

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 25, 2021

Findings Date: February 25, 2021

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: J-11960-20
Facility: WakeMed Cary Hospital
FID #: 990332
County: Wake
Applicant: WakeMed
Project: Develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP

Project ID #: J-11961-20
Facility: Valleygate Surgery Center
FID #: 200741
County: Wake
Applicant: Valleygate Surgery Center, LLC
Project: Develop a new ASC with no more than 1 operating room and 3 procedure rooms pursuant to the need determination in the 2020 SMFP

Project ID #: J-11962-20
Facility: Orthopaedic Surgery Center of Garner
FID #: 200740
County: Wake
Applicant: Orthopaedic Surgery Center of Garner, LLC
Project: Develop a new ASC with no more than 2 operating rooms and 2 procedure rooms pursuant to the need determination in the 2020 SMFP

Project ID #: J-11963-20
Facility: Rex Hospital
FID #: 953429
County: Wake
Applicant: Rex Hospital, Inc.
Project: Add no more than 1 operating room pursuant to the need determination in the 2020 SMFP for a total of no more than 32 operating rooms

Project ID #: J-11966-20
Facility: Duke Health Garner Ambulatory Surgical Center
FID #: 200744
County: Wake
Applicant: Duke University Health System, Inc.
Project: Develop a new ASC with no more than 1 operating rooms and 2 procedure rooms pursuant to the need determination in the 2020 SMFP

Project ID #: J-11967-20
Facility: Duke Health Green Level Ambulatory Surgical Center
FID #: 180422
County: Wake
Applicant: Duke University Health System, Inc.
Project: Add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC)

Each application was reviewed independently (or standing alone) against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After reviewing each application independently, the Healthcare Planning and Certificate of Need Section (CON Section) conducted a comparative analysis of all the applications to aid in determining which applications to approve. The Decision is at the end of these Required State Agency Findings (Findings), after the Comparative Analysis.

REVIEW CRITERIA

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

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

C
All Applications

Need Determination

The 2020 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional operating rooms in North Carolina by service area. Application of the need methodology in the 2020 SMFP identified a need for three additional operating rooms in the Wake County service area. Six applications were received by the Healthcare Planning and

Certificate of Need Section (CON Section) proposing to develop a total of 8 new operating rooms. However, pursuant to the need determination, only three operating rooms may be approved in this review.

Policies

Two policies in Chapter 4 of the 2020 SMFP are applicable to the applications received in response to the need determination.

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."

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed [WakeMed Cary Hospital] proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Surgery Center, LLC [**Valleygate Garner ASC**] proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner.

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 14-17, 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 18-19, 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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Surgery Center of Garner, LLC [**Orthopaedic Garner ASC**] proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner.

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 11-18, 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 19-20, 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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

Rex Hospital, Inc. [**UNC REX Hospital**] proposes to develop no more than one additional operating room at the existing hospital in Raleigh.

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 10-15, 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 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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke University Health System, Inc. [**Duke Garner ASC**] proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner.

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.2, pages 107-110, 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke University Health System, Inc. [**Duke Green Level ASC**] proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an 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, page 13, and Section N.2, pages 106-109, 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.

(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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

All Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed [WakeMed Cary Hospital] proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

Patient Origin

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 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 FFY2025	
	Patients	% of Total
Wake	6,186	70.3%
Johnston	490	5.6%
Harnett	471	5.4%
Durham	152	1.7%
Lee	131	1.5%
Cumberland	116	1.3%
Chatham	106	1.2%
Sampson	75	0.9%
Franklin	74	0.8%
Alamance	67	0.8%
Other*	934	10.5%
Total	8,802	100.0%

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

In Section C.3, page 24, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical (FFY2019) patient origin for surgical services at WakeMed Cary Hospital.

Analysis of Need

In Section C.4, pages 24-36, 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 and aging 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.
- The addition of surgical specialties and the higher complexity and surgical case times that are associated with those additional surgical specialties.
- 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 growth in robotic surgery and the addition of the Obstetric Emergency Department.

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 Q, page 117, the applicant provides a table showing the operating room inventories for WakeMed’s existing Wake County surgical facilities, which is summarized below:

**WakeMed System
 Current Operating Room Inventory by Facility**

Operating Room Type	WakeMed Raleigh*	WakeMed Cary Hospital	Capital City Surgery Center	Total
Dedicated Open Heart	4	0	0	4
Shared Inpatient/Outpatient	19	10	0	29
Dedicated Ambulatory Surgery	0	0	8	8
Dedicated C-Section	4	2	0	6
Total	27	12	8	47

Source: Section Q, page 117.

*The applicant states the WakeMed Raleigh operating room totals includes four shared operating rooms and one dedicated C-section operating room located at WakeMed North Hospital, which is licensed as part of WakeMed Raleigh.

Effective August 15, 2019, 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

Operating Rooms	Year 1 FFY2023	Year 2 FFY2024	Year 3 FFY2025
Shared Operating Rooms	11	11	11
Inpatient Surgical Cases	3,796	3,971	4,154
Outpatient Surgical Case	4,598	4,623	4,648
Total Surgical Cases	8,394	8,594	8,802
Inpatient Surgical Case Times	102.5	102.5	102.5
Outpatient Surgical Case Times	50.6	50.6	50.6
Inpatient Surgical Hours	6484.8	6783.8	7096.4
Outpatient Surgical Hours	3877.6	3898.7	3919.8
Total Surgical Hours	10362.4	10682.5	11016.2
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	6.91	7.12	7.34

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

Operating Rooms	Year 1 FFY2023	Year 2 FFY2024	Year 3 FFY2025
Open Heart Operating Rooms	4	4	4
Shared Operating Rooms	19	19	19
Inpatient Surgical Cases	8,112	8,154	8,196
Outpatient Surgical Case	10,835	11,423	12,042
Total Surgical Cases	18,947	19,577	20,238
Inpatient Surgical Case Times	190.9	190.9	190.9
Outpatient Surgical Case Times	121.4	121.4	121.4
Inpatient Surgical Hours	25809.7	25943.3	26076.9
Outpatient Surgical Hours	21922.8	23112.5	24365.0
Total Surgical Hours	47732.5	49055.8	50441.9
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	24.48	25.16	25.87

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

Operating Rooms	Year 1 FFY2023	Year 2 FFY2024	Year 3 FFY2025
Dedicated Ambulatory ORs*	7	7	7
Outpatient Surgical Cases	6,608	6,651	6,695
Surgical Case Times	60.1	60.1	60.1
Totals Surgical Hours	6619.0	6662.1	6706.2
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	5.04	5.08	5.11

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.

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

Operating Rooms	Year 1 FFY2023	Year 2 FFY2024	Year 3 FFY2025
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,669	1,743	1,821
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	1980.5	2068.4	2160.9
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	1.51	1.58	1.65

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

Operating Rooms	Year 1 FFY2023	Year 2 FFY2024	Year 3 FFY2025
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,457	1,516	1,579
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	1729.0	1799.0	1873.7
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	1.32	1.37	1.43

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 FY2019 (excluding cases performed in dedicated C-section operating rooms) and calculated the compound average growth rates (CAGR) for inpatient and outpatient surgical cases, as shown in the tables on pages 117-118.

Step 2: Based on the surgical case growth rates calculated above in Step 1, the applicant projected the surgical case volumes for inpatient and outpatient surgeries at WakeMed Raleigh, WakeMed Cary Hospital and Capital City Surgery Center through FFY2025, as shown in the tables on page 119 of the application.

Step 3: 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). On page 120, the applicant states, *“[I]n addition to new ASF cases created by population growth in Wake County, 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.”* Based on that assumption, the applicant projected the number of surgical cases that will shift from WakeMed’s existing surgical facilities to the two approved ASCs through FFY2025, as shown in the tables on pages 120-121 of the application.

Step 4: 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 5: 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 2020 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 126 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 FY2019 based on data reported to DHSR on the License Renewal Application forms for the years 2013 to 2020.

WakeMed Health Care System Surgical Cases, FY2012-FY2019

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	CAGR FY2012- FY2019
Total Surgical Cases*	28,136	30,124	30,514	30,388	31,594	31,169	33,761	32,968	1.51%
Percent Change		7.1%	1.3%	-0.4%	4.0%	-1.3%	8.3%	-2.3%	

Source: License Renewal Application forms, 2013-2020.

*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, FY2019-FY2025

	FY2019	FY2020	FY2021	FY2022	PY 1 FY2023	PY 2 FY2024	PY 3 FY2025	CAGR FY2019- FY2025
WakeMed Cary Hospital	8,235	8,074	8,414	8,202	8,394	8,594	8,802	
WakeMed Raleigh	19,264	20,884	19,917	18,347	18,947	19,577	20,238	
Capital City Surgery Center	6,822	6,710	6,866	6,565	6,608	6,651	6,695	
WakeMed Surgery Center North	-	-	-	1,599	1,669	1,743	1,821	
WakeMed Surgery Center Cary	-	-	-	1,401	1,457	1,516	1,579	
Total Surgical Cases	34,321	35,668	35,197	36,114	37,075	38,081	39,135	2.21%
Percent Change		3.92%	-1.32%	2.61%	2.66%	2.71%	2.77%	

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 1.51 percent per year from FY2012 to FY2019. The applicant’s utilization projections for all existing, approved and proposed WakeMed 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 2.21 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 FY2013 to FY2019, and by projected population growth and aging in the Wake County service area.
- On page 120 of the application, 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 to Medically Underserved Groups

In Section C.8, page 42, the applicant states it ensures access to healthcare services for all patients, regardless of income, payor status, gender, race, ethnicity, or physical handicap. The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Estimated Percentages of Patients by Group	
Low income persons	11.3
Racial and ethnic minorities	33.6%
Women	61.9%
Persons with disabilities	NA
The elderly	30.3%
Medicare beneficiaries	43.0%
Medicaid recipients	5.3%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Surgery Center, LLC [Valleygate Garner ASC] proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

Patient Origin

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 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 room in the third full operating year of the project.

County	Third Full Fiscal Year of Operation CY2025	
	Patients	% of Total
Wake	365	48.1%
Harnett	171	22.5%
Johnston	42	5.6%
Other*	180	23.7%
Total	759	100.0%

Source: Section C.3, page 29. The applicant states the “Other” category “includes portions of Wake, Harnett, and Johnston not previously accounted for, all other North Carolina counties, and out of state.”

In Exhibit C.3 and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the population of its proposed service area, as described in the applicant’s utilization projections in Section Q of the application.

Analysis of Need

In Section C.4, pages 31-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need for additional operating rooms identified in the 2020 State Medical Facilities Plan.
- The historical and projected growth and aging of the Wake, Johnston and Harnett County populations, particularly in the southeastern Wake County.
- Socioeconomic factors that make access to care more difficult in the proposed service area.
- The need for access to operating rooms for dental surgical procedures and for ambulatory surgical operating rooms.
- The cost-effectiveness of ambulatory surgery centers in comparison to hospital-based surgical services and the lack of access to ASC's in southeastern Wake County.
- The interest and support of area physicians and surgeons for the development of the proposed ASC.

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).
- The applicant provides information and data to support their assertions regarding the need for ambulatory surgical services in southeastern Wake County, including letters of support from physicians and surgeons.

Projected Utilization

In Section Q, the applicant provides projected utilization of the one operating room at the proposed Valleygate Garner ASC facility through the first three full fiscal operating years of the proposed project, as illustrated in the following table.

Projected Valleygate Garner ASC Utilization

Operating Rooms	Year 1 CY2023	Year 2 CY2024	Year 3 CY2025
Ambulatory Operating Rooms	1	1	1
Outpatient Surgical Cases	677	740	759
Outpatient Surgical Case Times	71.2	71.2	71.2
Total Surgical Hours	803	878	900
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	0.61	0.67	0.69

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization for the surgical specialties (excluding dental surgical services) at the proposed ASC, which is summarized below.

Step 1: The applicant identifies its proposed service area by census tract based on data provided by Claritas, as shown in the map and table on pages 120-121.

Step 2: The applicant calculates the ambulatory surgical use rates for each of the proposed surgical specialties (ENT, ophthalmology and plastic surgery) based on 2018 data, as shown in the tables on pages 122-123 of the application.

Step 3: The applicant estimates the percentage of ambulatory surgical cases that will be performed in ambulatory and hospital settings, respectively, as described on page 124 of the application.

Step 4: The applicant projects the number of ambulatory surgical cases that will be performed in ambulatory and hospital settings, respectively, as shown in the tables on pages 125-126 of the application.

Step 5: Based on the applicant's projections of outpatient surgical cases for each proposed surgical specialty, and the applicant's estimate of average case times for each surgical specialty, the applicant projects the total surgical hours needed by specialty.

Step 6: The applicant applied the operating room need methodology from the 2020 SMFP to project the total number of operating rooms needed in the proposed service area, as shown in the table on page 128 of the application.

Step 7: The applicant projects market share percentages for each surgical specialty for each operating year, and projects total surgical cases by surgical specialty through the first three full operating years of the proposed ASC, as shown in the tables on pages 129-130 of the application. The applicant states:

“The applicant assumes market share will increase as the community and referring providers become more comfortable with Valleygate and aware of its lower charge schedule and provider friendly structure. Residents in the service area will also develop a better understanding of appropriate use of the proposed facility by the third year. The applicant also conferred with leadership at Valleygate on the market shares to determine they were reasonable and achievable. Charges at the hospital are much higher than the freestanding rate schedule proposed for Valleygate. Increasingly consumers and third-party payers are choosing freestanding ASFs as a cost containment measure when the option is available.”

Step 8: The applicant projects that 10 percent of total surgical cases at the proposed ASC will originate from outside the proposed service (in-migration), as shown in the tables on pages 131-132 of the application.

Step 9: Based on the applicant's projections of total outpatient surgical cases for each proposed surgical specialty, and the applicant's estimate of average case times for each surgical specialty, the applicant projects the total surgical hours needed by specialty at the proposed ASC, as shown on page 133 of the application.

Step 10: Based on the applicant's projections of total outpatient surgical cases for each proposed surgical specialty to be performed at the proposed ASC, the applicant summarizes the total cases and total surgical hours needed at the proposed ASC, as shown in the table on page 134 of the application.

In Section Q, the applicant provides the assumptions and methodology used to project utilization for dental surgical services at the proposed ASC, which is summarized below.

Step 1: The applicant identifies its proposed service area as Wake County, as described on page 135 of the application.

Step 2: The applicant calculates the ambulatory surgical use rates for dental surgery based on 2018 data, and projects the total ambulatory dental surgical cases based on the projected Wake County population, as shown in the table on page 136 of the application.

Step 3: The applicant estimates the percentage of ambulatory dental surgical cases that will be performed in ambulatory and hospital settings, respectively, as described on page 137 of the application.

Step 4: The applicant projects the number of dental/oral ambulatory surgical cases that will be performed in ambulatory and hospital settings, respectively, as shown in the table on page 138 of the application.

Step 5: Based on the applicant's projections of dental/oral surgical cases, and the applicant's estimate of average case times for dental/oral surgical cases, the applicant projects the total surgical hours needed.

Step 6: The applicant applied the operating room need methodology from the 2020 SMFP to project the total number of operating rooms needed in the proposed service area, as shown in the table on page 140 of the application.

Step 7: The applicant projects market share percentages for dental/oral surgery for each operating year, and projects total surgical cases through the first three full operating years of the proposed ASC, as shown in the table on page 141 of the application. The applicant states:

“The applicant assumes market share will increase as the community and referring providers become more comfortable with Valleygate and aware of its lower charge schedule and provider friendly structure. Residents in the service area will also develop a better understanding of appropriate use of the proposed facility by the third year. The applicant also conferred with leadership at Valleygate on the market shares to determine they were reasonable and achievable. Charges at the hospital are much higher than the freestanding rate schedule proposed for Valleygate. Increasingly consumers and third-party payers are choosing freestanding ASFs as a cost containment measure when the option is available.”

Step 8: The applicant projects that 58.6 percent of total dental/oral surgical cases at the proposed ASC will originate from outside the proposed service (in-migration), as shown in the table on page 142 of the application. The applicant states:

“Historical data show that between, 2018 and YTD 2020, 58.6 percent of all Valleygate patients who received dental/oral surgery at Valleygate freestanding facilities, came from outside of the county where the facility is located. See Exhibit C.7, page 4, for Valleygate patient origin data. The applicant conservatively estimates that it will use the same percentage to forecast dental/oral surgery cases after in-migration. The applicant finds this estimate reasonable as history from Valleygate facilities shows large in-migration and communities that border southeastern Wake County, such as those in northern Harnett, and Johnson Counties, have no freestanding dental ASFs.”

Step 9: Based on the applicant's projections of total dental/oral surgical cases, and the applicant's estimate of average case times for dental/oral surgical cases, the applicant projects the total surgical hours needed for dental/oral surgical cases at the proposed ASC, as shown in the table on page 143 of the application.

Step 10: Based on the applicant's projections of total dental/oral surgical cases to be performed at the proposed ASC, the applicant summarizes the total dental/oral cases and total surgical hours needed at the proposed ASC, as shown in the table on page 143 of the application.

In Section Q, the applicant provides the assumptions and methodology used to project utilization for the one operating room and three procedure rooms at the proposed ASC, which is summarized below.

Step 1: The applicant sums the total projected surgical hours for all of the surgical specialties discussed above, and allocates the total projected surgical hours to the operating room and procedure rooms by assuming all surgical hours will be performed in the operating room up to 75 percent of capacity, and the remaining surgical hours are allocated to the procedure rooms, as shown in the table on page 144 of the application.

Step 2: The applicant calculates the percentages of surgical hours distributed to the operating rooms and procedure rooms, as shown in the table on page 145 of the application.

Step 3: The applicant calculates the operating room cases and procedure room cases, as shown in the table on page 146 of the application.

Step 4: The applicant calculates the operating room need based surgical hours using the standard surgical hours per operating room for Group 6 in the 2020 SFMP operating room need determination methodology, as shown in the table on page 146 of the application.

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

- The applicant's projections of total surgical case volumes by year at its proposed surgical facility are supported by the historical statewide surgical use rates based on DHSR utilization data and projected population data in the proposed service area from Claritas.
- The applicant states that its market share and in-migration assumptions are based on and supported by its historical experience operating an existing dental/oral ASC.
- 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, including estimates of the number of surgical procedures they expect to perform at the proposed ASC.

Access to Medically Underserved Groups

In Section C.8, page 61, the applicant states it ensures access to healthcare services for all patients, regardless of gender, gender preference, race, ethnicity, age, income, or disability status. The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Estimated Percentages of Patients by Group	
Low income persons	63.9%
Racial and ethnic minorities	40.4%
Women	51.4%
Persons with disabilities	5.8%
The elderly	20.9%
Medicare beneficiaries	20.9%
Medicaid recipients	55.1%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Surgery Center of Garner, LLC [**Orthopaedic Garner ASC**] proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP. In Section A.1, page 5, the applicant states that Orthopaedic Surgery Center of Garner, LLC is wholly owned by Rex Orthopedic Ventures, LLC, which is wholly owned by Rex Healthcare, Inc., the parent company for Rex Hospital, Inc. (UNC REX Hospital).

Patient Origin

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 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 SFY2026	
	Patients	% of Total
Wake	1,371	67.5%
Johnston	223	11.0%
Harnett	95	4.7%
Franklin	32	1.6%
Durham	30	1.5%
Sampson	27	1.3%
Wayne	23	1.1%
Nash	22	1.1%
Other*	208	10.2%
Total	2,031	100.0%

Source: Section C.3, page 25. The counties included in the “Other” category are listed below the table on page 25 of the application.

In Section C.3, page 26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the SFY2020 patient origin of Raleigh Orthopaedic Surgery Center surgeons who expect to shift surgical cases and procedure room procedures to the proposed ASF, applied to the total number of projected operating room and procedure room cases at the proposed ASF through SFY 2026, the third full fiscal year of the proposed project.

Analysis of Need

In Section C.4, pages 26-55, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The increase in the demand for ambulatory surgery services resulting from a significant shift of healthcare from inpatient to outpatient settings, and as a result of this trend, increasing concentration of higher acuity patients in inpatient settings due to the shift of lower acuity patients to outpatient settings.
- The historical growth in orthopedic surgical cases, particularly in the ASC setting in the Wake County service area.
- The historical and projected growth in surgical case volumes at Raleigh Orthopaedic Surgery Center.

- The high utilization of existing UNC Health System surgical facilities in Wake County.
- The projected growth and aging of the Wake County service area population, the continued commercial development in the Garner area, and the lack of ASC facilities in that part of the service area.

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

- The applicant provides data and information to support their assertions regarding the trends toward increasing demand for ambulatory surgery and ASC facilities, particularly for orthopedic surgical cases.
- 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).
- The applicant provides information and data to support their assertions regarding the projected growth in orthopedic surgical case volumes in Wake County ASCs.

Projected Utilization

In Section Q, 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		
	Adjusted Operating Room Planning Inventory	Proposed Adjusted Planning Inventory
UNC REX Hospital Holly Springs	3	3
Rex Surgery Center of Wakefield	2	2
Rex Surgery Center of Cary	4	4
UNC REX Hospital	24	25 [^]
Raleigh Orthopaedic Surgery Center	3	3
Raleigh Orthopaedic Surgery Center-West Cary	1	1
Orthopaedic Surgery Center of Garner	0	2 [^]
Total	37	40

Source: Section Q, Form C Methodology, page 1. Excludes C-section operating rooms.

[^]Includes the two operating rooms for Orthopaedic Surgery Center of Garner and one additional operating room proposed for UNC REX Hospital in a separate application in this review.

In Section Q, the applicant provides utilization projections for Orthopaedic Surgery Center of Garner, 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.

Orthopaedic Surgery Center of Garner

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

Projected Orthopaedic Surgery Center of Garner Utilization

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	1,634	1,830	2,031
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	1,940	2,171	2,410
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	1.5	1.7	1.8

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized as follows:

Step 1-The applicant identified the ROSC surgeons projected to shift surgical cases to the proposed Garner ASC, and calculated the growth rates in surgical case volumes for those surgeons from 2018 to 2020. See table on page 18 of Section Q.

Step 2-The applicant projected operating room and procedure room cases for those surgeons from SFY2024 to SFY2026 based on the assumptions that surgical case volumes would increase by 1.8, annually, for SFY2020 through SFY2026. See table on page 19 of Section Q.

Step 3-The applicant projected the percentage operating room and procedure room cases for those surgeons from SFY2024 to SFY2026. The applicant states, *“The percent of operating room cases and procedure room procedures projected to shift is based on several factors including the projected amount of time the surgeons are expected to practice at the proposed ASF, available block time, patient choice, and ROC’s efforts to ensure that operating room utilization is distributed evenly across its existing facility (Raleigh Orthopaedic Surgery Center), approved facility (Raleigh Orthopaedic Surgery Center-West Cary), and proposed facility (Orthopaedic Surgery Center of Garner).”* See table on page 20 of Section Q.

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

- The applicant’s utilization projections for Orthopaedic Surgery Center of Garner are supported by the applicant’s historical volume of surgical cases for the surgeons projected to practice at the proposed ASC.
- The applicant’s utilization projections are supported by letters from ROSC surgeons who have expressed support for the proposed project and their intention to practice at the proposed Garner ASC. 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 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	3	3	3
Outpatient Surgical Cases	3,002	2,909	2,811
Surgical Case Times	81.6	81.6	81.6
Totals Surgical Hours	4,083	3,956	3,822
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	3.1	3.0	2.9

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized as follows:

Step 1-The applicant calculated the growth rates in surgical case volumes for ROSC from 2018 to 2020. See table on page 17 of Section Q.

Step 2-The applicant projected operating room and procedure room cases for ROSC from SFY2021 to SFY2026 based on the assumptions that surgical case volumes would increase by 1.8, annually. See table on page 18 of Section Q.

Step 3-The applicant projected the operating room and procedure room cases for those surgeons that will shift surgical cases to the proposed ASC in Garner from SFY2024 to SFY2026. See discussion above and pages 18-21 of Section Q in the application.

Step 4-Based on the utilization projections included in the application for ROSC-West Cary (Project I.D. # J-11161-16), the applicant projects 1,136 surgical cases per year will shift from ROSC to ROSC-West Cary through the first three full fiscal years of operation of the proposed project. See discussion below and pages 21-22 of Section Q in the application.

Step 5-Based on the applicant’s projected shifts in surgical cases volumes from ROSC to Orthopaedic Surgery Center of Garner and ROSC-West Cary, the applicant projects the surgical case volumes that will remain at ROSC through the first three full fiscal years of operation of the proposed project. See the table on page 22 of Section Q in the application.

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 SFY2021 through the third year of the proposed project (SFY2026) are supported by the applicant’s historical 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-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

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,136	1,136	1,136
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	1,348	1,348	1,348
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	1.0	1.0	1.0

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 ambulatory surgical operating room at ROSC-West Cary is based on the utilization projections in the previously approved CON application (Project I.D. #J-11161-16), and the assumption that the Year 3 surgical case volume (1,136 surgical cases) will remain constant through the first three operating years of the proposed project.

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.
- 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 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

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Shared Operating Rooms	25	25	25
Inpatient Surgical Cases	8,579	8,692	8,807
Outpatient Surgical Case	11,584	11,842	12,106
Total Surgical Cases	20,164	20,535	20,913
Inpatient Surgical Case Times	186.3	186.3	186.3
Outpatient Surgical Case Times	135.0	135.0	135.0
Inpatient Surgical Hours	26,639	26,990	27,346
Outpatient Surgical Hours	26,064	26,645	27,238
Total Surgical Hours	52,703	53,635	54,584
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	27.0	27.5	28.0

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 1.3 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 2.2 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 SFY2022 (See Section Q, pages 7-8). The applicant provides the projected utilization of the operating rooms at UNC REX Hospital after the projected shifts in surgical cases, as summarized in the following table.

Projected UNC REX Hospital Surgical Utilization after Shifts

	FY2021	FY2022	FY2023	PY 1 FY2024	PY 2 FY2025	PY 3 FY2026
Inpatient Surgical Cases	8,985	9,103	9,224	9,345	9,468	9,593
Outpatient Surgical Cases	12,155	12,425	12,702	12,985	13,274	13,569
Inpatient Cases Shifted to UNC REX Holly Springs Hospital		-359	-556	-766	-776	-786
Outpatient Cases Shifted to UNC REX Holly Springs Hospital		-630	-1,007	-1,400	-1,432	-1,463
Inpatient Cases after Shifts	8,985	8,744	8,667	8,579	8,692	8,807
Outpatient Cases after Shifts	12,155	11,795	11,695	11,584	11,842	12,106

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

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Shared Operating Rooms	3	3	3
Inpatient Surgical Cases	851	862	874
Outpatient Surgical Case	1,556	1,591	1,626
Total Surgical Cases	2,407	2,453	2,500
Inpatient Surgical Case Times	186.3	186.3	186.3
Outpatient Surgical Case Times	135.0	135.0	135.0
Inpatient Surgical Hours	2,642	2,677	2,713
Outpatient Surgical Hours	3,501	3,579	3,659
Total Surgical Hours	6,143	6,256	6,371
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	3.2	3.2	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 is based on the surgical utilization projections in the previously approved CON application (Project I.D. #J-8669-11), and annual surgical case growth rates of 1.3 and 2.2 percent for inpatient and outpatient surgical cases, respectively. Also, the applicant states the utilization projections are further supported by the fact 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 historical growth rates in surgical services utilization UNC REX Hospital, and the historical and projected growth in the proposed 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.

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

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	2,968	2,998	3,028
Surgical Case Times	54.0	54.0	54.0
Totals Surgical Hours	2,672	2,698	2,726
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	2.0	2.1	2.1

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 two dedicated ambulatory surgical operating rooms is based on the assumption that surgical case volumes will increase by one percent per year from the facility’s SFY2020 utilization, which the applicant states is “*equivalent to one-quarter of the UNC Health system outpatient surgery CAGR from SFY 2018 to 2020.*”

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 SFY2021 through the third year of the proposed project (SFY2026) are supported by the applicant’s historical (SFY2020) 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

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	4	4	4
Outpatient Surgical Cases	4,413	4,458	4,502
Surgical Case Times	62.7	62.7	62.7
Totals Surgical Hours	4,612	4,658	4,705
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	3.5	3.6	3.6

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 decline by 3.2 percent from SFY2020, and then increase by one percent per year through the first three full fiscal years of operation of the proposed project. The applicant states, “*REX Surgery Center of Cary’s operating room utilization is projected to decline by 3.2 percent from SFY 2020 to 2021, equivalent to the SFY 2018 to 2020 CAGR, and then increase 1.0 percent annually from SFY 2021 to 2026, driven by physician recruitment, population growth, and the overall growth in UNC Health system volume and resulting need for capacity for surgery cases, which is equivalent to one-quarter of the UNC Health system outpatient surgery CAGR from SFY 2018 to 2020.*”

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 SFY2021 through the third year of the proposed project (SFY2026) are supported by the applicant’s historical (SFY2020) volume of surgical cases, projected population growth in the service area, and historical growth of UNC Health Care’s outpatient surgical services utilization.
- 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 FY2019 based on data reported to DHSR on the License Renewal Application forms for the years 2013 to 2020.

UNC REX Health Care System Surgical Cases, FY2012-FY2019

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	CAGR FY2012- FY2019
Total Surgical Cases*	28,271	28,781	28,956	29,084	29,135	30,327	30,427	32,504	2.01%
Percent Change		1.8%	0.6%	0.4%	0.2%	4.1%	0.3%	6.8%	

Source: License Renewal Application forms, 2013-2020.

*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 SFY2020 to SFY2026 based on data in Form C, Section Q of the application.

Projected UNC REX Health Care System Surgical Cases, SFY2020-SFY2026

	2020	2021	2022	2023	PY 1 2024	PY 2 2025	PY 3 2026	CAGR 2020- 2026
UNC REX Hospital	18,996	21,140	20,540	20,362	20,164	20,535	20,913	
REX Holly Springs Hospital			1,099	1,737	2,407	2,453	2,500	
Rex Surgery-Wakefield	2,462	2,881	2,910	2,939	2,968	2,998	3,028	
Rex Surgery-Cary	3,830	4,283	4,326	4,369	4,413	4,458	4,502	
Raleigh Orthopedic SC	3,982	3,365	3,158	3,189	3,002	2,909	2,811	
Raleigh Orthopedic SC-West	811	1,092	1,136	1,136	1,136	1,136	1,136	
Orthopaedic Surgery-Garner					1,634	1,830	2,031	
Total Surgical Cases	30,081	32,761	33,169	33,732	35,724	36,319	36,921	3.47%
Percent Change		8.91%	1.25%	1.70%	5.91%	1.67%	1.66%	

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 2.01 percent per year from FY2012 to FY2019. The applicant’s utilization projections for all existing, approved and proposed UNC REX surgical facilities in Wake County for the period from SFY2020 through SFY2026 are based on the assumption that surgical case volumes will increase at an average rate of 3.47 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 to Medically Underserved Groups

In Section C.8, page 60, the applicant states it will provide services without regard to race, color, national origin, disability, or age, and will not discriminate with regard to patient care access on the basis of income, ability to pay, or any other factor which might restrict access to services. On page 61, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Estimated Percentages of Patients by Group	
Low income persons	NA
Racial and ethnic minorities	17.7%
Women	50.0%
Persons with disabilities	NA
The elderly	22.8%
Medicare beneficiaries	20.3%
Medicaid recipients	1.3%

NA-Applicant states it does not maintain data on these categories.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

Rex Hospital, Inc. [UNC REX Hospital] proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

Patient Origin

On page 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty

groupings as shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 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 SFY2025	
	Patients	% of Total
Wake	12,776	62.2%
Johnston	1,752	8.5%
Harnett	767	3.7%
Franklin	727	3.5%
Wayne	551	2.7%
Nash	478	2.3%
Wilson	439	2.1%
Sampson	359	1.7%
Durham	328	1.6%
Cumberland	198	1.0%
Other*	2,162	10.5%
Total	20,535	100.0%

Source: Section C.3, page 19. The counties included in the “Other” category are listed below the table on page 19 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 because they are based on the SFY2020 patient origin for UNC REX Hospital’s surgical services.

Analysis of Need

In Section C.4, pages 20-33, 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 statewide and in Wake County.
- The redeployment of hospital-based operating rooms to ambulatory surgery centers has resulted in the high utilization rates for the remaining hospital-based operating rooms in the Wake County service area.
- The high utilization of existing UNC Health System surgical facilities in Wake County and the need for additional capacity to meet the additional surgical cases expected from new and expanded physician relationships and services, such as pediatric surgical specialties.

- The need for additional surgical capacity due to the increase in patient acuity and longer surgical case times, and the planned relocation of three operating rooms to the new Holly Springs hospital.

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

- The applicant provides data and information to support their assertions regarding the trends toward increasing demand for surgical services and the high utilization of existing hospital-based operating rooms in the Wake County service area.
- The applicant provides information and data to support their assertions regarding the projected growth in surgical case volumes at UNC Health Care facilities in the Wake County service area.

Projected Utilization

In Section Q, 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		
	Adjusted Operating Room Planning Inventory	Proposed Adjusted Planning Inventory
UNC REX Hospital Holly Springs	3	3
Rex Surgery Center of Wakefield	2	2
Rex Surgery Center of Cary	4	4
UNC REX Hospital	24	25 [^]
Raleigh Orthopaedic Surgery Center	3	3
Raleigh Orthopaedic Surgery Center-West Cary	1	1
Orthopaedic Surgery Center of Garner	0	2 [^]
Total	37	40

Source: Section Q, Form C Methodology, page 1. Excludes C-section operating rooms.

[^]Includes the one additional operating room proposed for UNC REX Hospital and two operating rooms for Orthopaedic Surgery Center of Garner proposed in a separate application in this review.

In Section Q, the applicant provides utilization projections for UNC REX Hospital, 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

Operating Rooms	Year 1 SFY2023	Year 2 SFY2024	Year 3 SFY2025
Shared Operating Rooms	25	25	25
Inpatient Surgical Cases	8,667	8,579	8,692
Outpatient Surgical Case	11,695	11,584	11,842
Total Surgical Cases	20,362	20,164	20,535
Inpatient Surgical Case Times	186.3	186.3	186.3
Outpatient Surgical Case Times	135.0	135.0	135.0
Inpatient Surgical Hours	26,912	26,639	26,990
Outpatient Surgical Hours	26,313	26,064	26,645
Total Surgical Hours	53,225	52,703	53,635
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	27.3	27.0	27.5

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 1.3 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 2.2 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 SFY2022 (See Section Q, pages 7-8). The applicant provides the projected utilization of the operating rooms at UNC REX Hospital after the projected shifts in surgical cases, as summarized in the following table.

Projected UNC REX Hospital Surgical Utilization after Shifts

	FY2021	FY2022	PY 1 FY2023	PY 2 FY2024	PY 3 FY2025
Inpatient Surgical Cases	8,985	9,103	9,224	9,345	9,468
Outpatient Surgical Cases	12,155	12,425	12,702	12,985	13,274
Inpatient Cases Shifted to UNC REX Holly Springs Hospital		-359	-556	-766	-776
Outpatient Cases Shifted to UNC REX Holly Springs Hospital		-630	-1,007	-1,400	-1,432
Inpatient Cases after Shifts	8,985	8,744	8,667	8,579	8,692
Outpatient Cases after Shifts	12,155	11,795	11,695	11,584	11,842

Source: Section Q, page 8.

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

Operating Rooms	Year 1 SFY2023	Year 2 SFY2024	Year 3 SFY2025
Shared Operating Rooms	3	3	3
Inpatient Surgical Cases	618	851	862
Outpatient Surgical Case	1,119	1,556	1,591
Total Surgical Cases	1,737	2,407	2,453
Inpatient Surgical Case Times	186.3	186.3	186.3
Outpatient Surgical Case Times	135.0	135.0	135.0
Inpatient Surgical Hours	1,919	2,642	2,677
Outpatient Surgical Hours	2,518	3,501	3,579
Total Surgical Hours	4,437	6,143	6,256
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	2.3	3.2	3.2

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 is based on the surgical utilization projections in the previously approved CON application (Project I.D. #J-8669-11), and annual surgical case growth rates of 1.3 and 2.2 percent for inpatient and outpatient surgical cases, respectively. Also, the applicant states the utilization projections are further supported by the fact 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 historical growth rates in surgical services utilization UNC REX Hospital, and the historical and projected growth in the proposed 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.

Orthopaedic Surgery Center of Garner

In a separate application in this review, the applicant proposes to develop a new ambulatory surgery center, Orthopaedic Surgery Center of Garner, with two operating rooms. In Section Q, the applicant provides projected utilization of the two operating rooms at the proposed ambulatory surgery center in Garner during the first three full fiscal operating years of the proposed project, as illustrated in the following table.

Projected Orthopaedic Surgery Center of Garner Utilization

Operating Rooms	Year 1* SFY2023	Year 2 SFY2024	Year 3 SFY2025
Dedicated Ambulatory ORs	0	2	2
Outpatient Surgical Cases	0	1,634	1,830
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	0	1,940	2,171
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	NA	1.5	1.7

Source: Section Q, Form C.

*The applicant projects the first year of operation for the proposed Garner ASC will be SFY2024.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized as follows:

Step 1-The applicant identified the ROSC surgeons projected to shift surgical cases to the proposed Garner ASC, and calculated the growth rates in surgical case volumes for those surgeons from 2018 to 2020. See table on page 18 of Section Q.

Step 2-The applicant projected operating room and procedure room cases for those surgeons from SFY2024 to SFY2026 based on the assumption that surgical case volumes would increase by 1.8%, annually, for SFY2020 through SFY2026. See table on page 19 of Section Q.

Step 3-The applicant projected the percentage operating room and procedure room cases for those surgeons from SFY2024 to SFY2026. The applicant states, *“The percent of operating room cases and procedure room procedures projected to shift is based on several factors including the projected amount of time the surgeons are expected to practice at the proposed ASF, available block time, patient choice, and ROC’s efforts to ensure that operating room utilization is distributed evenly across its existing facility (Raleigh Orthopaedic Surgery Center), approved 20 facility (Raleigh Orthopaedic Surgery Center-West Cary), and proposed facility (Orthopaedic Surgery Center of Garner).”* See table on page 20 of Section Q.

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

- The applicant’s utilization projections for Orthopaedic Surgery Center of Garner are supported by the applicant’s historical volume of surgical cases for the surgeons projected to practice at the proposed ASC.
- The applicant’s utilization projections are supported by letters from ROSC surgeons who have expressed support for the proposed project and their intention to practice at the proposed Garner ASC. 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 SFY2023	Year 2 SFY2024	Year 3 SFY2025
Dedicated Ambulatory ORs	3	3	3
Outpatient Surgical Cases	3,189	3,002	2,909
Surgical Case Times	81.6	81.6	81.6
Totals Surgical Hours	4,338	4,083	3,956
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	3.1	3.0

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized as follows:

Step 1-The applicant calculated the growth rates in surgical case volumes for ROSC from 2018 to 2020. See table on page 17 of Section Q.

Step 2-The applicant projected operating room and procedure room cases for ROSC from SFY2021 to SFY2026 based on the assumption that surgical case volumes would increase by 1.8%, annually. See table on page 17 of Section Q.

Step 3-The applicant projected the operating room and procedure room cases for those surgeons that will shift surgical cases to the proposed ASC in Garner from SFY2024 to SFY2026. See discussion above and pages 18-21 of Section Q in the application.

Step 4-Based on the utilization projections included in the application for ROSC-West Cary (Project I.D. # J-11161-16), the applicant projects 1,136 surgical cases per year will shift from ROSC to ROSC-West Cary through the first three full fiscal years of operation of the proposed project. See discussion below and pages 21-22 of Section Q in the application.

Step 5-Based on the applicant’s projected shifts in surgical cases volumes from ROSC to Orthopaedic Surgery Center of Garner and ROSC-West Cary, the applicant projects the surgical case volumes that will remain at ROSC through the first three full fiscal years of operation of the proposed project. See the table on page 22 of Section Q in the application.

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 SFY2021 through the third year of the proposed project (SFY2025) are supported by the applicant’s historical 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-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

Operating Rooms	Year 1 SFY2023	Year 2 SFY2024	Year 3 SFY2025
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,136	1,136	1,136
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	1,348	1,348	1,348
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	1.0	1.0	1.0

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 ambulatory surgical operating room at ROSC-West Cary is based on the utilization projections in the previously approved CON application (Project I.D. #J-11161-16), and the assumption that the Year 3 surgical case volume (1,136 surgical cases) will remain constant through the first three operating years of the proposed project.

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.
- 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

Operating Rooms	Year 1 SFY2023	Year 2 SFY2024	Year 3 SFY2025
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	2,939	2,968	2,998
Surgical Case Times	54.0	54.0	54.0
Totals Surgical Hours	2,645	2,672	2,698
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	2.0	2.0	2.1

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 two dedicated ambulatory surgical operating rooms is based on the assumption that surgical case volumes will increase by one percent per year from the facility’s SFY2020 utilization, which the applicant states is “*equivalent to one-quarter of the UNC Health system outpatient surgery CAGR from SFY 2018 to 2020.*”

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 SFY2021 through the third year of the proposed project (SFY2025) are supported by the applicant’s historical (SFY2020) 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

Operating Rooms	Year 1 SFY2023	Year 2 SFY2024	Year 3 SFY2025
Dedicated Ambulatory ORs	4	4	4
Outpatient Surgical Cases	4,369	4,413	4,458
Surgical Case Times	62.7	62.7	62.7
Totals Surgical Hours	4,566	4,612	4,658
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	3.5	3.5	3.6

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 decline by 3.2 percent from SFY2020, and then increase by one percent per year through the first three full fiscal years of operation of the proposed project. The applicant states, “*REX Surgery Center of Cary’s operating room utilization is projected to decline by 3.2 percent from SFY 2020 to 2021, equivalent to the SFY 2018 to 2020 CAGR, and then increase 1.0 percent annually from SFY 2021 to 2026, driven by physician recruitment, population growth, and the overall growth in UNC Health system volume and resulting need for capacity for surgery cases, which is equivalent to one-quarter of the UNC Health system outpatient surgery CAGR from SFY 2018 to 2020.*”

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 SFY2021 through the third year of the proposed project (SFY2025) are supported by the applicant’s historical (SFY2020) volume of surgical cases, projected population growth in the service area, and historical growth of UNC Health Care’s outpatient surgical services utilization.
- 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 FY2019 based on data reported to DHSR on the License Renewal Application forms for the years 2013 to 2020.

UNC REX Health Care System Surgical Cases, FY2012-FY2019

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	CAGR FY2012- FY2019
Total Surgical Cases*	28,271	28,781	28,956	29,084	29,135	30,327	30,427	32,504	2.01%
Percent Change		1.8%	0.6%	0.4%	0.2%	4.1%	0.3%	6.8%	

Source: License Renewal Application forms, 2013-2020.

*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 SFY2020 to SFY2026 based on data in Form C, Section Q of the application.

Projected UNC REX Health Care System Surgical Cases, SFY2020-SFY2025

	2020	2021	2022	PY 1 2023	PY 2 2024	PY 3 2025	CAGR 2020- 2025
UNC REX Hospital	18,996	21,140	20,540	20,362	20,164	20,535	
REX Holly Springs Hospital			1,099	1,737	2,407	2,453	
Rex Surgery-Wakefield	2,462	2,881	2,910	2,939	2,968	2,998	
Rex Surgery-Cary	3,830	4,283	4,326	4,369	4,413	4,458	
Raleigh Orthopedic SC	3,982	3,365	3,158	3,189	3,002	2,909	
Raleigh Orthopedic SC-West	811	1,092	1,136	1,136	1,136	1,136	
Orthopaedic Surgery-Garner					1,634	1,830	
Total Surgical Cases	30,081	32,761	33,169	33,732	35,724	36,319	3.84%
Percent Change		8.91%	1.25%	1.70%	5.91%	1.67%	

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 2.01 percent per year from FY2012 to FY2019. The applicant’s utilization projections for all existing, approved and proposed UNC REX surgical facilities in Wake County for the period from SFY2020 through SFY2025 are based on the assumption that surgical case volumes will increase at an average rate of 3.84 percent per year over the five-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 to Medically Underserved Groups

In Section C.8, page 38, the applicant states it will not discriminate with regard to patient care access on the basis of income, ability to pay, or any other factor which might restrict access to services. On page 43, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Estimated Percentages of Patients by Group	
Low income persons	NA
Racial and ethnic minorities	26.5%
Women	62.3%
Persons with disabilities	NA
The elderly	39.2%
Medicare beneficiaries	42.0%
Medicaid recipients	3.9%

NA-Applicant states it does not maintain data on these categories.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke University Health System, Inc. [**Duke Garner ASC**] proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

Patient Origin

On page 51, the 2020 SMFP states, “*An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.*” In Figure 6.1, page 57 of the 2020 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 SFY2026	
	Patients	% of Total
Wake	700	51.1%
Johnston	66	4.9%
Durham	59	4.3%
Franklin	49	3.5%
Cumberland	42	3.1%
Nash	26	1.9%
Harnett	33	2.4%
Orange	16	1.1%
Granville	13	0.9%
Vance	14	1.0%
Chatham	6	0.4%
Pitt	23	1.7%
Other States	50	3.6%
Other NC Counties	299	21.8%
Total	1,369	100.0%

Source: Section C.3, page 18.

In Section C.3, page 18, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the FY2020 ambulatory surgical patient origin for surgical services at Duke Raleigh Hospital, from which the applicant projects patients will shift following development of the proposed Garner ASC.

Analysis of Need

In Section C.4, pages 20-45, 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 utilization of Duke Raleigh Hospital’s surgical services.
- 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 population growth and continued economic development in the Garner area, and the need for improved geographic access to outpatient surgical services in that area.
- The need to add ambulatory surgery services to the growing array of DUHS primary care and specialty care services in an ambulatory medical setting planned at Duke Health Garner.
- The historical and projected growth and aging of the Wake County service area population.

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) and other sources.

Projected Utilization

In Section Q, Form C, Utilization, the applicant provides projected utilization for the one operating room and two procedure rooms at the Duke Garner ASC, as illustrated in the following table.

Projected Duke Garner ASC Utilization

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	541	888	1,369
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	642	1,054	1,625
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	0.5	0.8	1.2
Procedure Rooms			
# of Procedure Rooms	2	2	2
Total Procedures	108	178	274

Source: Section Q, Form C.

In a separate application in this review, the applicant proposes to add two operating rooms to Duke Green Level ASC, for a total of three operating rooms and five procedure rooms upon project completion. The applicant did not include a Form C, Utilization, for Duke Green Level ASC in the application. However, the applicant includes a projection of surgical cases for Duke Green Level ASC in Section Q, page 134 of the application. Those utilization projections are summarized in the table below based on the surgical case times for Group 6 facilities in the 2020 SMFP.

Projected Duke Green Level ASC Utilization

Operating Rooms	Year 1* SFY2024	Year 2 SFY2025	Year 3 SFY2026
Dedicated Ambulatory ORs	0	3	3
Outpatient Surgical Cases	0	1,733	2,302
Surgical Case Times	71.2	71.2	71.2
Totals Surgical Hours	0	2,057	2,731
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	NA	1.6	2.1

Source: Table in Section Q, page 134 of the application. Surgical case times and standard hours per OR per year are from Chapter 6 of the 2020 SMFP.

*The applicant states the first three Project Years for the Duke Green Level ASC will be FY2025-FY2027.

Duke Raleigh Hospital (DRAH) currently has 15 shared operating rooms. The applicant did not include a Form C, Utilization, for Duke Raleigh Hospital in the application. However, the applicant includes a projection of surgical cases for Duke Raleigh Hospital in Section Q, page 135 of the application. Those utilization projections are summarized in the table below based on the final surgical case times and standard hours per operating room per year in Chapter 6 of the 2020 SMFP.

Projected Duke Raleigh Hospital Utilization

Operating Rooms	Year 1 SFY2024	Year 2 SFY2025	Year 3 SFY2026
Shared Operating Rooms	15	15	15
Inpatient Surgical Cases	4,487	4,711	4,947
Outpatient Surgical Case	7,196	6,184	5,767
Total Surgical Cases	11,683	10,895	10,714
Inpatient Surgical Case Times	215	215	215
Outpatient Surgical Case Times	123.2	123.2	123.2
Inpatient Surgical Hours	16,078	16,881	17,727
Outpatient Surgical Hours	14,776	12,698	11,842
Total Surgical Hours	30,854	29,579	29,568
Group Assignment	3	3	3
Standard Hours per OR per Year	1,755	1,755	1,755
Total Surgical Hours/Standard Hours Per OR per Year	17.6	16.9	16.8

Source: Table in Section Q, page 135 application. Final surgical case times and standard hours per OR per year are from Chapter 6 of the 2020 SMFP.

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 Duke Raleigh Hospital and Duke University Hospital from FY2018 to FY2020. The applicant annualized FY2020 utilization based on data from July 2019 to February 2020.

Step 2: Based on the historical surgical case volumes from FY2018 to FY2020, growth and aging of the Wake County population, statistical data regarding surgical service utilization, 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 121 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 122 of the application.

Step 4: The applicant identified the percentage of 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 123 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 124.

Step 6: The applicant identifies historical (FY2020 annualized) outpatient surgical cases by facility and by specialty for DRAH and DUH, as summarized in the tables on page 125.

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 126-127.

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 Duke Garner ASC. See tables on pages 127-128.

Step 9: The applicant projects that the ASC-appropriate outpatient surgical cases that will shift to the proposed Duke Garner 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 Duke Garner 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 131 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 Duke Garner ASC from DRAH and DUH, the applicant projects the total surgical cases by specialty at the Duke Garner ASC in each of the first three operating years, as shown in the tables on pages 132-133 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), the Duke Green Level ASC, and the proposed Duke Garner ASC, through the first three operating years of the proposed project, as shown in the tables on pages 134-135 of the application.

Step 11: Based projected surgical case volumes for the DRAH, the Green Level ASC, and the Duke Garner ASC, the applicant projects the total operating room need for the facilities in the third operating year of the proposed project (SFY2026), based on the operating room need methodology in the 2020 SMFP, as shown in the table on page 136 of the application.

Step 12: Based on the applicant’s experience, and a review of ASC utilization data for Wake County providers, the applicant projects procedure room procedures will be equivalent to 20 percent of total operating room cases through the first three operating years of the proposed project, as shown in the table on pages 137 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 Duke Garner 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 Garner 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 FY2018 to FY2020 (annualized) based on data reported by the applicant in Section Q of the application.

Duke University Health Care System-Wake County Surgical Cases, FY2018-FY2020				
	FY2018	FY2019	FY2020**	CAGR FY2018-FY2020
Total Surgical Cases*	14,744	15,180	15,383	2.14%
Percent Change		2.96%	1.34%	

Source: Section Q, page 119 of the application.

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

**Applicant states FY2020 surgical volumes have been annualized based on July-February data.

The following table shows the applicant’s total projected surgical cases at all existing, approved and proposed DUHS surgical facilities in Wake County from FY2021 to FY2026 based on data in Section Q of the application.

Projected Duke University Health System-Wake County Surgical Cases, FY2021-FY2026

	FY2021	FY2022	FY2023	PY 1 FY2024	PY 2 FY2025	PY 3 FY2026	CAGR FY2021- FY2026
Duke Raleigh Hospital	15,700	16,028	16,367	15,726	14,265	13,810	
Duke Green Level ASC					1,733	2,302	
Duke Garner ASC				541	888	1,369	
Total Surgical Cases	15,700	16,028	16,367	15,726	15,998	16,112	0.52%
Percent Change		2.09%	2.12%	-3.92%	1.73%	0.71%	

Source: Section Q, pages 122, 134 and 135 of the application.

As shown in the tables above, the historical growth rates for surgical cases at DUHS surgical facilities in Wake County averaged 2.14 percent per year from FY2018 to FY2020. The applicant’s utilization projections for all existing, approved and proposed DUHS surgical facilities in Wake County for the period from FY2021 through FY2026 are based on the assumption that surgical case volumes will increase at an average rate of 0.52 percent per year over the five-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 to Medically Underserved Groups

In Section C.8, page 50, the applicant states all residents, including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups will have access to the proposed services. In Section L.3, page 102, the applicant projects the following payor mix during the third full fiscal year (FY2026) 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%	1.6%
Medicare *	44.0%	45.1%
Medicaid *	5.3%	2.7%
Insurance *	42.9%	43.2%
Other (Workers Comp, VA, TriCare)	5.8%	7.4%
Total	100.0%	100.0%

* Including any managed care plans

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke University Health System, Inc. [**Duke Green Level ASC**] proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

Patient Origin

On page 51, the 2020 SMFP states, “*An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.*” In Figure 6.1, page 57 of the 2020 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 SFY2027	
	Patients	% of Total
Wake	1,748	51.1%
Johnston	166	4.9%
Durham	148	4.3%
Franklin	121	3.5%
Cumberland	104	3.1%
Nash	63	1.9%
Harnett	82	2.4%
Orange	39	1.1%
Granville	32	0.9%
Vance	35	1.0%
Chatham	15	0.4%
Pitt	58	1.7%
Other States	123	3.6%
Other NC Counties	709	21.8%
Total	3,417	100.0%

Source: Section C.3, page 18.

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 because they are based on the FY2020 ambulatory surgical patient origin for surgical services at Duke Raleigh Hospital, from which the applicant projects patients will shift following development of the Duke Green Level ASC.

Analysis of Need

In Section C.4, pages 21-41, 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 utilization of Duke Raleigh Hospital’s surgical services.
- 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 settings over inpatient or hospital-based facilities.
- Projected growth 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 continuum of care along with a growing array of DUHS primary care and specialty care services in the proposed services area.
- The historical and projected growth and aging of the Wake County service area population.

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 DUHS surgical facilities and 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) and other sources.

Projected Utilization

In Section Q, Form C, Utilization, the applicant provides projected utilization for the three operating rooms and five procedure rooms at the Duke Green Level ASC through the first three full fiscal years, as illustrated in the following table.

Projected Duke Green Level ASC Utilization

Operating Rooms	Interim* SFY2024	Year 1 SFY2025	Year 2 SFY2026	Year 3 SFY2027
Dedicated Ambulatory ORs	3	3	3	3
Outpatient Surgical Cases	361	1,733	2,301	3,417
Surgical Case Times	71.2	71.2	71.2	71.2
Total Surgical Hours	428	2,057	2,731	4,055
Group Assignment	6	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	0.3	1.6	2.1	3.1
Procedure Rooms				
# of Procedure Rooms	5	5	5	5
Total Procedures	286	687	1,007	1,517

Source: Section Q, Form C Utilization.

*The applicant states the services will be offered January 31, 2024 and the first three full fiscal years of operation for the Duke Green Level ASC will be SFY2025-SFY2027.

In a separate application in this review, the applicant proposes to develop new ASC in Garner with one operating room and two procedure rooms upon project completion. The applicant did not include a Form C, Utilization, for Duke Garner ASC in the application. However, the applicant includes a projection of surgical cases for Duke Green Level ASC in Section Q, page 134 of the application. Those utilization projections are summarized in the table below based on the surgical case times for Group 6 facilities in the 2020 SMFP.

Projected Duke Garner ASC Utilization

Operating Rooms	Year 1 SFY2025	Year 2 SFY2026	Year 3 SFY2027
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	888	1,369	1,369
Surgical Case Times	71.2	71.2	71.2
Total Surgical Hours	1,054	1,625	1,625
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	0.8	1.2	1.2

Source: Table in Section Q, page 134 of the application. Surgical case times and standard hours per OR per year are from Chapter 6 of the 2020 SMFP.

Duke Raleigh Hospital (DRAH) currently has 15 shared operating rooms. The applicant did not include a Form C, Utilization, for Duke Raleigh Hospital in the application. However, the applicant includes a projection of surgical cases for Duke Raleigh Hospital in Section Q, page 135 of the application. Those utilization projections are summarized in the table below based on the final surgical case times and standard hours per operating room per year in Chapter 6 of the 2020 SMFP.

Projected Duke Raleigh Hospital Utilization

Operating Rooms	Year 1 SFY2025	Year 2 SFY2026	Year 3 SFY2027
Shared Operating Rooms	15	15	15
Inpatient Surgical Cases	4,711	4,947	5,194
Outpatient Surgical Case	6,184	5,767	5,314
Total Surgical Cases	10,895	10,714	10,508
Inpatient Surgical Case Times	215	215	215
Outpatient Surgical Case Times	123.2	123.2	123.2
Inpatient Surgical Hours	16,881	17,727	18,612
Outpatient Surgical Hours	12,698	11,842	10,911
Total Surgical Hours	29,579	29,568	29,523
Group Assignment	3	3	3
Standard Hours per OR per Year	1,755	1,755	1,755
Total Surgical Hours/Standard Hours Per OR per Year	16.9	16.8	16.8

Source: Table in Section Q, page 135 application. Final surgical case times and standard hours per OR per year are from Chapter 6 of the 2020 SMFP.

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 Duke Raleigh Hospital and Duke University Hospital from FY2018 to FY2020. The applicant annualized FY2020 utilization based on data from July 2019 to February 2020.

Step 2: Based on the historical surgical case volumes from FY2018 to FY2020, growth and aging of the Wake County population, statistical data regarding surgical service utilization, 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 120 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 121 of the application.

Step 4: The applicant identified the percentage of 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 122 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 123.

Step 6: The applicant identifies historical (FY2020 annualized) outpatient surgical cases by facility and by specialty for DRAH and DUH, as summarized in the tables on page 124.

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 page 126.

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 Duke Green Level ASC. See tables on page 127.

Step 9: The applicant projects that the ASC-appropriate outpatient surgical cases that will shift to the proposed Duke 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 Duke 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 131 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 Duke Green Level ASC from DRAH and DUH, the applicant projects the total surgical cases by specialty at the Duke Green Level ASC in each of the first three operating years, as shown in the tables on pages 132-133 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), the Duke Green Level ASC, and the proposed Duke Garner ASC, through the first three operating years of the proposed project, as shown in the tables on pages 134-135 of the application.

Step 11: Based projected surgical case volumes for the DRAH, the Green Level ASC, and the proposed Duke Garner ASC, the applicant projects the total operating room need for the facilities in the third operating year of the proposed project (SFY2027), based on the operating

room need methodology in the 2020 SMFP, as shown in the table on page 136 of the application.

On page 137, the applicant states projected procedure room volumes are consistent with the original projections in Project J-11557-18, and that DUHS has adjusted the volumes to reflect the new anticipated service date for the facility, as shown in the table on page 137 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 Duke 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 FY2018 to FY2020 (annualized) based on data reported by the applicant in Section Q of the application.

Duke University Health Care System-Wake County Surgical Cases, FY2012-FY2018				
	FY2018	FY2019	FY2020**	CAGR FY2018-FY2020
Total Surgical Cases*	14,744	15,180	15,383	2.14%
Percent Change		2.96%	1.34%	

Source: Section Q, pages 118-119 of the application.

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

**Applicant states FY2020 surgical volumes have been annualized based on July-February data.

The following table shows the applicant’s total projected surgical cases at all existing, approved and proposed DUHS surgical facilities in Wake County from FY2021 to FY2027 based on data in Section Q of the application.

Projected Duke University Health System-Wake County Surgical Cases, FY2021-FY2027

	FY2021	FY2022	FY2023	FY2024	PY 1 FY2025	PY 2 FY2026	PY 3 FY2027	CAGR FY2021- FY2026
Duke Raleigh Hospital	15,700	16,028	16,367	15,726	14,265	13,810	13,325	
Duke Green Level ASC					1,733	2,302	3,417	
Duke Garner ASC				541	888	1,369	1,369	
Total Surgical Cases	15,700	16,028	16,367	15,726	15,998	16,112	16,742	1.08%
Percent Change		2.09%	2.12%	-3.92%	1.73%	0.71%	3.91%	

Source: Section Q, pages 121, 134 and 135 of the application.

As shown in the tables above, the historical growth rates for surgical cases at DUHS surgical facilities in Wake County averaged 2.14 percent per year from FY2018 to FY2020. The applicant’s utilization projections for all existing, approved and proposed DUHS surgical facilities in Wake County for the period from FY2021 through FY2027 are based on the assumption that surgical case volumes will increase at an average rate of 1.08 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 to Medically Underserved Groups

In Section C.8, page 47, the applicant states all residents, including low income person, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups will have access to the proposed services. In Section L.3, page 101, the applicant projects the following payor mix during the third full fiscal year (FY2027) of operation following completion of the project, as illustrated in the following table.

Payor Source	Operating Rooms	Procedure Rooms
Self-Pay/Charity Care	1.6%	1.9%
Medicare *	47.2%	33.6%
Medicaid *	3.5%	6.3%
Insurance *	41.6	47.6%
Other (Workers Comp, VA, TriCare)	6.1%	10.6%
Total	100.0%	100.0%

* Including any managed care plans

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

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 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports 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, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicants do not propose to reduce a service, eliminate a service or 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

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed Cary Hospital proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

In Section E.2, pages 60-61, 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:

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 the reasons stated above.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section E.2, pages 71-76, 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:

The alternatives considered were:

- Maintain the status quo
- Develop more than one operating room
- Develop new operating rooms at another location
- 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 need identified by the applicant for dental/oral surgery and other surgical services.
- Developing more than one operating room is less effective because the applicant determined that one operating room and three procedure rooms would be adequate to efficiently meet the identified need.
- Developing operating rooms at another location is less effective because the identified site is located in an area without an ASF, has good road access and is appropriately zoned.

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 reasons stated above.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section E.2, pages 70-72, 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:

The alternatives considered were:

- Maintain the status quo
- Develop the ASC in a different location
- Develop a different number of operating rooms
- 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 need identified by the applicant for additional surgical capacity for ROC surgeons, particularly in the ASF setting.
- Developing the ASC in a different location is less effective because the applicant determined that the Garner service is rapidly growing and developing along the I-540 corridor, and currently lacks access to surgical services in an ambulatory setting.
- Developing a different number of operating rooms is less effective because the development of two operating rooms can best meet the identified need in an efficient manner.

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 reasons stated above.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

UNC REX Hospital proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

In Section E.2, pages 53-54, 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

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, the addition of surgical specialties and affiliated surgeons, and the expected impact of the relocation of three operating rooms to UNC REX Holly Springs Hospital.
- Developing more than one operating room at UNC REX Hospital is less effective because the applicant determined that one operating room could be developed with minimal capital expenditure, and would enable the applicant to pursue development of Orthopaedic Surgery Center of Garner.
- Developing operating rooms at another location is less effective because UNC REX Hospital is the only hospital surgical facility, and there is a need for additional 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 the reasons stated above.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section E.2, pages 61-65, 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 additional operating rooms at Duke Raleigh Hospital
- Develop three operating rooms in just one rather than two locations (Garner and Green Level)
- Develop the operating rooms at a different location
- Develop a different complement of operating rooms at Duke Garner ASC

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 Duke Raleigh Hospital, and would not enable the applicant to offer a lower cost, ambulatory surgical service alternative to meet the growing need for surgical services.
- Developing additional operating rooms at Duke Raleigh Hospital is less effective because the applicant determined patients would benefit from expanded capacity in ASC settings due to lower costs and improved geographic access.
- Developing three operating rooms at just one location is less effective because both identified service areas that would benefit from expanded access to ASC services.
- Developing three operating rooms at a different location is less effective because the applicant determined that no other Wake County locations better meets the identified needs for the proposed service area than the Garner and Green Level locations.
- Developing a different complement of operating rooms at Duke Garner ASC is less effective because the applicant determined that due to differences in the service area populations, developing one operating in Garner and three at the Green Level site was the better alternative.

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 reasons stated above.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke Green Level ASC proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

In Section E.2, pages 59-63, 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 additional operating rooms at Duke Raleigh Hospital
- Develop three operating rooms in just one rather than two locations (Garner and Green Level)
- Develop the operating rooms at a different location
- Develop a different complement of operating rooms at Duke Green Level ASC

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 Duke Raleigh Hospital, and would not enable the applicant to offer a lower cost, ambulatory surgical service alternative to meet the growing need for surgical services.
- Developing additional operating rooms at Duke Raleigh Hospital is less effective because the applicant determined patients would benefit from expanded capacity in ASC settings due to lower costs and improved geographic access.
- Developing three operating rooms at just one location is less effective because both identified service areas would benefit from expanded access to ASC services.
- Developing three operating rooms at a different location is less effective because the applicant determined that no other Wake County locations better meets the identified needs for the proposed service area than the Garner and Green Level locations.
- Developing a different complement of operating rooms at Duke Green Level ASC is less effective because the applicant determined that due to differences in the service area populations, developing one operating room in Garner and two at the Green Level site was the better alternative.

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 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.

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All Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed Cary Hospital proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

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
Total	\$2,265,178

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

In Section F.3, page 65, 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 63, the applicant states the capital cost will be funded as shown in the table below.

Type	WakeMed
Loans	\$
Accumulated reserves or OE *	\$2,265,178
Bonds	\$
Other (Specify)	\$
Total Financing	\$2,265,178

* OE = Owner's Equity

Exhibit F.2 contains a 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 \$578 million in cash and short-term investments as of September 30, 2019. The applicant adequately demonstrates the availability of sufficient funds for the capital needs 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.

	Project Year 1 FFY2023	Project Year 2 FFY2024	Project Year 3 FFY2025
Total Surgical Cases	8,394	8,594	8,802
Total Gross Revenues (Charges)	\$508,447,473	\$531,443,750	\$555,640,545
Total Net Revenue	\$119,131,840	\$124,441,194	\$130,026,137
Average Net Revenue per Case	\$14,192	\$14,480	\$14,772
Total Operating Expenses (Costs)	\$54,385,293	\$56,822,077	\$59,384,364
Average Operating Expense per Case	\$6,479	\$6,612	\$6,747
Net Income	\$64,746,547	\$67,619,117	\$70,641,773

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- 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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

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	\$850,000
Architect/Engineering Fees	\$34,000
Medical Equipment	\$889,629
Nonmedical Equipment	\$11,768
Furniture	\$229,087
Consultant Fees	\$100,00
Other	\$227,493
Total	\$2,341,977

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

In Section F.3, pages 79-80, the applicant projects start-up costs will be \$137,582 and initial operating expenses will be \$534,807 for a total working capital of \$672,389. In Section Q, 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 78, the applicant states the capital cost will be funded as shown in the table below.

Type	Valleygate Surgery Center
Loans	\$ 2,341,977
Accumulated reserves or OE *	\$
Bonds	\$
Total Financing	\$2,341,977

* OE = Owner's Equity

In Section F.3, page 80, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$672,389
(b)	Accumulated Reserves	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$672,389

Exhibit F.2 contains a September 14, 2020 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. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs 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 the second and third full fiscal years of operation, as shown in the table below.

	Project Year 1 CY2023	Project Year 2 CY2024	Project Year 3 CY2025
Total Operating Room Cases	677	740	759
Total Gross OR Revenues (Charges)	\$4,304,313	\$4,616,972	\$4,776,856
Total Net OR Revenue	\$1,127,568	\$1,219,108	\$1,263,889
Average Net Revenue per OR Case	\$1,666	\$1,647	\$1,665
Total Procedure Room (PR) Cases	1,141	1,584	2,332
Total Gross PR Revenues (Charges)	\$7,252,196	\$9,884,285	\$14,687,263
Total Net PR Revenue	\$1,899,802	\$2,609,937	\$3,886,044
Average Net Revenue per Procedure	\$1,665	\$1,648	\$1,666
Total Gross Revenue	\$11,556,509	\$14,501,257	\$19,464,119
Total Net Revenue	\$3,027,370	\$3,829,045	\$5,149,933
Total Operating Expenses (Costs)	\$3,079,586	\$3,711,942	\$4,346,150
Net Income	(\$52,216)	\$117,103	\$803,783

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- 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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

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	\$10,240,635
Architect/Engineering Fees	\$1,449,050
Medical Equipment	\$2,560,169
Nonmedical Equipment	\$378,900
Furniture	\$307,216
Consultant Fees	\$363,110
Other	\$1,597,854
Tenant Upfit Allowance	(\$2,850, 000)
Total	\$14,056,934

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

In Section F.3, page 75, the applicant projects start-up costs will be \$545,525 and initial operating expenses will be \$1,636,575 for a total working capital of \$2,182,100. In Section Q,

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 73, the applicant states the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	
Type	Orthopaedic Surgery Center of Garner
Loans	\$ 14,056,934
Accumulated reserves or OE *	\$
Bonds	\$
Total Financing	\$14,056,934

* OE = Owner's Equity

In Section F.3, page 76, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$2,182,100
(b)	Accumulated Reserves	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$2,182,100

Exhibit F.2 contains an August 31, 2020 letter from a Senior Vice President for First Citizens Bank stating that loans will be made available to the applicant for the capital and working capital costs of the project. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs 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.

	Project Year 1 SFY2024	Project Year 2 SFY2025	Project Year 3 SFY2026
Total Operating Room Cases	1,634	1,830	2,031
Total Gross OR Revenues (Charges)	\$41,398,256	\$47,731,759	\$54,579,395
Total Net OR Revenue	\$8,147,588	\$9,394,085	\$10,741,767
Average Net Revenue per OR Case	\$4,986	\$5,133	\$5,289
Total Procedure Room (PR) Cases	209	239	260
Total Gross PR Revenues (Charges)	\$3,636,518	\$4,192,867	\$3,897,194
Total Net PR Revenue	\$680,511	\$784,622	\$897,185
Average Net Revenue per Procedure	\$3,256	\$3,283	\$3,451
Total Gross Revenue	\$45,034,774	\$51,924,626	\$58,476,589
Total Net Revenue	\$8,828,099	\$10,178,707	\$11,638,952
Total Operating Expenses (Costs)	\$7,370,408	\$8,082,575	\$8,673,441
Net Income	\$1,457,691	\$2,096,132	\$2,965,511

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- 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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

UNC REX Hospital proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

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	\$174,078
Architect/Engineering Fees	\$26,294
Medical Equipment	\$165,716
Consultant Fees	\$1,500
Other	\$40,000
Total	\$407,588

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

In Section F.3, page 58, the applicant states there will be no start-up costs or initial operating expenses because UNC REX Hospital is an existing hospital.

Availability of Funds

In Section F.2, page 56, the applicant states the capital cost will be funded as shown in the table below.

Type	
Loans	\$
Accumulated reserves or OE *	\$407,588
Bonds	\$
Other (Specify)	\$
Total Financing	\$407,588

* OE = Owner's Equity

Exhibit F.2 contains a letter from a 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 \$312 million in cash and cash equivalents as of June 30, 2019. The applicant adequately demonstrates the availability of sufficient funds for the capital needs 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.

	Project Year 1 SFY2023	Project Year 2 SFY2024	Project Year 3 SFY2025
Total Surgical Cases	20,362	20,164	20,535
Total Gross Revenues (Charges)	\$624,062,890	\$636,515,939	\$667,675,625
Total Net Revenue	\$213,190,487	\$217,444,660	\$228,089,339
Average Net Revenue per Case	\$10,470	\$10,784	\$11,107
Total Operating Expenses (Costs)	\$180,196,879	\$183,943,146	\$192,639,806
Average Operating Expense per Case	\$8,850	\$9,122	\$9,381
Net Income	\$32,993,608	\$33,501,514	\$35,449,533

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- 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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

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	\$6,750,000
Architect/Engineering Fees	\$700,000
Medical Equipment	\$3,650,000
Nonmedical Equipment	\$400,000
Furniture	\$150,000
Other	\$50,000
Total	\$11,700,000

In Section F.1, page 66-67, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 68-70, the applicant projects start-up costs will be \$63,628 and initial operating expenses will be \$290,000 for a total working capital of \$353,628. In Section F.3, pages 68-70, 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 the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Duke University Health System
Loans	\$
Accumulated reserves or OE *	\$11,700,000
Bonds	\$
Total Financing	\$11,700,000

* 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.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Accumulated Reserves	\$353,628
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$353,628

Exhibit F.2 contains a September 10, 2020 letter from a Senior Vice President and Chief Financial Officer for DUHS documenting the applicant’s intention to fund the project capital and working capital costs with accumulated reserves of the applicant. Exhibit F.2 also contains the audited financial statements for DUHS which indicate the applicant had \$251 million in cash and cash equivalents as of June 30, 2019. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs 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 the third full fiscal year of operation, as shown in the table below.

	Project Year 1 SFY2024	Project Year 2 SFY2025	Project Year 3 SFY2026
Total Operating Room Cases	541	888	1,369
Total Gross OR Revenues (Charges)	\$4,218,103	\$7,020,878	\$10,790,751
Total Net OR Revenue	\$2,015,295	\$3,355,866	\$5,151,523
Average Net Revenue per OR Case	\$3,725	\$3,779	\$3,763
Total Procedure Room (PR) Cases	108	178	274
Total Gross PR Revenues (Charges)	\$268,165	\$448,971	\$706,008
Total Net PR Revenue	\$125,124	\$208,931	\$327,678
Average Net Revenue per Procedure	\$1,159	\$1,174	\$1,196
Total Gross Revenue	\$4,486,268	\$7,469,849	\$11,496,759
Total Net Revenue	\$2,140,419	\$3,564,797	\$5,479,201
Total Operating Expenses (Costs)	\$2,420,564	\$3,569,764	\$4,797,803
Net Income	(\$280,145)	(\$4,967)	\$681,398

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke Green Level ASC proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

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
Nonmedical Equipment	\$137,500
Furniture	\$75,000
Other	\$50,000
Total	\$6,000,000

In Section F.1, page 64-65, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 66-67, the applicant projects start-up costs will be \$171,657 and initial operating expenses will be \$450,000 for a total working capital of \$621,657. In Section F.3,

pages 66-67, 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 65, the applicant states the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	
Type	Duke University Health System
Loans	\$
Accumulated reserves or OE *	\$6,000,000
Bonds	\$
Total Financing	\$6,000,000

* OE = Owner's Equity

In Section F.3, page 68, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Accumulated Reserves	\$621,657
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$621,657

Exhibit F.2 contains a September 10, 2020 letter from a Senior Vice President and Chief Financial Officer for DUHS documenting the applicant's intention to fund the project capital and working capital costs with accumulated reserves of the applicant. Exhibit F.2 also contains the audited financial statements for DUHS which indicate the applicant had \$251 million in cash and cash equivalents as of June 30, 2019. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs 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.

	Project Year 1 SFY2025	Project Year 2 SFY2026	Project Year 3 SFY2027
Total Operating Room Cases	1,733	2,301	3,417
Total Gross OR Revenues (Charges)	\$14,736,542	\$20,293,786	\$30,729,889
Total Net OR Revenue	\$7,027,975	\$9,661,833	\$14,614,676
Average Net Revenue per OR Case	\$4,055	\$4,199	\$4,277
Total Procedure Room (PR) Cases	687	1,007	1,517
Total Gross PR Revenues (Charges)	\$1,746,036	\$2,607,486	\$4,008,658
Total Net PR Revenue	\$829,718	\$1,227,517	\$1,867,034
Average Net Revenue per Procedure	\$1,208	\$1,219	\$1,231
Total Gross Revenue	\$16,482,578	\$22,901,272	\$34,738,547
Total Net Revenue	\$7,857,693	\$10,889,350	\$16,481,710
Total Operating Expenses (Costs)	\$6,710,168	\$9,146,326	\$12,274,780
Net Income	\$1,147,525	\$1,743,024	\$4,206,930

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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:

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- 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.

- (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 51, the 2020 SMFP states, “An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 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 67-68 and 80 of the 2020 SMFP.

**Wake County Operating Room Inventory and Cases
 As Reported in the 2020 SMFP and on the 2019 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
Duke Health Green Level ASC	0	0	0	0	1	0	0	6
Duke Raleigh Hospital	0	0	15	0	0	3,328	7,474	3
Duke University Health System Total	0	0	15	0	1			
Rex Hospital Holly Springs	0	0	0	0	3	0	0	
Rex Surgery Center of Wakefield	0	2	0	0	0	0	0	5
Rex Surgery Center of Cary	0	4	0	0	0	0	4,585	6
Rex Hospital	3	0	25	-3	-1	8,366	12,019	2
Raleigh Orthopedic Surgery Center	0	4	0	0	-1	0	5,416	6
Raleigh Orthopedic Surgery-West Cary	0	0	0	0	1	0	0	
UNC Health Care System Total	3	10	25	-3	2			
WakeMed Surgery Center-Cary	0	0	0	0	1	0	0	
Capital City Surgery Center	0	8	0	0	0	0	6,712	6
WakeMed (incl. WakeMed North)	8	0	20	-5	-1	7,941	11,189	2
WakeMed Cary Hospital	2	0	9	-2	1	2,973	4,956	4
WakeMed System Total	10	8	29	-7	1			
OrthoNC ASC	0	0	0	0	1			
RAC Surgery Center	0	0	0	0	1			
Holly Springs Surgery Center	0	3	0	0	0	0	1,827	6
Blue Ridge Surgery Center	0	6	0	0	0	0	5,923	5
Raleigh Plastic Surgery Center^	0	1	0	0	0	0	340	6
Triangle Orthopedic Surgery Center*	0	2	0	0	0	0	2,403	6
Surgical Center for Dental Professionals*	0	2	0	0	0	0	0	
2019 SMFP Need Determination	0	0	0	0	2			
Total Wake County ORs	13	32	69	-10	8			

Source: 2020 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 FY2018, there were five existing or approved hospitals and ten existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 32 ambulatory and 69 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-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-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.

Also, pursuant to the need determination for two additional operating rooms for the Wake County service area in the 2019 SMFP, the following applications were approved:

Project ID # J-11747-19, Wake Spine and Specialty Surgery Center, 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.

Project ID # J-11752-19, Triangle Orthopaedics Surgery Center, 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.

Therefore, subsequent to the approvals in the 2018 and 2019 Wake operating room reviews, there are five existing or approved hospitals and 16 existing or approved ambulatory surgery facilities in Wake County. The 2020 SMFP shows a need for three additional operating rooms for the Wake County service area.

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed Cary Hospital proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

In Section G.2, page 71, 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 2020 SMFP for three 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.

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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section G.2, page 86, 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, *“The proposed project will not result in an unnecessary duplication of the existing or approved ORs located in Wake County. Rather, the project will address an unmet need and increase access to quality, affordable, surgical care for residents of Wake County and nearby areas.”*

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 2020 SMFP for three 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.

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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section G.2, page 80, 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, *“As described in Section C.4, OSCG and UNC REX Hospital believe the best alternative to meeting the need for additional operating room capacity in Wake County requires a balanced approach that includes an additional freestanding ASF site of care as well as an additional hospital-based operating room at UNC REX Hospital. Further, and as noted*

previously, there are currently no existing or approved freestanding ASFs in the Garner area and it is an ideal location to provide expanded geographic access to these services.”

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 2020 SMFP for three 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.

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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

UNC REX Hospital proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

In Section G.2, page 63, 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, *“Of note, UNC REX Hospital has generated a need for additional operating rooms in the last four SMFPs and according to 2020 LRAs, UNC REX Hospital provided the highest number of surgical cases of any licensed facility in Wake County in FFY 2019. ... Further, as described in Section C.4, UNC REX Hospital believes the best alternative to meeting the need for additional operating room capacity in Wake County requires a balanced approach that includes an additional hospital-based operating room at UNC REX Hospital as well as an additional freestanding ASF site of care.”*

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 2020 SMFP for three 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.

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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section G.2, page 80, 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, *“The robust growth of surgical cases (both inpatient and outpatient) at DRAH supports the need for DUHS to develop additional surgical capacity in Wake County. The proposed project effectively expands and enhances access to DUHS ambulatory surgical services in Wake County via develop of the proposed 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 2020 SMFP for three 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke Green Level ASC proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

In Section G.2, page 80, 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 robust growth of surgical cases (both inpatient and outpatient) at DRAH obviously supports the need for DUHS to develop additional surgical capacity in Wake County. The proposed project effectively expands and enhances access to DUHS ambulatory surgical services in Wake County via develop 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 2020 SMFP for three 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.

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.

- (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

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

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 operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Sections H.2 and H.3, pages 72-78, the

applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new 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 operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Sections H.2 and H.3, page 90, the applicant describes the methods that will be used to recruit or fill new positions and its proposed training and continuing education programs.

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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new 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 operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Sections H.2 and H.3, pages 82-83, the applicant describes the methods that will be used to recruit or fill new positions and its proposed training and continuing education programs.

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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

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 operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Sections H.2 and H.3, pages 65-66, the applicant describes the methods that will be used to recruit or fill new positions and its proposed training and continuing education programs.

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.

Project ID # J-11966-20/Duke Garner ASC/Develop new 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 H.1 and Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Sections H.2 and H.3, pages 85-86, the applicant describes the methods that will be used to recruit or fill new positions and its proposed training and continuing education programs.

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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to 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 H.1 and Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Sections H.2 and H.3, pages 85-86, the applicant describes the methods that will be used to recruit or fill new positions and its proposed training and continuing education programs.

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.

C
All Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed Cary Hospital proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

Ancillary and Support Services

In Section I.1, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. On page 79, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, pages 80-82, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.2-5 of the application. 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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

Ancillary and Support Services

In Section I.1, pages 92-93, the applicant identifies the necessary ancillary and support services for the proposed services and describes how each ancillary and support service is or will be made available. The applicant provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits I.1-3 of the application. 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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

Ancillary and Support Services

In Section I.1, page 85, the applicant identifies the necessary ancillary and support services for the proposed services. On page 85, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 86, 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 of the application. 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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

UNC REX Hospital proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

Ancillary and Support Services

In Section I.1, page 67, the applicant identifies the necessary ancillary and support services for the proposed services. On page 67, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 67, 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 of the application. 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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

Ancillary and Support Services

In Section I.1, page 87, the applicant identifies the necessary ancillary and support services for the proposed services. On page 87, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit C.4. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 88, the applicant describes its existing and proposed 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke Green Level ASC proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

Ancillary and Support Services

In Section I.1, page 87, the applicant identifies the necessary ancillary and support services for the proposed services. On page 87, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit C.4. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I.2, page 88, the applicant describes its existing and proposed 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.

- (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

The applicants do not 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, the applicants do not 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.

- (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

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

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed Cary Hospital proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

In Section K.1, page 85, the applicant states that the project involves renovation of 880 square feet of existing space. Line drawings are provided in Exhibit K.1.

On page 85, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 86, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section B, 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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section K.1, page 97, the applicant states that the project involves upfit of 10,000 square feet of leased space in a new building to be constructed by a third party. Line drawings are provided in Exhibit K.1.

On pages 100-102, 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. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed ASC based on the applicant's representations and supporting documentation.

On page 98, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 99, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 99-100, 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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section K.1, page 89, the applicant states that the project involves 1,651 square feet of new construction and renovation of 18,144 square feet of leased space in an existing building. Line drawings are provided in Exhibit C.1.

On page 90, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 90, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 91, 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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

UNC REX Hospital proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

In Section K.1, page 70, the applicant states that the project involves renovation of 425 square feet of existing space. Line drawings are provided in Exhibit C.1.

On page 70, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 71, 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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section K.1, page 92, the applicant states that the project involves upfit of 14,000 square feet of space in a new building planned for construction by DUHS. Line drawings are provided in Exhibit K.2.

On pages 95-97, 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. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed ASC based on the applicant's representations and supporting documentation.

On page 93, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 93, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 94, 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke Green Level ASC proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

In Section K.1, page 92, the applicant states that the project involves upfit of 9,000 square feet of space in the previously approved ASC currently under construction. Line drawings are provided in Exhibit K.2.

On page 93, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 93, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 94, 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 ... persons [with disabilities], 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
 Valleygate Garner ASC

C
 All Other Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

In Section L.1, page 90, the applicant provides the historical payor mix during FFY2019 for the proposed services, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay/Charity Care	7.43%
Medicare*	47.33%
Medicaid*	3.75%
Insurance*	39.09%
Other (Champus/VA/Other Government)	2.39%
Total	100.0%

Source: Table on page 90 of the application.

*Including any managed care plans.

In Section L.1, page 90, the applicant provides the following comparison.

	Percentage of Total Patients Served by WakeMed Cary Hospital during FFY2019	Percentage of the Population of Wake County
Female	61.9%	51.4%
Male	38.0%	48.6%
Unknown	0.1%	
64 and Younger	69.7%	88.0%
65 and Older	30.3%	12.0%
American Indian	0.2%	0.8%
Asian	5.0%	7.7%
Black or African-American	20.8%	21.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	66.4%	67.9%
Other Race	6.1%	2.5%
Declined / Unavailable	1.5%	

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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

In Section L.1, page 94, the applicant states the proposed facility is new and does not have historical patient or payor data. Raleigh Orthopaedic Surgery Center reported the following payor mix data during FFY2020:

Payor Category	Operating Room Services as Percent of Total
Self-Pay/Charity Care	1.0%
Medicare*	21.8%
Medicaid*	1.5%
Insurance*	75.7%
Total	100.0%

Source: 2021 License Renewal Application for Ambulatory Surgical Facility for Raleigh Orthopaedic Surgery Center.

*Including any managed care plans.

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 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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

In Section L.1, page 74, the applicant provides the historical payor mix for UNC REX Hospital's operating rooms for SFY2020, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	2.7%
Medicare*	42.0%
Medicaid*	3.9%
Insurance*	42.0%
Other (Workers Compensation, TRICARE)	9.4%
Total	100.0%

Source: Table on page 74 of the application.

*Including any managed care plans.

In Section L.1, page 73, the applicant provides the following comparison.

	Percentage of Total Patients Served by UNC REX Hospital during SFY2020	Percentage of the Population of Wake County
Female	61.0%	51.4%
Male	38.8%	48.6%
Unknown	0.0%	0.0%
64 and Younger	60.4%	88.0%
65 and Older	39.6%	12.0%
American Indian	0.2%	0.8%
Asian	1.8%	7.7%
Black or African-American	22.9%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	68.0%	67.9%
Other Race	5.2%	2.5%
Declined / Unavailable	1.9%	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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

In Section L.1, page 99, the applicant states the proposed facility is new and does not have historical patient or payor data. Duke Raleigh Hospital reported the following payor mix data during SFY2019 for outpatient surgical services:

Payor Category	Outpatient Operating Room Services as Percent of Total
Self-Pay/Charity Care	4.2%
Medicare*	33.8%
Medicaid*	3.2%
Insurance*	52.9%
Other	5.7%
Total	100.0%

Source: 2020 License Renewal Application for Hospitals for Duke Raleigh Hospital.

*Including any managed care plans.

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 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

In Section L.1, page 98, the applicant states the facility is not operational and does not have historical patient or payor data. Duke Raleigh Hospital reported the following payor mix data during SFY2019 for outpatient surgical services:

Payor Category	Outpatient Operating Room Services as Percent of Total
Self-Pay/Charity Care	4.2%
Medicare*	33.8%
Medicaid*	3.2%
Insurance*	52.9%
Other	5.7%
Total	100.0%

Source: 2020 License Renewal Application for Hospitals for Duke Raleigh Hospital.
 *Including any managed care plans.

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 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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA
 Valleygate Garner ASC
 Orthopaedic Garner ASC

C
 All Other Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 91, the applicant states it has no obligations under any applicable federal regulation but complies with all other federally mandated regulations related to minorities and handicapped individuals.

In Section L, page 91, the applicant states that during the last five years, one patient civil rights access complaint has been filed against WakeMed Cary Hospital. The

applicant states the complaint was investigated by the Office of Civil Rights and the case was closed on April 10, 2018.

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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

In Section L.2, the applicant states it is not an existing facility. Therefore, Criterion (13b) is not applicable.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

In Section L.2, the applicant states it is not an existing facility. Therefore, Criterion (13b) is not applicable.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 74-75, the applicant states it has no obligations under any applicable federal regulation but complies with all other federally mandated regulations related to minorities and handicapped individuals.

In Section L, page 75, the applicant states that during the last five years no patient civil rights 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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 100, the applicant states DUHS has no obligations under any applicable federal regulation but does not

discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.

In Section L, pages 101-102, the applicant states that during the last five years, five patient civil rights access complaints have been filed against DUHS. The applicant states the complaints were investigated by the Office of Civil Rights and describes how each of the cases has been resolved on pages 101-102 of the application.

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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 99, the applicant states DUHS has no obligations under any applicable federal regulation but does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.

In Section L, pages 100-101, the applicant states that during the last five years, five patient civil rights access complaints have been filed against DUHS. The applicant states the complaints were investigated by the Office of Civil Rights and describes how each of the cases has been resolved on pages 100-101 of the application.

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

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

In Section L.3, page 92, 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	2.24%
Charity Care	5.04%
Medicare *	47.89%
Medicaid *	3.77%
Insurance *	38.68%
Other	2.38%
Total	100.00%

Source: Table on page 92 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 2.24% of total services will be provided to self-pay patients, 5.04% to charity care patients, 47.89% to Medicare patients and 3.77% to Medicaid patients.

On page 92, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for surgical services at WakeMed Cary 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 based on the reasons stated above.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new 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
Self-Pay	4.06%
Medicare *	20.89%
Medicaid *	55.05%
Insurance *	16.31%
Other (Workers Comp, TRICARE/VA)	3.70%
Total	100.00%

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 4.06% of total operating room services will be provided to self-pay patients, 20.89% to Medicare patients and 55.05% to Medicaid patients.

In Section Q, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The applicant states that “*payor mix is based on applicant research for ASC cases in these specialties.*” The projected payor mix is reasonable and adequately supported.

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 based on the reasons stated above.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

In Section L.3, page 95, 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	0.8%
Medicare *	19.8%
Medicaid *	1.3%
Insurance *	67.5%
Other (Workers Comp, TRICARE)	10.6%
Total	100.0%

Source: Table on page 95 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 0.8% of total services will be provided to self-pay patients, 19.8% to Medicare patients and 1.3% to Medicaid patients.

On page 95, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (SFY2020) payor mix for the ROC surgeons that are expected to shift surgical cases to 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 based on the reasons stated above.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

In Section L.3, page 75, 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	2.7%
Medicare *	42.0%
Medicaid *	3.9%
Insurance *	42.0%
Other (Workers Comp, TRICARE)	9.4%
Total	100.00%

Source: Table on page 75 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 2.7% of total services will be provided to self-pay patients, 42.0% to Medicare patients and 3.9% to Medicaid patients.

On page 75, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical (SFY2020) payor mix for surgical services at 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 based on the reasons stated above.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

In Section L.3, page 102, 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/Charity Care	2.0%
Medicare *	44.0%
Medicaid *	5.3%
Insurance *	42.9%
Other (Workers Comp, VA, TRICARE)	5.8%
Total	100.00%

Source: Table on page 102 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 total services will be provided to self-pay/charity care patients, 44.0% to Medicare patients and 5.3% to Medicaid patients.

On page 103, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. On page 103, the applicant states, “*Operating room services payor mix is derived from DUHS’s existing payor mix of outpatient surgical cases within each specialty at DRAH and DUH.*” The projected payor mix is reasonable and adequately supported.

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 based on the reasons stated above.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

In Section L.3, page 101, 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/Charity Care	1.6%
Medicare *	47.2%
Medicaid *	3.5%
Insurance *	41.6%
Other (Workers Comp, VA, TRICARE)	6.1%
Total	100.00%

Source: Table on page 101 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 1.6% of total services will be provided to self-pay/charity care patients, 47.2% to Medicare patients and 3.5% to Medicaid patients.

On page 102, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. On page 102, the applicant states, “*Operating room services payor mix is derived from DUHS’s existing payor mix of outpatient surgical cases within each specialty at DRAH and DUH.*” The projected payor mix is reasonable and adequately supported.

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 based on the reasons stated above.

- (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.

All Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

In Section L, page 93, 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.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

In Section L, page 106, 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.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

In Section L, page 96, 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.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

In Section L, page 76, 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.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

In Section L, page 104, 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.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

In Section L, page 104, 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.

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 51, the 2020 SMFP states, “*An operating room’s ‘service area’ is the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.*” In Figure 6.1, page 57 of the 2020 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 67-68 and 80 of the 2020 SMFP.

**Wake County Operating Room Inventory and Cases
 As Reported in the 2020 SMFP and on the 2019 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
Duke Health Green Level ASC	0	0	0	0	1	0	0	6
Duke Raleigh Hospital	0	0	15	0	0	3,328	7,474	3
Duke University Health System Total	0	0	15	0	1			
Rex Hospital Holly Springs	0	0	0	0	3	0	0	
Rex Surgery Center of Wakefield	0	2	0	0	0	0	0	5
Rex Surgery Center of Cary	0	4	0	0	0	0	4,585	6
Rex Hospital	3	0	25	-3	-1	8,366	12,019	2
Raleigh Orthopedic Surgery Center	0	4	0	0	-1	0	5,416	6
Raleigh Orthopedic Surgery-West Cary	0	0	0	0	1	0	0	
UNC Health Care System Total	3	10	25	-3	2			
WakeMed Surgery Center-Cary	0	0	0	0	1	0	0	
Capital City Surgery Center	0	8	0	0	0	0	6,712	6
WakeMed (incl. WakeMed North)	8	0	20	-5	-1	7,941	11,189	2
WakeMed Cary Hospital	2	0	9	-2	1	2,973	4,956	4
WakeMed System Total	10	8	29	-7	1			
OrthoNC ASC	0	0	0	0	1			
RAC Surgery Center	0	0	0	0	1			
Holly Springs Surgery Center	0	3	0	0	0	0	1,827	6
Blue Ridge Surgery Center	0	6	0	0	0	0	5,923	5
Raleigh Plastic Surgery Center^	0	1	0	0	0	0	340	6
Triangle Orthopedic Surgery Center*	0	2	0	0	0	0	2,403	6
Surgical Center for Dental Professionals*	0	2	0	0	0	0	0	
2019 SMFP Need Determination	0	0	0	0	2			
Total Wake County ORs	13	32	69	-10	8			

Source: 2020 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 FY2018, there were five existing or approved hospitals and ten existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 32 ambulatory and 69 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-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-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.

Also, pursuant to the need determination for two additional operating rooms for the Wake County service area in the 2019 SMFP, the following applications were approved:

Project ID # J-11747-19, Wake Spine and Specialty Surgery Center, 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.

Project ID # J-11752-19, Triangle Orthopaedics Surgery Center, 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.

Therefore, subsequent to the approvals in the 2018 and 2019 Wake operating room reviews, there are five existing or approved hospitals and 16 existing or approved ambulatory surgery facilities in Wake County. The 2020 SMFP shows a need for three additional operating rooms for the Wake County service area.

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

WakeMed Cary Hospital proposes to develop no more than 1 shared operating room at WakeMed Cary Hospital for a total of no more than 13 operating rooms (11 operating rooms and 2 C-section operating rooms) pursuant to the need determination in the 2020 SMFP.

In Section N, pages 101-103, 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 101, 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 proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described above.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

Valleygate Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 3 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section N, pages 108-111, 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 108, the applicant states,

“VSC will offer Wake County a new competitor. VSC does not own any ORs. As a new freestanding competitor in southeastern Wake County, VSC will provide market competition in access, price, and quality. The competitive option for consumers and others for whom price is a concern will also give third party payors like Medicaid an alternative.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described above.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

Orthopaedic Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 2 operating rooms and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section N, pages 100-106, 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 100, the applicant states,

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to surgical services. ... The proposed project will provide cost containment for surgical procedures. For those patients who do not require a more intensive setting, ASFs are able to provide care at a lower cost because of the lower intensity setting (e.g., no emergency room, no intensive care, no inpatient services, no overhead related to intensive hospital-based services). In a freestanding ASF, there are no other hospital-based expenses allocated to surgery services; the only expenses are those generated directly by services provided by the ASF. As a result, patients and payors will not incur the charges associated with hospital-based care. For all payors, the proposed lower charge structure will increase the affordability of the services offered in the facility, and policies will ensure that even those without a third-party payor have access to needed services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described above.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

UNC REX Hospital proposes to develop no more than one additional operating room at the existing hospital in Raleigh pursuant to the need determination in the 2020 SMFP.

In Section N, pages 79-83, 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 79, the applicant states,

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to surgery services. ... As discussed below and further in Section C.4, UNC REX Hospital has demonstrated an ability to efficiently provide surgical services with fewer resources, which results in a lower cost of care for the service. UNC REX Hospital performs more surgical cases than any other facility in Wake County, supported by a highly efficient service with lower costs. 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 describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described above.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

Duke Garner ASC proposes to develop a new ambulatory surgery center (ASC) with no more than 1 operating room and 2 procedure rooms in Garner pursuant to the need determination in the 2020 SMFP.

In Section N, pages 107-110, 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 107, the applicant states,

“DUHS is the only integrated health system currently without an operational freestanding ASC in Wake County. It also has by far the fewest number of licensed operating rooms of any of the major health systems in the county. Moreover, there are currently no ambulatory surgery facilities in the Garner area. This project will therefore better serve local residents and will promote competition in the Wake County service area for surgical services. Competition is healthy for providers, as it spurs continuous quality improvement, and serves as motivation for seeking maximum cost effectiveness. The proposed ASC will enable DUHS to better meet the needs of its existing local patient population, will promote cost-effectiveness, quality, and access to services via operation of a freestanding ASC to better serve local residents, and to ensure more timely provision of and convenient access to cost-effective, high quality outpatient surgical services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described above.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

Duke Green Level ASC proposes to add no more than 2 operating rooms pursuant to the need determination in the 2020 SMFP for a total of no more than 3 operating rooms upon completion of this project and Project I.D. # J-11557-18 (develop an ASC).

In Section N, pages 106-108, 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 106, the applicant states,

“DUHS is the only integrated health system currently without an operational freestanding ASC in Wake County. It also has the fewest number of licensed operating rooms of any of the major health systems in the county. This project will therefore better serve local residents and will promote competition in the Wake County service area for surgical services. Competition is healthy for providers, as it spurs continuous quality improvement, and serves as motivation for seeking maximum cost effectiveness. And residents will have access to an alternative ASC conveniently located in western Wake County. The proposed additional operating rooms will enable DUHS to better meet the needs of its existing local patient population, will promote cost-effectiveness, quality, and access to services via operation of a freestanding ASC to better serve local residents, and to ensure more timely provision of and convenient access to cost-effective, high quality outpatient surgical services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described 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.

C All Applications

Project ID # J-11960-20/WakeMed Cary Hospital/Add 1 OR

In Section Q, Form A, page 116, the applicant identifies two hospitals and one ambulatory surgical facility located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of this type of facility located in North Carolina.

In Section O.3, page 112, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure 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 these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all three facilities, the

applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # J-11961-20/Valleygate Garner ASC/Develop new ASC

In Section Q, Form A, page 117, the applicant identifies the three ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of this type of facility located in North Carolina.

In Section O.3, page 113, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure 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 these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # J-11962-20/Orthopaedic Garner ASC/Develop new ASC

In Section Q, Form A, the applicant identifies twelve hospitals and seven ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 of this type of facility located in North Carolina.

In Section O.3, page 110, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected. According to the files in the Acute and Home Care Licensure Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all 19 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # J-11963-20/Rex Hospital/Add 1 OR

In Section Q, Form A, the applicant identifies twelve hospitals and seven ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 of this type of facility located in North Carolina.

In Section O.3, pages 85-86, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected. According to the files in the Acute and Home Care Licensure Section, DHSR, during the 18 months

immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all 19 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # J-11966-20/Duke Garner ASC/Develop new ASC

In Section Q, Form A, the applicant identifies four ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four of this type of facility located in North Carolina.

In Section O.3, page 116, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure 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 these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID # J-11967-20/Duke Green Level ASC/Add 2 ORs to ASC

In Section Q, Form A, the applicant identifies four ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four of this type of facility located in North Carolina.

In Section O.3, page 115, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure 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 these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all four facilities, the applicant provided 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.

G.S. 131E-183(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

The applications are conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

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

10A NCAC 14C .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- **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 2020 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Valleygate Garner ASC.** 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 2020 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Orthopaedic Garner ASC.** This proposal would develop a new ASC with two operating rooms. 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 2020 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **UNC REX 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 2020 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- C- **Duke Garner ASC.** This proposal would develop a new ASC with one operating room. 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 2020 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 2020 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- **WakeMed Cary Hospital.** In Section Q, pages 117-132, 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- **Valleygate Garner ASC.** In Section Q, pages 119-146, 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- **Orthopaedic Garner ASC.** In Section Q, Form C Methodology and Assumptions, pages 1-26, 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 1-26, 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 Garner ASC.** In Section Q, pages 119-137, 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 118-137, 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 2020 SMFP, no more than three operating rooms may be approved for Wake County in this review. Because the six applications in this review collectively propose to develop eight additional operating rooms, all the applications cannot be approved. 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 proposals should be approved.

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

- Project I.D. # J-11960-20 / **WakeMed Cary Hospital** / Add one operating room for a total of 13 operating rooms (11 operating rooms and 2 C-section operating rooms)
- Project I.D. # J-11961-20 / **Valleygate Surgery Center** / Develop a new ASC with one operating room and three procedure rooms
- Project I.D. # J-11962-20 / **Orthopaedic Surgery Center of Garner** / Develop a new ASC with two operating rooms and two procedure rooms
- Project I.D. # J-11963-20 / **Rex Hospital** / Add one operating room for a total of 32 operating rooms
- Project I.D. # J-11966-20 / **Duke Health Garner Ambulatory Surgical Center** / Develop a new ASC with one operating room and two procedure rooms
- Project I.D. # J-11967-20 / **Duke Health Green Level Ambulatory Surgical Center** / Add two operating rooms for a total of three operating rooms

As the above description of each proposed project indicates, two applications are proposing new multispecialty ambulatory surgery centers (ASC) with one operating room each, one application is proposing a new orthopedic ASC with two operating rooms, and one application is proposing to add two operating rooms to an approved multispecialty ASC. The ASCs applications each project to perform between approximately 750 and 3,500 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 25 operating rooms (excluding three C-section operating rooms) and projects to perform approximately 21,000 surgeries in PY3. WakeMed Cary Hospital would have eleven operating rooms (excluding two C-section operating rooms) and projects to perform approximately 8,800 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

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. 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	1	3
Raleigh	RAC Surgery Center*	0	0	0	0	1	1
North Raleigh	OrthoNC Ambulatory Surgery Center*	0	0	0	0	1	1
Raleigh	Wake Spine and Specialty 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 and two additional operating rooms in the 2019 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. **Duke Green Level ASC** propose to add two operating rooms to an approved ambulatory surgery center in Cary. **Duke Garner ASC, Valleygate Garner ASC, and Orthopaedic Garner ASC** all propose to develop operating rooms in a new ASC to be located in Garner. As indicated in the table above, there are no existing or approved operating rooms located in Garner. Therefore, with regard to expanding geographic access to surgical services, **Duke Garner ASC, Valleygate Garner ASC, and Orthopaedic Garner ASC** are more effective alternatives because they propose to develop the operating rooms in Garner.

Competition

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer operating rooms than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

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 2021 SMFP. Table 6B shows a total of 110 existing and approved operating rooms in Wake County, excluding the need determination for three operating rooms in the 2020 SMFP.

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

	Adjusted Operating Room Planning Inventory	Applicants' Operating Rooms as a Percent of Total Wake County Operating Rooms
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	
UNC Health System	37	33.6%
WakeMed Surgery Center-Cary	1	
WakeMed Surgery Center-North Raleigh	1	
Capital City Surgery Center	7	
WakeMed	22	
WakeMed Cary Hospital	10	
WakeMed Health System	41	37.3%
Duke Green Level Ambulatory Surgery Center	1	
Duke Raleigh Hospital	15	
Duke University Health System	16	14.5%

Source: 2021 SMFP, Table 6B: Projected Operating Room Need for 2023.

As shown in the table above, the WakeMed Health System controls 37.3 percent of the existing and approved operating rooms in Wake County, the UNC Health System controls 33.6 percent, and the Duke Health System controls 14.5 percent. Valleygate Garner ASC states that it does not own or operate any existing surgical facilities in Wake County, 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 **Vallygate Garner ASC** is the most effective alternative and the applications submitted by **Duke Garner ASC** and **Duke Green Level ASC** are more effective alternatives than the applications submitted by **WakeMed Cary Hospital**, **Orthopaedic Garner ASC** and **UNC REX Hospital**.

Historical Utilization

The following table shows projected operating room surplus or deficit for the existing providers of surgical services in Wake County who have submitted applications in this review. The projected operating room deficits, from the 2020 State Medical Facilities Plan, Table 6B, Projected Operating Room Need for 2022, are based on the historical utilization of existing providers of surgical services in the service area. Generally, applications proposing to develop additional operating rooms in the health systems with the highest projected operating room deficits are the more effective alternative with regard to this comparative factor.

Projected 2022 Operating Room Need for Wake County by Health System

	Adjusted Operating Room Planning Inventory	Projected Operating Room Deficit (Surplus) 2022
UNC Health System	37	2.58
Duke University Health System	16	0.86
WakeMed Health System	41	(2.09)

Source: 2020 SMFP, Table 6B.

As the table above shows, based on the operating room need determination methodology for Wake County in the 2020 SMFP, the UNC Health System is projected to have the highest operating room deficit in 2022. Therefore, the applications submitted by **Orthopaedic Garner ASC** and **UNC REX Hospital** are the more effective proposals with respect to this comparative factor. The applications submitted by **Valleygate Garner ASC**, **WakeMed Cary Hospital**, **Duke Garner ASC** and **Duke Green Level ASC** are less effective with respect to this comparative factor.

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	WakeMed Cary Hospital	Valleygate Garner ASC	Ortho Garner ASC	UNC REX Hospital	Duke Garner ASC	Duke Green Level ASC
Bariatric	X					
Breast	X					
Cardiothoracic	X			X		
Cardiovascular	X			X		
Colorectal	X					
Gastroenterology	X			X		
General Surgery	X			X	X	X
Gynecology	X			X	X	X
Neurosurgery	X			X		X
Obstetrics	X			X		
Open Heart Surgery				X		
Ophthalmology	X	X		X	X	X
Oral/Dental Surgery	X	X		X		
Orthopedic	X		X	X	X	X
Otolaryngology	X	X		X	X	X
Pain Management				X		
Pediatrics	X			X		
Plastic Surgery	X	X		X	X	X
Podiatry	X			X		X
Pulmonary	X					
Spine	X		X			
Thoracic	X			X		
Urology	X			X	X	X
Vascular	X			X		X

Source: WakeMed Cary Hospital, pages 17-18 of the application. Valleygate Garner ASC, page 23 of the application, Orthopaedic Garner ASC, page 22 of the application, UNC REX Hospital, 2020 Renewal Application for Hospital form, page 12. Duke Garner ASC, page 16 of the application, and Duke Green Level ASC, page 16 of the application

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 **Valleygate Garner ASC, Orthopaedic Garner ASC, Duke Garner ASC** 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 110 existing or approved 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.

	Total ORs*	IP ORs	% IP of Total ORs	OP ORs**	% OP of Total ORs	Shared ORs	% Shared of Total ORs
Wake County Operating Rooms	110	3	2.7%	38	34.5%	69	62.7%

Source: 2021 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 FY2019, based on data reported in the 2021 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	-	6,127	6,127	100%
Raleigh Plastic Surgery	ASC	-	319	319	100%
Raleigh Orthopedic Surgery	ASC	-	5,513	5,513	100%
Rex Surgery Center Wakefield	ASC	-	2,131	2,131	100%
Rex Surgery Center Cary	ASC	-	4,584	4,584	100%
Rex Hospital	Hospital Shared	8,334	11,942	20,276	59%
Capital City Surgery Center	ASC	-	6,822	6,822	100%
WakeMed	Hospital Shared	7,988	11,276	19,264	59%
WakeMed Cary Hospital	Hospital Shared	3,142	3,740	6,882	54%
Holly Springs Surgery Center	ASC	-	2,217	2,217	100%
Triangle Orthopedic Surgery Center	ASC	-	2,682	2,682	100%
Duke Raleigh Hospital	Hospital Shared	3,568	7,415	10,983	68%
Totals		23,032	64,768	87,800	74%

Source: 2021 SMFP, Table 6B.

As the table above shows, 74% of the total Wake County surgical cases in FFY2019 were performed as ambulatory (outpatient) surgeries. Wake County currently has 16 existing and approved ASCs. Based on the fact that 74 percent of Wake County’s FFY2019 surgical cases were ambulatory surgery cases and that ASC operating rooms represent 34.5 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 **Valleygate Garner ASC, Orthopaedic Garner ASC, Duke Garner ASC** 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 ... persons [with disabilities], 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
WakeMed Cary Hospital	\$29,496,050	\$3,351	22.7%
Valleygate Garner ASC	\$94,371	\$124	7.5%
Orthopaedic Garner ASC	\$345,091	\$170	3.2%
UNC REX Hospital	\$14,074,985	\$673	6.2%
Duke Garner ASC	\$94,226	\$69	1.8%
Duke Green Level ASC	\$283,954	\$83	1.9%

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 and as a percent of net revenue. Therefore, the application submitted by **WakeMed Cary Hospital** is the most effective alternative 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

Applicant	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
WakeMed Cary Hospital	\$280,208,145	\$555,640,545	50.4%
Valleygate Garner ASC	\$985,544	\$4,776,856	20.6%
Orthopaedic Garner ASC	\$10,801,974	\$54,579,395	19.8%
UNC REX Hospital	\$280,184,372	\$667,675,625	42.0%
Duke Garner ASC	\$5,058,404	\$10,790,751	46.9%
Duke Green Level ASC	\$14,168,969	\$30,729,889	46.1%

Source: Form F.2 for each applicant.

As shown in the table above, **WakeMed Cary Hospital** projects more than 50 percent of its surgical services will be provided to Medicare patients. The application submitted by **WakeMed Cary Hospital** is the most effective application 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 of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

Services to Medicaid Patients - Project Year 3

	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
WakeMed Cary Hospital	\$22,067,265	\$555,640,545	4.0%
Valleygate Garner ASC	\$2,597,742	\$4,776,856	54.4%
Orthopaedic Garner ASC	\$721,397	\$54,579,395	1.3%
UNC REX Hospital	\$25,823,444	\$667,675,625	3.9%
Duke Garner ASC	\$247,011	\$10,790,751	2.3%
Duke Green Level ASC	\$421,089	\$30,729,889	1.4%

Source: Form F.2 for each applicant.

As shown in the table above, **Valleygate Garner ASC** projects 54.4% of its surgical services will be provided to Medicaid patients. The application submitted by **Valleygate Garner ASC** is the most effective application 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, regarding this factor, the application proposing the lowest average net revenue per patient day, surgical case or procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Net Revenue per Surgical Case - Project Year 3

	Net Revenue	# of Cases	Net Revenue/Case
WakeMed Cary Hospital	\$130,026,137	8,802	\$14,772
Valleygate Garner ASC	\$1,263,889	759	\$1,665
Orthopaedic Garner ASC	\$10,741,767	2,031	\$5,289
UNC REX Hospital	\$228,089,339	20,913	\$10,907
Duke Garner ASC	\$5,151,523	1,369	\$3,763
Duke Green Level ASC	\$14,614,676	3,417	\$4,277

Source: Form F.2 for each application.

As shown in the table above, **Valleygate Garner ASC** projects the lowest net revenue per surgical case in the third operating year. Therefore, the application submitted by **Valleygate Garner ASC** is the most effective application 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 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 (Form F.2). Generally, the application proposing the lowest average operating expense per surgical case 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
WakeMed Cary Hospital	\$59,384,364	8,802	\$6,747
Valleygate Garner ASC	\$1,066,626	759	\$1,405
Orthopaedic Garner ASC	\$7,828,007	2,031	\$3,854
UNC REX Hospital	\$192,639,806	20,913	\$9,211
Duke Garner ASC	\$3,888,202	1,369	\$2,840
Duke Green Level ASC	\$9,239,771	3,417	\$2,704

Source: Forms F.2 in each application.

As shown in the table above, **Valleygate Garner ASC** projects the lowest average operating expense per surgical case in the third operating year. Therefore, the application submitted by **Valleygate Garner ASC** is the most effective application 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 lists the comparative factors and indicates whether each application was more effective, less effective or equally 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.

Comparative Factor	WakeMed Cary Hospital	Valleygate Garner ASC	Orthopaedic Garner ASC	UNC REX Hospital	Duke Garner ASC	Duke Green Level ASC
Conformity with Review Criteria	Yes	Yes	Yes	Yes	Yes	Yes
Geographic Accessibility	Less effective	More effective	More effective	Less effective	More effective	Less effective
Competition	Less effective	Most effective	Less effective	Less effective	More effective	More effective
Historical Utilization	Less effective	Less effective	More effective	More effective	Less effective	Less effective
Scope of Services	More effective	Less effective	Less effective	More effective	Less effective	Less effective
Access to Lower Cost Services	Less effective	More effective	More effective	Less effective	More effective	More effective
Projected Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Net Revenue per Surgical Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Operating Expense per Surgical Case	Inconclusive	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 three operating rooms. Therefore, only three operating rooms can be approved.

As shown in the table above, Valleygate Garner ASC was determined to be the most or more effective alternative for the following three factors:

- Geographic accessibility
- Competition
- Patient access to lower cost surgical services

As shown in the table above, Orthopaedic Garner ASC was determined to be a more effective alternative for the following three factors:

- Geographic accessibility
- Historical Utilization
- Patient access to lower cost surgical services

As shown in the table above, Duke Garner ASC was determined to be a more effective alternative for the following three factors:

- Geographic accessibility
- Competition

- Patient access to lower cost surgical services

DECISION

Each application is individually conforming to the need determination in the 2020 SMFP for three additional operating rooms in Wake County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of operating rooms that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following applications are approved:

- Project I.D. # J-11961-20 / **Valleygate Surgery Center** / Develop a new ASC with one operating room and three procedure rooms
- Project I.D. # J-11962-20 / **Orthopaedic Surgery Center of Garner** / Develop a new ASC with one operating room and two procedure rooms
- Project I.D. # J-11966-20 / **Duke Health Garner Ambulatory Surgical Center** / Develop a new ASC with one operating room and two procedure rooms

And the following applications are denied:

- Project I.D. # J-11960-20 / **WakeMed Cary Hospital** / Add one operating room for a total of 13 operating rooms (11 operating rooms and 2 C-section operating rooms)
- Project I.D. # J-11963-20 / **Rex Hospital** / Add one operating room for a total of 32 operating rooms
- Project I.D. # J-11967-20 / **Duke Health Green Level Ambulatory Surgical Center** / Add two operating rooms for a total of three operating rooms

Project I.D. # J-11961-20 / **Valleygate Surgery Center** is approved subject to the following conditions.

1. Valleygate Surgery Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop a new ambulatory surgery center with no more than one operating room and three procedure rooms pursuant to the need determination in the 2020 SMFP.
3. Upon completion of the project, Valleygate Surgery Center shall be licensed for no more than one operating room and three procedure rooms.
4. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the

Healthcare Planning and Certificate of Need Section. The form is available online at:
<https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.

- b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on November 1, 2021 and so forth.
5. The certificate holder 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.
 6. The certificate holder 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.
 7. For the first three years of operation following completion of the project, the certificate holder 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 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.
 8. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
 9. 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.
 10. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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. The certificate holder 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.

Project I.D. # J-11963-20 / **Orthopaedic Surgery Center of Garner** is approved subject to the following conditions.

1. Orthopaedic Surgery Center of Garner, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop a new ambulatory surgery center with no more than one operating room and two procedure rooms pursuant to the need determination in the 2020 SMFP.
3. Upon completion of the project, Orthopaedic Surgery Center of Garner shall be licensed for no more than one operating room and two procedure rooms.
4. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on November 1, 2021 and so forth.
5. The certificate holder 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.
6. The certificate holder 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.
7. For the first three years of operation following completion of the project, the certificate holder 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 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.

8. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
9. 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.
10. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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. The certificate holder 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.

Project I.D. # J-11966-20 / **Duke Health Garner Ambulatory Surgical Center** is approved subject to the following conditions.

1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
2. The certificate holder shall develop a new ambulatory surgery center with no more than one operating room and two procedure rooms pursuant to the need determination in the 2020 SMFP.
3. Upon completion of the project, Duke Health Garner Ambulatory Surgical Center shall be licensed for no more than one operating room and two procedure rooms.
4. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.

- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on November 1, 2021 and so forth.
5. The certificate holder 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.
6. The certificate holder 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.
7. For the first three years of operation following completion of the project, the certificate holder 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 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.
8. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
9. 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.
10. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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. The certificate holder 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.