ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: August 25, 2017
Findings Date: August 25, 2017

Project Analyst: Gregory F. Yakaboski
Team Leader: Lisa Pittman

Project ID #: J-11336-17
Facility: Rex Hospital
FID #: 953429
County: Wake
Applicant: Rex Hospital, Inc.
Project: Acquire a 5th unit of fixed cardiac catheterization equipment

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

Rex Hospital, Inc., (UNC Rex or UNC Rex Healthcare), proposes to acquire a unit of fixed cardiac catheterization equipment to be located on the hospital campus pursuant to the need determination in the 2017 State Medical Facilities Plan (2017 SMFP) for a total of five units of fixed cardiac catheterization equipment upon project completion.

Need Determination

The 2017 SMFP includes a Need Determination for one unit of fixed cardiac catheterization equipment in the Wake County Cardiac Catheterization Service Area. UNC Rex does not propose to develop more units of fixed cardiac catheterization equipment than are determined to be needed in the 2017 SMFP for the Wake County Cardiac Catheterization Service Area. Therefore, the application is consistent with the need determination.

Policies

The following policy is applicable in this review:

- POLICY GEN-3: BASIC PRINCIPLES

POLICY GEN-3: BASIC PRINCIPLES states:

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

Policy GEN-3

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 26-29 and Section C, pages 41-44 and Exhibit O.1. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section B, pages 28-29 and Section C, pages 41-44 and 47-52. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section B, pages 28-29, Section C, pages 32-33 and 41-44. and the applicant's pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the fixed cardiac catheterization equipment need determination in the 2017 SMFP. The application is consistent with Policy GEN-3.

Conclusion

In summary, the application is conforming to the fixed cardiac catheterization equipment need determination in the 2017 SMFP for one unit of fixed cardiac catheterization equipment in the

Wake County Cardiac Catheterization Service Area, and Policy GEN-3. 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

UNC Rex proposes to acquire a unit of fixed cardiac catheterization equipment to be located on the hospital campus pursuant to the need determination in the 2017 SMFP for a total of five units of fixed cardiac catheterization equipment upon project completion.

Patient Origin

On page 171, the 2017 SMFP defines the service area for fixed cardiac catheterization equipment as *"A cardiac catheterization (fixed or shared) equipment's service area is the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county. Counties lacking a licensed acute care hospital are grouped with the single county where the largest proportion of patients received inpatient acute care services, as measured by acute inpatient days, unless two counties with licensed acute care hospitals each provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. In that case, the county lacking a licensed acute care hospital is grouped with both the counties which provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. The three most recent years of available acute care days patient origin data are combined and used to create the multicounty service areas. These data are updated and reviewed every three years, with the most recent update occurring in the North Carolina 2017 State Medical Facilities Plan" Figure* 5-1 shows Wake County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Wake County. Facilities may also serve residents of counties not include in their service area.

In Section C, page 34, the applicant provides a table showing the historical patient origin for cardiac catheterization for the last full fiscal year (Full FY) [7/1/15 to 6/30/16], as show in the table below:

Patient Origin for Cardiac Catheterization at UNC Rex: 7/1/15 to 6/30/16

County	# of Procedures	% of Total
Wake	2,379	42.6%
Sampson	548	9.8%
Johnston	512	9.2%
Wayne	376	6.7%
Harnett	314	5.6%
Franklin	261	4.7%
Wilson	230	4.1%
Granville	152	2.7%
Vance	150	2.7%
Nash	134	2.4%
Cumberland	44	0.8%
Warren	43	0.8%
Lee	30	0.5%
Durham	27	0.5%
Chatham	21	0.4%
Orange	5	0.1%
Person	5	0.1%
Alamance	4	0.1%
Caswell	1	0.0%
Other*	350	6.3%
Total	5,587	100.0%

Source: Table page 34

*Other includes Ashe, Beaufort, Bladen, Brunswick, Cabarrus, Carteret, Catawba, Chowan, Columbus, Craven, Dare, Duplin, Edgecombe, Forsyth, Greene, Guilford, Halifax, Henderson, Herford, Hyde, Jones, Lenoir, Mecklenburg, Moore, New Hanover, Northampton, Onslow, Pamlico, Pender, Pitt, Randolph, Robeson, Rockingham, Stokes, Union, and Wilkes counties in North Carolina, as well as other states.

In Section C, pages 35-36, the applicant identifies the origin of the patient population it proposes to serve during the first three years of operation following project completion, as illustrated in the table below:

Patient Origin for Cardiac Catheterization at UNC Rex: OY1 through OY3

County	OY1(7/1/18 to 6/30/19) # of Procedures	OY2(7/1/19 to 6/30/20) # of Procedures	OY3(7/1/20 to 6/30/21) # of Procedures	% of Total
Wake	2,264	2,282	2,299	42.6%
Sampson	522	526	530	9.8%
Johnston	488	492	495	9.2%
Wayne	358	361	364	6.7%
Harnett	299	302	304	5.6%
Franklin	248	250	252	4.7%
Wilson	219	221	223	4.1%
Granville	145	146	147	2.7%
Vance	142	144	145	2.7%
Nash	128	129	130	2.4%
Cumberland	42	42	42	0.8%
Warren	41	41	42	0.8%
Lee	28	28	29	0.5%
Durham	26	26	26	0.5%
Chatham	20	20	20	0.4%
Orange	5	5	5	0.1%
Person	5	5	5	0.1%
Alamance	3	3	3	0.1%
Caswell	1	1	1	0.0%
Other*	333	336	339	6.3%
Total	5,318	5,359	5,401	100.0%

Source: Table pages 35-36.
*Other includes Ashe, Beaufort, Bladen, Brunswick, Cabarrus, Carteret, Catawba, Chowan, Columbus, Craven, Dare, Duplin, Edgecombe, Forsyth, Greene, Guilford, Halifax, Henderson, Herford, Hyde, Jones, Lenoir, Mecklenburg, Moore, New Hanover, Northampton, Onslow, Pamlico, Pender, Pitt, Randolph, Robeson, Rockingham, Stokes, Union, and Wilkes counties in North Carolina, as well as other states.

On page 36, the applicant states that projected patient origin is based on historic patient origin *"UNC Rex assumed patient origin will remain consistent with its historical patient origin through the third year."* The applicant adequately identified the population it proposes to serve.

Analysis of Need

In Section C, pages 36-44, 63-64 and Exhibit C.4, UNC Rex documents the need for the proposal based on four main factors, including the methodology and assumptions, which are summarized below:

- *2017 SMFP Adjusted Need Determination* (p.37-39)

  The 2017 SMFP contained an adjusted need determination for one unit of cardiac catheterization equipment in the Wake County Cardiac Catheterization Service Area the basis of which was UNC Rex's adjusted need determination submitted in 2016.

- *UNC Rex Historical Cardiac Catheterization Utilization* (p.39-41)

In Section C, the applicant documents historical utilization of the cardiac catheterization equipment at UNC Rex as shown in the table below:

	FFY2011	FFY2012	FFY2013	FFY2014	FFY2015	FFY2016
# of Existing Fixed Units	3	4	4	4	4	4
Total Capacity	4,500	6,000	6,000	6,000	6,000	6,000
Diagnostic Equivalent Procedures	3,132	3,875	5,029	6,006	6,934	7,326
Utilization Percentage	69.6%	64.6%	83.8%	100.1%	115.6%	122.1%
Annual Growth	Na	23.7%	29.8%	19.4%	15.4%	5.7%
# of Units Needed based on Units being utilized at 80% capacity	2.61	3.23	4.19	5.0	5.78	6.10

Source: Tables on page 39 and 41.

As shown in the table above, in FFY2016 the four units of fixed cardiac catheterization equipment at UNC Rex operated at 122.1% of capacity and UNC Rex demonstrated the need for two additional units of fixed cardiac catheterization equipment at UNC Rex.

- *Impact of Capacity Constraints* (p.41-43)

  High demand for cardiac catheterization services at UNC Rex has negatively impacted this service in the following ways:

  - Staff two of its cardiac catheterization units 14.5 hours per weekday (7-9:30)
  - Staff two of its cardiac catheterization units 12.5 hours per weekday (7-7:30)
  - Finish scheduled cases after 9:30 pm…resulting in patients fasting for most of the day and then having to stay in the hospital for overnight observation.
  - Contract with FirstHealth for use of its mobile catheterization. The mobile catheterization unit is less technologically advanced and requires a patient to actually exit the main building and enter a mobile trailer
  - Negatively impacts timeliness, cost, quality and equipment (see pages 42-43)

- *Alignment with Federal Payment Models* (p.43-44)

  The Centers for Medicare & Medicaid Services (CMS) has developed a new bundled payment program for certain heart procedures which will require UNC Rex to ensure that it has sufficient cardiac catheterization capacity available to timely serve all its patients.

  In Section E-1, pages 72-73, the applicant discusses the alternatives considered and why the proposal was chosen.

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

Projected Utilization

On page 6 of Form C in Section Q of the application UNC Rex provides projected utilization during the first three years of operation of the cardiac catheterization units following project completion, as illustrated in the table below:

	OY1 (7/1/18 to 6/30/19)	**OY1 (7/1/19 to 6/30/20)**	**OY1 (7/1/20 to 6/30/21)**
# of Units	5	5	5
Total Capacity (# of Units x 1,500)	7,500	7,500	7,500
Diagnostic Equivalent Procedures	7,006	7,061	7,115
Utilization Percentage (Procedures/Capacity)	93.4%	94.1%	94.9%

Source: Tables pages 6-7 of Form C in Section Q.

In Section Q, Form C, the applicant provides the assumptions and methodology used to project the fixed cardiac catheterization equipment utilization, which are summarized below.

- UNC Rex's fiscal year (FY) runs from July 1st through June 30th of the following year.
- OY1 = July 1, 2018 to June 30, 2019
- OY2 = July 1, 2019 to June 30, 2020
- OY3 = July 1, 2020 to June 30, 2021
- UNC Rex opened its North Carolina Heart and Vascular Hospital on the UNC Rex campus during March of FY17 and consolidated its cardiac catheterization equipment in the North Carolina Heart and Vascular Hospital building.
- To demonstrate cardiac catheterization procedures for FY17 UNC Rex utilized actual figures for July 2016 through February 2017 and, while cardiac catheterization unit utilization is typically greater in the second half of each FY (January through June), UNC Rex assumed that *"its utilization during the remaining months of FY2017, with the exception of March, will be consistent with its monthly average from the first eight months of the year."* UNC Rex *"expects that the opening of the North Carolina Heart and Vascular Hospital in March temporarily diminished its capacity to provide cardiac catheterization services as patients, providers and staff transitioned to a new environment with new equipment. …UNC REX assumes that utilization in March will be one-half of the monthly average during the first eight months of FY17."*

In the table below, UNC Rex provided historical utilization of it cardiac catheterization services.

	FY14	FY15	FY16	FY17*	CAGR
# of Units	4	4	4	4	
Total Capacity (# of Units x 1,500)	6,000	6,000	6,000	6,000	
Diagnostic Equivalent Procedures	5,702	6,614	7,245	6,899	6.6%
Utilization Percentage (Procedures/Capacity)	95%	110%	121%	115%	

*Based on 8 months actual procedures and 4 months projected.

Section 10A NCAC 14C .1603(c)(1) [Performance Standards] of the Criteria and Standards for Cardiac Catheterization Equipment states that an applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall"

> *"demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;"*

Section 10A NCAC 14C .1601 of the Criteria and Standards for Cardiac Catheterization Equipment defines "capacity" of a unit of cardiac catheterization equipment *"as 1500 diagnostic-equivalent procedures per year. One therapeutic cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. … All other procedures are valued at one diagnostic-equivalent procedure."*

As shown in the table above in FY17 the applicant has or is projected to perform 6,899 diagnostic-equivalent procedures. If UNC Rex projects 0.00% growth through OY3 the 5 units of cardiac catheterization equipment (4 existing units and 1 proposed unit) will be operating at 91.98% of capacity in OY3 [Utilization percentage = Procedures/ Capacity. 6,899 procedures / 7,500 (5 units x 1,500) = 0.9198 or 91.98% capacity]. As stated above, UNC Rex was conservative in annualizing it's procedures in FY17. In the previous year, FY16, UNC Rex performed 7,245 diagnostic-equivalent procedures. In the table above, UNC Rex performed 346 less cardiac catheterization procedures from FY16 to FY17. The applicant adequately addressed this reduction based on a move of the existing cardiac catheterization services into the new North Carolina Heart and Vascular Hospital building on the UNC Rex campus in March of 2017 and a very conservative approach to annualizing the cardiac catheterization procedures for the last four months of FY17.

In From C in Section Q of the application, the applicant notes that:

- the compound annual growth rate for cardiac catheterization services at UNC Rex for FY14 through FY17 is 6.6%. (See Form C, page 4)
- the compound annual growth rate for cardiac catheterization services in Wake County is 0.8%. (See Form C, page 5)
- projects utilization of cardiac catheterization procedures for OY1-OY3 based on the Wake County CAGR (0.8%), which is less than the CAGR for cardiac catheterization services at UNC Rex (6.6%).

UNC Rex's assumptions and methodology for projecting utilization were reasonable and adequately supported.

As discussed above, the current number of cardiac catheterization procedures being performed at UNC Rex, even assuming 0.00% growth in cardiac catheterization procedures through OY3, adequately supports the proposed project.

Projected utilization of the existing and proposed units of fixed cardiac catheterization equipment is based on reasonable and adequately supported assumptions.

Access

In Section L, page 105, the applicant states *"UNC REX is in full compliance with Title III of the Americans with Disabilities Act, the Civil Rights Act, and all other federally mandated regulations concerning minorities and handicapped persons."* In Section L, pages 105-106, the applicant projects that 68.9% of the patients who will receive cardiac catheterization services at Rex Hospital in OY2(7/1/19 to 6/30/20) will have all or part of their services paid for by Medicare or Medicaid as illustrated in the table below

Payor Source	**UNC Rex: Total Patient Days**	**UNC Rex: Cardiac Catheterization**
Medicare	49.9%	65.1%
Medicaid	9.1%	3.8%
Commercial/Managed Care	37.6%	26.9%
Self-Pay	2.3%	3.3%
Other*	1.0%	0.9%
Total	100.0%	100.0%

Source: Table page 105.
*Other: includes workers comp. and other government

The projected payor mix for cardiac cauterization services is based on the historical payor mix for cardiac catheterization services. (See page 106)

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

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to 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.

NA

(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-1, pages 72-73, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – the applicant states that the existing cardiac catheterization units at UNC Rex are insufficient to handle the existing and increasing volume for the cardiac catheterization services at UNC Rex leading to unnecessary overnight stays, long patient wait times, cancelled procedures, delayed elective procedures, and having to contract with a mobile provider. Therefore, maintaining the status quo is not the least costly or most effective alternative.

2. Purchase or Lease Existing Cardiac Catheterization Capacity- UNC Rex currently leases a mobile cardiac catheterization unit, however, that approach has deficiencies based on the equipment and location. There is only one other provider of mobile cardiac catheterization services in North Carolina, however, the provider is affiliated with Duke University Health System, which has a hospital in Wake County. Further, even if an agreement for services could be worked out the issues associated with mobile cardiac catheterization units currently being experienced by UNC Rex would still be present. UNC Rex has been unable to reach an agreement with WakeMed with respect to either leasing or purchasing some of its existing cardiac catheterization unit capacity. Therefore, purchase or lease of existing cardiac catheterization capacity is problematic.

3. Utilize Cardiac Catheterization Capacity at WakeMed- A different hospital in Wake County, WakeMed, has existing available cardiac catheterization capacity. However, UNC Rex has not been able to work out an arrangement with WakeMed to access this excess cardiac catheterization capacity. In addition, UNC Rex states that UNC Rex cardiologists utilizing WakeMed cardiac catheterization equipment would result in inefficiencies and increased costs for physicians, patients and the healthcare system as a whole.

After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is for UNC Rex to add a 5th unit of fixed cardiac catheterization equipment pursuant to the need determination for Wake County in the 2017 SMFP.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need for an additional unit of fixed cardiac catheterization equipment in Wake County. Therefore, the application is conforming to this criterion subject to the following conditions:

1. **Rex Hospital, Inc. shall materially comply with all representations made in its certificate of need application.**

2. **Rex Hospital, Inc. shall acquire no more than one fixed cardiac catheterization unit as part of this project, for a total of five fixed cardiac catheterization units.**

3. **Rex Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section F and Form F.1a of the application and that would otherwise require a certificate of need.**

4. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Rex Hospital, Inc. 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.**

5. **Rex Hospital, Inc. 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 the 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

UNC Rex proposes to acquire a 5th unit of fixed cardiac catheterization equipment.

Capital and Working Capital Costs

In Section F, page 74, and Form F.1a in Section Q, the applicant projects the total capital cost of the project will be $54,320, which includes:

Medical Equipment	$39,320
Contingency	$15,000
Total	**$54,320**

In Section F, page 77, the applicant projects no working capital costs (start-up and initial operating expenses) as the proposed service is not a new service at UNC Rex.

Availability of Funds

In Section F, page 75, the applicant states that the proposed project will be financed through the accumulated reserves of UNC Rex.

In Exhibit F.2-1, the applicant provides a letter from Andrew Zukowski, Chief Financial Officer of UNC Rex, which states that $54,320 is available from the existing accumulated cash reserves of UNC Rex for the proposed project. The letter refers to the audited consolidated balance sheets of UNC Rex in Exhibit F.2-2 and specifically the lines "Cash and Cash Equivalents" and "Assets Limited As To Use", see page 8, which lines have $91,014,000 and $265,476,000 respectively as of June 30, 2016.

The applicant adequately designates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statements (Form F.4), the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	OY1	OY2	OY3
Number of Cardiac Catheterization Procedures	5,318	5,359	5,401
Total Gross Revenues (Charges)	$156,175,106	$162,104,078	$168,258,135
Total Net Revenue	$43,996,979	$45,667,263	$47,400,958
Average Net Revenue per procedure	$8,273.22	$8,521.60	$8,776.33
Total Operating Expenses (Costs)	$30,433,710	$31,504,207	$32,612,807
Average Operating Expense per procedure	$5,722.77	$5,878.75	$6,038.29
Net Income	$13,563,269	$14,163,056	$14,788,151

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. 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

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. 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

UNC Rex proposes to acquire a unit of fixed cardiac catheterization equipment to be located on the hospital campus pursuant to the need determination in the 2017 State Medical Facilities Plan (2017 SMFP) for a total of five units of fixed cardiac catheterization equipment upon project completion.

On page 171, the 2017 SMFP defines the service area for fixed cardiac catheterization equipment as *"A cardiac catheterization (fixed or shared) equipment's service area is the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county. Counties lacking a licensed acute care hospital are grouped with the single county where the largest proportion of patients received inpatient acute care services, as measured by acute inpatient days, unless two counties with licensed acute care hospitals each provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. In that case, the county lacking a licensed acute care hospital is grouped with both the counties which provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. The three most recent years of available acute care days patient origin data are combined and used to create the multicounty service areas. These data are updated and reviewed every three years, with the most recent update occurring in the North Carolina 2017 State Medical Facilities Plan" Figure* 5-1 shows Wake County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Wake County. Facilities may also serve residents of counties not include in their service area.

For all of North Carolina Table 9W: *Fixed Cardiac Catheterization Equipment, Capacity and Volume* in the 2017 SMFP only shows a need in the Cumberland County service area for one unit of fixed cardiac catheterization equipment. However, Table 9Y: *Fixed Cardiac Catheterization Equipment Need Determination* only shows a need determination for one unit of fixed cardiac catheterization equipment in the Wake County Cardiac Catheterization Service Area. The footnotes to Table 9Y state *"The need determination in the Wake County service area is in response to a petition that was approved by the State Health Coordinating Council. … A need determination in the Cumberland County service area was removed in response to a petition that was approved by the State Health Coordinating Council"* (See page 185.)

The proposal by UNC Rex is for one unit of fixed cardiac catheterization equipment at UNC Rex which is located in the Wake County Cardiac Catheterization Service Area and is thus conforming to the need determination in the 2017 SMFP.

The discussions regarding analysis of need, alternatives and competition found in Criteria (3) (4) and (18a), respectively, are incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved units of fixed cardiac catheterization equipment 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 H, page 91, and Form H in Section Q, the applicant projects staffing for UNC Rex's cardiac catheterization services in the second operating year, as illustrated in the following table:

Position	Current FTEs [as of 2/28/17]	# FTEs to be Added	Projected # FTEs [7/1/19 to 6/30/20]
Coord/Diagnostic Services	3.30		3.30
Coord/Diagnostic Scheduling Sv	1.12		1.12
Cardiovascular Specialist	16.97	4.24	21.21
RN/Cardiovascular Specialist	12.56	3.14	15.70
Vascular & Intrv Technologist	4.83		4.83
Anesthesia Technician	1.76		1.76
Patient Care Assistant	2.00		2.00
Materials Specialist	0.50		0.50
Total	43.04	7.38	50.42

As shown in the table above, the applicant projects to employ 50.42 FTEs for cardiac catheterization services in the second operating year. In Section H.4, page 93, the applicant identifies Dr. Ravish Sachar as the Medical Director of the cardiac catheterization services. Exhibit H.4 contains a letter from Ravish Sachar, MD, which expresses his commitment to serve as Medical Director for the cardiac catheterization service. In Section H, pages 91-92, the applicant describes the methods used to recruit and fill vacant or new positions.

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

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed cardiac catheterization 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 I, page 95, the applicant identifies the necessary ancillary and support services and indicates how they are or will be made available. Exhibit H.4 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on page 95 of the application and includes letters of support in Exhibit I.2. Exhibits I-1 contains a letter from the President of UNC Rex documenting the current availability of all necessary ancillary and support services for the proposed project. The applicant adequately demonstrates that the 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.

NA

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

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

C

In Section L, page 104, the applicant reports that 68.9% of the patients who received cardiac catheterization services at Rex Hospital had some or all of their services paid for by Medicare or Medicaid during the last full fiscal year (full FY) [7/1/15 to 6/30/16] as shown in the table below

Payor Source	**UNC Rex: Total Patient Days**	**UNC Rex: Cardiac Catheterization**
Medicare	49.9%	65.1%
Medicaid	9.1%	3.8%
Commercial/Managed Care	37.6%	26.9%
Self-Pay	2.3%	3.3%
Other*	1.0%	0.9%
Total	100.0%	100.0%

Source: Table page 104.
*Other: includes workers comp. and other government

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 applicant's 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 applicant demonstrates that it 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;

C

In Section L, page 104, the applicant states *"UNC REX had no obligations to provide uncompensated care, community service or access to care by medically underserved, minorities or handicap persons during the last three years. However, in order to maintain UNC REX's Section 501(c)(3) tax-exempt status, it is necessary to fulfill a general obligation to provide access to healthcare services for all patients needing care, regardless of their ability to pay. UNC REX does this on a routine basis for all patients regardless of referral source."* On page 105, the applicant states *"No civil rights access complaints have been filed against UNC REX in the past five years."* The application is conforming to this criterion.

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

C

In Section L, page 105, the applicant states *"UNC REX is in full compliance with Title III of the Americans with Disabilities Act, the Civil Rights Act, and all other federally mandated regulations concerning minorities and handicapped persons."* In Section L, pages 105-106, the applicant projects that 68.9% of the patients who will receive cardiac catheterization services at Rex Hospital in OY2(7/1/19 to 6/30/20) will have all or part of their services paid for by Medicare or Medicaid as illustrated in the table below

Payor Source	UNC Rex: Total Patient Days	UNC Rex: Cardiac Catheterization
Medicare	49.9%	65.1%
Medicaid	9.1%	3.8%
Commercial/Managed Care	37.6%	26.9%
Self-Pay	2.3%	3.3%
Other*	1.0%	0.9%
Total	100.0%	100.0%

Source: Table page 104.
*Other: includes workers comp. and other government

The projected payor mix for cardiac cauterization services is based on the historical payor mix for cardiac catheterization services. (See page 106) The applicant adequately demonstrates that medically underserved populations will have access to the proposed 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 L.5, page 106, the applicant states *"Persons will have access to services at UNC REX through referrals from physicians of the medical staff. Typically, patients are also admitted through the emergency department. For specific procedures, patients are admitted by the physician with privileges at the hospital, who will perform the procedure."* The applicant adequately demonstrates that UNC Rex will offer a range of means by which a person can access cardiac catheterization services. Therefore, 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 M, page 107, the applicant states *"UNC REX currently receives cardiology fellows from UNC-Chapel Hill School of Medicine, who train in each of UNC REX's four cardiac catheterization units…and who will have the availability of the fifth lab proposed in this project. …UNC REX has more than 60 agreements with health professional training programs throughout the Southeast… In addition to its academic relationships, UNC REX supports community-based healthcare professional organizations. UNC REX is a member of the Healthcare Works! Coalition, a coordinated effort between local facilities and community colleges to enhance the careers of healthcare workers in the region. UNC REX serves as a Wake Area Health Education Center-affiliated training site for American Heart Association sanctioned training programs."* Exhibit M-1 contains a list of clinical affiliation agreements and a sample agreement. The information provided in Section M is reasonable and credible and supports a finding of conformity to this criterion.

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

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

C

UNC Rex proposes to acquire a unit of fixed cardiac catheterization equipment to be located on the hospital campus pursuant to the need determination in the 2017 State Medical Facilities Plan (2017 SMFP) for a total of five units of fixed cardiac catheterization equipment upon project completion.

On page 171, the 2017 SMFP defines the service area for fixed cardiac catheterization equipment as *"A cardiac catheterization (fixed or shared) equipment's service area is the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county. Counties lacking a licensed acute care hospital are grouped with the single county where the largest proportion of patients received inpatient acute care services, as measured by acute inpatient days, unless two counties with licensed acute care hospitals each provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. In that case, the county lacking a licensed acute care hospital is grouped with both the counties which provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. The three most recent years of available acute care days patient origin data are combined and used to create the multicounty service areas. These data are updated and reviewed every three years, with the most recent update occurring in the North Carolina 2017 State Medical Facilities Plan" Figure* 5-1 shows Wake County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Wake County. Facilities may also serve residents of counties not include in their service area.

For all of North Carolina Table 9W: *Fixed Cardiac Catheterization Equipment, Capacity and Volume* in the 2017 SMFP only shows a need in the Cumberland County service area for one unit of fixed cardiac catheterization equipment. However, Table 9Y: *Fixed Cardiac Catheterization Equipment Need Determination* only shows a need determination for one unit of fixed cardiac catheterization equipment in the Wake County Cardiac Catheterization Service Area. The footnotes to Table 9Y state *"The need determination in the Wake County service*

area is in response to a petition that was approved by the State Health Coordinating Council. … A need determination in the Cumberland County service area was removed in response to a petition that was approved by the State Health Coordinating Council" (See page 185.)

The proposal by UNC Rex is for one unit of fixed cardiac catheterization equipment at UNC Rex which is located in the Wake County Cardiac Catheterization Service Area and is thus conforming to the need determination in the 2017 SMFP.

In Section N, pages 109-111, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates 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 applicant adequately demonstrates that it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicant demonstrates that it will continue to provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

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

In Section A, page 15, the applicant states that it currently owns, leases, or manages one facility in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, one incident occurred at the facility within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems had been corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the facility, the applicant

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

(21) Repealed effective July 1, 1987.

(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 application is conforming with all applicable Criteria and Standards for cardiac catheterization equipment and cardiac angioplasty equipment. The specific criteria are discussed below.

SECTION .1600 – CRITERIA AND STANDARDS FOR CARDIAC CATHETERIZATION EQUIPMENT AND CARDIAC ANGIOPLASTY EQUIPMENT

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:

(1) each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;

-C- Section 10A NCAC 14C .1601 of the Criteria and Standards for Cardiac Catheterization Equipment defines "capacity" of a unit of cardiac catheterization equipment *"as 1500 diagnostic-equivalent procedures per year. One therapeutic cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. … All other procedures are valued at one diagnostic-equivalent procedure."* In Section C, pages 56-57, the applicant projects cardiac catheterization utilization, including as a percentage of capacity, during the fourth quarter of the third year following completion of the proposed project, as illustrated in the table below:

		OY3- 4th Quarter [CY2020]
# of units fixed cardiac catheterization equipment		1
Diagnostic Procedures	142 x 1	142
Interventional (Therapeutic) Procedures	121 x 1.75	212
Total Diagnostic-Equivalent Procedures		354
Capacity per quarter (# of Units x 1,500 / 4 quarters)		375
Utilization of Capacity (Diagnostic-Equivalent Procedures / Capacity)	354/375	94.0%

Source: Table on page 57.

As show in the table above, the proposed item of cardiac catheterization equipment is projected to be utilized at an annual rate of 94% as measured during the fourth quarter of the third year following completion of the proposed project.

(2) if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;

-C- In Section C, pages 57-58, the applicant projects UNC Rex's 14 cardiac catheterization teams performing over 150 therapeutic cardiac catheterization procedures during the third year of operation following completion of the proposed project as shown in the table below:

Procedure	**# of cardiac catheterization teams**	**OY3 utilization**	**OY3 utilization per cardiac catheterization team**
Interventional (Therapeutic)	14	2,277	163

As shown in the table above, each of the 14 cardiac catheterization teams at UNC Rex is projected to perform 163 interventional (therapeutic) cardiac catheterization procedures during OY3 which exceeds the minimum of 100 annual therapeutic cardiac catheterization procedures per cardiac catheterization team required by this rule.

(3) if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;

-C- In Section C, page 58, the applicant projects UNC Rex's 14 cardiac catheterization teams shall be performing over 200 diagnostic-equivalent therapeutic cardiac catheterization procedures during the third year of operation following completion of the proposed project as shown in the table below:

Procedure	# of cardiac catheterization teams	OY3 utilization	OY3 utilization per cardiac catheterization team
Diagnostic	14	3,103	222
Interventional (Therapeutic)	14	2,277 x 1.75 =3,984*	284
Total Diagnostic-Equivalent Procedures	14	7,087	506

Source: Table on page 58.
*Interventional (Therapeutic) converted to Diagnostic-Equivalent by multiplying # of procedures by 1.75.

As shown in the table above, each of the 14 cardiac catheterization teams at UNC Rex are projected to perform 506 diagnostic-equivalent cardiac catheterization procedures during OY3 which exceeds the minimum of 200 annual diagnostic-equivalent procedures per cardiac catheterization team required by this rule.

(4) at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;

-C- In Section C, pages 59-62, the applicant demonstrates that at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the defined primary cardiac catheterization service area.

(b) An applicant proposing to acquire mobile cardiac catheterization equipment shall:

(1) demonstrate that each existing item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Health Service Regulation;

(2) demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment;

(3) demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;

(4) demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the applicant's third year of operation; and

(5) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.

(c) An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:

(1) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;

-C- Section 10A NCAC 14C .1601 of the Criteria and Standards for Cardiac Catheterization Equipment defines "capacity" of a unit of cardiac catheterization equipment *"as 1500 diagnostic-equivalent procedures per year. One therapeutic cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures. ... All other procedures are valued at one diagnostic-equivalent procedure."* In Section C, pages 62-63, the applicant documents cardiac catheterization utilization, including as a percentage of capacity, during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation, as illustrated in the table below:

		FFY 2016
# of units fixed cardiac catheterization equipment		4
Diagnostic Procedures	3,458	3,458
Interventional (Therapeutic) Procedures x 1.75 equals Diagnostic-Equivalent Procedures	2,210 x 1.75	3,868
Total Diagnostic-Equivalent Procedures		7,326
Total Capacity (# of Units x 1,500)	4 x 1,500	6,000
Utilization of Capacity (Diagnostic-Equivalent Procedures / Capacity)		122%*

Source: Table on page 64
*Applicant calculates this as 121%

As show in the table above, UNC Rex's existing four units of cardiac catheterization equipment, excluding mobile, operated at 122% of capacity, on average, as measured during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation which exceeds the minimum of 80% of capacity as required by this rule.

(2) demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and

-C- In Section C, pages 64-65, the applicant demonstrates that its four existing units of fixed cardiac catheterization equipment shall be utilized at an average annual rate of at least 60 percent of capacity as measured during the fourth quarter of the third year following completion of the proposed project as shown in the table below:

		OY3- 4th Quarter [CY2020]
# of units fixed cardiac catheterization equipment		4
Diagnostic Procedures x 1 equals Diagnostic-Equivalent Procedures	570	570
Interventional (Therapeutic) Procedures x 1.75 equals Diagnostic-Equivalent Procedures	483 x 1.75	845
Total Diagnostic-Equivalent Procedures		1,415
Capacity per quarter (# of Units x 1,500 / 4 quarters)		1,500
Utilization of Capacity (Diagnostic-Equivalent Procedures / Capacity)		94%

Source: Table on page 65.

As show in the table above, the existing units of cardiac catheterization equipment are projected to be utilized at an annual rate of 94% as measured during the fourth quarter of the third year following completion of the proposed project.

(3) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

-C- In Section C, pages 63-65, and Form C in Section Q, the applicant documents all of the assumptions and data used in the development of this projections in this Rule.

(d) An applicant proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable State Medical Facilities Plan shall:

(1) demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project; and

(2) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

-NA- The applicant does not propose to acquire shared fixed cardiac catheterization equipment.

(e) If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria:

(1) the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under; and

(2) the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.

-NA- The applicant does not propose to perform cardiac catheterization procedures on patients age 14 and under as part of the proposed project.