

1 10A NCAC 14C .2101 is amended as published in 33:03 NCR 137-140 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).~~ "Approved
9 operating rooms" means those operating rooms that were approved for a certificate of need by the
10 Healthcare Planning and Certificate of Need Section (Agency) prior to the date on which the
11 applicant's proposed project was submitted to the Agency, but that have not been licensed.
- 12 (2) ~~"Operating room" means a room as defined in G.S. 131E-176(18c), which includes an inpatient~~
13 ~~operating room, an outpatient or ambulatory surgical operating room, or a shared operating room.~~
14 "Dedicated C-section operating room" means an operating room as defined in Chapter 6 in the 2018
15 State Medical Facilities Plan. For purposes of this Section, Chapter 6 in the 2018 State Medical
16 Facilities Plan is hereby incorporated by reference including subsequent amendments and editions.
17 This document is available at no cost at <https://www.ncdhhs.gov/dhsr/ncsmfp/index.html>.
- 18 (3) ~~"Ambulatory surgical program" means a program as defined in G.S. 131E-176(1c).~~ "Existing
19 operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals that
20 were reported in the Ambulatory Surgical Facility License Renewal Application Form or in the
21 Hospital License Renewal Application Form submitted to the Acute and Home Care Licensure and
22 Certification Section of the Division of Health Service Regulation, and that were licensed prior to
23 the beginning of the review period.
- 24 (4) ~~"Dedicated cesarean section operating room" means an operating room as defined in the applicable~~
25 ~~State Medical Facilities Plan.~~ "Health System" shall have the same meaning as defined in Chapter
26 6 in the 2018 State Medical Facilities Plan.
- 27 (5) ~~"Existing operating rooms" means those operating rooms in ambulatory surgical facilities and~~
28 ~~hospitals which were reported in the License Application for Ambulatory Surgical Facilities and~~
29 ~~Programs and in Part III of Hospital Licensure Renewal Application Form submitted to the Acute~~
30 ~~and Home Care Licensure and Certification Section of the Division of Health Service Regulation~~
31 ~~and which were licensed and certified prior to the beginning of the review period.~~ "Operating room"
32 means a room as defined in G.S. 131E-176(18c).
- 33 (6) ~~"Approved operating rooms" means those operating rooms that were approved for a certificate of~~
34 ~~need by the Certificate of Need Section prior to the date on which the applicant's proposed project~~
35 ~~was submitted to the Agency but that have not been licensed.~~ "Operating Room Need Methodology"
36 means the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 State Medical
37 Facilities Plan.

- 1 (7) ~~"Multispecialty ambulatory surgical program" means a program as defined in G.S. 131E-176(15a).~~
 2 ~~"Service area" means the Operating Room Service Area as defined in Chapter 6 in the 2018 State~~
 3 ~~Medical Facilities Plan.~~
- 4 (8) ~~"Outpatient or ambulatory surgical operating room" means an operating room used solely for the~~
 5 ~~performance of surgical procedures which require local, regional or general anesthesia and a period~~
 6 ~~of post operative observation of less than 24 hours.~~
- 7 (9) ~~"Related entity" means the parent company of the applicant, a subsidiary company of the applicant~~
 8 ~~(i.e., the applicant owns 50 percent or more of another company), a joint venture in which the~~
 9 ~~applicant is a member, or a company that shares common ownership with the applicant (i.e., the~~
 10 ~~applicant and another company are owned by some of the same persons).~~
- 11 (10) ~~"Service area" means the Operating Room Service Area as defined in the applicable State Medical~~
 12 ~~Facilities Plan.~~
- 13 (11) ~~"Shared operating room" means an operating room that is used for the performance of both~~
 14 ~~ambulatory and inpatient surgical procedures.~~
- 15 (12) ~~"Specialty area" means an area of medical practice in which there is an approved medical specialty~~
 16 ~~certificate issued by a member board of the American Board of Medical Specialties and includes~~
 17 ~~the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology,~~
 18 ~~urology, orthopedics, and oral surgery.~~
- 19 (13) ~~"Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24c).~~
- 20 (14) ~~"Surgical case" means an individual who receives one or more surgical procedures in an operating~~
 21 ~~room during a single operative encounter.~~

22

23 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
 24 *Eff. November 1, 1990;*
 25 *Amended Eff. March 1, 1993;*
 26 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
 27 *becomes effective, whichever is sooner;*
 28 *Amended Eff. January 4, 1994;*
 29 *Temporary Amendment Eff. January 1, 1999;*
 30 *Temporary Eff. January 1, 1999 Expired on October 12, 1999;*
 31 *Temporary Amendment Eff. January 1, 2000;*
 32 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*
 33 *originally proposed to be effective August 2000;*
 34 *Amended Eff. April 1, 2001;*
 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, ~~2018.~~2018.*
11 *Amended Eff. December 1, 2018.*

1 10A NCAC 14C .2103 is amended as published in 33:03 NCR 137-140 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. An applicant proposing to increase the number of operating rooms (excluding dedicated C-section~~
6 ~~operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition~~
7 ~~to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year~~
8 ~~following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018~~
9 ~~State Medical Facilities Plan. The applicant is not required to use the population growth factor.~~

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

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

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

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

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

26 ~~(B) — in a service area which has 6 to 10 operating rooms, if the difference is a positive number~~
 27 ~~greater than or equal to 0.3, then the need is the next highest whole number for fractions of~~
 28 ~~0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the~~
 29 ~~difference is a negative number or a positive number less than 0.3, then the need is zero;~~
 30 ~~and~~

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

36 ~~(d) An applicant that has one or more existing or approved dedicated C section operating rooms and is proposing to~~
 37 ~~develop an additional dedicated C section operating room in the same facility shall demonstrate that an average of at~~

1 ~~least 365 C sections per room were performed in the facility's existing dedicated C section operating rooms in the~~
 2 ~~previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C~~
 3 ~~section rooms during the third year of operation following completion of the project.~~

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

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

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

20 ~~(f)(b)~~ The applicant shall document the assumptions and provide data supporting the methodology used for each
 21 projection in this Rule.

22
 23 *History Note: Authority G.S. 131E-177; 131E-183(b);*
 24 *Eff. November 1, 1990;*
 25 *Amended Eff. March 1, 1993;*
 26 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
 27 *becomes effective, whichever is sooner;*
 28 *Amended Eff. January 4, 1994;*
 29 *Temporary Amendment Eff. January 1, 2002; July 1, 2001;*
 30 *Amended Eff. August 1, 2002;*
 31 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*
 32 *August 1, 2002;*
 33 *Amended Eff. April 1, 2003;*
 34 *Temporary Amendment Eff. January 1, 2005;*
 35 *Amended Eff. November 1, 2005;*
 36 *Temporary Rule Eff. February 1, 2006;*
 37 *Amended Eff. November 1, 2006;*

1 *Temporary Amendment Eff. February 1, 2008;*
2 *Amended Eff. November 1, 2008;*
3 *Temporary Amendment Eff. February 1, 2009;*
4 *Amended Eff. November 1, 2009;*
5 *Temporary Amendment Eff. February 1, 2010;*
6 *Amended Eff. November 1, 2010;*
7 *Temporary Amendment Eff. February 1, ~~2018-2018~~;*
8 *Amended Eff. December 1, 2018.*