

December 6, 2017



Ms. Martha Frisone, Assistant Chief
Health Planning and Certificate of Need Section
North Carolina Division of Facilities Services
809 Ruggles Drive
Raleigh, NC 27603

2085 Frontis Plaza Boulevard
Winston Salem, NC 27103

novanthealth.org

Re: Proposed Changes in CON Criteria and Standards for Surgical Services and
Operating Rooms – 10A NCAC 14C .2101 Definitions and 10A NCAC 14C .2103
Performance Standards

Dear Ms. Frisone:

Novant Health has several concerns regarding the proposed CON Criteria and Standards for Surgical Services and Operating Rooms as reflected in the attached suggested changes.

Our interpretation of the proposed language is that the Operating Room Need Methodology in the State Medical Facilities Plan (SMFP) must be used in the CON process to justify the need for new operating rooms as reflected in the language in 10A NCAC 14C .2103 Performance Standards below.

- (a) *“A proposal to establish a new ... **shall demonstrate the need for the number of proposed operating rooms in the facility ... based on the Operating Room Need Methodology ...**”*
 - (b) *“A proposal to increase the number of operating rooms ... **shall demonstrate the need for the number of proposed operating rooms in the facility ... based on the Operating Room Need Methodology ...**”*
1. With the complex changes made to the OR Methodology this past summer we understand the need to reference the Operating Room Need Methodology in the SMFP to make sure CON applicants are using the relevant hours of operation and surgical case times, and other relevant sections of the methodology in projecting future need. However, including the methodology in total appears to imply a requirement that this is the only acceptable methodology. We do not believe this was the intent. The attached document includes suggestions to 10A NCAC 14C .2101(10), the definition for Operating Room Need Methodology. The proposed change reflects excluding Step 5, which references how future need is projected using population growth. This would make it clear that other methodologies and growth rates were acceptable, but hours of operation and surgical case times from the State Medical Facilities Plan would be required to project future need.

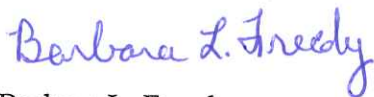
Step 5 also includes an adjustment for case times greater than one standard deviation from the mean. While this step is necessary for statewide planning purposes, it should

not be a specific requirement for an individual facility projecting future need. Additional language is included in the attached suggestions in 10A NCAC 14C .2103(f) to include relevant sections of Step 5 in the Performance Standards.

2. Another concern regards using old data from old Licensure Renewal Applications when in most cases a more current LRA would be available. Language has been included in the attached document in 10A NCAC 14C .2101(10) to require the most current data to be used for case times and hours of operation for grouping existing facilities. Case times and volumes may change from year to year and an applicant should be given the opportunity to use most current data, if changes are reasonable and explained in the application.
3. When discussing the operating room need in the “health system” in the performance standards, “in the service area” has been added in the attached changes to clarify that this is specific to the OR service area as defined.
4. Additional language has been added to 10A NCAC 14C .2103(f) which discusses the assumptions used by the applicant, including a specific requirement for additional detailed assumptions to account for case time variations.
5. We believe this language does not take into consideration operating rooms included in the SMFP based upon an adjustment to a need determination in particular those with different methodologies or for only one operating room. However, the SHCC left open the possibility of future petitions for one operating room need designations, which would be reasonable in some cases. Referencing the OR Methodology in total requires two new operating rooms be identified. Therefore, any future application for one operating room submitted would be non-conforming to the language in the rules as proposed. The attached document includes a new 10A NCAC 14C .2103(e) to address this situation. This is similar to language added to the rules in previous years for special need petitions.

Please let me know if you have any questions regarding our suggested changes. Nancy Bres Martin with NBM HPA has worked with Novant Health in the review of the rules and the development of these comments. Please contact me or Ms. Bres Martin to discuss these suggestions if needed.

Sincerely,



Barbara L. Freedy
Director, Certificate of Need
Novant Health, Inc.

1 10A NCAC 14C .2101 is proposed for amendment under temporary procedures as follows:

2
3 **SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING**
4 **ROOMS**

5
6 **10A NCAC 14C .2101 DEFINITIONS**

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

- 8 (1) "Ambulatory surgical facility" means a facility as defined in G.S. 131E-176(1b).
- 9 (2) ~~"Operating room" means a room as defined in G.S. 131E-176(18c), which includes an inpatient~~
10 ~~operating room, an outpatient or ambulatory surgical operating room, or a shared operating room.~~
11 "Ambulatory surgical program" means a program as defined in G.S. 131E-176(1c).
- 12 (3) ~~"Ambulatory surgical program" means a program as defined in G.S. 131E-176(1c).~~ "Approved
13 operating rooms" means those operating rooms that were approved for a certificate of need prior to
14 the date on which the applicant's proposed project was submitted to the Agency but that have not
15 been licensed.
- 16 (4) "Dedicated cesarean section operating room" or "Dedicated C-section operating room" means an
17 operating room as defined in the applicable Chapter 6 in the 2018 State Medical Facilities Plan. For
18 purposes of this Section, Chapter 6 in the 2018 State Medical Facilities Plan is hereby incorporated
19 by reference including subsequent amendments and editions. This document is available at no cost
20 at <https://www2.ncdhhs.gov/dhsr/ncsmfp/index.html>.
- 21 (5) "Existing operating rooms" means those operating rooms in ambulatory surgical facilities and
22 hospitals which that were reported in the License Application for Ambulatory Surgical Facilities
23 and Programs Facility License Renewal Application Form and in Part III of the Hospital Licensure
24 License Renewal Application Form submitted to the Acute and Home Care Licensure and
25 Certification Section of the Division of Health Service Regulation and which that were licensed and
26 certified prior to the beginning of the review period.
- 27 (6) ~~"Approved operating rooms" means those operating rooms that were approved for a certificate of~~
28 ~~need by the Certificate of Need Section prior to the date on which the applicant's proposed project~~
29 ~~was submitted to the Agency but that have not been licensed.~~ "Health system" shall have the same
30 meaning as defined in Chapter 6 in the 2018 State Medical Facilities Plan.
- 31 (7) ~~"Multispecialty ambulatory surgical program" means a program as defined in G.S. 131E-176(15a).~~
32 "Inpatient operating room" means an operating room in a hospital as defined in G.S. 131E-176(13)
33 used solely for the performance of surgical procedures on inpatients.
- 34 (8) ~~"Outpatient or ambulatory surgical operating room" means an operating room used solely for the~~
35 ~~performance of surgical procedures which require local, regional or general anesthesia and a period~~
36 ~~of post-operative observation of less than 24 hours.~~ "Multispecialty ambulatory surgical program"
37 means a program as defined in G.S. 131E-176(15a).

- 1 (9) ~~"Related entity" means the parent company of the applicant, a subsidiary company of the applicant~~
2 ~~(i.e., the applicant owns 50 percent or more of another company), a joint venture in which the~~
3 ~~applicant is a member, or a company that shares common ownership with the applicant (i.e., the~~
4 ~~applicant and another company are owned by some of the same persons). "Operating room" means~~
5 ~~a room as defined in G.S. 131E-176(18c), and includes an inpatient operating room, an outpatient~~
6 ~~or ambulatory surgical operating room, or a shared operating room.~~
- 7 (10) ~~"Service area" means the Operating Room Service Area as defined in the applicable State Medical~~
8 ~~Facilities Plan. "Operating Room Need Methodology" means Steps 1 through 4 and Steps 6 and 7~~
9 ~~in the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 Annual State~~
10 ~~Medical Facilities Plan including subsequent amendments and editions, except as follows:~~
11 ~~(a) the applicant's most current Annual Licensure Renewal Application will be utilized in~~
12 ~~determining adjusted case times in Step 3, including any explanations regarding changes in case~~
13 ~~time in the Annual Licensure Renewal Application; and,~~
14 ~~(b) the applicant's most current Annual Licensure Renewal Application will be utilized in grouping~~
15 ~~facilities in Step 4;~~
- 16 (11) ~~"Shared operating room" means an operating room that is used for the performance of both~~
17 ~~ambulatory and inpatient surgical procedures. "Outpatient or ambulatory surgical operating room"~~
18 ~~means an operating room used solely for the performance of surgical procedures that require local,~~
19 ~~regional, or general anesthesia, and a period of post-operative observation of less than 24 hours.~~
- 20 (12) ~~"Specialty area" means an area of medical practice in which there is an approved medical specialty~~
21 ~~certificate issued by a member board of the American Board of Medical Specialties and includes~~
22 ~~the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology,~~
23 ~~urology, orthopedics, and oral surgery. "Service area" means the Operating Room Service Area as~~
24 ~~defined in Chapter 6 in the 2018 State Medical Facilities Plan.~~
- 25 (13) ~~"Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24c).~~
26 ~~"Shared operating room" means an operating room that is used for the performance of both~~
27 ~~ambulatory and inpatient surgical procedures.~~
- 28 (14) ~~"Surgical case" means an individual who receives one or more surgical procedures in an operating~~
29 ~~room during a single operative encounter. "Specialty ambulatory surgical program" means a~~
30 ~~program as defined in G.S. 131E-176(24f).~~
- 31 (15) ~~"Specialty area" means an area of medical practice in which there is an approved medical specialty~~
32 ~~certificate issued by a member board of the American Board of Medical Specialties and includes~~
33 ~~the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology,~~
34 ~~urology, orthopedics, and oral surgery.~~

35
36 *History Note:* Authority G.S. 131E-177(1); 131E-183(b);
37 *Eff. November 1, 1990;*

1 *Amended Eff. March 1, 1993;*
2 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
3 *becomes effective, whichever is sooner;*
4 *Amended Eff. January 4, 1994;*
5 *Temporary Amendment Eff. January 1, 1999;*
6 *Temporary Eff. January 1, 1999 Expired on October 12, 1999;*
7 *Temporary Amendment Eff. January 1, 2000;*
8 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*
9 *originally proposed to be effective August 2000;*
10 *Amended Eff. April 1, 2001;*
11 *Temporary Amendment Eff. January 1, 2002; July 1, 2001;*
12 *Amended Eff. August 1, 2002;*
13 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*
14 *August 1, 2002;*
15 *Amended Eff. April 1, 2003;*
16 *Temporary Amendment Eff. January 1, 2005;*
17 *Amended Eff. November 1, 2005;*
18 *Temporary Rule Eff. February 1, 2006;*
19 *Amended Eff. November 1, 2006;*
20 *Temporary Amendment Eff. February 1, 2008;*
21 *Amended Eff. November 1, ~~2008~~. 2008;*
22 *Temporary Amendment Eff. February 1, 2018.*

1 10A NCAC 14C .2103 is proposed for amendment under temporary procedures as follows:

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3 **10A NCAC 14C .2103 PERFORMANCE STANDARDS**

4 ~~(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and~~
5 ~~52 weeks a year.~~

6 ~~(b)(a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to~~
7 ~~establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-~~
8 ~~section operating rooms and operating rooms identified as needed in the Annual State Medical Facilities Plan as a~~
9 ~~result of a petition for an adjustment to need determination), to convert a specialty ambulatory surgical program to a~~
10 ~~multispecialty ambulatory surgical ~~program~~ program, or to add a specialty to a specialty ambulatory surgical program~~
11 ~~shall: shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be~~
12 ~~developed or expanded in the third operating year of the project based on the Operating Room Need Methodology, as~~
13 ~~defined in 10A NCAC 14C .2101 (10) set forth in the 2018 State Medical Facilities Plan including subsequent~~
14 ~~amendments and editions.~~

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

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

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

33 (B) ~~— in a service area which has 6 to 10 operating rooms, if the difference is a positive number~~
34 ~~greater than or equal to 0.3, then the need is the next highest whole number for fractions of~~
35 ~~0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the~~
36 ~~difference is a negative number or a positive number less than 0.3, then the need is zero;~~
37 ~~and~~

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

6 (e)-(b) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms and
 7 operating rooms identified as needed in the Annual State Medical Facilities Plan as a result of a petition for an
 8 adjustment to need determination) in a service area ~~shall~~ shall demonstrate the need for the number of proposed
 9 operating rooms in addition to the existing and approved operating rooms in all of the licensed facilities identified in
 10 response to 10A NCAC 14C .2102(b)(2) the applicant's health system in the service area in the third operating year
 11 of the proposed project based on the Operating Room Need Methodology , as defined in 10A NCAC 14C .2101 (10) set
 12 forth in the 2018 State Medical Facilities Plan including subsequent amendments and editions.

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

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

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

31 (B) — in a service area which has 6 to 10 operating rooms, if the difference is a positive number
 32 greater than or equal to 0.3, then the need is the next highest whole number for fractions of
 33 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the
 34 difference is a negative number or a positive number less than 0.3, then the need is zero;
 35 and

36 (C) — in a service area which has five or fewer operating rooms, if the difference is a positive
 37 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-, as defined in 10A NCAC 14C .2101 (10) set forth in the 2018 State Medical Facilities Plan including subsequent amendments and editions.~~

~~(f)~~(e) -A proposal to increase the number of operating rooms in a service area based upon a petition for an adjustment to need determination for additional 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 service area in the third operating year of the proposed project based on reasonable assumptions.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule, including:

(1) assumptions associated with the baseline data utilized in the projections;

(2) assumptions associated with the growth rate utilized in the projections; and,

(3) if the applicant's case times are more than one standard deviation above the mean for the relevant group as identified in Step 5 of the operating room methodology in the annual State Medical

1 Facilities Plan, the applicant shall provide documentation to justify the case times utilized in the
2 projections are reasonable.-

3 (4) if the applicant is a new provider, case time will be the mean for the relevant group as identified in
4 Step 5 of the operating room methodology in the annual State Medical Facilities Plan.

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6 *History Note: Authority G.S. 131E-177; 131E-183(b);*
7 *Eff. November 1, 1990;*
8 *Amended Eff. March 1, 1993;*
9 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
10 *becomes effective, whichever is sooner;*
11 *Amended Eff. January 4, 1994;*
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17 *Temporary Amendment Eff. January 1, 2005;*
18 *Amended Eff. November 1, 2005;*
19 *Temporary Rule Eff. February 1, 2006;*
20 *Amended Eff. November 1, 2006;*
21 *Temporary Amendment Eff. February 1, 2008;*
22 *Amended Eff. November 1, 2008;*
23 *Temporary Amendment Eff. February 1, 2009;*
24 *Amended Eff. November 1, 2009;*
25 *Temporary Amendment Eff. February 1, 2010;*
26 *Amended Eff. November 1, ~~2010~~ 2010;*
27 *Temporary Amendment Eff. February 1, 2018.*