ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	September 27, 2016
Findings Date:	September 27, 2016
Project Analyst:	Gregory F. Yakaboski
Assistant Chief:	Martha J. Frisone
Project ID #:	J-11161-16
Facility:	Raleigh Orthopaedic Surgery Center- West Cary
FID #:	160151
County:	Wake
Applicants:	Rex Orthopaedic Ventures, LLC Rex Hospital Inc. ASC JV LLC Group I Ventures Panther Creek LLC Orthopaedic Surgery Center of Raleigh LLC
Project:	Develop a single-specialty ambulatory surgical facility by relocating one existing operating room from Raleigh Orthopaedic Surgery Center and developing two new procedure rooms

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC (collectively "the applicants") propose to develop a new, free-standing single-specialty ambulatory surgical (AMSU) facility to be known as Raleigh Orthopaedic Surgery Center-West Cary (ROSC-West Cary) in Cary by relocating one operating room (OR) from Raleigh Orthopaedic Surgery Center (ROSC), an existing AMSU, and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms. Orthopaedic

Surgery Center of Raleigh LLC (Lessee) will be the operating entity of ROSC-West Cary and is owned by ASC JV LLC and Rex Orthopedic Ventures (whose owner is Rex Hospital). Rex Hospital, Inc. is also the current owner of the land. Orthopaedic Surgery Center of Raleigh LLC is the operating entity that developed and operates ROSC. Group I Ventures Panther Creek LLC is the lessor of the building and land. Rex Hospital Inc. will manage the proposed AMSU which will be located at the intersection of Highway 55 and McCrimmon Parkway.

Need Determination

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 2016 SMFP.

Policies

There is one policy applicable to this review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES 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 are required to submit a plan for 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."*

In Section III.4, pages 37-39, the applicants provide a written statement describing the proposed project's plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant demonstrates that its proposal is conforming to all applicable policies in the 2016 SMFP. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

The applicants proposed to develop a new, free-standing single-specialty AMSU facility in Cary to be known as ROSC-West Cary by relocating one existing OR from ROSC and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms.

Population to be Served

On page 62, the 2016 SMFP defines the service area for ORs as *"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* [on page 67]*."* Figure 6-1 shows Wake County as a single county OR service area. Thus, the service area for this proposal is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section III.6, page 41, the applicants provide the projected patient origin for the relocated OR during the first two operating years (OY) following completion of the project, as shown in the table below.

ROSC-West Cary Operating Room
Projected Patient Origin

County	OY 1	OY 2	%
Wake	791	823	75.37%
Johnston	83	87	7.94%
Harnett	43	45	4.10%
Franklin	20	21	1.93%
Durham	12	13	1.16%
Wayne	11	11	1.02%
Sampson	10	10	0.93%
Nash	8	8	0.77%
Wilson	7	8	0.71%
Lee	7	7	0.62%
Cumberland	5	6	0.52%
Orange	4	5	0.42%
Granville	4	4	0.37%
Chatham	3	3	0.31%
Alamance	1	2	0.14%
Other*	39	40	3.69%
Totals	1,050	1,092	100.00%

*Other includes Bladen, Brunswick, Carteret, Craven, Dare, Duplin, Edgecombe, Forsyth, Guilford, Halifax, Hertford, Hoke, Hyde, Iredell, Mecklenburg, Montgomery, Moore, New Hanover, Northampton, Onslow, Pender, Person, Pitt, Randolph, Richmond, Roberson, Scotland, Vance, Wilkes, Wilson and other counties.

In Section III.6, page 141, the applicants provide the projected patient origin for the two procedure rooms during OYs 1 and 2, as shown in the table below.

ROSC-West Cary Procedure Rooms
Projected Patient Origin

County	OY 1	OY 2	%
Wake	99	104	75.37%
Johnston	10	11	7.94%
Harnett	5	6	4.10%
Franklin	3	3	1.93%
Durham	2	2	1.16%
Wayne	1	1	1.02%
Sampson	1	1	0.93%
Nash	1	1	0.77%
Wilson	1	1	0.71%
Lee	1	1	0.62%
Cumberland	1	1	0.52%
Orange	1	1	0.42%
Granville	0	1	0.37%
Chatham	0	0	0.31%
Alamance	0	0	0.14%
Other*	5	5	3.69%
Totals	132	138	100.00%

*Other includes Bladen, Brunswick, Carteret, Craven, Dare, Duplin, Edgecombe, Forsyth, Guilford, Halifax, Hertford, Hoke, Hyde, Iredell, Mecklenburg, Montgomery, Moore, New Hanover, Northampton, Onslow, Pender, Person, Pitt, Randolph, Richmond, Roberson, Scotland, Vance, Wilkes, Wilson and other counties.

On page 41, the applicants provide the assumptions and methodology used to project patient origin for both the OR and the procedure rooms, as follows:

> *"The patient origin percentages for the proposed ROSC-WC facility with one operating room for Years 1 and 2 (2018 and 2019) are assumed to be the same as the historical 2015 patient origin for the Raleigh Orthopaedic Clinic Cary office because this is the closest office location in Wake County with historical data. Many patients from Wake and nearby counties who have utilized the Raleigh Orthopaedic Clinic Cary office are likely to have future need for ambulatory surgical procedures. Therefore, it is reasonable to assume that the patient origin for the proposed ROSC-WC facility would be very similar. The patient origin percentages for procedure room cases are based on the same patient origin percentages as the projected OR cases for the ROSC-WC facility."*

The applicants adequately identify the population to be served.

Analysis of Need

In Section III, pages 18-34, and referenced exhibits, the applicants discuss eight factors which they state support the need to relocate an existing OR and develop two new procedure rooms in West Cary. The eight factors are listed below along with the pages where each factor is discussed in the application:

- *Responding to the growth in the population in western Wake County* (Pages 18-19)
- *Reacting to trends in ambulatory surgery center (ASC) utilization* (Pages 19-20)
- *Expanding access to a new ASC that provides cost effective surgical services* (Pages 22-23, 28)
- *Relocating an existing operating room to a new freestanding facility where it can be highly utilized in combination with procedure rooms* (Page 28)
- *Increasing patient choice through the development of a new single specialty ASC* (Page 28)
- *Supporting physician productivity* (Pages 28-29)
- *Enhancing physicians' practice growth and physician recruitment* (Page 29)
- *Providing operating room and procedure room capacity based on projected utilization for the numbers of participating surgeons* (Pages 30-34)

In Section III, page 34, the applicants discuss why they believe there is a need for the two new procedure rooms.

In Section III, pages 35-37 and 47, the applicants discuss why they believe that the proposed AMSU is needed in West Cary and how the needs of the patients who will continue to use the three remaining ORs at ROSC will be met.

In Section III, page 44, the applicants discuss the alternatives considered and why the proposal was chosen.

In Section III, page 45, the applicants identify all providers of outpatient surgical services in the service area, which is Wake County.

The information provided by the applicants in the pages referenced above is reasonable and adequately supported.

Projected Utilization – Operating Rooms

In Section IV.1, page 49, the applicants provide projected utilization of the OR at ROSC-West Cary during the first three OYs [Calendar Years (CYs) 2018 – 2020], as illustrated in the table below:

ROSC-West Cary Operating Room

	OY 1 (CY 2018)	**OY 2 (CY 2019)**	**OY 3 (CY 2020)**
# of ORs	1	1	1
Total Cases	1,050	1,092	1,136

In Section III, pages 30-34, the applicants provide the assumptions and methodology used to project utilization, which are summarized below.

Step #1: The applicants provide both historical utilization and projected utilization for calendar years 2016 and 2017. The projected utilization for CY2016 and CY2017 are based on a 4% annual increase over the actual utilization data from the previous year. The applicants state the projected 4% annual increases are reasonable given that ROSC has additional surgeons projected to begin their practices in September 2016 and 2017 and also based on the fact that the most recent actual utilization shows an 18.77% increase over the previous year's utilization. (See application page 31)

Step #2: ROSC OR utilization is projected for CY2018 based on a four percent annual increase over projected utilization for CY2017 and a shift of 800 cases from ROSC to the proposed ROSC-West Cary. On page 31, the applicants state *"The assumption of 800 cases to be shifted from ROSC to ROSC-WC is based on the assumption that eight ROC physicians will shift an average of 100 cases per surgeon in 2018. This expected shift of cases is reasonable and conservative because currently there are 19 surgeons on staff at ROSC with an average annual OR utilization of 197 cases per physician. The eight ROC surgeons who will perform surgery cases at ROSC-WC include three current ROC physicians, three physicians who have committed to join ROC and begin practice in September 2016 plus two physicians to be recruited in 2017."* (See application page 31)

Step #3: The applicants project utilization for OY1 (CY2018) at ROSC-WC of 1,050 ambulatory cases based on the projected 800 OR cases shifted from ROSC

plus 250 OR cases to be performed by UNC orthopedic surgeons. On page 32, the applicants state *"The assumption that UNC orthopedic surgeons will perform 250 cases in the operating room at ROSC-WC is based on three surgeons performing an average of 83.33 cases per surgeon in 2018. This is a reasonable and conservative assumption because three full-time orthopedic surgeons work 56 hours per week on average and perform 31 procedures per month. Also, approximately 80 percent of all orthopedic surgery can be performed as outpatient surgery."* (See application page 32)

Step #4: Projected utilization for OY2 (2019) and OY3 (2020) for both ROSC and ROSC-West Cary is based on a 4% annual growth rate. The applicants state the utilization of a 4% growth rate is reasonable and supported based on the shift of an increasing percentage of orthopedic cases from hospitals to AMSUs, the newly recruited physicians and the growth and aging of the population. (See application page 32) Projected utilization is illustrated in the following table.

ROSC Operating Rooms

	2012-2013	**2013-2014**	**2014-2015**	**2016**	**2017**	**2018**	**2019**	**2020**
# of ambulatory ORs	4	4	4	4	4	3	3	3
# of ambulatory surgery cases	411	3,148	3,739	3,889	4,044	3,406	3,542	3,684
Annual % increase							4.0%	4.0%
Cases shifted from ROSC to ROSC-West Cary						800	-na-	-na-

ROSC-West Cary Operating Room

	2012-2013	**2013-2014**	**2014-2015**	**2016**	**2017**	**2018**	**2019**	**2020**
# of ambulatory ORs						1	1	1
ROC Surgeons OR cases (shifted in 2018 only)						800	832	865
UNC Surgeons OR cases						250	260	270
# of ambulatory surgery cases						1,050	1,092	1,136
Annual % increase						-na-	4.00%	4.00%

Step #5: Utilization rates were calculated for both ROSC and ROSC-West Cary. On page 33, the applicants state that these rates are *"based on the SMFP assumptions that each OR is staffed and available nine hours per day and five days per week and utilized at least 80 percent of the available time. These assumptions provide 1,872 for the "standard number of hours per operating room per year. ... Raleigh Orthopaedic Surgery Center intends to continue to staff and schedule the use of its operating rooms nine hours per day five days per week, for at least 260 days per year for greater than 80 percent of the available time in order to accommodate the high utilization. One of the ways that this is accomplished is that the staff all work together as a team to*

minimize operating room turnover times between cases." (See application page 33)

ROSC Operating Rooms

	Calendar Year Projections				
	2016	**2017**	**2018**	**2019**	**2020**
# of ambulatory ORs	4	4	3	3	3
# of ambulatory surgery cases	3,889	4,044	3,406	3,542	3,684
Annual hours based on 1.5 hrs/procedure	5,833	6,066	5,109	5,313	5,526
1872 hrs x # of ORs	7,488	7,488	5,616	5,616	5,616
Utilization Rate	77.90%	81.01%	90.97%	94.61%	98.39%

ROSC-West Cary Operating Room

	Calendar Year Projections				
	2016	**2017**	**2018**	**2019**	**2020**
# of ambulatory ORs			1	1	1
ROC surgeons OR cases			800	832	865
UNC surgeons OR cases			250	260	270
# of ambulatory surgery cases			1,050	1,092	1,136
Annual hours based on 1.5 hrs/procedure			1,575	1,638	1,704
1872 hrs x # of ORs			1,872	1,872	1,872
Utilization Rate			84.13%	87.50%	91.00%

Step #6 Calculate the number of ORs needed at both ROSC and ROSC-West Cary. (See application page 34.)

	OY1 (2018)	**OY2 (2019)**	**OY3 (2020)**
ROSC			
# of ambulatory surgery cases	3,406	3,542	3,684
Annual hours based on 1.5 hrs/ procedure	5,109	5,313	5,526
Divided by 1,872	2.73	2.84	2.95
# of ORs needed whole number >0.5	3	3	3
ROSC- West Cary			
# of ambulatory surgery cases	1,050	1,092	1,136
Annual hours based on 1.5 hrs/ procedure	1,575	1,638	1,704
Divided by 1,872	0.84	0.88	0.91
# of ORs needed whole number >0.5	1	1	1

In Section IV, page 49, the applicants provide historical and projected utilization for the ORs at both ROSC and the proposed ROSC-West Cary, as illustrated in the table below.

	10/1/13-9/30/14	10/1/14-9/30/15	CY 2016** (Projected)	CY 2017 (Projected)	OY 1 (CY 2018) (Projected)	OY 2 (CY 2019) (Projected)	OY 3 (CY 2020) (Projected)
ROSC							
# of ORs	4	4	4	4	3	3	3
OP Cases	3,148	3,739	3,889	4,044	3,406	3,542	3,684
ROSC-West Cary							
# of ORs	0	0	0	0	1	1	1
OP Cases	0	0	0	0	1,050***	1,092	1,136
Total ORs	4	4	4	4	4	4	4
Total OP Cases	3,148	3,739	3,889	4,044	4,456	4,634	4,820
Difference	-na-	591	150	155	412	178	186
% change in total OP cases	-na-	18.77%	4.0%	4.0%	10.2%	4.0%	4.0%

As shown in the table above, in OY 3 (CY 2020), the applicants project that 1,135.7 outpatient surgical cases will be performed in the one OR at the proposed ROSC-West Cary, which documents a need for one OR consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	1135.7	1703.5	0.9	1.0

Furthermore, in CY2020, the third project year following completion of the proposed project, the applicants project that a total of 4,820 surgical cases will be performed at ROSC and ROSC-West Cary combined. In FFY2015, 3,739 surgical cases were performed at ROSC. Over that approximate five year period of time, the applicants are projecting an average overall increase of 216 cases per year (4,820-3,739 = 1,081/ 5 years = 216 cases per year). On page 31, the applicants state that three new physicians have committed to join ROC and begin practice in September 2016 and two additional physicians are being recruited in 2017 for a total of five new physicians by the end of 2017. The applicants state that currently, the average OR utilization per physician is 197 cases per year. Thus, the applicants expect to add five new physicians and project 216 additional surgical cases per year for an average of 43 surgical cases per year per new physician (216 cases / 5 physicians = 43). This analysis assumes all new cases are performed by the new physicians. The existing surgeons could also increase their cases.

Projected utilization is based on reasonable and adequately supported assumptions.

Projected Utilization – Procedure Room

In Section IV.1, page 49, the applicants provide projected utilization of the two proposed procedure rooms during the first three operating years, as illustrated in the table below:

Procedure Room

	OY 1 (CY 2018)	OY 2 (CY 2019)	OY 3 (CY 2020)
# of Procedure Rooms	2	2	2
Total Procedure Room Cases	132	138	143

The applicants project the number of cases to be performed in the two procedure rooms based on the 2015 ratio of OR cases to procedure room cases at ROSC. (See application page 34)

Based on review and analysis of: 1) the information provided by the applicants in Section III, pages 18-34, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicants' response to the comments received at the public hearing, the applicants adequately document the need to relocate one existing outpatient OR from ROSC to the proposed ROSC-West Cary facility, which will be licensed as an AMSU.

Access

In Section VI, pages 54-55, the applicants state *"The facility will not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability or ability to pay. ... no patient will be denied care or treatment due to an inability to pay. Raleigh Orthopaedic Surgery Center- West Cary will accept charity care referrals as documented in Exhibits 21 and 25."*

In Section VI.6, page 53, the applicants outline specific strategies to ensure access to its services by indigent and other medically underserved persons, especially those who do not have access to physician services. These strategies include:

- Having written to multiple community agencies and documented its commitment to provide charity care.
- Provision of translator services, patient education information in multiple languages and staff who speak Spanish.
- Stated willingness to accept charity care/ indigent referrals from community physicians, community agencies and area hospitals.
- Intensive marketing and community education regarding the benefits of orthopaedic ambulatory surgery.

In Section VI.14, pages 58, the applicants provide the projected payor mix for the OR at the proposed ROSC-West Cary facility during Operating Year Two (CY 2019), as shown in the following table:

Raleigh Orthopaedic Surgery Center Payor Mix CY 2019 (1/1/19-12/31/19)	
Payor	**Cases as % of Total Cases**
Self-Pay / Indigent	0.57%
Medicare / Medicare Managed Care	18.44%
Medicaid	3.00%
Commercial Insurance	65.84%
Other (Workers Comp, TriCare)	12.16%
Total	100.00%

As shown in the table above, the applicants project that 18.44% of all cases will be covered by Medicare and 3.0% of all the cases will be covered by Medicaid. On page 59, the applicants state that the projected 3.0% Medicaid projection is based on increased access for Medicaid patients and the projection that both ROSC-West Cary and ROSC will be approved and enrolled as Medicaid providers in North Carolina. Currently, as shown on page 58 of the application, the existing ROSC facility Medicaid payor mix for October 1, 2014 to September 30, 2015 was 0.00%. Upon completion of the proposed project the existing ROSC facility is projecting 3.0% of all OR and procedure room cases will be covered Medicaid.

The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants identify the population to be served, adequately demonstrate the need that this population has for the proposed project and adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

The applicants proposed to develop a new, free-standing single-specialty AMSU facility in Cary to be known as ROSC-West Cary by relocating one OR from the existing ROSC facility and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms.

According to Table 6A, on page 77 of the 2016 SMFP, there are 111 ORs in Wake County. The total number of ORs (111) will not increase as a result of this proposal, the only change will where one of the existing ORs is located within Wake County.

ROSC is currently licensed for four dedicated outpatient ORs. The proposed ROSC-West Cary facility will be located approximately 14 miles from ROSC. Main traffic corridors, connect the proposed facility and existing facilty. The proposed ROSC-West Cary facility will be located in the same Operating Room Service Area as ROSC (Wake County).

In Section III, page 34, the applicants provide projected utilization at CMH, as illustrated in the tables below.

	OY1 (2018)	OY2 (2019)	OY3 (2020)
ROSC			
# of ambulatory surgery cases	3,406	3,542	3,684
Annual hours based on 1.5 hrs/ procedure	5,109	5,313	5,526
Divided by 1872	2.73	2.84	2.95
# of ORs needed whole number >0.5	3	3	3

As shown in the tables above, the applicants project that the three remaining dedicated outpatient ORs at ROSC will provide adequate capacity to meet projected utilization.

In Section VI.6, page 55, the applicants outline specific strategies to ensure access to its services by indigent and other medically underserved persons, especially those who do not have access to physician services. These strategies include:

- Having written to multiple community agencies and documented its commitment to provide charity care.
- Provision of translator services, patient education information in multiple languages and staff who speak Spanish.
- Stated willingness to accept charity care/ indigent referrals from community physicians, community agencies and area hospitals.
- Intensive marketing and community education regarding the benefits of orthopaedic ambulatory surgery.

In Section III.3, page 37, that applicants state that:

- Medically underserved patients will have access to both facilities in accordance with the same business office and charity care policies.
- The scope of services offered at ROSC and ROSC-West Cary will be very similar.
- ROSC and ROSC-West Cary will both serve all payor categories of patients.
- Patient charges at both ROSC and ROSC-West Cary will be the same.
- The cost to the patient, for the same outpatient surgical procedure will be the same

In addition, currently ROSC is not certified for Medicaid as a payor source. As part of the proposed project, both ROSC and ROSC-West Cary will become approved and enrolled Medicaid providers and the applicants project that Medicaid will be the payor source for 3.0% of the OR and procedure room cases for both ROSC-West Cary and ROSC. (See application pages 58-59)

ROSC is an existing AMSU. ROSC-West Cary will be an AMSU. Both will be located in Wake County and both are owned, in whole or in part by the same legal entities. The same physician practice will utilize both facilities. Therefore, it is reasonable to conclude that both facilities will provide similar access to underserved groups.

The applicants demonstrate that the needs of the population presently served will be adequately met and that the proposal will not adversely affect the ability of medically underserved groups to obtain needed health care. Therefore, the application is conforming to this criterion.

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

CA

The applicants propose to develop a new, free-standing single-specialty AMSU facility in Cary to be known as ROSC-West Cary by relocating one OR from ROSC and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms.

According to Table 6A, on page 77 of the 2016 SMFP, there are 111 ORs in Wake County. The total number of ORs (111) will not increase as a result of this proposal, the only change will be where one of the ORs is located within Wake County.

In Section III.8, pages 128-133, the applicants describe the alternatives considered, which included maintaining the status quo, relocating two ORs or the proposed project. The applicants discuss the limitations of the current capacity at ROSC, ambulatory surgery volume projections at ROSC and the inefficiencies of keeping all four existing ORs at ROSC in terms of scheduling options and projected growth in volume.

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

The applicants adequately demonstrate that the proposed alternative is the most effective or least costly alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC shall materially comply with all representations made in the certificate of need application.**

2. **Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need**

3. **Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC shall construct a single specialty ambulatory surgical facility licensed for no more than one operating room.**

4. **Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC shall meet all criteria to receive accreditation of the ambulatory surgical facility from JCAHO, AAAHC or a comparable accreditation authority within two years following completion of the facility.**

5. **Upon licensure of ROSC-West Cary Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC shall take the steps necessary to delicense one operating room at ROSC such that ROSC shall be licensed for no more than three operating rooms.**

6. **Procedures performed in the minor procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the hospital's license renewal application as procedures performed in an operating room.**

7. **Rex Orthopaedic Ventures, LLC, Rex Hospital Inc., ASC JV LLC, Group I Ventures Panther Creek LLC and Orthopaedic Surgery Center of Raleigh LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

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

The applicants propose to develop a new, free-standing single-specialty AMSU facility in Cary to be known as ROSC-West Cary by relocating one OR from the existing ROSC facility and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms.

According to Table 6A, on page 77 of the 2016 SMFP, there are 111 ORs in Wake County. The total number of ORs (111) will not increase as a result of this proposal, the only change will where one of the ORs is located within Wake County.

Capital and Working Capital Costs

In Section VIII.1, page 165, the applicants project the total capital cost of the project will be $9,521,498, which includes:

Orthopaedic Surgery Center of Raleigh LLC (lessee and operating entity)

Fixed Equipment Purchase/Lease	$ 79,569
Movable Equipment Purchase/Lease	$1,480,807
Furniture	$ 150,000
Financing Costs	$ 10,000
Other (Project Contingency)	$ 190,000
Total:	$1,909,656

Group I Ventures Panther Creek, LLC (Lessor)

Site Costs- Land Purchase	$1,584,000
Site Preparation Costs	$ 542,500
Shell Building Construction Contract	$2,923,142
ASC Interior Upfit	$1,641,200
Architect/Engineering Fees	$ 411,000
Financing Costs	$ 10,000
Contingency for Interest and Other	$ 500,000
Total	$7,611,842

According to the applicants, the combined capital cost is $9,521,498 ($1,909,656 + $7,611,842 = $9,521,498). However, the correct total is $9,522,218, a difference of only $720.

In Section IX.1-3, page 77, the applicants project the total working capital costs (start-up and initial operating expenses) will be $480,000.

Availability of Funds

In Section VIII.3, page 73, the applicants state that Orthopaedic Surgery Center of Raleigh LLC's portion of the capital cost of the proposed project will be financed by a conventional loan and that Group I Ventures Panther Creek, LLC's portion of the capital cost of the proposed project will also be financed by a conventional loan. In Section IX, page 77, the applicants state that the working capital costs of the proposed project will be financed by a line of credit.

In Exhibit 31, the applicants provide a letter from Stephen Covil, Senior Vice President of First Citizens Bank which states First Citizens Bank is committed to provide financing to Orthopaedic Surgery Center of Raleigh, in the amount of $1,909,656, to develop a new AMSU with one operating room and two new procedure rooms in Cary.

In Exhibit 32, the applicants provide a letter from Stephen Covil, Senior Vice President of First Citizens Bank which states First Citizens Bank is committed to provide financing to Group I Ventures Panther Creek, LLC, in the amount of $7,611,842, to purchase the land and construct a new AMSU in Cary.

In Exhibit 37, the applicants provide a letter from Stephen Covil, Senior Vice President of First Citizens Bank which states First Citizens Bank is committed to provide financing to Orthopaedic Surgery Center of Raleigh, LLC, in the amount of $480,000, to cover the projected capital cost and working capital costs of the proposed AMSU in Cary.

The applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project, including the $720 for the capital cost. There is a contingency of $500,000 included in the total capital cost as calculated by the applicants.

Financial Feasibility

In the projected revenue and expense statement (Forms B and C), the applicants project revenues will exceed operating expenses in each of the first three operating years following completion of the proposed project, as shown in the table below.

	OY 1 (CY 2018)	OY 2 (CY 2019)	OY 3 (CY 2020)
Total Gross Revenue	$20,050,342	$21,479,881	$23,014,164
Total Net Revenue	$6,047,664	$6,478,848	$6,941,624
Total Expenses	$3,939,952	$4,064,389	$4,200,480
Net Income	$2,107,712	$2,414,459	$2,741,144

In the Gross Revenue Worksheets (Form D) and the Net Revenue Worksheets (Form E), the applicants project the average gross and net revenues during the first three operating years following completion of the proposed project. The projections for the third operating year are shown in the table below.

OY 3 (CY 2020)	ORs	Procedure Room	Combined
Average Gross Revenue Per Case (All Payors)	$19,907	$2,797	$22,704
Average Net Revenue Per Case (Self Pay/Indigent/Charity)	$1,991	$280	$2,271
Average Net Revenue Per Case (Medicare/Medicare Managed Care)	$2,886	$406	$3,292
Average Net Revenue Per Case (Medicaid)	$3,298	$463	$3,761
Average Net Revenue Per Case (Commercial and Managed Care)	$6,877	$966	$7,843
Average Net Revenue Per Case (Workers Comp, VA & Other Gov't)	$6,876	$966	$7,842
Average Net Revenue Per Case (All Payors Combined)	$6,006	$844	$6,850

The assumptions used by the applicants in preparation of the pro formas are reasonable including projected utilization, costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicants propose to develop a new, free-standing single-specialty AMSU facility in Cary to be known as ROSC-West Cary by relocating one OR from the existing ROSC facility and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms.

On page 62, the 2016 SMFP defines the service area for ORs as *"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* [on page 67]*."* Figure 6-1 shows Wake County as a single county OR service area. Thus, the service area for this proposal is Wake County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 77 of the 2016 SMFP, there are 111 existing or approved ORs in Wake County, as shown in the following table.

	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
Holly Springs Surgery Center	0	0	0	3	3
Rex Surgery Center of Wakefield	0	0	0	3	3
Rex Hospital Holly Springs	0	0	0	3	3
Blue Ridge Surgery Center	0	6	0	0	6
Raleigh Plastic Surgery Center	0	1	0	0	1
Southern Eye Associates Ophthalmic Surgery Center (Closed)	0	2	0	<-2>	0
Rex Surgery Center of Cary, LLC	0	4	0	0	4
Capital City Surgery Center	0	6	0	2	8
Triangle Orthopaedics Surgery Center	0	2	0	0	2
Raleigh Orthopaedic Surgery Center	0	4	0	0	4
Rex Hospital	3	3	24	<-6>	24
Wake Med	7	4	16	0	27
Duke Raleigh Hospital	0	0	15	0	15
Wake Med Cary Hospital	2	0	9	0	11
Total*	12	32	64	3	111

*Does not include CON adjustments for C-Section ORs.

The total number of ORs (111) will not increase as a result of this proposal, the only change will be where one of the ORs is located within Wake County.

The applicants adequately demonstrate the necessity to relocate the one existing OR and develop two new procedure rooms to meet the needs of their current and projected patients. Thus, the applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved ORs in Wake County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.2, page 62, the applicants project staffing at the proposed facility in the second operating year, as illustrated in the following table:

ROSC-West Cary Proposed Staffing OY 2 (CY 2019)	
Position	**# of Full Time Equivalent (FTE) Positions**
Surgery Center Director	0.25
Clinical Coordinator	1.0
Registered Nurse (RN)	4.0
Surgical Technicians	1.5
Medical Records/Coder	0.5
All "non-health professionals"	1.0
TOTAL	**8.25**

As shown in the table above, the applicants project to employ 8.25 FTEs in the second operating year. In Section VII.3, page 63 and 66, the applicants state that staffing will be accomplished through advertising, staff referrals from related entities, recruitment of new graduates from nursing and surgical technologist training programs and contacts with other health professionals and institutions. Exhibit 27 contains a letter signed by G. Hadley Callaway, M.D., which expresses his commitment to serve as Medical Director for the proposed ROSC-West Cary facility.

Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in the pro forma financial statements.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed ambulatory surgical services. Therefore, the application is conforming to this criterion.

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

C

In Section II.1, page 9, the applicants identify the ancillary services that will be provided. Most of the ancillary services will be provided directly by ROSC-West Cary. In the chart on page 9 and in Section II.2(a), page 10, the applicants state that anesthesiology services will be provided by American Anesthesiology, laboratory and pharmacy consulting will be provided by Rex Hospitals, Inc., and pathology services will be provided by Rex Pathology Associates, PA. Exhibits 7 and 8 contain letters from these providers confirming their commitment to provide services to ROSC-West Cary. Exhibit 10 contains a sample transfer agreement with Rex Hospital, Inc. Exhibit 18 contains letters from physicians support letters from providers, expressing support for the proposed project and the type of ambulatory surgical cases they plan to perform at the proposed ROSC-West Cary facility. Exhibit 36 contains a draft

management services agreement with Rex Hospital, Inc. which includes Rex Hospital providing a surgery center director and certain clinical services. Exhibit 43 contains a draft of a surgery center services agreement between Orthopaedic Surgery Center of Raleigh, LLC and ROSC. In Section V.4, page 52, the application states that *"the applicants have established existing referral relationships through Raleigh Orthopaedic Clinic, Rex Hospital and UNC Hospitals. Please see the list of high volume external referral sources in Exhibit 23."* Exhibit 23 contains a list of referral sources.

The applicants adequately demonstrate that all necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

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

NA

(11) Repealed effective July 1, 1987.

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

C

The applicants propose to occupy 13,025 square feet of a new building to be constructed on a 3 acre portion of a 14.47 acre site located on at the intersection of Highway 55 and McCrimmon Parkway in Cary. In Section III, pages 38-39 and in XI.8, page 85, the applicants discuss the features and methods that will be used to maintain energy efficient operations and sustainability and contain costs of utilities. Exhibit 41 contains a letter from Douglas A. Kuhns, AIA LEED AP which provides cost estimates relating to site development, construction and professional fees for the proposed ROSC-West Cary facility which are consistent with the costs estimates found on page 72 of the application. In Section XI, page 83, the applicants state the *"the proposed ambulatory surgery center will occupy 13,025 S.F. of new construction. Additional shell space may be constructed for separate medial offices"* The development of physician offices is exempt from review.

The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the proposed construction project. Furthermore, the applicants adequately demonstrate that the proposed construction project would not unduly increase the costs and charges of providing ambulatory surgery services. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that applicable energy saving features have been incorporated into the construction plans. Therefore, 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;

C

ROSC West Cary does not yet exist. The dedicated outpatient OR to be relocated is on the license of ROSC. In Section VI.13, pages 58, the applicants provide the payor mix for ROSC during FFY 2015, as shown in the following table:

Raleigh Orthopaedic Surgery Center Payor Mix FFY 2014 (10/1/14-9/30/15)	
Payor	**Cases as % of Total Cases**
Self-Pay / Indigent	0.57%
Medicare / Medicare Managed Care	18.44%
Medicaid	0.00%
Commercial Insurance	68.84%
Other (Workers Comp, TriCare)	12.16%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

	Percent of Population					
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table, 2014 Estimate as of December 22, 2015.
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."*

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants demonstrate that the facility currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

In Section VI.11, page 57, the applicants state that ROSC has no obligation to provide uncompensated care. In Section VI.10, page 57, the applicants state that there have been no civil rights equal access complaints filed in the last five years. The application is conforming to this criterion.

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

C

In Section VI.14, pages 58, the applicants provide the projected payor mix for the OR at the proposed ROSC-West Cary facility during OY2 (CY 2019), as shown in the following table:

Raleigh Orthopaedic Surgery Center Payor Mix CY 2019 (1/1/19-12/31/19)	
Payor	**Cases as % of Total Cases**
Self-Pay / Indigent	0.57%
Medicare / Medicare Managed Care	18.44%
Medicaid	3.00%
Commercial Insurance	65.84%
Other (Workers Comp, TriCare)	12.16%
Total	100.00%

As shown in the table above, the applicants project that 18.44% of all cases will be covered by Medicare and 3.0% of all the cases will be covered by Medicaid. On page 59, the applicants state that the projected 3.0% Medicaid projection is based on increased access for Medicaid patients and the projection that both ROSC-West Cary and ROSC will be approved and enrolled as Medicaid providers in North Carolina. Currently, as shown on page 58 of the application, the existing ROSC facility Medicaid payor mix for October 1, 2014 to September 30, 2015 was 0.00%. Upon completion of the proposed project the existing ROSC facility is projecting 3.0% of all OR and procedure room cases will be covered by Medicaid.

The applicants demonstrate that medically underserved groups would have adequate access to the proposed ambulatory surgical services. Therefore, 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 Section VI.9, page 57, the applicants describe the range of means by which a person will have access to the proposed ROSC-West Cary. The information provided by the applicants is reasonable and adequately supports the determination 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 Section V.1, page 50, the applicants describe how the proposed AMSU will accommodate the clinical needs of area health professional training programs. They state:

"Raleigh Orthopaedic Surgery Center-West Cary will establish clinical training agreements with health professional training programs.

...

Access to the facility will be offered to the programs during normal hours of operation when registered nurses or other clinical staff are available for appropriate student supervision."

Exhibit 20 contains a letter from the Executive Director of the Raleigh Orthopaedic Surgery Center addressed to the Wake Technical Community College Dean of the Perry Health Sciences Campus offering the proposed AMSU as a clinical training site for nursing and surgical technologist students.

The information provided is reasonable and adequately supports a determination 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 applicants propose to develop a new, free-standing single-specialty AMSU facility in Cary to be known as ROSC-West Cary by relocating one OR from the existing ROSC facility and developing two new procedure rooms at the new AMSU. The project does not include any gastrointestinal (GI) endoscopy procedure rooms.

According to Table 6A, on page 77 of the 2016 SMFP, there are 111 ORs in Wake County. See table below. The total number of ORs (111) will not increase as a result of this proposal, the only change will be where one of the ORs is located within Wake County.

	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
Holly Springs Surgery Center	0	0	0	3	3
Rex Surgery Center of Wakefield	0	0	0	3	3
Rex Hospital Holly Springs	0	0	0	3	3
Blue Ridge Surgery Center	0	6	0	0	6
Raleigh Plastic Surgery Center	0	1	0	0	1
Southern Eye Associates Ophthalmic Surgery Center (Closed)	0	2	0	<-2>	0
Rex Surgery Center of Cary, LLC	0	4	0	0	4
Capital City Surgery Center	0	6	0	2	8
Triangle Orthopaedics Surgery Center	0	2	0	0	2
Raleigh Orthopaedic Surgery Center	0	4	0	0	4
Rex Hospital	3	3	24	<-6>	24
Wake Med	7	4	16	0	27
Duke Raleigh Hospital	0	0	15	0	15
Wake Med Cary Hospital	2	0	9	0	11
Total*	12	32	64	3	111

*Does not include CON adjustments for C-Section ORs.

On page 62, the 2016 SMFP defines the service area for ORs as *"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* [on page 67]*."* Figure 6-1 shows Wake County as a single county OR service area. Thus, the service area for this proposal is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section V.7, pages 52-53, the applicants discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicants adequately demonstrate that they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicants propose to develop a new, free-standing single-specialty ASC facility in Cary to be known as ROSC-West Cary by relocating one OR from the existing ROSC facility and developing two new procedure rooms at the new ASC. The project does not include any gastrointestinal (GI) endoscopy procedure rooms. In Section I, page 5, Orthopaedic Surgery Center of Raleigh, LLC d/b/a Raleigh Orthopaedic Surgery Center, states that it has no other licensed healthcare facilities in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision Orthopaedic Surgery Center of Raleigh, LLC d/b/a Raleigh Orthopaedic Surgery Center, was not found to be out of compliance with any Medicare conditions of participation. At this time, Orthopaedic Surgery Center of Raleigh, LLC d/b/a Raleigh Orthopaedic Surgery Center, is in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Orthopaedic Surgery Center of Raleigh, LLC d/b/a Raleigh Orthopaedic Surgery Center, the applicants 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.

(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

The Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

-C- In Section II.10, page 14, the applicants state that the projected utilization for the OR at ROSC-West Cary is *"based on the assumption that the operating rooms shall be considered to be available for use five days per week and 52 weeks a year."*

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

(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities

Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

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

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

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

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

-C- In Section II.10, page 15, the applicants state that the operating room service area for the proposed project is Wake County which has more than ten operating rooms. As shown in the table below, in OY 3 (CY 2020), the applicants project that 1,135.7 outpatient cases will be performed in the one OR at the proposed ROSC-West Cary, which documents a need for one OR consistent with this Rule.

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	1,135.7	1,703.5	0.9	1.0

The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

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

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

for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

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

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

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

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

-NA- The applicants do not propose to increase the number of ORs in the service area (Wake County).

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

-NA- The applicants are not proposing to develop an additional dedicated C-section OR.

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

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

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

-NA- The applicants are not proposing to convert a specialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

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

-C- In Section III, pages 18-34, the applicants document the assumptions and provide data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.