

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 28, 2020

Findings Date: January 28, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: J-11804-19

Facility: RAC Surgery Center

FID #: 180414

County: Wake

Applicant(s): RAC Surgery Center, LLC

Fresenius Vascular Care Raleigh MSO, LLC

Project: Change of scope and cost overrun for Project ID#J-11551-18 (Develop a new ambulatory surgical facility in Raleigh with one operating room and two procedures focused on vascular access procedures for patients with end stage renal disease pursuant to the determination in the 2018 SMFP for additional operating rooms)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicants, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC, collectively referred to hereinafter as “the applicant”, propose a change of scope and cost overrun for Project ID#J-11551-18 (Develop a new ambulatory surgical facility in Raleigh with one operating room (OR) and two procedure rooms focused on vascular access procedures for patients with end stage renal disease pursuant to the determination in the 2018 SMFP for additional operating rooms).

A Certificate of Need was issued February 28, 2019 for Project J-11551-18, develop a new ambulatory surgical facility (ASF) in Raleigh with one operating room and two procedure rooms focused on vascular access procedures for patients with end stage renal disease pursuant to the determination in the 2018 State Medical Facility Plan (SMFP) for additional operating rooms. This application is a change of scope to add one additional procedure room for a total of one operating room and three procedure rooms upon completion of this project and Project J-11551-18. This application includes a cost-overrun of \$1,792,511 which results in a total combined capital cost of \$3,792,511. The cost overrun application is necessary due to the underestimated increase in construction costs.

Need Determination

Project ID# J-11551-19 was found to be conforming to the need determination in Wake County for additional operating rooms (ORs) in the 2018 SMFP. The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2019 State Medical Facilities Plan (2019 SMFP). Also, there are no policies in the 2019 SMFP applicable to this review. Therefore, Criterion (1) is not applicable to this review.

Policies

Project ID# J-11551-18 was found to be consistent with Policy GEN-3 and Policy GEN-4 as published in the 2018 SMFP. The applicant proposes no changes in the current application which would affect that determination. There are no policies in the 2019 SMFP that are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Project ID# J-11551-18 was previously approved to develop one operating room and two procedure rooms. In the original review, the application was conforming to this criterion. The applicant proposes no changes that would affect that determination. Therefore, the application is conforming to this criterion.

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

The applicant proposes a change of scope and cost overrun for Project ID#J-11551-18 (Develop a new ASF with one OR and two procedure rooms).

Patient Origin

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

The application for Project ID#J-11551-18 adequately identified the current and projected patient origin for the facility at the time of that application and no changes are proposed in this application which would affect that determination.

Analysis of Need

In Section C, pages 22 and 26-27, the applicant describes the scope of the previously approved project, Project ID# J-11551-18 and explains the changes it proposes to make in this change of scope and cost overrun application compared with the previously approved project. The applicant summarizes the need for the proposed changes as summarized below:

- The applicant states that the owner of the building where the applicant intended to lease space for the proposed project, offered to lease the entire second floor of the building as opposed to the smaller first floor, as proposed in Project ID# J-11551-18. The applicant states that the larger space allows an additional procedure room to accommodate the new projected growth.
- The applicant projects that the total capital cost to develop a new ambulatory surgical facility with one operating room and three procedure rooms will be \$3,792,511, an increase of \$1,792,511 over the previously approved capital expenditure, which exceeds the 115 percent statutory limit for capital expenditures. The applicant states the increase in capital cost is due to the increased construction costs for the additional procedure room. The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

RAC Surgery Center – Previously Approved and Proposed Capital Cost			
	Previously Approved Cost (J-11551-18)	Capital Costs Projected (J-11904-19)	Difference
Site Preparation	\$350,000	\$855,447	\$505,447
Construction/Renovation Contract(s)	\$875,443	\$1,852,053	\$976,610
Architect/Engineering Fees	\$80,000	\$120,000	\$40,000
Furniture	\$25,000	\$0	\$102,000
Consultant Fees	\$45,000	\$65,000	\$20,000
Other	\$449,557	\$598,011	\$148,454
Total Capital Costs	\$2,000,000	\$3,792,511	\$1,792,511

- The applicant states that the actual volume and growth rate of OR and procedure room procedures in 2018 and 2019 were higher than what was projected in the previously approved application. In this application, the applicant provides updated historical and projected utilization to reflect a more accurate growth rate at the proposed facility. The applicant states that due to the higher than expected growth rate, an additional procedure room is needed to accommodate the new projected growth.

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

- The applicant adequately demonstrates the projected cost of construction has increased since the original application was approved.
- The applicant adequately explains the necessity of the increased capital expenditure to develop the project as approved in Project ID# J-11551-18.
- The applicant adequately demonstrates the need for the additional procedure room based on the higher than expected growth in procedures than what was previously projected in Project ID# J-11551-18.

Projected Utilization

In Project ID# J-11551-18, the applicant based their projected utilization on the 2018 annualized volume of OR and procedure room procedures performed at the affiliated Cary and Raleigh vascular access centers that together will serve as the primary referral sources for the proposed ASC. The applicant projected 1,218 OR-appropriate procedures and 4,490 procedure room-appropriate procedures. The annual growth rate from 2016 to 2018 was 6.0 percent for OR-appropriate procedures and 1.6 percent for procedure room-appropriate procedures for an overall growth rate of 2.5 percent.

In Section C, page 23, of this application, the applicant states that actual 2018 volume exceeded the volume of cases projected in the original application and the 2019 annualized data shows

a higher growth rate. The annual growth rate from 2016 to 2019 annualized for OR and procedure room volume was 8.6 percent, 6 percent higher than the growth rate projected in Project ID# J-11551-18.

In Section Q, the applicant provides the updated projected utilization based on the actual volume and growth rate, as illustrated in the following table.

RAC Surgery Center, LLC			
Operating Rooms	Year 1 FFY 10/1/2020- 9/30/2021	Year 2 FFY 10/1/2021- 9/30/2022	Year 1 FFY 10/1/2022- 9/30/2023
Dedicated Ambulatory ORs	1	1	1
Outpatient Surgical Cases	1,558	1,814	1,875
Surgical Case Times	68.6	68.6	68.6
Total Surgical Hours	1,427[1,781]	1,671[2,074]	1,727[2,144]
Group Assignment	6	6	6
Standard Hours per OR Year	1,312.50	1,312.50	1,312.50
Total Surgical Hours/standard Hours Per OR per Year	1.09[1.36]	1.27[1.58]	1.32[1.63]
Procedure Rooms			
# of Procedure Rooms	4[3]	4[3]	4[3]
Total Procedures	4,835	5,249	5,433

Source: Section C, Form C

Note: The figures in the brackets are based on the information presented in Project ID# J-11551-18 and using the OR Need Methodology Calculator. These numbers differ from the numbers presented in this application. In Section C, page 64, the applicant stated four procedure rooms, however, the applicant is proposing three procedure rooms.

In Section C, pages 25, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Operating Room

Step 1: The applicant projects a 5 percent growth of OR cases during the interim period 10/1/2019 to 9/30/2020 based on annualized 2019 procedures performed at the Raleigh and Cary vascular access centers, assuming a 25 percent loss of patients in Cary.

Step 2: The applicant projects a 4 percent growth for Year 1 based on ESRD market.

Step 3: The applicant projects new patients with “*fistula creation*” based on ASC licensure and capability.

Step 4: The applicant projects downstream procedures for new patients receiving “*fistula creations*” for Year 1 based on the following assumptions:

- Of the total patients that received a “*fistula creation*” 75 percent will return for two “*maturation procedures.*”
- The “*maturation*” visits occur 4 to 6 months post “*fistula creation.*”
- 17.1 percent will receive stents and 7.3 percent will receive “*thrombectomy.*”

Step 5: The applicant states that year 2 projected volumes are based on 3.5 percent growth from Year 1.

Step 6: The applicant projects that new patient “*fistula*” volume will double in Year 2.

Step 7: The applicant projects downstream procedures in Year 2 based on the following assumptions:

- 75 percent of “*fistula creation*” patients will return for two “*maturation procedures.*”
- Of these patients, 17.1 percent will receive stents and 7.3 percent will receive “*thrombectomy.*”

Step 8: The applicant projects volume growth for Year 3 based on the 3.5 percent growth from Year 2. The applicant projects “*fistulas*” will grow at 2.5 percent.

Procedure Room

Step 1: The applicant projects a 5 percent growth of OR cases during the interim period 10/1/2019 to 9/30/2020 based on annualized 2019 procedures performed at the Raleigh and Cary vascular access centers, assuming a 25 percent loss of patients at Cary.

Step 2: The applicant projects a 4 percent growth for Year 1 based on ESRD market.

Step 3: The applicant projects new patients with “*fistula creation*” based on ASC licensure and capability.

Step 4: The applicant projects downstream procedures for new patients receiving “*fistula creations*” for Year 1 based on the following assumptions:

- Of the total patients that received a “*fistula creation*” 75 percent will return for two “*maturation procedures.*”
- The “*maturation*” visits occur 4 to 6 months post “*fistula creation.*”
- 66 percent will receive angioplasty and 9.6 percent will receive “*fistulagram.*”

Step 5: The applicant states that Year 2 projected volumes are based on 3.5 percent growth from Year 1.

Step 6: The applicant projects downstream procedures in Year 2 based on the following assumptions:

- 75 percent “*fistula creation*” patients will return for two “*maturation procedures.*”
- Of these patients, 66 percent will receive angioplasty and 9.6 percent will receive “*fistulagram.*”

Step 7: The applicant projects volume growth for Year 3 based on the 3.5 percent growth from Year 2. The applicant projects “*fistulas*” will grow at 2.5 percent.

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

- The applicant’s utilization projections are based on the historical utilization of the existing Raleigh and Cary vascular access centers’ actual 2018 volume of cases expected to shift to RAC Surgery Center, LLC and the annual growth rate from 2016 to 2019 annualized.
- The applicant’s experience with regards to number and types of procedures that will be required for ESRD patients.

Access

In Project ID#J-11551-18, the applicant adequately demonstrated the projected payor mix for the second full fiscal year and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.
- The applicant adequately explains the need to change the scope of the previously approved application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately 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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose the reduction, elimination, or relocation of 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.

CA

In Section E, pages 33-34, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Develop a New ESRD-Focused ASC as Proposed in Project ID#J-11551-18-The applicant states that this was not a cost-effective alternative due to the increase in construction costs. The applicant states that the proposed project will no longer meet the needs of its patient population.

Develop a New ESRD-Focused ASC on the Second Floor with 1 OR and 2 procedure rooms-The applicant states this is not the most cost-effective alternative because it would require additional expenditures in the future to convert the space into a procedure room and would disrupt care during renovations.

Develop a New ESRD-Focused ASC on the Second Floor with 1 OR and 3 procedure rooms-The applicant states the proposed project is the most effective alternative because it allows the applicant to renovate without interrupting services, meet the need of the growing patient population, and avoids additional costs to renovate the space in the future.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

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 reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall materially comply with the representations in this application and the representations in Project ID#J-11551-18. Where representations conflict, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall materially comply with the last made representation.**
- 2. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall develop no more than one operating room and three procedure rooms upon completion of this project and Project J-11551-18 (Develop a new ambulatory surgical facility in Raleigh with one operating room and two procedure rooms focused on vascular access procedures for patients with end stage renal disease).**
- 3. Upon completion of the project, RAC Surgery Center, LLC shall be licensed for no more than three procedure rooms.**
- 4. The total combined capital expenditure for both projects is \$3,792,511, an increase of \$1,792,511 over the capital expenditure of \$2,000,000 previously approved in Project ID# J-11551-18.**
- 5. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 7. For the first three years of operation following completion of the project, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 8. The procedure room 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, RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

- a. Payor mix for the services authorized in this certificate of need.**
- b. Utilization of the services authorized in this certificate of need.**
- c. Revenues and operating costs for the services authorized in this certificate of need.**
- d. Average gross revenue per unit of service.**
- e. Average net revenue per unit of service.**
- f. Average operating cost per unit of service.**

11. RAC Surgery Center, LLC and Fresenius Vascular Care Raleigh MSO, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

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

C

The applicant proposes a change of scope and cost overrun for Project ID#J-11551-18 (Develop a new ASF with one OR and two procedure rooms).

The applicant projects that the total capital cost to develop a new ambulatory surgical facility with one operating room and three procedure rooms will be \$3,792,511, an increase of \$1,792,511 over the previous approved capital expenditures, which exceeds the 115 percent statutory limit for capital expenditures. The applicant states the increase in capital cost is due to the increased construction costs for the additional procedure room. The following table compares the previously approved capital cost and the proposed capital cost, as reported on Form F.1b in Section Q.

RAC Surgery Center, LLC – Previously Approved and Proposed Capital Cost			
	Previously Approved Cost (J-11551-18)	New total Costs Projected (J-11904-19)	Difference
Site Preparation	\$350,000	\$855,447	\$505,447
Construction/Renovation Contract(s)	\$875,443	\$1,852,053	\$976,610
Architect/Engineering Fees	\$80,000	\$120,000	\$40,000
Furniture	\$25,000	\$0	\$102,000
Consultant Fees	\$45,000	\$65,000	\$20,000
Other	\$449,557	\$598,011	\$148,454
Total Capital Costs	\$2,000,000	\$3,792,511	\$1,792,511

In Section C, pages 28-29, the applicant provides information to explain the need for the projected increase in capital expenditures.

In Section F, pages 41-42, the applicant projects that start-up costs will be \$0 and initial operating expenses will be \$1,907,489 for a total working capital of \$1,907,489. On page 42, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 40, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing			
Type	RAC Surgery Center, LLC	Fresenius Vascular Care Raleigh MSO, LLC	Total
Loans	\$0	\$3,792,511	\$3,792,511
Accumulated reserves or OE *	\$0	\$0	\$0
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing	\$0	\$3,792,511	\$3,792,511

*OE = Owner's Equity

In Section F, page 42, the applicant states that the working capital needs of the project will be funded by National Medical Care, Inc., which is a wholly-owned affiliate of Fresenius Medical Care (FMC), the applicant's parent corporation, as shown in the table below.

Sources of Financing for Working Capital by Fresenius Vascular Care Raleigh MSO, LLC		Amount
(a)	Loans	\$1,907,489
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$1,907,489

In Section F.2, page 40, the applicant states that the \$3,792,511 in projected capital costs for the proposed ambulatory surgical facility will be funded by a line of credit from National Medical Care, Inc. Exhibit F-5.1 contains a letter from the Senior Vice President and Treasurer for National Medical Care, Inc. stating that a loan will be made available to Fresenius Vascular Care Raleigh MSO, LLC for the capital cost and working capital of the project. Exhibit F-5.3, page 156, contains the 2018 Annual Report for Fresenius Medical Care which indicates FMC had over \$2 billion in cash and cash equivalents as of December 31, 2018.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, page 69, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

RAC Surgery Center, LLC	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Surgical Cases	1,558	1,814	1,875
Total Gross Revenues (Charges)	\$47,637,239	\$53,853,741	\$55,164,263
Total Net Revenue	\$15,980,624	\$18,066,042	\$18,505,677
Average Net Revenue per Case	\$10,257.14	\$9,959.23	\$9,869.69
Total Operating Expenses (Costs)	\$8,779,951	\$9,437,809	\$9,640,878
Average Operating Expense per Case	\$5,635.40	\$5,202.76	\$5,141.80
Net Income	\$7,200,683	\$8,628,233	\$8,864,799

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

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

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

- (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

The applicant proposes a change of scope and cost overrun for Project ID#J-11551-18 (Develop a new ASF with one OR and two procedure rooms).

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

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

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

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

Source: 2019 SMFP

^Underutilized facility, excluded from need determination calculations.

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

As the table above indicates, as of FY2017, there were five existing or approved hospitals and ten existing or approved ambulatory surgery facilities in Wake County with a total of 13 inpatient, 31 ambulatory and 68 shared operating rooms. Also, pursuant to the need

determination for six additional operating rooms for the Wake County service area in the 2018 SMFP, the following applications were approved:

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

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

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

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

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

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

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

In Project ID#J-11551-18, the applicant adequately demonstrated that the project would not result in unnecessary duplication of existing or approved services in the service area and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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 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

In Section H, page 48, the applicant states its projected staffing has changed from what was proposed as part of Project ID# J-11551-18 due to the growth in procedures beyond what was projected in the previous application and the additional procedure room. The total projected FTEs in the second full fiscal year of operation increased from 17.5 to 20.6. In Section Q, page 74, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff (J-11551-18)	Projected FTE Staff (J-11904-19)
	2nd Full Fiscal Year 1/1/2021-12/31/2021	2nd Full Fiscal Year 10/1/2021-9/30/2022
CRNAs	0.0	0.4
Registered Nurses	8.0	9.0
Surgical Technicians	0.0	1.2
Radiology Technologists	4.0	4.0
Administrator	3.0	2.0
Director of Nursing	1.0	1.0
Marketing	1.0	1.0
Center Manager	0.5	1.0
Procedure Tech/MA	0.0	1.0
TOTAL	17.5	20.6

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q.

In Project ID# J-11551-18, the applicant adequately described the methods to be used to recruit or fill new positions and its proposed training and continuing education programs and no changes are proposed in this application which affect that determination.

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 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

In Section I, page 49, the applicant states that no parts of Section I differs from the original application.

Project ID# J-11551-18 was found conforming to this criterion and no changes are proposed in this application which affect that determination.

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 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

The applicant does 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 applicant does 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. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not 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

In Section K, page 53, the applicant states that the project involves up fitting 10,370 square feet of leased space. Line drawings are provided in Exhibit K-8. The applicant states that this expands the available square footage from 6,488 square feet to 10,370, as proposed in Project ID# J-11551-18.

Project ID# J-11551-18 was found conforming to this criterion and no changes are proposed in this application which affect that determination.

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.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

Neither the applicant or any related entity own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

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

NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

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

C

In Project ID# J-11551-18, the applicant projected the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating and Procedure Room Services as Percent of Total
Self-Pay	1.4%
Charity Care	1.0%
Medicare*	56.9%
Medicaid*	6.1%
Insurance*	34.7%
Total	100.0%

Source: Section L, page 56

*Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.4% of total services will be provided to self-pay patients, 1.0% to charity care patients, 56.9% to Medicare patients and 6.1% to Medicaid patients.

In Project ID# J-11551-18, the application was conforming to this Criterion, and the applicant proposes no changes in this application which affect that determination.

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.

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

C

In Project ID# J-11551-18, the application was conforming to this Criterion, and the applicant proposes no changes in this application which affect that determination.

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.

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

C

In Project ID# J-11551-18, the application was conforming to this Criterion and the applicant proposes no changes in the current application which would affect that determination.

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.

- (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

The applicant proposes a change of scope and cost overrun for Project ID#J-11551-18 (Develop a new ASF with one OR and two procedure rooms).

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

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

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

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

Source: 2019 SMFP

^Underutilized facility, excluded from need determination calculations.

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

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

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

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

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

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

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

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

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

In Project ID# J-11551-18, the application was conforming to this Criterion, and the applicant proposes no changes in this application which affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 reasons stated above.

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

NA

In Section O, page 60, the applicant states neither they nor any related entities owns, operates or manages an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

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

demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

In Project ID# J-11551-18, the application was conforming to Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2103, and the applicant proposes no changes in the current application which would affect that determination. The applicant does not propose any other changes in this application which would make any other Criteria and Standards applicable to this review. Therefore, the application is conforming with this criterion.