

1 10A NCAC 14C .2101 is amended under temporary procedures with changes 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] Agency, but that~~
15 ~~have not 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~~ that were reported in the License Application for Ambulatory Surgical Facilities
23 ~~and Programs~~ Facility License Renewal Application Form and or in Part III of the Hospital
24 ~~Licensure~~ License Renewal Application Form submitted to the Acute and Home Care Licensure and
25 Certification Section of the Division of Health Service Regulation Regulation, and which that
26 licensed and 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 the Methodology for Projecting~~
9 ~~Operating Room Need in Chapter 6 in the 2018 State Medical Facilities Plan.~~
- 10 (11) ~~"Shared operating room" means an operating room that is used for the performance of both~~
11 ~~ambulatory and inpatient surgical procedures. "Outpatient or ambulatory surgical operating room"~~
12 ~~means an operating room used [solely] for the performance of surgical procedures that require local,~~
13 ~~regional, or general anesthesia, and a period of post-operative observation of less than 24 hours.~~
- 14 (12) ~~"Specialty area" means an area of medical practice in which there is an approved medical specialty~~
15 ~~certificate issued by a member board of the American Board of Medical Specialties and includes~~
16 ~~the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology,~~
17 ~~urology, orthopedics, and oral surgery. "Service area" means the Operating Room Service Area as~~
18 ~~defined in Chapter 6 in the 2018 State Medical Facilities Plan.~~
- 19 (13) ~~"Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24e).~~
20 ~~"Shared operating room" means an operating room that is used for the performance of both~~
21 ~~ambulatory and inpatient surgical procedures.~~
- 22 (14) ~~"Surgical case" means an individual who receives one or more surgical procedures in an operating~~
23 ~~room during a single operative encounter. "Specialty ambulatory surgical program" means a~~
24 ~~program as defined in G.S. 131E-176(24f).~~
- 25 (15) ~~"Specialty area" means an area of medical practice in which there is an approved medical specialty~~
26 ~~certificate issued by a member board of the American Board of Medical Specialties and includes~~
27 ~~the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology,~~
28 ~~urology, orthopedics, and oral surgery.~~

29
30 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
31 *Eff. November 1, 1990;*
32 *Amended Eff. March 1, 1993;*
33 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
34 *becomes effective, whichever is sooner;*
35 *Amended Eff. January 4, 1994;*
36 *Temporary Amendment Eff. January 1, 1999;*
37 *Temporary Eff. January 1, 1999 Expired on October 12, 1999;*

1 *Temporary Amendment Eff. January 1, 2000;*
2 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*
3 *originally proposed to be effective August 2000;*
4 *Amended Eff. April 1, 2001;*
5 *Temporary Amendment Eff. January 1, 2002; July 1, 2001;*
6 *Amended Eff. August 1, 2002;*
7 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*
8 *August 1, 2002;*
9 *Amended Eff. April 1, 2003;*
10 *Temporary Amendment Eff. January 1, 2005;*
11 *Amended Eff. November 1, 2005;*
12 *Temporary Rule Eff. February 1, 2006;*
13 *Amended Eff. November 1, 2006;*
14 *Temporary Amendment Eff. February 1, 2008;*
15 *Amended Eff. November 1, ~~2008~~. 2008;*
16 *Temporary Amendment Eff. February 1, 2018.*

1 10A NCAC 14C .2103 is amended with changes under temporary procedures as follows:

2
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), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical
9 ~~program program,~~ or to add a specialty to a specialty ambulatory surgical program ~~shall:~~ shall demonstrate the need
10 for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third
11 operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical
12 Facilities ~~Plan including subsequent amendments and editions,~~ Plan. The applicant is not required to use the
13 population growth factor.

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

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

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

32 (B) ~~— in a service area which has 6 to 10 operating rooms, if the difference is a positive number~~
33 ~~greater than or equal to 0.3, then the need is the next highest whole number for fractions of~~
34 ~~0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the~~
35 ~~difference is a negative number or a positive number less than 0.3, then the need is zero;~~
36 ~~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) in a
 7 service area ~~shall:~~ shall demonstrate the need for the number of proposed operating rooms in addition to the existing
 8 and approved operating rooms in ~~all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2)~~
 9 the applicant's health system in the third operating year of the proposed project based on the Operating Room Need
 10 Methodology set forth in the 2018 State Medical Facilities [Plan including subsequent amendments and editions:]
 11 Plan. The applicant is not required to use the population growth factor.

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

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

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

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

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

1 if the difference is a negative number or a positive number less than 0.2, then the need is
2 zero.

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

8 ~~(e)~~(d) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory
9 surgical program or to add a specialty area to a specialty ambulatory surgical program shall:

10 (1) provide documentation to show that each existing ambulatory surgery program in the service area
11 that performs ambulatory surgery in the same specialty area as proposed in the application is
12 currently utilized an average of at least ~~1,872~~ 1,312.5 hours per operating room per year, ~~excluding~~
13 ~~dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be~~
14 ~~calculated as follows: [(Number of projected inpatient cases, excluding open heart and C sections~~
15 ~~performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times~~
16 ~~1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section~~
17 ~~operating rooms; year; and~~

18 (2) demonstrate the need in the third operating year of the project based on the ~~following formula:~~
19 ~~[(Total number of projected outpatient cases for all ambulatory surgery programs in the service area~~
20 ~~times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed~~
21 ~~outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area.~~
22 ~~The need is demonstrated if the difference is a positive number greater than or equal to one, after~~
23 ~~the number is rounded to the next highest number for fractions of 0.50 or greater. Operating Room~~
24 ~~Need Methodology set forth in the 2018 State Medical Facilities [Plan including subsequent~~
25 ~~amendments and editions.] Plan. The applicant is not required to use the population growth factor.~~

26 ~~(f)~~(e) The applicant shall document the assumptions and provide data supporting the methodology used for each
27 projection in this Rule.

28
29 *History Note: Authority G.S. 131E-177; 131E-183(b);*

30 *Eff. November 1, 1990;*

31 *Amended Eff. March 1, 1993;*

32 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
33 *becomes effective, whichever is sooner;*

34 *Amended Eff. January 4, 1994;*

35 *Temporary Amendment Eff. January 1, 2002; July 1, 2001;*

36 *Amended Eff. August 1, 2002;*

1 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*
2 *August 1, 2002;*
3 *Amended Eff. April 1, 2003;*
4 *Temporary Amendment Eff. January 1, 2005;*
5 *Amended Eff. November 1, 2005;*
6 *Temporary Rule Eff. February 1, 2006;*
7 *Amended Eff. November 1, 2006;*
8 *Temporary Amendment Eff. February 1, 2008;*
9 *Amended Eff. November 1, 2008;*
10 *Temporary Amendment Eff. February 1, 2009;*
11 *Amended Eff. November 1, 2009;*
12 *Temporary Amendment Eff. February 1, 2010;*
13 *Amended Eff. November 1, ~~2010~~ 2010;*
14 *Temporary Amendment Eff. February 1, 2018.*