

**Fiscal Impact Analysis for
Permanent Rule Readoption without Substantial Economic Impact**

Agency Proposing Rule Change

Department of Health and Human Services, Division of Health Service Regulation

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Impact Summary

Federal Government Impact	No
Local Government Impact	No
Private Sector Impact	Minimal
State Government Impact	No
Substantial Economic Impact	No

Statutory Authority

G.S. 131E-177
G.S. 131E-183(b)

Rule Citations

10A NCAC 14C – Certificate of Need

- 10A NCAC 14C .0202 ~~Determination of Review~~ Definitions (Readopt with Substantive Changes)
- 10A NCAC 14C .0203 Filing Applications (Readopt with Substantive Changes)
- 10A NCAC 14C .0205 Extension of Review Period (Readopt with Substantive Changes)
- 10A NCAC 14C .0303 Replacement Equipment (Readopt with Substantive Changes)
- 10A NCAC 14C .2101 Definitions (Readopt with Substantive Changes)
- 10A NCAC 14C .2103 Performance Standards (Readopt with Substantive Changes)
- 10A NCAC 14C .2201 Definitions (Readopt with Substantive Changes)
- 10A NCAC 14C .2203 Performance Standards (Readopt with Substantive Changes)
- 10A NCAC 14C .3901 Definitions (Readopt with Substantive Changes)
- 10A NCAC 14C .3903 Performance Standards (Readopt with Substantive Changes)

See proposed rule text in Appendix A.

BACKGROUND AND PURPOSE

Article 9 of Chapter 131E of the North Carolina General Statutes (CON Law) requires that a person obtain a certificate of need (CON) from the Department of Health and Human Services (Department) before developing or offering a “new institutional health service.” The term “new institutional health service” is defined in G.S. 131E-176(16). The new institutional health services relevant to this fiscal impact analysis include:

- Developing a new kidney disease treatment center (dialysis facility) [G.S. 131E-176(16)a];
- Adding dialysis stations to an existing or approved dialysis facility [G.S. 131E-176(16)c];
- Relocating existing dialysis stations from one dialysis facility or campus to another [G.S. 131E-176(16)c];
- Developing a new hospital if the proposal includes developing new ORs [G.S. 131E-176(16)u];
- Developing a new ambulatory surgical facility (ASF) [G.S. 131E-176(16)a];
- Adding new operating rooms (ORs) to an existing or approved ASF or hospital [G.S. 131E-176(16)u];
- Adding new gastrointestinal endoscopy (GI) rooms to an existing or approved ASF or hospital [G.S. 131E-176(16)u]; and
- Relocating ORs or GI endoscopy rooms from one licensed facility or campus to another [G.S. 131E-176(16)u].

The Department delegated the authority to enforce the CON Law to the Healthcare Planning and Certificate of Need Section (CON Section) in the Division of Health Service Regulation (Division).

In order to obtain a CON, a person must submit a completed application form and be approved by the CON Section to develop the proposed project. The CON cannot be issued until all appeals are resolved.

The CON Section is required to review all CON applications using the review criteria found in G.S. 131E-183(a). In addition, pursuant to G.S. 131E-183(b), the Division is authorized to adopt rules for the review of proposals which may vary based on the type of health service.

The CON Law authorizes the Department to develop the State Medical Facilities Plan (SMFP), which is prepared annually by the Department and the North Carolina State Health Coordinating Council (SHCC), a 25-member advisory body appointed by the Governor. The SMFP is approved by the Governor each year. Pursuant to G.S. 150B-2(8a)k, the SMFP is not a rule. Session Law 2003-229 amended the Administrative Procedure Act to state that the State Medical Facilities Plan is exempt from the Act and its procedural and analytical requirements for rulemaking.

In 2018, the Division reviewed 63 CON rules to determine if each rule was:

- Unnecessary;
- Necessary with substantive public interest; or
- Necessary without substantive public interest.

Twenty-one rules were determined to be unnecessary and they expired February 1, 2019 pursuant to G.S. 150B-21.3A. Three rules were determined to be necessary without substantive public interest effective January 19, 2019. Thirty-nine rules were determined to be necessary with substantive public interest. These rules must be readopted by 2024 and they will be readopted in four groups. The first group (Group 1) consists of the 10 rules which are the subject of this fiscal impact analysis. The following is a brief summary of each rule in Group 1.

RULE SUMMARIES

10A NCAC 14C .0202 Definitions

The Division proposes to change the title of this rule from Determination of Review to Definitions and to delete paragraphs (a)-(f). The proposed text defines 14 terms used throughout the Subchapter.

10A NCAC 14C .0203 Filing Applications

The Division proposes to delete paragraphs (a)-(e). The proposed text of the new paragraphs (a)-(j) describe the steps for filing an application beginning with how to obtain an application form to when the application is considered complete for review.

10A NCAC 14C .0205 Extension of Review Period

The Division proposes to change the title from Review Period to Extension of Review Period and to delete paragraphs (a)-(d). The proposed text of the new paragraph (a) describes the circumstances under which a non-expedited review may be extended by the CON Section for an additional 60 days beyond the 90 days authorized by G.S. 131E-185(a1). The proposed text of the new paragraph (b) requires the CON Section to notify the applicant when the review has been extended.

10A NCAC 14C .0303 Replacement Equipment

The Division proposes to delete paragraphs (a)-(e). The proposed text of the new paragraph (a) describes the purpose of this Rule like the deleted paragraph (a). The proposed text of the new paragraph (b) defines a term used only in the context of replacement equipment. The proposed text of the new paragraph (c) describes when replacement equipment would not be comparable.

Operating Rooms

10A NCAC 14C .2101 Definitions

10A NCAC 14C .2101 is a definitions rule. The Division proposes to change the reference to the section in .2101(1), to delete the adoption by reference language in .2101(2), and to change references to the 2018 SMFP to the annual SMFP in .2101(2), (4), (6), and (7).

10A NCAC 14C .2103 Performance Standards

The Division proposes to remove the parentheses in .2103(a), change the reference to the 2018 SMFP to the annual SMFP in .2103(a), and reword .2103(b) for clarity without a change in meaning.

Dialysis Stations

10A NCAC 14C .2201 Definitions

The Division proposes to delete the existing definitions and replace them with the proposed text which defines terms used in the proposed text of 10A NCAC 14C .2203 Performance Standards.

10A NCAC 14C .2203 Performance Standards

The Division proposes to delete paragraphs (a)-(c). The proposed text of the new paragraphs (a) and (b) lowers the minimum utilization threshold from 3.2 patients per station per week to 2.8 patients per station per week. The purpose of the change is to be consistent with the assumptions in the facility need methodology in the 2020 SMFP. In addition, the proposed text of paragraphs (c) and (d) creates a new performance standard for new facilities dedicated to home hemodialysis or peritoneal dialysis training and support services and expansions of those facilities.

GI Endoscopy Rooms

10A NCAC 14C .3901 Definitions

The Division proposes to delete the existing definitions and replace them with the proposed text which defines terms used in the proposed text of 10A NCAC 14C .3903 Performance Standards.

10A NCAC 14C .3903 Performance Standards

The Division proposes to delete paragraphs (a)-(e). The proposed text of the new paragraph does not change the performance standard, which is statutory. See G.S. 131E-182(a). Rather, the rule has been rewritten to improve clarity and eliminate the requirement of paragraph (d) which was determined to be unnecessary.

IMPACT ANALYSIS

10A NCAC 14C .0202 ~~Determination of Review~~ Definitions

The proposed text defines 14 terms used throughout the Subchapter. The proposed text of this rule will have no measurable impact on health care providers, applicants or the CON Section.

10A NCAC 14C .0203 Filing Applications

The proposed text would result in the following substantive changes:

- Applicants would be required by rule to print the original, place it between a front and back cover, and bind it with metal paper fasteners. Currently, following this instruction in the application form for printing and binding the original is voluntary.
- Applicants would still be able to submit the copy printed and bound the same way as the original or they may submit the copy in an electronic format. If the applicant chooses to submit the copy in an electronic format, the proposed text would require the applicant to submit the files on a USB flash drive which has not been encrypted or password protected. Currently, an electronic copy may be submitted on a CD or DVD or a flash drive.
- Applicants would no longer be allowed to submit the fee required by G.S. 131E-182(c) after the application deadline. The change is necessitated by the Division's interpretation of G.S. 131E-182(c) which states "An applicant must submit the fee with the application." Emphasis added.
- Applicants that use the wrong application form would no longer be allowed to resubmit the application on the correct application form.

The instructions in the application form for binding are as follows:

Each volume of the application should be bound together by punching two holes in the left hand margin and fastening the pages together with a metal paper fastener (e.g., ACCO ® Paper Fasteners). Place a sturdy cover on the front and back to protect the first and last pages from damage. **Do not submit the application in a 3-ring binder or notebook.**

Virtually all applicants already follow the instructions in the application form for printing and binding the original and copy.

Submitting an electronic second copy is voluntary and changing the requirement from saving the copy on a CD/DVD to saving it on a USB flash drive is driven by the fact that most new computers do not come with a built

in CD/DVD drive. One consultant who offered comments about the proposed text stated that CDs and DVDs are less expensive than flash drives. However, another consultant requested that we require flash drives, not CDs or DVDs because new computers do not come with CD/DVD drives built in. The Division concluded that it is possible that applicants may not be able to obtain CDs and DVDs in the future. Moreover, the CON Section and applicants would most likely have to purchase an external device for reading and burning CDs or DVDs.

The CON Section has determined that the CON Law requires that the entire application fee accompany the application. It is too speculative to project whether this will result in more incomplete applications. Most applicants already submit the correct application fee with the application.

The CON Section is aware of only two applications that were submitted on the wrong application form in the last 25 years. Moreover, the application forms have been extensively revised and are now very similar regardless of the type of proposal. Shortly, the section plans to reduce the number of different forms from 11 to 2. It would not be impossible for a proposal submitted on the wrong form to nevertheless be found conforming to all statutory and regulatory review criteria.

The proposed text of this rule will have no measurable impact on health care providers, applicants or the CON Section.

10A NCAC 14C .0205 Extension of Review Period

The Division proposes to change the title of this rule to make it clear that the rule relates to extension of the review period.

The text of the new paragraph (a), like the text of the deleted paragraph (b), lists the reasons why the CON Section may extend the review. However, the proposed text reduces the list from seven reasons to three. Deleted reasons (2), (6) and (7) are essentially the same and have been combined in the new reason (1). Deleted reasons (1) and (3) have never been used by the CON Section. Deleted reason (5) is perplexing as the public hearing must be held within the 20 days following the end of the written comment period which is always the first 30 days of the review period. That means that there would be at least 40 days after the public hearing to finish the review within the 90-day review period. Deleted reason (4) is the new reason (3) but reworded. The new reason (2) is related to the new reason (3) in that the timing of the request for clarifying information may be such that the applicant has not had time to provide a response.

The text of the new paragraph (b), like the text of the deleted paragraph (d), requires the CON Section to notify the applicant that the review has been extended and makes it clear that failure to receive the notice prior to the last day of the 90-day review period does not entitle the applicant to a certificate of need or to proceed with the proposal without a certificate of need.

The proposed text of this rule will have no measurable impact on health care providers, applicants or the CON Section.

10A NCAC 14C .0303 Replacement Equipment

Since this rule was last amended in 2003, G.S. 131E-184 was amended to add a new exemption for replacement equipment costing more than \$2,000,000. The text of the deleted paragraphs was determined to be: unnecessary; unclear; or impose requirements not supported by the statutory definition of replacement equipment or the new replacement equipment exemption.

The text of the new paragraph (a) is worded differently from the text of the deleted paragraph (a) without changing the substance of the rule.

The text of the new paragraph (b) defines a term used only in the context of replacement equipment. This term was previously defined in a different rule which has expired. Defining it in 10A NCAC 14C .0303 places it where providers and the CON Section staff are more likely to find it.

The text of the new paragraph (c), like the text of the deleted paragraph (e), describes when replacement equipment is not comparable. However, the proposed text is clearer and shortens the time frame during which a provider may not replace refurbished or reconditioned equipment without first obtaining a certificate of need if the acquisition would be a new institutional health service. The time frame is shortened from three years to less than 12 months. It is too speculative to project whether this will result in more replacement exemptions or fewer CON applications for replacement equipment. Any estimates would be just unsupported guesses as to how many additional exemption notices or CON applications would be received and in what year they might be expected to be received.

The proposed text of this rule may provide an unquantified benefit to health care providers and the CON Section by reducing the applicants time to prepare a CON application and the CON Section's time to review that application for some equipment replaced within 12 months to three years of acquisition.

Operating Rooms

10A NCAC 14C .2101 Definitions

10A NCAC 14C .2103 Performance Standards

The only proposed changes for 10A NCAC 14C .2101 are to change the reference to the section, to delete the adoption by reference language in .2101(2), and to update three references to the 2018 SMFP to the annual SMFP.

The only proposed changes for 10A NCAC 14C .2103 are to update one reference to the 2018 SMFP to the annual SMFP in effect at the time the review began in paragraph (a) and to reword paragraph (b) without changing the substance of the rule.

The proposed text of these rules would have no measurable impact on health care providers, applicants or the CON Section.

GI Endoscopy Rooms

10A NCAC 14C .3901 Definitions

10A NCAC 14C .3903 Performance Standards

The proposed text of the definitions rule defines the terms used in the proposed text of 10A NCAC 14C .3903.

The text of 10A NCAC 14C .3903 has been rewritten as one paragraph without changing what an applicant must demonstrate except for deleting paragraphs (a), (c) and (d) which were determined to be unnecessary. Moreover, instead of the applicant defining the service area, the service area is now defined as the county where the proposed GI endoscopy room would be located. This may reduce the burden on applicants slightly as they will not have to provide information in the application about utilization of facilities located in other counties. However, it is too speculative to project whether this will result in more CON applications for GI endoscopy rooms. Any estimate would be just an unsupported guess as to how many additional CON applications would be received and in what year they might be expected to be received.

The proposed text of these rules would have no measurable impact on health care providers, applicants or the CON Section.

Dialysis Stations

10A NCAC 14C .2201 Definitions

The proposed text of the definitions rule defines the terms used in the proposed text of 10A NCAC 14C .2203. The proposed text of this rule would have no measurable impact on health care providers, applicants or the CON Section.

Dialysis Stations

10A NCAC 14C .2203 Performance Standards

Background – The SMFP has included a county and a facility need methodology for determining the need for additional dialysis stations for more than 25 years. Unlike other beds, services and equipment covered by the SMFP where need is determined once a year, need for dialysis stations was determined twice a year and published in a Semi-annual Dialysis Report (SDR) (a supplement to the SMFP). In 2019, the Department and the SHCC recommended to the Governor that need for dialysis stations be determined on an annual basis starting with the 2020 SMFP. The Governor approved the change on December 4, 2019 when he signed the 2020 SMFP.

Pursuant to G.S. 131E-183(a)(3) (Criterion 3), an applicant proposing to develop a new dialysis facility or stations must demonstrate the need the population expected to use the proposed facility or stations has for the proposed services. In addition, pursuant to G.S. 131E-183(a)(6) (Criterion 6), the applicant must demonstrate that the proposal will not result in an unnecessary duplication of existing or approved dialysis facilities or stations in the service area. An applicant is expected to provide historical and projected utilization data in its application in order to demonstrate conformity with these statutory review criteria.

When reviewing a CON application proposing to develop a new dialysis facility or stations for conformity with the statutory review criteria and 10A NCAC 14C .2203 Performance Standards, the CON Section analyzes the applicant's projected number of in-center dialysis patients using the same assumptions used in the facility need methodology in the applicable SMFP. This ensures a predictable and consistent approach in analyzing the representations made in the CON application.

The Division's proposed amendments to rules 10A NCAC 14C .2201 and .2203 will ensure that the rules applied by the Division in reviewing CON applications proposing new dialysis facilities or stations are consistent with the assumptions and methodology used in the facility need methodology in the 2020 SMFP. Temporary rules were adopted effective February 1, 2020. The temporary rules are in effect for review cycles beginning in 2020. The proposed text of 10A NCAC 14C .2203 would be in effect for dialysis reviews that begin in 2021.

The new dialysis facility need methodology has been adopted as part of the 2020 SMFP, which is not a rule and is explicitly exempt from the Administrative Procedures Act. Regardless of whether the text of 10A NCAC 14C .2203 is amended, CON applications proposing to develop the dialysis stations in the 2020 SMFP and subsequent SMFPs will be submitted to the Division and will have to be reviewed against the statutory and regulatory review criteria.

Summary of Expected Costs and Benefits

Federal Government Impact No impact as the Federal Government is not subject to the NC CON Law.

Local Government Impact	The workload for the local government sector will not change as a result of the proposed text.
Private Sector Impact	The workload for the private sector will not change as a result of the proposed text.
State Government Impact	The workload for State Government will not change as a result of the proposed text.

Federal Government Impact

Health service facilities owned by the Federal Government and located in North Carolina are not subject to the North Carolina CON Law. Thus, they are not required to file a CON application and are not impacted by the proposed text.

Local Government and Private Sector Impact

Most CON applications are submitted by the private sector but there are health service facilities in North Carolina owned by a local government entity, such as a county or hospital authority. However, the expected impact on both sectors is expected to be identical.

Facility Need Applications – It is not anticipated that the effort and time required to complete a CON application proposing a new dialysis facility or stations would be any different than it would have been if the facility need methodology had not been changed and there was no need to amend the rule to be consistent with the new facility need methodology. Whether or not a CON application can be approved is dependent on several factors, not just whether the application is conforming to the Performance Standards rule. The applicant will still be required to demonstrate conformity with statutory review criteria that also require historical and projected utilization, a description of the assumptions and methodology used to project utilization and supporting documentation.

The deleted paragraphs (a) and (b) did not expressly state that they applied only to proposals to develop in-center dialysis facilities or stations. The new paragraphs (a) and (b) make it clear that they apply only to proposals to develop in-center dialysis facilities or stations. The proposed text does not change how the applicant would project the number of in-center dialysis patients it would serve in each of the first three operating years after completion of the project. Nor does it change the burden on the applicant with respect to describing the assumptions and methodology used to project in-center dialysis patients or providing supporting documentation.

Before 2020, facility need was determined every six months. Beginning in 2020, facility need will be determined annually. While the facility will trigger a need sooner at the lower threshold than it would have at the higher threshold, need will only be determined every 12 months, not again in six months. The threshold was lowered to ensure that facilities would be able to apply once per year for roughly the same number of stations that they would have been able to apply for twice a year. It is too speculative to project what impact the lower threshold (2.8 patients per station per week, not 3.2) would have on the number of applications submitted. Any estimate of the impact that might have on the number of applications submitted would be an unsupported guess as to how many and when they might be submitted.

Home Hemodialysis Applications – A certificate of need has always been required for proposals to develop new dialysis facilities or stations for home hemodialysis training and support services and the CON Section determined that 10A NCAC 14C .2203 was applicable to those proposals. Between 2008 and October 2018, the CON Section received three applications proposing to develop a new dialysis facility for home hemodialysis training and support services. All three applications were denied because the applicant failed to demonstrate conformity with 10A

NCAC 14C .2203. In October 2018, the Division Director issued a declaratory ruling requested by one of the dialysis providers, which states:

The number of home hemodialysis patients that can be served by a single station in a week differs from the number of in-center dialysis patients that can be served in a week. At this time, however, the Agency does not have a standard for home hemodialysis utilization. As part of the periodic review of rules process, 10A NCAC 14C .2203 was determined by the Agency to be necessary with substantive public interest. This means that the rule will need to be re-promulgated. The reason the rule was designated by the Agency as necessary with substantive public interest is the need to reword the existing subparts (a) and (b) so that it is clear that they apply only to proposals involving in-center dialysis stations and to add a new performance standard specifically for home hemodialysis stations.

Since the issuance of the declaratory ruling, the CON Section has received four applications proposing to develop a new dialysis facility for home hemodialysis training and support services. Although currently there is no standard for home hemodialysis training and support services, pursuant to G.S 131E-183(a)(3), the applicant still has the burden to demonstrate that the patients expected to use the home hemodialysis training and support services need them. The applicant must demonstrate that projected utilization is based on reasonable and adequately supported assumptions and one of the assumptions the applicant would need to provide is how many home hemodialysis patients can be trained in a year on one station.

The new paragraphs (c) and (d) would establish a performance standard for proposals to develop dialysis facilities and stations dedicated to home hemodialysis training and support services. The standard proposed in the rule is based on assumptions in approved applications proposing to develop a dialysis facility dedicated to home hemodialysis training and support services and on feedback from the providers about what the standard should be if there was one. Promulgating a standard provides transparency for the applicants and a benchmark for the CON Section analysts. The proposed performance standard would be a factor that providers would have to consider when determining whether to apply. However, since the primary payor for dialysis services is Medicare, the fact that the federal government is encouraging dialysis facilities to start new patients on home hemodialysis, not in-center dialysis, is another factor a provider would have to consider, and it could result in more applications. On the other hand, since home hemodialysis training and support services may be provided by facilities that offer in-center dialysis services and a CON is not usually required to add the service, that factor may limit the number of applications. The proposed rule may result in more applications, but it is too speculative to project what impact promulgating a performance standard would have on the number of applications submitted. Any estimate would be an unsupported guess as to how many and when they might be submitted.

The proposed text of 10A NCAC 14C .2203 would not have any measurable impact on the workload of local government or private sector applicants proposing to develop new dialysis stations pursuant to the facility need methodology in the SMFP or applicants proposing to develop a new dialysis facility or stations for home hemodialysis training and support services.

State Government Impact

The issue is whether the proposed text of 10A NCAC 14C .2203 would significantly change the number of applications received by the CON Section in a given year which propose to develop new dialysis stations pursuant to the facility need methodology (facility-need applications) or for home hemodialysis training and support services.

Facility Need Applications – As shown in Table 1, between 2016 to 2019, the number of facility-need applications received in a given year varied from a low of 54 in 2017 to a high of 67 in 2018. The four-year average is 61 applications. As shown in Table 2, between 2016 to 2019, only 37 percent of the dialysis facilities that had a need for additional stations applied for stations. The number of facilities that applied is lower than the number of facility-need applications filed because the same facility could apply twice in the same calendar year when need was determined semi-annually. As shown in Table 3, between 2016 to 2019, the ratio of facility-need applications filed to the number of facilities that filed a facility-need application averaged 1.2. Thus, only a small number of facilities applied twice in the same calendar year.

Table 1

Calendar Year	Number of Facility-Need Applications Received
2016	57
2017	54
2018	67
2019	64
Average	61

Table 2

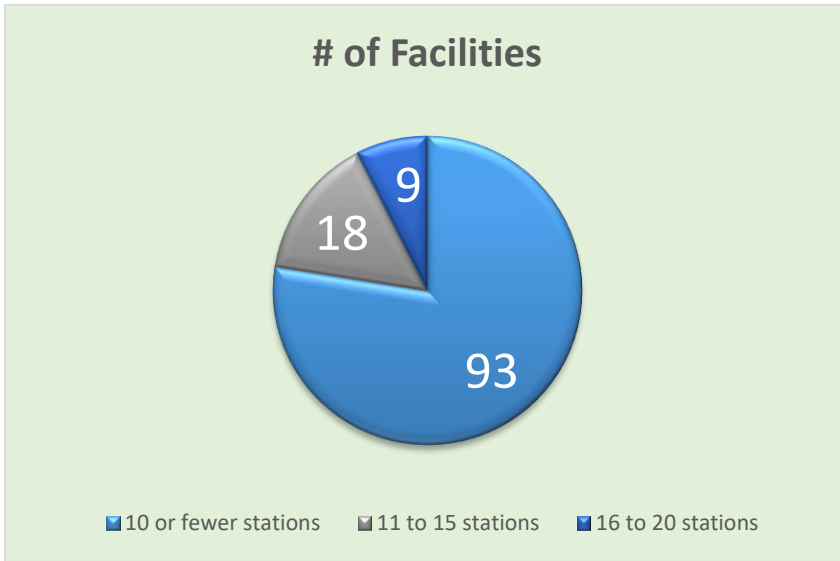
Calendar Year	Number of Facilities that Triggered a Need for Additional Dialysis Stations	Number of Facilities that Applied for Additional Dialysis Stations	Number of Facilities that Applied as a Percentage of the Number of Facilities that Triggered a Need for Additional Dialysis Stations
2016	129	51	40%
2017	133	40	30%
2018	139	59	42%
2019	154	57	37%
Average	139	52	37%

Table 3

Calendar Year	Number of Facilities that Applied for Additional Dialysis Stations	Number of Facility-Need Applications Received	Ratio of the Number of Facility-Need Applications Received to the Number of Facilities that Applied for Additional Dialysis Stations
2016	51	57	1.1
2017	40	54	1.4
2018	59	67	1.1
2019	57	64	1.1
Average	52	61	1.2

According to Table 9E in the 2020 SMFP, based on the facility need methodology, 120 dialysis facilities have a need for a total of 877 additional stations. At this time, it is unknown how many dialysis facilities will have a need in the 2021 SMFP. As shown in Chart 1, 93 of the 120 facilities, or 78 percent, have a need for 10 or fewer stations. 18 percent have a need for 11 to 15 stations and 9 percent have a need for 16 to 20 stations.

Chart 1



Assuming 37 percent of the 120 facilities that have a need determination in the 2020 SMFP apply for the additional stations in 2020, then the CON Section could expect that 45 facilities would file a facility-need application [120 x 37% = 45]. This is a number slightly lower than the four-year average (52) but well within the range (40-59). In the first review period of 2020, 24 facilities filed an application pursuant to the facility need methodology.

Under the new facility need methodology, need is only determined once per year but a facility that has a need determination may apply up to three times during the calendar year for those stations. For example, if a facility has a facility need determination for 20 stations (the maximum), but chooses to apply for only 10 stations in the first review period, it may apply later in the year for the remaining 10 stations (or less). It is too speculative to estimate how many facilities may chose to apply for only a portion of the need and then submit a second (or third) application later in the year for the remaining stations. However, for 93 of the facilities, filing twice in the same calendar year is unlikely since they need 10 or fewer stations and filing twice means paying at least the \$5,000 base filing fee twice.

It is reasonable to assume that the number of facility-need applications received in a year under the new facility need methodology will not vary significantly from the number received in previous years when facility need was determined twice a year.

Home Hemodialysis Applications – The discussion regarding home hemodialysis applications in the Local Government and Private Sector section is incorporated herein by reference, including the conclusion that it is too speculative to project what impact promulgating a performance standard would have on the number of applications submitted. Any estimate would be an unsupported guess as to how many and when they might be submitted.

Appendix A

10A NCAC 14C .0202 is proposed for readoption with substantive changes 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.

10A NCAC 14C .0203 is proposed for readoption with substantive changes 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 DHRS.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.

10A NCAC 14C .0205 is proposed for reoption with substantive changes 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 proposed for readoption with substantive changes 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.*

10A NCAC 14C .2101 is proposed for readoption with substantive changes 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/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;
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.*

10A NCAC 14C .2103 is proposed for readoption with substantive changes 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 proposed for readoption with substantive changes 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 renal 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) — ~~"Histocompatibility testing" means laboratory testing procedures which determine compatibility 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 used to accommodate the equipment and supplies needed to perform dialysis 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 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 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.*

10A NCAC 14C .2203 is proposed for readoption with substantive changes 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 shall document the need for the total number of home hemodialysis stations in the facility based on 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 shall document the need for the total number of home hemodialysis stations in the facility based on 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 proposed for readoption with substantive changes 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(18e).)~~
- ~~(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 proposed for readoption with substantive changes 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.*