

10A NCAC 14C .0202 is readopted with changes as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .0202 DETERMINATION OF REVIEW DEFINITIONS

~~(a) After receipt of a letter of intent, the agency shall determine whether the proposed project requires a certificate of need.~~

~~(b) When any of the equipment listed in G.S. 131E-176(16)(f1) or (p) is acquired in parts or piecemeal fashion, the acquisition shall be determined to require a certificate of need on the date that the components are assembled.~~

~~(c) If the agency determines that the project requires a certificate of need, the agency shall determine the appropriate review category or categories for the proposed project, the type or types of application forms to be submitted, the number of separate applications to be submitted, the applicable review period for each application, and the deadline date for submitting each application, as contained in this Subchapter.~~

~~(d) Copies of the application forms may be obtained from the agency.~~

~~(e) Proposals requiring review shall be reviewed according to the categories and schedule set forth in the duly adopted State Medical Facilities Plan in effect at the time the scheduled review period commences, as contained in this Subchapter.~~

~~(f) Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period.~~

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 and editions,] 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] 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: Filed as a Temporary Amendment 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;

Eff. October 1, 1981;

Amended Eff. November 1, 1996; January 4, 1994; January 1, 1990; January 1, 1987;

Temporary Amendment Eff. January 1, 2000;

Amended Eff. April 1, ~~2001~~, 2001;

Readopted Eff. January 1, 2021.

10A NCAC 14C .0203 is readopted with changes as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .0203 FILING APPLICATIONS

~~(a) A certificate of need application shall not be reviewed by the Certificate of Need Section until it is filed in accordance with this Rule.~~

~~(b) An original and a copy of the application shall be file stamped as received by the agency no later than 5:30 p.m. on the 15th day of the month preceding the scheduled review period. In instances when the 15th of the month falls on a weekend or holiday, the filing deadline is 5:30 p.m. on the next business day. An application shall not be included in a scheduled review if it is not received by the agency by this deadline. Each applicant shall transmit, with the application, a fee to be determined according to the formula as stated in G.S. 131E-182(c).~~

~~(c) After an application is filed, the agency shall determine whether it is complete for review. An application shall not be considered complete if:~~

- ~~(1) the requisite fee has not been received by the agency; or~~
- ~~(2) a signed original and copy of the application have not been submitted to the agency on the appropriate application form.~~

~~(d) If the agency determines the application is not complete for review, it shall mail notice of such determination to the applicant within five business days after the application is filed and shall specify what is necessary to complete the application. If the agency determines the application is complete, it shall mail notice of such determination to the applicant prior to the beginning of the applicable review period.~~

~~(e) Information requested by the agency to complete the application must be received by the agency no later than 5:30 p.m. on the last working day before the first day of the scheduled review period. The review of an application shall commence in the next applicable review period that commences after the application has been determined to be complete.~~

(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 ~~Paragraph (d)(1)~~ 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;

1 *Amended Eff. December 1, 1994;*
2 *Temporary Amendment Eff. January 1, 2000;*
3 *Amended Eff. April 1, 2001;*
4 *Temporary Amendment Eff. February 16, 2004;*
5 *Amended Eff. August 1, 2004;*
6 *Temporary Amendment Eff. February 1, 2006;*
7 *Amended Eff. November 1, 2006;*
8 *Temporary Amendment Eff. January 1, 2008;*
9 *Amended Eff. July 1, ~~2008~~, 2008;*
10 *Readopted Eff. January 1, 2021.*

10A NCAC 14C .2101 is readopted with changes as published in 35:02 NCR 100-106 as follows:

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 ~~Healthcare Planning and Certificate of Need Section (Agency)~~ CON Section prior to the date on which the applicant's proposed project was submitted to the Agency, 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 ~~2018 annual~~ State Medical Facilities Plan. ~~For purposes of this Section, Chapter 6 in the 2018 State Medical Facilities Plan is hereby incorporated by reference including subsequent amendments and editions. This document is available at no cost at <https://www.ncdhhs.gov/dhsr/nsmfp/index.html>.~~
- (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 ~~2018 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 ~~2018 annual~~ State Medical Facilities Plan.
- (7) "Service area" means the Operating Room Service Area as defined in Chapter 6 in the ~~2018 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;*

1 *Temporary Amendment Eff. January 1, 2002; July 1, 2001;*
2 *Amended Eff. August 1, 2002;*
3 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*
4 *August 1, 2002;*
5 *Amended Eff. April 1, 2003;*
6 *Temporary Amendment Eff. January 1, 2005;*
7 *Amended Eff. November 1, 2005;*
8 *Temporary Rule Eff. February 1, 2006;*
9 *Amended Eff. November 1, 2006;*
10 *Temporary Amendment Eff. February 1, 2008;*
11 *Amended Eff. November 1, 2008.*
12 *Temporary Amendment Eff. February 1, 2018;*
13 *Amended Eff. December 1, ~~2018~~, 2018;*
14 *Readopted Eff. January 1, 2021.*

10A NCAC 14C .2103 is readopted with changes as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) An applicant proposing to increase the number of operating ~~rooms~~ rooms (~~excluding dedicated C-section operating rooms~~) rooms, excluding dedicated C-section operating ~~rooms~~ 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 ~~2018 annual~~ 2018 annual State Medical Facilities ~~Plan~~ Plan in effect at the time the review began. The applicant is not required to use the population growth factor.

(b) The applicant shall ~~document~~ provide the assumptions and ~~provide data supporting the~~ methodology used for ~~each projection in 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; 2018;
Readopted Eff. January 1, 2021.

10A NCAC 14C .2203 is readopted with changes as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .2203 PERFORMANCE STANDARDS

~~(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.~~

~~(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.~~

~~(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.~~

(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;] 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 [services] 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 [services] 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;

1 *Amended Eff. August 1, 2004;*
2 *Temporary Amendment Eff. January 1, 2005;*
3 *Amended Eff. November 1, 2005;*
4 *Temporary Amendment Eff. February 1, 2006;*
5 *Amended Eff. November 1, 2006;*
6 *Temporary Amendment Eff. February 1, 2010;*
7 *Amended Eff. November 1, 2010;*
8 *Temporary Amendment Eff February 1, ~~2020~~ 2020;*
9 *Readopted Eff. January 1, 2021.*