

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 27, 2020

Findings Date: January 27, 2020

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

### COMPETITIVE REVIEW

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Project ID #: J-11747-19  
Facility: Wake Spine and Specialty Surgery Center  
FID #: 190370  
County: Wake  
Applicant: Wake Spine and Specialty Surgery Center, LLC  
Project: Develop a new specialty ambulatory surgery center in Raleigh with one operating room and three procedure rooms pursuant to the need determination in the 2019 SMFP

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Project ID #: J-11752-19  
Facility: Triangle Orthopaedics Surgery Center  
FID #: 101146  
County: Wake  
Applicant: Triangle Orthopaedics Surgery Center, LLC  
Project: Add one operating room to an existing specialty ambulatory surgery center (ASC) in Raleigh pursuant to the need determination in the 2019 SMFP for a total of three operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC

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Project ID #: J-11753-19  
Facility: Duke Health Green Level Ambulatory Surgical Center  
FID #: 180422  
County: Wake  
Applicant: Duke University Health System, Inc.  
Project: Add two operating rooms to an approved multispecialty ambulatory surgery center in Cary pursuant to the need determination in the 2019 SMFP for a total of three operating rooms and five procedure rooms upon project completion

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Project ID #: J-11759-19  
Facility: WakeMed Cary Hospital  
FID #: 990332  
County: Wake  
Applicant: WakeMed  
Project: Develop one additional operating room at the existing hospital in Cary pursuant to the need determination in the 2019 SMFP for a total of 11 shared operating rooms and two dedicated C-section operating rooms upon project completion

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Project ID #: J-11761-19  
Facility: Rex Hospital  
FID #: 953429  
County: Wake  
Applicant: Rex Hospital, Inc.  
Project: Develop two additional operating rooms at the existing hospital in Raleigh pursuant to the need determination in the 2019 SMFP for a total of 26 shared operating rooms and three dedicated C-section operating rooms upon completion of Project I.D. # J-8669-11 (relocate three operating rooms to Rex Hospital Holly Springs), Project I.D. # J-11555-18 (develop two additional operating rooms pursuant to the need determination in the 2018 SMFP), and this project

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## REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

### C

#### All Applications

#### Need Determination

The 2019 State Medical Facilities Plan (SMFP) includes a need determination for two additional operating rooms in the Wake County Operating Room Service Area. Five applications were received by the Agency for this review cycle.

#### Policies

There are two policies in the 2019 SMFP applicable to this review: Policy GEN-3: Basic Principles, and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

### **Policy GEN-3**

Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Policy GEN-4**

Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

**WSSSC.** Wake Spine and Specialty Surgery Center, LLC [WSSSC] proposes to develop a new specialty ambulatory surgery center in Raleigh with one operating room and three procedure rooms.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Wake County service area.

*Policy GEN-3.* In Section B.3, pages 14-16, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$5 million. In Section B.4, page 17, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

*Conclusion.* The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Wake County;
  - The applicant adequately documents how the project will promote equitable access to operating room services in Wake County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**TOSC.** Triangle Orthopaedics Surgery Center, LLC [TOSC] proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Wake County service area.

*Policy GEN-3.* In Section B.3, pages 11-15, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$5 million. In Section B.4, pages 15-17, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

*Conclusion.* The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Wake County;
  - The applicant adequately documents how the project will promote equitable access to operating room services in Wake County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**Duke Green Level ASC.** Duke University Health System, Inc. [**Duke Green Level ASC**] proposes to add two operating rooms to an approved multispecialty ambulatory surgery center in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Wake County service area.

*Policy GEN-3.* In Section B.3, page 13, and Section N.1, pages 109-112, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$5 million. In Section B.4, pages 14-15, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application

includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

*Conclusion.* The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Wake County;
  - The applicant adequately documents how the project will promote equitable access to operating room services in Wake County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**WakeMed Cary Hospital.** WakeMed [WakeMed Cary Hospital] proposes to develop one additional operating room at the existing hospital in Cary.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Wake County service area.

*Policy GEN-3.* In Section B.3, pages 12-15, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.4, pages 15-16, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

*Conclusion.* The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Wake County;
  - The applicant adequately documents how the project will promote equitable access to operating room services in Wake County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**UNC REX Hospital.** Rex Hospital, Inc. d/b/a UNC REX Hospital [**UNC REX Hospital**] proposes to develop two additional operating rooms at the existing hospital in Raleigh for a total of 26 shared operating rooms and three dedicated C-section operating rooms upon completion of Project I.D. # J-8669-11 (relocate three operating rooms to Rex Hospital Holly Springs), Project I.D. # J-11555-18 (develop two additional operating rooms pursuant to the need determination in the 2018 SMFP), and this project.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Wake County service area.

*Policy GEN-3.* In Section B.3, pages 10-14, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is less than \$2 million. Therefore, Policy GEN-4 is not applicable to this application.

*Conclusion.* The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

- The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Wake County;
- The applicant adequately documents how the project will promote equitable access to operating room services in Wake County; and
- The applicant adequately documents how the project will maximize healthcare value for the resources expended.

### **Decision**

The applications submitted by each of the five applicants are conforming to the need determination and to the applicable policies in the 2019 SMFP. The limit on the number of operating rooms that can be approved is two (2). Collectively, the applicants propose a total of eight operating rooms. Therefore, all of the applications cannot be approved. See the end of the Required State Agency Findings.

- (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**

#### All Applications

**WSSSC.** Wake Spine and Specialty Surgery Center, LLC [WSSSC] proposes to develop a new specialty ambulatory surgery center on Six Forks Road in Raleigh with one operating room and three procedure rooms. In Section A.1, page 5, the applicant states WSSSC is a legal entity whose sole member is Raleigh Neurosurgical Clinic, Inc.

N.C. Gen. Stat. § 131E-176 defines a multispecialty ambulatory surgical program as a “*formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.*” In Section C.1, page 20, WSSSC identifies the specialty areas of spine, orthopedic, neurology, ophthalmology, retina and pain management. Therefore, the applicant does not specifically identify all of the specialties required to meet the definition of a multispecialty ambulatory surgical program.

### **Patient Origin**

On page 55, the 2019 SMFP states, “*An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” In Figure 6.1, page 60 of the 2019 SMFP, Wake County is shown as a single-county operating room service area. Thus,

the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin for the applicant’s proposed operating room.

County	Third Full Fiscal Year of Operation FFY2024	
	Patients	% of Total
Wake	393	56.2%
Johnston	78	11.2%
Harnett	42	6.0%
Sampson	27	3.8%
Franklin	24	3.5%
Cumberland	16	2.3%
Nash	13	1.8%
Wayne	11	1.5%
Halifax	9	1.4%
Wilson	9	1.3%
Durham	9	1.3%
Other	68	9.8%
<b>Total</b>	<b>700</b>	<b>100.0%</b>

Source: Section C.3, page 23.

The following table illustrates projected patient origin for the applicants’ proposed procedure rooms.

County	Third Full Fiscal Year of Operation FFY2024	
	Patients	% of Total
Wake	2,616	63.8
Johnston	521	12.7
Harnett	283	6.9
Sampson	98	2.4
Franklin	90	2.2
Cumberland	57	1.4
Nash	57	1.4
Other	377	9.2
<b>Total</b>	<b>4,100</b>	<b>100.0%</b>

Source: Section C.3, page 24.

In Section C.3, page 24, the applicant provides the assumptions and methodology used to project their patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 25-31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need determination for operating rooms for the Wake County service area identified in the 2019 SMFP.
- Physician support for the proposed ambulatory surgical center (ASC).
- Historical and projected growth and aging of the service area population.
- Projected growth of the ambulatory surgical facility market and projected growth in ambulatory surgical cases and procedures.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides documentation of the physician support for the proposed ASC.
- The applicant's population growth projections are based on data from the North Carolina Office of State Budget and Management (NCOSBM).
- The applicant provides information to support its assertions regarding projected growth of the ambulatory surgical facility market and projected growth in ambulatory surgical cases and procedures.

*Projected Utilization*

In Section Q, the applicant provides projected utilization of the operating room and three procedure rooms at the proposed ambulatory surgery center as illustrated in the following table.

**Projected WSSSC Utilization**

<b>Operating Rooms</b>	<b>Year 1 CY2020</b>	<b>Year 2 CY2021</b>	<b>Year 3 CY2023</b>
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	600	650	700
Surgical Case Times	76.6	76.6	76.6
Totals Surgical Hours	766	830	894
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	0.58	0.63	0.68
<b>Procedure Rooms</b>			
# of Procedure Rooms	3	3	3
Total Procedures	3,900	4,000	4,100

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant's utilization projections for the operating room and procedure rooms are based on surgical case estimates for the physicians who have expressed their intention to perform surgical procedures at the proposed ASC. In Section C.4, page 27, the applicant states:

“The following tables identify the 11 local physicians, their specialty, and their projected ambulatory case volumes to be performed annually at WSSSC after an initial 3-month ramp-up period:

***Surgical Case Performance***

***Projected OR Cases***

<i>Physician</i>	<i>Specialty</i>	<i>Projected OR Cases</i>
<i>Robert Lee Allen, M.D.</i>	<i>Neurosurgery</i>	<i>63</i>
<i>Andrey Belayev, M.D.</i>	<i>Neurosurgery</i>	<i>46</i>
<i>Brandon C. Burnsed, M.D.</i>	<i>Neurosurgery</i>	<i>42</i>
<i>Lars Gardner, D.O.</i>	<i>Neurosurgery</i>	<i>76</i>
<i>Timothy B. Garner, M.D.</i>	<i>Neurosurgery</i>	<i>113</i>
<i>Laith Khoury, M.D.</i>	<i>Neurosurgery</i>	<i>75</i>
<i>Russell R. Margraf, M.D.</i>	<i>Neurosurgery</i>	<i>200</i>
<i>Kenneth J. Rich, M.D.</i>	<i>Neurosurgery</i>	<i>112</i>
<b><i>Total Projected OR Cases</i></b>		<b><i>727</i></b>

*Source: Physician Performance Letters*

***Projected Procedure Room Cases***

<i>Physician</i>	<i>Specialty</i>	<i>Projected OR [sic] Cases</i>
<i>Thomas J. Weber, Jr., D.O.</i>	<i>Pain Management</i>	<i>2,200</i>
<i>Michael W. Kelly, M.D.</i>	<i>Ophthalmology</i>	<i>1,500</i>
<i>Isaac Porter, M.D.</i>	<i>Ophthalmology</i>	<i>550</i>
<i>Andrey Belayev, M.D.</i>	<i>Neurosurgery</i>	<i>157</i>
<i>Brandon C. Burnsed, M.D.</i>	<i>Neurosurgery</i>	<i>117</i>
<b><i>Total Projected Procedure Room Cases</i></b>		<b><i>4,524</i></b>

*Source: Physician Performance Letters*

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections are based on estimates of operating room and procedure room case volumes provided by physicians who have expressed their intention to perform surgical cases at the proposed ASC.
- In Exhibit 4.C (Tab 6) of the application, the applicant provides copies of the letters from physicians which document the physicians support for the proposed project, and include projections of operating room and procedure case volumes that correspond to the projections shown in the tables above. In the letters, the physicians state the estimates are based on their review of their historical (2018) case volumes.

**Access**

In Section C.8, page 35, the applicant states it will not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. In Section L.3,

page 70, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Payor Source</b>	<b>Operating Rooms and Procedure Rooms</b>
Medicare*	50.7%
Medicaid*	1.5%
Insurance*	38.8%
Self-Pay	0.6%
Champus	4.7%
Workers Compensation	3.7%
Total	100.0%

\* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support its assumptions.

**TOSC.** Triangle Orthopaedics Surgery Center, LLC [**TOSC**] proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms, and convert the specialty ASC to a multispecialty ASC. TOSC is an existing orthopedic ASC with two operating rooms located on ACC Boulevard in Raleigh which was developed pursuant to a need determination in the 2010 SMFP for a Single Specialty Ambulatory Surgery Demonstration Project.

### **Patient Origin**

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin for the applicant’s operating rooms.

County	Third Full Fiscal Year of Operation CY2023	
	Patients	% of Total
Wake	2,551	51.5%
Durham	414	8.4%
Johnston	394	7.9%
Franklin	274	5.5%
Orange	150	3.0%
Wayne	138	2.8%
Harnett	130	2.6%
Wilson	97	2.0%
Nash	93	1.9%
Granville	93	1.9%
Alamance	76	1.5%
Person	74	1.5%
Other States	78	1.6%
Other NC Counties*	386	7.9%
<b>Total</b>	<b>4,951</b>	<b>100.0%</b>

Source: Section C.3, page 23. The counties included in the “Other NC Counties” category are shown in the table on page 23 and in the footnote to the table on pages 23-24.

In Section C.3, page 24, the applicant provides the assumptions and methodology used to project their patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 25-42, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need determination for operating rooms for the Wake County service area identified in the 2019 SMFP.
- Historical and projected growth and aging of the service area population.
- Advances in surgical and anesthesia techniques that have shifted surgical procedures to ambulatory settings.
- The growth in ambulatory surgical services due to changes in reimbursement, cost savings and patient choice.

- Physician support for the proposed addition of operating rooms to the existing ASC and physician recruitment to increase the size of the TOSC medical staff.
- The historical and projected utilization of the TOSC operating rooms.
- The need for additional multispecialty ASC operating rooms based on the significant percentage of total surgical cases that are ambulatory surgical cases and the current inventory of operating rooms in the Wake County service area.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides documentation of the physician support for the proposed ASC.
- The applicant’s population growth projections are based on data from the North Carolina Office of State Budget and Management (NCOSBM).
- The applicant provides information to support its assertions regarding projected growth of the ambulatory surgical case volumes and the need for ambulatory surgical operating rooms.

*Projected Utilization*

In Section Q, the applicant provides projected utilization of the four operating rooms, as illustrated in the following table.

**Projected TOSC Utilization**

Operating Rooms	Year 1 CY2021	Year 2 CY2022	Year 3 CY2023
Dedicated Ambulatory ORs	4	4	4
Outpatient Surgical Cases	3,933	4,437	4,951
Surgical Case Times	92	92	92
Totals Surgical Hours	6,031	6,803	7,592
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	4.6	5.2	5.8

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

**Step 1:** The applicant calculated the TOSC market share for ambulatory orthopedic surgical services as 12 percent based on TOSC FY2018 surgical case volume and the total ambulatory orthopedic surgical cases reported by all Wake County providers for FY2018, as shown in the table on page 101.

**Step 2:** The applicant calculates the TOSC market share for ambulatory orthopedic surgical services as 12.1 percent for CY2018 based on TOSC CY2018 surgical case volume and the total orthopedic surgical cases for all Wake County providers for FY2018 and projects the TOSC market share for ambulatory orthopedic surgical services as 12.7 percent for CY2019 based on TOSC surgical case volumes for the most recent 12 months (May 1, 2018 to April 30, 2019) and the total ambulatory orthopedic surgical cases for all Wake County providers for FY2018, as shown on the table on page 101.

**Step 3:** The applicant projects the total ambulatory orthopedic surgical cases for all Wake County providers for the time period from 2018 to 2023 based on the assumption that total ambulatory orthopedic surgical case volume will grow by 2 percent, annually, due to “*population growth and aging, changes in technology and changes in reimbursement to shift more cases to ASFs to support cost savings,*” as shown in the table on page 102.

**Step 4:** The applicant projects total TOSC ambulatory orthopedic surgical case volumes by years based on its projected market shares and the total ambulatory orthopedic surgical cases for all Wake County providers for the time period from 2018 to 2023 (Step 3), as shown in the table on page 102. The applicant assumes its market share of total ambulatory orthopedic surgical cases will increase to 13 percent in 2020, and then increase by one percentage point per year from 2020 to 2023, or from 13 to 16 percent, due to “*additional capacity, greater scheduling options, cost savings, physician recruitment, growth of existing and new orthopedic surgeon practices.*”

**Step 5:** The applicant projects the surgical case volumes for pain management, general surgery and plastic surgery based on the surgical case volume estimates provided in the physician letters of support for each of those specialties, as shown in the table on page 104.

**Step 6:** The applicant combines the projections of total ambulatory orthopedic surgical cases (Step 4) with the total surgical case volumes for pain management, general surgery and plastic surgery (Step 5) to project total surgical case for the TOSC ASC, as shown in the table on page 105 of the application.

**Step 7:** Based on the total projected surgical case volumes (Step 6), the applicant calculates the total surgical hours and number operating rooms needed at TOSC, as shown on page 106 of the application.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s projections of total ambulatory orthopedic surgical case volumes by year are supported by projected population growth and aging in the Wake County service area.
- The applicant’s utilization projections and ambulatory orthopedic surgical case volumes at the TOSC ASC are based on and supported by the applicant’s historical utilization and by TOSC ASC’s historical ambulatory orthopedic surgical case market share.
- The applicant’s utilization projections for the pain management, general surgery, and plastic surgery specialties are based on estimates of surgical case volumes provided by physicians who have expressed their intention to perform surgical cases at the proposed ASC. See Exhibit C.4.

### Access

In Section C.8, page 47, the applicant states it will not discriminate against anyone based on age, race, color, ethnicity, religion, gender, disability or ability to pay. In Section L.3, page 86, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Payor Source</b>	<b>Operating Rooms</b>
Self-Pay	2.9%
Charity Care	0.2%
Medicare*	24.3%
Medicaid*	4.8%
Insurance*	55.5%
Workers Compensation	6.6%
TRICARE	4.0%
Other (Liability Insurance)	1.6%
Total	100.0%

\* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support its assumptions.

**Duke Green Level ASC.** Duke University Health System, Inc. [**Duke Green Level ASC**] proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion. As part of settlement for Project I.D. # J-11557-18, the applicant was approved to develop a multispecialty ambulatory surgery center with one operating room and five procedure rooms pursuant to the Wake County operating room need determination in the 2018 SMFP.

### **Patient Origin**

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin for the applicant’s proposed ambulatory surgery center.

County	Third Full Fiscal Year of Operation FY2025	
	Patients	% of Total
Wake	1,691	52.0%
Johnston	159	4.9%
Durham	128	3.9%
Franklin	115	3.5%
Cumberland	102	3.1%
Nash	57	1.7%
Harnett	62	1.9%
Orange	42	1.3%
Granville	34	1.0%
Vance	28	0.9%
Alamance	23	0.7%
Chatham	19	0.6%
Person	10	0.3%
Guilford	13	0.4%
Other States	124	3.8%
Other NC Counties*	648	19.9%
<b>Total</b>	<b>3,254</b>	<b>100.00%</b>

Source: Section C.3, page 19.

\*On page 19, the applicant states the counties included in this category represent less than one percent of patients.

In Section C.3, pages 19-20, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 20-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The historical growth in ambulatory surgery volumes at DUHS facilities, particularly in Wake County, and the utilization of surgical capacity at the Duke Raleigh Hospital.
- The historical utilization of surgical services at DUHS facilities in Durham County by residents of Wake County.

- The trend toward moving surgical cases to outpatient settings due to technological advancements, improvements in anesthesia and pain management, the development of minimally invasive procedures, and the cost advantages of outpatient setting over inpatient or hospital-based facilities.
- Projected growth and aging of the Wake County population, particularly in the western portion of the county, and the need for improved geographic access to outpatient surgical services in the western portion of Wake County.
- The need to add ambulatory surgery services to the growing array of DUHS primary care and specialty care services in an ambulatory medical setting.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides information and data to support its assertions regarding the growth in surgical case volumes for the residents of Wake County.
- The applicant provides information to support its assertion that the historical trend is toward moving surgical cases to outpatient settings.
- The applicant provides population growth projections for the proposed service area based on data from the North Carolina Office of State Budget and Management (NCOSBM), Truven and other sources.

*Projected Utilization*

In Section Q, the applicant provides projected utilization for the three operating rooms and five procedure rooms at the Duke Green Level ASC, as illustrated in the following table.

**Projected Duke Green Level ASC Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Dedicated Ambulatory ORs	3	3	3
Outpatient Surgical Cases	1,393	2,444	3,254
Surgical Case Times	76.6	76.6	76.6
Totals Surgical Hours	1,778	3,121	4,154
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.4	2.4	3.2
<b>Procedure Rooms</b>			
# of Procedure Rooms	5	5	5
Total Procedures	339	566	819

Source: Section Q, Form C.

Duke Raleigh Hospital (DRAH) currently has 15 shared operating rooms. In Section Q, the applicant provides projected utilization of Duke Raleigh Hospital’s shared operating rooms during the first three operating years of the proposed project, as illustrated in the following table.

**Projected Duke Raleigh Hospital Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Shared Operating Rooms	15	15	15
Inpatient Surgical Cases	3,865	3,928	3,991
Outpatient Surgical Case	7,531	7,256	7,172
<b>Total Surgical Cases</b>	<b>11,396</b>	<b>11,183</b>	<b>11,164</b>
Inpatient Surgical Case Times	207.0	207.0	207.0
Outpatient Surgical Case Times	112.0	112.0	112.0
Inpatient Surgical Hours	13,334	13,551	13,771
Outpatient Surgical Hours	14,058	13,544	13,389
<b>Total Surgical Hours</b>	<b>27,392</b>	<b>27,095</b>	<b>27,159</b>
Group Assignment	3	3	3
Standard Hours per OR per Year	1,755	1,755	1,755
<b>Total Surgical Hours/Standard Hours Per OR per Year</b>	<b>15.6</b>	<b>15.4</b>	<b>15.5</b>

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

**Step 1:** The applicant reviewed the historical surgical case volumes at existing DUHS surgical facilities from FY2015 to FY2019.

**Step 2:** Based on the historical surgical case volumes from FY2015 to FY2019, growth and aging of the Wake County population, statistical data regarding surgical use rates, and the applicant’s physician recruitment plans, the applicant projects the annual growth rates for inpatient and outpatient surgical cases at the Duke University Hospital (DUH) and Duke Raleigh Hospital (DRAH) facilities, as shown in the table on page 126 of the application.

**Step 3:** Based on the projected surgical case growth rates (Step 2), the applicant projects the surgical case volumes for DUH and DRAH through the first three operating years of the proposed project, as shown in the table on page 127 of the application.

**Step 4:** The applicant identified the FY2019 outpatient surgical cases performed at DUH and DRAH that would be potentially appropriate candidates to have the surgery in an ambulatory surgery center based on the criteria described on page 128 of the application.

**Step 5:** Based on the percentages of ASC-appropriate cases identified in Step 4, the applicant projects the outpatient operating room cases appropriate for an ASC for DUH and DRAH through the first three operating years of the proposed project, as shown in the table on page 129.

**Step 6:** The applicant identifies historical (FY2018 and FY2019 combined) outpatient surgical cases by facility and by specialty, as summarized in the table on page 130.

**Step 7:** Based on historical outpatient surgical utilization by specialty (Step 6), and the anticipated surgical specialties that will practice at the proposed ASC, the applicant projects the potential number of ASC-appropriate outpatient surgical cases by specialty (Step 5) that could shift from DUH and DRAH to an ASC. See tables on pages 131-132.

**Step 8:** Based on projections of ASC-appropriate outpatient surgical cases by specialty projected to shift to the Arrington ASC to be developed in Durham (Project I.D. # J-11508-18), the applicant excludes those cases from the total number of ASC-appropriate outpatient surgical cases by specialty that will shift from DUH and DRAH to the Green Level ASC. See tables on pages 132-133.

**Step 9:** The applicant projects that the ASC-appropriate outpatient surgical cases that will shift to the proposed Green Level ASC will primarily be from DRAH, with a lesser percentage shifting from DUH. The applicant does not project any ASC-appropriate outpatient surgical cases will shift to the Green Level ASC from Duke Regional Hospital or Davis Ambulatory Surgical Center. The applicant provides its projections of the percentage of ASC-appropriate outpatient surgical cases that will shift from Duke University Hospital and Duke Raleigh Hospital to the proposed ASC by specialty in each of the first three operating years of the proposed project in the tables on page 137 of the application.

**Step 10:** Based on the applicant's projections of the percentage of ASC-appropriate outpatient surgical cases by specialty that will shift to the Green Level ASC from DRAH and DUH, the applicant projects the total surgical cases by specialty at the Green Level ASC in each of the first three operating years, as shown in the tables on pages 138-139 of the application. Also, the applicant provides projected surgical case volumes for DUH and DRAH, after the projected shift of ASC-appropriate outpatient surgical cases to the approved Arrington ASC (Project # J-11508-18) and the Green Level ASC, through the first three operating years of the proposed project, as shown in the table on page 140 of the application.

**Step 11:** Based projected surgical case volumes for the DRAH and the Green Level ASC, the applicant projects the total operating room need for both facilities in the third operating year of the proposed project (FY2025), based on the operating room need methodology in the 2019 SMFP, as shown in the table on page 141 of the application.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant's projections of total ambulatory surgical case volumes by year at DUH and DRAH are supported by the historical growth rates of ambulatory surgical case volumes at those facilities and by projected population growth and aging in the Wake County service area.
- The applicant's projections of total ambulatory surgical case volumes by year that will shift from DUH and DRAH to the Green Level ASC are supported by the applicant's historical experience with regard to surgical volumes by specialty and the numbers and types of ASC-appropriate surgical cases that could reasonably be expected to shift to the Green Level ASC, as well as other factors such as patient cost advantages, improved geographic access, and the advantages to both physicians and patients of having access to a newer, more modern facility,
- Exhibit C.4 contains copies of letters from surgeons expressing support for the proposed project and their intention to perform surgical cases at the facility.

*Duke University Health Care System-Wake County*

The following table shows the total surgical cases at Duke Raleigh Hospital from FY2015 to FY2019 based on data reported by the applicant in Section Q of the application.

**Duke University Health Care System-Wake County Surgical Cases, FY2012-FY2018**

	FY2015	FY2016	FY2017	FY2018	FY2019	CAGR FY2012- FY2018
Total Surgical Cases*	12,862	13,649	13,989	14,692	15,114	4.12%
<b>Percent Change</b>		6.12%	2.49%	5.03%	2.87%	

Source: Section Q, pages 122-123 of the application.

\*Includes surgical cases performed in Duke Raleigh Hospital's procedure rooms.

The following table shows the applicant's total projected surgical cases at all existing, approved and proposed UNC REX surgical facilities in Wake County from FY2019 to FY2025 based on data in Form C, Section Q of the application.

**Projected Duke University Health System-Wake County Surgical Cases, FY2019-FY2025**

	FY2019	FY2020	FY2021	FY2022	PY 1 FY2023	PY 2 FY2024	PY 3 FY2025	CAGR FY2019- FY2025
Duke Raleigh Hospital	10,989	11,344	11,648	11,958	11,396	11,183	11,164	
Duke Green Level ASC					1,393	2,444	3,254	
Total Surgical Cases	10,989	11,344	11,648	11,958	12,789	13,627	14,418	4.63%
<b>Percent Change</b>		3.23%	2.68%	2.66%	6.95%	6.55%	5.80%	

Source: Section Q, Form C combined.

As shown in the tables above, the historical growth rates for surgical cases at DUHS surgical facilities in Wake County averaged 4.12 percent per year from FY2015 to FY2019. The applicant's utilization projections for all existing, approved and proposed DUHS surgical facilities in Wake County for the period from FY2019 through FY2025 are based on the assumption that surgical case volumes will increase at an average rate of 4.63 percent per year over the six-year period.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant's utilization projections are supported by the historical utilization experience of the DUHS's existing operating rooms, and by the projected Wake County population growth.
- The applicant's utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit C.4.

**Access**

In Section C.8, page 48, the applicant states it is committed to providing services to all patients, and will not discriminate against anyone based on race, age, gender, disability, or the patient's ability to pay. In Section L.3, page 105, the applicant projects the following payor mix during the second full fiscal year (FY2023) of operation following completion of the project, as illustrated in the following table.

Payor Source	Operating Rooms	Procedure Rooms
Self-Pay/Charity Care	2.0%	1.9%
Medicare *	43.7%	33.6%
Medicaid *	4.7%	6.3%
Insurance *	45.4%	47.7%
Other Govt, Workers Comp	4.3%	10.6%
Total	100.0%	100.0%

\* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support its assumptions.

**WakeMed Cary Hospital.** WakeMed [WakeMed Cary Hospital] proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 shared surgical operating rooms and two dedicated C-Section operating rooms) upon project completion. WakeMed Cary Hospital is currently licensed for a total of 11 operating rooms (nine share surgical operating rooms and two dedicated C-Section operating rooms). In Project I.D. #J-11428-17, the applicant was approved to relocate one shared operating room from WakeMed Raleigh Campus to WakeMed Cary Hospital for a total of 12 operating rooms (10 share surgical operating rooms and two dedicated C-Section operating rooms) at WakeMed Cary Hospital.

**Patient Origin**

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas

are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin for the applicant’s operating rooms in the third full operating year of the project.

County	Third Full Fiscal Year of Operation FY2023	
	Patients	% of Total
Wake	7,186	74.5%
Harnett	511	5.3%
Johnston	395	4.1%
Durham	174	1.8%
Chatham	135	1.4%
Lee	135	1.4%
Cumberland	96	1.0%
Alamance	77	0.8%
Sampson	58	0.6%
Franklin	48	0.5%
Other*	830	8.6%
<b>Total</b>	<b>9,645</b>	<b>100.0%</b>

Source: Section C.3, page 22. The counties included in the “Other” category are shown in the tables on pages 22-23 of the application.

In Section C.3, page 23, the applicant provides the assumptions and methodology used to project their patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 24-33, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The historical and projected growth of the Wake, Johnston and Harnett County populations, and particularly in western and southern Wake County.
- The historical growth in surgical case volumes at WakeMed Cary Hospital and the increase in average inpatient and outpatient surgical case times.
- Shift in proportion of inpatient surgical cases versus outpatient surgical cases, and the higher complexity and surgical case times that are associated with that shift.
- Changes in the types of surgeons and surgeries at WakeMed Cary Hospital, including the addition of neurosurgery, bariatric surgery, breast surgery and vascular surgery.
- The increase in acute care bed capacity and the designation of the WakeMed Cary Hospital as a Level III Trauma Center by the Office of Emergency Medical Services (OEMS), both of which will increase the need for inpatient surgical capacity.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides population growth projections for the proposed service area based on data from the North Carolina Office of State Budget and Management (NCOSBM) and ESRI.
- The applicant provides information and data to support their assertions regarding the historical growth in surgical case volumes and average surgical case times at WakeMed Cary Hospital.

*Projected Utilization*

In Section C.6, page 36 the applicant provides a table showing the operating room inventories for WakeMed’s existing Wake County surgical facilities, which is summarized below:

<b>WakeMed System</b>				
	<b>Inpatient ORs</b>	<b>Shared ORs</b>	<b>Ambulatory ORs</b>	<b>Total ORs*</b>
WakeMed Raleigh (incl. WakeMed North)	4	19	0	23
WakeMed Cary Hospital	0	10	0	10
Capital City Surgery Center	0	0	8	8
<b>WakeMed System Total</b>	<b>4</b>	<b>29</b>	<b>8</b>	<b>41</b>

Source: Section C.6, page 36.

\*Excludes three dedicated C-Section operating rooms at WakeMed Raleigh Campus, one dedicated C-Section operating room at WakeMed North Hospital, and two dedicated C-Section operating rooms at WakeMed Cary Hospital.

In Section C.6, page 37, the applicant states,

*“The CON Section has given tacit approval through the settlement process to WakeMed for Project No. J-11564-18, which will create a new freestanding ASF in North Raleigh by relocating an existing operating room from Capital City Surgery Center. At the time of submission, the certificate of need for Project No. J-11564-18 had not been transmitted. ... In addition, the CON Section has given tacit approval through the settlement process to WakeMed for Project No. J-11565-18, which will create a freestanding ASF with 1 operating room in Cary, from the Wake County service area allocation in the 2018 SMFP. At the time of submission, the certificate of need for Project No. J-11565-18 had not been transmitted.”*

Effective August 15, 2019, which is the date of submission of this application, the Agency issued a Certificate of Need to WakeMed Surgery Center-Cary, LLC, for Project I.D. # J-11564-18, to develop a new ambulatory surgical facility by developing no more than one operating room from the need determination in the 2018 SMFP and three procedure rooms. Effective October 24, 2019, the Agency issued a Certificate of Need to WakeMed for Project I.D. # J-11564-18, WakeMed Surgery Center-North Raleigh, to develop a new multispecialty ambulatory surgery center in Raleigh with one operating room relocated from Capital City Surgery Center and three new procedure rooms.

In Section Q, the applicant provides utilization projections for WakeMed Cary Hospital, and for WakeMed’s other existing and approved Wake County surgical facilities through the first three operating years of the proposed project as discussed below.

*WakeMed Cary Hospital*

In Section Q, the applicant provides projected utilization of the shared operating rooms at the WakeMed Cary Hospital, as illustrated in the following table.

**Projected WakeMed Cary Hospital Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2021</b>	<b>Year 2 FY2022</b>	<b>Year 3 FY2023</b>
Shared Operating Rooms	11	11	11
Inpatient Surgical Cases	3,769	3,968	4,177
Outpatient Surgical Case	5,829	5,296	5,468
Total Surgical Cases	9,598	9,264	9,645
Inpatient Surgical Case Times	93.2	93.2	93.2
Outpatient Surgical Case Times	46.0	46.0	46.0
Inpatient Surgical Hours	5,854.5	6,163.6	6,488.3
Outpatient Surgical Hours	4,468.9	4,060.3	4,192.1
Total Surgical Hours	10,323.4	10,223.4	10,680.4
Group Assignment	4	4	4
Standard Hours per OR per Year	1,500	1,500	1,500
Total Surgical Hours/Standard Hours Per OR per Year	6.88	6.82	7.12

Source: Section Q, Form C.

*WakeMed Raleigh (Including WakeMed North Hospital)*

In Section Q, the applicant provides projected utilization of the four open heart and 19 shared operating rooms at WakeMed Raleigh Campus and WakeMed North Hospital, as illustrated in the following table.

**Projected WakeMed Raleigh Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2021</b>	<b>Year 2 FY2022</b>	<b>Year 3 FY2023</b>
Open Heart Operating Rooms	4	4	4
Shared Operating Rooms	19	19	19
Inpatient Surgical Cases	8,327	8,414	8,502
Outpatient Surgical Case	14,386	13,191	14,230
Total Surgical Cases	22,713	21,605	22,732
Inpatient Surgical Case Times	179.3	179.3	179.3
Outpatient Surgical Case Times	118.6	118.6	118.6
Inpatient Surgical Hours	24,884	25,144	25,407
Outpatient Surgical Hours	28,436	26,074	28,128
Total Surgical Hours	53,320	51,218	53,535
Group Assignment	2	2	2
Standard Hours per OR per Year	1,950	1,950	1,950
Total Surgical Hours/Standard Hours Per OR per Year	27.34	26.27	27.45

Source: Section Q, Form C.

*Capital City Surgery Center*

In Section Q, the applicants provide projected utilization for the dedicated ambulatory surgery operating rooms at the Capital City Surgery Center (CCSC), as illustrated in the following table.

**Projected Capital City Surgery Center Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2021</b>	<b>Year 2 FY2022</b>	<b>Year 3 FY2023</b>
Dedicated Ambulatory ORs*	8	7	7
Outpatient Surgical Cases	7,109	6,758	6,833
Surgical Case Times	60.3	60.3	60.3
Totals Surgical Hours	7,145	6,792	6,867
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	5.45	5.18	5.23

Source: Section Q, Form C.

\*In Project I.D. # J-11564-18, the applicant was approved to relocate one dedicated ambulatory surgery operating room from CCSC to a new ASC, WakeMed Surgery Center-North Raleigh, which will decrease the number of operating rooms at CCSC from eight to seven in the second year of the proposed project.

*WakeMed Surgery Center-North Raleigh*

In Section Q, the applicant provides projected utilization of the one operating room at the approved (Project I.D. # J-11564-18) ambulatory surgery center in North Raleigh as illustrated in the following table.

**Projected WakeMed Surgery Center-North Raleigh Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2021</b>	<b>Year 2 FY2022</b>	<b>Year 3 FY2023</b>
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	2,031	2,162	2,302
Surgical Case Times	76.6	76.6	76.6
Totals Surgical Hours	2,593	2,760	2,939
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.98	2.10	2.24

Source: Section Q, Form C.

*WakeMed Surgery Center-Cary*

In Section Q, the applicant provides projected utilization of the one operating room at the approved (Project I.D. # J-11565-18) ambulatory surgery center in Cary as illustrated in the following table.

**Projected WakeMed Surgery Center-Cary Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2021</b>	<b>Year 2 FY2022</b>	<b>Year 3 FY2023</b>
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,450	1,531	1,618
Surgical Case Times	76.6	76.6	76.6
Totals Surgical Hours	1,851	1,955	2,066
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.41	1.49	1.57

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization at the existing and approved WakeMed surgical facilities in Wake County, which is summarized below.

**Step 1:** The applicant reviewed the historical surgical case volumes at each of the surgical facilities operating in Wake County from FY2015 to FY2018, and organized those surgical volumes into three categories, including hospital surgical inpatients, hospital surgical outpatients, and freestanding ambulatory surgery center (ASC) outpatients, as shown in the tables on pages 115-116.

**Step 2:** Based on the surgical case volumes for the three categories of patients identified in Step 1 above, the applicant calculated the average annual growth rates for each category from FY2015 to FY2018, as shown in the table on page 116 of the application.

**Step 3:** Based on the surgical case growth rates calculated above in Step 2, the applicant projects the surgical case volumes for the three categories (hospital surgical inpatients, hospital surgical outpatients, and freestanding ASC outpatients) through FY2023, as shown in the table on page 117 of the application.

**Step 4:** The applicant reviewed the historical surgical case volumes at each of the existing WakeMed surgical facilities operating from FY2015 to FY2019, as shown in the table on page 117 of the application. Based on the surgical case growth rates at WakeMed Cary Hospital from FY2015-FY2019, the applicant projects the surgical case volumes for hospital surgical inpatients and hospital surgical outpatients for WakeMed Cary Hospital through FY2023, as shown in the table on page 118 of the application. Based on the surgical case growth rates at WakeMed Raleigh Campus (including WakeMed North Hospital) from FY2015 to FY2019, the applicant projects the surgical case volumes for hospital surgical inpatient and outpatients for WakeMed Raleigh Campus through FY2023, as shown on page 118. Based on the surgical case growth rates at Capital City Surgery Center from FY2015-FY2019, the applicant projects the surgical case volumes for ASC surgical outpatients for Capital City Surgery Center through FY2023, as shown in the table on page 119 of the application.

**Step 5:** The applicant projects that some outpatient surgical case volume will shift from its existing Wake County facilities to the approved WakeMed Surgery Center-Cary facility (Project I.D. # J-11564-18), and also to the approved WakeMed Surgery Center-North Raleigh facility (Project I.D.# J-11565-18). Based on the proximity of the existing surgical facilities to the two approved ASCs, and on surgeon practice patterns, the applicant projects the number of surgical cases that will shift from the existing surgical facilities to the proposed ASCs through FY2024, as shown in the tables on page 120 of the application.

**Step 6:** Based on the applicant's projections of the outpatient surgical cases that will shift from the existing WakeMed surgical facilities to the approved North Raleigh and Cary ASCs, the applicant projects total outpatient surgical case volumes at the approved WakeMed Surgery Center-North Raleigh and WakeMed Surgery Center-Cary through the first three operating years of the proposed project, as shown in the tables on page 121 of the application.

**Step 7:** Based on the applicant's projections of inpatient and outpatient surgical cases for each of their existing and proposed surgical facilities, the applicant applied the operating room need methodology from the 2019 SMFP to project the total number of operating rooms needed at each existing and approved WakeMed facility through the first three operating years of the proposed project, as shown in the tables on pages 122-125 of the application.

**Step 8:** Based on the applicant's projections of inpatient and outpatient surgical cases for each of their existing and proposed surgical facilities, the applicant projects the total number of surgical operating rooms needed in the WakeMed System in the first three operating years of the proposed project, as shown in the table on page 125 of the application.

#### *WakeMed Health Care System-Wake County*

The following table shows the total surgical cases at all WakeMed surgical facilities in Wake County from FY2012 to FY2018 based on data reported to DHSR on the License Renewal Application forms for the years 2013 to 2019.

**WakeMed Health Care System Surgical Cases, FY2012-FY2018**

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	CAGR FY2012- FY2018
Total Surgical Cases*	28,136	30,124	30,514	30,388	31,594	31,169	33,761	3.08%
<b>Percent Change</b>		7.1%	1.3%	-0.4%	4.0%	-1.3%	8.3%	

Source: License Renewal Application forms, 2013-2019.

\*Excludes C-Section procedures in dedicated C-Section operating rooms.

The following table shows the applicant's total projected surgical cases at all existing, approved and proposed WakeMed surgical facilities in Wake County from FY2019 to FY2025 based on data in Form C, Section Q of the application.

**Projected WakeMed Health Care System Surgical Cases, FY2018-FY2023**

	FY2018	FY2019	FY2020	PY 1 FY2021	PY 2 FY2022	PY 3 FY2023	CAGR FY2018- FY2023
WakeMed Cary Hospital	7,929	8,870	9,226	9,598	9,264	9,645	
WakeMed Raleigh	19,130	20,518	21,577	22,713	21,605	22,732	
Capital City Surgery Center	6,712	6,952	7,030	7,109	6,758	6,833	
WakeMed Surgery Center North				2,031	2,162	2,302	
WakeMed Surgery Center Cary				1,450	1,531	1,618	
Total Surgical Cases	33,771	36,340	37,833	42,901	41,320	43,130	5.01%
<b>Percent Change</b>		7.61%	4.11%	13.40%	-3.69%	4.38%	

Source: Section Q, Form C combined.

As shown in the tables above, the historical growth rates for surgical cases at WakeMed surgical facilities in Wake County averaged 3.08 percent per year from FY2012 to FY2018. The applicant's utilization projections for all existing, approved and proposed WakeMed surgical facilities in Wake County for the period from FY2018 through FY2023 are based on the assumption that surgical case volumes will increase at an average rate of 5.01 percent per year over the five-year period.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant's projections of total inpatient and outpatient surgical case volumes by year at its existing surgical facilities are supported by the historical growth rates of surgical case volumes at those facilities from FY2012 to FY2018, and by projected population growth and aging in the Wake County service area.
- The applicant states projections of total ambulatory surgical case volumes by year that will shift from the existing WakeMed surgical facilities to the North Raleigh and Cary ASCs are based on its belief that *"a certain percentage of its existing hospital-based outpatient surgery volume will shift to these new facilities, as physician practice patterns change and new ASFs are developed in closer proximity to physician offices and to local residents."*
- Exhibit I.3 contains copies of letters from surgeons expressing support for the proposed project and their intention to perform surgical cases at the facility.

**Access**

In Section C.8, pages 39-47, the applicant states it is committed to providing services to all patients, and will not discriminate against anyone based on income, payer status, race, ethnicity, age, sex, physical handicap, or the patient’s ability to pay. In Section L.3, page 89, the applicant projects the following payor mix during the third full fiscal year (FY2023) of operation following completion of the project, as illustrated in the following table.

<b>Payor Source</b>	<b>Entire Facility</b>	<b>Operating Rooms</b>
Self-Pay	4.53%	2.33%
Charity Care	5.53%	5.04%
Medicare *	44.47%	47.59%
Medicaid *	4.94%	3.76%
Insurance *	38.45%	38.90%
Other	2.08%	2.39%
Total	100.00%	100.00%

\* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support its assumptions.

**UNC REX Hospital.** Rex Hospital, Inc. d/b/a UNC REX Hospital [**UNC REX Hospital**] proposes to develop two additional operating rooms at the existing hospital in Raleigh for a total of 26 shared operating rooms and three dedicated C-section operating rooms upon completion of Project I.D. # J-8669-11 (relocate three operating rooms to Rex Hospital Holly Springs), Project I.D. # J-11555-18 (develop two additional operating rooms pursuant to the need determination in the 2018 SMFP), and this project.

**Patient Origin**

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the projected patient origin for the UNC REX Hospital operating rooms in the third full fiscal year of operation (FY2025).

County	Third Full Fiscal Year of Operation FY2025	
	Patients	% of Total
Wake	14,263	64.4%
Johnston	1,736	7.8%
Harnett	854	3.9%
Franklin	847	3.8%
Wayne	558	2.5%
Nash	530	2.4%
Wilson	467	2.1%
Sampson	355	1.6%
Durham	315	1.4%
Cumberland	181	0.8%
Other*	2,049	9.2%
Total	22,155	100.0%

Source: Section C.3, page 18.

\*The applicant lists the counties included in this category on page 18 of the application.

In Section C.3, page 19, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 26-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The increasing demand for surgical services in the Wake County service area from 2012 to 2018.
- The historical trend toward relocating hospital-based operating rooms to ambulatory surgery facilities has had the effect of reducing the overall surgical capacity for Wake County providers, and has increased the need for additional operating rooms, particularly in the hospital setting.

- The historical operating room utilization and projected operating room deficits for the UNC Health Care System and UNC REX Hospital based on the 2019 SMFP Proposed 2020 SMFP operating room need methodology.
- The planned recruitment of additional surgeons and relocation of specialty services from Chapel Hill to Raleigh.
- The planned relocation of three operating rooms from UNC REX Hospital to UNC REX Holly Springs Hospital when that project becomes operational.
- The projected growth and aging of the Wake County population.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides information and data to support its assertion regarding the growth in surgical case volumes in North Carolina and Wake County.
- The applicant provides information to support its assertion that the historical trend toward relocating hospital-based operating rooms to ambulatory surgery facilities has had the effect of reducing the overall surgical capacity for Wake County providers.
- The applicant provides population growth projections for the proposed service area based on data from the North Carolina Office of State Budget and Management (NCOSBM) and other sources.

*Projected Utilization*

In Section Q, Form C Methodology, page 1, the applicant provides a table showing the operating room inventories for UNC Health Care’s existing, approved and proposed Wake County surgical facilities, which is summarized below:

**UNC Health Care**

	<b>Adjusted Operating Room Planning Inventory</b>	<b>Proposed Adjusted Planning Inventory</b>
UNC REX Hospital Holly Springs	3	3
Rex Surgery Center of Wakefield	2	2
Rex Surgery Center of Cary	4	4
UNC REX Hospital*	22	26
Raleigh Orthopaedic Surgery Center	3	3
Raleigh Orthopaedic Surgery Center-West Cary	1	1
<b>Total</b>	<b>35</b>	<b>39</b>

Source: Section Q, Form C Methodology, page 1.

\*The additional operating rooms in the Proposed Adjusted Planning Inventory for UNC Rex Hospital include two additional operating rooms approved in the settlement of the 2018 Wake County operating room review (Project I.D. # J-11555-18) and the two additional operating rooms proposed in this application.

In Section Q, the applicant provides utilization projections for UNC REX Hospital’s operating rooms, and for UNC Health Care’s other existing, approved and proposed Wake County surgical facilities through the first three operating years of the proposed project as discussed below.

*UNC REX Hospital*

In Section Q, Form C, the applicant provides projected utilization of UNC REX Hospital’s operating rooms during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

**Projected UNC REX Hospital Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Shared Operating Rooms	26	26	26
Inpatient Surgical Cases	8,418	8,298	8,381
Outpatient Surgical Case	12,948	13,181	13,774
<b>Total Surgical Cases</b>	<b>21,366</b>	<b>21,479</b>	<b>22,155</b>
Inpatient Surgical Case Times	169.4	169.4	169.4
Outpatient Surgical Case Times	124.6	124.6	124.6
Inpatient Surgical Hours	23,767	23,428	23,662
Outpatient Surgical Hours	26,888	27,374	28,603
<b>Total Surgical Hours</b>	<b>50,655</b>	<b>50,802</b>	<b>52,266</b>
Group Assignment	2	2	2
Standard Hours per OR per Year	1,950	1,950	1,950
<b>Total Surgical Hours/Standard Hours Per OR per Year</b>	<b>26.0</b>	<b>26.1</b>	<b>26.8</b>

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant states projected utilization of the hospital’s operating rooms is based on the assumption that inpatient surgical case volumes will increase by an average annual growth rate of one percent, based on the historical growth rates for inpatient surgical case volumes and the projected population growth in the Wake County service area. The applicant assumes outpatient surgical case volumes will increase at an average annual growth rate of 4.5 percent through the first three operating years of the proposed project based on the historical growth rates for outpatient surgical case volumes, the projected population growth in the Wake County service area, and the increasing shift from inpatient to outpatient settings for surgical cases. Also, the applicant states it will recruit at least eight new surgeons and will relocate pediatric and other subspecialty services from Chapel Hill to Raleigh, which will result in an increase in the utilization of surgical services at UNC REX Hospital.

The applicant projects that surgical cases will shift from UNC REX Hospital to UNC REX Holly Springs Hospital when that facility becomes operational in FY2022 (See Section Q, pages 4-5). The applicant provides the projected utilization of the operating rooms at UNC REX Hospital after the projected shifts in surgical cases, as shown in the following table.

**Projected UNC REX Hospital Surgical Utilization after Shifts**

	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>PY 1 FY2023</b>	<b>PY 2 FY2024</b>	<b>PY 3 FY2025</b>
Inpatient Surgical Cases	8,710	8,797	8,885	8,974	9,064	9,155
Outpatient Surgical Cases	12,231	12,781	13,355	13,955	14,582	15,237
Inpatient Cases Shifted to UNC REX Holly Springs Hospital			-359	-556	-766	-774
Outpatient Cases Shifted to UNC REX Holly Springs Hospital			-630	-1,007	-1,400	-1,463
<b>Inpatient Cases after Shifts</b>	<b>8,710</b>	<b>8,797</b>	<b>8,526</b>	<b>8,418</b>	<b>8,298</b>	<b>8,381</b>
<b>Outpatient Cases after Shifts</b>	<b>12,231</b>	<b>12,781</b>	<b>12,725</b>	<b>12,948</b>	<b>13,181</b>	<b>13,774</b>

Source: Section Q, page 5.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections for UNC REX Hospital are based on the hospital’s historical surgical utilization, and are supported by the projected growth in the service area population.
- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

*UNC REX Holly Springs Hospital*

In Project I.D. # J-8669-11, Rex Hospital, Inc. was approved to develop a new 50-bed acute care hospital with three shared operating rooms in Holly Springs. The project is currently under development. In Section Q, the applicant provides projected utilization of the three shared operating rooms to be developed at the UNC REX Holly Springs Hospital during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

**Projected UNC REX Holly Springs Hospital Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Shared Operating Rooms	3	3	3
Inpatient Surgical Cases	618	851	860
Outpatient Surgical Case	1,119	1,556	1,626
<b>Total Surgical Cases</b>	<b>1,737</b>	<b>2,407</b>	<b>2,485</b>
Inpatient Surgical Case Times	169.4	169.4	169.4
Outpatient Surgical Case Times	124.6	124.6	124.6
Inpatient Surgical Hours	1,745	2,403	2,427
Outpatient Surgical Hours	2,324	3,231	3,376
<b>Total Surgical Hours</b>	<b>4,069</b>	<b>5,634</b>	<b>5,803</b>
Group Assignment	2	2	2
Standard Hours per OR per Year	1,950	1,950	1,950
<b>Total Surgical Hours/Standard Hours Per OR per Year</b>	<b>2.1</b>	<b>2.9</b>	<b>3.0</b>

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant states projected utilization is based on the surgical utilization projections in the previously approved CON application (Project I.D. #J-8669-11), and that since that approval, the southern Wake County area of Holly Springs and Fuquay-Varina have grown substantially.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections for UNC REX Holly Springs Hospital are based on the projected surgical utilization for the new hospital in the previously approved application, and are supported by the projected growth in the proposed service area.
- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

*Rex Surgery Center of Wakefield*

In Section Q, the applicant provides projected utilization of the two operating rooms at the existing ambulatory surgery center in Wakefield during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

**Projected Rex Surgery Center of Wakefield Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	1,530	1,530	1,530
Surgical Case Times	94.6	94.6	94.6
Totals Surgical Hours	2,412	2,412	2,412
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.8	1.8	1.8

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant states projected utilization of the two dedicated ambulatory surgical operating rooms is based on the assumption that surgical case volumes will remain stable at the actual FY2019 surgical case volume of 1,530 outpatient surgical cases. On page 10, the applicant states, *“The proposed project is not expected to impact Rex Surgery Center of Wakefield’s utilization in future years.”*

The applicant’s projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections for Rex Surgery Center of Wakefield for the period FY2020 through the third year of the proposed project (FY2025) are supported by the applicant’s historical (FY2019) surgical case volume.
- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

*Rex Surgery Center of Cary*

In Section Q, the applicant provides projected utilization of the four operating rooms at the existing ambulatory surgery center in Cary during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

**Projected Rex Surgery Center of Cary Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Dedicated Ambulatory ORs	4	4	4
Outpatient Surgical Cases	4,501	4,501	4,501
Surgical Case Times	57.0	57.0	57.0
Totals Surgical Hours	4,276	4,276	4,276
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	3.3	3.3	3.3

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant states projected utilization of the four dedicated ambulatory surgical operating rooms is based on the assumption that surgical case volumes will remain flat at the FY2019 volume of 4,501 surgical cases through the first three full fiscal years of operation of the proposed project.

The applicant’s projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections for Rex Surgery Center of Cary for the period FY2020 through the third year of the proposed project (FY2025) are supported by the applicant’s historical (FY2019) volume of surgical cases.
- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

*Raleigh Orthopaedic Surgery Center*

In Section Q, the applicant provides projected utilization of the three operating rooms at the existing ambulatory surgery center in Raleigh during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

**Projected Raleigh Orthopaedic Surgery Center Utilization**

Operating Rooms	Year 1 FY2022	Year 2 FY2023	Year 3 FY2024
Dedicated Ambulatory ORs	3	3	3
Outpatient Surgical Cases	3,721	3,797	3,875
Surgical Case Times	83.0	83.0	83.0
Totals Surgical Hours	5,148	5,253	5,360
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	3.9	4.0	4.1

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant states projected utilization of the three dedicated ambulatory surgical operating rooms is based on the utilization projections in the previously approved CON application to develop Raleigh Orthopaedic Surgery Center-West Cary (Project I.D. #J-11161-16), and the assumption that surgical case volumes will grow at an average annual rate of 2.04 percent through the first three operating years of the proposed project, which is consistent with the 2018 to 2024 projected Wake County population growth based on data from the NCOSBM.

The applicant’s projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections for Raleigh Orthopaedic Surgery Center for the period FY2020 through the third year of the proposed project (FY2025) are supported

by the applicant’s historical volume of surgical cases, and by the projected Wake County population growth.

- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

*Raleigh Orthopaedic Surgery Center-West Cary*

In Section Q, the applicant provides projected utilization of the operating room at the new ambulatory surgery center to be developed in Cary (Project I.D. # J-11161-16) during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

**Projected Raleigh Orthopaedic Surgery Center-West Cary Utilization**

<b>Operating Rooms</b>	<b>Year 1 FY2023</b>	<b>Year 2 FY2024</b>	<b>Year 3 FY2025</b>
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,147	1,171	1,195
Surgical Case Times	76.6	76.6	76.6
Totals Surgical Hours	1,465	1,495	1,525
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.1	1.1	1.2

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization. Specifically, the applicant states projected utilization of the dedicated ambulatory surgical operating room is based on the utilization projections in the previously approved CON application (Project I.D. #J-11161-16), and the assumption that surgical case volumes will grow at average annual rate of 2.04 percent through the first three operating years of the proposed project, which is consistent with the 2018 to 2024 projected Wake County population growth based on data from the NCOSBM.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections are supported by the historical utilization experience of the Raleigh Orthopaedic Surgery Center’s existing operating rooms, and by the projected Wake County population growth.
- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

*UNC REX Health Care System-Wake County*

The following table shows the total surgical cases at all UNC REX surgical facilities in Wake County from FY2012 to FY2018 based on data reported to DHSR on the License Renewal Application forms for the years 2013 to 2019.

**UNC REX Health Care System Surgical Cases, FY2012-FY2018**

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	CAGR FY2012- FY2018
Total Surgical Cases*	28,271	28,781	28,956	29,084	29,135	30,327	30,427	1.23%
<b>Percent Change</b>		1.8%	0.6%	0.4%	0.2%	4.1%	0.3%	

Source: License Renewal Application forms, 2013-2019.

\*Excludes C-Section procedures in dedicated C-Section operating rooms.

The following table shows the applicant’s total projected surgical cases at all existing, approved and proposed UNC REX surgical facilities in Wake County from FY2019 to FY2025 based on data in Form C, Section Q of the application.

**Projected UNC REX Health Care System Surgical Cases, FY2019-FY2025**

	FY2019	FY2020	FY2021	FY2022	PY 1 FY2023	PY 2 FY2024	PY 3 FY2025	CAGR FY2019- FY2025
UNC REX Hospital	20,329	20,941	21,578	21,251	21,366	21,479	22,155	
REX Holly Springs Hospital				1,099	1,737	2,407	2,485	
Rex Surgery-Wakefield	1,530	1,530	1,530	1,530	1,530	1,530	1,530	
Rex Surgery-Cary	4,501	4,501	4,501	4,501	4,501	4,501	4,501	
Raleigh Orthopedic SC	5,414	4,410	3,474	3,613	3,721	3,797	3,875	
Raleigh Orthopedic SC-West		525	1,071	1,114	1,147	1,171	1,195	
Total Surgical Cases	31,774	31,907	32,154	33,108	34,002	34,885	35,741	1.98%
<b>Percent Change</b>		0.42%	0.77%	2.97%	2.70%	2.60%	2.45%	

Source: Section Q, Form C combined.

As shown in the tables above, the historical growth rates for surgical cases at UNC REX surgical facilities in Wake County averaged 1.23 percent per year from FY2012 to FY2018. The applicant’s utilization projections for all existing, approved and proposed UNC REX surgical facilities in Wake County for the period from FY2019 through FY2025 are based on the assumption that surgical case volumes will increase at an average rate of 1.98 percent per year over the six-year period.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections are supported by the historical utilization experience of the UNC REX Health Care System’s existing operating rooms, and by the projected Wake County population growth.
- The applicant’s utilization projections are supported by letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

**Access**

In Section C.8, pages 36-41, the applicant states it is committed to providing services to all patients, and will not discriminate against anyone based on income, payer status, race, ethnicity, age, sex, physical handicap, or the patient’s ability to pay. In Section L.3, page 69,

the applicant projects the following payor mix during the third full fiscal year (FY2025) of operation following completion of the project, as illustrated in the following table.

<b>Payor Source</b>	<b>Entire Facility</b>	<b>Operating Rooms</b>
Self-Pay	5.4%	3.0%
Medicare *	43.5%	42.2%
Medicaid *	5.6%	4.0%
Insurance *	44.2%	48.2%
Other	1.3%	2.6%
Total	100.0%	100.0%

\* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support its assumptions.

- (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.

**NA**  
All Applications

None of the applications in this review propose to reduce or eliminate a service, or to relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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**  
All Applications

**WSSSC.** WSSSC proposes to develop a new specialty ambulatory surgery center on Six Forks Road in Raleigh with one operating room and three procedure rooms.

In Section E, page 45, the applicant states no alternatives exist to meet the needs of the proposed project. On page 45, the applicants state that their proposal is the most effective alternative because,

*“No alternatives exist for WSSSC to meet the needs for the proposed project. ... Raleigh Neurosurgical Clinic, LLC has a lease on a currently under construction MOB on Six Forks Road 0.6 miles from its existing clinical practice The MOB is intended to consolidate Raleigh Neurosurgical Clinic physicians and services. If WSSSC is awarded the CON for one OR, then WSSSC will be developed on the first floor of the MOB. If WSSSC is not awarded the CON for one OR, then Raleigh Neurosurgical Clinic will continue to develop their clinical practice as originally designed in the floor plans.”*

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because no alternatives exist.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reason stated above.

**TOSC.** TOSC proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC.

In Section E, pages 58-60, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Develop CON-exempt project that adds two procedure rooms
- Develop two additional operating rooms and two procedure rooms
- Develop two additional operating rooms with no additional specialties
- Develop the project as proposed

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Developing a CON-exempt project that adds two procedure rooms would not address the need for additional operating rooms in Wake County as identified in the 2019 SMFP.
- Developing two additional operating rooms and two procedure rooms would not be feasible due to site constraints at the existing surgical facility.
- Developing two additional operating rooms with no additional specialties is less effective because it limits access to other surgical specialties for both patients and surgeons. Also, single specialty ASC operating rooms already represent a significant proportion of ASC operating rooms in Wake County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Duke Green Level ASC.** Duke Green Level ASC proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion.

In Section E, pages 60-65, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo
- Develop two operating rooms at Duke Raleigh Hospital
- Relocate operating rooms from Duke Raleigh Hospital to a new ASC
- Develop a new ASC in another geographic location
- Develop a different complement of operating rooms

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Maintaining the status quo would not address the growing demand for outpatient surgery at Duke Raleigh Hospital.
- Developing two operating rooms at Duke Raleigh Hospital is less effective because patients would benefit more by having outpatient surgical procedures performed in an ASC setting located in the western portion of Wake County.
- Relocating operating rooms from Duke Raleigh Hospital is less effective due to the high utilization of surgical services at the hospital, and because it would not be responsive to the 2019 SMFP need determination for two additional operating rooms for Wake County.
- Developing the new ASC in another geographic location was determined to be less effective because no other location was deemed superior to the Green Level Road location.
- The growing demand for surgical services, population growth and surgical specialties support the need for three operating rooms at the Green Level facility.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**WakeMed Cary Hospital.** WakeMed Cary Hospital proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 shared surgical operating rooms and two dedicated C-Section operating rooms) upon project completion.

In Section E, pages 57-59, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo
- Develop more than one operating room at WakeMed Cary Hospital
- Develop new operating rooms at another WakeMed facility
- Relocate existing operating rooms within the WakeMed system
- Develop the project as proposed

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Maintaining the status quo would not address the growing demand for surgical services and capacity constraints at WakeMed Cary Hospital.
- Developing more than one operating room at WakeMed Cary Hospital is less effective because the applicant determined that one operating room would be sufficient to meet the need at this time.
- Developing operating rooms at another WakeMed facility is less effective because WakeMed Cary Hospital has the greatest need for additional capacity.
- Relocating existing operating rooms from other WakeMed facilities was determined to be less effective because the facilities need the operating rooms or, in the case of Capital City Surgery Center, the process would be expensive, complex and time-consuming.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**UNC REX Hospital.** UNC REX Hospital proposes to develop two additional operating rooms at the existing hospital in Raleigh.

In Section E, pages 49-50, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo
- Develop a different number of operating rooms
- Develop the operating rooms in a different location
- Develop the operating rooms in an ASC

On page 50, the applicant states its proposal is the most effective alternative because,

*“Compared to these alternatives, UNC REX believes that the proposed project to add two operating rooms is the most effective alternative to meet the need for additional operating rooms in Wake County.”*

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Maintaining the status quo would not address the growing demand for surgical services at UNC REX Hospital and the expected impact of the relocation of three operating rooms to UNC REX Holly Springs Hospital.
- Developing less than two operating rooms at UNC REX Hospital is less effective because the applicant determined that two operating rooms are needed and could be developed with minimal capital expenditure.
- Developing operating rooms at another location is less effective because UNC REX Hospital is the only hospital surgical facility, and the greatest need is for hospital-based surgical capacity.
- Developing operating rooms at an ASC is less effective because the greatest need is for hospital-based surgical capacity.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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**

### **All Applications**

**WSSSC.** WSSSC proposes to develop a new specialty ambulatory surgery center on Six Forks Road in Raleigh with one operating room and three procedure rooms.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, page 89, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract	\$2,520,000
Architect/Engineering Fees	\$277,200
Medical Equipment	\$2,275,713
Furniture	\$200,000
Consultant Fees	\$62,000
Other	\$345,887
<b>Total</b>	<b>\$5,680,800</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 48-49, the applicant projects start-up costs will be \$684,679 and initial operating expenses will be \$815,321 for a total working capital of \$1,500,000. On page 48, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F.2, page 46, the applicant states the capital cost will be funded as shown in the table below.

Type	WSSSC
Loans	\$ 5,320,800
Accumulated reserves or OE *	\$
Bonds	\$
Tenant Improvement Allowance	\$360,000
<b>Total Financing</b>	<b>\$5,680,800</b>

\* OE = Owner's Equity

In Section F.3, page 49, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

<b>Sources of Financing for Working Capital</b>		<b>Amount</b>
(a)	Loans	\$
(b)	Accumulated Reserves	\$
(c)	Lines of credit	\$1,500,000
(d)	Bonds	\$
(e)	<b>Total</b>	<b>\$1,500,000</b>

Exhibit F.2 (Tab 11) contains an August 5, 2019 letter from a Senior Vice President for First Citizens Bank stating that a loan will be made available to the applicant for the capital and working capital costs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that

revenues will exceed operating expenses in each of the first three full fiscal years of operation, as shown in the table below.

	<b>Project Year 1 FFY2022</b>	<b>Project Year 2 FFY2023</b>	<b>Project Year 3 FFY2024</b>
Total Operating Room Cases	600	650	700
Total Gross OR Revenues (Charges)	\$20,887,200	\$23,759,190	\$26,866,161
Total Net OR Revenue	\$3,759,696	\$4,157,858	\$4,567,247
Average Net Revenue per OR Case	\$6,266	\$6,397	\$6,525
Total Procedure Room (PR) Cases	3,900	4,000	4,100
Total Gross PR Revenues (Charges)	\$17,421,300	\$18,761,400	\$20,191,957
Total Net PR Revenue	\$34,66,839	\$3,639,712	\$3,816,280
Average Net Revenue per Procedure	\$889	\$910	\$931
Total Gross Revenue	\$38,308,500	\$42,520,590	\$47,058,118
Total Net Revenue	\$7,226,535	\$7,797,570	\$8,383,527
Total Operating Expenses (Costs)	\$6,767,626	\$7,029,710	\$7,350,153
Net Income	\$458,908	\$767,859	\$1,033,375

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**TOSC.** TOSC proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 118, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract	\$3,932,501
Architect/Engineering Fees	\$169,675
Medical Equipment	\$1,200,000
Other	\$350,000
<b>Total</b>	<b>\$5,652,176</b>

In Section Q and Exhibit K.1, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 63, the applicant states there will be no start-up costs or initial operating expenses because TOSC is an existing and operational ASC.

**Availability of Funds**

In Section F.2, page 61, the applicant states the capital cost will be funded as shown in the table below.

Type	TOSC
Loans	\$ 5,652,176
Accumulated reserves or OE *	\$
Bonds	\$
Other (Specify)	\$
<b>Total Financing</b>	<b>\$5,652,176</b>

\* OE = Owner's Equity

Exhibit F.2 contains an August 8, 2019 letter from a Senior Vice President for First Citizens Bank stating that a loan will be made available to the applicant for the capital costs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years of operation, as shown in the table below.

	<b>Project Year 1 CY2021</b>	<b>Project Year 2 CY2022</b>	<b>Project Year 3 CY2023</b>
Total Surgical Cases	3,933	4,437	4,951
Total Gross Revenues (Charges)	\$36,112,694	\$41,125,413	\$46,456,144
Total Net Revenue	\$11,921,623	\$13,385,800	\$14,901,598
Average Net Revenue per Case	\$3,031	\$3,017	\$3,010
Total Operating Expenses (Costs)	\$10,260,419	\$11,485,370	\$12,627,705
Average Operating Expense per Case	\$2,609	\$2,589	\$2,551
Net Income	\$1,661,204	\$1,900,430	\$2,273,893

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Duke Green Level ASC.** Duke Green Level ASC proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract	\$3,675,000
Architect/Engineering Fees	\$412,500
Medical Equipment	\$1,650,000
Non-Medical Equipment	\$137,500
Furniture	\$75,000
Consultant Fees	\$50,000
<b>Total</b>	<b>\$6,000,000</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 68-69, the applicant projects that start-up costs will be \$225,000 and initial operating expenses will be \$275,000 for a total working capital of \$500,000. On pages 68-69, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F.2, page 67, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>	
Type	Duke University Health System
Loans	\$
Accumulated reserves or OE *	\$6,000,000
Bonds	\$
Other (Specify)	\$
<b>Total Financing</b>	<b>\$6,000,000</b>

\* OE = Owner's Equity

In Section F.3, page 70, the applicant states that the working capital needs of the project will be funded as shown in the table below.

<b>Sources of Financing for Working Capital</b>		<b>Amount</b>
(a)	Loans	\$
(b)	Accumulated Reserves of DUHS	\$500,000
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	<b>Total *</b>	<b>\$500,000</b>

In Section F.2, page 67, the applicant states that the \$6,00,000 capital cost for the project will be funded by the accumulated reserves of Duke University Health System, Inc. (DUHS). In Section F.3, page 70, the applicant states that the \$500,000 working capital cost for the proposed project will be funded by the accumulated reserves of DUHS. Exhibit F.2 contains a letter from the Chief Financial Officer for DUHS documenting that the funds will be made available for the capital and working capital costs of the project. Exhibit F.2 also contains the audited financial statements for DUHS which indicate the health system had \$278 million in

cash and cash equivalents, \$6.2 billion in assets, and \$3.6 billion in net assets, as of June 30, 2018.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the second and third full fiscal operating years of the project, as shown in the table below.

	<b>Project Year 1 FY2023</b>	<b>Project Year 2 FY2024</b>	<b>Project Year 3 FY2025</b>
Total Surgical Cases	1,393	2,444	3,254
Total Gross Revenues (Charges)	\$12,863,480	\$22,054,395	\$29,824,057
Total Net Revenue	\$4,240,872	\$7,248,292	\$9,807,714
Average Net Revenue per Case	\$3,044	\$2,966	\$3,014
Total Operating Expenses (Costs)	\$4,512,831	\$6,683,703	\$8,701,187
Average Operating Expense per Case	\$3,240	\$2,735	\$2,674
Net Income (Loss)	(\$271,959)	\$564,589	\$1,106,527

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**WakeMed Cary Hospital.** WakeMed Cary Hospital proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 shared surgical operating rooms and two dedicated C-Section operating rooms) upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 133, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract	\$755,700
Architect/Engineering Fees	\$95,550
Medical Equipment	\$919,154
Non-Medical Equipment	\$42,500
Other	\$452,274
<b>Total</b>	<b>\$2,265,178</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 62, the applicant states there will be no start-up costs or initial operating expenses because WakeMed Cary Hospital is an existing hospital.

**Availability of Funds**

In Section F.2, page 60, the applicant states the capital cost will be funded as shown in the table below.

<b>Sources of Capital Cost Financing</b>	
<b>Type</b>	<b>WakeMed</b>
Loans	\$
Accumulated reserves or OE *	\$2,265,178
Bonds	\$
Other (Specify)	\$
<b>Total Financing</b>	<b>\$2,265,178</b>

\* OE = Owner's Equity

Exhibit F.2 contains an August 5, 2019 letter from a Vice President, Finance for WakeMed documenting that the funds will be made available for the capital costs of the project. Exhibit F.2 contains the audited financial statements for WakeMed which indicate the hospital had \$117 million in cash and cash equivalents, \$1.8 billion in assets, and \$1.0 billion in net assets, as of September 30, 2018

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years of operation, as shown in the table below.

	<b>Project Year 1 FFY2021</b>	<b>Project Year 2 FFY2022</b>	<b>Project Year 3 FFY2023</b>
Total Surgical Cases	9,598	9,264	9,645
Total Gross Revenues (Charges)	\$553,991,835	\$573,797,972	\$618,611,492
Total Net Revenue	\$130,340,652	\$134,658,329	\$145,128,178
Average Net Revenue per Case	\$13,580	\$14,536	\$15,047
Total Operating Expenses (Costs)	\$57,548,327	\$59,932,548	\$64,544,379
Average Operating Expense per Case	\$5,996	\$6,469	\$6,692
Net Income	\$72,792,325	\$74,725,781	\$80,583,799

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**UNC REX Hospital.** UNC REX Hospital proposes to develop two additional operating rooms at the existing hospital in Raleigh.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract	\$170,000
Architect/Engineering Fees	\$30,000
Medical Equipment	\$550,000
Consultant Fees	\$3,000
Other	\$36,000
<b>Total</b>	<b>\$789,000</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 53, the applicant states there will be no start-up costs or initial operating expenses because the project does not involve a new service.

**Availability of Funds**

In Section F.2, page 51, the applicant states that the capital cost will be funded, as shown in the table below.

Type	Rex Hospital, Inc.
Loans	\$
Accumulated reserves or OE *	\$789,000
Bonds	\$
Other (Specify)	\$
<b>Total Financing</b>	<b>\$789,000</b>

\* OE = Owner's Equity

In Section F.2, page 51, the applicant states that the \$789,000 in project capital costs for the proposed operating rooms will be funded by the accumulated reserves of Rex Hospital, Inc. Exhibit F.2 contains an August 15, 2019 letter from the Chief Financial Officer for Rex Hospital, Inc. documenting that the funds will be made available for the capital costs of the project. Exhibit F.2 contains the audited financial statements for Rex Healthcare, Inc. which indicate the hospital had \$140 million in cash and cash equivalents, \$1.1 billion in assets, and \$576 million in net assets, as of June 30, 2018.

**Financial Feasibility**

The applicant provided pro forma financial statements for the surgical services at Rex Hospital for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal operating years of the project, as shown in the table below.

	<b>Project Year 1 FY2023</b>	<b>Project Year 2 FY2024</b>	<b>Project Year 3 FY2025</b>
Total Surgical Cases	21,366	21,479	22,155
Total Gross Revenues (Charges)	\$654,485,865	\$677,681,523	\$719,905,488
Total Net Revenue	\$236,783,201	\$245,156,834	\$260,399,685
Average Net Revenue per Case	\$11,082	\$11,414	\$11,754
Total Operating Expenses (Costs)	\$173,822,422	\$179,932,865	\$190,846,839
Average Operating Expense per Case	\$8,135	\$8,377	\$8,614
Net Income	\$62,960,779	\$65,223,969	\$69,552,846

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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**  
 All Applications

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the

2019 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Wake County, and the inpatient and outpatient case volumes for each provider, from pages 70-71 and 82-83 of the 2019 SMFP.

**Wake County Operating Room Inventory and Cases  
 As Reported in the 2019 SMFP and on the 2018 License Renewal Applications**

	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
Rex Hospital Holly Springs	0	0	0	0	3	0	0	
Rex Surgery Center of Wakefield	0	0	0	0	2	0	0	
Rex Surgery Center of Cary	0	4	0	0	0	0	4,854	6
Rex Hospital	3	3	24	-3	-5	8,453	12,636	2
Raleigh Orthopedic Surgery Center	0	4	0	0	-1	0	4,384	6
Raleigh Orthopedic Surgery-West Cary	0	0	0	0	1	0	0	
<b>UNC Health Care System Total</b>	<b>3</b>	<b>11</b>	<b>24</b>	<b>-3</b>	<b>0</b>			
Capital City Surgery Center	0	8	0	0	0	0	5,388	6
WakeMed (incl. WakeMed North)	8	0	20	-5	0	8,184	9,893	2
WakeMed Cary Hospital	2	0	9	-2	0	3,041	4,663	4
<b>WakeMed System Total</b>	<b>10</b>	<b>8</b>	<b>29</b>	<b>-7</b>	<b>0</b>			
Holly Springs Surgery Center	0	3	0	0	0	0	478	6
Blue Ridge Surgery Center	0	6	0	0	0	0	7,043	5
Raleigh Plastic Surgery Center^	0	1	0	0	0	0	380	6
Triangle Orthopedic Surgery Center*	0	2	0	0	0	0	2,437	6
Duke Raleigh Hospital	0	0	15	0	0	4,094	11,084	3
Surgical Center for Dental Professionals*	0	0	0	0	2	0	0	
<b>Total Wake County ORs</b>	<b>13</b>	<b>31</b>	<b>68</b>	<b>-10</b>	<b>2</b>			

Source: 2019 SMFP

^Underutilized facility, excluded from need determination calculations.

\*Ambulatory surgery demonstration projects included in the inventory, but not included in the need determination calculations.

As the table above indicates, as of FY2017, there were five existing or approved hospitals and ten existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 31 ambulatory and 68 shared operating rooms. Also, pursuant to the need determination for six additional operating rooms for the Wake County service area in the 2018 SMFP, the following applications were approved:

Project I.D. # J-11551-18, RAC Surgery Center, Develop a new ambulatory surgery center in Raleigh with one operating room from the need determination in the 2018 SMFP and two procedure rooms focused on vascular access procedures for patients with end stage renal disease.

Project I.D. # J-11555-18, Rex Hospital, Develop two additional operating rooms from the need determination in the 2018 SMFP at the existing hospital in Raleigh.

Project I.D. # J-11557-18, Duke Health Green Level Ambulatory Surgical Center, Develop a new multispecialty ambulatory surgery center in Cary with one operating room from the need determination in the 2018 SMFP and five procedure rooms.

Project I.D. # J-11561-18, Ortho NC ASC, Develop a new specialty ambulatory surgery center in Raleigh with one operating room from the need determination in the 2018 SMFP and one procedure room focused on orthopedic and pain management procedures.

Project I.D. # J-11564-18, WakeMed Surgery Center-North Raleigh, Develop a new multispecialty ambulatory surgery center in Raleigh with one operating room relocated from Capital City Surgery Center and three procedure rooms.

Project I.D. # J-11565-18, WakeMed Surgery Center-Cary, Develop a new multispecialty ambulatory surgery center in Cary with one operating room from the need determination in the 2018 SMFP and three procedure rooms.

Therefore, subsequent to the approvals in the 2018 Wake operating room review, there are five existing or approved hospitals and 15 existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 35 ambulatory and 70 shared operating rooms. The 2019 SMFP shows a need for two additional operating rooms for the Wake County service area.

**WSSSC.** WSSSC proposes to develop a new specialty ambulatory surgery center on Six Forks Road in Raleigh with one operating room and three procedure rooms.

In Section G.2, pages 52-53, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating room services in Wake County. The applicant states, "*WSSSC offers patients and physicians an alternative for surgical services that is not owned or operated by a hospital system in Wake County.*"

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for two operating rooms in the Wake County service area and the applicant proposes to develop one operating room.
- The applicant adequately demonstrates that the proposed operating room is needed in addition to the existing or approved operating rooms in Wake County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**TOSC.** TOSC proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC.

In Section G.2, pages 69-70, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating rooms services in Wake County. The applicant states, *“Based on discussions with physicians and center leadership, TOSC determined that it would be beneficial to have an additional multispecialty ASF option in Wake County to provide needed capacity for surgeons who prefer an ASF that is independent of the health systems.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for two operating rooms in the Wake County service area and the applicant proposes to develop two operating rooms.
- The applicant adequately demonstrates that the proposed operating rooms are needed in addition to the existing or approved operating rooms in Wake County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Duke Green Level ASC.** Duke Green Level ASC proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion.

In Section G.2, pages 75-77, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating rooms services in Wake County. The applicant states, *“The proposed project effectively expands and enhances access to DUH ambulatory surgical services in Wake County via development of additional OR capacity in the approved freestanding ASC.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for two operating rooms in the Wake County service area and the applicant proposes to develop two operating rooms.
- The applicant adequately demonstrates that the proposed operating rooms are needed in addition to the existing or approved operating rooms in Wake County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**WakeMed Cary Hospital.** WakeMed Cary Hospital proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 shared surgical operating rooms and two dedicated C-Section operating rooms) upon project completion.

In Section G.2, pages 67-68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating rooms services in Wake County. The applicant states, “*WakeMed Cary is located in the fastest-growing area of Wake County, where it is currently the only acute care hospital in operation, and where surgical utilization and case times, particularly inpatient surgery, are increasing dramatically.*”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for two operating rooms in the Wake County service area and the applicant proposes to develop one operating room.
- The applicant adequately demonstrates that the proposed operating room is needed in addition to the existing or approved operating rooms in Wake County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**UNC REX Hospital.** UNC REX Hospital proposes to develop two additional operating rooms at the existing hospital in Raleigh.

In Section G.2, page 57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating rooms services in Wake County. The applicant states, *“Given the continued push to lower the total cost of care and focus on population health by all payors, including Medicare and BCBS, UNC REX Hospital needs the additional capacity proposed in this application to serve a growing patient population.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for two operating rooms in the Wake County service area and the applicant proposes to develop two operating rooms.
- The applicant adequately demonstrates that the proposed operating rooms are needed in addition to the existing or approved operating rooms in Wake County.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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 All Applications

**WSSSC.** In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 54-56, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 59, the applicant identifies the proposed medical director. In Exhibit I.3 (Tab 16), the applicant provides a copy of a letter from the proposed medical director indicating an interest in

serving as medical director for the proposed services. In Section I.3, pages 59-60, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**TOSC.** In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 71-72, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 75, the applicant identifies the proposed medical director. In Exhibit H.4, the applicant provides a copy of a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section I.3, pages 75-76, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Duke Green Level ASC.** In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 80-81, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 84, the applicant identifies the proposed co-medical directors. In Exhibit I.3, the applicant provides copies of letters from the proposed co-medical directors indicating an interest in serving as medical directors for the proposed services. In Section I.3, page 85, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**WakeMed Cary Hospital.** In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 69-75, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 79, the applicant identifies the proposed medical director. In Exhibit I.6, the applicant provides a copy of a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section I.3, page 79, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**UNC REX Hospital.** In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 59-60, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3, page 62, the applicant identifies the proposed medical director. In Exhibit I.3, the applicant provides a copy of a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section I.3, page 62, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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.

**WSSSC.** In Section I.1, page 58, the applicant states the following ancillary and support services are necessary for the proposed services:

Billing and Accounting	Business Office/Admitting
Facility Management	Human Resources
Information Management	Legal Services
Materials Management	Medical Records
Planning and Marketing	Precertification and Insurance
Purchasing	Quality Management/Utilization Review
Scheduling	Staff Education

On page 58, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1 (Tab 14).

In Section I.2, page 59, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2 (Tab 15).

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**TOSC.** In Section I.1, page 73, the applicant states the following ancillary and support services are necessary for the proposed services:

Anesthesiology	Pathology
Laboratory	Portable X-ray
Pharmacy	Sterile Processing
Patient Registration/Billing	Medical Records/Coding
Administration	Management Services
Housekeeping	

On pages 73-74, the applicant adequately explains how each ancillary and support service will be made available and provide supporting documentation in Exhibit I.1.

In Section I.2, page 74, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit C.4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Duke Green Level ASC.** In Section I.1, page 82, the applicant states the following ancillary and support services are necessary for the proposed services:

Administration	Laundry
Maintenance	Housekeeping
Pharmacy	Pathology
Medical Supplies	Dietary
Reception	Medical Records
Anesthesiology	

On page 82, the applicant adequately explains how each ancillary and support service will be made available.

In Section I.2, page 83, the applicant describes its efforts to develop relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**WakeMed Cary Hospital.** In Section I.1, page 76, the applicant states the following ancillary and support services are necessary for the proposed services:

24-hour Emergency Department	Diagnostic Imaging
Pathology	Laboratory
Respiratory Therapy	Infection Control
Pharmacy	Clinical Engineering
Case Management	Social Work
Environmental Services	Food & Nutrition
Materials Processing	Security and Safety
Patient Financial Services	Health Information
Human Resources	Pastoral Care

On page 76, the applicant adequately explains how each ancillary and support service will be made available and provide supporting documentation in Exhibit I.1.

In Section I.2, pages 77-79, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.2, I.3, I.4 and I.5.

The applicant adequately demonstrate that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**UNC REX Hospital.** In Section I.1, page 61, the applicant states that the following ancillary and support services are necessary for the proposed services:

Laboratory	Radiology
Pharmacy	Dietary
Administration	Housekeeping/Maintenance

On page 61, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1.

In Section I.2, page 61, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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**  
All Applications

None of the applicants project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, none of the applicants project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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**

All Applications

None of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

**C**

All Applications

**WSSSC.** WSSSC proposes to develop a new specialty ambulatory surgery center with one operating room and three procedure rooms. In Section K.2, page 63, the applicant states the project involves upfitting 9,000 square feet of leased space in a medical office building located at 5241 E. Six Forks Road in Raleigh. Line drawings are provided in Exhibit K-2 (Tab 17).

In Section K.3, page 64, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, page 64, the applicant adequately explains why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, page 64, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

In Section K.4, pages 65-66, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**TOSC.** TOSC proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC. In Section K.2, page 79, the applicant states the project involves a 5,856 square foot addition to the existing ASC, which is located at 7921 ACC Boulevard in Raleigh. The applicant states it proposes to convert two unlicensed procedure rooms, which are being developed as a CON-exempt project, to two operating rooms. Line drawings are provided in Exhibit K.1.

In Section K.3, pages 79-80, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, page 80, the applicant adequately explains why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, page 80-81, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Duke Green Level ASC.** Duke Green Level ASC proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion. In Section K.1, page 88, the applicant states that the project involves the upfitting of 40,000 square feet of space in a medical office building under development at 3208 Green Level West Road in Cary. Line drawings are provided in Exhibit K.2.

In Section K.3, page 89, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, pages 89-90, the applicant adequately explains why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, pages 90-91, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

In Section K.4, pages 91-100, the applicant identifies the site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**WakeMed Cary Hospital.** WakeMed Cary Hospital proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 shared surgical operating rooms and two dedicated C-Section operating rooms) upon project completion. In Section K.1, page 82, the applicant states that the project involves renovation of 880 square feet of space in the surgical department of the existing hospital on Kildaire Farm Road in Cary. Line drawings are provided in Exhibit K.1.

In Section K.3, page 82, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, page 83, the applicant adequately explains why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services.

In Section B.11, pages 15-16, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**UNC REX Hospital.** UNC REX Hospital proposes to develop two additional operating rooms at the hospital's main campus at 4420 Lake Boone Trail in Raleigh. In Section K.2, page 64, the applicant states that the project involves the renovation of 870 square feet of existing space. Line drawings are provided in Exhibit C.1.

In Section K.3, page 64, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, page 65, the applicant adequately explains why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, page 65, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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;

**NA**  
**WSSSC**

**C**  
 All Other Applications

**WSSSC.** Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable.

**TOSC.** In Section L.1, page 85, the applicant provides the historical payor mix for TOSC's operating rooms for FFY2018, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	1.6%
Charity Care	0.3%
Medicare*	15.0%
Medicaid*	5.0%
Insurance*	63.0%
Workers Compensation	7.8%
TRICARE	5.0%
Other	2.3%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 85 of the application.  
 \*Including any managed care plans.

In Section L.1, page 84, the applicant provides the following comparison.

	Percentage of Total Patients Served by TOSC during FFY2018	Percentage of the Population of Wake County
Female	54.0%	51.3%
Male	46.0%	48.7%
Unknown	0.0%	0.0%
64 and Younger	78.0%	88.8%
65 and Older	22.0%	11.2%
American Indian	0.2%	0.8%
Asian	1.0%	7.2%
Black or African-American	14.0%	21.1%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	72.0%	68.4%
Other Race	12.7%	12.7%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

**Duke Green Level ASC.** In Section L.1, page 101, the applicant states there is no historical payor source data because Duke Green Level ASC is not an existing facility. In Section L.1, page 102, the applicant provides the following comparison based on inpatients and outpatients served at Duke Raleigh Hospital (DRAH) in FY2019.

	Percentage of Inpatients Patients Served by DRAH during FY2018	Percentage of Outpatients Patients Served by DRAH during FY2018	Percentage of the Population of Service Area
Female	54.4%	54.1%	51.3%
Male	45.6%	45.9%	48.7%
Unknown	0.0%	0.0%	0.0%
64 and Younger	48.6%	67.8%	88.8%
65 and Older	51.4%	32.2%	11.6%
American Indian	0.2%	0.6%	0.8%
Asian	1.2%	1.8%	7.5%
Black or African-American	19.5%	18.2%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%	0.1%
White or Caucasian	74.5%	73.1%	60.3%
Other Race	2.9%	3.2%	10.3%
Declined / Unavailable	1.8%	2.9%	0.0%

Duke Green Level will be a new facility owned by DUHS. The applicant does not currently provide ambulatory surgical services in Cary. In Section L.3, page 105, the applicant states that its projected payor mix for the ASC is based upon the historical outpatient surgical payor mix for DRAH and DUH, and the surgical specialties projected to be provided at the facility.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services at DRAH in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

**WakeMed Cary Hospital.** In Section L.1, page 87, the applicant provides the historical payor mix for WakeMed Cary Hospital's operating rooms for FFY2018, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay/Charity Care	7.50%
Medicare*	47.08%
Medicaid*	3.74%
Insurance*	39.28%
Other (Champus/VA/Other Government)	2.40%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 87 of the application.

\*Including any managed care plans.

In Section L.1, page 87, the applicant provides the following comparison.

	Percentage of Total Patients Served by WakeMed Cary Hospital during FFY2018	Percentage of the Population of Wake County
Female	60.3%	51.3%
Male	38.16%	48.7%
Unknown	1.54%	0.0%
64 and Younger	70.48%	88.4%
65 and Older	29.52%	11.6%
American Indian	0.20%	0.8%
Asian	4.80%	7.5%
Black or African-American	19.49%	21.0%
Native Hawaiian or Pacific Islander	0.11%	0.1%
White or Caucasian	66.89%	68.1%
Other Race	5.53%	2.5%
Declined / Unavailable	2.98%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

**UNC REX Hospital.** In Section L.1, page 68, the applicant provides the historical payor mix for UNC REX Hospital's operating rooms for FY2019, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	3.0%
Medicare*	42.2%
Medicaid*	4.0%
Insurance*	48.2%
Other (Workers Compensation, TRICARE)	2.6%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 68 of the application.

\*Including any managed care plans.

In Section L.1, page 67, the applicant provides the following comparison.

	Percentage of Total Patients Served by UNC REX Hospital during FY2019	Percentage of the Population of Wake County
Female	63.1%	51.3%
Male	36.9%	48.7%
Unknown	0.0%	0.0%
64 and Younger	59.7%	88.4%
65 and Older	40.4%	11.6%
American Indian	0.2%	0.8%
Asian	1.8%	7.5%
Black or African-American	22.1%	21.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	68.6%	68.1%
Other Race	4.9%	2.5%
Declined / Unavailable	2.3%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application 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;

**NA**  
**WSSSC**

**C**  
**All Other Applications**

**WSSSC.** Neither the applicant nor any related entities own, operate or manage an existing health service facility located in North Carolina. Therefore, Criterion (13b) is not applicable.

**TOSC.** Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 85, the applicant state it has no obligations to provide uncompensated care, community service or access by minorities and persons with disabilities, but that TOSC provides access to medically underserved groups including charity care and Medicaid patients.

In Section L.2, page 85, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Duke Green Level ASC.** Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 103, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, but that DUHS provides services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor.

In Section L.2, page 104, the applicant states that during the last five years, four patient civil rights access complaints have been filed against DUHS. The applicant

reports that three of the complaints have been closed without further investigation and one complaint is pending.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**WakeMed Cary Hospital.** Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 88, the applicant states it has no obligations to provide uncompensated care, community service or access by minorities and persons with disabilities, but provides access for those patient groups in accordance with all regulatory requirements.

In Section L.2, page 88, the applicant states that during the last five years, one patient civil rights access complaint has been filed against WakeMed Cary Hospital. The applicant reports the complaint has been investigated and closed by the Office of Civil Rights.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**UNC REX Hospital.** Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 68, the applicant states UNC REX Hospital has no obligations to provide uncompensated care, community service or access by minorities and persons with disabilities, but that that they provide access to healthcare services to all patients needing care, regardless of their ability to pay.

In Section L.2, page 69, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against UNC REX Hospital.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that 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 All Applications

**WSSSC.** In Section L.3, page 70, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Payor Category</b>	<b>Operating Room and Procedure Room Services as Percent of Total</b>
Self-Pay	0.6%
Medicare *	50.7%
Medicaid *	1.5%
Insurance *	38.8%
Champus	4.7%
Workers Compensation	3.7%
Total	100.0%

Source: Table on page 70 of the application.

\* Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.6% of total services will be provided to self-pay patients, 50.7% to Medicare patients and 1.5% to Medicaid patients.

On page 70, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical experience of the physicians and physician groups expected to perform surgical cases at the proposed ASC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**TOSC.** In Section L.3, page 86, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	2.9%
Charity Care	0.2%
Medicare*	24.3%
Medicaid*	4.8%
Insurance*	55.5%
Workers Compensation	6.6%
TRICARE	4.0%
Other	1.6%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 86 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.9% of total services will be provided to self-pay patients, 0.2% to charity care patients, 24.3% to Medicare patients and 4.8% to Medicaid patients.

On pages 86-87, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience for the surgical specialties projected to practice at the ASC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Duke Green Level ASC.** In Section L.3, page 105, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total	Procedure Room Services as Percent of Total
Self-Pay/Charity	2.0%	1.9%
Medicare *	43.7%	33.6%
Medicaid *	4.7%	6.3%
Insurance *	45.4%	47.7%
Workers Comp, VA, TRICARE	4.3%	10.6%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 105 of the application.

\* Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.0% of operating room services will be provided to self-pay/charity patients, 43.7% to Medicare patients and 4.7% to Medicaid patients.

On pages 105-106, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience and the surgical specialties and types of cases and procedures projected for the proposed ASC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**WakeMed Cary Hospital.** In Section L.3, page 89, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	2.33%
Charity Care	5.04%
Medicare *	47.59%
Medicaid *	3.76%
Insurance *	38.90%
Other	2.39%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 89 of the application.

\* Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.33% of total services will be provided to self-pay patients, 5.04 % to charity care patients, 47.59% to Medicare patients and 3.76% to Medicaid patients.

On page 89, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical (FY2018) experience.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**UNC REX Hospital.** In Section L.3, page 69, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	3.0%
Medicare*	42.2%
Medicaid*	4.0%
Insurance*	48.2%
Other (Workers Compensation, TRICARE)	2.6%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 69 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.0% of total services will be provided to self-pay patients, 42.2% to Medicare patients and 4.0% to Medicaid patients.

On pages 69-70, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical (SFY2019) experience.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to 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** All Applications

**WSSSC.** In Section L.5, page 71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**TOSC.** In Section L.5, page 87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Duke Green Level ASC.** In Section L.5, page 107, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**WakeMed Cary Hospital.** In Section L.5, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

**UNC REX Hospital.** In Section L.5, page 70, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that 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

#### All Applications

**All Applications.** In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that all of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all of the applications are conforming 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

#### All Applications

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Wake County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Wake County, and the inpatient and outpatient case volumes for each provider, from pages 70-71 and 82-83 of the 2019 SMFP.

**Wake County Operating Room Inventory and Surgical Cases**

	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
Rex Hospital Holly Springs	0	0	0	0	3	0	0	
Rex Surgery Center of Wakefield	0	0	0	0	2	0	0	
Rex Surgery Center of Cary	0	4	0	0	0	0	4,854	6
Rex Hospital	3	3	24	-3	-5	8,453	12,636	2
Raleigh Orthopedic Surgery Center	0	4	0	0	-1	0	4,384	6
Raleigh Orthopedic Surgery-West Cary	0	0	0	0	1	0	0	
<b>UNC Health Care System Total</b>	<b>3</b>	<b>11</b>	<b>24</b>	<b>-3</b>	<b>0</b>			
Capital City Surgery Center	0	8	0	0	0	0	5,388	6
WakeMed (incl. WakeMed North)	8	0	20	-5	0	8,184	9,893	2
WakeMed Cary Hospital	2	0	9	-2	0	3,041	4,663	4
<b>WakeMed System Total</b>	<b>10</b>	<b>8</b>	<b>29</b>	<b>-7</b>	<b>0</b>			
Holly Springs Surgery Center	0	3	0	0	0	0	478	6
Blue Ridge Surgery Center	0	6	0	0	0	0	7,043	5
Raleigh Plastic Surgery Center^	0	1	0	0	0	0	380	6
Triangle Orthopedic Surgery Center*	0	2	0	0	0	0	2,437	6
Duke Raleigh Hospital	0	0	15	0	0	4,094	11,084	3
Surgical Center for Dental Professionals*	0	0	0	0	2	0	0	
<b>Total Wake County ORs</b>	<b>13</b>	<b>31</b>	<b>68</b>	<b>-10</b>	<b>2</b>			

Source: 2019 SMFP

^Underutilized facility, excluded from need determination calculations.

\*Ambulatory surgery demonstration projects included in the inventory, but not included in the need determination calculations.

As the table above indicates, as of FY2017, there were five existing or approved hospitals and ten existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 31 ambulatory and 68 shared operating rooms. Pursuant to the need determination for six additional operating rooms for the Wake County service area in the 2018 SMFP, the following applications were approved:

Project I.D. # J-11551-18, RAC Surgery Center, Develop a new ambulatory surgery center in Raleigh with one operating room from the need determination in the 2018 SMFP and two procedure rooms focused on vascular access procedures for patients with end stage renal disease.

Project I.D. # J-11555-18, Rex Hospital, Develop two additional operating rooms from the need determination in the 2018 SMFP at the existing hospital in Raleigh.

Project I.D. # J-11557-18, Duke Health Green Level Ambulatory Surgical Center, Develop a new multispecialty ambulatory surgery center in Cary with one operating room from the need determination in the 2018 SMFP and five procedure rooms.

Project I.D. # J-11561-18, Ortho NC ASC, Develop a new single-specialty ambulatory surgery center in Raleigh with one operating room from the need determination in the 2018 SMFP and one procedure room focused on orthopedic and pain management procedures.

Project I.D. # J-11564-18, WakeMed Surgery Center-North Raleigh, Develop a new multispecialty ambulatory surgery center in Raleigh with one operating room relocated from Capital City Surgery Center and three procedure rooms.

Project I.D. # J-11565-18, WakeMed Surgery Center-Cary, Develop a new multispecialty ambulatory surgery center in Cary with one operating room from the need determination in the 2018 SMFP and three procedure rooms.

Therefore, subsequent to the approved applications in the 2018 Wake operating room review, there are five existing or approved hospitals and 15 existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 35 ambulatory and 70 shared operating rooms.

**WSSSC.** WSSSC proposes to develop a new specialty ambulatory surgery center with one operating room and three procedure rooms.

In Section N.1, page 75, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 75, the applicant states,

*“Choice helps promote competition and competition helps promote better alternatives for patients. The WSSSC will complement the needs and growing demands of the patients, staff, and physicians within the service area.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**TOSC.** TOSC proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC.

In Section N.1, pages 89-91, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 91, the applicant states,

*“Competition in Wake County will also be enhanced by the development of a new multispecialty ASF that is intensely focused on quality of care, patients satisfaction and cost-effectiveness. These are the characteristics that have enabled TOSC to achieve success and high utilization as a demonstration project ASF.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**Duke Green Level ASC.** Duke Green Level ASC proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion.

In Section N.1, page 109, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 109, the applicant states,

*“DUHS is the only integrated health system currently without a freestanding ASC in Wake County. This will therefore better serve local residents and will promote competition in the Wake County service area.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**WakeMed Cary Hospital.** WakeMed Cary Hospital proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 share surgical operating rooms and two dedicated C-Section operating rooms) upon project completion.

In Section N.1, page 98, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 98, the applicant states,

*“The proposed project will allow WakeMed Cary operating room capacity to be sufficiently-sized to meet current and projected demand without capacity constraints. This in turn will allow WakeMed to remain competitive.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)

- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

**UNC REX Hospital.** UNC REX Hospital proposes to develop two additional operating rooms at the existing hospital in Raleigh.

In Section N, pages 73-76, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 73, the applicant states, *“The proposed project will enable UNC REX Hospital to continue to provide its patient population with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment and efficient utilization of existing resources.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons stated above.

- (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.

**NA**  
**WSSSC**

**C**  
All Other Applications

**WSSSC.** WSSSC proposes to develop a new specialty ambulatory surgery center with one operating room and three procedure rooms. In Section A.7, page 10, the applicant states neither it nor any related entity own, operate or manage a similar existing health care facility in North Carolina. Therefore, Criterion (20) is not applicable.

**TOSC.** TOSC proposes to add two operating rooms to an existing specialty ambulatory surgery center (ASC) in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC. In Section A.7, page 9, the applicant identifies one facility, Triangle Orthopaedic Surgery Center (TOSC), located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O.3, page 96, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in the TOSC facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in that facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the TOSC facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Duke Green Level ASC.** Duke Green Level ASC proposes to add two operating rooms to an approved multispecialty ambulatory surgery center on Green Level West Road in Cary, Duke Health Green Level Ambulatory Surgery Center, for a total of three operating rooms and five procedure rooms upon project completion. Duke Green Level Ambulatory Surgery Center is part of the Duke University Health System (DUHS). In Section Q, Form A, the applicant identifies one ambulatory surgery center, the James E. Davis Ambulatory Surgery Center, and three hospitals, Duke University Hospital, Duke Regional Hospital, and Duke Raleigh Hospital, that are owned or managed by DUHS.

In Section O.3, page 118, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at the facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in those facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the DUHS facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**WakeMed Cary Hospital.** WakeMed Cary Hospital proposes to develop one additional operating room at the existing hospital in Cary, for a total of 13 operating rooms (11 shared surgical operating rooms and two dedicated C-Section operating rooms) upon project completion. In Section Q, Form A, the applicant identifies one ambulatory surgery center, Capital City Surgery Center, and two hospitals, WakeMed Raleigh Campus (includes WakeMed North Hospital) and WakeMed Cary Hospital, that are owned or managed by WakeMed.

In Section O.3, page 109, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at the facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in those facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the WakeMed facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**UNC REX Hospital.** UNC REX Hospital proposes to develop two additional operating rooms at the existing hospital in Raleigh. UNC REX Hospital is part of the UNC Health Care System. In Section Q, Form A, the applicant identifies 13 health care facilities owned or managed by UNC Health Care System.

In Section O.3, page 79, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred at one UNC Health Care System facility, UNC REX Hospital. In Section O.3, page 79, the applicant states that a plan of correction for UNC REX Hospital was accepted and the hospital is back in compliance with all CMS conditions as of July 18, 2019. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the UNC Health Care System facilities are back in compliance with all CMS Conditions of Participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all UNC Health Care System facilities, the applicant provides sufficient evidence that quality care has been provided in the past. 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

### All Applications

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

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

(a) *An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

- C- **WSSSC.** This proposal would develop a new ASC with one operating room. The applicant does not have any other existing or approved operating rooms. The applicant projects sufficient surgical cases and hours to demonstrate the need for one operating room in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **TOSC.** This proposal would develop two additional operating rooms, for a total of four operating rooms, at an existing ASC. The applicant projects sufficient surgical cases and hours to demonstrate the need for two additional operating rooms in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Duke Green Level ASC.** This proposal would develop two additional operating rooms at an approved ASC. The applicant projects sufficient surgical cases and hours to demonstrate the need for two operating rooms in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- C- **WakeMed Cary Hospital.** This proposal would develop one additional operating room at an existing hospital. The applicant projects sufficient surgical cases and hours to demonstrate the need for one operating room in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - C- **UNC REX Hospital.** This proposal would develop two additional operating rooms at an existing hospital. The applicant projects sufficient surgical cases and hours to demonstrate the need for two operating rooms in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*
- C- **WSSSC.** In Section C.4, pages 25-31, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
  - C- **TOSC.** In Section Q, pages 99-106, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
  - C- **Duke Green Level ASC.** In Section Q, pages 121-142, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
  - C- **WakeMed Cary Hospital.** In Section Q, pages 114-126, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
  - C- **UNC REX Hospital.** In Section Q, Form C Methodology and Assumptions, pages 1-17, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2019 State Medical Facilities Plan, no more than two additional operating rooms may be approved for Wake County in this review. Because the five applications in this review collectively propose to develop eight additional operating rooms to be located in Wake County, all of the applications cannot be approved for the total number of operating rooms proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

**WSSSC.** Wake Spine and Specialty Surgery Center, LLC, Project ID # J-11747-19, proposes to develop a new specialty ambulatory surgery center in Raleigh with one operating room and three procedure rooms. The applicant projects to perform 700 total surgical cases in the one operating room in Project Year 3.

**TOSC.** Triangle Orthopaedics Surgery Center, LLC, Project ID #J-11752-19, proposes to add two operating rooms to an existing specialty ambulatory surgery center in Raleigh for a total of four operating rooms upon project completion, and convert the specialty ASC to a multispecialty ASC. The applicant projects to perform 4,951 total surgical cases in the four operating rooms in Project Year 3.

**Duke Green Level ASC.** Duke University Health System, Inc. d/b/a Green Level Ambulatory Surgery Center, Project ID #J-11753-19, proposes to add two operating rooms to an approved multispecialty ambulatory surgery center in Cary, for a total of three operating rooms and five procedure rooms. The applicant proposes to perform 3,254 total surgical cases in the three operating rooms in Project Year 3.

**WakeMed Cary Hospital.** WakeMed, Project ID #J-11759-19, proposes to develop one additional operating room at the hospital in Cary. The applicant projects to perform 9,645 total surgical cases in its 11 operating rooms (excluding two dedicated C-Section operating rooms) in Project Year 3.

**UNC REX Hospital.** Rex Hospital, Inc., Project ID #J-11761-19, proposes to develop two additional operating rooms at the main hospital in Raleigh. The applicant projects to perform 22,155 total surgical cases in its 26 operating rooms (excluding three dedicated C-Section operating rooms) in Project Year 3.

As the above description of each proposed project indicates, one application is proposing a new specialty ambulatory surgery center (ASC) with one operating room, one application is proposing to add two operating rooms to an existing specialty ASC and convert to a multispecialty ASC, and one application is proposing to add two operating rooms to an approved multispecialty ASC. The ASCs applications each project to perform between approximately 700 and 5,000 surgeries in Project Year 3

(PY3). The two other projects propose to add operating rooms to an acute care hospital. UNC REX Hospital would have 26 operating rooms (excluding three C-section operating rooms) and projects to perform approximately 22,000 surgeries in PY3. WakeMed Cary Hospital would have eleven operating rooms (excluding two C-section operating rooms) and projects to perform approximately 10,000 surgeries in PY3. The hospitals project a significantly greater number of total surgeries than the proposed ASC projects. Because of the significant differences in types of facilities, numbers of operating rooms, numbers of projected surgeries, types of proposed surgical services offered, total revenues and expenses, and the differences in presentation of pro forma financial statements, some of the comparative factors may be of less value and result in less than definitive outcomes than if all applications were for similar facilities and services.

### **Conformity with Statutory and Regulatory Review Criteria**

Table 6C, page 85, of the 2019 SMFP identifies a need for two additional operating rooms in Wake County. As shown in Table 6B, pages 82-83, UNC Health Care and Duke Raleigh Hospital show a projected deficit of operating rooms in 2021, which results in the Wake County need determination for two operating rooms. However, the application process is not limited to the provider (or providers) that shows a deficit and creates the need for additional operating rooms. Any provider can apply to develop the two operating rooms in Wake County. Furthermore, it is not necessary that an existing provider have a projected deficit of operating rooms to apply for more operating rooms. However, it is necessary that an applicant adequately demonstrate the need to develop its project as proposed.

All applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, all applications are equally effective alternatives.

### **Geographic Accessibility (Location within the Service Area)**

The following table identifies the existing and approved Wake County operating rooms by location, facility name, and type of operating room. As the table below shows, the existing and approved Wake County operating rooms are located in Raleigh, North Raleigh, Cary and Holly Springs.

**Wake County Existing and Approved Operating Rooms by Location**

Location		IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	Total ORs
Holly Springs	Rex Hospital Holly Springs	0	0	0	0	3	3
North Raleigh	Rex Surgery Center of Wakefield	0	0	0	0	2	2
Cary	Rex Surgery Center of Cary	0	4	0	0	0	4
Raleigh	Rex Hospital*	3	0	24	-3	0	24
Raleigh	Raleigh Orthopedic Surgery Center	0	4	0	0	-1	3
Cary	Raleigh Orthopedic Surgery-West Cary	0	0	0	0	1	1
Raleigh	Capital City Surgery Center*	0	8	0	0	-1	7
Raleigh	WakeMed	7	0	16	-5	-1	15
North Raleigh	WakeMed North Hospital	1	0	4	-1	0	4
North Raleigh	WakeMed Surgery Center-North Raleigh*	0	0	0	0	1	1
Cary	WakeMed Cary Hospital	2	0	9	-2	1	10
Cary	WakeMed Surgery Center-Cary*	0	0	0	0	1	1
Holly Springs	Holly Springs Surgery Center	0	0	0	0	3	3
Raleigh	Blue Ridge Surgery Center	0	6	0	0	0	6
Raleigh	Raleigh Plastic Surgery Center	0	1	0	0	0	1
Raleigh	Triangle Orthopedic Surgery Center	0	2	0	0	0	2
Raleigh	RAC Surgery Center*	0	0	0	0	1	1
North Raleigh	OrthoNC Ambulatory Surgery Center*	0	0	0	0	1	1
Raleigh	Duke Raleigh Hospital	0	0	15	0	0	15
Cary	Duke Green Level Ambulatory Surgery Center*	0	0	0	0	1	1
Raleigh	Surgical Center for Dental Professionals	0	0	0	0	2	2

\*Includes ambulatory surgery facilities and operating rooms that were approved pursuant to settlement of Wake County operating room review for the need determination for six additional operating rooms in the 2018 SMFP. Also includes one operating room to be relocated from Capital City Surgery Center to WakeMed Surgery Center-North Raleigh.

**WakeMed Cary Hospital and UNC REX Hospital** propose to develop the additional operating rooms at existing hospitals in Cary and Raleigh, respectively. All of the other applicants propose to develop the operating rooms in ambulatory surgery centers. **WSSSC** proposes to develop a new ambulatory surgery center in Raleigh. **Duke Green Level ASC** propose to add two operating rooms to an approved ambulatory surgery center in Cary, and **TOSC** proposes to add two operating rooms to an existing ambulatory surgery center in Raleigh. Therefore, with regard to expanding geographic access to surgical services, all of the proposals are equally effective alternatives because they all propose to develop the operating rooms in either Raleigh or Cary.

**Competition**

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The following table identifies the adjusted planning inventory of operating rooms for each applicant as a percent of the total existing and approved Wake County operating rooms, based on Table 6B of the 2020 SMFP. Table 6B shows a total of 108 existing and approved operating rooms in Wake County, excluding the need determination for two operating rooms in the 2019 SMFP.

**Applicants' Existing and Approved Wake County Operating Rooms as Percent of Total**

	<b>Adjusted Operating Room Planning Inventory</b>	<b>Applicants' Operating Rooms as a Percent of Total Wake County Operating Rooms</b>
Rex Hospital Holly Springs	3	
Rex Surgery Center of Wakefield	2	
Rex Surgery Center of Cary	4	
Rex Hospital	24	
Raleigh Orthopedic Surgery Center	3	
Raleigh Orthopedic Surgery-West Cary	1	
<b>UNC REX Health System</b>	<b>37</b>	<b>34.3%</b>
WakeMed Surgery Center-Cary	1	
Capital City Surgery Center	8	
WakeMed	22	
WakeMed Cary Hospital	10	
<b>WakeMed Health System</b>	<b>41</b>	<b>38.0%</b>
<b>Triangle Orthopaedics Surgery Center</b>	<b>2</b>	<b>1.9%</b>
Duke Green Level Ambulatory Surgery Center	1	
Duke Raleigh Hospital	15	
<b>Duke University Health System</b>	<b>16</b>	<b>14.8%</b>

Source: 2020 SMFP, Table 6B: Projected Operating Room Need for 2022.

As shown in the table above, the WakeMed Health System controls 38 percent of the existing and approved operating rooms in Wake County, the UNC REX Health System controls 34.3 percent, and the Duke Health System controls 14.8 percent. In contrast, TOSC controls 1.9 percent of the existing and approved operating rooms in Wake County. WSSSC states that it does not own or operate any existing surgical facilities, and, therefore, the proposed facility would be a new provider of surgical services in Wake County. Therefore, with regard to increasing competition for surgical services in Wake County, the application submitted by **WSSSC** is the most effective alternative and the application submitted by **TOSC** is a more effective alternative than the applications submitted by **WakeMed Cary Hospital**, **UNC REX Hospital** and **Duke Green Level ASC**.

**Scope of Services**

The following table shows each applicant's projected scope of services (surgical specialties) to be provided at the proposed facilities. Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

Surgical Specialty	WSSSC	TOSC	Duke Green Level ASC	WakeMed Cary Hospital	UNC REX Hospital
Cardiothoracic				X	X
Cardiovascular				X	X
Gastroenterology				X	X
General Surgery		X	X	X	X
Gynecology			X	X	X
Obstetrics				X	X
Open Heart Surgery					X
Ophthalmology	X		X	X	X
Oral Surgery				X	X
Orthopedic	X	X	X	X	X
Otolaryngology			X	X	X
Neurology/Spine	X		X	X	X
Pain Management	X	X			X
Pediatrics				X	
Plastic Surgery		X	X	X	X
Podiatry			X	X	X
Pulmonary				X	
Thoracic				X	X
Urology			X	X	X
Vascular			X	X	X

Source: WSSSC, page 20 of the application. TOSC, pages 18-19 of the application. WakeMed Cary Hospital, pages 17-18 of the application. Duke Green Level ASC, page 21 of the application. UNC REX Hospital, 2019 Renewal Application for Hospital form, page 12.

Therefore, the applications submitted by **WakeMed Cary Hospital** and **UNC REX Hospital** applications are more effective with respect to this comparative factor. The applications submitted by **WSSSC, TOSC, and Duke Green Level ASC** are the less effective proposals with respect to this comparative factor.

**Patient Access to Lower Cost Surgical Services**

There are currently 102 operating rooms (excluding dedicated C-Section and trauma operating rooms) in the Wake County operating room service area. Operating rooms can be licensed either under a hospital license or an ambulatory surgery center license. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be appropriately performed either in a hospital licensed operating room (either

shared inpatient/outpatient operating rooms or dedicated ambulatory surgery operating rooms) or in a non-hospital licensed operating room at an ambulatory surgery center; however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room at an ASC. Nonetheless, along with inpatient surgical services, there are some outpatient surgical services that must be performed in a hospital setting.

The following table identifies the existing and approved inpatient (IP), outpatient (OP) and shared inpatient/outpatient operating rooms in Wake County.

	<b>Total ORs*</b>	<b>IP ORs</b>	<b>% IP of Total ORs</b>	<b>OP ORs**</b>	<b>% OP of Total ORs</b>	<b>Shared ORs</b>	<b>% Shared of Total ORs</b>
Wake County Operating Rooms	110	3	2.7%	36	32.7%	71	64.5%

Source: 2020 SMFP.

\*Total operating rooms includes existing and approved operating rooms and excludes dedicated C-Section and designated trauma operating rooms.

\*\*Includes two single-specialty demonstration project operating rooms at Triangle Orthopaedics Surgery Center.

The table below shows the percentage of total Wake County surgical cases that were ambulatory surgeries in FY2018, based on data reported in the 2020 SMFP.

**Ambulatory Surgical Cases as Percent of  
 Total Wake County Surgical Cases**

Wake County Surgical Facility	Type of ORs	Inpatient Cases	Ambulatory (Outpatient) Cases	Total Cases	Percent Ambulatory
Blue Ridge Surgery Center	ASC	-	5,923	5,923	100%
Raleigh Plastic Surgery	ASC	-	340	340	100%
Raleigh Orthopedic Surgery	ASC	-	5,416	5,416	100%
Rex Surgery Center Wakefield	ASC	-	41	41	100%
Rex Surgery Center Cary	ASC	-	4,585	4,585	100%
Rex Hospital	Hospital Shared	8,366	12,019	20,385	59%
Capital City Surgery Center	ASC	-	6,712	6,712	100%
WakeMed	Hospital Shared	7,810	8,449	16,259	52%
WakeMed North Hospital	Hospital Shared	131	2,740	2,871	95%
WakeMed Cary Hospital	Hospital Shared	2,973	4,956	7,929	63%
Holly Springs Surgery Center	ASC	-	1,827	1,827	100%
Triangle Orthopedic Surgery	ASC	-	2,403	2,403	100%
Duke Raleigh Hospital	Hospital Shared	3,328	7,474	10,802	69%
<b>Totals</b>		<b>22,608</b>	<b>62,885</b>	<b>85,493</b>	<b>74%</b>

Source: 2020 SMFP, Table 6B.

As the table above shows, 74% of the total Wake County surgical cases in FY2018 were performed as ambulatory (outpatient) surgeries. Wake County currently has fifteen existing and approved ASCs. Based on the fact that 74 percent of Wake County’s FY2018 surgical cases were ambulatory surgery cases and that ASC operating rooms represent 33 percent of the total existing and approved Wake County operating rooms, projects proposing the development of ASC operating rooms would represent more effective alternatives.

Therefore, the applications submitted by **WSSSC, TOSC, and Duke Green Level ASC** are the more effective proposals with respect to this comparative factor. The **WakeMed Cary Hospital** and **UNC REX Hospital** applications are less effective with respect to this comparative factor.

**Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

*Projected Charity Care*

The following table shows each applicant’s projected charity care to be provided in the project’s third full operating year. Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor.

**CHARITY CARE  
PROJECT YEAR 3**

APPLICANT	Projected Total Charity Care	Charity Care per Surgical Case	Percent of Total Net Surgical Revenue
WSSSC	\$1,343,308	\$1,919	29.4%
TOSC	\$278,017	\$56	1.9%
Duke Green Level ASC	\$592,227	\$182	6.0%
WakeMed Cary Hospital	\$32,813,475	\$3,402	22.6%
UNC REX Hospital	\$15,664,092	\$707	6.0%

Source: Form F.2 for each applicant.

As shown in the table above, **WakeMed Cary Hospital** projects the most charity care in dollars, and also projects the highest charity care per surgical case. WSSSC projects the most charity care as a percent of net revenue. Therefore, the applications submitted by **WakeMed Cary Hospital** and **WSSSC**, generally speaking, are the most effective alternatives with regard to access to charity care. However, the differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

*Projected Medicare*

The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicare patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage to services to Medicare patients is the more effective alternative with regard to this comparative factor.

**Services to Medicare Patients - Project Year 3**

	<b>Medicare Gross Revenue</b>	<b>Total Gross Revenue</b>	<b>Medicare % of Total Gross Revenue</b>
WSSSC	\$22,052,267	\$47,058,118	46.9%
TOSC	\$11,277,180	\$46,456,144	24.3%
Duke Green Level ASC	\$12,617,767	\$29,824,057	42.3%
WakeMed Cary Hospital	\$309,985,908	\$618,611,492	50.1%
UNC REX Hospital	\$364,848,858	\$719,101,413	50.7%

Source: Form F.2 for each applicant.

As shown in the table above, **UNC REX Hospital** and **WakeMed Cary Hospital** project more than 50 percent of their surgical services will be provided to Medicare patients. **WSSSC** projects 46.9% and **Duke Green Level ASC** projects 42.3% of their services will be for Medicare patients.

The applications submitted by **UNC REX Hospital** and **WakeMed Cary Hospital** are the most effective applications with regard to serving Medicare patients. However, the differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

*Projected Medicaid*

The following table shows each applicant's percentage of gross revenue (charges) projected to be provided to Medicaid patients in the applicant's third full year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage to services to Medicaid patients is the more effective alternative with regard to this comparative factor.

**Services to Medicaid Patients - Project Year 3**

	<b>Medicaid Gross Revenue</b>	<b>Total Gross Revenue</b>	<b>Medicaid % of Total Gross Revenue</b>
WSSSC	\$1,384,031	\$47,058,118	2.9%
TOSC	\$2,231,790	\$46,456,144	4.8%
Duke Green Level ASC	\$1,465,086	\$29,824,057	4.9%
WakeMed Cary Hospital	\$24,499,456	\$618,611,492	4.0%
UNC REX Hospital	\$29,345,431	\$719,101,413	4.1%

Source: Form F.2 for each applicant.

As shown in the table above, **Duke Green Level ASC** and **TOSC** project 4.9% and 4.8% of their surgical services will be provided to Medicaid patients, respectively.

The applications submitted by **Duke Green Level ASC** and **TOSC** are the most effective applications with regard to serving Medicaid recipients. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

**Projected Average Net Revenue per Case**

The following table shows the projected average net surgical revenue per OR and per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing the lowest average net revenue is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

**Revenue per Operating Room and per Surgical Case - Project Year 3**

	Net Revenue	# of Cases	Net Revenue/Case
WSSSC	\$4,567,247	700	\$6,525
TOSC	\$14,901,598	4,951	\$3,010
Duke Green Level ASC	\$9,807,714	3,254	\$3,014
WakeMed Cary Hospital	\$145,128,178	9,645	\$15,047
UNC REX Hospital	\$260,399,685	22,155	\$11,754

Source: Form F.2 for each application.

As shown in the table above, **TOSC** and **Duke Green Level ASC** project the lowest net revenue per surgical case in the third operating year. Therefore, the applications submitted by **TOSC** and **Duke Green Level ASC** are the most effective applications with respect to net revenue per surgical case. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

**Projected Average Operating Expense per Case**

The following table compares the projected average operating expense in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form F.3). Generally, the application proposing the lowest average operating expense is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

**Operating Expense per Surgical Case - Project Year 3**

	Operating Expense*	# of Surgical Cases	Operating Expense per Surgical Case
WSSSC	\$3,951,663	700	\$5,645
TOSC	\$12,627,705	4,951	\$2,551
Duke Green Level ASC	\$8,701,187	3,254	\$2,674
WakeMed Cary Hospital	\$64,544,379	9,645	\$6,692
UNC REX Hospital	\$190,846,839	22,155	\$8,614

Source: Forms F.3 in each application.

\*Except for WSSSC, operating expenses for the ambulatory surgery center applications include expenses for both the proposed operating rooms and procedure rooms.

As shown in the table above, **TOSC** and **Duke Green Level ASC** project the lowest operating expense per surgical case in the third operating year. Therefore, the applications submitted by **TOSC** and **Duke Green Level ASC** are the most effective applications with respect to operating

expense per surgical case. However, differences in the types of facilities and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

### SUMMARY

The following table is a summary of the comparative factors, and indicates whether each application was most effective, more effective, equally effective or less effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

<b>Comparative Factor</b>	<b>WSSSC</b>	<b>TOSC</b>	<b>Duke Green Level ASC</b>	<b>WakeMed Cary Hospital</b>	<b>UNC REX Hospital</b>
Conformity with Review Criteria	Yes	Yes	Yes	Yes	Yes
Geographic Accessibility	Equally Effective	Equally Effective	Equally Effective	Equally Effective	Equally Effective
Competition	<b>Most Effective</b>	<b>More Effective</b>	Less Effective	Less Effective	Less Effective
Scope of Services	Less Effective	Less Effective	Less Effective	<b>More Effective</b>	<b>More Effective</b>
Patient Access to Lower Cost Surgical Services	<b>More Effective</b>	<b>More Effective</b>	<b>More Effective</b>	Less Effective	Less Effective
Access by Underserved Groups: Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

All applications are conforming to all applicable statutory and regulatory review criteria, and thus all applications are approvable standing alone. However, collectively they propose a total of eight operating rooms but the need determination is for only two operating rooms. Therefore, only two operating rooms can be approved.

As shown in the table above, WSSSC was determined to be the most or more effective alternative for the following two factors:

- Competition
- Patient access to lower cost surgical services

As shown in the table above, TOSC was determined to be a more effective alternative for the following two factors:

- Competition
- Patient access to lower cost surgical services

## **DECISION**

Based upon the comparative factors as discussed and evaluated above, the applications submitted by WSSSC and TOSC are the more effective alternatives proposed in this review for new operating rooms to be located in Wake County and are therefore conditionally approved. The approval of the applications submitted by UNC REX Hospital, WakeMed Cary Hospital and Duke Green Level ASC would result in operating rooms in excess of the need determination for Wake County. Consequently, the applications submitted by UNC REX Hospital, WakeMed Cary Hospital and Duke Green Level ASC are denied.

**The application submitted by Wake Spine and Specialty Surgery Center, LLC is approved subject to the following conditions.**

- 1. Wake Spine and Specialty Surgery Center, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Wake Spine and Specialty Surgery Center, LLC shall develop a new specialty ambulatory surgical facility by developing no more than one operating room and three procedure rooms.**
- 3. Upon completion of the project, Wake Spine and Specialty Surgery Center, LLC shall be licensed for no more than one operating room and three procedure rooms.**
- 4. Wake Spine and Specialty Surgery Center, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. Wake Spine and Specialty Surgery Center, LLC 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 following licensure of the facility.**
- 6. For the first three years of operation following completion of the project, Wake Spine and Specialty Surgery Center, LLC shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 7. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**

8. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
9. Wake Spine and Specialty Surgery Center, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
10. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Wake Spine and Specialty Surgery Center, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
  - a. Payor mix for the services authorized in this certificate of need.
  - b. Utilization of the services authorized in this certificate of need.
  - c. Revenues and operating costs for the services authorized in this certificate of need.
  - d. Average gross revenue per unit of service.
  - e. Average net revenue per unit of service.
  - f. Average operating cost per unit of service.
11. Wake Spine and Specialty Surgery Center, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

The application submitted by TOSC is approved subject to the following conditions.

1. Triangle Orthopaedics Surgery Center, LLC shall materially comply with all representations made in the certificate of need application.
2. Triangle Orthopaedics Surgery Center, LLC shall develop one additional operating room for a total of three operating rooms, and convert the existing specialty ambulatory surgical facility to a multispecialty ambulatory surgical facility.
3. Upon completion of the project, Triangle Orthopaedics Surgery Center, LLC shall be licensed for no more than three operating rooms and one procedure room.
4. Triangle Orthopaedics Surgery Center, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
5. Triangle Orthopaedics Surgery Center, LLC 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 following licensure of the facility.

- 6. For the first three years of operation following completion of the project, Triangle Orthopaedics Surgery Center, LLC shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 7. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 8. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
- 9. Triangle Orthopaedics Surgery Center, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 10. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Triangle Orthopaedics Surgery Center, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. Payor mix for the services authorized in this certificate of need.**
  - b. Utilization of the services authorized in this certificate of need.**
  - c. Revenues and operating costs for the services authorized in this certificate of need.**
  - d. Average gross revenue per unit of service.**
  - e. Average net revenue per unit of service.**
  - f. Average operating cost per unit of service.**
- 11. Triangle Orthopaedics Surgery Center, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**