

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 13, 2013
PROJECT ANALYST: Gene DePorter
TEAM LEADER: Lisa Pitman

PROJECT I.D. NUMBER: J-10149-13/ Rex Hospital, Inc. / Acquire and install fixed fluoroscopy equipment in existing OR/ Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Rex Hospital, Inc. (Rex Hospital) proposes to acquire one unit of fixed fluoroscopy equipment to create a hybrid operating room (OR) in one of the existing 27 operating rooms at Rex Hospital. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP). However, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 43 of the 2013 SMFP, is applicable to the review of this proposal. Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the

applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section III.2, page 51, the applicant states:

"There are no need determinations in the 2013 SMFP specific to the proposed project."

Rex Hospital states, on page 53, that since the project includes only up-fits to an existing operating room to accommodate the new equipment, the ability to improve energy efficiencies and conservation of resources will be a function of the current efficiencies present in the existing space. In addition, Rex's engineering management team constantly works to improve and conserve energy and more efficiently use hospital resources.

In Section III. 2, page 53, the applicant states; *"The proposed equipment will meet or exceed the North Carolina State Energy Conservation Code. Please see Exhibit 17 for a copy of Rex's written statement describing the project's plan to assure improved energy and water conservation in accordance with GEN-4 requirements."*

The applicant adequately demonstrates the proposal includes a commitment to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and 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

In Section II.1(a), page 16, the applicant, Rex Hospital, whose parent company is Rex Healthcare, Inc. proposes to acquire one unit of fixed fluoroscopy equipment to create a hybrid operating room in one of its 27 existing operating rooms which include 3 dedicated C-Section rooms and 24 shared inpatient/outpatient (IP/OP) operating rooms.

Operating Room Renovations

The applicant proposes to reconfigure 912 square feet of space in O.R. # 15 to accommodate the fixed fluoroscopy equipment and creation of an equipment room and a control room within the renovated operating room. The proposal consists of the following components:

- Renovation to include lead-lined walls,
- Creation of an equipment and control room within O.R. # 15, and
- Ceiling work to accommodate proposed equipment.

In Section III.1 (a), page 43, the applicant states:

“The proposed fixed fluoroscopy equipment will enable Rex to advance its provision of surgical services and support the evolution of clinical care at the hospital. As such, the acquisition of this equipment will allow Rex to continue to provide state-of-the-art care.”

Services Proposed – Hybrid Operating Room

In Section II, pages 16-17, the applicant states that locating the proposed fixed fluoroscopy equipment in an operating room will enable Rex Hospital to deliver services in a manner not currently available. Vascular conditions requiring intervention have traditionally been treated with either open surgery in an operating room or with a minimally invasive approach in a vascular interventional radiology room. According to the applicant, the ideal approach is to combine methods. Therefore, Rex Hospital is proposing to install fixed fluoroscopic imaging equipment in an existing operating room. This will enable Rex Hospital to provide *“less invasive, more accurate, and very accurate and very precise treatment of arterial and venous diseases and other conditions.”*

In Section III.1 (a), pages 41-42, the applicant lists the following benefits for the proposed equipment in an operating room:

- Image quality is superior on fixed imaging systems. Fixed fluoroscopy equipment will allow for better visualization during vascular intervention surgical cases than what is currently possible using a mobile C-arm.
- The proposed equipment will optimize patient care by eliminating the need to schedule multiple procedures on different days or to transfer patients between operating room and imaging during the procedure.
- Installation of the proposed equipment in an operating room will facilitate conversion of the procedure to an open procedure, if necessary, without relocating the patient.

The applicant confirms that this project does not include cardiac catheterization equipment as defined in N.C.G.S. 131E-176(2)(f). The proposed equipment will not be used to provide cardiac catheterization procedures. Nor will the proposed equipment be used to diagnose heart abnormalities or to perform surgical procedures on the coronary blood vessels of the heart.

Population to be served

In Section III.4 (a)-(b), pages 56-57, the following two tables illustrate the patient origin for inpatient services for Rex Healthcare and the Rex Vascular Interventional Surgical Services:

Rex Healthcare
FY 2012 Acute Care Discharges

County	% Patients
Wake	78.7%
Johnston	5.4%
Franklin	3.1%
Harnett	2.7%
Durham	1.3%
Other	8.7%
Total	100.0%

Source: Rex internal data

Rex Vascular Interventional Surgical Cases
FY 2012 Patient Origin

County	% Patients
Wake	71.1%
Franklin	5.5%
Johnston	5.5%
Harnett	3.6%
Other	14.2%
Total	100.0%

Source: Rex Internal Data.

One patient is assumed equivalent to one case

In Section III, page 59, the applicant states that it does not expect any change in its patient origin as a result of the proposed project. The following table illustrates the interim and first three full fiscal years of interventional surgical case volume. Rex Hospital's vascular interventional surgical cases for FYs 2016-2018 are projected to be constant at 978 cases per year.

**Rex Vascular Interventional Surgical Cases
Interim and Projected Cases**

County	FY 2013 Cases	FY 2014 Cases	FY 2015 Cases	FY 2016 Cases	FY 2017 Cases	FY 2018 Cases
Wake	501	596	696	696	696	696
Franklin	39	42	54	54	54	54
Johnston	39	42	54	54	54	54
Harnett	25	30	35	35	35	35
Other	100	119	139	139	139	139
Total	705	838	978	978	978	978

Source: Rex Internal Data, Form C

One patient is assumed equivalent to one case

The applicant states, on pages 57-59, that Wake, Franklin, Johnston and Harnett counties represent 86% of its historical and projected patient origin for vascular interventional surgical cases. The applicant adequately identified the population proposed to be served.

Need for the Proposed Project

In Section II.1(a), pages 16-17, the applicant discusses interventional radiology:

“Interventional radiology is a rapidly growing field of medicine that uses image guided, minimally invasive diagnostic and therapeutic techniques to perform procedures that many times prevent the need for conventional, traditional open surgery. These procedures involve very small incisions and are provided at a lower risk to patients. This results in several benefits to the patient, including: less pain, shorter recovery periods, and lower costs to the patient.”

On page 18, the applicant discussed the proposed fixed fluoroscopy equipment: The proposed equipment is designed for imaging in the operating room setting and will provide greater accuracy in image-guided procedures at a low radiation dose. The system enables image guided surgery, one stop pre- and post-operative imaging, endovascular therapy, and provides the anesthesiologist with free access to the patient. In addition, ergonomically designed controls improve staff circulation and efficiency. On pages 39-43, the applicant discusses the development of Rex Hospital’s surgical and vascular services, including *“a paradigm shift in the treatment of vascular diseases from the once traditional open surgical approaches to minimally invasive approaches. Moreover, according to the Advisory Board, procedures that are best performed, and in some cases can only be performed in a vascular operating room setting, will experience growth from 2010 through 2015 as illustrated in the table below.*

Service	Projected Growth 2010-2015
<i>Cardiac Valve Surgery</i>	9%

<i>Percutaneous Valve Surgery</i>	228%
<i>Abdominal Aortic Aneurysm Endografts</i>	153%
<i>Thoracic Aortic Aneurysm Endografts</i>	51%
<i>Carotid Artery Stent Procedures</i>	136%

Projected Utilization

In Section III.1(b), pages 44-51, the applicant describes the evolution of vascular interventional services at Rex Hospital. Four surgeons from an independent physician practice, Carolina Vascular, performed vascular surgery at Rex Hospital until FY 2012 when Rex Hospital created Rex Vascular Specialists, an employed physician practice. This group began in August 2011 with the employment of one physician. During the transition, there was a temporary decline in vascular surgery volume which has rebounded. The development of the Rex Vascular Specialists practice has continued with the addition of 4 more physicians for a total of 5 specialists. These physicians are in the early stages of practice ramp-up. The applicant notes that even while in the ramp-up phase of practice development, the specialists are on pace to perform approximately 705 cases in FY 2013. The following table illustrates the historical vascular interventional surgical cases at Rex Hospital.

Physician	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013 YTD (Jul.-Dec. '12)	FY 2013 Annualized
Carolina Vascular Practice						
Dr. Edrington	172	163	79	19	-	
Dr. Clark	153	132	109	5	-	
Dr. Longo	153	173	63	2	-	
Dr. Fogartie	137	93	34	4	-	
Subtotal	615	561	285	30	0	0
Rex Vascular Surgical Specialists						
Dr. Mendes	-	-	-	221	139	278
Dr. deFreitas	-	-	-	-	54	130
Dr. Fulton	-	-	-	-	20	60
Dr. Ford	-	-	-	2	14	42
Dr. Kim	-	-	-	-	-	195
Subtotal	0	0	0	223	227	
Total Cases	615	561	285	253	227	705

*FY 2013 YTD includes procedures performed from July 1, 2012 to December 31, 2012 and excludes 65 cases performed by Dr. Kim from Feb. 2013 – May 2013.

Source: Rex internal data

On page 46, the applicant provides the methodology it used for annualizing the 2013 vascular interventional surgical cases, as shown below.

Physician	Date MD	# Months	# Cases in	FY 2013
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	Started	Data in FY 2013	FY 2013	Annualized Cases
Dr. Mendes	Aug. '11	6	139	278
Dr. deFreitas	Aug. '12	5	54	130
Dr. Fulton	Sept. '12	4	20	60
Dr. Ford	Sept. '12	4	14	42
Dr. Kim	Feb. '13	4	65	195
Total Cases			292	705

The applicant also calculated the growth in cases since the transition to employed vascular surgeons, noting that most of those physicians are new to the area and have not reached their maximum productivity levels.

Growth in Cases since Transition to Employed Vascular Surgeons

	FY 2012	FY 2013 Annualized	# Increase	% Increase
Total Cases	253	705	452	178%

On pages 46-47, the applicant explains the methodology used for its case projections by physician.

- Beginning June 2013, operating room block time for the vascular surgeons will increase from 1.5 days per week to 5 days per week – more than triple the current available operating time.
- Dr. Mendes’ volume will increase as his emergency call duty is shared among the new physicians; however projections keep his case load at FY 2013 levels.
- The productivity of Drs. deFreitas and Kim will increase to 250 cases per year beginning in FY 2015. In FY 2014, each will perform 80% of 250, or 200 cases each.
- Drs. Fulton and Ford split their time between UNC Hospitals and Rex Hospital, thus the applicant estimates they represent 0.8 FTE at Rex Hospital. By FY 2015 combined they will perform 80% of the case load of Drs. deFreitas and Kim. FY 2014 reflects an 80% ramp-up.

Physician	FY 2013 Annualized Cases	Projections				
		FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Dr. Mendes	278	278	278	278	278	278
Dr. deFreitas	130	200	250	250	250	250

Dr. Fulton	60	80	100	100	100	100
Dr. Ford	42	80	100	100	100	100
Dr. Kim	195	200	250	250	250	250
Total Cases	705	838	978	978	978	978

In pages 48-49, Rex Hospital further explains why it believes its projections are conservative:

- The new fluoroscopy equipment will result in better imaging and shorter average case times.
- The methodology used results in a more reasonable and conservative compound annual growth rate (CAGR) than the 178% change seen from FY 2012 to FY 2013. The CAGR from FY 2013 – FY 2018 is 6.8%.

Next, the applicant assumes that the inpatient and outpatient vascular interventional procedures will maintain the same procedure splits as FY 2013 YTD, as shown in the following table.

	FY 2013 YTD	Percent of the Total
Inpatient procedures	89	39.2%
Outpatient procedures	138	60.8%
Total	227	100.0%

In the following table, the applicant illustrates the projected mix of patients and the resulting projected utilization of the hybrid operating room.

	FY 2013 Annualized	Projected FY 2014	Projected FY 2015	Projected FY 2016	Projected FY 2017	Projected FY 2018
Total Cases	705	838	978	978	978	978
Inpatient	276	329	383	383	383	383
Outpatient	428	509	595	595	595	595
Total Hours	1,471	1,750	2,042	2,042	2,042	2,042
OR Capacity	2,340	2,340	2,340	2,340	2,340	2,340
% Utilization	63%	75%	87%	87%	87%	87%

The applicant shows in the above table that the projected surgical hours for these cases will grow from 1,471 hours in FY 2013 to 2,042 in FYs 2015-2018 resulting in 87% by FY 2015. This will exceed the standard hours per operating room definition in the 2013 SMFP of 1,872 hours per year per operating room or 80% utilization.

In Section III.1(b), pages 50-51 the applicant summarizes its need for the project:

“In summary, Rex has clearly demonstrated the quantitative need for the proposed project. Rex conservatively projects that the new vascular operating room will perform

978 total vascular interventional surgical cases by the third project year, which represents 87% capacity utilization and exceeds the performance target of 80 percent.

Rex believes that it has a need for the proposed equipment regardless of the projected level of utilization in order to maximize the efficiency of its vascular surgeons and deliver the highest quality clinical care. As discussed above, Rex expects its number of vascular interventional surgical cases to increase in the future based on the recent addition of vascular surgeons to its medical staff. Irrespective of these additional physicians and their volume, Rex believes the proposed equipment is needed in order to support its current patients. Nonetheless, the projection methodology above demonstrates that the proposed equipment will be well-utilized based on reasonable and conservative assumptions.”

Access

In Section VI, pages 73-74, Rex Hospital states that it 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 summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population has for a hybrid operating room, and adequately demonstrated the extent to which all residents, including the medically underserved, will have access to the proposed services. Therefore, the application is conforming to this criterion

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

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 53-56, the applicant describes the alternatives considered as maintaining the status quo, placing the fluoroscopy equipment in a procedure room or placing fluoroscopy equipment in an operating room. Maintaining the status quo was rejected because it would result in the continued use of a mobile c-arm to perform visualization in the OR. Locating the fluoroscopy equipment in a procedure room is not as efficient and effective as placing it in an OR.

Rex Hospital determined that the project as proposed in the application is the most cost-effective, resource responsible, and accessible alternative. In Section III.3, page 55-56, the applicant stated the following:

“The proposed project will enable less invasive, more accurate and very precise treatment of arterial and venous diseases and conditions. Not only will the proposed equipment provide quick and detailed information for shorter, more accurate treatment with substantially less X-ray exposure when compared to traditional devices, but also patients can be diagnosed and treated in one room in one visit, for less downtime and a speedier recovery. Further, complex cases will be more easily treated given that the room will be designed to handle both minimally invasive percutaneous operations and open surgical procedures. As such, the proposed project will promote safety and quality in the delivery of healthcare services as the proposed equipment will be used to support surgical procedures and its enhanced image quality will allow for the substitution of minimally invasive procedures for open procedures, thereby reducing patients’ lengths of stay and overall cost to the system.”

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to provide fixed fluoroscopy equipment in an existing operating room (Room 15). The application is conforming to all applicable statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. Therefore, the application is conforming with this criterion and approved subject to the following conditions.

- 1. Rex Hospital, Inc. d/b/a Rex Hospital shall materially comply with all representations made in its certificate of need application.**
- 2. Rex Hospital, Inc. d/b/a Rex Hospital 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 which would otherwise require a certificate of need.**
- 3. Rex Hospital, Inc. d/b/a Rex Hospital, shall acquire no more than one fixed fluoroscopy imaging equipment system to be installed in an existing operating room.**
- 4. Upon completion of the project, Rex Hospital, Inc. d/b/a Rex Hospital shall be licensed for no more than 27 operating rooms, including 3 dedicated C-Section and 24 shared inpatient/ambulatory surgery operating rooms.**
- 5. Prior to issuance of the certificate of need, Rex Hospital, Inc. d/b/a Rex Hospital, shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**

- (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

In Section VIII.1 (a)-(b), page 101, the applicant indicates that Rex Hospital will be responsible for all capital costs. Capital costs are based upon equipment estimates from vendors, project architects and contractors.

In Section VIII. 2(a), page 101, the applicant provides the following list of medical equipment valued at more than \$10,000, that is included in the proposed project.

Equipment	Cost/FMV
Fixed Fluoroscopy Equipment	\$1,679,861
Integration System	\$126,570
OR Lights	\$38,987
Flat Panel and Monitor	\$27,717
EIZO Monitor System	\$238,800
Portable Ultrasound*	\$60,000
Reading Station	\$15,000

* The portable Ultrasound will not be used to perform routine diagnostic Ultrasound procedures; it will be used for guiding access only.

The total capital cost of the project will be \$2,758,606, including \$771,482 for materials and labor, \$1,679,861 for the fixed fluoroscopy equipment, \$181,249 for consulting fees \$5,500 for furnishings and \$120,514 for Contingency, Insurance and Escalation. In Section IX, page 109, the applicant states that the project involves an existing service. Therefore, there are no start-up expenses or initial operating expenses. In Section VIII.3, page 104, the applicant states that the project will be funded by means of Rex Healthcare accumulated reserves (\$2,758,606). Exhibit 22 contains a June 17, 2013 letter signed by the Senior Vice President for Finance and Chief Financial Officer of Rex Healthcare which states:

“As the Chief Financial Officer, I am responsible for the financial operations of Rex Healthcare. As such I am very familiar with the organization’s financial position. The total capital expenditure for this project is estimated to be \$2,758,606. There are no start-up costs related o this project.

Rex Healthcare will fund the capital cost from accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the line items ‘Cash and Cash Equivalentents’ and ‘Assets Limited As To Use’ in the audited financial statements included with this Certificate of Need application.”

Exhibit 23 of the application contains the audited financial statements for Rex Healthcare for the years ending June 30, 2012 and June 30, 2011. As of June 30, 2012 Rex Healthcare had \$70,527,000 in cash and cash equivalents and \$448,193,000 in net assets (total liabilities less total assets). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project, for Rex Healthcare and vascular interventional surgical cases. The applicant projects that revenues will exceed operating expenses in each of the first three operating years for vascular interventional surgical services and for Rex Healthcare. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable including projected utilization. Section-Financials Tab, pages 121-128 provides the pro forma and assumptions. See Criterion (3) for discussion of utilization projections. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and 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.

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The applicant proposes to acquire and install a fixed fluoroscopy unit in Operating Room 15 to establish a hybrid operating room. The applicant does not propose any new services or additional beds or equipment. The endovascular imaging equipment system, to be located in an existing OR, will allow Rex Hospital to perform open surgical procedures as well as image guided endovascular procedures in the same operating room. The applicant adequately demonstrates the need to acquire an endovascular imaging equipment system to create a hybrid OR in an existing OR. See Criterion (3) for additional discussion. The applicant adequately demonstrated that the proposal would not result in an unnecessary duplication of existing and approved services. 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.

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In Section VII.1 (a) (b), pages 92-93, the applicant provides the current and projected staffing during the second full fiscal year for the hospital's proposed hybrid operating room for Vascular Interventional Surgical service, as illustrated in the table below.

POSITION	CURRENT FTES	PROJECTED FTES FY 2017
Registered Nurse/Circulator	1.8	1.8

Anesthesia Technician	1.8	1.8
Surgical Technician	1.8	1.8
Patient Care Assistant	1.8	18
Diagnostic Technician	1.8	1.8
Total	9.0	9.0

As illustrated in the above table, the applicant projects to maintain the current staffing level through FY 2017, but notes that Interventional Technicians will replace diagnostic technicians when the proposed equipment becomes operational in FY 15. The applicant further notes that physician fees are billed separately and not included in the Pro Formas.

In Section VII.2 (a) (b), pages 94-95, the applicant illustrates that the 9.0 FTE staff for the hybrid operating room cover the following areas; 1.2 FTE for Pre-Op, 1.2 FTE for Post-Op and 6.6 FTEs for the operating room. The staffing numbers will remain the same through 2017. Rex does not propose to change its hours of operation as part of the proposed project. As such, services will continue to be offered on a twenty-four hours a day, seven days a week basis.

The proposed project is not dependent upon additional physician recruitment. All needed physicians are in place. The Chief Medical Officer is Linda Butler, M.D. (Pediatrics). The applicant demonstrated the availability of adequate health manpower and management personnel to provide the proposed services, and 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.

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The applicant currently provides vascular surgical services and the necessary ancillary and support services are currently available. In Section II.2 (a), page 21, the applicant states:

“As an existing full service acute care hospital, Rex currently has all ancillary and support services in place necessary to support hospital operations. These existing ancillary support services will also support the additional fixed fluoroscopy equipment proposed in this application. Patients that are treated in the operating room may require use of any of Rex’s ancillary and support services including laboratory, radiology, pharmacy, dietary, housekeeping, maintenance and Administration, among others”

See Exhibit 6 of the application for a copy of a letter from the Senior Vice President of Finance and Chief Financial Officer at Rex Healthcare attesting to the availability of ancillary and support services. Exhibit 27 contains letters of support from physicians and others for the proposed hybrid OR.

As an existing hospital, Rex has existing referral and transfer relations with area healthcare providers. As an example, Exhibit 7 contains the EMTALA policy which describes in part referral and transfer relations.

The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI. 4(f), page 116, the applicant provides the following table that illustrates construction cost and total cost per square foot for the proposed project.

	Estimated SF	Construction Cost per SF	Total Cost per SF
Total	912	\$845.92	\$3,024.79

Exhibit 25 contains a certified cost estimate for construction costs of the proposed project by a certified architect dated May 28, 2013 indicating the construction cost is \$771,482. The architect's estimate is consistent with the applicant's projected capital cost for construction contained in Section VIII. 2, page 102. Exhibit 3 contains line drawings for the proposed project.

In Section XI.7, page 117, the applicant states:

“Given that the project includes only upfits to an existing operating room to accommodate the new equipment, the ability to improve energy efficiencies and conservation of resources rests in the efficiencies present in its existing facility. ...The proposed equipment will meet or exceed the North Carolina State Energy Conservation Code. Please see Exhibit 17 for a copy of Rex's written statement describing the project's plan to assure improved energy and water conservation in accordance with GEN-4 requirements.”

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project it proposes and that the construction cost will not unduly increase costs and charges for health services, and that applicable energy saving features have been incorporated into the construction plans. See Criterion (5) for discussion of costs and charges. The application is conforming to this criterion.

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

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

C

In Section VI.12 and VI.13, page 89, the applicant provides the payor mix during Fiscal Year 2012 for the entire hospital and for the vascular services department, as illustrated in the table below:

Rex Healthcare FY 2012		
Payor	Entire Facility	Vascular Interventional Surgical Cases
Commercial Insurance	44.9%	26.1%
Medicaid	5.7%	2.8%
Medicare/Medicare Managed Care	44.2%	68.4 %
Other (CHAMPUS / Workman Comp)	1.0%	0.0%
Self Pay / Indigent / Charity	4.2%	2.8%
Total	100.0%	100.0%

Payor mix for the entire facility is based on patient days.

Payor mix for vascular services is based on cases.

In Section VI.2, page 73-79, 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. Please see Exhibit 19 for a copy of Rex’s Admission Policy as well as its Patient Rights and Responsibilities Policy, which details Rex’s commitment to serve any patient, regardless of age, race, sex, creed, religion, disability, or patient’s ability to pay. In particular, as stated in Rex’s Patient Rights and Responsibilities Policy, patients have the right to receive ‘care that is free of discrimination’ and ‘medically necessary treatment regardless of [their] ability to pay.’

...

*Rex is fully committed to the health and well being of the residents of Wake County.
 ...Rex seeks to impact all of its neighbors through a variety of means to prevent illness and improve the quality of life in the area.*

...

Rex’s services have been and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured.”

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Wake County and statewide

	June 2010 Total # of Medicaid Eligible’s as % of Total Population*	June 2010 Total # of Medicaid Eligible’s Age 21 and older as % of Total Population*	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)*
Wake County	9.8%	3.3%	18.4%
Statewide	17.0%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically use the vascular interventional surgical services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that medically underserved populations currently have adequate access to the services offered at Rex Hospital. 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 88, 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. However, in order to maintain

Rex’s § 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.”

In Section VI.4 (a), page 82, the applicant states:

“Rex provides access to care to all patients regardless of age, race, national or ethnic origin, disability, sex, income, or ability to pay. Patients are admitted and services are rendered in compliance with:

- *Title VI of Civil Rights Act of 1963.*
- *Section 504 of Rehabilitation Act of 1973.*
- *The Age Discrimination Act of 1975.”*

In FY 2012 Rex Healthcare reports that it provided \$109 million in bad debt and charity care.

See Exhibit 19 for a copy of the applicants’ Policy and Procedure regarding Rex Hospital’s admission policies and Exhibit 20 for the Patient Financial Assistance Policy. The applicant states on page 87; *“No civil rights equal access complaints have been filed against Rex in the past five years.”* Therefore, the application is conforming to this criterion.

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

C

In Section VI.14 (a) (b), pages 90-91, the applicant provides the projected payor mix for the second full fiscal year of operations for the entire facility and for vascular interventional surgical services, as illustrated in the table below:

Rex Hospital Second Full Fiscal Year FY 2017		
Payor	Entire Facility	Vascular Interventional Surgical Cases
Managed Care/Commercial	44.9%	26.1%
Medicaid	5.7%	2.8%
Medicare/Medicare Managed Care	44.2%	68.4%
Other (CHAMPUS / Workman Comp)	1.0%	0.0%
Self Pay / Indigent/Charity	4.2%	2.8%
Total	100.0%	100.0%

*Payor mix for the entire facility is based on patient days.

Payor mix for vascular services is based on cases.

As illustrated in the table above, the applicant projects no change in the payor mix.

The applicant demonstrated 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 86, the applicant states:

“Persons will have access to services at Rex through referrals from physicians on 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 identified the range of means by which patients will have access to the proposed 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 V.1 (a), page 65, the applicant states:

“Rex Healthcare has extensive relationships with area clinical training programs. Rex has more than 60 agreements with health professional training programs throughout the southeast, as demonstrated in Exhibit 18.”

These programs include agreements with UNC, Duke University, and East Carolina University. Rex also has agreements with local programs such as Durham Technical Community College. Rex also supports community based healthcare professional organizations. Rex is also a member of Healthcare Works! Coalition, a coordinated effort between local facilities and community colleges to enhance the careers of healthcare workers in the region.

The applicant demonstrates that the facility will continue to accommodate the clinical needs of health professional training programs in the area. The information provided is reasonable and credible and supports a finding of conformity with 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

Rex Hospital proposes to acquire one unit of fix fluoroscopy equipment to create a hybrid OR, in one of the 27 operating rooms located at Rex Hospital. In Section V.7, pages 70-72, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost effectiveness, quality and access. See also Sections II.6-7, pages 24-26; Section III.1, 2, 3, 6, 7, pages 38-61; Sections V.7, VI, VII, and XI.7 where the applicant discusses the impact of the proposed project on cost effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to the proposed service area. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrated the need for one unit of fixed fluoroscopy equipment to create a hybrid OR and that it is a cost effective alternative.
- The applicant demonstrated that it has and will continue to provide adequate access to the proposed services. In Section VI.2, page 73-79, 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.”

- The applicant adequately demonstrated that it has and will continue to provide quality services. Exhibit 8 contains a letter from the Rex Hospital Chief Financial Officer documenting that proposed services will be operated in conformance with all applicable, facility, programmatic, and service specific licensure, certification, and The Joint Commission accreditation standards.

Therefore, the application is conforming to this criterion.

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

C

Rex Hospital is currently licensed by the North Carolina Department of Health and Human Services, is accredited by The Joint Commission and certified by CMS for Medicare and Medicaid participation. According to the files in Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. 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 Major Medical Equipment, promulgated in 10A NCAC 14C .3100. The specific criteria are discussed below.

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

10A NCAC 14C .3103 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.
- C- Rex Hospital used the Acute Care Facility/Medical Equipment application form.

- (b) An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services; unless the applicant documents that other providers outside of the applicant's existing service area are expected to refer patients to the applicant.
- C- In Section II, page 28, the applicant defined the service area for the proposed hybrid OR based on its current patient origin. The applicant states the primary service area includes Wake, Franklin, Johnston and Harnett counties which collectively account for 85.8 percent of the total volume of the proposed project.

County	% of Total
Wake	71.1%
Franklin	5.5%
Johnston	5.5%
Harnett	3.6%
Other	14.2%
Total	100.0%

- (c) An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.
- C- In Section II, page 28, the applicant describes its experience in providing care to the patients to be served by the proposed project. The applicant states:

“This service area is based on the current patient origin for Rex’s vascular surgical intervention cases. In addition, these counties are also consistent with Rex’s service area for other higher level tertiary services.”

In Section I. 12(c), the applicant describes in detail its experience in cardiovascular services.

- (d) An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.
- C- See Exhibit 10 for a letter that documents the proposed equipment is approved for the clinical uses proposed by the applicant by the U.S. Food and Drug Administration.

- (e) An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:
 - (1) receiving/registering area;
 - (2) waiting area;
 - (3) pre-procedure area;
 - (4) procedure area or rooms;
 - (5) post-procedure areas, including observation areas; and
 - (6) administrative and support areas.

- C- The project line drawings included in Exhibit 3 identify each of the areas listed above.

- (f) An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and federal, state, and local manufacture's standards for the type of major medical equipment to be installed.

- C- Exhibit 11 contains a letter from the Chief Financial Officer of Rex Hospital, documenting that the project will be developed in accordance with federal, state, and local building codes and standards.

10A NCAC 14C .3104 NEED FOR SERVICES

- (a) An applicant proposing to acquire major medical equipment shall provide the following information:
 - (1) the number of patients who will use the service, classified by diagnosis;

- C- See Section II, pages 30-32, for the number of patients projected to use the hybrid OR, classified by diagnosis for the first three years of operation for the proposed equipment.

- (2) the number of patients who will use the service, classified by county of residence;

- C- In Section II, page 32, the applicant provides the following number of patients who will use the service, by county for the first three years of operation.

County	Historical Distribution	Projected Cases (Patients)		
		FY 2016	FY 2017	FY 2018
Wake	71.1%	696	696	696
Franklin	5.5%	54	54	54

Johnston	5.5%	54	54	54
Harnett	3.6%	35	35	35
Other*	14.2%	62	62	62
Total	100.0%	978	978	978

Note: "Other" includes Chatham, Cumberland, Granville, Lee, Nash, Vance and Wayne Counties.

Totals may not foot due to computer rounding.

- (3) documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;
- NA- Not Applicable. Rex is proposing to acquire and locate fixed fluoroscopy equipment in an operating room in order to deliver services in a manner not currently available.
- (4) quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and
- C- In Section II, page 33, the applicant provides the following quarterly projected utilization for the proposed equipment for the first three years following completion of the proposed project:

Projected Number Patients by Quarter

Quarter	FY 16	FY 17	FY 18
First	245	245	245
Second	245	245	245
Third	245	245	245
Fourth	245	245	245
Total	978	978	978

Totals may not foot due to computer rounding.

- (5) all the assumptions and data supporting the methodology used for the projections in this Rule.
- C- The applicant provides the assumptions and methodology in Section III.1 (b), pages 43- 51 and the Section for Financials, pages 126-128.

- (b) An applicant proposing to acquire new major medical technology shall provide the following information:
- (1) the number of patients who will use the service, classified by diagnosis;
 - (2) the number of patients who will use the service, classified by county of residence;
 - (3) quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;
 - (4) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;
 - (5) documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and
 - (6) all the assumptions and data supporting the methodology used for the projections in this Rule.

-NA- In Section II, 1(a), page 17, the applicant states the following;

“...the patients that will be treated using this equipment are currently being treated at Rex using other means, such as a mobile C-arm during surgery or through separate procedures in a vascular interventional radiology room and in an operating room; the purpose of the proposed equipment is to support the advancement of clinical care at Rex.” The proposed hybrid operating room will consolidate two services into one location.

10A NCAC 14C .3105 SUPPORT SERVICES

An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.

-C- In Section II. 8, page 35, the applicant states,

“As an existing full-service acute care hospital, Rex currently has all necessary ancillary and support service infrastructure in place. This infrastructure as well as existing ancillary and support staff will be sufficient to support the fixed fluoroscopy equipment proposed in this application. Patients that are treated in the operating room may require the use of any of Rex’s existing ancillary and support services including laboratory, radiology, pharmacy, dietary, housekeeping, maintenance, and administration among others.”

See Exhibit 6 for a letter from the Financial Officer of Rex Hospital, documenting the hospital's willingness to continue providing ancillary and support services after the proposed project is developed.

10A NCAC 14C .3106 STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire major medical equipment or new major medical technology shall document that:

- (1) trained and qualified clinical staff shall be employed, and
- (2) trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.

-C- Section VII.1 (b), page 93 addresses the staffing for the proposed project. Exhibit 12 includes job descriptions and Exhibit 13 contains a letter from the Senior Vice President of Finance and Chief Financial Office of Rex Healthcare referencing the hospital's history of hiring and employing trained and qualified clinical, technical and support staff in accordance with 10 NCAC 14C .3106(a) (b). The trained and qualified clinical staff includes RNs, surgeons, anesthesiologists, technical and support staff.

In Section VII the applicant indicates that the 9.0 current FTEs is sufficient to cover the projected volume of cases in the hybrid operating room through FY 2017. In Section VII. 3(b), page 96 the applicant states that; *"No new positions will result from the proposed project."*

In Exhibit 15 the applicant provides a description of the educational competencies required of staff relevant to the proposed service and staff responsibilities.

(b) An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.

-C- Exhibit 14 contains the curricula vitae for the physicians who will use the proposed equipment. The curricula vitae document that these physicians have the relevant residency training, formal continuing medical education courses, and prior on-the-job experience with the same or similar equipment. In addition Siemens will provide 64 hours of on-site training (Reference Exhibit 5, page 4 of 5).

(c) An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:

- (1) certification in cardiopulmonary resuscitation and basic cardiac life support; and
- (2) an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.

-C- Exhibit 12 contains job descriptions which reference the fact that all staff utilizing the proposed equipment who will have clinical contact with the patient and are required to maintain Basic Cardiac Life Support (BCLS). BCLS training is a requirement every two years for all RNs and support staff. Rex also provides Advance Cardiac Life Support (ACLS) training. Exhibit 16 contains a copy of the Rex ACLS renewal class schedule.

Exhibit 15 includes policies related to Rex's core competencies for existing staff as well as orientation and training for new staff. In addition, the vendor will be providing 32 hours of on site training and 32 hours of follow-up training, for the proposed fixed fluoroscopic equipment, for operating room nursing staff, technicians, and physicians.