TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

ORIGINAL

JAN 0 8 2018

OAH USE ONLY
VOLUME:
ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHSR

2. Rule citation & name: 10A NCAC 14C .2101 Definitions

3. Action: ☐ Adoption ☒ Amendment ☐ Repeal

4. Was this an Emergency Rule: ☐ Yes ☒ No Effective date:

5. Provide dates for the following actions as applicable:

   a. Proposed Temporary Rule submitted to OAH: 11/07/17

   b. Proposed Temporary Rule published on the OAH website: 11/14/17

   c. Public Hearing date: 11/29/17

   d. Comment Period: 11/16/17 – 12/11/17

   e. Notice pursuant to G.S. 150B-21.1(a3)(2): 11/07/17

   f. Adoption by agency on: 1/03/18

   g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 02/01/18

   h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

   ☐ A serious and unforeseen threat to the public health, safety or welfare.
   ☐ The effective date of a recent act of the General Assembly or of the U.S. Congress.
   Cite:
   Effective date:
   ☐ A recent change in federal or state budgetary policy.
   Effective date of change:
   ☐ A recent federal regulation.
   Cite:
   Effective date:
   ☐ A recent court order.
   Cite order:
   ☒ State Medical Facilities Plan.
   ☐ Other:

Explain: Several subject matters are addressed in the State Medical Facilities Plan (SMFP). The operating room need methodology was changed in the 2018 SMFP. Revisions to existing Certificate of Need rules are required to compliment or to be made consistent with the SMFP signed by the governor on December 11, 2017. The effective date of the 2018 SMFP is January 1, 2018.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

The change to the existing Certificate of Need (CON) definitions rule for the criteria and standards for surgical services and operating rooms is required to compliment or to be made consistent with the State Medical Facilities Plan (SMFP) that will become effective January 1, 2018. The operating room need determination methodology found in the SMFP underwent substantial changes as a result of a workgroup directed by the State Health Coordinating Council (SHCC). The revised need methodology was approved for inclusion in the 2018 SMFP by the SHCC and subsequently signed for approval by the governor on December 11, 2017. This rule is being revised so that correct terminology reflective of the need methodology changes shall be used by 2018 CON applicants for surgical services and operating rooms. The changes include deletion of the definition for the currently used term "related entity" and replacement with the definition for "health system." These terms are not the same and the new term has been added in the changed SMFP methodology. The definition for "surgical case" is being deleted since the term no longer applies in the changed SMFP methodology. Two definitions are being added and one revised to provide clarity in SMFP terminology references. One definition has been revised to correct inaccuracy in the rule. In addition, the definitions have been alphabetized.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ Yes
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ No

9. Rule-making Coordinator: Nadine Pfeiffer Phone: 919-855-3811 E-Mail: Nadine.pfeiffer@dhhs.nc.gov	10. Signature of Agency Head*: * If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.
Agency contact, if any: Martha Frisone, Chief Phone: 919-855-3879 E-Mail: martha.frisone@dhhs.nc.gov	Typed Name: Mark Payne Title: Director, Division of Health Service Regulation E-Mail: mark.payne@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY	
Action taken: ☐ Date returned to agency:	Submitted for RRC Review:

STATE HEALTH COORDINATING COUNCIL

2018

STATE MEDICAL FACILITIES PLAN

Health Service Regulation
HEALTH AND HUMAN SERVICES

North Carolina Department of Health and Human Services
Division of Health Service Regulation

I hereby approve the North Carolina 2018 State Medical Facilities Plan effective January 1, 2018.

Roy Cooper, Governor

12/11/2017
Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MEMORANDUM

TO: Governor Cooper

FROM: Mandy Cohen

SUBJECT: North Carolina 2018 State Medical Facilities Plan

DATE: November 2, 2017

I am forwarding for your review and approval the North Carolina 2018 State Medical Facility Plan (SMFP) as recommended by the North Carolina State Health Coordinating Council (SHCC). Also attached is a summary of the need determinations and summer petitions from the 2017 planning cycle.

I support the SHCC and the implementation of the 2018 SMFP.

Additional background information is available on all areas, if desired. It would greatly facilitate the publication and distribution of the SMFP if you could approve or request changes before the end of November.

MC:mf

Attachments: 2018 State Medical Facilities Plan
Summary of Need Determinations and Summer Petitions

WWW.NCDHHS.GOV
TEL 919-855-4900 • FAX 919-715-0991
LOCATION: 101 BLAIR DRIVE • ADAMS BUILDING • RALEIGH, NC 27603
MAILING ADDRESS: 2001 MAIL SERVICE CENTER • RALEIGH, NC 27699-2001
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

November 2, 2017

The Honorable Roy Cooper, Governor
State of North Carolina
20301 Mail Service Center
Raleigh, NC 27699-0301

Dear Governor Cooper:

On behalf of the North Carolina State Health Coordinating Council, I am pleased to forward our recommendations for the North Carolina 2018 State Medical Facilities Plan. This Plan is the culmination of a year's work by the council, its committees and Healthcare Planning staff.

The council has devoted a significant amount of time to the review and discussion of a variety of issues prior to making its recommendations for the upcoming year. The Proposed Plan was disseminated broadly and examined in six public hearings held across the state, and any petitions and comments received during this year-long process were duly considered.

This final document represents the council's recommendations regarding health care needs to be addressed in the 2018 certificate of need reviews.

Sincerely,

Christopher G. Ullrich, M.D., Chairman
N.C. State Health Coordinating Council

Enclosure

cc: Mandy Cohen, MD, Secretary, DHHS
Mark Payne, Director, DHSR

NORTH CAROLINA 2018
STATE MEDICAL FACILITIES PLAN

Effective January 1, 2018

Prepared by the
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section

Under the direction of the
North Carolina State Health Coordinating Council

For information contact the
North Carolina Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

https://www2.ncdhhs.gov/dhsr/ncsmfp/index.html

(919) 855 - 3865

NOTE: Data used in the North Carolina 2018 State Medical Facilities Plan was last updated October 6, 2017.

The North Carolina Department of Health and Human Services does not discriminate on the basis of race, color, national origin, sex, religion, age or disability in employment or the provision of services.

TABLE OF CONTENTS

Long-Term Care Facilities and Services

Appendices

DISCLAIMER

The North Carolina 2018 State Medical Facilities Plan is subject to revision throughout the year. Notices containing updates and changes will be posted on the North Carolina Division of Health Service Regulation web page at www2.ncdhhs.gov/dhsr/ncsmfp as they are approved. Check the web site for updates.

CHAPTER 6
OPERATING ROOMS

Summary of Operating Room Inventory and Utilization

"Operating room" is defined in G.S. 131E-76(6a) as "...a room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room." In the fall of 2017, the combined inventory of operating rooms in hospitals and ambulatory surgical facilities in North Carolina consisted of 155 dedicated inpatient surgery rooms, including 96 dedicated C-Section rooms, 293 dedicated ambulatory surgery rooms and 930 shared operating rooms. Data from the 2017 Hospital and Ambulatory Surgical Facility License Renewal Applications indicated that of the total reported surgical cases, excluding C-Section cases, 72.2 percent of the cases were ambulatory cases and 27.8 percent of the cases were inpatient cases.

Changes from the Previous Plan

Several substantive changes to the Operating Room methodology have been incorporated into the North Carolina 2018 State Medical Facilities Plan. The changes are summarized below:

- Facilities are grouped by the total number of surgical hours derived from data reported on the License Renewal Application.
- Operating room deficits and surpluses are calculated separately for each health system.
- Availability and utilization assumptions are based on the group to which the facility is assigned.
- Need determination calculations use case times reported by the facility, adjusted for outliers.
- When a need is calculated, the minimum need determination is two operating rooms. The maximum operating room need determination in a single service area is six. These changes will be evaluated after the first year of implementation of the new methodology.

In addition, one of the reporting requirements for the Single Specialty Ambulatory Surgical Facility Demonstration project has been revised.

The inventory and case data have been updated and references to dates have been advanced by one year, as appropriate.

Assumptions of the Methodology

For the purposes of the operating room methodology, a "health system" includes all licensed health service facilities with operating rooms located in the same service area that are owned or leased by:

1. the same legal entity (i.e., the same individual, trust or estate, partnership, corporation, hospital authority, or the State or political subdivision, agency or instrumentality of the State); or
2. the same parent corporation or holding company; or
3. a subsidiary of the same parent corporation or holding company; or
4. a joint venture in which the same parent, holding company, or a subsidiary of the same parent or holding company is a participant and has the authority to propose changes in the location or number of ORs in the health service facility.

A health system consists of one or more health service facilities. In the event that the relocation or transfer of operating rooms to a different health system generates a need, the need determination will not appear until the relocated or transferred operating rooms are licensed in their new location.

For the 2018 State Medical Facilities Plan, when a need is calculated, the minimum need determination for operating rooms is set to two, after rounding. In addition, the maximum operating room need determination in a service area in a single year will not exceed six, regardless of the deficit calculated. The Agency will reevaluate these two adjustments in 2018 to recommend whether to continue them.

Certificate of Need applications for new operating rooms are not restricted to the entity(ies) that generated the deficits.

Sources of Data

Data on the number of cases and procedures for the North Carolina 2018 State Medical Facilities Plan were taken from the "2017 Hospital License Renewal Application" and the "2017 Ambulatory Surgical Facility License Renewal Application" as submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation. *(Note: For the North Carolina 2018 State Medical Facilities Plan, one operating room for each Level I and Level II trauma center and one operating room for each designated burn intensive care unit are excluded in Table 6B.)*

Inventory data for the North Carolina 2018 State Medical Facilities Plan were compiled by staff based on License Renewal Applications, supplemented with data from the most recent licenses issued by the Acute and Home Care Licensure and Certification Section and with project approval letters from Certificate of Need.

Population data by county for 2016 and 2020 were obtained from the North Carolina Office of State Budget and Management.

Methodology for Projecting Operating Room Need

The following narrative describes the assumptions and methodology used in determining the operating room inventory and in projecting need for additional operating room capacity. The objective of the methodology is to arrive at a reasonable assessment of the adequacy of current resources for performing surgery, compared with an estimate of need for additional capacity.

Step 1 – Delineation of Service Areas

Definitions:

Single county operating room service area: A county with at least one licensed facility with one or more operating rooms.

Multicounty operating room service area: A group of counties including:

- one or two counties with at least one licensed facility with at least one operating room **and**;
- one or more counties with no licensed facility with at least one operating room.

All counties are either single county operating room service areas or are part of a multicounty operating room service area. A multicounty operating room service area may consist of multiple counties with no licensed facility with at least one operating room grouped with either one or two counties, each of which has at least one licensed facility that includes at least one operating room.

The three most recent years of available surgical patient origin data are combined and used to create the multicounty operating room service areas. These data are updated and reviewed every three years. The operating room service areas are then updated, as indicated by the data. The first update occurred in the North Carolina 2011 State Medical Facilities Plan. The following decision rules are used to determine multicounty operating room service area groupings:

a. Counties with no licensed facility with at least one operating room are grouped with the single county where the largest proportion of patients had surgery, as measured by number of surgical cases, unless:

   (1) Two counties with licensed facilities with at least one operating room each provided surgical services to at least 35 percent of the residents who received surgical services, as measured by number of surgical cases.

b. If a.(1) is true, then the county with no licensed facility with at least one operating room is grouped with both the counties which provided surgical services to at least 35 percent of the residents who received surgical services, as measured by number of surgical cases.

A county lacking a licensed facility with at least one operating room becomes a single county operating room service area upon licensure of a facility with at least one operating room in that county. If a certificate of need is issued for development of a facility with at least one operating room in a county lacking a facility with at least one operating room, the operating room(s) for which the certificate of need has been issued will be included in the inventory of operating rooms in that county's multicounty operating room service area until those operating rooms are licensed.

In 2006, in response to an adjusted need determination petition, the State Health Coordinating Council added Swain County to the Jackson-Graham multicounty operating room service area. This created a multicounty operating room service area that included two counties that have licensed facilities with at least one operating room and one county lacking a licensed facility with at least one operating room.

An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.

Step 2 – Inventory of Operating Rooms ***(Columns D through J, Table 6A)***

a. In each operating room service area, list the number of operating rooms by type, and sum them for each health system by summing the following for all licensed hospitals and ambulatory surgical facilities:
   (1) Number of Inpatient Operating Rooms *(Column D)*
   (2) Number of Ambulatory Operating Rooms *(Column E)*
   (3) Number of Shared Operating Rooms *(Column F)*

b. For each facility:
   (1) Exclude the number of dedicated C-Section operating rooms as summed from the Hospital License Renewal Application. *(Column G)*
   (2) Exclude one operating room for each Level I and Level II Trauma Center and one additional operating room for each designated Burn Intensive Care Unit. *(Column H)*
   (3) List the number of operating rooms *(Column I)* and C-Section operating rooms *(Column J)* for which certificates of need have been issued or settlement agreements signed but operating rooms were not licensed/delicensed as of September 30 of the reporting year. *(Columns I and J)*

c. Enter placeholders for need determinations from previous plans that are pending certificate of need review. *(Columns I and Column J)*

Step 3 – Determine Each Facility's Adjusted Case Times

a. For each facility, compare the "Average 'Case Time' in Minutes" for inpatient and ambulatory cases on the annual License Renewal Application to its average case time used in the methodology in the previous year's State Medical Facilities Plan. *(Note: For the 2018 State Medical Facilities Plan only, compare the case time reported on the 2017 License Renewal Application to the case time reported on the 2016 License Renewal Application.)*

(1) If either the inpatient or ambulatory case time is more than 10% longer than the previous year's case time, then the "Adjusted Case Time" is the previous year's reported case time plus 10%.

(2) If either the inpatient or ambulatory case time is more than 20% shorter than the previous year's case time, then the Adjusted Case Time is the previous year's reported case time minus 20%.

(3) If neither of the above situations occurs, then the Adjusted Case Time is the average case time(s) reported on the License Renewal Application.

Step 4 – Group Facilities *(Columns K through M, Table 6A)*

a. For each hospital, multiply the total inpatient surgical cases reported in the "Surgical Cases by Specialty Area" table on the annual Hospital License Renewal Application by the inpatient average case time from Step 3. Then divide by 60 to obtain the total inpatient surgical hours.

b. For each facility, multiply the total ambulatory cases reported in the Surgical Cases by Specialty Area table on the annual License Renewal Application by the ambulatory average case time from Step 3. Then divide by 60 to obtain the total ambulatory surgical hours.

c. Add the total inpatient and ambulatory surgical hours together to obtain each facility's "Total Surgical Hours for Grouping." *(Column K)*

d. Assign each facility to a group based on the following criteria *(Column L):*

Group	Facility Type
1	Academic Medical Center Teaching Hospitals
2	Hospitals reporting more than 40,000 surgical hours
3	Hospitals reporting 15,000 to 40,000 surgical hours
4	Hospitals reporting less than 15,000 surgical hours
5	Separately licensed ambulatory surgical facilities that perform at least 50% of their procedures in either ophthalmology or otolaryngology, or a combination of the two specialties.
6	All separately licensed ambulatory surgical facilities not in group 5.

e. For purposes of the State Medical Facilities Plan, the average operating room is anticipated to be staffed based on its group membership and utilized at least 75 percent of the available time. Assumptions regarding hours per day and days per year of availability are shown in the table below. Multiply the Hours per Day by the Days Per Year. Then multiply by 75% to obtain the "Standard Hours per Operating Room per Year." *(Column M)*

Group	Hours per Day	Days per Year	Standard Hours per Operating Room per Year
1	10	260	1,950.0
2	10	260	1,950.0
3	9	260	1,755.0
4	8	250	1,500.0
5	7	250	1,312.5
6	7	250	1,312.5

Step 5 – Project Future Operating Room Requirements Based on Growth of Operating Room Hours ***(Columns D through K, Table 6B)***

a. Determine the utilization rate for each licensed facility providing surgical services and exclude from all further calculations the operating rooms and corresponding procedures in chronically underutilized licensed facilities located in operating room service areas with more than one licensed facility. Do not exclude operating rooms in facilities located in service areas where all facilities are chronically underutilized. Chronically underutilized licensed facilities are defined as licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.

If ORs in a chronically underutilized facility have received approval to be relocated to a new facility, include the ORs and procedures for the underutilized facility in the calculations. Do not remove the ORs from the underutilized facility's inventory or put ORs for the new facility into its inventory until the new facility is licensed.

b. For Groups 2 through 6, use the Adjusted Case Time (Step 3) to calculate the average (mean) inpatient and ambulatory case times for each group. If this average exceeds one standard deviation above the mean case time for its group, substitute the value equivalent to the mean plus one standard deviation of the Adjusted Case Time to obtain the "Final Inpatient Case Time" *(Column E)* and "Final Ambulatory Case Time" *(Column G)*, as applicable. Otherwise use the Adjusted Case Time (Step 3). Facilities that perform no surgical procedures in the category being calculated are excluded from the calculations. For the 2018 State Medical Facilities Plan, the average Final Inpatient and Ambulatory Case Times for each group are as follows:

Group	Average Final Inpatient Case Time in Minutes	Average Final Ambulatory Case Time in Minutes
1	230.8	131.3
2	197.3	116.9
3	175.6	106.6
4	115.3	73.3
5	--	45.0
6	--	68.6

c. For each facility, multiply the inpatient surgical cases reported on the License Renewal Application *(Column D)* by the average inpatient case time from Step 5-b, and multiply the ambulatory surgical cases reported on the License Renewal Application *(Column F)* by the

average ambulatory case time from Step 5-b. Sum these amounts for each facility to obtain the "Total Adjusted Estimated Surgical Hours." *(Column H)*

d. For purposes of these need projections, the number of surgical hours is anticipated to change in direct proportion to the change in the general population of the operating room service area. For each service area with a projected population increase, calculate the "Growth Factor" based on each service area's projected population change between the "data year" (2016) and the "target year" for need projections (2020) using population figures from the North Carolina Office of State Budget and Management. *(Column I: Growth Factor = 2020 Service Area Population minus 2016 Service Area Population, then divided by the 2016 Service Area Population.)* If the calculated population growth is negative, the Growth Factor is considered to be zero.

e. Multiply each facility's Total Adjusted Estimated Surgical Hours *(Column H)* for the most recent fiscal year by each service area's Growth Factor *(Column I)*. Then add the product to the Total Adjusted Estimated Surgical Hours to determine the "Projected Surgical Hours for 2020." *([Column H x Column I] + Column H = Column J)*

f. Divide each facility's Projected Surgical Hours for 2020 by the Standard Hours per Operating Room per Year (based on group assignment) to determine the "Projected Surgical Operating Rooms Required in 2020." *(Column J, Table 6B ÷ Column M, Table 6A = Column K, Table 6B)*

Step 6 – Determination of Health System Deficit/Surplus *(Columns L - M, Table 6B)*

a. Sum the operating rooms, adjustments, and exclusions for each facility to obtain the "Adjusted Planning Inventory." *(Column L)*

b. Subtract the Adjusted Planning Inventory from the Projected Surgical Operating Rooms Required in 2020 to obtain the surpluses and deficits for each facility. *(Note: In Column M, projected deficits appear as positive numbers indicating that the methodology projects that more operating rooms will be needed in 2020 than are in the current inventory.)* Then sum the deficits and surpluses for each facility in each health system to arrive at the "Projected Operating Room Deficit or Surplus." *(Column K – Column L = Column M)*

Step 7 – Determination of Service Area Operating Room Need ***(Column N, Table 6B)***

a. Round the health system deficits according to the rounding rules, below:

If a health system located in an operating room service area with more than 10 operating rooms in the Adjusted Planning Inventory has a projected fractional deficit of 0.50 or greater, round the deficit to the next highest whole number. For each health system in an operating room service area with more than 10 operating rooms and a projected deficit less than 0.50 or in which there is a projected surplus, there is no need.

If a health system located in an operating room service area with six to 10 operating rooms in the Adjusted Planning Inventory has a projected fractional deficit of 0.30 or greater, round the deficit to the next highest whole number. For each health system in an operating room service area with six to 10 operating rooms and a projected deficit less than 0.30 or in which there is a projected surplus, there is no need.

If a health system located in an operating room service area with five or fewer operating rooms in the Adjusted Planning Inventory has a projected fractional deficit of 0.20 or greater, round the deficit to the next highest whole number. For each health system in an operating room service area with five or fewer operating rooms and a projected deficit less than 0.20 or in which there is a projected surplus, there is no need.

b. Add all rounded health systems deficits. Then adjust for any placeholders for need determinations in previous State Medical Facilities Plans to calculate the "Service Area Need." *(Column N)*

c. For the 2018 State Medical Facilities Plan, the Service Area Need must be at least two to show an Operating Room Need Determination in Table 6C. If the Service Area Need is greater than six, then the Operating Room Need Determination in Table 6C is equal to six.

NOTE: "Dedicated C-Section Operating Rooms" and associated cases are excluded from the calculation of need for additional operating rooms by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a "Dedicated C-Section Operating Room" shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan. There are no other operating room exclusions for which this protocol is applicable.

A "Dedicated C-Section Operating Room" shall only be used to perform Cesarean Sections and other procedures performed on the patient in the same visit to the C-Section Operating Room, such that a patient receiving another procedure at the same time as the Cesarean Section would not need to be moved to a different operating room for the second procedure.

REQUEST FOR TECHNICAL CHANGE

AGENCY: DHHS – Division of Health Service Regulation

RULE CITATION: 10A NCAC 41C .2101

DEADLINE FOR RECEIPT: Friday, January 12, 2018

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

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

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

Line 14, consider adding a comma after "Agency"

Lines 22 thru 26, is this statement correct that there are two separate forms to be filed to one Section within DHSR? If that is not a correct statement, please consider clarifying this clause.

Line 25, if the statement above is correct, consider adding a comma after "Regulation" to clarify the sentence

Line 33, define or delete "solely" Is the term necessary for this definition?

Page 2, line 12, define or delete "solely" Is the term necessary for this definition?

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

10A NCAC 14C .2101 is amended under temporary procedures 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).

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

(3) ~~"Ambulatory surgical program" means a program as defined in G.S. 131E-176(1c).~~ "Approved operating rooms" means those operating rooms that were approved for a certificate of need prior to the date on which the applicant's proposed project was submitted to the Agency but that have not been licensed.

(4) "Dedicated cesarean section operating room" or "Dedicated C-section operating room" means an operating room as defined in ~~the applicable~~ 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://www2.ncdhhs.gov/dhsr/ncsmfp/index.html.

(5) "Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals ~~which~~ that were reported in the ~~License Application for~~ Ambulatory Surgical ~~Facilities and Programs~~ Facility License Renewal Application Form and in ~~Part III of~~ the Hospital ~~Licensure~~ License Renewal Application Form submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation and ~~which~~ that were licensed and certified prior to the beginning of the review period.

(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.~~ "Health system" shall have the same meaning as defined 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).~~ "Inpatient operating room" means an operating room in a hospital as defined in G.S. 131E-176(13) used solely for the performance of surgical procedures on inpatients.

(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.~~ "Multispecialty ambulatory surgical program" means a program as defined in G.S. 131E-176(15a).

(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).~~ "Operating room" means a room as defined in G.S. 131E-176(18c), and includes an inpatient operating room, an outpatient or ambulatory surgical operating room, or a shared operating room.

(10) ~~"Service area" means the Operating Room Service Area as defined in the applicable State Medical Facilities Plan.~~ "Operating Room Need Methodology" means the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 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.~~ "Outpatient or ambulatory surgical operating room" means an operating room used solely for the performance of surgical procedures that require local, regional, or general anesthesia, and a period of post-operative observation of less than 24 hours.

(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.~~ "Service area" means the Operating Room Service Area as defined in Chapter 6 in the 2018 State Medical Facilities Plan.

(13) ~~"Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24e).~~ "Shared operating room" means an operating room that is used for the performance of both ambulatory and inpatient surgical procedures.

(14) ~~"Surgical case" means an individual who receives one or more surgical procedures in an operating room during a single operative encounter.~~ "Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24f).

(15) "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.

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.~~ 2008;
Temporary Amendment Eff. February 1, 2018.

TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

ORIGINAL

JAN 0 8 2018

OAH USE ONLY
VOLUME:
ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHSR

2. Rule citation & name: 10A NCAC 14C .2103 Performance Standards

3. Action: ☐ Adoption ☒ Amendment ☐ Repeal

4. Was this an Emergency Rule: ☐ Yes ☒ No Effective date:

5. Provide dates for the following actions as applicable:

   a. Proposed Temporary Rule submitted to OAH: 11/07/17

   b. Proposed Temporary Rule published on the OAH website: 11/14/17

   c. Public Hearing date: 11/29/17

   d. Comment Period: 11/16/17 – 12/11/17

   e. Notice pursuant to G.S. 150B-21.1(a3)(2): 11/07/17

   f. Adoption by agency on: 1/03/18

   g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 02/01/18

   h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

   ☐ A serious and unforeseen threat to the public health, safety or welfare.
   ☐ The effective date of a recent act of the General Assembly or of the U.S. Congress.
   Cite:
   Effective date:
   ☐ A recent change in federal or state budgetary policy.
   Effective date of change:
   ☐ A recent federal regulation.
   Cite:
   Effective date:
   ☐ A recent court order.
   Cite order:
   ☒ State Medical Facilities Plan.
   ☐ Other:

Explain: Several subject matters are addressed in the State Medical Facilities Plan (SMFP). The operating room need methodology was changed in the 2018 SMFP. Revisions to existing Certificate of Need rules are required to compliment or to be made consistent with the SMFP signed by the governor on December 11, 2017. The effective date of the 2018 SMFP is January 1, 2018.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

The change to the existing Certificate of Need (CON) performance standards rule for the criteria and standards for surgical services and operating rooms is required to compliment or to be made consistent with the State Medical Facilities Plan (SMFP) that will become effective January 1, 2018. The operating room need methodology found in the SMFP underwent substantial changes as a result of a workgroup directed by the State Health Coordinating Council (SHCC). The revised need methodology was approved for inclusion in the 2018 SMFP by the SHCC and subsequently signed for approval by the governor on December 11, 2017. This rule is being revised so that correct performance standards reflective of the operating room need methodology changes shall be used by 2018 CON applicants for surgical services and operating rooms. The methodology changes are reflected in rule by reference to the SMFP. These temporary rule amendment adoptions are required for an applicant's compliance with a CON application submission for an operating room need determination in the 2018 SMFP.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ Yes
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Martha Frisone, Chief

Phone: 919-855-3879

E-Mail: martha.frisone@dhhs.nc.gov

10. Signature of Agency Head*:

*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: Mark Payne

Title: Director, Division of Health Service Regulation

E-Mail: mark.payne@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY	
Action taken: ☐ Date returned to agency:	Submitted for RRC Review:

STATE HEALTH COORDINATING COUNCIL

2018

STATE MEDICAL FACILITIES PLAN

Health Service Regulation
HEALTH AND HUMAN SERVICES

North Carolina Department of Health and Human Services
Division of Health Service Regulation

I hereby approve the North Carolina 2018 State Medical Facilities Plan effective January 1, 2018.

Roy Cooper, Governor

12/11/2017
Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MEMORANDUM

TO: Governor Cooper

FROM: Mandy Cohen

SUBJECT: North Carolina 2018 State Medical Facilities Plan

DATE: November 2, 2017

I am forwarding for your review and approval the North Carolina 2018 State Medical Facility Plan (SMFP) as recommended by the North Carolina State Health Coordinating Council (SHCC). Also attached is a summary of the need determinations and summer petitions from the 2017 planning cycle.

I support the SHCC and the implementation of the 2018 SMFP.

Additional background information is available on all areas, if desired. It would greatly facilitate the publication and distribution of the SMFP if you could approve or request changes before the end of November.

MC:mf

Attachments: 2018 State Medical Facilities Plan
Summary of Need Determinations and Summer Petitions

WWW.NCDHHS.GOV
TEL 919-855-4900 • FAX 919-715-0991
LOCATION: 101 BLAIR DRIVE • ADAMS BUILDING • RALEIGH, NC 27603
MAILING ADDRESS: 2001 MAIL SERVICE CENTER • RALEIGH, NC 27699-2001
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

November 2, 2017

The Honorable Roy Cooper, Governor
State of North Carolina
20301 Mail Service Center
Raleigh, NC 27699-0301

Dear Governor Cooper:

On behalf of the North Carolina State Health Coordinating Council, I am pleased to forward our recommendations for the North Carolina 2018 State Medical Facilities Plan. This Plan is the culmination of a year's work by the council, its committees and Healthcare Planning staff.

The council has devoted a significant amount of time to the review and discussion of a variety of issues prior to making its recommendations for the upcoming year. The Proposed Plan was disseminated broadly and examined in six public hearings held across the state, and any petitions and comments received during this year-long process were duly considered.

This final document represents the council's recommendations regarding health care needs to be addressed in the 2018 certificate of need reviews.

Sincerely,

Christopher G. Ullrich, M.D., Chairman
N.C. State Health Coordinating Council

Enclosure

cc: Mandy Cohen, MD, Secretary, DHHS
Mark Payne, Director, DHSR

NORTH CAROLINA 2018
STATE MEDICAL FACILITIES PLAN

Effective January 1, 2018

Prepared by the
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section

Under the direction of the
North Carolina State Health Coordinating Council

For information contact the
North Carolina Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

https://www2.ncdhhs.gov/dhsr/ncsmfp/index.html

(919) 855 - 3865

NOTE: Data used in the North Carolina 2018 State Medical Facilities Plan was last updated October 6, 2017.

The North Carolina Department of Health and Human Services does not discriminate on the basis of race, color, national origin, sex, religion, age or disability in employment or the provision of services.

TABLE OF CONTENTS

Long-Term Care Facilities and Services

Appendices

DISCLAIMER

The North Carolina 2018 State Medical Facilities Plan is subject to revision throughout the year. Notices containing updates and changes will be posted on the North Carolina Division of Health Service Regulation web page at www2.ncdhhs.gov/dhsr/ncsmfp as they are approved. Check the web site for updates.

CHAPTER 6
OPERATING ROOMS

Summary of Operating Room Inventory and Utilization

"Operating room" is defined in G.S. 131E-76(6a) as "...a room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room." In the fall of 2017, the combined inventory of operating rooms in hospitals and ambulatory surgical facilities in North Carolina consisted of 155 dedicated inpatient surgery rooms, including 96 dedicated C-Section rooms, 293 dedicated ambulatory surgery rooms and 930 shared operating rooms. Data from the 2017 Hospital and Ambulatory Surgical Facility License Renewal Applications indicated that of the total reported surgical cases, excluding C-Section cases, 72.2 percent of the cases were ambulatory cases and 27.8 percent of the cases were inpatient cases.

Changes from the Previous Plan

Several substantive changes to the Operating Room methodology have been incorporated into the North Carolina 2018 State Medical Facilities Plan. The changes are summarized below:

- Facilities are grouped by the total number of surgical hours derived from data reported on the License Renewal Application.
- Operating room deficits and surpluses are calculated separately for each health system.
- Availability and utilization assumptions are based on the group to which the facility is assigned.
- Need determination calculations use case times reported by the facility, adjusted for outliers.
- When a need is calculated, the minimum need determination is two operating rooms. The maximum operating room need determination in a single service area is six. These changes will be evaluated after the first year of implementation of the new methodology.

In addition, one of the reporting requirements for the Single Specialty Ambulatory Surgical Facility Demonstration project has been revised.

The inventory and case data have been updated and references to dates have been advanced by one year, as appropriate.

Assumptions of the Methodology

For the purposes of the operating room methodology, a "health system" includes all licensed health service facilities with operating rooms located in the same service area that are owned or leased by:

1. the same legal entity (i.e., the same individual, trust or estate, partnership, corporation, hospital authority, or the State or political subdivision, agency or instrumentality of the State); or
2. the same parent corporation or holding company; or
3. a subsidiary of the same parent corporation or holding company; or
4. a joint venture in which the same parent, holding company, or a subsidiary of the same parent or holding company is a participant and has the authority to propose changes in the location or number of ORs in the health service facility.

A health system consists of one or more health service facilities. In the event that the relocation or transfer of operating rooms to a different health system generates a need, the need determination will not appear until the relocated or transferred operating rooms are licensed in their new location.

For the 2018 State Medical Facilities Plan, when a need is calculated, the minimum need determination for operating rooms is set to two, after rounding. In addition, the maximum operating room need determination in a service area in a single year will not exceed six, regardless of the deficit calculated. The Agency will reevaluate these two adjustments in 2018 to recommend whether to continue them.

Certificate of Need applications for new operating rooms are not restricted to the entity(ies) that generated the deficits.

Sources of Data

Data on the number of cases and procedures for the North Carolina 2018 State Medical Facilities Plan were taken from the "2017 Hospital License Renewal Application" and the "2017 Ambulatory Surgical Facility License Renewal Application" as submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation. *(Note: For the North Carolina 2018 State Medical Facilities Plan, one operating room for each Level I and Level II trauma center and one operating room for each designated burn intensive care unit are excluded in Table 6B.)*

Inventory data for the North Carolina 2018 State Medical Facilities Plan were compiled by staff based on License Renewal Applications, supplemented with data from the most recent licenses issued by the Acute and Home Care Licensure and Certification Section and with project approval letters from Certificate of Need.

Population data by county for 2016 and 2020 were obtained from the North Carolina Office of State Budget and Management.

Methodology for Projecting Operating Room Need

The following narrative describes the assumptions and methodology used in determining the operating room inventory and in projecting need for additional operating room capacity. The objective of the methodology is to arrive at a reasonable assessment of the adequacy of current resources for performing surgery, compared with an estimate of need for additional capacity.

Step 1 – Delineation of Service Areas

Definitions:

Single county operating room service area: A county with at least one licensed facility with one or more operating rooms.

Multicounty operating room service area: A group of counties including:

- one or two counties with at least one licensed facility with at least one operating room **and**;
- one or more counties with no licensed facility with at least one operating room.

All counties are either single county operating room service areas or are part of a multicounty operating room service area. A multicounty operating room service area may consist of multiple counties with no licensed facility with at least one operating room grouped with either one or two counties, each of which has at least one licensed facility that includes at least one operating room.

The three most recent years of available surgical patient origin data are combined and used to create the multicounty operating room service areas. These data are updated and reviewed every three years. The operating room service areas are then updated, as indicated by the data. The first update occurred in the North Carolina 2011 State Medical Facilities Plan. The following decision rules are used to determine multicounty operating room service area groupings:

a. Counties with no licensed facility with at least one operating room are grouped with the single county where the largest proportion of patients had surgery, as measured by number of surgical cases, unless:

   (1) Two counties with licensed facilities with at least one operating room each provided surgical services to at least 35 percent of the residents who received surgical services, as measured by number of surgical cases.

b. If a.(1) is true, then the county with no licensed facility with at least one operating room is grouped with both the counties which provided surgical services to at least 35 percent of the residents who received surgical services, as measured by number of surgical cases.

A county lacking a licensed facility with at least one operating room becomes a single county operating room service area upon licensure of a facility with at least one operating room in that county. If a certificate of need is issued for development of a facility with at least one operating room in a county lacking a facility with at least one operating room, the operating room(s) for which the certificate of need has been issued will be included in the inventory of operating rooms in that county's multicounty operating room service area until those operating rooms are licensed.

In 2006, in response to an adjusted need determination petition, the State Health Coordinating Council added Swain County to the Jackson-Graham multicounty operating room service area. This created a multicounty operating room service area that included two counties that have licensed facilities with at least one operating room and one county lacking a licensed facility with at least one operating room.

An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.

Step 2 – Inventory of Operating Rooms ***(Columns D through J, Table 6A)***

a. In each operating room service area, list the number of operating rooms by type, and sum them for each health system by summing the following for all licensed hospitals and ambulatory surgical facilities:
   (1) Number of Inpatient Operating Rooms *(Column D)*
   (2) Number of Ambulatory Operating Rooms *(Column E)*
   (3) Number of Shared Operating Rooms *(Column F)*

b. For each facility:
   (1) Exclude the number of dedicated C-Section operating rooms as summed from the Hospital License Renewal Application. *(Column G)*
   (2) Exclude one operating room for each Level I and Level II Trauma Center and one additional operating room for each designated Burn Intensive Care Unit. *(Column H)*
   (3) List the number of operating rooms *(Column I)* and C-Section operating rooms *(Column J)* for which certificates of need have been issued or settlement agreements signed but operating rooms were not licensed/delicensed as of September 30 of the reporting year. *(Columns I and J)*

c. Enter placeholders for need determinations from previous plans that are pending certificate of need review. *(Columns I and Column J)*

Step 3 – Determine Each Facility's Adjusted Case Times

a. For each facility, compare the "Average 'Case Time' in Minutes" for inpatient and ambulatory cases on the annual License Renewal Application to its average case time used in the methodology in the previous year's State Medical Facilities Plan. *(Note: For the 2018 State Medical Facilities Plan only, compare the case time reported on the 2017 License Renewal Application to the case time reported on the 2016 License Renewal Application.)*

(1) If either the inpatient or ambulatory case time is more than 10% longer than the previous year's case time, then the "Adjusted Case Time" is the previous year's reported case time plus 10%.

(2) If either the inpatient or ambulatory case time is more than 20% shorter than the previous year's case time, then the Adjusted Case Time is the previous year's reported case time minus 20%.

(3) If neither of the above situations occurs, then the Adjusted Case Time is the average case time(s) reported on the License Renewal Application.

Step 4 – Group Facilities *(Columns K through M, Table 6A)*

a. For each hospital, multiply the total inpatient surgical cases reported in the "Surgical Cases by Specialty Area" table on the annual Hospital License Renewal Application by the inpatient average case time from Step 3. Then divide by 60 to obtain the total inpatient surgical hours.

b. For each facility, multiply the total ambulatory cases reported in the Surgical Cases by Specialty Area table on the annual License Renewal Application by the ambulatory average case time from Step 3. Then divide by 60 to obtain the total ambulatory surgical hours.

c. Add the total inpatient and ambulatory surgical hours together to obtain each facility's "Total Surgical Hours for Grouping." *(Column K)*

d. Assign each facility to a group based on the following criteria *(Column L):*

Group	Facility Type
1	Academic Medical Center Teaching Hospitals
2	Hospitals reporting more than 40,000 surgical hours
3	Hospitals reporting 15,000 to 40,000 surgical hours
4	Hospitals reporting less than 15,000 surgical hours
5	Separately licensed ambulatory surgical facilities that perform at least 50% of their procedures in either ophthalmology or otolaryngology, or a combination of the two specialties.
6	All separately licensed ambulatory surgical facilities not in group 5.

e. For purposes of the State Medical Facilities Plan, the average operating room is anticipated to be staffed based on its group membership and utilized at least 75 percent of the available time. Assumptions regarding hours per day and days per year of availability are shown in the table below. Multiply the Hours per Day by the Days Per Year. Then multiply by 75% to obtain the "Standard Hours per Operating Room per Year." *(Column M)*

Group	Hours per Day	Days per Year	Standard Hours per Operating Room per Year
1	10	260	1,950.0
2	10	260	1,950.0
3	9	260	1,755.0
4	8	250	1,500.0
5	7	250	1,312.5
6	7	250	1,312.5

Step 5 – Project Future Operating Room Requirements Based on Growth of Operating Room Hours *(Columns D through K, Table 6B)*

a. Determine the utilization rate for each licensed facility providing surgical services and exclude from all further calculations the operating rooms and corresponding procedures in chronically underutilized licensed facilities located in operating room service areas with more than one licensed facility. Do not exclude operating rooms in facilities located in service areas where all facilities are chronically underutilized. Chronically underutilized licensed facilities are defined as licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.

   If ORs in a chronically underutilized facility have received approval to be relocated to a new facility, include the ORs and procedures for the underutilized facility in the calculations. Do not remove the ORs from the underutilized facility's inventory or put ORs for the new facility into its inventory until the new facility is licensed.

b. For Groups 2 through 6, use the Adjusted Case Time (Step 3) to calculate the average (mean) inpatient and ambulatory case times for each group. If this average exceeds one standard deviation above the mean case time for its group, substitute the value equivalent to the mean plus one standard deviation of the Adjusted Case Time to obtain the "Final Inpatient Case Time" *(Column E)* and "Final Ambulatory Case Time" *(Column G)*, as applicable. Otherwise use the Adjusted Case Time (Step 3). Facilities that perform no surgical procedures in the category being calculated are excluded from the calculations. For the 2018 State Medical Facilities Plan, the average Final Inpatient and Ambulatory Case Times for each group are as follows:

Group	Average Final Inpatient Case Time in Minutes	Average Final Ambulatory Case Time in Minutes
1	230.8	131.3
2	197.3	116.9
3	175.6	106.6
4	115.3	73.3
5	--	45.0
6	--	68.6

c. For each facility, multiply the inpatient surgical cases reported on the License Renewal Application *(Column D)* by the average inpatient case time from Step 5-b, and multiply the ambulatory surgical cases reported on the License Renewal Application *(Column F)* by the

average ambulatory case time from Step 5-b. Sum these amounts for each facility to obtain the "Total Adjusted Estimated Surgical Hours." *(Column H)*

d. For purposes of these need projections, the number of surgical hours is anticipated to change in direct proportion to the change in the general population of the operating room service area. For each service area with a projected population increase, calculate the "Growth Factor" based on each service area's projected population change between the "data year" (2016) and the "target year" for need projections (2020) using population figures from the North Carolina Office of State Budget and Management. *(Column I: Growth Factor = 2020 Service Area Population minus 2016 Service Area Population, then divided by the 2016 Service Area Population.)* If the calculated population growth is negative, the Growth Factor is considered to be zero.

e. Multiply each facility's Total Adjusted Estimated Surgical Hours *(Column H)* for the most recent fiscal year by each service area's Growth Factor *(Column I)*. Then add the product to the Total Adjusted Estimated Surgical Hours to determine the "Projected Surgical Hours for 2020." *([Column H x Column I] + Column H = Column J)*

f. Divide each facility's Projected Surgical Hours for 2020 by the Standard Hours per Operating Room per Year (based on group assignment) to determine the "Projected Surgical Operating Rooms Required in 2020." *(Column J, Table 6B ÷ Column M, Table 6A = Column K, Table 6B)*

Step 6 – Determination of Health System Deficit/Surplus *(Columns L - M, Table 6B)*

a. Sum the operating rooms, adjustments, and exclusions for each facility to obtain the "Adjusted Planning Inventory." *(Column L)*

b. Subtract the Adjusted Planning Inventory from the Projected Surgical Operating Rooms Required in 2020 to obtain the surpluses and deficits for each facility. *(Note: In Column M, projected deficits appear as positive numbers indicating that the methodology projects that more operating rooms will be needed in 2020 than are in the current inventory.)* Then sum the deficits and surpluses for each facility in each health system to arrive at the "Projected Operating Room Deficit or Surplus." *(Column K – Column L = Column M)*

Step 7 – Determination of Service Area Operating Room Need ***(Column N, Table 6B)***

a. Round the health system deficits according to the rounding rules, below:

If a health system located in an operating room service area with more than 10 operating rooms in the Adjusted Planning Inventory has a projected fractional deficit of 0.50 or greater, round the deficit to the next highest whole number. For each health system in an operating room service area with more than 10 operating rooms and a projected deficit less than 0.50 or in which there is a projected surplus, there is no need.

If a health system located in an operating room service area with six to 10 operating rooms in the Adjusted Planning Inventory has a projected fractional deficit of 0.30 or greater, round the deficit to the next highest whole number. For each health system in an operating room service area with six to 10 operating rooms and a projected deficit less than 0.30 or in which there is a projected surplus, there is no need.

If a health system located in an operating room service area with five or fewer operating rooms in the Adjusted Planning Inventory has a projected fractional deficit of 0.20 or greater, round the deficit to the next highest whole number. For each health system in an operating room service area with five or fewer operating rooms and a projected deficit less than 0.20 or in which there is a projected surplus, there is no need.

b. Add all rounded health systems deficits. Then adjust for any placeholders for need determinations in previous State Medical Facilities Plans to calculate the "Service Area Need." *(Column N)*

c. For the 2018 State Medical Facilities Plan, the Service Area Need must be at least two to show an Operating Room Need Determination in Table 6C. If the Service Area Need is greater than six, then the Operating Room Need Determination in Table 6C is equal to six.

NOTE: "Dedicated C-Section Operating Rooms" and associated cases are excluded from the calculation of need for additional operating rooms by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a "Dedicated C-Section Operating Room" shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan. There are no other operating room exclusions for which this protocol is applicable.

A "Dedicated C-Section Operating Room" shall only be used to perform Cesarean Sections and other procedures performed on the patient in the same visit to the C-Section Operating Room, such that a patient receiving another procedure at the same time as the Cesarean Section would not need to be moved to a different operating room for the second procedure.

REQUEST FOR TECHNICAL CHANGE

AGENCY: DHHS – Division of Health Service Regulation

RULE CITATION: 10A NCAC 41C .2103

DEADLINE FOR RECEIPT: Friday, January 12, 2018

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

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

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

Page 1, line 12; page 2, line 10; and page 3, lines 24 thru 25, delete the clause "including subsequent amendments and editions"

Page 1, line 12; page 2, line 11; and page 3, line 25, should "is not required" be "may"? Please review

Page 3, line 9, should the term "area" be placed between "specialty" and "to a" as tjat os a defined term? Please review

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

10A NCAC 14C .2103 is amended with changes under temporary procedures 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.~~

~~(b)~~ (a) 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~~ program, or to add a specialty to a specialty ambulatory surgical program ~~shall:~~ shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan including subsequent amendments and editions. The applicant is not required to use the population growth factor.

~~(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)~~ (b) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area ~~shall:~~ shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in ~~all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2)~~ the applicant's health system in the third operating year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan including subsequent amendments and editions. The applicant is not required to use the population growth factor.

~~(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)~~ (c) 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~~ approved, and proposed dedicated C-section rooms during the third year of operation following completion of the project.

~~(e)~~ (d) 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~~ 1,312.5 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;~~ year; 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.~~ Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan including subsequent amendments and editions. The applicant is not required to use the population growth factor.

~~(f)~~ (e) 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.~~ 2010;
Temporary Amendment Eff. February 1, 2018.