

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 27, 2012

PROJECT ANALYST: Michael J. McKillip

SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-8815-12 / WakeMed / Relocate two single specialty operating rooms from an ambulatory surgery center, Southern Eye Associates Ophthalmic Surgery Center, to WakeMed Raleigh Campus, and convert them to shared operating rooms, for a total 23 operating rooms at WakeMed Raleigh Campus / Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

The applicant, WakeMed, proposes to relocate two existing single specialty operating rooms from an ambulatory surgery center located on Lake Boone Trail in Raleigh, Southern Eye Associates Ophthalmic Surgery Center, to WakeMed Raleigh Campus, and convert them to shared operating rooms. Southern Eye Associates Ophthalmic Surgery Center is listed as a “chronically underutilized” facility in the table of “Underutilized Facilities: Excluded from the Need Determinations” on page 82 of the 2012 State Medical Facilities Plan (SMFP). The 2012 SMFP defines chronically underutilized facilities 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.” The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2012 SMFP. There are no policies in the 2012 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, WakeMed, proposes to relocate two existing single specialty operating rooms from an ambulatory surgery center located on Lake Boone Trail in Raleigh, Southern Eye Associates Ophthalmic Surgery Center, to WakeMed Raleigh Campus, and convert them to shared operating rooms. In Section II.1, pages 11-12, the applicant describes the proposed project as follows:

“In correspondence dated March 16, 2012, the Certificate of Need Section issued an Exemption from Review determination approving WakeMed’s acquisition of Southern Eye Associates Ophthalmic Surgery Center, which has two existing surgical operating rooms (please see Attachment 4 for correspondence between WakeMed and the CON Section). In this certificate of need application, WakeMed proposes to relocate these two operating rooms from their current location at 2801 Blue Ridge Road in Raleigh to WakeMed Raleigh Campus, and to convert these rooms from single-specialty ambulatory surgery to shared operating rooms....

The two operating rooms will be relocated to the existing surgical suite at WakeMed Raleigh Campus, in Operating Rooms 17 and 18, which are among the four ORs that will be vacated upon the opening of WakeMed Capital City Surgery Center (CCSC), an ambulatory surgery center located on Sunnybrook Road in Raleigh, adjacent to WakeMed Raleigh. CCSC will have a total of eight surgical operating rooms (approved in Project No. J-8364-09). Four of these ORs will be relocated from a previously-approved project (Project No. J-7350-05), with the other four ORs to be relocated from WakeMed Raleigh Campus, per Project No. J-8364-09.

The project will involve minor renovations to Operating Room 17 and 18 at WakeMed Raleigh Campus, two existing operating rooms within the surgical suite, along with equipment required to utilize these ORs. The project involves renovations to 942 square feet. No new construction is required. WakeMed Raleigh Campus has adequate pre-operative and recovery capacity and support space to accommodate the relocated operating rooms. At project completion, WakeMed Raleigh Campus will have a complement of 20 surgical operating rooms, in addition to 3 dedicated C-section ORs. WakeMed North, which is licensed under WakeMed Raleigh Campus, will continue to operate 4 ambulatory surgical ORs.”

Population to be Served

In Application Section III.6, the applicant provides projected patient origin for WakeMed Raleigh Campus operating rooms in the first two years of operation (FY2013 and FY2014), as shown in the table below.

| County | Percent of Total |
|---------------|-------------------------|
| Wake | 66.0% |
| Johnston | 9.67% |
| Franklin | 4.71% |
| Harnett | 4.12% |
| Nash | 2.25% |
| Sampson | 1.59% |
| Other* | 11.66% |
| TOTAL | 100.0% |

*The applicant lists the counties included in the “Other” category on pages 79-80 of the application.

On page 83 of the application, the applicant states, “*WakeMed anticipates no significant changes in patient origin as a result of this project, and believes that historic patient origin is the best predictor of future patient origin.*” See Section III.6, pages 78-83 of the application. The applicant adequately identified the population proposed to be served.

Need to Relocate the Two Operating Rooms

In Section III.1(b) of the application, the applicant describes the factors supporting the need for the proposed project, including, the historical utilization and capacity of WakeMed’s existing operating rooms (pp. 65-66), the need for shared operating rooms (pp. 66-68), the addition of surgeons to the medical staff at WakeMed Raleigh Campus (p. 68), and population growth and aging (pp. 68-72).

In Section IV.1, pages 91-92, the applicant provides tables showing the historical and projected utilization for the operating rooms at WakeMed Raleigh Campus and WakeMed North through the first three years of operation (FY2010-FY2015) for the proposed project, which is summarized below:

WakeMed Raleigh Campus Operating Room Utilization

| Year | Operating | Outpatient | Inpatient | Total | Percent |
|-------------|------------------|-------------------|------------------|--------------|----------------|
|-------------|------------------|-------------------|------------------|--------------|----------------|

| | Rooms* | Surgical Cases | Surgical Cases** | Surgical Cases | Change |
|--------|--------|----------------|------------------|----------------|--------|
| FY2010 | 18 | 9,042 | 7,021 | 16,063 | --- |
| FY2011 | 18 | 9,022 | 7,013 | 16,035 | -0.2% |
| FY2012 | 18 | 8,659 | 7,018 | 15,677 | -2.2% |
| FY2013 | 16 | 6,457 | 7,524 | 13,981 | -10.8% |
| FY2014 | 16 | 6,605 | 7,710 | 14,315 | 2.4% |
| FY2015 | 16 | 6,756 | 7,900 | 14,656 | 2.4% |

*Excludes four dedicated open heart surgery operating rooms and three dedicated C-Section surgical operating rooms. In FY2013, the applicant assumes four operating rooms will be relocated from WakeMed Raleigh Campus to Capital City Surgery Center (Project I.D. # J-8364-09), and two operating rooms will be relocated to WakeMed Raleigh Campus as a result of this project [18 – 4 + 2 = 16 shared operating rooms].

**Excludes surgical cases performed in the four dedicated open heart surgery operating rooms and three dedicated C-Section surgical operating rooms.

WakeMed North Operating Room Utilization

| Year | Operating Rooms* | Outpatient Surgical Cases | Inpatient Surgical Cases** | Total Surgical Cases | Percent Change |
|--------|------------------|---------------------------|----------------------------|----------------------|----------------|
| FY2010 | 4 | 3,520 | 0 | 3,520 | |
| FY2011 | 4 | 3,367 | 0 | 3,367 | -4.3% |
| FY2012 | 4 | 3,607 | 0 | 3,607 | 7.1% |
| FY2013 | 4 | 3,798 | 0 | 3,798 | 5.3% |
| FY2014 | 4 | 3,958 | 174 | 4,132 | 8.8% |
| FY2015 | 4 | 4,116 | 251 | 4,367 | 5.7% |

*Excludes one dedicated C-Section surgical operating room scheduled to be operational in FY2014 (Project I.D. # J-7843-07). Also, the applicant assumes the four ambulatory surgical operating rooms will be converted to shared operating rooms in FY2014 as part of Project I.D. # J-7843-07 and Project I.D. # J-8180-08.

**Excludes surgical cases performed in the dedicated C-Section surgical operating room.

On pages 36-48 of the application, the applicant describes its assumptions and methodology for projecting utilization of the operating rooms at WakeMed Raleigh Campus and WakeMed North as follows:

“Step-by-Step Operating Room Need Methodology Application

Step 1: Identify the group of counties that reasonably reflects the geographic market area for inpatient and outpatient surgery patients’ counties of origin as served by WakeMed Raleigh Campus, where the two operating rooms will be relocated, and WakeMed North, whose operating rooms are licensed under WakeMed Raleigh.

As a major health care system in central North Carolina, WakeMed provides an extensive range of tertiary-level services, including invasive cardiology, Level I trauma, pediatrics, neonatal intensive care, inpatient and outpatient rehabilitation, neurosurgery and neurosciences, and orthopaedic surgery.

Furthermore, WakeMed owns and operates one of North Carolina's largest patient transport services, including a fleet of critical care ground transport units and an air ambulance program. Because of this range of tertiary services, WakeMed provides services to patients in significant numbers from many North Carolina counties. In Calendar Year 2011, WakeMed Raleigh Campus treated surgical patients from 79 North Carolina counties, plus Out of State patients.

The following table [shown on page 38 of the application] provides a distribution of patients by county, in descending order, for surgery cases served at WakeMed Raleigh Campus in FY 2011. The definition of an appropriate functional geographic market area for WakeMed Raleigh's surgery services is based on this patient origin by county.

WakeMed's analysis of this patient origin distribution of surgery patients determined a natural break in case volumes occurs between the 16th and 17th ranked counties, given that the top 16 counties each had at least 50 cases. Accounting for approximately 96 percent of WakeMed Raleigh Campus surgery cases, these top 16 counties were selected as the appropriate group for purposes of assessing the market need/demand for WakeMed Raleigh Campus surgery services. Definition of this geographic market area minimizes the number of surgery cases that are to be projected from "Other" areas.

These 16 counties, and their proximity to existing WakeMed surgery programs, are highlighted in the following map [shown on page 39 of the application].

Step 2: For each of the counties identified in Step 1, obtain the most recent total population estimates and projections for the years 2010 through 2015 from the North Carolina Office of State Budget and Management (OSBM).

***Table II.10
Total Population by County for WakeMed Raleigh Campus Surgical Services***

Geographic Market Area, 2010-2015
Source: N.C. Office of State Budget and Management, State Demographer's Office
Updated: 9/1/2011

| <i>County</i> | <i>2010</i> | <i>2011</i> | <i>2012</i> | <i>2013</i> | <i>2014</i> | <i>2015</i> | <i>percent change 2010-15</i> |
|-------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------------------------|
| <i>Cumberland</i> | 326,673 | 333,592 | 340,032 | 345,979 | 351,471 | 356,543 | 9.1% |
| <i>Duplin</i> | 58,729 | 59,656 | 60,595 | 61,527 | 62,463 | 63,397 | 7.9% |
| <i>Durham</i> | 268,925 | 274,379 | 279,836 | 285,289 | 290,745 | 296,200 | 10.1% |
| <i>Franklin #</i> | 60,978 | 62,224 | 63,880 | 65,051 | 66,486 | 67,727 | 11.1% |
| <i>Granville</i> | 60,547 | 61,430 | 62,310 | 63,190 | 64,073 | 64,955 | 7.3% |
| <i>Halifax</i> | 54,627 | 54,388 | 54,145 | 53,905 | 53,664 | 53,423 | -2.2% |
| <i>Harnett #</i> | 115,579 | 119,211 | 122,844 | 126,480 | 130,113 | 133,746 | 15.7% |
| <i>Johnston #</i> | 170,151 | 175,194 | 180,240 | 185,282 | 190,328 | 195,372 | 14.8% |
| <i>Lee</i> | 58,059 | 58,838 | 59,617 | 60,399 | 61,178 | 61,957 | 6.7% |
| <i>Nash #</i> | 96,215 | 97,466 | 98,667 | 99,900 | 101,115 | 102,339 | 6.4% |
| <i>Orange</i> | 134,325 | 136,438 | 138,550 | 140,660 | 142,772 | 144,885 | 7.9% |
| <i>Sampson #</i> | 63,481 | 63,655 | 63,826 | 64,000 | 64,172 | 64,345 | 1.4% |
| <i>Vance</i> | 45,477 | 45,682 | 45,888 | 46,094 | 46,300 | 46,507 | 2.3% |
| <i>Wake^</i> | 907,314 | 932,665 | 958,015 | 983,367 | 1,008,719 | 1,034,069 | 14.0% |
| <i>Wayne #</i> | 122,893 | 123,726 | 124,558 | 125,389 | 126,221 | 127,053 | 3.4% |
| <i>Wilson #t</i> | 81,643 | 82,423 | 83,148 | 83,874 | 84,598 | 85,323 | 4.5% |
| <i>Geographic Market Area Total</i> | 2,625,616 | 2,680,967 | 2,736,151 | 2,790,386 | 2,844,418 | 2,897,841 | 10.4% |

*Note: The symbol “^” denotes primary service area county
 The symbol “#” denotes secondary service area county*

*The total population of the geographic market area is **projected to increase by** [emphasis in original] 10.4 percent from 2010-2015, with growth concentrated in Wake County and contiguous counties of Durham, Franklin, Harnett and Johnston.*

Because WakeMed forecasts that Project Years 1-3 will be FYs 2013-2015, it is useful to calculate the compound annual growth rate (CAGR) for each county for the years 2012-2015 (2012 is the baseline year). Please see the table below

Table II.11
Total Population Compound Annual Growth
Rate by County, 2012-2015

**Based on Projections from OSBM in Table 11.10
 (Rounded to 4 decimal places)**

| County | Total Population CAGR, 2012-15 |
|-------------------------------------|---|
| <i>Cumberland</i> | <i>1.5931%</i> |
| <i>Duplin</i> | <i>1.5182%</i> |
| <i>Durham</i> | <i>1.9124%</i> |
| <i>Franklin #</i> | <i>1.9684%</i> |
| <i>Granville</i> | <i>1.3954%</i> |
| <i>Halifax</i> | <i>-0.4465%</i> |
| <i>Harnett #</i> | <i>2.8748%</i> |
| <i>Johnston #</i> | <i>2.7236%</i> |
| <i>Lee</i> | <i>1.2916%</i> |
| <i>Nash #</i> | <i>1.2255%</i> |
| <i>Orange</i> | <i>1.5015%</i> |
| <i>Sampson #</i> | <i>0.2703%</i> |
| <i>Vance</i> | <i>0.4476%</i> |
| <i>Wake ^</i> | <i>2.5791%</i> |
| <i>Wayne #</i> | <i>0.6633%</i> |
| <i>Wilson #</i> | <i>0.8644%</i> |
| Geographic Market Area Total | 1.9322% |

Note: The symbol “^” denotes primary service area county
 The symbol “#” denotes secondary service area county

Approximately 96 percent of WakeMed Raleigh Campus’s surgery patients originate from the 16-county geographic market area defined above. However, approximately 91 percent of total surgery patients originate from the 8-county primary and secondary service areas — the population of these counties is generally growing more rapidly than the other counties in the remainder of the geographic service area. The total population of the primary and secondary service areas is projected to increase 6.8 percent from 2012-2015, compared with only 4.5 percent for the remaining non-service area counties in the geographic market area.

To more accurately reflect the service area counties’ population growth and contribution to patient origin, WakeMed multiplied each county’s population CAGR by its percent of total surgery patient origin at WakeMed Raleigh Campus. This method ‘weights’ each county’s population growth by its proportion of surgery patient origin, placing greater emphasis on counties that contribute higher proportions of surgery patients, as well as counties that are experiencing higher population growth. For instance, Wake County contributes 66 percent of WakeMed Raleigh’s surgery patients, and has a population CAGR of 2.5791 percent — the method credits Wake County for its high proportion of surgery patients and its projected high population growth. Please see the table below.

Table II.12
Total Population CAGR by County Weighted by
WakeMed Raleigh Campus Surgery Percent Patient Origin
(Rounded to 4 decimal places)

| <i>Column:</i> | <i>1</i> | <i>2</i> | <i>3 = (1 x 2)</i> |
|-------------------------------------|---|--|---|
| <i>County</i> | <i>Total Population CAGR, 2012-15</i> | <i>CY2011 WakeMed Raleigh Surgery Patient Origin</i> | <i>Population CAGR x Percent Patient Origin</i> |
| <i>Cumberland</i> | <i>1.5931%</i> | <i>0.67%</i> | <i>0.0107%</i> |
| <i>Duplin</i> | <i>1.5182%</i> | <i>0.39%</i> | <i>0.0059%</i> |
| <i>Durham</i> | <i>1.9124%</i> | <i>0.66%</i> | <i>0.0126%</i> |
| <i>Franklin #</i> | <i>1.9684%</i> | <i>4.71%</i> | <i>0.0927%</i> |
| <i>Granville</i> | <i>1.3954%</i> | <i>0.98%</i> | <i>0.0137%</i> |
| <i>Halifax</i> | <i>-0.4465%</i> | <i>0.79%</i> | <i>-0.0035%</i> |
| <i>Harnett #</i> | <i>2.8748%</i> | <i>4.12%</i> | <i>0.1183%</i> |
| <i>Johnston #</i> | <i>2.7236%</i> | <i>9.67%</i> | <i>0.2635%</i> |
| <i>Lee</i> | <i>1.2916%</i> | <i>0.44%</i> | <i>0.0056%</i> |
| <i>Nash #</i> | <i>1.2255%</i> | <i>2.25%</i> | <i>0.0275%</i> |
| <i>Orange</i> | <i>1.5015%</i> | <i>0.29%</i> | <i>0.0044%</i> |
| <i>Sampson #</i> | <i>0.2703%</i> | <i>1.59%</i> | <i>0.0943%</i> |
| <i>Vance</i> | <i>0.4476%</i> | <i>0.65%</i> | <i>0.0029%</i> |
| <i>Wake ^</i> | <i>2.5791%</i> | <i>66.00%</i> | <i>1.7023%</i> |
| <i>Wayne #</i> | <i>0.6633%</i> | <i>1.28%</i> | <i>0.0085%</i> |
| <i>Wilson #</i> | <i>0.8644%</i> | <i>1.27%</i> | <i>0.0110%</i> |
| <i>Geographic Market Area Total</i> | | | <i>2.2804%</i> |

*Note: The symbol “^” denotes primary service area county
 The symbol “#” denotes secondary service area county*

Overall, when the weighted CAGRs for the geographic market area are totaled, the result is a projected weighted growth rate for the geographic market area counties of 2.2804 percent for 2012-2015.

Step 3: Obtain WakeMed Raleigh Campus and WakeMed North Health plex surgical volumes for FYs 2008-2011 from Licensure Renewal Applications on file at the Division of Health Service Regulation, and prorated FY 2012 surgical volumes for both facilities from WakeMed internal data, based on five months’ data.

| Table II.13 | | | | |
|---|----------------|----------------|----------------|----------------|
| Surgery Volumes at WakeMed Raleigh and WakeMed North | | | | |
| Excluding C-Section Cases | | | | |
| FY5 2008-2012 | | | | |
| Fiscal Year | WakeMed | WakeMed | WakeMed | WakeMed |

| | Raleigh Inpatient Cases | Raleigh Outpatient Cases | North Inpatient Cases | North Outpatient Cases |
|--------------------------|--|---|--------------------------------------|---------------------------------------|
| 2008 | 8,395 | 9,165 | 0 | 3,820 |
| 2009 | 7,839 | 9,334 | 0 | 3,843 |
| 2010 | 7,898 | 9,042 | 0 | 3,520 |
| 2011 | 7,788 | 9,022 | 0 | 3,367 |
| 2012 (5 mos. annualized) | 7,797 | 8,659 | 0 | 3,607 |

Step 4: Apply weighted compound annual growth rate (CAGR) (from Step 2) for total population for the geographic market area to surgery volumes at WakeMed Raleigh Campus and WakeMed North for Project Years 1-3 (FYs 2013-2015).

WakeMed Raleigh Campus derives approximately 96 percent of its total surgery patients from the 16-county geographic market area defined in Step 1. However, WakeMed Raleigh gets 91 percent of its surgical patients from its 8-county primary and secondary service area. Therefore, a conservative method of projecting surgery volume would be to apply the weighted total population CAGR for the 16-county region, calculated at approximately 2.2804 percent in Step 2, to the Project Year 1-3 surgical volumes at WakeMed Raleigh Campus and WakeMed North.

WakeMed North Healthplex currently provides only outpatient surgery. In FY 2015, WakeMed plans to operationalize 61 acute care beds at WakeMed North (approved in Project Nos. J-7843-07 and J-8180-08). WakeMed North's four surgical operating rooms will transition from outpatient-only to shared inpatient/outpatient at this time. Surgery projections for WakeMed North are consistent with projections made in earlier CON applications.

Table II.14
WakeMed Raleigh Campus
Projected Surgery Cases from Geographic Market Area
Project Years 1-3 (FY's 2013-2015)

| Fiscal Year | Inpatient Cases | Outpatient Cases | Total Cases |
|--------------------|----------------------------|-----------------------------|------------------------|
| 2012-current year | 7,797 | 8,659 | 16,456 |
| 2013-Year 1 | 7,975 | 8,856 | 16,831 |
| 2014-Year 2 | 8,157 | 9,058 | 17,215 |
| 2015-Year 3 | 8,343 | 9,265 | 17,608 |

Step 5: Apply percentage factor to account for Out of Area cases during Project Years 1-3.

The weighted total population CAGR calculated in Step 3 accounts for only 96 percent of Raleigh Campus surgery patient origin. In order to accurately factor in the out-of-area patient origin, projected cases from the geographic

market area in Step 5 are multiplied by 0.04167 (the inverse of 0.96). Please see the table below.

Table II.15
WakeMed Raleigh Campus
Projected Surgery Cases from Geographic Market Area and Out Of Area
Project Years 1-3 (FY5 2013-2015)
Excluding Cases Performed in Dedicated C-Section Rooms
Out of Area cases calculated by multiplying Geographic Market Area
cases by 0.04 167

| Fiscal Year | Inpatient Cases | Outpatient Cases | Total Cases |
|--|------------------------|-------------------------|--------------------|
| Cases from Geographic Market Area - From Step 4 (from Table II.14) | | | |
| 2013-Year 1 | 7,975 | 8,856 | 16,831 |
| 2014-Year 2 | 8,157 | 9,058 | 17,215 |
| 2015-Year 3 | 8,343 | 9,265 | 17,608 |
| Step 5 -- Cases from Out Of Area | | | |
| 2013-Year 1 | 332 | 369 | 701 |
| 2014-Year 2 | 340 | 377 | 717 |
| 2015-Year 3 | 348 | 386 | 734 |
| Grand Total Surgery Cases (Geographic Market Area plus Out Of Area) | | | |
| 2013-Year 1 | 8,307 | 9,225 | 17,532 |
| 2014-Year 2 | 8,497 | 9,435 | 17,932 |
| 2015-Year 3 | 8,691 | 9,651 | 18,342 |

Step 6: Project the impact of WakeMed Capital City Surgery Center on outpatient surgical utilization at WakeMed Raleigh Campus.

In mid-2012, WakeMed Capital City Surgery Center (CCSC) (Project No. J-8364-09) will open with 8 multispecialty ambulatory surgical operating rooms: 4 ORs relocated from WakeMed Apex Surgery Center (Project No. J-7350-05) and 4 ORs relocated from WakeMed Raleigh Campus. This new facility, located adjacent to WakeMed Raleigh, will provide a convenient, accessible location for ambulatory surgery in central Raleigh. In Project No. J-8364-09, CCSC was envisioned to accommodate up to two-thirds of the outpatient surgery cases performed at WakeMed Raleigh Campus, allowing for fewer schedule disruptions and providing a venue for physicians who prefer to perform their outpatient surgery cases in a non-hospital setting.

During the development of CCSC, it became apparent that the potential impact of this shift had been overestimated. To date, a total of 22 surgeons have invested in CCSC; the majority of these physicians have historically not performed their surgical cases at WakeMed facilities. Surgeons who currently perform their inpatient and outpatient cases at WakeMed Raleigh Campus

have indicated that they intend to shift relatively few of their outpatient surgical cases to CCSC. Therefore, the percentage reduction in outpatient surgery cases at WakeMed Raleigh Campus resulting from the opening of CCSC has been reduced to from 65 percent to 30 percent. WakeMed believes the impact of this shift will be felt in FY 2013, the first full year of operation of CCSC. The growth in surgery volume at CCSC will be fueled by the physician investors, as well as by this more moderate shift in cases.

The impact of CCSC on WakeMed Raleigh's outpatient surgical case volume is shown in the following table.

Table II.16
WakeMed Raleigh Campus
Projection of Outpatient Surgery Cases Shifted to Capital City Surgery Center

| <i>Column:</i> | <i>1</i> | <i>2</i> | <i>3 = (1 - 2)</i> |
|--------------------|---|---|---|
| Fiscal Year | Projected Outpatient Surgery Cases at WakeMed Raleigh (from Table II.15) | Cases Projected to be Shifted to CCSC (30% of total) | Outpatient Surgery Cases That Will Remain at WakeMed Raleigh |
| 2013-Year 1 | 9,225 | 2,767 | 6,458 |
| 2014-Year 2 | 9,435 | 2,830 | 6,605 |
| 2015-Year 3 | 9,651 | 2,895 | 6,756 |

Overall inpatient and outpatient surgery volume at WakeMed Raleigh Campus is projected to grow 2.2804 percent per year through FY 2015. Outpatient surgery at WakeMed Raleigh is reduced by 30 percent in FY 2013, to reflect the opening of CCSC and corresponding shift of outpatient cases to that facility.

Table II.17
Surgery Volumes at WakeMed Raleigh and WakeMed North
Project Years 1-3 (FY5 2013-2015)
Excluding Cases Performed in Dedicated C-Section Rooms

| Fiscal Year | WakeMed Raleigh Campus | | | WakeMed North | | |
|--------------------|-------------------------------|-------------------------|--------------------|------------------------|-------------------------|--------------------|
| | Inpatient Cases | Outpatient Cases | Total Cases | Inpatient Cases | Outpatient Cases | Total Cases |
| | | | | | | |

| | <i>(from Table II.15)</i> | <i>(from Table II.16)</i> | | | | |
|--------------------|---------------------------|---------------------------|--------|-----|-------|-------|
| <i>2013-Year 1</i> | 8,307 | 6,458 | 14,765 | 0 | 3,798 | 3,798 |
| <i>2014-Year 2</i> | 8,497 | 6,605 | 15,102 | 174 | 3,958 | 4,132 |
| <i>2015-Year 3</i> | 8,691 | 6,756 | 15,447 | 251 | 4,116 | 4,367 |

Step 7: Project trauma cases and cases performed in dedicated open heart surgery operating rooms in Years 1-3 from the total surgical cases projected in Step 4, and exclude these from the projected totals.

WakeMed Raleigh Campus is a Level 1 Trauma Center, and as such, treats a significant number of trauma cases in its operating rooms each year, although the volume fluctuates each year; in other words, there is no consistent trend in trauma cases. Trauma surgery cases do not necessarily correlate with the overall number of trauma patients that present each year. Given the unpredictable nature of trauma services, it is difficult to project trauma surgical cases on an annual basis. Over the last few years, WakeMed Raleigh has averaged approximately 350 trauma surgery cases. For this methodology, WakeMed conservatively projects 350 annual trauma surgery cases each for the current year (FY 2012) and for Years 1-3 (FYs 2013-2015), and excludes these from the inpatient surgery total below.

As North Carolina's busiest heart program, WakeMed Raleigh Campus routinely ranks among the state's leading providers of open heart surgery, and is licensed for four dedicated open heart surgery operating rooms. In FY 2011, WakeMed Raleigh Campus performed 775 open heart surgery cases in its dedicated open heart ORs. WakeMed projects that open heart surgery will grow at a nominal rate of 0.5% per year through FY 2015. In the table below, these open heart cases are projected for FYs 2012-2015 and excluded from WakeMed Raleigh's inpatient surgery case totals.

Table II.18
WakeMed Raleigh Campus
Inpatient Surgery - Exclusion of Trauma Cases and Cases Performed in
Dedicated Open Heart Surgery Operating Rooms
Project Years 1-3 (FY5 2013-2015)

| <i>Column:</i> | <i>1</i> | <i>2</i> | <i>3</i> | <i>4=(1-2-3)</i> |
|--------------------|--------------|---------------|----------------------|------------------------|
| <i>Fiscal Year</i> | Total | Trauma | Surgery Cases | Total Inpatient |

| | <i>Inpatient Surgery Cases</i> | <i>Surgery Cases</i> | <i>Performed in Dedicated Open Heart ORs</i> | <i>Cases minus Trauma & Open Heart Cases</i> |
|-------------|--|--------------------------|--|--|
| 2013-Year 1 | 8,307 | 350 | 783 | 7,174 |
| 2014-Year 2 | 8,497 | 350 | 787 | 7,360 |
| 2015-Year 3 | 8,691 | 350 | 791 | 7,550 |

Step 8: Calculate surgical volumes at WakeMed Raleigh Campus and WakeMed North Healthplex for Project Years 1-3, excluding trauma cases and cases performed in dedicated open heart surgery operating rooms, as well as outpatient cases shifted to CCSC.

The table below summarizes projected inpatient and outpatient surgery volumes at WakeMed Raleigh Campus and WakeMed North in the current year (FY 2012) and in Years 1-3 (FY 2013-2015).

Table II.19
Surgery Volumes at WakeMed Raleigh and WakeMed North
Project Years 1-3 (FYs 2013-2015)
Excludes Cases Performed in Dedicated Open Heart ORs, Trauma Cases, and Cases Performed
in Dedicated C-Section Rooms
Excludes Outpatient Cases Shifted to CCSC

| <i>Fiscal Year</i> | <i>WakeMed Raleigh Campus</i> | | | <i>WakeMed North</i> | | |
|--------------------|---|--|------------------------|----------------------------|-----------------------------|------------------------|
| | <i>Inpatient Cases (from Table II.18)</i> | <i>Outpatient Cases (from Table II.16)</i> | <i>Total Cases</i> | <i>Inpatient Cases</i> | <i>Outpatient Cases</i> | <i>Total Cases</i> |
| 2013-Year 1 | 7,174 | 6,458 | 13,632 | 0 | 3,798 | 3,798 |
| 2014-Year 2 | 7,360 | 6,605 | 13,965 | 174 | 3,958 | 4,132 |
| 2015-Year 3 | 7,550 | 6,756 | 14,306 | 251 | 4,116 | 4,367 |

Operating Room Methodology Assumptions

- The first step in the methodology developed a database of surgery patients originating from the 16-county market area for FYs 2008-2011. To ensure a valid analysis, C-sections, open heart surgery and minor procedure cases were excluded.*
- With the opening of the proposed WakeMed Capital City Surgery Center (Project No. J-8364-09) in FY 2013, WakeMed Raleigh Campus will experience a 30 percent reduction in outpatient surgery volume.*
- WakeMed Raleigh surgical cases are projected to grow by 2.2804 percent per year, per the weighted population CAGR calculated in Step 2.*
- WakeMed anticipates that inpatient surgery cases performed in*

dedicated open heart surgery ORs will increase by 0.5 percent per year, a function of the increased number of acute care beds at WakeMed Raleigh Campus and development of new emergency department capacity at WakeMed Brier Creek Healthplex in north Raleigh and WakeMed South Healthplex in Garner.

- *WakeMed North will continue to perform only outpatient surgery until FY 2014, when inpatient beds open at that facility and its four operating room transition to shared inpatient/outpatient ORs. Projections for inpatient surgery are consistent with projections made in previous CON applications involving inpatient beds at WakeMed North.*

The following table shows a summary of the historical and projected surgical case volumes (excluding C-Section cases and open heart surgery cases and operating rooms) for both WakeMed Raleigh Campus and WakeMed North Healthplex combined through the first three operating years following completion of the proposed project. For WakeMed Raleigh Campus, total number of operating rooms listed excludes four dedicated open heart surgery operating rooms and three dedicated C-Section surgical operating rooms. Also, in FY2013, the applicant assumes four operating rooms will be relocated from WakeMed Raleigh Campus to Capital City Surgery Center (Project I.D. # J-8364-09), and two operating rooms will be relocated to WakeMed Raleigh Campus as a result of this project [18 – 4 + 2 = 16 shared operating rooms]. For WakeMed North Healthplex, totals exclude one dedicated C-Section surgical operating room scheduled to be operational in FY2014 (Project I.D. # J-7843-07). Also, the applicant assumes the four ambulatory surgical operating rooms WakeMed North will be converted to shared operating rooms in FY2014 as part of Project I.D. # J-7843-07 and Project I.D. # J-8180-08.

**WakeMed Raleigh Campus and WakeMed North Healthplex Combined
 Historical and Projected Operating Room Utilization**

| Year | Operating Rooms* | Outpatient Surgical Cases | Inpatient Surgical Cases** | Total Surgical Cases | Percent Change |
|---------------|-------------------------|----------------------------------|-----------------------------------|-----------------------------|-----------------------|
| FY2008 Actual | 22 | 12,985 | 7,471 | 20,456 | --- |
| FY2009 Actual | 22 | 13,177 | 7,005 | 20,182 | -1.3% |
| FY2010 Actual | 22 | 12,562 | 7,021 | 19,583 | -3.0% |
| FY2011 Actual | 22 | 12,389 | 7,013 | 19,402 | -0.9% |

| | | | | | |
|------------------|----|--------|-------|--------|-------|
| FY2012 Projected | 22 | 12,266 | 7,018 | 19,284 | -0.6% |
| FY2013 Year 1 | 20 | 10,255 | 7,524 | 17,779 | -7.8% |
| FY2014 Year 2 | 20 | 10,563 | 7,884 | 18,447 | 3.8% |
| FY2015 Year 3 | 20 | 10,872 | 8,151 | 19,023 | 3.1% |

Source: FY2008-FY2011 data are from WakeMed's *Hospital License Renewal Application* for the years 2009-2012. FY2012-FY2015 data are from Section IV.1, pages 91-92 of the application.

*See discussion above regarding the number and types of operating rooms projected to be operational at WakeMed Raleigh Campus and WakeMed North Healthplex by fiscal year.

**Excludes surgical cases performed in the four dedicated open heart surgery operating rooms and three dedicated C-Section surgical operating rooms at WakeMed Raleigh Campus, as well as the one dedicated C-Section surgical operating rooms to be developed at WakeMed North.

As indicated in the above table, the applicant projects it will perform 8,151 inpatient surgical cases and 10,872 outpatient surgical cases in the 20 shared operating rooms at WakeMed Raleigh Campus and WakeMed North Healthplex in the third operating year of the proposed project (FY2015). Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be 22 [(10,872 X 1.5 hours) + (8,151 X 3.0 hours) = 40,761 hours; 40,761 hours/1,872 hours = 21.8].

However, in "Step 5" of the methodology, the applicant inappropriately projects additional surgical cases for "out of area" patients that were already included in the baseline FY2012 surgical case volumes from which the applicant projects its utilization, resulting in an overstatement of surgical case volumes in the future periods. The following tables show the revised utilization projections for WakeMed Raleigh Campus and WakeMed North Healthplex with "Step 5" omitted from the methodology.

**WakeMed Raleigh Campus
 Projected Surgery Cases from Geographic Market Area
 Excluding Out of Area Cases (Applicant's "Step 5")**

| Fiscal Year | Inpatient Cases | Outpatient Cases | Total Cases |
|-------------|-----------------|------------------|-------------|
| 2013-Year 1 | 7,975 | 8,856 | 16,831 |
| 2014-Year 2 | 8,157 | 9,058 | 17,215 |
| 2015-Year 3 | 8,343 | 9,265 | 17,608 |

**Revised Projections for Applicant's "Step 6"
 WakeMed Raleigh Campus
 Projected Outpatient Surgery Cases to Shift to Capital City Surgery Center**

| Fiscal Year | Projected Outpatient Surgery Cases at WakeMed Raleigh | Cases Projected to be Shifted to CCSC (30% of total) | Outpatient Surgery Cases Remaining at WakeMed Raleigh |
|-------------|---|--|---|
| | | | |

| | | | |
|-------------|-------|-------|-------|
| 2013-Year 1 | 8,856 | 2,657 | 6,199 |
| 2014-Year 2 | 9,058 | 2,717 | 6,341 |
| 2015-Year 3 | 9,265 | 2,780 | 6,485 |

**Revised Total Projected Surgery Cases at WakeMed Raleigh Campus
 Excluding Out of Area Cases (Applicant's "Step 5")**

| Fiscal Year | Inpatient Cases | Outpatient Cases | Total Cases |
|-------------|-----------------|------------------|-------------|
| 2013-Year 1 | 7,975 | 6,199 | 14,174 |
| 2014-Year 2 | 8,157 | 6,341 | 14,498 |
| 2015-Year 3 | 8,343 | 6,485 | 14,828 |

Revised "Step 7"

**Total Projected Inpatient Surgery Cases at WakeMed Raleigh Campus
 Excluding Trauma Surgery Cases and Surgery Cases Performed in Open Heart Surgery ORs**

| Fiscal Year | Inpatient Cases | Trauma Surgery Cases | Surgery Cases in Open Heart Surgery ORs | Total Inpatient Cases minus Trauma and Open Heart |
|-------------|-----------------|----------------------|---|---|
| 2013-Year 1 | 7,975 | 350 | 783 | 6,842 |
| 2014-Year 2 | 8,157 | 350 | 787 | 7,020 |
| 2015-Year 3 | 8,343 | 350 | 791 | 7,202 |

Revised "Step 8"

**Total Projected Surgery Cases at WakeMed Raleigh Campus and WakeMed North Healthplex
 Excluding Trauma Surgery Cases, Surgery Cases Performed in Open Heart Surgery ORs, and
 Outpatient Cases Shifted to CCSC**

| Fiscal Year | WakeMed Raleigh Campus | | | WakeMed North | | |
|-------------|------------------------|------------------|-------------|-----------------|------------------|-------------|
| | Inpatient Cases | Outpatient Cases | Total Cases | Inpatient Cases | Outpatient Cases | Total Cases |
| 2013-Year 1 | 6,842 | 6,199 | 13,041 | 0 | 3,798 | 3,798 |
| 2014-Year 2 | 7,020 | 6,341 | 13,361 | 174 | 3,958 | 4,132 |
| 2015-Year 3 | 7,202 | 6,485 | 13,687 | 251 | 4,116 | 4,367 |

The following table shows a summary of the historical and revised projected surgical case volumes (excluding C-Section cases and open heart surgery cases and operating rooms) for both WakeMed Raleigh Campus and WakeMed North Healthplex combined through the first three operating years following completion of the proposed project.

**WakeMed Raleigh Campus and WakeMed North Healthplex Combined
 Historical and Revised Projected Operating Room Utilization**

| Year | Operating Rooms* | Outpatient Surgical Cases | Inpatient Surgical Cases** | Total Surgical Cases | Percent Change |
|------|------------------|---------------------------|----------------------------|----------------------|----------------|
|------|------------------|---------------------------|----------------------------|----------------------|----------------|

| | | | | | |
|--------|----|--------|-------|--------|--------|
| FY2008 | 22 | 12,985 | 7,471 | 20,456 | --- |
| FY2009 | 22 | 13,177 | 7,005 | 20,182 | -1.3% |
| FY2010 | 22 | 12,562 | 7,021 | 19,583 | -3.0% |
| FY2011 | 22 | 12,389 | 7,013 | 19,402 | -0.9% |
| FY2012 | 22 | 12,266 | 7,018 | 19,284 | -0.6% |
| FY2013 | 20 | 9,997 | 6,842 | 16,839 | -12.7% |
| FY2014 | 20 | 10,299 | 7,194 | 17,493 | 3.9% |
| FY2015 | 20 | 10,601 | 7,453 | 18,054 | 3.2% |

Source: FY2008-FY2011 data are from WakeMed’s *Hospital License Renewal Application* for the years 2009-2012. FY2012-FY2015 data are from Section IV.1, pages 91-92 of the application, revised to exclude the applicant’s “Step 5” from the methodology..

*For WakeMed Raleigh Campus, totals exclude four dedicated open heart surgery operating rooms and three dedicated C-Section surgical operating rooms. In FY2013, the applicant assumes four operating rooms will be relocated from WakeMed Raleigh Campus to Capital City Surgery Center (Project I.D. # J-8364-09), and two operating rooms will be relocated to WakeMed Raleigh Campus as a result of this project [18 – 4 + 2 = 16 shared operating rooms]. For WakeMed North Healthplex, totals exclude one dedicated C-Section surgical operating room scheduled to be operational in FY2014 (Project I.D. # J-7843-07). Also, the applicant assumes the four ambulatory surgical operating rooms WakeMed North will be converted to shared operating rooms in FY2014 as part of Project I.D. # J-7843-07 and Project I.D. # J-8180-08.

**Excludes surgical cases performed in the four dedicated open heart surgery operating rooms and three dedicated C-Section surgical operating rooms at WakeMed Raleigh Campus, as well as the one dedicated C-Section surgical operating rooms to be developed at WakeMed North.

The revised inpatient and outpatient surgical utilization projections for WakeMed Raleigh Campus and WakeMed North following correction of the applicant’s error are shown below.

Revised Inpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|-------|
| FY2013-Project Year 1 | 6,842 | 0 | 6,842 |
| FY2014-Project Year 2 | 7,020 | 174 | 7,194 |
| FY2015-Project Year 3 | 7,202 | 251 | 7,453 |

Revised Outpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|--------|
| FY2013-Project Year 1 | 6,199 | 3,798 | 9,997 |
| FY2014-Project Year 2 | 6,341 | 3,958 | 10,299 |
| FY2015-Project Year 3 | 6,485 | 4,116 | 10,601 |

As indicated in the above table, after revising the applicant’s projections to exclude “Step 5” of the methodology, the applicant is projected to perform 7,453 inpatient surgical cases and 10,601

outpatient surgical cases in the 20 shared operating rooms at WakeMed Raleigh Campus and WakeMed North Healthplex in the third operating year of the proposed project (FY2015). Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be 20 $[(10,601 \times 1.5 \text{ hours}) + (7,453 \times 3.0 \text{ hours}) = 38,261 \text{ hours}; 38,261 \text{ hours}/1,872 \text{ hours} = 20.4]$.

In its 2012 Hospital License Renewal Application, WakeMed reported that it performed 7,013 inpatient surgical cases (excluding C-Section and open heart surgery procedures) and 12,389 outpatient surgical cases in the 22 existing operating rooms at WakeMed Raleigh Campus (18 shared operating rooms) and WakeMed North Healthplex (4 outpatient operating rooms) in FY2011. Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be 21 $[(12,389 \times 1.5 \text{ hours}) + (7,013 \times 3.0 \text{ hours}) = 39,623 \text{ hours}; 39,623 \text{ hours}/1,872 \text{ hours} = 21.2]$. In its 2012 Hospital License Renewal Application, WakeMed Cary Hospital reported that it performed 1,961 inpatient surgical cases (excluding C-Section procedures) and 6,145 outpatient surgical cases in the 9 existing shared operating rooms at the hospital in FY2011. Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required at WakeMed Cary Hospital would be 8 $[(6,145 \times 1.5 \text{ hours}) + (1,961 \times 3.0 \text{ hours}) = 15,101 \text{ hours}; 15,101 \text{ hours}/1,872 \text{ hours} = 8.1]$. Therefore, based on utilization data reported in the hospitals' most recent Hospital License Renewal Application forms, WakeMed's existing operating rooms are currently operating at or near the utilization standards required in 10A NCAC 14C .2103 (b)(1).

In this application, the applicant's utilization projections are based on population growth projections from the North Carolina Office of State Budget and Management for years 2010 through 2015 for the applicant's primary and secondary service areas. The applicant weighted the population growth projections based on the historical proportion of WakeMed surgery patients originating from each of the service area counties (See "Step 2", pp. 41-42), and applied the "weighted total population CAGR [compound average growth rate]," calculated by the applicant as 2.2804 percent, to its FY2012 surgical case volumes to project surgical case volumes at WakeMed North Healthplex and WakeMed Raleigh Campus through the first three operating years following completion of the project (FY2013-FY2015). The applicant states that FY2012 surgical case volumes were projected based 5 months of actual data annualized. The applicant projects that 30 percent of the projected outpatient surgical case volumes for WakeMed Raleigh Campus will shift to the Capital City Surgery Center (Project I.D. # J-8364-09) upon completion of that project (See "Step 6", pp. 44-46). In "Step 7" of the projections, the applicant projects trauma surgery cases and open heart surgical cases based on historical utilization of those services, and deducts those cases from its total projected inpatient surgical cases for WakeMed North Healthplex and WakeMed Raleigh Campus through the first three operating years following completion of the project. Exhibit 34 of the application contains letters from physicians and surgeons expressing support for the proposed project. Based on the projected population growth in the applicant's service area and the historical utilization of the applicant's surgical services, the applicant's utilization projections are reasonable. Therefore, the applicant adequately demonstrated the need to relocate the two operating rooms to WakeMed Raleigh Campus.

In summary, the applicant adequately demonstrated the need the population projected to be served has for the proposed project. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant, WakeMed, proposes to relocate two existing single specialty operating rooms from an ambulatory surgery center located on Lake Boone Trail in Raleigh, Southern Eye Associates Ophthalmic Surgery Center, to WakeMed Raleigh Campus, and convert them to shared operating rooms. In Section III.3(c), page 75, the applicant states:

“Southern Eye Associates Ophthalmic Surgery Center will no longer provide surgical services following the finalization of WakeMed’s acquisition of their two operating rooms. Patient who require eye surgery will have access to surgical operating rooms within the WakeMed system at WakeMed Raleigh Campus, WakeMed Cary Hospital, WakeMed North Healthplex and WakeMed Capital City Surgery Center. The operating rooms proposed for relocation to WakeMed Raleigh will have the capability to be used for eye surgery. Patients seeking eye surgery within Wake County may also utilize Rex Hospital, Rex Surgery Center of Cary, Duke Raleigh Hospital, and Blue Ridge Surgery Center.”

In Section III.3(d), page 75, the applicant states:

“The operating rooms to be relocated from Southern Eye Associates Ophthalmic Surgery Center are single-specialty ambulatory surgical ORs that have historically been used only for eye surgery. The 2012 State Medical Facilities Plan considers these operating rooms to be ‘chronically underutilized,’ as they have been utilized under 40 percent in each of the last two years. Relocation of these ORs to WakeMed Raleigh Campus and conversion to shared multispecialty operating rooms will increase the number of surgical specialties that may utilize them, and will allow use by both inpatients and outpatients. Thus, access to surgical services will be improved within Wake County. WakeMed Raleigh Campus has a long track record of providing access to medically underserved groups, as is demonstrated in Section VI.”

The following table shows the surgical case volumes for ambulatory ophthalmic surgery for the existing Wake County providers based on data reported to the Division of Health Service Regulation for FY2011.

| Provider | FY2011 Ambulatory Ophthalmic Surgical Cases | FY2011 Percent of Total |
|---|---|-------------------------------|
| Blue Ridge Surgery Center | 1,147 | 12.3% |
| Duke Raleigh Hospital | 2,022 | 21.7% |
| Rex Hospital | 4,257 | 45.7% |
| Rex Surgery Center of Cary | 80 | 0.8% |
| Southern Eye Associates Ophthalmic Surgery Center | 463 | 5.0% |
| WakeMed (Raleigh and North Healthplex) | 521 | 5.6% |
| WakeMed Cary Hospital | 835 | 9.0% |
| Total | 9,325 | 100% |

Source: 2012 Ambulatory Surgical Facility License Renewal Application and 2012 Hospital License Renewal Application.

As shown in the table above, Southern Eye Associates Ophthalmic Surgery Center’s surgical cases represented only 5 percent of the total ambulatory ophthalmic surgery cases performed by Wake County providers in FY2011. Also, Southern Eye Associates Ophthalmic Surgery Center reported the following payer mix for its surgical and non-surgical services combined for FY2011:

| Payer Category | Surgical and Non-Surgical Cases Combined | Surgical and Non-Surgical Services as % of Total |
|--------------------------------|---|---|
| Self Pay/Indigent/Charity | 34 | 3.3% |
| Medicare/Medicare Managed Care | 810 | 78.8% |
| Medicaid | 19 | 1.8% |
| Commercial Insurance | 162 | 15.8% |
| Other | 3 | 0.2% |
| Total | 1,028 | 100.0% |

In Section VI.14 of the application, the applicant projects the following payer mix for surgical services at WakeMed Raleigh Campus in the second operating year of the project.

| Payer Category | Surgical Services as % of Total |
|---|------------------------------------|
| Self Pay/Indigent/Charity | 7.6% |
| Medicare/Medicare Managed Care | 28.3% |
| Medicaid | 19.9% |
| Commercial Insurance (incl. Blue Cross, SEHP) | 0.7% |
| Managed Care | 39.0% |
| Other (worker comp, other government) | 4.5% |
| Total | 100.0% |

The applicant adequately demonstrates that the relocation of the two existing operating rooms will not have a negative effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care. In addition, the applicant demonstrates that the needs of the population presently served will be met adequately by the proposed relocation. Therefore, the application is conforming to this criterion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

In Section III.8, pages 86-88, the applicant describes the alternatives considered, including maintaining the status quo and relocating the operating rooms to another existing or new facility.

- The applicant states it rejected the status quo alternative due to several disadvantages, including the fact that the current site of the operating rooms is not owned by WakeMed, and its states “*WakeMed generally does not provide services in buildings it does not own.*” Further, the applicant states the operating rooms are configured for eye surgery, and would require significant renovation to accommodate other types of surgery, and the current site lacks several important ancillary and support services, such as laboratory, radiology, and pharmacy, which would be cost-prohibitive to develop at the current site. Also, the applicant would be precluded from using the operating rooms for inpatient surgical procedures if they remained at the current site.
- The applicant considered the alternative of relocating the two operating rooms to WakeMed Cary Hospital, but rejected it due to the uncertainty of the outcome of pending litigation which involves the addition of three shared operating rooms to WakeMed Cary Hospital.
- The applicant considered the alternative of relocating the two operating rooms to WakeMed North Healthplex, but rejected it due to the uncertainty of the needs at that facility following completion of the projects that will transition it to a 61-bed inpatient facility. Also, WakeMed’s plans to include an ambulatory surgery center at the WakeMed Apex were abandoned due to a lack of physician interest in that location.
- The applicant states it considered the alternative of relocating the two operating rooms to the Capital City Surgery Center, but rejected that alternative because “*WakeMed administration believes that CCSC is appropriately-sized with 8 ORs and 3 procedure rooms.*”
- The applicant considered the alternative of relocating the two operating rooms to another new surgery center with two operating rooms, but rejected it because a two-operating room surgery center would have “*too few ORs, lack on-site support services, and limited flexibility.*” Also, a new ambulatory surgery center would not address the need for additional shared operating room capacity.

On page 88, the applicant states

“WakeMed concluded that the most effective alternative would be to relocate the two surgical operating rooms recently acquired from Southern Eye Associates Ophthalmic Surgery Center to WakeMed Raleigh, and to convert these ORs from single-specialty ambulatory surgical to shared inpatient/outpatient. The proposed project can be completed quickly and for nominal capital cost. Further, doing so allows these ORs to be utilized for both inpatient and outpatient surgery, up to seven days a week, and will permit surgeons representing a variety of specialties the opportunity to perform cases. More importantly, relocation of operating rooms to WakeMed Raleigh Campus will provide that facility with additional OR capacity that will serve its long-term needs and the needs of its patients.”

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. WakeMed shall materially comply with all representations made in the certificate of need application.**
- 2. WakeMed shall relocate two existing single-specialty operating rooms from Southern Eye Associates Ophthalmic Surgery Center to WakeMed Raleigh Campus, and convert them to shared surgical operating rooms. Upon completion of this project and Project I.D. # J-8364-09, WakeMed Raleigh Campus shall be licensed for no more than 16 shared operating rooms, 4 dedicated open heart operating rooms, and 3 dedicated C-section operating rooms. Under the same license, and following completion of Project I.D. # J-7843-07, WakeMed North Healthplex shall be licensed for no more than 4 shared operating rooms and 1 dedicated C-section operating room.**
- 3. WakeMed shall provide documentation that the two existing single-specialty operating rooms from Southern Eye Associates Ophthalmic Surgery Center are de-licensed following completion of the project.**
- 4. WakeMed shall not acquire, as part of this project, any equipment that is not included in the project’s proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

5. WakeMed shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section, in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, the applicant projects its capital cost for the project to be \$991,785. In Section VIII.3, the applicant states the capital cost will be financed with accumulated reserves. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit 29 of the application, the applicant provides a letter from the Senior Vice President and Chief Financial Officer for WakeMed, which states

“This letter is to confirm that WakeMed plans to utilize accumulated reserves to fund the proposed relocation of two existing operating rooms to WakeMed Raleigh Campus. The total cost of project is \$991,775 for renovations and related equipment. ... As you can see from the audited financial statements for the year ended September 30, 2011, WakeMed had more than adequate current assets to fund the projected capital expenditure for this project. ... Please accept this letter as commitment of necessary funds to develop the entire project.”

Exhibit 30 of the application contains audited financial statements for WakeMed for the year ended September 30, 2011, which document that WakeMed had \$706 million in current assets as of September 30, 2011, including cash and cash equivalents of \$162 million and short term investments of \$370 million. The applicant adequately demonstrated the availability of funds for the projected capital costs described in the application.

In pro forma financial statements (Form B) for WakeMed Raleigh Campus, the applicant projects revenue will exceed operating costs (expenses) in each of the first three operating years. Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application and Criterion (3) for utilization assumptions. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

WakeMed has acquired the ambulatory surgery center that operated as Southern Eye Associates Ophthalmic Surgery Center. The applicant proposes to relocate two licensed operating rooms from the ambulatory surgery center, which is located on Lake Boone Trail in Raleigh, , to existing space within the surgery suite at WakeMed Raleigh Campus. The two operating rooms would be developed in the space vacated by two of the four operating rooms WakeMed will relocate to Capital City Surgery Center, which is an outpatient facility under development across Sunnybrook Road from the hospital. The following table shows the FY2011 surgical operating room utilization for Wake County providers:

Existing Wake County Operating Room Utilization – FY2011

| | # of Rooms | Inpatient Surgical Cases | Outpatient Surgical Cases | Total Surgical Cases |
|--|------------|--------------------------|---------------------------|----------------------|
| Blue Ridge Surgery Center | 6 | 0 | 6,935 | 6,935 |
| Raleigh Plastic Surgery | 1 | 0 | 220 | 220 |
| Southern Eye Associates Surgery Center | 2 | 0 | 463 | 463 |
| Rex Surgery Center of Cary | 4 | 0 | 1,821 | 1,821 |
| Rex Hospital (1) | 27 | 6,546 | 22,410 | 28,956 |
| WakeMed (2) | 25 | 7,788 | 12,389 | 20,177 |
| WakeMed Cary Hospital (3) | 9 | 1,961 | 6,145 | 8,106 |
| Duke Raleigh Hospital (4) | 15 | 3,750 | 11,877 | 15,627 |

Source: Operating room inventory is from the *2012 State Medical Facilities Plan*, Table 6A. Utilization data is from the *Proposed 2013 State Medical Facilities Plan*, Table 6A.

- (1) Operating rooms totals for Rex Hospital exclude 3 dedicated C-section operating rooms.
- (2) Operating room totals for WakeMed exclude 3 dedicated C-section operating rooms and 1 trauma/burn operating room.
- (3) Operating room totals for WakeMed Cary Hospital exclude 2 dedicated C-section operating rooms.
- (4) Operating room totals for Duke Raleigh Hospital include 2 operating rooms relocated from Raleigh Women’s Health Center.

The following table shows the approved Wake County operating room projects and the current status of those projects. All four of the projects are new ambulatory surgery centers.

Approved Wake County Operating Room Projects

| | # of Operating Rooms | Project Status |
|---------------------------------------|----------------------|--------------------|
| Orthopaedic Surgery Center of Raleigh | 4 | Under Development |
| WakeMed Capital City Surgery Center | 8 | Under Development |
| Holly Springs Surgery Center | 3 | Pending Litigation |
| Triangle Orthopedic Surgery Center | 2 | Under Development |

Both the Orthopaedic Surgery Center of Raleigh and WakeMed Capital City Surgery Center projected operating room utilization that is predicated on the facility’s surgeons shifting ambulatory surgery cases from the hospital to the outpatient facility.

FY2011, the Southern Eye Associates Ophthalmic Surgery Center reported 463 surgical cases in their two existing single specialty operating rooms, which is equivalent to average utilization of 19 percent of capacity based on the utilization standards in the 2012 SMFP operating room need methodology [2 OR X 1,872 = 3,744 total available surgical hours; 463 surgical cases X 1.5 hours/case = 694.5 hours of utilization; 694.5 hours of surgical utilization/3,744 available surgical hours = 0.185].

The revised inpatient and outpatient surgical utilization projections for WakeMed Raleigh Campus and WakeMed North following correction of the applicant’s error, as discussed in Criterion (3), are shown below.

Revised Inpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|-------|
| FY2013-Project Year 1 | 6,842 | 0 | 6,842 |
| FY2014-Project Year 2 | 7,020 | 174 | 7,194 |
| FY2015-Project Year 3 | 7,202 | 251 | 7,453 |

Revised Outpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|--------|
| FY2013-Project Year 1 | 6,199 | 3,798 | 9,997 |
| FY2014-Project Year 2 | 6,341 | 3,958 | 10,299 |
| FY2015-Project Year 3 | 6,485 | 4,116 | 10,601 |

As indicated in the above table, after revising the applicant’s projections to exclude “Step 5” of the methodology, the applicant is projected to perform 7,453 inpatient surgical cases and 10,601 outpatient surgical cases in the 20 shared operating rooms at WakeMed Raleigh Campus and WakeMed North Healthplex in the third operating year of the proposed project (FY2015). Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be 20 [(10,601 X 1.5 hours) + (7,453 X 3.0 hours) = 38,261 hours; 38,261 hours/1,872 hours = 20.4].

WakeMed projected utilization for the operating rooms at WakeMed Raleigh Campus and WakeMed North Healthplex, and demonstrated the need to add the two operating rooms to the WakeMed Raleigh Campus. The applicant proposes to relocate two existing operating rooms within Wake County, and does not propose to develop additional operating rooms in the Wake County service area. Consequently, the applicants adequately demonstrate the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Wake County. Therefore, the application is conforming with this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 117, the applicant project the incremental staffing required for the two additional operating rooms to be relocated to the WakeMed Raleigh Campus, as shown in the table below.

| Incremental Staff Required | FTEs |
|-----------------------------------|-------------|
| Registered Nurse (RN) | 3.59 |
| Surgical Technicians | 1.79 |
| Total | 5.38 |

In Sections VII.1 and VII.2, pages 116-118, the applicant provides current and proposed staffing tables for the surgical services department at WakeMed Raleigh Campus, which shows the administrative, clinical, and support personnel that will be available to support the proposed operating rooms. In Section VII.3, page 118, and Section VII.7, pages 122-123, the applicant describes its recruitment and retention processes which will be used to recruit the additional surgical services staff identified in Section VII.2. In Section VII.9, page 125, the applicant identifies H. West Lawson, M.D. as the Chief Medical Officer for WakeMed Raleigh Campus. In Section II.10, page 59, the applicant states, “*WakeMed Raleigh Campus currently has 185 physicians on its medical staff that could utilize surgical operating rooms, as well as 37 anesthesiologists.*” Exhibit 34 contains copies of letters of support from 21 physicians and surgeons expressing support for the project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section II.2 of the application, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at WakeMed Raleigh Campus, including pre-operative and post-operative services, radiology, laboratory, pharmacy, reception, registration, and maintenance services. In Section V.2 of the application, the applicant provides a list of facilities with which they have transfer agreements. In Exhibit 34 of the application, the applicant provides letters from physicians supporting the proposed project. In Section II.1, the applicant states anesthesia services will be provided by American Anesthesiology. The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.13, page 114, the applicant provides the payer mix during FY2011 for the existing surgical services at WakeMed Raleigh Campus and WakeMed North Healthplex, as shown in the tables below.

| WakeMed Raleigh Campus Payer Category | Surgical Services as % of Total |
|--|--|
| Self Pay/Indigent/Charity | 7.6% |
| Medicare/Medicare Managed Care | 28.3% |
| Medicaid | 19.9% |
| Commercial Insurance (incl. Blue Cross, SEHP) | 0.7% |
| Managed Care | 39.0% |
| Other (worker comp, other government) | 4.5% |
| Total | 100.0% |

| WakeMed North Healthplex Payer Category | Surgical Services as % of Total |
|--|--|
| Self Pay/Indigent/Charity | 2.7% |
| Medicare/Medicare Managed Care | 16.7% |
| Medicaid | 6.7% |
| Commercial Insurance (incl. Blue Cross, SEHP) | 0.4% |
| Managed Care | 69.6% |
| Other (worker comp, other government) | 3.9% |
| Total | 100.0% |

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY2008-2009, respectively. The data in the table was obtained on July 25, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

| | Total # of Medicaid Eligibles as % of Total Population | Total # of Medicaid Eligibles Age 21 and older as % of Total Population | % Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center) |
|------------------|---|--|---|
| County | | | |
| Wake | 9.8% | 3.3% | 18.4% |
| Statewide | 17.0% | 6.7% | 19.7% |

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the applicants.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 113, the applicant states

“WakeMed has no obligation under any applicable Federal regulation to provide uncompensated care and community service. It has not had such requirements in the past three years. However, under EMTALA, WakeMed cannot turn away a patient who needs emergency care.”

In Section VI.10, page 113, the applicant states that there have not been any civil rights access complaints filed against WakeMed facilities in the past five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, page 115, the applicant projects the payer mix for the surgical services at WakeMed Raleigh Campus for the second operating year following project completion (FY2014), as shown in the table below.

| WakeMed Raleigh Campus Payer Category | Surgical Services as % of Total |
|--|--|
| Self Pay/Indigent/Charity | 7.6% |
| Medicare/Medicare Managed Care | 28.3% |
| Medicaid | 19.9% |
| Commercial Insurance (incl. Blue Cross, SEHP) | 0.7% |
| Managed Care | 39.0% |
| Other (worker comp, other government) | 4.5% |
| Total | 100.0% |

In Section IV.14, page 115, the applicant states, “*For this project, WakeMed used the current payer mix for surgical services at WakeMed Raleigh Campus as the basis for projected payer mix.*” The applicant demonstrated that the proposed relocation of two operating rooms will provide adequate access to medically underserved populations. Therefore, the application is conforming with this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In V.9, page 112, the applicant describes the range of means by which a person will access their services. The application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 of the application, the applicant states they have extensive relationships with many health professional training programs. Section V.1(a), pp. 94-95, includes a list of institutions with which the applicant has these arrangements. Exhibit 19 contains copies of “*sample agreements*” with area health professional training programs. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.

- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

In Section V.7, pages 104-105, the applicant states

“The addition of two shared operating rooms at WakeMed Raleigh Campus will foster competition on a number of levels. As noted above, the development of surgical services in Wake County over the past several years has focused almost exclusively on outpatient ambulatory surgical services. Patients in Wake County now have a number of outpatient ambulatory surgical centers from which to choose. Unfortunately, shared OR capacity has not experienced a similar boom. WakeMed Raleigh Campus’s existing surgical operating rooms were utilized at 88 percent in FY 2011, illustrating the need for more shared surgical capacity. This extremely high utilization limits WakeMed Raleigh’s flexibility and patient’s ability to schedule surgical procedures at the hospital, which in turn limits patients’ options and choice. This is especially concerning given the fact that WakeMed Raleigh Campus must accommodate unscheduled emergency and trauma cases, a situation that ambulatory providers do not face. Adding additional ambulatory surgical capacity will not materially enhance competition, given the ambulatory surgical centers that have been approved in years past, and will not remedy patients’ needs for additional inpatient capacity.

Adding two additional more shared operating rooms at WakeMed Raleigh Campus will increase the options available to patients seeking to schedule surgical procedures. Patients choose to have elective procedures done in the hospital setting for a number of reasons: because the hospital is closer to their homes, because they are more comfortable in a hospital setting should complications arise during their procedure, or because of existing co-morbidities that make the hospital setting a safer option. Trauma and other emergency patients also have a need for additional inpatient surgical capacity; these patients cannot be treated in the ambulatory setting.

The convenient location and accessible parking have made WakeMed Raleigh Campus attractive to consumers, and the addition of two shared operating rooms will enable WakeMed Raleigh Campus to continue providing high-quality services and offering a choice to patients. Additional shared surgical capacity will also make the site more attractive for surgeons who, in WakeMed’s experience, are often unwilling or unable to provide services in an ambulatory

surgical center that is located away from their offices and emergency and inpatient resources. Adding two shared operating rooms at WakeMed Raleigh will give both patients and physicians greater flexibility and greater options in scheduling surgical procedures.”

The information provided by the applicant is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to surgical services in Wake County. Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

WakeMed is certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at WakeMed within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

WakeMed proposes to relocate two existing single specialty operating rooms from an ambulatory surgery center located on Lake Boone Trail in Raleigh, Southern Eye Associates Ophthalmic Surgery Center, to WakeMed Raleigh Campus, and convert them to shared operating rooms. Therefore, the Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

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

10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, 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 identify each of the following specialty areas that will be provided in the facility:

- (1) gynecology;*
- (2) otolaryngology;*
- (3) plastic surgery;*
- (4) general surgery;*
- (5) ophthalmology;*
- (6) orthopedic;*
- (7) oral surgery; and*
- (8) other specialty area identified by the applicant.*

-NA- The applicant proposes to relocate two existing operating rooms from Southern Eye Associates Ophthalmic Surgery Center, a single-specialty ambulatory surgical facility, to its existing surgical department at WakeMed Raleigh Campus. The applicant is not proposing to establish a new ambulatory surgical facility, or establish a new campus of an existing facility, or establish a new hospital, or convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program.

(b) An applicant proposing to increase the number of operating rooms in a service area, 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 provide the following information:

- (1) the number and type of operating rooms in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area, (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*
- (2) the number and type of operating rooms to be located in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*
- (3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;*
- (4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and*

cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;

- (5) *a description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;*
- (6) *the hours of operation of the proposed new operating rooms;*
- (7) *if the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;*
- (8) *the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items included in the reimbursement; and*
- (9) *identification of providers of pre-operative services and procedures which will not be included in the facility's charge.*

-NA- The applicant is not proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(c) *An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:*

- (1) *the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*

-C- In Section II.10, page 29, the applicant provides a table showing the number and type of operating rooms at each of the WakeMed facilities.

| Operating Room Type | WakeMed Raleigh Campus* | WakeMed Cary Hospital | WakeMed North** | WakeMed Capital City Surgery Center*** | Southern Eye Associates Surgery Center | Total |
|----------------------------|--------------------------------|------------------------------|------------------------|---|---|--------------|
| Dedicated Open Heart | 4 | 0 | 0 | 0 | 0 | 4 |
| Shared | 14 | 9 | 0 | 0 | 0 | 23 |
| Dedicated Ambulatory | 0 | 0 | 4 | 8 | 2 | 14 |
| Dedicated C-Section | 3 | 2 | 1 | 0 | 0 | 6 |
| Total | 21 | 11 | 5 | 8 | 2 | 47 |

*WakeMed Raleigh Campus currently has 18 shared operating rooms, but was approved to relocate four operating rooms to Capital City Surgery Center (Project I.D. #J-8364-09).

**WakeMed North Healthplex is approved (Project I.D. # J-7843-07) to develop one dedicated C-Section operating room, but the project is not operational. WakeMed North Healthplex is licensed as part of WakeMed Raleigh Campus.

***WakeMed Capital City Surgery Center (Project I.D. #J-8364-09) is approved but not operational, and includes four shared operating rooms to be relocated from WakeMed Raleigh Campus, and four ambulatory surgical operating rooms approved in Project I.D. #J-7350-05, but not developed.

- (2) *the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*

-C- In Section II.10, page 29, the applicant provides a table showing the number and type of operating rooms to be located at each of the WakeMed facilities after completion of the proposed project.

| Operating Room Type | WakeMed Raleigh Campus | WakeMed Cary Hospital | WakeMed North | WakeMed Capital City Surgery Center | Total |
|----------------------------|-------------------------------|------------------------------|----------------------|--|--------------|
| Dedicated Open Heart | 4 | 0 | 0 | 0 | 4 |
| Shared | 16 | 9 | 4 | 0 | 29 |
| Dedicated Ambulatory | 0 | 0 | 0 | 8 | 8 |
| Dedicated C-Section | 3 | 2 | 1 | 0 | 6 |
| Total | 23 | 11 | 5 | 8 | 47 |

- (3) *the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;*

-C- In Section II.10, page 30, the applicant provides a table showing the number of inpatient and outpatient surgical cases, excluding trauma, open heart, and C-section surgical cases, performed during the most recent 12-month period (CY2011) at each of the WakeMed facilities.

| Surgery Type | WakeMed Raleigh Campus | WakeMed Cary Hospital | WakeMed North | WakeMed Capital City Surgery Center | Southern Eye Associates Surgery Center* | Total |
|---------------------|-------------------------------|------------------------------|----------------------|--|--|---------------|
| Inpatient | 6,688 | 2,128 | 0 | N/A | 0 | 8,816 |
| Outpatient | 9,064 | 7,752 | 3,378 | N/A | 463 | 20,657 |
| Total | 15,752 | 9,880 | 3,378 | N/A | 463 | 29,473 |

*Southern Eye Associates Surgery Center data is for FY2011, as reported in the 2012 Ambulatory Surgical Facility License Renewal Application.

- (4) *the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first*

three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

- C- In Section II.10, page 31, the applicant provides tables showing the projected number of inpatient and outpatient surgical cases, excluding trauma, open heart, and C-section surgical cases, to be performed at WakeMed Raleigh Campus and WakeMed North Healthplex for each of the first three operating years, as shown below.

Inpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|-------|
| FY2013-Project Year 1 | 7,174 | 0 | 7,174 |
| FY2014-Project Year 2 | 7,360 | 174 | 7,534 |
| FY2015-Project Year 3 | 7,550 | 251 | 7,801 |

Outpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|--------|
| FY2013-Project Year 1 | 6,458 | 3,798 | 10,256 |
| FY2014-Project Year 2 | 6,605 | 3,958 | 10,563 |
| FY2015-Project Year 3 | 6,756 | 4,116 | 10,872 |

However, the utilization projections for WakeMed Raleigh Campus were overstated because the applicant accounted for in-migration twice in Step 5 of its projections. Criterion (3) discusses all of the steps in the applicant’s methodology and the correction made to reflect a more accurate projection. The revised utilization projections following correction of the applicant’s error are shown below.

Revised Inpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed Raleigh Campus | WakeMed North | Total |
|-----------------------|------------------------|---------------|-------|
| FY2013-Project Year 1 | 6,842 | 0 | 6,842 |
| FY2014-Project Year 2 | 7,020 | 174 | 7,194 |
| FY2015-Project Year 3 | 7,202 | 251 | 7,453 |

Revised Outpatient Surgical Cases by Facility, FY2013-FY205

| Operating Year | WakeMed | WakeMed | Total |
|----------------|---------|---------|-------|
|----------------|---------|---------|-------|

| | Raleigh Campus | North | |
|-----------------------|---------------------------|--------------|--------|
| FY2013-Project Year 1 | 6,199 | 3,798 | 9,997 |
| FY2014-Project Year 2 | 6,341 | 3,958 | 10,299 |
| FY2015-Project Year 3 | 6,485 | 4,116 | 10,601 |

(5) *a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;*

-C- In Section II.10, pages 31-48 of the application, the applicant provides a detailed description of and documentation to support the assumptions and methodology used in the development of the projections. An analysis of the assumptions, methodology, and utilization projections was conducted in Criterion (3), as well as the correction of Step 5 of the methodology to more accurately project utilization. This analysis is included by reference.

(6) *the hours of operation of the facility to be expanded;*

-C- In Section II.10, page 48 of the application, the applicant provides a table showing the hours of operation for surgical services at WakeMed Raleigh Campus.

(7) *the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;*

-C- In Section II.10, page 49 of the application, the applicant provides the average reimbursement (“net revenue per case”) received per procedure for the 20 surgical procedures most commonly performed in WakeMed Raleigh Campus’s operating rooms during the preceding 12 months (FY2011) and a list of all services and items included in the reimbursement. In Section II.10, pages 48-49, the applicant states, “Also note that this reflects net revenue related to the surgical procedure, including OR time, post-op (PACU) care, lab, pharmacy, intraoperative monitoring , transfusions, and supplies.” The table is shown below:

Table II.21
WakeMed Raleigh Campus
Average Net Revenue per Case, Top 20 Surgical Procedures
FY2011

| ICD-9 Code | Procedure | Average Net Revenue Per Case |
|-----------------------|----------------------------------|---|
| 51.23 | <i>Laparoscopic cholecyste</i> | \$2,613 |
| 47.01 | <i>Lap appendectomy</i> | \$2,892 |
| 80.51 | <i>Excision intervert disc</i> | \$3,419 |
| 56.0 | <i>Tu remove ureter obstruct</i> | \$3,855 |
| 20.01 | <i>Myringotomy w intubation</i> | \$786 |
| 81.02 | <i>Oth cerv fusion ant/ant</i> | \$10,097 |
| 23.41 | <i>Crown application</i> | \$828 |

| | | |
|-------|------------------------------------|----------|
| 7.936 | <i>Op red-int fix tib/fibu</i> | \$3,431 |
| 28.3 | <i>Tonsillectomy/adenoid</i> | \$1,133 |
| 81.07 | <i>Lmb/lmsac fus post/pos</i> | \$19,630 |
| 79.32 | <i>Op red-int fix rad/ulna</i> | \$3,699 |
| 81.54 | <i>Total knee replacement</i> | \$11,300 |
| 3927 | <i>Dialysis arteriovenosto</i> | \$2,040 |
| 36.13 | <i>Aortocor bypass-3 cor ar</i> | \$16,872 |
| 30.9 | <i>Spinal canal explor NEC</i> | \$2,923 |
| 59.8 | <i>Ureteral catheterization</i> | \$1,693 |
| 66.29 | <i>Bilat endos occ tube NE</i> | \$1,140 |
| 69.52 | <i>Aspirat curet-post deli</i> | \$1,027 |
| 38.12 | <i>Head & neck endarter NE</i> | \$3,287 |
| 36.12 | <i>Aortocor bypass-2 cor ar</i> | \$15,053 |

(8) *the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and*

-C- In Section II.10, page 50 of the application, the applicant provides the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be most commonly performed in WakeMed Raleigh Campus's operating rooms and a list of all services and items included in the reimbursement. In Section II.10, page 49, the applicant states, "This reflects net revenue related to the surgical procedure, including OR time, post-op (PACU) care, lab, pharmacy, intraoperative monitoring, transfusions, and supplies." The table is shown below:

Table II.22
WakeMed Raleigh Campus
Projected Average Net Revenue per Case, Top 20 Surgical Procedures
Project Years 1-3

| ICD-9 Code | Procedure | FY 2013 | FY 2014 | FY 2015 |
|-------------------|----------------------------------|----------------|----------------|----------------|
| 51.23 | <i>Laparoscopic cholecyste</i> | \$2,809 | \$2,913 | \$3,021 |
| 47.01 | <i>Lap appendectomy</i> | \$3,110 | \$3,225 | \$3,344 |
| 80.51 | <i>Excision intervert disc</i> | \$3,676 | \$3,812 | \$3,953 |
| 56.0 | <i>Tu remove ureter obstruct</i> | \$4,146 | \$4,299 | \$4,458 |
| 20.01 | <i>Myringotomy w intubation</i> | \$845 | \$876 | \$908 |
| 81.02 | <i>Oth cerv fusion ant/ant</i> | \$10,858 | \$11,260 | \$11,677 |
| 23.41 | <i>Crown application</i> | \$890 | \$923 | \$957 |
| 7.936 | <i>Op red-int fix tib/fibu</i> | \$3,690 | \$3,827 | \$3,969 |
| 28.3 | <i>Tonsillectomy/adenoid</i> | \$1,218 | \$1,263 | \$1,310 |
| 81.07 | <i>Lmb/lmsac fus post/pos</i> | \$21,109 | \$21,890 | \$22,700 |
| 79.32 | <i>Op red-int fix rad/ulna</i> | \$3,977 | \$4,124 | \$4,277 |
| 81.54 | <i>Total knee replacement</i> | \$12,153 | \$12,603 | \$13,069 |
| 3927 | <i>Dialysis arteriovenosto</i> | \$2,194 | \$2,275 | \$2,359 |
| 36.13 | <i>Aortocor bypass-3 cor ar</i> | \$18,143 | \$18,814 | \$19,510 |

| | | | | |
|-------|------------------------------------|----------|----------|----------|
| 30.9 | <i>Spinal canal explor NEC</i> | \$3,143 | \$3,259 | \$3,380 |
| 59.8 | <i>Ureteral catheterization</i> | \$1,821 | \$1,888 | \$1,958 |
| 66.29 | <i>Bilat endos occ tube NE</i> | \$1,226 | \$1,271 | \$1,318 |
| 69.52 | <i>Aspirat curet-post deli</i> | \$1,104 | \$1,145 | \$1,187 |
| 38.12 | <i>Head & neck endarter NE</i> | \$3,534 | \$3,665 | \$3,801 |
| 36.12 | <i>Aortocor bypass-2 cor ar</i> | \$16,188 | \$16,787 | \$17,408 |

- (9) *identification of providers of pre-operative services and procedures which will not be included in the facility's charge.*

-C- In Section II.10, page 50 of the application, the applicant identifies the providers of pre-operative services and procedures not included in the facility's charge, including anesthesiology, laboratory, radiologists, and other physician services.

(d) *An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:*

- (1) *the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;*
- (2) *a description of the ownership interests of physicians in the proposed ambulatory surgical facility;*
- (3) *a commitment that the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;*
- (4) *for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;*
- (5) *for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;*
- (6) *for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self-pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self-pay surgical cases;*
- (7) *for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;*
- (8) *for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;*
- (9) *for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;*
- (10) *for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;*
- (11) *a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;*

- (12) *a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;*
- (13) *descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;*
- (14) *if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;*
- (15) *a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;*
- (16) *a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;*
- (17) *a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:*
 - (A) *patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;*
 - (B) *patient outcome results for each of the applicant's patient outcome measures;*
 - (C) *the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and*
 - (D) *the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.*

-NA- The applicant is not proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

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.*

-C- In Section II.10, page 52 of the application, the applicant states the program is considered to be available for use five days per week and 52 weeks per year.

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

- (1) *demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: $\{[(\text{Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases}$*

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- WakeMed is located in the Wake County Service Area, which has more than 10 operating rooms. The applicant proposes to operate 15 shared operating rooms at WakeMed Raleigh Campus, excluding four open heart, three dedicated C-section, and one trauma operating room [23 – 4 – 3 – 1 = 15]. Also, the applicant proposes to operate 4 shared operating rooms at WakeMed North Healthplex, which is licensed as part of WakeMed Raleigh Campus, excluding one dedicated C-section operating rooms [5 – 1 = 4]. Therefore, WakeMed Raleigh will operate a total of 19 shared operating rooms at both locations. In Section II.10, page 47 of the application, the applicant projects it will perform 10,872 outpatient surgical cases and 7,801 inpatient surgical cases in the third year of operation [(10,872 X 1.5 hours) + (7,801 X 3.0 hours) = 39,711 hours; 39,711 hours/1,872 hours = 21.2 operating rooms]. However, the applicant's projections for WakeMed Raleigh Campus were overstated. See Criterion (3) for an analysis and correction of the applicant's projections to reverse the double-counting of out-of-area patients. The analysis is herein incorporated by reference. Based on revised projections, the applicant would be projected to perform 10,601 outpatient surgical cases and 7,453 inpatient surgical cases in the third year of operation [(10,601 X 1.5 hours) + (7,453 X 3.0 hours) = 38,261 hours; 38,261 hours/1,872 hours = 20.4 operating rooms]. Thus, the application is conforming with this rule.

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

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

-NA- The applicant does propose to increase the number of operating rooms in the service area.

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

-NA- The applicant does propose to develop an additional C-section operating room.

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

- (1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and*
- (2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.*

-NA- The applicant does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

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

-C- In Section II.10, pages 31-48 of the application, the applicant provides documentation to support the assumptions and methodology used in the development of the projections.

10A NCAC 14C .2104 SUPPORT SERVICES

(a) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.

-NA- The applicant is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

(b) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:

- (1) emergency services;*
- (2) support services;*
- (3) ancillary services; and*
- (4) public transportation.*

- NA- The applicant is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

10A NCAC 14C .2105 STAFFING AND STAFF TRAINING

(a) An applicant proposing 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 a facility, 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 identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas in the facility to be developed or expanded:

- (1) administration;*
- (2) pre-operative;*
- (3) post-operative;*
- (4) operating room; and*
- (5) other.*

- C- In Section II.10, page 58, and Sections VII.1, VII.2, and VII.6 of the application, the applicant identifies and documents the availability of the number of proposed staff to be utilized in the areas listed in this rule.

(b) The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.

- C- In Section II.10, page 59, the applicant states, “WakeMed Raleigh Campus currently has 185 physicians on its medical staff that could utilize surgical operating rooms, as well as 37 anesthesiologists.” Exhibit 17 contains the criteria used by the facility in extending surgical and anesthesia privileges to medical personnel.

(c) The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.

- C- In Section II.10, page 59 of the application, the applicant provides documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital in the service area.

(d) The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.

- NA- The applicant is not proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

10A NCAC 14C .2106 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

-NA- The applicant is not proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

(b) An applicant proposing to establish a licensed ambulatory surgical facility or a new hospital shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.

-NA- The applicant is not proposing to establish a licensed ambulatory surgical facility or a new hospital.

(c) All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.

-C- In Section II.10, page 61 of the application, and Exhibit 32, the applicant provides documentation that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

(d) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a floor plan of the proposed facility identifying the following areas:

- (1) receiving/registering area;*
- (2) waiting area;*
- (3) pre-operative area;*
- (4) operating room by type;*
- (5) recovery area; and*
- (6) observation area.*

-NA- The applicant is not proposing to establish a licensed ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

(e) An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:

- (1) physicians;*

- (2) *ancillary services;*
- (3) *support services;*
- (4) *medical equipment;*
- (5) *surgical equipment;*
- (6) *receiving/registering area;*
- (7) *clinical support areas;*
- (8) *medical records;*
- (9) *waiting area;*
- (10) *pre-operative area;*
- (11) *operating rooms by type;*
- (12) *recovery area; and*
- (13) *observation area.*

-NA- The applicant does not propose to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program.