A NCAC 14C .1705STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 1, 1987; Amended Eff. November 1, 1989; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. January 1, 2013; January 4, 1994; Repealed Eff. February 1, 2016.

SECTION .1800 - CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

10A NCAC 14C .1801 PURPOSE AND SCOPE

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. March 16, 2017.

10A NCAC 14C .1802 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. December 1, 2016.

10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

10A NCAC 14C .1804 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. November 1, 1996; Repealed Eff. March 16, 2017.

10A NCAC 14C .1805SUPPORT SERVICES10A NCAC 14C .1806STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

SECTION .1900 - CRITERIA AND STANDARDS FOR LINEAR ACCELERATORS

10A NCAC 14C .1901 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Approved LINAC" means a linear accelerator (LINAC) that was issued a certificate of need but is not being used to provide services as of the application deadline for the review period.
- (2) "Equivalent Simple Treatment Visit (ESTV)" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (3) "Existing LINAC" means a LINAC that is being used to provide services as of the application deadline for the review period.
- (4) "LINAC service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (5) "Linear accelerator (LINAC)" shall have the same meaning as defined in G.S. 131E-176(14g).
- (6) "Proposed LINAC" means the LINAC proposed in the application under review.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; *Eff. January 4, 1994;* Amended Eff. November 1, 1996; Temporary Amendment January 1, 1999; Temporary Amendment Eff. January 1, 1999 expired October 12, 1999; Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. April 1, 2001; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Readopted Eff. January 1, 2022.

10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177; 131E-183; NC 2009 State Medical Facilities Plan, Chapter 9: Radiation Therapy Services – Linear Accelerator; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. January 1, 1999; Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999: Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. April 1, 2001; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Temporary Amendment Eff. February 1, 2010;

Amended Eff. November 1, 2010; Repealed Eff. February 1, 2016.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- (2) identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- (3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;
- (5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the project either:
 - (a) 6,750 or more ESTVs per LINAC; or
 - (b) serve 250 or more patients per LINAC.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996 Temporary Amendment Eff. January 1, 1999; Temporary Amendment effective January 1, 1999 expired October 12, 1999; Temporary Amended Eff. January 1, 2000; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006. Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. April 1, 2001; Temporary Amendment Eff. March 15, 2002; January 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Readopted Eff. January 1, 2022.

10A NCAC 14C .1904SUPPORT SERVICES10A NCAC 14C .1905STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Repealed Eff. February 1, 2016.

SECTION .2000 - CRITERIA AND STANDARDS FOR HOME HEALTH SERVICES

10A NCAC 14C .2001 DEFINITIONS The following definitions shall apply to this Section:

- (1) "Home health agency" shall have the same meaning as defined in G.S. 131E-176(12).
- (2) "Service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. September 1, 1980; Amended Eff. March 1, 1996; July 1, 1995; July 1, 1991; February 1, 1985; May 1, 1983; Readopted Eff. January 1, 2023.

10A NCAC 14C .2002 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. March 1, 1996; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Repealed Eff. February 1, 2016.

10A NCAC 14C .2003 PERFORMANCE STANDARDS

An applicant proposing to develop a new Medicare-certified home health agency pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization for each of the first three full fiscal years of operation following completion of the project;
- (2) project to serve at least 325 residents of the proposed service area during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used to provide the projected utilization required in Item (1) of this Rule.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. March 1, 1996; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Readopted Eff. January 1, 2023.

10A NCAC 14C .2004 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .2005 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. March 1, 1996; Repealed Eff. February 1, 2016.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2101 DEFINITIONS

The following definitions apply to all rules in this Section:

- (1) "Approved operating rooms" means those operating rooms that were approved for a certificate of need by the CON Section prior to the date on which the applicant's proposed project was submitted to the CON Section, but that have not been licensed.
- (2) "Dedicated C-section operating room" means an operating room as defined in Chapter 6 in the annual State Medical Facilities Plan.
- (3) "Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals that were reported in the Ambulatory Surgical Facility License Renewal Application Form or in the Hospital License Renewal Application Form submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, and that were licensed prior to the beginning of the review period.

- (4) "Health System" shall have the same meaning as defined in Chapter 6 in the annual State Medical Facilities Plan.
- (5) "Operating room" means a room as defined in G.S. 131E-176(18c).
- (6) "Operating Room Need Methodology" means the Methodology for Projecting Operating Room Need in Chapter 6 in the annual State Medical Facilities Plan.
- (7) "Service area" means the Operating Room Service Area as defined in Chapter 6 in the annual State Medical Facilities Plan.

History Note: Authority G.S. 131E-177(1); 131E-183(b); *Eff. November 1, 1990;* Amended Eff. March 1, 1993; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. January 4, 1994; Temporary Amendment Eff. January 1, 1999; Temporary Eff. January 1, 1999 Expired on October 12, 1999; Temporary Amendment Eff. January 1, 2000; Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000; Amended Eff. April 1, 2001; Temporary Amendment Eff. January 1, 2002; July 1, 2001; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Rule Eff. February 1, 2006; Amended Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008. Temporary Amendment Eff. February 1, 2018; Amended Eff. December 1, 2018; Readopted Eff. January 1, 2021.

10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT

Authority G.S. 131E-177; 131E-183(b); *History Note: Eff. November 1. 1990:* Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. January 4, 1994; Temporary Amendment Eff. July 1, 2001; Temporary Amendment Eff. January 1, 2002; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Repealed Eff. February 1, 2016.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) An applicant proposing to increase the number of operating rooms, excluding dedicated C-section operating rooms, in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan in effect at the time the review began. The applicant is not required to use the population growth factor.

(b) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. November 1, 1990; Amended Eff. March 1, 1993; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner: Amended Eff. January 4, 1994; Temporary Amendment Eff. January 1, 2002; July 1, 2001; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Rule Eff. February 1, 2006; Amended Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Temporary Amendment Eff. February 1, 2018; Amended Eff. December 1, 2018; Readopted Eff. January 1, 2021.

10A NCAC 14C .2104SUPPORT SERVICES10A NCAC 14C .2105STAFFING AND STAFF TRAINING10A NCAC 14C .2106FACILITY

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. November 1, 1990; Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. January 4, 1994; Temporary Amendment Eff. July 1, 2001; Temporary Amendment Eff. January 1, 2002; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Repealed Eff. February 1, 2016.

SECTION .2200 - CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2201 DEFINITIONS

The following definitions shall apply to this Section:

- (1) "Dialysis" means the artificially aided process of transferring body wastes from a person's blood to a dialysis fluid to permit discharge of the wastes from the body.
- (2) "Dialysis facility" means a kidney disease treatment center as defined in G.S. 131E-176(14e).
- (3) "Dialysis station" means the treatment area in a dialysis facility used to accommodate the equipment and supplies needed to perform hemodialysis on a single patient.
- (4) "Hemodialysis" means the form of dialysis in which the blood is circulated outside the body through equipment that permits transfer of waste through synthetic membranes.
- (5) "Home hemodialysis" means hemodialysis performed in a location other than a dialysis facility by the patient after the patient is trained in a dialysis facility to perform the hemodialysis.
- (6) "In-center hemodialysis" means hemodialysis performed in a dialysis facility.
- (7) "Peritoneal dialysis" means the form of dialysis in which a dialysis fluid is introduced into the person's peritoneal cavity and is subsequently withdrawn. This form of dialysis is performed in a location other than a dialysis facility by the patient after the patient is trained in a dialysis facility to perform the peritoneal dialysis.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. September 1, 1980; Amended Eff. November 1, 1989; November 1, 1983; Readopted Eff. January 1, 2021.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. March 1, 1989; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Repealed Eff. February 1, 2016.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

(b) An applicant proposing to increase the number of in-center dialysis stations in:

- (1) an existing dialysis facility; or
- (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.

(c) An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.

(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.

(e) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. January 1, 2003; January 1, 2002; Eff. April 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Temporary Amendment Eff. February 1, 2020; Readopted Eff. January 1, 2021.

10A NCAC 14C .2204SCOPE OF SERVICES10A NCAC 14C .2205STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. March 1, 1989; Repealed Eff. February 1, 2016.

SECTION .2300 - CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

10A NCAC 14C .2301 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Amended Eff. February 1, 2008; Repealed Eff. January 1, 2022.

10A NCAC 14C .2302 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Amended Eff. February 1, 2008; Repealed Eff. February 1, 2016.

10A NCAC 14C .2303 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Amended Eff. February 1, 2008; Repealed Eff. January 1, 2022.

10A NCAC 14C .2304SUPPORT SERVICES10A NCAC 14C .2305STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Amended Eff. February 1, 2008; Repealed Eff. February 1, 2016.

SECTION .2400 – CRITERIA AND STANDARDS FOR INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

10A NCAC 14C .2401 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Catchment area" means as defined in G.S. 122C-3(4).
- (2) "Intermediate care facility for individuals with intellectual disabilities" means as defined in G.S. 131E-176(14a).

History Note: Authority G.S. 131E-177(1); 131E-177(5); 131E-183; Eff. December 1, 1981; Amended Eff. November 1, 1996; September 1, 1989; Readopted Eff. January 1, 2022.

10A NCAC 14C .2402 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1), (5); 131E-183; Eff. December 1, 1996; Repealed Eff. February 1, 2016.

10A NCAC 14C .2403 PERFORMANCE STANDARDS

(a) An applicant proposing to add intermediate care facility for individuals with intellectual disabilities (ICF/IID) beds to an existing facility shall not be approved unless the average occupancy, over the six months immediately preceding the submittal of the application, of the total number of ICF/IID beds within the facility in which the new beds are to be operated was at least 90 percent.

(b) An applicant proposing to establish new ICF/IID beds shall not be approved unless occupancy is projected to be at least 90 percent for the total number of ICF/IID beds proposed to be operated in the entire facility, no later than one year following the completion of the proposed project.

(c) An applicant proposing to establish new ICF/IID beds shall comply with one of the following models:

- (1) a residential community based freestanding facility with six beds or less, i.e., group home model; or
- (2) a community-based facility with 7 to 15 beds if documentation is provided that a facility of this size is necessary because adequate residential community based freestanding facilities are not available in the Area Authority catchment area to meet the needs of the population to be served.

(d) No more than three ICF/IID facilities housing a combined total of 18 persons shall be developed on contiguous pieces of property.

History Note: Authority G.S. 131E-177(1); 131E-177(5); 131E-183; Eff. November 1, 1996; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Readopted Eff. January 1, 2022.

10A NCAC 14C .2404 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .2405 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1), (5); 131E-183; Eff. December 1, 1996; Repealed Eff. February 1, 2016.

SECTION .2500 – CRITERIA AND STANDARDS FOR SUBSTANCE USE DISORDER (CHEMICAL DEPENDENCY TREATMENT) BEDS

10A NCAC 14C .2501 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. March 1, 1983; Amended Eff. November 1, 1996; October 1, 1984. Temporary Amendment Eff. January 1, 2001; Amended Eff. August 1, 2002; Repealed Eff. January 1, 2022.

10A NCAC 14C .2502 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. December 1, 1996; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

10A NCAC 14C .2503 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. November 1, 1996; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2006; Amended Eff. January 1, 2007; Repealed Eff. January 1, 2022.

10A NCAC 14C .2504 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .2505 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. December 1, 1996; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

SECTION .2600 - CRITERIA AND STANDARDS FOR PSYCHIATRIC BEDS

10A NCAC 14C .2601 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. May 1, 1983; Amended Eff. August 1, 2009; November 1, 1989; Repealed Eff. January 1, 2022.

10A NCAC 14C .2602 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. December 1, 1996; Temporary Amendment Eff. February 1, 2006; Amended Eff. August 1, 2009; November 1, 2006; Repealed Eff. February 1, 2016.

10A NCAC 14C .2603 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. November 1, 1996; Repealed Eff. January 1, 2022.

10A NCAC 14C .2604 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .2605 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. May 1, 1983; Amended Eff. November 1, 1989; Repealed Eff. February 1, 2016.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2701 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Adjusted MRI procedure" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (2) "Approved MRI scanner" means a magnetic resonance imaging (MRI) scanner that was issued a certificate of need but is not being used to provide services as of the application deadline for the review period.
- (3) "Existing MRI scanner" means an MRI scanner that is being used to provide services as of the application deadline for the review period.
- (4) "Fixed MRI scanner" means an MRI scanner that is not a mobile MRI scanner.
- (5) "Fixed MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (6) "Host site" means the location where the mobile MRI scanner provides services.
- (7) "Magnetic resonance imaging (MRI) scanner" shall have the same meaning as defined in G.S. 131E-176(14m).
- (8) "Mobile MRI scanner" means an MRI scanner that is moved weekly to provide services at two or more host sites.
- (9) "Mobile MRI scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (10) "Proposed MRI scanner" means the MRI scanner proposed in the application under review.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Eff. February 1, 1994;

Temporary Amendment Eff. January 1, 1999;

Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;

Temporary Amendment Eff. January 1, 2000;

Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;

Temporary Amendment Eff. January 1, 2001;

Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001;

Temporary Amendment Eff. January 1, 2002;

Amended Eff. August 1, 2002;

Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;

Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Temporary Amendment Eff. February 1, 2009; Amended Eff. November 1, 2009; Temporary Amendment Eff. February 1, 2010; Amended Eff. November 1, 2010; Readopted Eff. January 1, 2022.

10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT

History Note:

Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Temporary Amendment Eff. January 1, 2003; January 1, 2002; Amended Eff. August 1, 2004; April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Repealed Eff. February 1, 2016.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;
- (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;
- (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;
- (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:
 - (A) 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
 - (B) 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or

- (C) 1,310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and
- (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operation following completion of the project.

(b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;
- (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;
- (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
- (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;
- (5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner;
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- (7) provide the assumptions and methodology used to project the utilization required by Subparagraph
 (6) of this Paragraph;
- (8) project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operation following completion of the project; and
- (9) project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform during the third full fiscal year of operation following completion of the project as follows:
 - (A) 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
 - (B) 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
 - (C) 1,310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Eff. February 1, 1994;

Temporary Amendment Eff. January 1, 1999;

Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;

Temporary Amendment Eff. January 1, 2000;

Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;

Temporary Amendment Eff. January 1, 2001;

Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001;

Temporary Amendment Eff. January 1, 2002;

Temporary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective, August 1, 2002;

Temporary Amendment Eff. January 1, 2003;

Amended Eff. August 1, 2004; April 1, 2003;

Temporary Amendment Eff. January 1, 2005;

Amended Eff. November 1, 2005;

Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Readopted Eff. January 1, 2022; Temporary Amendment Eff. January 27, 2023; Amended Eff. January 1, 2024.

10A NCAC 14C .2704SUPPORT SERVICES10A NCAC 14C .2705STAFFING AND STAFF TRAINING

History Note: Authorit

Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

SECTION .2800 - CRITERIA AND STANDARDS FOR REHABILITATION SERVICES

10A NCAC 14C .2801 DEFINITIONS

The following definitions shall apply to this Section:

- (1) "Approved rehabilitation beds" means rehabilitation beds that were issued a certificate of need but are not licensed as rehabilitation beds as of the application deadline for the review period.
- (2) "Average daily census (ADC)" means the total number of inpatient rehabilitation days of care provided during a full fiscal year of operation divided by 365 days.
- (3) "Existing rehabilitation beds" means rehabilitation beds that are licensed as rehabilitation beds as of the application deadline for the review period.
- (4) "Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed rehabilitation beds expressed as a percentage.
- (5) "Proposed rehabilitation beds" means the rehabilitation beds proposed in the application under review.
- History Note: Authority G.S. 131E-177; 131E-183(b); Eff. May 1, 1991; Amended Eff. February 1, 1993; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Readopted Eff. January 1, 2023.

10A NCAC 14C .2802 INFORMATION REQUIRED BY APPLICANT

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. May 1, 1991; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

10A NCAC 14C .2803 PERFORMANCE STANDARDS

An applicant proposing to develop rehabilitation beds pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization of all existing, approved, and proposed rehabilitation beds on the hospital license during each of the first three full fiscal years of operation following completion of the project;
- (2) project that the occupancy rate for all existing, approved, and proposed rehabilitation beds on the hospital license shall be at least 70 percent during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used to provide the projected utilization and occupancy rate required in Items (1) and (2) of this Rule.
- History Note: Authority G.S. 131E-177; 131E-183(b); Eff. November 1, 1996; Readopted Eff. January 1, 2023.

10A NCAC 14C .2804 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .2805 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. May 1, 1991; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

10A NCAC 14C .2806 QUALITY OF SERVICES

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. May 1, 1991; Temporary Repeal Eff. February 1, 2006; Repealed Eff. November 1, 2006.

SECTION .2900 - CRITERIA AND STANDARDS FOR BONE MARROW TRANSPLANTATION SERVICES

10A NCAC 14C .2901 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .2902 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

10A NCAC 14C .2903 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .2904 SUPPORT SERVICES

10A NCAC 14C .2905 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

SECTION .3000 - CRITERIA AND STANDARDS FOR SOLID ORGAN TRANSPLANTATION SERVICES

10A NCAC 14C .3001 DEFINITIONS

10A NCAC 14C .3002 **INFORMATION REQUIRED OF APPLICANT** 10A NCAC 14C .3003 SUPPORT SERVICES 10A NCAC 14C .3004 ADDITIONAL REQUIREMENTS FOR HEART, HEART/LUNG OR LUNG TRANSPLANTATION SERVICES 10A NCAC 14C .3005 ADDITIONAL REQUIREMENTS FOR LIVER TRANSPLANTATION SERVICES 10A NCAC 14C .3006 ADDITIONAL REQUIREMENTS FOR PANCREAS TRANSPLANTATION **SERVICES** 10A NCAC 14C .3007 **REQUIREMENTS FOR KIDNEY** TRANSPLANTATION ADDITIONAL **SERVICES** 10A NCAC 14C .3008 STAFFING AND STAFF TRAINING 10A NCAC 14C .3009 ACCESSIBILITY

History Note: Authority G.S. 131E-177(1); 131E-183; 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

10A NCAC 14C .3101PURPOSE AND SCOPE10A NCAC 14C .3102DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. March 16, 2017.

10A NCAC 14C .3103 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. January 1, 1997; November 1, 1996; Repealed Eff. February 1, 2016.

10A NCAC 14C .3104 NEED FOR SERVICES

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. March 16, 2017.

10A NCAC 14C .3105SUPPORT SERVICES10A NCAC 14C .3106STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

SECTION .3200 - CRITERIA AND STANDARDS FOR LITHOTRIPTOR EQUIPMENT

10A NCAC 14C .3201 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. October 1, 2016.

10A NCAC 14C .3202 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

10A NCAC 14C .3203 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. October 1, 2016.

10A NCAC 14C .3204SUPPORT SERVICES10A NCAC 14C .3205STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Repealed Eff. February 1, 2016.

SECTION .3300 - CRITERIA AND STANDARDS FOR AIR AMBULANCE

10A NCAC 14C .3301DEFINITIONS10A NCAC 14C .3302INFORMATION REQUIRED OF APPLICANT10A NCAC 14C .3303PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Temporary Amendment Eff. May 15, 2002; Amended Eff. April 1, 2007; April 1, 2005; April 1, 2003; Repealed Eff. January 1, 2013.

10A NCAC 14C .3304 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .3305 STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. February 1, 1994; Temporary Amendment Eff. May 15, 2002; Amended Eff. April 1, 2003; Repealed Eff. January 1, 2013.

SECTION .3400 - CRITERIA AND STANDARDS FOR BURN INTENSIVE CARE SERVICES

10A NCAC 14C .3401 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Amended Eff. November 1, 1996; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .3402 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

10A NCAC 14C .3403 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .3404SUPPORT SERVICES10A NCAC 14C .3405STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

SECTION .3500 - CRITERIA AND STANDARDS FOR ONCOLOGY TREATMENT CENTERS

10A NCAC 14C .3501DEFINITIONS10A NCAC 14C .3502INFORMATION REQUIRED OF APPLICANT

History Note: Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994; Temporary Repeal Eff. February 1, 2006; Repealed Eff. November 1, 2006.

10A NCAC 14C .3503 RESERVED FOR FUTURE CODIFICATION

10A NCAC 14C .3504SUPPORT SERVICES10A NCAC 14C .3505STAFFING AND STAFF TRAINING

History Note: Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994; Temporary Repeal Eff. February 1, 2006; Repealed Eff. November 1, 2006.

SECTION .3600 - CRITERIA AND STANDARDS FOR GAMMA KNIFE

10A NCAC 14C .3601 DEFINITIONS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .3602 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

10A NCAC 14C .3603 PERFORMANCE STANDARDS

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Expired Eff. February 1, 2019 pursuant to G.S. 150B-21.3A.

10A NCAC 14C .3604SUPPORT SERVICES10A NCAC 14C .3605STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Repealed Eff. February 1, 2016.

SECTION .3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

10A NCAC 14C .3701 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Approved PET scanner" means a positron emission tomography (PET) scanner that was issued a certificate of need but is not being used to provide services as of the application deadline for the review period.
- (2) "Existing PET scanner" means a PET scanner that is being used to provide services as of the application deadline for the review period.
- (3) "Fixed PET scanner" means a PET scanner that is not mobile.
- (4) "Fixed PET scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (5) "Host site" means the location where the mobile PET scanner provides services.
- (6) "Mobile PET scanner" means a PET scanner that is moved weekly to provide services at two or more host sites.
- (7) "Mobile PET scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (8) "Positron emission tomography scanner" shall have the same meaning as defined in G.S. 131E-176(19a).
- (9) "Proposed PET scanner" means the PET scanner proposed in the application under review.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. January 1, 2001; Temporary Amendment Eff. January 1, 2002; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; April 1, 2003; Readopted Eff. January 1, 2022.

10A NCAC 14C .3702 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Temporary Amendment Eff. January 1, 2002;
Temporary Amendment effective January 1, 2002 amends and replaces a permanent rulemaking originally proposed to be effective August 1, 2002;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. February 1, 2006;
Amended Eff. November 1, 2006;
Temporary Amendment Eff. February 1, 2008;
Amended Eff. November 1, 2008;
Repealed Eff. February 1, 2016.

10A NCAC 14C .3703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;
- (2) identify the approved fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed fixed PET scanner service area;
- (3) identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed fixed PET scanner service area during the 12 months before the application deadline for the review period;
- (4) identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed fixed PET scanner service area;
- (5) provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner during each of the first three full fiscal years of operation following completion of the project;
- (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph; and
- (7) project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.

(b) An applicant proposing to acquire a mobile PET scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing mobile PET scanners owned or operated by the applicant or a related entity that provided services at host sites located in the proposed mobile PET scanner service area during the 12 months before the application deadline for the review period;
- (2) identify the approved mobile PET scanners owned or operated by the applicant or a related entity that will provide services at host sites located in the proposed mobile PET scanner service area during the first three full fiscal years following completion of the project;
- (3) identify the existing fixed PET scanners owned or operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;
- (4) identify the approved fixed PET scanners owned and operated by the applicant or a related entity and located in the proposed mobile PET scanner service area;
- (5) identify the existing and proposed host sites for each mobile PET scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile PET scanner;
- (6) provide projected utilization of the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner during each of the first three full fiscal years of operation following completion of the project;
- (7) provide the assumptions and methodology used to project the utilization required by Subparagraph
 (6) of this Paragraph; and
- (8) project that the PET scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile PET scanner shall perform 2,080 or more procedures per PET scanner during the third full fiscal year of operation following completion of the project.

History Note: Authority G.S. 131E-177(1); 131E-183(b);

Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. January 1, 2002; January 1, 2001; Amended Eff. August 1, 2002;

Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;

Temporary Amendment Eff. January 1, 2003;

Amended Eff. August 1, 2004; April 1, 2003;

Temporary Amendment Eff. January 1, 2005;

Amended Eff. November 1, 2005;

Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Readopted Eff. January 1, 2022.

10A NCAC 14C .3704SUPPORT SERVICES10A NCAC 14C .3705STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Eff. January 4, 1994; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2006; Amended Eff. November 1, 2006; Repealed Eff. February 1, 2016.

SECTION .3800 - CRITERIA AND STANDARDS FOR ACUTE CARE HOSPITAL BEDS

10A NCAC 14C .3801 DEFINITIONS

The following definitions shall apply to this Section:

- (1) "Applicant hospital" means the hospital where the applicant proposes to develop the new acute care beds and includes all campuses on one license.
- (2) "Approved beds" means acute care beds in a hospital that were issued a certificate of need but are not licensed as of the application deadline for the review period.
- (3) "Average daily census (ADC)" means the total number of acute care days of care provided during a full fiscal year of operation divided by 365 days.
- (4) "Existing beds" means acute care beds in a hospital that are licensed as of the application deadline for the review period.
- (5) "Hospital system" means all hospitals in the proposed service area owned or operated by the applicant or a related entity.
- (6) "Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed acute care hospital beds expressed as a percentage.
- (7) "Proposed beds" means the acute care beds proposed to be developed in a hospital in the application under review.
- (8) "Qualified applicant" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (9) "Service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. January 1, 2004; Eff. August 1, 2004; Readopted Eff. January 1, 2023.

10A NCAC 14C .3802 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. January 1, 2004; Eff. August 1, 2004; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Repealed Eff. February 1, 2016.

10A NCAC 14C .3803 PERFORMANCE STANDARDS

An applicant proposing to develop new acute care beds in a hospital pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) document that it is a qualified applicant;
- (2) provide projected utilization of the existing, approved, and proposed acute care beds for the applicant hospital during each of the first three full fiscal years of operation following completion of the project;
- (3) project an occupancy rate of the existing, approved, and proposed acute care beds for the applicant hospital during the third full fiscal year of operation following completion of the project that equals or exceeds the target occupancy percentage;
- (4) provide projected utilization of the existing, approved, and proposed acute care beds for the hospital system during each of the first three full fiscal years of operation following completion of the project;
- (5) project an average occupancy rate of the existing, approved, and proposed acute care beds for the hospital system during the third full fiscal year of operation following completion of the project that equals or exceeds the target occupancy percentage of:
 - (a) 66.7 percent if the ADC is less than 100;
 - (b) 71.4 percent if the ADC is 100 to 200;
 - (c) 75.2 percent if the ADC is 201 to 399; or
 - (d) 78.0 percent if the ADC is greater than 400; and
- (6) provide the assumptions and methodology used to project the utilization and occupancy rates required in Items (2), (3), (4), and (5) of this Rule.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. January 1, 2004; Eff. August 1, 2004; Readopted Eff. January 1, 2023.

10A NCAC 14C .3804SUPPORT SERVICES10A NCAC 14C .3805STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. January 1, 2004; Eff. August 1, 2004; Repealed Eff. February 1, 2016.

SECTION .3900 - CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILTIES

10A NCAC 14C .3901 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Approved gastrointestinal (GI) endoscopy rooms" means GI endoscopy rooms that were approved for a certificate of need by the CON Section prior to the date the application was submitted but that are not licensed as of the date the application is submitted.
- (2) "Existing GI endoscopy rooms" means GI endoscopy rooms that were licensed prior to the beginning of the review period.
- (3) "GI endoscopy procedure" means each upper endoscopy, esophagoscopy, or colonoscopy procedure performed on a patient during a single visit to the licensed health service facility.
- (4) "Licensed health service facility" means either a hospital as defined in G.S. 131E-176(13) or an ambulatory surgical facility as defined in G.S. 131E-176(1b).
- (5) "New GI endoscopy room" means a GI endoscopy room that is not included in the inventory of GI endoscopy rooms in the State Medical Facilities Plan as of the date the application is submitted.
- (6) "Service area" means the county where the proposed GI endoscopy room will be developed.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Readopted Eff. January 1, 2021.

10A NCAC 14C .3902 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177; 131E-183(b); Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Repealed Eff. February 1, 2016.

10A NCAC 14C .3903 PERFORMANCE STANDARDS

An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:

(1) identify the proposed service area;

- (2) identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;
- (3) provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;
- (4) project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and
- (5) provide the assumptions and methodology used to project the utilization required by this Rule.

History Note: Authority G.S. 131E-177; 131E-183(b); Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Readopted Eff. January 1, 2021.

10A NCAC 14C .3904SUPPORT SERVICES10A NCAC 14C .3905STAFFING AND STAFF TRAINING10A NCAC 14C .3906FACILITY

History Note: Authority G.S. 131E-177; 131E-183(b); Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Repealed Eff. February 1, 2016.

SECTION .4000 - CRITERIA AND STANDARDS FOR HOSPICE INPATIENT FACILITIES AND HOSPICE RESIDENTIAL CARE FACILITIES

10A NCAC 14C .4001 DEFINITIONS

The following definitions shall apply to this Section:

- (1) "Approved beds" means hospice inpatient facility or hospice residential care facility beds that were issued a certificate of need but are not licensed as of the application deadline for the review period.
- (2) "Average daily census (ADC)" means the total number of days of care provided in the hospice inpatient facility or hospice residential care facility beds during a full fiscal year of operation divided by 365 days.
- (3) "Existing beds" means hospice inpatient facility or hospice residential care facility beds that are licensed as of the application deadline for the review period.
- (4) "Hospice inpatient facility beds" means inpatient beds in a facility licensed in accordance with the rules in Subchapter 10A NCAC 13K which are hereby incorporated by reference including subsequent amendments.
- (5) "Hospice residential care facility beds" means group residential care beds in a facility licensed in accordance with the rules in Subchapter 10A NCAC 13K.
- (6) "Occupancy rate" means the ADC divided by the total number of existing, approved, and proposed hospice inpatient facility or hospice residential care facility beds expressed as a percentage.

(7) "Proposed beds" means the hospice inpatient facility or hospice residential care facility beds proposed in the application under review.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Readopted Eff. January 1, 2023.

10A NCAC 14C .4002 INFORMATION REQUIRED OF APPLICANT

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Repealed Eff. February 1, 2016.

10A NCAC 14C .4003 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new hospice inpatient facility beds pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) provide projected utilization of all existing, approved, and proposed hospice inpatient facility beds on the license during each of the first three full fiscal years of operation following completion of the project;
- (2) project that the occupancy rate for all existing, approved, and proposed hospice inpatient facility beds on the license shall be at least 65 percent during the third full fiscal year of operation following completion of the project; and
- (3) provide the assumptions and methodology used to provide the projected utilization and occupancy rate required by Subparagraphs (1) and (2) of this Paragraph.
- (b) An applicant proposing to develop new hospice residential care facility beds shall:
 - (1) provide projected utilization of all existing, approved, and proposed hospice residential care facility beds on the license during each of the first three full fiscal years of operation following completion of the project;
 - (2) project that the occupancy rate for all existing, approved, and proposed hospice residential care facility beds on the license shall be at least 65 percent during the third full fiscal year of operation following completion of the project; and
 - (3) provide the assumptions and methodology used to provide the projected utilization and occupancy rate required by Subparagraphs (1) and (2) of this Paragraph.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Temporary Amendment Eff. February 1, 2008; Amended Eff. November 1, 2008; Readopted Eff. January 1, 2023.

10A NCAC 14C .4004SUPPORT SERVICES10A NCAC 14C .4005STAFFING AND STAFF TRAINING

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. February 1, 2006; Eff. November 1, 2006; Repealed Eff. February 1, 2016.

10A NCAC 14C .4006 FACILITY

History Note: Authority G.S. 131E-177(1); 131E-183;

Temporary Adoption Eff. February 1, 2008; Eff. November 1, 2008; Repealed Eff. February 1, 2016.