

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 1, 2016

Findings Date: April 1, 2016

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: J-11112-15

Facility: Duke University Hospital

FID #: 090108

County: Durham

Applicant: Duke University Health System, Inc.

Project: Replace two existing magnetic resonance imaging (MRI) scanners and relocate them to the Center for Living in the Wallace Building

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.

C

Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (DUH), proposes to replace two existing magnetic resonance imaging scanners (MRI). One is currently located at Lenox Baker, an outpatient clinic on the DUH campus, and the other is currently located at an outpatient clinic on Page Road. Both replacement MRI scanners will be relocated to the Wallace Building at the Center for Living located on the Duke University campus. Additionally, once the Page Road MRI scanner is replaced and relocated to the Center for Living, DUH proposes to move one of the Alliance Imaging MRI scanners now located at Lenox Baker to Page Road.

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 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2015 SMFP that is applicable to this review: Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES.

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 of 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.”

The proposed capital expenditure for this project is greater than \$5 million. In Section III.2, page 19, the applicant addresses Policy GEN-4 and the center’s plan for energy efficiency and water conservation. The applicant states:

“The construction to be undertaken for this project is relatively minimal, but Duke is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. Water conserving fixtures and faucets will be specified. LED fixtures are planned for the use wherever possible. Duke will comply with state and local building codes and will avail itself of sustainable initiatives to the extent reasonable and appropriate.”

The applicant adequately demonstrates the proposal includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to Condition 3 in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to replace two existing MRI scanners and relocate them to the Center for Living in the Wallace Building located on the DUH campus in Durham. One of the MRI scanners to be relocated and replaced is currently located at Lenox Baker on the DUH campus. The second MRI scanner to be relocated and replaced is located at an outpatient clinic on Page Road. The MRI scanner at Page Road will then be replaced by an existing Alliance Imaging MRI scanner currently located at Lenox Baker.

Population to be Served

On page 146, the 2015 SMFP defines a fixed MRI's service area as "*a single county, except where there is no licensed acute care hospital located within the county. Counties lacking a licensed acute care hospital are grouped with the single county where the largest proportion of patients received inpatient acute care services, as measured by acute inpatient days, unless two counties with licensed acute care hospitals each provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. In that case, the county lacking a licensed acute care hospital is grouped with both counties which provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days.*" Table 9P on page 155 of the SMFP shows Duke University Hospital is located in the Durham/ Caswell Service Area.

Thus, the service area for this project is Durham and Caswell counties. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a) and (b), pages 21-22, the applicant identifies the population currently utilizing services at DUH, as illustrated below.

**Historical Patient Origin by County
 FY2015**

County	Entire Facility Inpatient		Lenox Baker Outpatient Clinic		Page Road Outpatient Clinic	
	Patients	Percent	Patients	Percent	Patients	Percent
Durham	9,916	31%	669	22.6%	448	32%
Wake	3,893	12%	336	11.4%	445	31%
Orange	1,287	4%	179	6.1%	104	7%
Alamance	1,145	4%	130	4.4%	38	3%
Granville	1,081	3%	64	2.2%	32	2%
Person	1,022	3%	58	2.0%	13	1%
Vance	837	3%	0	0.0%	0	0%
Cumberland	818	3%	103	3.5%	27	2%
Robeson	495	2%	0	0.0%	0	0%
Franklin	482	2%	0	0.0%	0	0%
Guilford	476	1%	95	3.2%	11	1%
Johnston	374	1%	0	0.0%	12	1%
Nash	0	0%	46	1.6%	0	0%
Chatham	0	0%	0	0.0%	14	1%
Other NC	6,444	20%	882	29.8%	190	13%
Other States	3,594	11%	393	13.3%	79	6%
Total	31,864	100%	2,955	100.0%	1,413	100%

The applicant states that historically, Durham and Wake counties account for approximately 43% of the entire inpatient population at DUH and 34% and 63% of patients that received outpatient MRI services at Lenox Baker and Page Road, respectively. The applicant states on page 22, that the services offered at Page Road will remain the same with the exception of the MRI scanner being owned by Alliance Imaging instead of DUHS.

On page 24, the applicant provides the population to be served by county of residence for MRI services to be provided at the Center for Living for the first two years of operation following completion of the proposed project, as illustrated in the table below.

**Center for Living
 Projected Patient Origin by County**

County	Operating Year (OY) 1 (FY2018)		Operating Year (OY) 2 (FY2019)	
	Patients	Percent	Patients	Percent
Alamance	137	4.4%	141	4.4%
Cumberland	109	3.5%	112	3.5%
Durham	706	22.6%	725	22.6%
Granville	68	2.2%	69	2.2%
Guilford	100	3.2%	103	3.2%
Nash	49	1.6%	50	1.6%
Orange	189	6.1%	194	6.1%
Person	61	2.0%	63	2.0%
Wake	355	11.4%	364	11.4%
Other NC	931	29.8%	956	29.8%
All Other	415	13.3%	426	13.3%
Total	3,119	100.0%	3,204	100.0%

On page 24, the applicant provides the assumptions and methodology used to project patient origin. The applicant assumes projected patient origin will be consistent with its historical patient origin.

The applicant adequately identifies the population to be served.

Analysis of Need

On page 12, the applicant states:

- There are three MRI scanners currently located at Lenox Baker. One is owned by DUH and the other two are owned by Alliance Imaging. The three MRI scanners are located in trailers.
- The applicant states the patient environment at Lenox Baker is outdated and not optimal.
- The Lenox Baker clinic has the lowest average patient satisfaction scores and the most outdated waiting area.
- Both DUH MRI scanners proposed to be replaced were purchased in 2008 and are fully depreciated and at the end of their useful life.
- DUI intends to close Lenox Baker Clinic.

On page 14, the applicant states that the proposed MRI suite will be located on the lower level of the Wallace Building which will be renovated to include a waiting area, registration space, a reading room, prep space and a nursing station. The applicant states the proposed

project will enhance patient convenience and the coordination of care for orthopaedic patients as the Duke Sports Sciences Institute is also located in the Wallace Building.

In Section III.1, pages 14-18, the applicant discusses the following factors which it states support the need for the proposal:

- Population Growth in the Primary Service Area
- Growth Forecast and Market Opportunity as determined by Sg2 an analytics-based healthcare consultant

Population Growth

On page 15, the applicant states the population of the primary service area is projected increase 7.3% between 2014 - 2019.

Growth Forecast and Market Opportunity

Sg2 uses a proprietary web-based tool that projects trends across service lines, procedures and diseases. DUH projects continued MRI growth based on the following, as stated on page 16 of the application:

- *“Total ambulatory MRI volumes with the DUH primary service area (which includes Alamance, Durham, Granville, Orange, Person, Vance and Wake Counties) are projected to grow 16.1% by 2019 and 26.8% by 2024, a rate faster than projected national growth.*
- *Spine and Orthopedics service lines combine to account for more than half (58.1%) of all hospital and clinic-based MRI procedures in 2014 ...*
- *... [T]he 5-year growth rate beginning in 2014 for orthopedics MRI procedures in the service area was projected at 12.7%.”*

The applicant provides tables on page 17 which illustrate the projected outpatient volumes by location for the primary service area and the projected growth by service line. On page 15, the applicant provides historical MRI utilization during FY2013-FY2015, as shown below.

FY	Outpatient MRI Procedures	Inpatient MRI Procedures	Total MRI Procedures
2013	26,963	6,516	33,479
2014	27,527	6,782	34,319
2015	28,779	7,096	35,875

Source: DUH LRA and DUH finance

On page 18, the applicant states that all of the DUH MRI locations are well utilized. The applicant provides a table on page 18, which illustrates the number of MRIs, hours of

operation, unweighted scans and utilization for each MRI location during FY 2015, as summarized in the table below.

Location	# of Scanners	Day/Times of Operations	Total Capacity	Total Unweighted Volume	Utilization Rate
Cancer Center	3	M-F 7:00 a.m. – 11:00 p.m.	13,800	12,128	88%
Duke Medicine Pavilion	2	M-F DMP2: 24hrs DMP3: 7:00 a.m. – 11:00 p.m.	16,425	10,997	67%
		Sat: DMP2: 7:00 a.m. – 11:00 p.m. DMP3: 7:00 a.m. – 3:00 p.m. Sun: DMP2: 7:00 a.m. -11:00 p.m. DMP3: Closed			
Duke North	2	M-F 8:00 a.m. – 4:00 p.m.	4,064	3,660	90%
Lenox Baker	3	M-F 7:30 a.m. – 4:00 p.m.	6,469	5,630	87%
Southpoint	1	M-F 7:30 a.m. – 4:00 p.m.	2,156	1,795	83%
Page Road	1	M-F 7:30 a.m. – 4:00 p.m.	2,156	1,536	71%

In Section IV, page 28, the applicant projects utilization for the proposed project, as shown in the table below.

Center for Living – Wallace Building			
	OY1 FY 2018	OY2 FY 2019	OY3 FY 2020
# of MRI Scanners	2	2	2
# of MRI Scans	3,930	4,037	4,150
# of Weighted MRI Scans	4,842	4,974	5,114

On page 29, the applicant states it assumes the volumes at the Page Road clinic will remain essentially unchanged after the replacement of the Duke owned MRI scanner with one of the Alliance Imaging MRI scanners. In FY 2015, the Page Road clinic reported 1,535 scans and is projected to perform 1,565 in FY 2016.

The applicant's assumptions regarding projected utilization can be found in Section IV, page 29. On page 29, the applicant reports that DUH's outpatient MRI utilization has grown 6.7% in the past 2 years.

The applicant adequately demonstrates the projected utilization is based on reasonable and adequately supported assumptions. The applicant adequately demonstrates the need the population to be served has for the proposed services.

Access

In Section VI.2, page 35, the applicant states:

“The Services of Duke University Hospital are open to all area and non area residents for inpatient, outpatient, and other healthcare services ... There is no discrimination on the basis of race, ethnicity, age, gender, or disability.”

In Section VI.15, page 41, the applicant projects that 29.5% of its patients in OY2 will be Medicare beneficiaries and 14.0% 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 proposed MRI services.

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; and adequately 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 19-20, the applicant describes the six alternatives considered which include the following:

- 1) Maintain the Status Quo – The applicant states that maintaining the status quo was not an option because the Lenox Baker clinic requires patients to receive their MRI scans in trailers and the MRI scanners used are old and fully depreciated. Therefore, this option was rejected.
- 2) Upgrade the equipment in the existing location – The applicant states that this alternative would not resolve the issues of the Lenox Baker clinic operating its MRI scanners out of trailers, which can be inconvenient for some patients. Therefore, this option was rejected.
- 3) Relocate existing equipment to new location – The applicant states the existing equipment is old and past its useful life. Therefore, this option was rejected.
- 4) Relocate the Alliance equipment to the Center for Living and replace the existing Duke scanner at Page Road at its existing location – The applicant states the services operated at Lenox Baker, in trailers, are being relocated to internal clinic space at the Center for Living in the Wallace Building, in newly created space. While maintaining the Page Road clinic MRI services on the existing exterior pad, is more efficient and a better long-term alternative to install the Duke owned scanners at the Wallace Building, leaving the Alliance owned MRI scanner to be operated at a location where it can be easily moved at the end of the service agreement. Therefore, this option was rejected.
- 5) Replace/relocate only one MRI scanner to the Center for Living – The applicant states the projected volumes for the services currently provided at Lenox Baker cannot adequately be accommodated on a single machine. Additionally, the applicant reports that the location is the primary site for training of Residents, Medical Students and MRI technician students. Sufficient space and capacity is needed to accommodate them. Therefore, this option was rejected.

- 6) Pursue the Project as Proposed – The applicant states that the proposed project, as presented in this application, is the most effective and cost effective alternative to meet the increasing need for outpatient MRI services.

The applicant adequately demonstrates that the proposed project to relocate and replace existing MRI scanners is the least costly or most effective alternative to meet the identified need.

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. Duke University Health System, Inc. d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.**
 - 2. Duke University Health System, Inc. d/b/a Duke University Hospital shall acquire no more than two fixed magnetic resonance imaging scanners to replace two existing magnetic resonance imaging scanners relocate the replacement magnetic resonance imaging scanners to the Center for Living in the Wallace Building.**
 - 3. Duke University Health System, Inc. d/b/a Duke University Hospital shall 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.**
 - 4. Duke University Health System, Inc. d/b/a Duke University 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 that would otherwise require a certificate of need.**
 - 5. Duke University Health System, Inc. d/b/a Duke University Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The applicant proposes to replace two existing MRI scanners and relocate them to the Center for Living in the Wallace Building. The proposed project involves renovation of 3,363 square feet of space in the Center for Living.

Capital and Working Capital Costs

In Section VIII, page 50, the applicant projects the total capital cost of the proposed project will be \$7,338,000 including:

Costs	Total Costs
Construction Contract	\$ 2,654,000
Fixed Equipment Purchased/Lease	\$ 3,827,108
Movable Equipment Purchase/Lease	\$ 392,892
Furniture	\$ 30,000
Architect/Engineering Fees	\$ 346,000
CON/permits/inspection	\$ 38,000
Other (training/moving/storage)	\$ 50,000
Total Capital Costs	\$ 7,338,000

In Section IX, page 55, the applicant states there are no start-up or initial operating expenses for this project, which involves replacing existing equipment and relocating it to existing space.

Availability of Funds

In Section VIII.3, page 51, the applicant states that the total capital cost will be funded with Duke University Health System accumulated reserves. Exhibit 14 contains a November 13, 2015 letter signed by the Senior Vice President, Chief Financial Officer and Treasure, which states:

“This will certify that Duke University Health System has as much as \$8,000,000 in accumulated reserves to devote to the replacement and relocation of MRI equipment and service to the Wallace Clinic.”

Exhibit 8 contains the audited consolidated financial statements for Duke University Health System, Inc. and Affiliates for years ending June 30, 2015 and 2014. According to the financial statements, as of June 30, 2015, DUHS had \$434,366,000 in cash and cash equivalents, \$1,140,014,000 in current assets, \$5,039,776,000 in total assets and \$3,182,882,000 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

In the pro forma financial statement for the service component (Form C), the applicant projects that revenues will exceed operating expenses in each of the first three operating years following project completion, as illustrated in the table below.

	PY 1 FFY2018	PY 2 FFY2019	PY 3 FFY2020
Projected # of Procedures	3,930	4,037	4,150
Projected Average Charge per Procedure	\$ 3,933	\$ 3,933	\$ 3,933
Projected Average Reimbursement Rate	\$ 1,113	\$ 1,118	\$ 1,123
Gross Patient Revenue	\$ 15,456,527	\$ 15,878,078	\$ 16,322,581
Deductions from Gross Patient Revenue	\$ 11,083,894	\$ 11,364,821	\$ 11,660,924
Net Patient Revenue	\$ 4,372,633	\$ 4,513,257	\$ 4,661,657
Total Expenses	\$ 2,820,307	\$ 3,037,940	\$ 3,072,083
Net Income	\$ 1,552,326	\$ 1,475,316	\$ 1,589,574

Additionally, in Form B, the applicant projects that revenues will exceed operating expenses in each of the first three years for the entire Duke University Health System.

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

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

The applicant proposes to replace and relocate two existing MRI scanners and relocate them to the Center for Living in the Wallace Building.

On page 146, the 2015 SMFP defines a fixed MRI's service area as "a single county, except where there is no licensed acute care hospital located within the county. Counties lacking a

licensed acute care hospital are grouped with the single county where the largest proportion of patients received inpatient acute care services, as measured by acute inpatient days, unless two counties with licensed acute care hospitals each provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. In that case, the county lacking a licensed acute care hospital is grouped with both counties which provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days.” Table 9P on page 155 of the SMFP shows Duke University Hospital is located in the Durham/Caswell Service Area. Thus, the service area for this project is Durham and Caswell counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved fixed and mobile MRI scanners operating in Durham and Caswell counties as reported in the 2015 SMFP.

Service Provider	Fixed	Total Scans	Outpatient		Inpatient		Adjusted Total
			No Contrast	Contrast	No Contrast	Contrast	
Duke Regional Hosp.	2	5,908	2,962	1,160	1,339	447	7,265
Duke University Hosp.	9	26,214	7,918	11,780	2,191	4,325	35,262
Duke University Hosp.	4	7,265	3,586	3,679	0	0	8,737
Durham Diagnostic Imaging-Indep. Park	1	2,871	1,791	1,080	0	0	3,303
Triangle Ortho Assoc.	1	3,674	3,469	205	0	0	3,756
	Mobile						
Durham Diagnostic Imaging @ Triangle Medical Park		788	566	222	0	0	877
Raleigh Neurology Associates		82	33	49	0	0	102
Triangle Ortho Assoc.		324	306	18	0	0	331

As shown in the table above, there are 17 fixed MRI scanners in the service area and three sites where mobile MRI services are available. The applicant does not propose to add an MRI scanner to the inventory, but rather to relocate and replace two of the existing fixed MRI scanners.

Additionally, the applicant states in Section III, page 26, *“The relocation of the MRI services from Lenox Baker to the Center for Living is marginal in distance.”* The applicant further states on page 26, that the proposed relocation of its existing MRI services is due to the physical inadequacies of the existing Lenox Baker clinic, which the applicant proposes to close once all the MRI equipment has been relocated to other sites.

The applicant adequately demonstrates that the proposal to replace and relocate two existing MRI scanners would not result in an unnecessary duplication of existing and approved MRI 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.

C

In Section VII.1, pages 43-44, the applicant provides the current and proposed staffing, as shown in the table below.

Position	Current FTE Positions FFY2015	PY2 FTE Positions FFY2018
Nurse	1.0	1.0
Technologists	2.0	2.0
Clerical	0.88	1.00
Total	3.88	4.00

As illustrated in the table above, and reported on page 45, the applicant anticipates an increase of 0.12 FTEs for additional clerical staff. In Section VII.6, page 45, the applicant describes its experience and process for recruiting and retaining staff. On page 46, the applicant states that Dr. Thomas A. Owens, is DUH's Chief of Staff.

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, page 9, the applicant identifies the ancillary and support services that are required for the proposed project which will also be available after the MRI scanners have been relocated to the Center for Living in the Wallace Building. In Section V, pages 31-34, the applicant discusses coordination with the existing health care system. The information provided in these sections and exhibits is reasonable and 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.12 and VI.13, page 40, the applicant provides the payor mix during FY 2015 for the entire hospital and for the MRI services at Lenox Baker, as illustrated in the table below:

FY 2015 (7/1/14-6/30/15)
Patients as a Percent of Total Utilization

	DUH Entire Facility	Lenox Baker Services
Self Pay/Indigent/Charity	5.5%	1.6%
Medicare/Medicare Managed Care	38.4%	23.5%
Medicaid	19.1%	13.7%
Commercial Insurance	1.1%	1.6%
Managed Care	29.4%	47.7%
Other*	6.4%	9.8%
Total	100.0%	97.9%

Includes: Duke Select, Champus Tricare, Durham VA, Tricare Standard, other non-NC Medicaid, or other governmental agencies and programs

In Section VI.2, page 35, the applicant states, “*There is no discrimination on the basis of race, ethnicity, age, gender, or disability.*”

Exhibit 6 contains a copy of DUH’s admission policy, which states:

“DUHS does not deny medical treatment to any individual on basis of race, color, sex, national origin, diagnosis, disability, political affiliation, sexual orientation or preference (including gender identity or expression), veteran status, religion, ability to pay or conditions of reimbursement.”

Exhibit 9, contains a copy of DUH’s discounts and financial assistance policies.

The United States Census Bureau¹ 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	% Caucasian	% Persons in Poverty	% < Age 65 with a Disability	% < Age 65 without Health Insurance
Durham	11%	52%	42%	19%	7%	18%
Caswell	20%	49%	61%	20%	15%	17%
Statewide	15%	51%	64%	17%	10%	15%

Source: [http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015.](http://www.census.gov/quickfacts/table_2014%20Estimate%20as%20of%20December%2022,%202015)

*These statistics are not comparable to other geographic levels of these estimates.

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 39, the applicant states:

“Duke University Health System hospitals have now satisfied the requirements of applicable Federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill-Burton funds previously received.”

In Section VI.10, page 39, the applicant states DUH is not aware of any civil rights equal access complaints filed against the hospital within the past five years. The applicant reports two incidents on page 39, which occurred outside the five year timeframe. 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.15, page 41, the applicant provides the projected payor mix for the MRI services to be provided at the Center for Living during the second full operating year following project completion, as shown in the table below.

FY 2019

Payor Category	% of Total Utilization
Self Pay/Indigent/Charity	1.1%
Medicare/Medicare Managed Care	29.5%
Medicaid	14.0%
Commercial Insurance	1.6%
Managed Care	44.0%
Other	9.8%
Total	100.0%

On page 42, the applicant states the projected payor mix is based on the current payor mix at Lenox Baker. 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, page 38, the applicant describes the range of means by which a person will have access to the proposed services, which is typically by physician referral. The applicant adequately demonstrates that the facility will offer a 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, page 31, the applicant describes Duke's five year residency and fellowship program in Diagnostic Radiology. DUH also recently started a program which requires all second year medical students to take a Radiology rotation as part of their core curriculum. DUH also provides onsite training for MRI technician students from UNC and Wake Technical College.

The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

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

C

The applicant proposes to replace and relocate existing MRI services from Lenox Baker to the Center for Living in the Wallace Building.

On page 146, the 2015 SMFP defines a fixed MRI's service area as "*a single county, except where there is no licensed acute care hospital located within the county. Counties lacking a licensed acute care hospital are grouped with the single county where the largest proportion of patients received inpatient acute care services, as measured by acute inpatient days, unless two counties with licensed acute care hospitals each provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days. In that case, the county lacking a licensed acute care hospital is grouped with both counties which provided inpatient acute care services to at least 35 percent of the residents who received inpatient acute care services, as measured by acute inpatient days.*" Table 9P on page 155 of the SMFP shows Duke University Hospital is located in the Durham/Caswell Service Area. Thus, the service area for this project is Durham and Caswell counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved fixed and mobile MRI scanners operating in Durham and Caswell counties as reported in the 2015 SMFP.

Service Provider	Fixed	Total Scans	Outpatient		Inpatient		Adjusted Total
			No Contrast	Contrast	No Contrast	Contrast	
Duke Regional Hosp.	2	5,908	2,962	1,160	1,339	447	7,265
Duke University Hosp.	9	26,214	7,918	11,780	2,191	4,325	35,262
Duke University Hosp.	4	7,265	3,586	3,679	0	0	8,737
Durham Diagnostic Imaging-Indep. Park	1	2,871	1,791	1,080	0	0	3,303
Triangle Ortho Assoc.	1	3,674	3,469	205	0	0	3,756
	Mobile						
Durham Diagnostic Imaging @ Triangle Medical Park		788	566	222	0	0	877
Raleigh Neurology Associates		82	33	49	0	0	102
Triangle Ortho Assoc.		324	306	18	0	0	331

As shown in the table above, there are 17 fixed MRI scanners in the service area and three sites where mobile MRI services are available. The applicant does not propose to add an MRI scanner to the inventory, but rather to relocate and replace two of the existing fixed MRI scanners.

In Section V.7, page 34, 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.

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 for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The 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 discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

The application is conforming to this criterion.

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

C

Duke University Hospital is a Level 1 Trauma Center and an academic medical center teaching hospital owned by Duke University Health System. On page 8, the applicant states DUH has provided radiology services, including MRI services to residents of North Carolina and other states for many years. In FY 2015, DUH provided more than 35,000 MRI scans to inpatients and outpatients on multiple DUH campuses in Durham County.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Duke University Health System. 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 all DUHS hospitals, the applicant provides 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.

NA

The applicant proposes to replace two existing MRI scanners. Therefore the Criteria and Standards for Magnetic Resonance Imaging Scanner, promulgated in 10A NCAC 14C .2700, are not applicable to this review.