Fiscal Impact Analysis for
Permanent Rule Amendment without Substantial Economic Impact

Agency Proposing Rule Change

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

Contact Persons

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Impact Summary

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

Statutory Authority

N.C. Gen. Stat. § 131E-177
N.C. Gen. Stat. § 131E-183(b)

Rule Citations

10A NCAC 14C – Certificate of Need

- 10A NCAC 14C .2101 Definitions (Amend)
- 10A NCAC 14C .2103 Performance Standards (Amend)

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 the CON Law and includes developing new operating rooms (ORs) in a licensed health service facility. The only two licensed health service facilities with ORs are hospitals and ambulatory surgical facilities. The term "new institutional health service" also includes relocating existing ORs from one licensed health service facility or campus to another. The Department delegated the authority to enforce the CON Law to 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 Division to develop the proposed project. The CON cannot be issued until all appeals are resolved.

The Division is required to review all CON applications using the review criteria found in N.C. Gen. Stat. § 131E-183(a). In addition, pursuant to N.C. Gen. Stat. § 131E-183(b), the Division is authorized to adopt rules for the review of particular types of applications which may vary based on the type of health service. The Division adopted rules for the review of CON applications involving ORs in 2002. (Prior to that, the rules addressed ambulatory surgical facilities, not ORs.)

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 N.C. Gen. Stat. § 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.

The SMFP has included a methodology for determining the need for additional ORs (OR Need Methodology) since 2002. In 2017, the Department and the SHCC recommended to the Governor that the OR Need Methodology be changed in the 2018 SMFP and the Governor approved the new OR Need Methodology on December 11, 2017 when he signed the 2018 SMFP.

The changes to the OR Need Methodology involve Grouping, Average Case Times and Standard Hours per OR per Year. In addition, need determinations are based on Health System, not Service Area. See Table 6 in Appendix B for a comparison of the old and new OR need methodologies. However, anyone can apply for a CON, not just the Health System that triggers the need determination. What has not changed is the use of a population growth factor to project surgical hours in the future.

Pursuant to N.C. Gen. Stat. § 131E-183(a)(3) (Criterion 3), an applicant proposing to develop new ORs in a licensed health service facility must demonstrate the need the population expected to use the proposed ORs has for the proposed ORs. In addition, pursuant to N.C. Gen. Stat. § 131E-183(a)(6) (Criterion 6), the applicant must demonstrate that the proposal will not result in an unnecessary duplication of existing or approved ORs in the Service Area. When reviewing a CON application proposing to develop new ORs for conformity with Criteria (3) and (6) and 10A NCAC 14C .2103 Performance Standards, the Division analyzes historical and projected utilization data using the same assumptions and methodology used in the OR Need Methodology in the applicable SMFP. This ensures a predictable and consistent approach in analyzing the representations made in the CON application. 10A NCAC 14C .2103 Performance Standards was written such that applicants are required to demonstrate the need for the number of proposed ORs using the same assumptions about average case times and standard hours per OR per year as the OR Need Methodology in the SMFP.

The Division's proposed amendments to rules 10A NCAC 14C .2101 and .2103 will ensure that the rules applied by the Division in reviewing CON applications proposing new ORs are consistent with the assumptions and methodology used in the OR Need Methodology in the 2018 SMFP. Temporary rules were adopted effective February 1, 2018. The temporary rules are expected to be in effect for all but the December 1 review cycle in 2018. The proposed text of 10A NCAC 14C .2103 would be in effect for OR reviews that begin on or after December 1, 2018.

Rule Summaries

10A NCAC 14C .2101 Definitions

10A NCAC 14C .2101 is a definitions rule. The Division proposes to amend the rule to remove unnecessary terms and define new terms based on the proposed text for 10A NCAC 14C .2103 Performance Standards. In addition, at the request of the attorneys for the Rules Review Commission, the terms are being placed in alphabetical order.

10A NCAC 14C .2103 Performance Standards

The original permanent rule and the temporary rule contains six (6) subparts which apply to all of the following types of proposals.

1. Increasing the number of ORs in a Service Area.
2. Establishing a new ambulatory surgical facility even if all of the ORs would be relocated from another facility.
3. Developing ORs as part of a new hospital or hospital campus even if all of the ORs would be relocated from another facility.
4. Developing a new dedicated C-section OR if the facility already has one or more dedicated C-section ORs. The rule does not apply if the hospital proposing to develop a new dedicated C-section OR does not already have a dedicated C-section OR.
5. Adding a specialty to a specialty ambulatory surgical program.
6. Converting a specialty ambulatory surgical program to a multispecialty surgical program.

As part of the permanent rulemaking, the Division proposes to delete four subparts: (b), (c), (d), and (e). The Division also proposes to completely rewrite subpart (a) and change subpart (f) to subpart (b) with no change in the wording. The proposed text for 10A NCAC 14C .2103 would require an applicant to demonstrate conformity with the rule only for proposals that would result in an increase in the number of ORs in the Service Area starting with the December 1, 2018 review cycle. In order to be approved to increase the number of ORs in a Service Area, there has to be a need determination for additional ORs in the applicable SMFP for that Service Area. Applicants would no longer have the burden of demonstrating conformity with the rule for the types of proposals described in 2-6 above. Note: all of the proposals described in 1-6 above would still be subject to CON review and the applicant would still have to demonstrate conformity with the statutory review criteria.

Impact Analysis

The new OR Need Methodology has been adopted as part of the 2018 SMFP, which is not a rule and is explicitly exempt from the Administrative Procedures Act. Regardless of whether or not the text of 10A NCAC 14C .2103 is amended, CON applications proposing to develop the ORs in the 2018 SMFP and subsequent SMFPs will be submitted to the Division and will have to be reviewed against the statutory and regulatory review criteria. Moreover, pursuant to N.C. Gen. Stat. § 131E-183(1), the number of ORs available in the SMFP is a determinative limit on the number of ORs that can be approved by the Division. In other words, regardless of how many CON applications are received for a need determination, the maximum number of new ORs that can be approved for development is the number in the need

determination. This analysis describes the impact of the proposed procedural changes needed to conform to the 2018 SMFP.

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	Repeal of the four subparts will make approval easier but may increase the cost of litigation. The workload for the local government sector will not change as a result of the proposed text.
Private Sector Impact	Repeal of the four subparts will make approval easier but may increase the cost of litigation. The workload for the private sector will not change as a result of the proposed text.
State Government Impact	The number of OR applications in response to a need determination will increase in the next few years. The cost associated with the additional applications is estimated to be $99,368 in 2018 and $73,446 in 2019.

Federal Government Impact

Hospitals and ambulatory surgical 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 before adding or relocating ORs 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 hospitals and ambulatory surgical 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.

Repeal of the Four Subparts – It is not anticipated that the effort and time required to complete a CON application proposing to relocate ORs, develop a new dedicated C-section OR, add a specialty to a specialty ambulatory surgical program or convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program would be any different than it would have been if the four subparts were not repealed. This is because 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. It may make it easier for an applicant to obtain approval because the applicant will not be restricted by these subparts as to how it demonstrates conformity with the statutory review criteria. Whether repealing the four subparts would affect the likelihood of litigation or impact the cost of litigation is uncertain.

CON Applications Proposing New ORs – It is not anticipated that the effort and time required to complete a CON application proposing new ORs would be any different than it would have been if the OR Need Methodology had not been changed and there was no need to amend the rules to be consistent with the new methodology. Whether or not a CON application can be approved is dependent on a number of factors, not just whether or not the application is conforming to the Performance Standards rule.

The original permanent rule and the temporary rule requires an applicant to project how many inpatient and outpatient surgical cases it would perform in each of the first three operating years after completion of the project. Furthermore, the CON application form asks the applicant to describe the assumptions and

methodology used to project inpatient and outpatient surgical cases and to provide supporting documentation. To determine if the application conformed to the original permanent rule, projected surgical cases in the third operating year were converted to surgical hours and then to the number of ORs needed using the four steps described below.

1. Multiply the projected number of inpatient surgical cases (excluding certain types of cases) by an average case time of three (3) hours.
2. Multiply the projected number of outpatient surgical cases by an average case time of one and a half (1.5) hours.
3. Add the results together.
4. Divide by 1,872 hours per OR per year.

The proposed text of 10A NCAC 14C .2103 Performance Standards does not change how a CON applicant would project the number of inpatient and outpatient surgical cases it would perform 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 inpatient and outpatient surgical cases or providing supporting documentation. The steps used to calculate the number of ORs needed are the same. What is proposed to change are the factors used in three of the four steps. Those changes are highlighted below.

1. Multiply the projected number of inpatient cases by the final inpatient case time (existing facilities) or the average final inpatient case time for the group (new facilities) published in the SMFP instead of every applicant using an average case time of three hours.
2. Multiply the projected number of outpatient cases by the final ambulatory case time (existing facilities) or the average final ambulatory case time for the group (new facilities) published in the SMFP instead of every applicant using an average case time of one and a half hours.
3. Add the results together.
4. Divide by the standard hours per OR per year for the group instead of every applicant dividing by 1,872 hours per OR per year.

The proposed text of 10A NCAC 14C .2103 would not have any impact on the workload of local government or private sector applicants proposing to develop new ORs pursuant to a need determination in the SMFP.

State Government Impact

The first step of the analysis was to determine how many OR need determinations there were from 2002 to 2016 by service area. The results are shown in Table 1.

Table 1

SMFP Year	# of Service Areas Showing Need	Total # of ORs Needed
2002	4	8
2003	1	6
2004	2	7
2005	2	4
2006	8	9
2007	none	none
2008	2	10
2009	4	5
2010	4	9
2011	1	1
2012	none	none
2013	1	1
2014	none	none
2015	none	none
2016	6	12
2017	4	4
Total	**39**	**76**
Average per Service Area *	**2**	**6**

* The averages were rounded to whole numbers since it is not possible to have a "partial" service area or a "partial" OR. The average number of service areas showing need was calculated by dividing by 16, the number of years from 2002 to 2017. However, the average number of ORs needed per need determination was calculated by dividing by only 12 because there were no need determinations in 4 of the 16 years.

As shown in Table 1, the OR need methodology in effect from 2002 to 2017 generated a need in 12 of the 16 years for a total of 76 additional ORs in 39 different service areas. The average is approximately six additional ORs per year in approximately two different service areas. However the numbers vary greatly as 10 ORs were needed in two different service areas in the 2008 SMFP while nine ORs were needed in eight different service areas in the 2006 SMFP.

The second step was to determine how many CON applications were received from 2002 to 2017 where 10A NCAC 14C .2103 Performance Standards was applicable and how many of those applications were submitted in response to a need determination. This date range was chosen because the last time the OR need methodology was changed was in the 2002 SFMP. The results are shown in Table 2.

Table 2

SMFP Year	Total # of OR Applications Received	# of OR Applications Received in Response to a Need Determination for ORs
2002	6	4
2003	4	2
2004	6	3
2005	20	2
2006	16	12
2007	5	no need determination for ORs
2008	12	6
2009	9	5
2010	20	16
2011	3	1
2012	3	no need determination for ORs
2013	5	1
2014	4	no need determination for ORs
2015	2	no need determination for ORs
2016	16	13
2017	11	8
Total	**142**	**73**
Average *	**9**	**6**

* The averages were rounded to whole numbers since it is not possible to have a "partial" CON application. The average for all OR applications was calculated by dividing by 16, the number of years from 2002 to 2017. However, the average for OR applications in response to a need determination was calculated by dividing by only 12 because there were no need determinations in 4 of the 16 years.

As shown in Table 2, a total of 142 OR applications were received from 2002 to 2017 where 10A NCAC 14C .2103 Performance Standards applied to the review. Table 2 also shows that the number of OR applications varies from year to year with no apparent pattern. The average for the 16-year period is approximately nine applications per year. In 2005 and 2010, 20 OR applications were received. In 2016, 16 OR applications were received and in 2017, 11 OR applications were received. Of the 142 OR applications received from 2002 to 2017, 73 or 51 percent were in response to a need determination for additional ORs. The remaining 69 applications, an average of 4 per year, were subject to 10A NCAC 14C .2103 but were not submitted in response to a need determination.

The third step was to determine the number of CON applications that will be received for the OR need determinations in the 2018 SMFP. The results are shown in Table 3.

Table 3

Service Area	Total # of ORs Needed in the 2018 SMFP	Review Cycle Begins	Estimated # of CON Applications to be Received
Cumberland *	1	May 1, 2018	1
Buncombe / Madison / Yancey	2	June 1, 2018	3
Forsyth	4	June 1, 2018	5
Catawba *	1	July 1, 2018	1
Wake	6	September 1, 2018	7
Mecklenburg	6	November 1, 2018	7
Durham	4	December 1, 2018	3
Orange	6	December 1, 2018	2
Total	**30**		**29**
Average per Service Area**	**4**		**4**

* The OR need determinations for Cumberland and Catawba County are the result of petitions submitted during the summer petition cycle showing a special need in those service areas not addressed by the new OR Need Methodology.

** The averages were rounded to whole numbers since it is not possible to have a "partial" CON application or a "partial" OR.

As shown in Table 3, the 2018 SMFP includes eight need determinations for a total of 30 additional ORs.

The fourth step was to estimate the number of CON applications that would be received each year in response to OR need determinations in the 2018 and 2019 SMFPs. The assumptions used to estimate the number of OR CON applications each year are described below.

- For 2018, the number of service areas showing a need and the number of ORs needed in each service area is known. However, the number of applications that may be received for each need determination is unknown. The estimates are based on knowledge of the existing hospitals and ambulatory surgical facilities located in each service area and it is assumed that at least one new provider not already present in the service area will apply for some or all of the ORs available in each service area.
- For 2019, based on very preliminary data, five service areas may show a need for up to 29 ORs. Those numbers are subject to change. The number of applications expected to be received for each need determination is unknown. The estimates are based on knowledge of the existing hospitals and ambulatory surgical facilities located in each service area and it is assumed that at least one new provider not already present in the service area will apply for some or all of the ORs available in each service area.

There are too many uncertainties to estimate the number of OR CON applications that may be received after 2019. In addition to the uncertainties described above, there is the chance that the methodology could be modified in some way in the future or the CON Law could be amended or repealed.

The results are shown in Table 4.

Table 4

SMFP Year	# of Service Areas Showing a Need	Total # of New ORs Needed	Estimated # of CON Applications in Response to a Need Determination
2018 (Temporary Rule Applies)	6	20	24
2018 (Proposed Text of 10A NCAC 14C .2103 Applies)	2	10	5
2019 (Proposed Text of 10A NCAC 14C .2103 Applies)	5	29	23

The number of OR applications received in response to an OR Need Determination is expected to increase as a result of the new OR Need Methodology, at least in the short term. However, the staff effort and time required to review a CON application is not dependent on the type of project. The statutory process and review criteria are the same regardless of the type of project. While the application forms do vary by type of project, they have been designed to be as similar as possible. The length and complexity of the completed applications is also not dependent on the type of project being reviewed.

The impact of eliminating subparts (b), (c), (d), and (e) is uncertain. It may make it easier for an applicant to obtain approval because the applicant will not be restricted by these subparts as to how it demonstrates conformity with the statutory review criteria. However, any estimate would be just an unsupported guess as to how many additional applications and in what year they might be expected to be filed.

The fifth step was to estimate the cost associated with the increased number of OR applications in response to a need determination.

The applications would be assigned to one of eight project analysts to review. For a competitive review[1] with four applications, the analyst would typically be given two months to work on the review or approximately 80 hours per application (2 months = 8 weeks; 8 weeks / 4 applications = 2 weeks per application; 2 weeks = 80 hours). The average annual salary (without benefits) for a project analyst is $67,308 and the average tenure is 10 years. Total annual compensation is $101,755 or $48.92 per hour ($101,755 / 2,080 hours per year = $48.92 per hour). The estimated cost per application is $3,914 (80 hours x $48.92).

The project analyst would give the draft decision and findings to one of three managers (co-signer) to review. The co-signer would typically need one day per application (8 hours) to complete their review. The average annual salary (without benefits) for a co-signer is $71,428 and the average tenure is 7 years. Total annual compensation is $105,735 or $50.83 per hour ($105,735 / 2,080 hours per year = $50,83 per hour). The estimated cost per application is $407 (8 hours x $50.83).

The combined estimated cost per application is $4,320 ($3,914 + $407).

[1] Pursuant to 10A NCAC 14C .0202(f), if the approval of one application may require the disapproval of another application submitted in the same review cycle for the same service, the review is competitive. Pursuant to N.C. Gen. Stat. § 131E-183(a)(1), the need determination is a determinative limit on the number of ORs that can be approved by the Division. If the need determination is for two additional ORs but four applications are received, each proposing to develop two additional ORs, then the approval of one of the applications would require the denial of the other three applications even if they are conforming to all applicable statutory and regulatory review criteria.

The results are shown in Table 5.

Table 5

	CY 2018	CY 2019
A. Total Compensation for the Project Analyst per Application	$3,914	$3,914
B. Total Compensation for the Co-signer per Application	$407	$407
C. Total per Application (A + B)	$4,320	$4,320
D. Estimated # of OR Applications in Response to a Need Determination (from Table 4)	29	23
E. Average # of OR Applications in Response to a Need Determination 2002 -2017 (from Table 2)	6	6
F. Incremental # of OR Applications in Response to a Need Determination (D - E)	23	17
G. Estimated Cost to Review Incremental OR Need Determination Applications (C x F)	$99,368	$73,446

The last step of the analysis was to determine if the new OR Need Methodology and the proposed text of 10A NCAC 14C .2103 will have any impact on the total number of CON applications of all project types received in 2018 and 2019 which could potentially impact the Division. As shown in the table below, on average OR applications equal less than 5% of the total number of applications received. The percentage ranged from 1.7% in 2003 to a high of 12.7% in 2010.

The results are shown in Table 6.

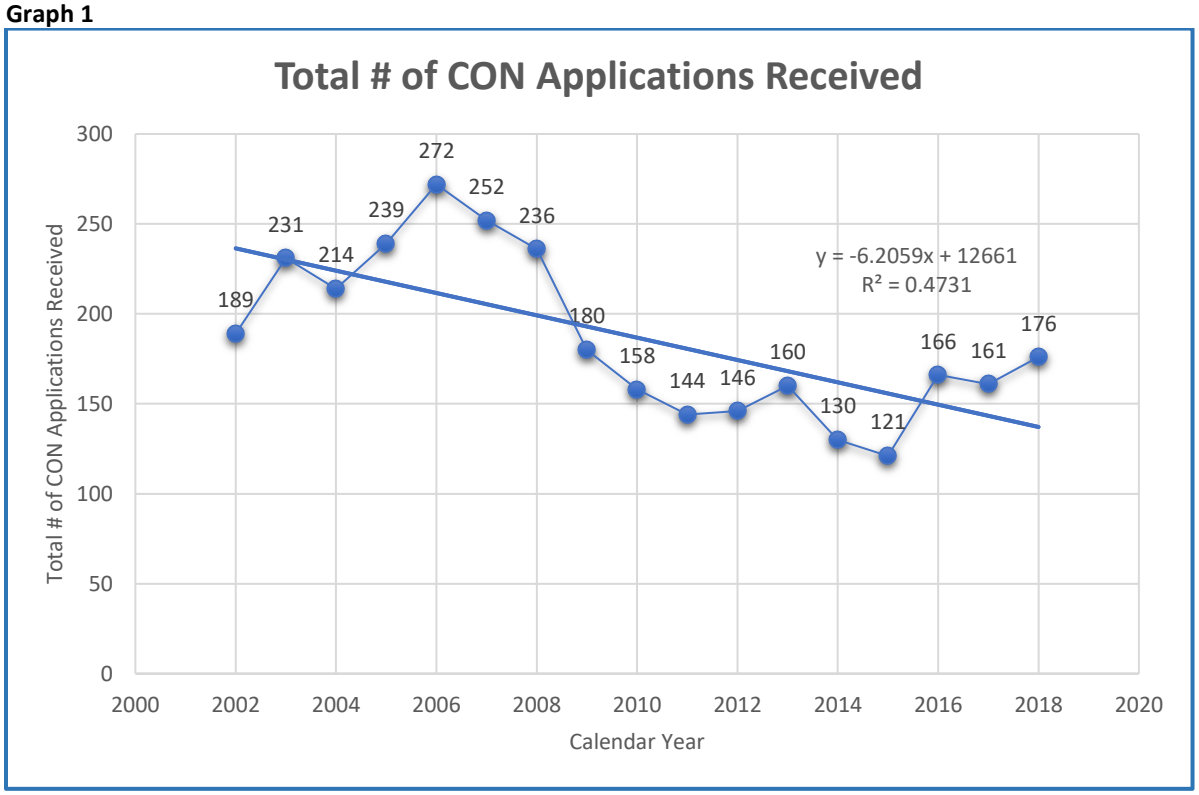
Table 6

Year	Total # of OR Applications Received	# of OR Applications in Response to a Need Determination	Total # of CON Applications Received of all Types	# of OR Applications as a % of the Total # of CON Applications Received
2002	6	4	189	3.2%
2003	4	2	231	1.7%
2004	6	3	214	2.8%
2005	20	2	239	8.4%
2006	16	12	272	5.9%
2007	5	0	252	2.0%
2008	12	6	236	5.1%
2009	9	5	180	5.0%
2010	20	16	158	12.7%
2011	3	1	144	2.1%
2012	3	0	146	2.1%
2013	5	1	160	3.1%
2014	4	0	130	3.1%
2015	2	0	121	1.7%
2016	16	13	166	9.6%
2017	11	8	161	6.8%
Total	**142**	**73**	**2,999**	**75.2%**
Average *	**9**	**5**	**187**	**4.7%**

* The averages for applications were rounded to whole numbers since it is not possible to have a "partial" CON application.

Graph 1 below illustrates the total number of CON applications received each year starting in 2002 through 2017 and the estimated number to be received in 2018 based on four months of actual data.

Graph 1



The trend from 2006 to 2015 is for fewer CON applications of all types each year. The exact reasons are unknown and the data in Graph 1 shows that the number varies from year to year. The decline after 2006 may be attributed in part to the recession that began in 2008 and to changes made to the CON Law by the General Assembly in 2013. Those changes eliminated the need to apply for a CON for a substantial number of replacement and renovation projects.

There was some increase in the total number of CON applications in 2016 and 2017 but the reasons for that are also unknown. Moreover, the number received in 2017 was slightly lower than the number received in 2016. Thus, there is some uncertainty about whether the increases experienced in 2016 and 2017 will continue.

A total of 78 applications have been received for the first five review cycles in 2018 or an average of 16 applications each review cycle (78 / 5 = 16). Of those, ten are OR CON applications and nine of those is pursuant to a need determination. Assuming that the Division continues to receive an average of 16 applications for each of the remaining seven review cycles in 2018, a total of 176 applications may be received in 2018 (16 x 11 = 176). Given that the last time the Division received more than 176 applications was 2009, it is assumed that the Division will also receive 176 applications in 2019. The results are shown in Table 7.

Table 7

Year	Estimated # of OR Applications	Estimated Total # of Applications
2018	29	176
2019	23	176

The Division currently employs eight project analysts to review CON applications, the same number the Division had in 2006 when it received 272 applications. Thus, in 2006, each project analyst reviewed an average of approximately 34 applications (272 / 8 = 34). Moreover, in 2006, the Division employed only two persons who supervised the analyst's reviews (co-signers). The Division currently employs three persons to supervise the analyst's reviews. It is not anticipated that the Division would require any additional staff as a result of any increase in the number of OR CON applications resulting from the proposed text of 10A NCAC 14C .2103. Nor is it anticipated that the existing staff will be unable to complete review of all the applications received within the statutory deadline of 150 days even if the number of applications received in 2018 and 2019 is more than the number received during 2016 or 2017. It is also not anticipated that staff will need to work excessive hours to complete the reviews.

Appendix A

10A NCAC 14C .2101 is proposed for amendment as follows:

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

10A NCAC 14C .2101 DEFINITIONS

The following definitions apply to all rules in this Section:

(1) ~~"Ambulatory surgical facility" means a facility as defined in G.S. 131E-176(1b).~~ "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) prior to the date on which the applicant's proposed project was submitted to the Agency, but that have not been licensed.

(2) ~~"Operating room" means a room as defined in G.S. 131E-176(18c), which includes an inpatient operating room, an outpatient or ambulatory surgical operating room, or a shared operating room.~~ "Dedicated C-section operating room" means an operating room as defined in Chapter 6 in the 2018 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) ~~"Ambulatory surgical program" means a program as defined in G.S. 131E-176(1c).~~ "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) ~~"Dedicated cesarean section operating room" means an operating room as defined in the applicable State Medical Facilities Plan.~~ "Health System" shall have the same meaning as defined in Chapter 6 in the 2018 State Medical Facilities Plan.

(5) ~~"Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals which were reported in the License Application for Ambulatory Surgical Facilities and Programs and in Part III of Hospital Licensure Renewal Application Form submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation and which were licensed and certified prior to the beginning of the review period.~~ "Operating room" means a room as defined in G.S. 131E-176(18c).

(6) ~~"Approved operating rooms" means those operating rooms that were approved for a certificate of need by the Certificate of Need Section prior to the date on which the applicant's proposed project was submitted to the Agency but that have not been licensed.~~ "Operating Room Need Methodology" means the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 State Medical Facilities Plan.

(7) ~~"Multispecialty ambulatory surgical program" means a program as defined in G.S. 131E-176(15a).~~ "Service area" means the Operating Room Service Area as defined in Chapter 6 in the 2018 State Medical Facilities Plan.

~~(8) "Outpatient or ambulatory surgical operating room" means an operating room used solely for the performance of surgical procedures which require local, regional or general anesthesia and a period of post-operative observation of less than 24 hours.~~

~~(9) "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).~~

~~(10) "Service area" means the Operating Room Service Area as defined in the applicable State Medical Facilities Plan.~~

~~(11) "Shared operating room" means an operating room that is used for the performance of both ambulatory and inpatient surgical procedures.~~

~~(12) "Specialty area" means an area of medical practice in which there is an approved medical specialty certificate issued by a member board of the American Board of Medical Specialties and includes the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, urology, orthopedics, and oral surgery.~~

~~(13) "Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24c).~~

~~(14) "Surgical case" means an individual who receives one or more surgical procedures in an operating room during a single operative encounter.~~

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.~~ 2018;

Amended Eff. December 1, 2018.

10A NCAC 14C .2103 is proposed for amendment as follows:

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) ~~In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.~~ An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

~~(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:~~

~~(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and~~

~~(2) The number of rooms needed is determined as follows:~~

~~(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;~~

~~(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and~~

~~(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.~~

(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected

~~inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and~~

~~(2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.~~

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

Appendix B

Table 6

	OR Need Methodology 2010-2017 SMFPs	New OR Need Methodology 2018 SMFP	Change
Service Area	Single county unless the there are no ORs in the county in which case that county is part of a Multicounty Service Area as shown in Figure 6.1 Operating Room Service Areas in Chapter 6 of the SMFP.	Single county unless the there are no ORs in the county in which case that county is part of a Multicounty Service Area as shown in Figure 6.1 Operating Room Service Areas in Chapter 6 of the SMFP.	No
Inventory	The inventory includes the number of existing and approved inpatient, shared, dedicated ambulatory, dedicated C-Section ORs in the Service Area.	The inventory includes the number of existing and approved inpatient, shared, dedicated ambulatory, dedicated C-Section ORs in the Service Area.	No
Surgery Hours	For each Service Area, calculate the total surgery hours for all facilities in the Service Area based on number of surgical cases reported in the annual license renewal applications for the previous federal fiscal year.	For each Health System in the service area, calculate the total surgery hours for the Health System based on the number of surgical cases reported in the annual license renewal applications for the previous federal fiscal year.	Yes
Grouping	Not applicable	There are six (6) groups. Four (4) groups are for hospitals and two (2) groups are for ambulatory surgical facilities. Each facility is assigned to a group.	Yes
Average Case Times	Multiple inpatient surgical cases by three (3) hours per case and outpatient surgical cases by one and a half (1.5) hours per case.	For each facility in the Service Area, obtain the average case times for inpatient and ambulatory surgical cases from the facility's license renewal application for the previous fiscal year. Make adjustments as required by the methodology.	Yes
Population Growth Factor	Increase / decrease projected surgery hours for each facility based on the projected Population Growth Factor for the Service Area.	Increase / decrease surgery hours for each facility based on the projected Population Growth Factor for the Service Area.	No
Standard Hours per OR per year	1,872 hours per OR per year	Varies by Grouping	Yes
Need Determination	Divide total projected surgery hours for all facilities in each Service Area by 1,872 hours per OR per year. Calculate the deficit/surplus for each Service Area by subtracting the number of existing and approved ORs in the Service Area from the projected number of ORs needed. Round to the nearest whole number as required by the methodology.	Divide total projected surgery hours for each Health System in the Service Area by the Standard Hours for each Grouping. Calculate the deficit/surplus for each Health System by subtracting the number of existing and approved ORs from the projected number of ORs needed. Round to the nearest whole number as required by the methodology.	Yes