

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 23, 2016

Findings Date: September 23, 2016

Project Analyst: Celia C. Inman

Assistant Chief: Martha J. Frisone

Project ID #: J-11199-16

Facility: Rex Hospital

FID #: 953429

County: Wake

Applicant: Rex Hospital, Inc.

Project: Acquire a fourth heart-lung bypass machine

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

NA

The applicant, Rex Hospital, Inc., proposes to acquire a fourth heart-lung bypass machine to support its existing open heart surgery services.

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 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2016 SMFP which are applicable to this review.

Conclusion

In summary, 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 State SMFP. There are no policies in the 2016 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.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 applicant, Rex Hospital, Inc., also does business as UNC Rex Healthcare. The University of North Carolina Health Care System is the sole member and parent of UNC Rex Healthcare, Inc. The applicant proposes to acquire a fourth heart-lung bypass machine to support its existing open heart surgery services. In Section I, page 11, the applicant states:

“For informational purposes, Rex historically owned and operated four heart-lung bypass machines but voluntarily gave up the fourth machine several years ago.”

Rex currently owns three heart-lung bypass machines, each of which is currently in operation at Rex Hospital Main Campus. Rex Hospital’s 2016 License Renewal Application (LRA) shows Rex Hospital performed a total of 460 open heart surgery procedures utilizing a heart-lung bypass machine during fiscal year 2015.

Population to be Served

On pages 103-106, the 2016 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in G.S. 131E-176(18b) *“means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.”*

Table 7A, page 104 of the 2016 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2014, providing a statewide total of 9,627 surgeries.

The 2016 SMFP does not discuss a need methodology or provide a definition of “service area” for open heart surgery services. However, on page 62, the 2016 SMFP defines the service area for operating rooms as the 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.” Figure 6.1 on page 67 of the SMFP shows Wake County as a single county operating room service area.

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

In Section III.5, page 53, the applicant provides the projected patient origin for Rex Hospital open heart surgical services, as summarized below.

Rex Hospital Open Heart Surgical Projected Patient Origin

County	Year 1 7/1/17-6/30/18		Year 2 7/1/18-6/30/19	
	# Patients	% Patients	# Patients	% Patients
Wake	269	39.8%	300	39.8%
Johnston	101	14.9%	112	14.9%
Wayne	75	11.1%	84	11.1%
Harnett	38	5.7%	43	5.7%
Franklin	37	5.4%	41	5.4%
Sampson	37	5.4%	41	5.4%
Wilson	32	4.8%	36	4.8%
Other*	87	12.9%	97	12.9%
Total	676	100.0%	753	100.0%

Totals may not sum due to rounding

*Other is identified on page 53 of the application and includes Duplin, Carteret, Chatham, Chowan, Cumberland, Davidson, Durham, Granville, Halifax, Lee, Lenoir, Moore, Nash, New Hanover, Onslow, Person, Vance, and Warren counties in North Carolina and other states.

On page 53, the applicant states that it does not expect any change in its patient origin as a result of the proposed project, which is consistent with the service’s current patient origin by percentage, as provided on page 51 of the application.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant discusses the need for the additional heart-lung bypass machine in Section III.1, pages 31-45. On page 32, the applicant states:

“Given the life-saving nature of the service, Rex believes that it has a need for the acquisition of a fourth heart-lung bypass machine in order to ensure sufficient capacity to accommodate both scheduled and emergency situations.”

The applicant further states that Rex expects its number of open heart surgical cases to increase in the future based on:

- the historical growth of its open heart surgical cases (pages 36-40),
- the population growth and aging (pages 32-34),
- growth of cardiac services in Wake County (pages 34-37),
- additional physician recruitment (page 44), and
- increased transfers from community hospitals affiliated with the UNC Health Care System (pages 41-43).

In addition to the need based on open heart surgical cases, on pages 39-40, the applicant discusses Rex’s need for additional heart-lung machine availability for potential emergencies for non-open heart cases.

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

Projected Utilization

In Section III.1, page 38, the applicant provides Rex’s historical open heart surgery cases from fiscal year 2013 (FY13) through annualized fiscal year 2016 (FY16), showing a three-year compound average growth rate (CAGR) of 17.4%.

	FY13	FY14	FY15	FY16*
Open heart cases utilizing a heart-lung bypass machine	336	380	442	544
Percent Growth		13.1%	16.3%	23.0%
Three-Year CAGR				17.4%

Numbers may not foot due to rounding

*Annualized (10 months of data – 7/1/15-4/30/16)

The applicant states that given Rex’s most recent year of growth of 23%, projecting an annual increase of 17.4% through the project years might be reasonable; however, in an effort to provide a more conservative projection, Rex states that it based its projections on a lower growth rate of 11.5%, resulting in the projected utilization shown on page 41 and below.

	FY16*	FY17	FY18	FY19	FY20
Open heart cases utilizing a heart-lung bypass machine	544	606	676	753	840
Percent Growth	23.0%	11.5%	11.5%	11.5%	11.5%

*Annualized (10 months of data – 7/1/15-4/30/16)

As shown in the table above, Rex expects to perform 840 open heart surgical cases utilizing a heart-lung bypass machine in the third project year (July 1, 2019-June 30, 2020). Based on its 11.5% annual growth assumption, Rex will exceed the performance standard of 200 open-heart surgical cases per machine in the third year of operation (840 cases / 4 machines = 210 cases).

On page 44, the applicant states that the projected volume above does not include cases that require heart-lung bypass machines to be placed on precautionary standby or the flexible capacity needed to ensure that at least one machine is available for urgent or emergent cases that require immediate care. As the applicant discusses on pages 39-40 of the application, FY2016 annualized data includes 145 cases for which a heart-lung bypass machine was placed on precautionary standby to provide services in the event of an emergency, but in which patients were not ultimately placed on bypass. Thus, these cases were not included in the total open heart surgery cases recorded in 2016. Assuming that the number of precautionary standby cases remains constant through the third project year, Rex expects its four heart-lung bypass machines to be utilized for heart surgeries or placed on precautionary standby for 985 cases (840 + 145 = 985).

In addition to precautionary standby needs, heart-lung bypass machines are also critical in “failure to wean” cases, which result in the continued use of the machine after the surgery is complete, which the applicant states, further supports the need for Rex’s additional heart-lung machine capacity.

On page 45, the applicant states:

“The projection methodology above demonstrates that the proposed equipment will be well-utilized based on reasonable and conservative assumptions.”

The applicant demonstrates the projected utilization is based on reasonable and adequately supported assumptions. Thus, the applicant adequately demonstrates the need the identified population has for the proposed services.

Access

In Section VI.2, page 67, the applicant states:

“... Rex Healthcare prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the patient’s ability to pay.”

In Section VI.15, page 84, the applicant projects that 33.7% of Rex Hospital surgical patients and 56.1% of its open heart surgery patients will be Medicare beneficiaries and 4.1% of Rex surgical patients and 3.8% of its open heart surgery patients will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicant adequately identifies the population to be served; adequately demonstrates the need the population to be served has for the proposed services based on reasonable and supported utilization projections and assumptions; and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the 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 III.3, pages 48-49, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant states:

“Maintaining the status quo would represent a failure on the part of Rex to ensure adequate heart-lung bypass capacity for both scheduled and emergency open heart surgery patients.”

The applicant states that due to the critical and life-saving nature of the proposed equipment, maintaining the status quo would be contrary to Rex's mission to provide quality care. Therefore, this alternative was rejected.

- 2) Acquire Heart-Lung Bypass Machine for Emergency Use Only – The applicant states that this alternative would not fully support the need for additional capacity for both scheduled and emergency cases as described in Section III.1. Therefore, this alternative was rejected.
- 4) Acquire Heart-Lung Bypass Machine to be Utilized as Proposed – The applicant states that the proposed project, as presented in this application, provides the most cost-effective, resource responsible, and accessible alternative to meet Rex's identified need for the services.

The applicant demonstrates that the proposed project to acquire a fourth heart-lung bypass machine is the most effective alternative to meet Rex's identified need for additional capacity for both scheduled and emergent heart-lung bypass machine utilization.

Furthermore, the application is conforming to all other statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Rex Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Rex Hospital, Inc. 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 and that would otherwise require a certificate of need.**
 - 3. Rex Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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 applicant proposes to acquire a fourth heart-lung bypass machine. The project does not involve any construction or renovation.

Capital and Working Capital Costs

In Section VIII, page 97, the applicant projects the total capital cost of the proposed project will be \$403,919, including equipment, consultant fees and “*minor finish refreshment if needed, e.g., patch and paint*”.

In Section IX, page 102, the applicant states there are no start-up or initial operating expenses for this project.

Availability of Funds

In Section VIII.3, page 97, the applicant states that the total capital cost will be funded with Rex Healthcare accumulated reserves. Exhibit 15 contains a letter from the Interim Chief Financial Officer of UNC Rex Healthcare and Rex Hospital, Inc. which documents Rex’s commitment to fund the proposed project and the availability of funds. Exhibit 16 contains the audited combined financial statements for Rex Healthcare, Inc. and Subsidiaries for years ending June 30, 2015 and 2014. According to the financial statements, as of June 30, 2015, Rex Healthcare had \$69,809,000 in cash and cash equivalents, \$217,427,000 in total current assets, and \$319,663 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant projects a positive net income for Rex Hospital Main Campus surgical services in each of the first three operating years of the project, as shown in the table below.

Rex Hospital Main Campus Surgical Services*	Project Year 1 7/1/17- 6/30/18	Project Year 2 7/1/18- 6/30/19	Project Year 3 7/1/19- 6/30/20
Surgical Cases**	20,778	21,083	21,380
Projected Average Charge per Admission	\$ 28,619	\$ 29,465	\$ 30,362
Gross Patient Revenue	\$ 594,652,955	\$ 621,200,540	\$ 649,142,222
Deductions from Gross Patient Revenue	\$ 404,126,148	\$ 422,167,887	\$ 441,157,054
Net Patient Revenue	\$ 190,526,807	\$ 199,032,653	\$ 207,985,168
Total Expenses	\$ 153,780,303	\$ 160,463,119	\$ 167,488,565
Net Income	\$ 36,746,504	\$ 38,569,534	\$ 40,496,603

Source: Pro Forma Financial Statements Form C, Form D and Form E

*In Section X, page 104, the applicant states, “*Please note that Rex does not have the ability to isolate revenues and expenses associated with the provision of open heart surgery services. As a result, the revenues and expenses shown on Forms C, D, and E are representative of the entire surgical services department at Rex Hospital’s main campus.*”

**Exhibit 19

The applicant also projects a positive net income for the entire UNC Rex Healthcare facility in each of the first three operating years of the project as illustrated in Form B in the pro forma financial section of the application, page 115.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the related assumption notes in the pro forma financials for the assumptions regarding costs and charges. Also see Exhibit 19, which contains Sections III, VI, and VII of concurrently filed Project ID #J-11198-16, which provides the documentation for Rex Hospital's total surgical services projected utilization, payor percentages and staffing to support the statement of income provided above from data in Forms C, D, and E. The discussion regarding projected utilization of heart-lung bypass cases found in Criterion (3) is incorporated herein by reference. The discussion regarding projected utilization of total surgical services at Rex Hospital found in Criterion (3) of the Findings for concurrently filed (and Conditionally Approved) Project ID #J-11198-16 is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates 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

On pages 103-106, the 2016 SMFP discusses open heart surgery services in North Carolina. Open heart surgery services, as defined in G.S. 131E-176(18b) "*means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.*"

Table 7A, page 104 of the 2016 SMFP, indicates there were 22 open-heart surgery programs in North Carolina in 2014, providing a statewide total of 9,627 surgeries.

The 2016 SMFP does not discuss a need methodology or provide a definition of "service area" for open heart surgery services. However, on page 62, the 2016 SMFP defines the service area for operating rooms as the 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.*" Figure 6.1 on page 67 of the SMFP shows Wake County as a single county operating room service area.

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

Rex Hospital, Inc. proposes to acquire a fourth heart-lung bypass machine. The applicant does not propose any new or expanded services. Rex Hospital's 2016 LRA shows Rex Hospital operated three heart-lung bypass machines and performed a total of 460 open heart surgery procedures utilizing a heart-lung bypass machine in FFY 2015.

WakeMed is the only other provider of open heart services in the applicant's service area. Based on data provided in its 2016 LRA, WakeMed operates five heart-lung bypass machines and performed 607 open heart surgeries in FFY 2015.

In Section III.6(b), page 54, the applicant states:

“As discussed in Sections II.1 and III.1, the need for the proposed project is based on the growth of Rex's cardiology program, including open heart surgical cases, as well as additional physician recruitment, an expected increase of transfers from community hospitals within the UNC Health Care System, and projected population growth in Wake County and surrounding areas. Given Rex's projected continued growth and the critical, life-saving nature of this service, the need at Rex cannot be met by another provider. The acquisition of this equipment will allow Rex to continue to provide life-saving care to its patients. In particular, Rex is one of only two open heart surgery providers in the service area, both of which have experienced increasing volume of open heart surgery. With the need to maintain available capacity for patients of this broad service area, particularly for a service with a substantial portion of emergency or urgent cases, no other provider can effectively meet this need.”

Consequently, the applicant adequately demonstrates the proposed project would not result in any unnecessary duplication of existing or approved health service capabilities or facilities in the applicant's service area. Therefore, 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.1-2, pages 86-87, the applicant provides the current and proposed staffing for the open heart surgical program at Rex Hospital, as summarized in the following table.

**Rex Hospital
Open Heart Surgical Services
Current and Proposed Staffing**

Position	Current # FTEs	Proposed # FTEs (Year Two)
Clinical Manager	1.0	1.0
Staff Nurse	7.5	9.0
Surgical Technician	6.4	8.0
Perfusionist	4.0	5.0
Total	18.9	23.0

The proposed staffing results in an increase of 4.1 full-time equivalent (FTE) positions in the open heart surgery program at Rex Hospital; however, the proposed project does not involve any new positions, only incremental increases for the increased capacity.

In Section VII, pages 88-90, the applicant describes its recruitment and retention procedures, and indicates that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. Exhibit 14 contains a copy of Rex's criteria for extending surgical and anesthesia privileges to physicians and a copy of Rex's Medical Staff Bylaws. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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.2, pages 23-24, the applicant identifies the ancillary and support services that are required for the proposed project as including laboratory, radiology, pharmacy, dietary, housekeeping, maintenance, and administration services, among others. Exhibit 5 contains a letter from Rex Hospital, Inc.'s President documenting the availability of the necessary ancillary and support services. The applicant discusses coordination with the existing health care system in Section V, pages 59-64. The applicant provides supporting documentation in Exhibits 9, 10, 11, and 18. The information provided in these sections and exhibits is reasonable and adequately supports a finding of conformity with 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 VI.13 and VI.15, pages 82 and 84, the applicant provides the current payor mix during FY 2015 and the projected payor mix for the second year of operation,

respectively, for Rex Hospital open heart and total surgical services, as illustrated in the tables below:

**Rex Hospital
Open Heart Surgical Procedures as a Percent of Total**

	FY2015	FY2019
Self-Pay / Indigent / Charity	1.8%	1.8%
Medicare/Medicare Managed Care	56.1%	56.1%
Medicaid	3.8%	3.8%
Commercial / Managed Care	38.2%	38.2%
Total	100.0%	100.0%

Totals may not sum due to rounding

**Rex Hospital
Total Surgical Procedures as a Percent of Total**

	FY2015	FY2019
Self-Pay / Indigent / Charity	2.3%	2.3%
Medicare/Medicare Managed Care	33.7%	33.7%
Medicaid	4.1%	4.1%
Commercial / Managed Care	59.9%	59.9%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section VI.2, page 67, the applicant discusses access to its services and states:

“Hospital policies and procedures do not discriminate with regard to patient care access on the basis of race, ethnicity, sex, age, religion, income, residence or any other factor which might restrict access to services.”

Exhibit 12 contains copies of Rex’s non-discrimination, admissions, and patient payment policies. The applicant further states that in addition to fair and equitable policies and procedures, Rex has undertaken many community-minded initiatives to make its service more accessible to all residents in the service area.

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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 81, the applicant states:

"Rex Hospital has had no obligations to provide uncompensated care, community service or access to care by medically underserved, minorities or handicapped persons during the last three years.

...

Finally, Rex Hospital is in full compliance with Title III of the ADA, the Civil Rights Act, and all other federally mandated regulations concerning minorities and handicapped persons."

In Section VI.10 (a), page 80, the applicant states that no civil rights equal access complaints have been filed against Rex 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, page 84, the applicant provides the projected payor mix for the second year of operations, as shown in the following table.

**Rex Hospital Main Campus
Projected Procedures as a Percent of Total
July 1, 2018- June 30, 2019**

Payor Category	Open Heart	Total Surgical Services
Self Pay/ Indigent /Charity	1.8%	2.3%
Medicare/ Medicare Managed Care	56.1%	33.7%
Medicaid	3.8%	4.1%
Commercial / Managed Care	38.2%	59.9%
Total	100.0%	100.0%

Totals may not sum due to rounding

On pages 84-85, the applicant provides the assumptions and methodology used to project payor mix. The applicant states that payor mix for its surgery services will not change from its historical mix as a result of the proposed project. The applicant states that it does not have the ability to isolate revenues and expenses associated with the provision of open heart surgery services; therefore, the payor mix shown on Forms C, D, and E are representative of the entire surgical services department at Rex Hospital Main Campus. The applicant demonstrates that medically underserved populations will have adequate 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 VI.9(a), page 79, the applicant describes the range of means by which a person will have access to the proposed services. The information provided is reasonable and adequately supports a finding of conformity 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, pages 59-60, the applicant describes how the facility will accommodate the clinical needs of area health professional training programs. The applicant states that Rex Healthcare has extensive relationships with area clinical training programs, as demonstrated by the more than 60 existing agreements with health professionals throughout the Southeast including, UNC, Duke University, East Carolina University, Durham Technical College and Western Carolina University. See Exhibit 9 which provides a list of the affiliate agreements. The information provided in Section V.1 and Exhibit 9 is reasonable and adequately 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

The applicant proposes to acquire a fourth heart-lung bypass machine. The applicant does not propose to add services, or acquire equipment for which there is a need determination methodology in the 2016 SMFP. Rex Hospital's 2016 LRA shows Rex Hospital operates three heart-lung bypass machines and performed a total of 460 open heart surgery procedures utilizing a heart-lung bypass machine in FFY 2015.

WakeMed is the only other provider of open heart services in the applicant's service area. Based on data provided in its 2016 LRA, WakeMed operates five heart-lung bypass machines and performed 607 open heart surgeries in FFY 2015.

In Section III.6(b), page 54, the applicant states:

"As discussed in Sections II.1 and III.1, the need for the proposed project is based on the growth of Rex's cardiology program, including open heart surgical cases, as well as additional physician recruitment, an expected increase of transfers from community hospitals within the UNC Health Care System, and projected population growth in Wake County and surrounding areas. Given Rex's projected continued growth and the critical, life-saving nature of this service, the need at Rex cannot be met by another provider. The acquisition of this equipment will

allow Rex to continue to provide life-saving care to its patients. In particular, Rex is one of only two open heart surgery providers in the service area, both of which have experienced increasing volume of open heart surgery. With the need to maintain available capacity for patients of this broad service area, particularly for a service with a substantial portion of emergency or urgent cases, no other provider can effectively meet this need.”

In Section V.7, pages 64-66, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The proposed project is consistent with the basic policies of the 2016 SMFP. The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area and will thus be in compliance with the spirit and legislative intent of the CON Law.”

The applicant states the following in regard to cost effectiveness of the proposed project:

- The proposed equipment, along with the existing heart-lung machines, will be stored in a pump room and moved into any of Rex’s operating rooms for open heart surgery cases when needed, rather than having a dedicated OR for open heart surgeries, which is an effective use of physical and financial resources; and
- As a member of UNC Health Care, Rex benefits from cost savings through the consolidation of multiple services and large economies of scale.

In regard to how the proposed project will promote safety and quality, the applicant states:

- The proposed project will serve to improve the quality of open heart surgical services at Rex through expanded capacity; and
- The proposed project will promote safety and quality in the delivery of healthcare services as the proposed equipment will be used to support both scheduled and non-scheduled open heart cases, thereby ensuring access to critically necessary care.

In regard to how the proposed project will promote access to the proposed services, the applicant states:

- Rex cares for all patients regardless of their ability to pay or any other perceived level of underservice; and
- The proposed project will allow Rex to ensure sufficient heart-lung bypass capacity to meet growing demand.

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

The information provided by the applicant 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 to acquire a fourth heart-lung bypass machine. 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 discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is 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 I.12, pages 9-10, the applicant lists the facilities and programs owned by Rex Hospitals, Inc. (UNC Rex Healthcare). The University of North Carolina Healthcare System owns or manages nine licensed healthcare facilities in North Carolina, including Rex Healthcare. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, incidents occurred at three of the nine licensed facilities 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 Agency is waiting for CMS final determination on one facility and waiting for a Plan of Correction from the other two facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Rex and the other eight facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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

SECTION .1700 – CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND HEART-LUNG BYPASS MACHINES

10A NCAC 14C .1703 PERFORMANCE STANDARDS

- (a) An applicant that proposes to develop open-heart surgery services shall:
- (1) demonstrate that the projected utilization and proposed staffing patterns are such that each open heart surgical team shall perform at least 150 open heart surgical procedures in the third year following completion of the project; and
 - (2) document the assumptions and provide data supporting the methodology used to make these projections.

-NA- The applicant does not propose to develop open-heart surgery services.

- (b) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate either:
- (1) that the applicant's projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C .1703(b)(3)) will be at least 200 open heart surgical procedures per machine during the third year following completion of the project;
 - (2) that the projected annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than a machine acquired pursuant to 10A NCAC 14C .1703(b)(3)), will be at least 900 hours per year during the third year following completion of the project, as measured in minutes used or staffed on standby for all procedures; or
 - (3) that the proposed machine is needed to provide coverage for open-heart surgery emergencies and will not be scheduled for use at the same time as the applicant's equipment used to support scheduled open heart surgical procedures.

- C- In Section II.8, pages 29-30, the applicant projects to exceed the performance standard under subsection (b)(1) of this Rule, performing 210 surgical cases per machine. The assumptions and calculations used to project utilization of Rex's three existing and one additional heart-lung bypass machines are provided in Section III.1(b), pages 40-45. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.