REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .0202

DEADLINE FOR RECEIPT: Friday, December 11, 2020

***NOTE:* This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (2), line 25, please delete "and editions" and insert a comma after "amendments"

In (3), line 27, is "service area" as defined in G.S. 131E-176(24a)? And are those service areas defined in the State Medical Facilities Plan?

In (12), Page 2, line 11, so that I'm clear – while there is no review period in January, the agency will still adhere to the statutory deadlines?

In (13), line 14, please insert a comma after "reference"

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 30, 2020

10A NCAC 14C .0202 is readopted 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, 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: *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.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .0203

DEADLINE FOR RECEIPT: Friday, December 11, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), what are the contents of these forms? I see that G.S. 131E-182 states:

> **§ 131E-182. Application.**
>
> (b) An application for a certificate of need shall be made on forms provided by the Department. The application forms, which may vary according to the type of proposal, shall require such information as the Department, by its rules deems necessary to conduct the review. An applicant shall be required to furnish only that information necessary to determine whether the proposed new institutional health service is consistent with the review criteria implemented under G.S. 131E-183 and with duly adopted standards, plans and criteria.

I see that the application may vary based upon the type of proposal but what is required? Is this set forth in another rule (such as the SMFP) or law (such as 131E-183?), as required by G.S. 150B-8(2a)(d)?

In (c)(1), line 31, what do you mean by "describe"?

In (d)(4), line 9, since you refer to "applicant" (singular), please state "he or she" instead of "they." However, if the applicant can be a corporate entity, please retain "they."

In (f), line 11, I believe you mean to refer to "Subparagraph (e)(1)"

And so that I'm clear – you will accept an electronic copy, but the original must be printed and bound?

In (h), so that I'm clear – what else could be outstanding? The fee?

And on lines 16-17, you refer to the "contact individual identified in Section A of the application" – so that I'm clear, this is not the "applicant" as defined by Rule .0202(1)?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 30, 2020

10A NCAC 14C .0203 is readopted 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) 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.~~ 2008;
Readopted Eff. January 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .0205

DEADLINE FOR RECEIPT: Friday, December 11, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

What is the purpose of this Rule? I do not read the law to mandate the Department to state under what circumstances the statutorily allowed extension will occur, and Paragraph (a) says it will mostly occur when staff can't get to it. Then (b) says that not receiving the notice of extension won't result in an automatic CON. But the law clearly states that projects may not proceed without the approval. So, what purpose does this Rule serve? What is it regulating?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 30, 2020

10A NCAC 14C .0205 is readopted as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .0205 EXTENSION OF REVIEW PERIOD

~~(a) The review of an application for a certificate of need shall be completed within 90 days from the beginning date of the review period for the application, except as provided in Paragraph (b) of this Rule.~~

~~(b) Except in the case of an expedited review, the period for review may be extended for up to 60 days by the agency if it determines that, for one or more of the following reasons, it cannot complete the review within 90 days:~~

~~(1) the extension is necessary to consider conflicting, contradictory, or otherwise relevant matters;~~

~~(2) the total number of applications assigned to the project analyst for review, including those in other review periods, preclude the project analyst from completing the review within 90 days;~~

~~(3) the complexity of the application or applications to be reviewed make it necessary to extend the review period;~~

~~(4) the review of an applicant's response to the agency's request for additional information has not been completed;~~

~~(5) the timing of the public hearing which was held for the application or applications under review does not allow sufficient time to consider the information presented;~~

~~(6) extension of previous reviews necessitated that the project analyst delay the commencement of the review; or~~

~~(7) the unavailability of the project analyst due to illness, annual leave, litigation associated with other reviews, or other duties and responsibilities.~~

~~(c) In the case of an expedited review, the review period may be extended only if the Agency has requested additional substantive information from the applicant in accordance with G.S. 131E-185(c).~~

~~(d) Applicants will be provided written notice of the extension of the review period after the agency determines that an extension is necessary. Failure to receive such notice prior to the last day of the scheduled review period, however, does not entitle an applicant to a certificate of need nor authorize an applicant to proceed with a project without one.~~

(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: *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; 131E-185;
Eff. October 1, 1981;
Amended Eff. January 4, 1994; January 1, 1990; January 1, ~~1982.~~ 1982;
Readopted Eff. January 1, 2021.

10A NCAC 14C .0303 is readopted as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .0303 REPLACEMENT EQUIPMENT

~~(a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a).~~

~~(b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.~~

~~(c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.~~

~~(d) Replacement equipment is comparable to the equipment being replaced if:~~

~~(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and~~

~~(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and~~

~~(3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.~~

~~(e) Replacement equipment is not comparable to the equipment being replaced if:~~

~~(1) the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or~~

~~(2) the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or~~

~~(3) the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or~~

~~(4) the replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease; or~~

~~(5) the replacement equipment is a dedicated PET scanner and the existing equipment is:~~

~~(A) a gamma camera with coincidence capability; or~~

~~(B) nuclear medicine equipment that was designed, built, or modified to detect only the single photon emitted from nuclear events other than positron annihilation.~~

(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.~~ 2003;
Readopted Eff. January 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .2101

DEADLINE FOR RECEIPT: Friday, December 11, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (1), line 6, you deleted "Agency," so please either replace or define the term on line 7.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 30, 2020

10A NCAC 14C .2101 is readopted 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, 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/ncsmfp/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;

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.~~ 2018;
Readopted Eff. January 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .2103

DEADLINE FOR RECEIPT: Friday, December 11, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), lines 4 and 5, please set the phrase "excluding dedicated C-section operating rooms" off with a comma.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 30, 2020

10A NCAC 14C .2103 is readopted 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 ~~(excluding dedicated C-section 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 ~~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 .2201 is readopted with changes as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .2201 DEFINITIONS

~~The definitions in this Rule will apply to all rules in this Section:~~

~~(1) "End stage renal disease (ESRD) services" means those dialysis or transplantation services necessary for the treatment of patients with end stage renal disease provided by transplantation centers, dialysis centers or dialysis facilities.~~

~~(2) "Renal transplantation center" means a hospital unit which furnishes directly rental transplantation and other medical and surgical specialty services required for transplant candidates or patients.~~

~~(3) "Renal dialysis center" is a hospital unit which furnishes the full spectrum of diagnostic, therapeutic, and rehabilitative services.~~

~~(4) "Renal dialysis facility" is a unit, usually freestanding, which furnishes dialysis service to ESRD patients.~~

~~(5) "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.~~

~~(6) "Hemodialysis" means the form of dialysis in which the blood is circulated outside the body through an apparatus which permits transfer of waste through synthetic membranes.~~

~~(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.~~

~~(8) "Maintenance dialysis" is the term used to describe routine repetitive dialysis treatments necessary to sustain life of patients with ESRD.~~

~~(9) "Self care dialysis or home dialysis training" means the systematic training of patients and their helpers in the techniques of self care dialysis.~~

~~(10) "Self care dialysis" means the self administration of maintenance dialysis treatments in ESRD facility or elsewhere and may be assisted by an aide who is either a family member or a non family member assistant.~~

~~(11) "Dialysis station" means a unit in an ESRD facility equipped with the apparatus for performing hemodialysis or peritoneal dialysis on a single patient. Stations may designated for maintenance dialysis, self care dialysis, self care training, or isolation.~~

~~(12) "Isolation station" means a dialysis station located apart from other maintenance dialysis stations to serve patients who either have or are suspected to have an infectious disease, i.e., hepatitis.~~

~~(13) "Shift" means the scheduled time when a group of patients are provided their dialysis treatment.~~

~~(14) "Transplantation" means a surgical procedure in which a functioning kidney is removed from a donor and implanted in the patient with ESRD.~~

~~(15) "Organ procurement" means the process of acquiring kidneys for transplantation from potential donors.~~

~~(16) "Histocompatability testing" means laboratory testing procedures which determine compatability between a potential donor organ and a potential organ transplant recipient.~~

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 [~~dialysis~~] 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 [~~the patient's home~~] 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 [~~the patient's home~~] 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.~~ 1983;
Readopted Eff. January 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Department of Health and Human Services

RULE CITATION: 10A NCAC 14C .2203

DEADLINE FOR RECEIPT: Friday, December 11, 2020

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (b)(2), line 21, I do not think you need the semicolon at the end of the line.

In (c), this Paragraph says it governs both home hemodialysis or peritoneal dialysis but it then only goes on to state what is required for home hemodialysis. Should this Paragraph state what is required for peritoneal dialysis? Or is it a subset of home hemodialysis?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 30, 2020

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;

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;

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.~~ 2020;
Readopted Eff. January 1, 2021.

10A NCAC 14C .3901 is readopted as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .3901 DEFINITIONS

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

~~(1) "Ambulatory surgical facility" means a facility as defined in G.S. 131E-176(1b).~~

~~(2) "Gastrointestinal (GI) endoscopy room" means a room as defined in G.S. 131E-176(7d) that is used to perform one or more GI endoscopy procedures.~~

~~(3) "Gastrointestinal (GI) endoscopy procedure" means a single procedure, identified by CPT code or ICD-9-CM procedure code, performed on a patient during a single visit to the facility for diagnostic or therapeutic purposes.~~

~~(4) "Operating room" means a room as defined in G.S. 131E-176(18c).)~~

~~(5) "Related entity" means the parent company of the applicant, a subsidiary company of the applicant (i.e., the applicant owns 50 percent or more of another company), a joint venture in which the applicant is a member, or a company that shares common ownership with the applicant (i.e., the applicant and another company are owned by some of the same persons).~~

~~(6) "Service area" means the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.~~

(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.~~ 2006;
Readopted Eff. January 1, 2021.

10A NCAC 14C .3903 is readopted as published in 35:02 NCR 100-106 as follows:

10A NCAC 14C .3903 PERFORMANCE STANDARDS

~~(a) In providing projections for operating rooms, as required in this rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding ten days for holidays.~~

~~(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.~~

~~(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.~~

~~(d) If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:~~

- ~~(1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or~~
- ~~(2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.~~

~~(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.~~

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.~~ 2006;
Readopted Eff. January 1, 2021.