ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: July 20, 2017
Findings Date: July 20, 2017

Project Analyst: Bernetta Thorne-Williams
Team Leader: Fatimah Wilson

Project ID #: J-11331-17
Facility: Duke University Hospital
FID #: 943138
County: Durham
Applicant(s): Duke University Health System, Inc.
Project: Acquire one dedicated cardiac magnetic resonance imaging scanner at Duke University Hospital pursuant to Policy AC-3

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (DUH) proposes to acquire one dedicated cardiac magnetic resonance imaging (MRI) scanner to be located on the Duke University Hospital campus in the Duke Medicine Pavilion pursuant to Policy AC-3 in the 2017 State Medical Facilities Plan (SMFP) for a total of three dedicated cardiac MRI scanners upon project completion.

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 2017 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

The following two policies are applicable to this review:

- Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects
- Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects states**:**

"Projects for which certificates of need are sought by Academic Medical Center Teaching Hospitals may qualify for exemption from the need determinations of this document. The Healthcare Planning and Certificate of Need Section shall designate as an Academic Medical Center Teaching Hospital any facility whose application for such designation demonstrates the following characteristics of the hospital:

1. *Serves as a primary teaching site for a school of medicine and at least one other health professional school, providing undergraduate, graduate and postgraduate education.*

2. *Houses extensive basic medical science and clinical research programs, patients and equipment.*

3. *Serves the treatment needs of patients from a broad geographic area through multiple medical specialties."*

Duke University Hospital was designated as an Academic Medical Center Teaching Hospital on July 21, 1983, as reported in Appendix F of the 2017 SMFP.

"Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 provided the projects are necessary to meet one of the following unique academic medical needs:

1. *Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty that are specifically required for an expansion of students or residents, as certified by the head of the relevant associated professional school; the applicant shall provide documentation that the project is consistent with any relevant standards, recommendations or guidance from specialty education accrediting bodies; or*

2. *With respect to the acquisition of equipment, is necessary to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching (including teaching within*

the clinical setting), research, administrative or other academic responsibilities within the academic medical center teaching hospital or medical school; or

3. *Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity sponsoring the research; and including, to the extent applicable, documentation pertaining to grants, funding, accrediting or other requirements, and any proposed clinical application of the asset; or"*

In Section B, page 15, the applicant states DUH qualifies for Policy AC-3 based on prongs 2 and 3. In Exhibit B.3, the applicant provides a letter dated April 10, 2017 from the Dean of the School of Medicine and the Vice Chancellor for Academic Affairs, stating DUH's plans to recruit an additional faculty member whose primary focus will be cardiac magnetic resonance imaging to begin in January 2018. The applicant further states on page 16, that the existing cardiac MRI scanners do not have sufficient capacity to accommodate the additional procedures projected to be performed by the new faculty member, for both the faculty member's research and clinical activities. The applicant also states that additional capacity is also necessary to allow the existing faculty who depend on this equipment to continue their research, teaching and clinical activities. The applicant further states on page 16 that DUH anticipates "*significant expansion of research activities*".

4. *Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.*

A project submitted by an Academic Medical Center Teaching Hospital under this policy that meets one of the above conditions shall demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers and has capacity within the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital.

The Academic Medical Center Teaching Hospital shall include in its application an analysis of the cost, benefits and feasibility of engaging that provider in a collaborative effort that achieves the academic goals of the project as compared with the certificate of need application proposal. The Academic Medical Center Teaching Hospital shall also provide a summary of a discussion or documentation of its attempt to engage the provider in discussion regarding its analysis and conclusions.

The Academic Medical Center Teaching Hospital shall include in its application a discussion of any similar assets within 20 miles that are under the control of the applicant or the associated professional school and the feasibility of using those assets to meet the unique teaching or research needs of the Academic Medical Center Teaching Hospital.

For each of the first five years of operation the approved applicant shall submit to Certificate of Need a detailed description of how the project achieves the academic requirements of the appropriate section(s) of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.

Applicants who are approved for Policy AC-3 projects after January 1, 2012 shall report those Policy AC-3 assets (including beds, operating rooms and equipment) on the appropriate annual license renewal application or registration form for the asset. The information to be reported for the Policy AC-3 assets shall include: (a) inventory or number of units of AC-3 Certificate of Need-approved assets (including all beds, operating rooms and equipment); (b) the annual volume of days, cases or procedures performed for the reporting year on the Policy AC-3 approved asset; and (c) the patient origin by county. Neither the assets under (a) above nor the utilization from (b) above shall be used in the annual State Medical Facilities Plan need determination formulas, but both the assets and the utilization will be available for informational purposes to users of the State Medical Facilities Plan.

This policy does not apply to a proposed project or the portion thereof that is based solely upon the inability of the State Medical Facilities Plan methodology to accurately project need for the proposed service(s), due to documented differences in patient treatment times that are attributed to education or research components in the delivery of patient care or to differences in patient acuity or case mix that are related to the applicant's academic mission. However, the applicant may submit a petition pursuant to the State Medical Facilities Plan Petitions for Adjustments to Need Determinations process to meet that need or portion thereof.

Policy AC-3 projects are required to materially comply with representations made in the certificate of need application regarding academic based need. If an asset originally developed or acquired pursuant to Policy AC-3 is no longer used for research and/or teaching, the Academic Medical Center Teaching Hospital shall surrender the certificate of need."

On page 16, the applicant states it is not aware of any non-Academic Medical Center Teaching Hospitals (AMCTH) within 20 miles of DUH that currently offer dedicated cardiac MRI services. Additionally, on page 16, the applicant states that there are no hospitals that have dedicated cardiovascular MRI equipment. The applicant states the reason for this is because it is not feasible to accommodate additional cardiac MRI research and teaching activities on other non-dedicated MRI equipment. The applicant further states even if there were any other hospitals that had MRI capacity that were configured specifically for the specialized cardiovascular procedures provided at DUH, it would not be efficient or cost effective to create a second site for the provision of these services. Furthermore, on page 17, the applicant states that cardiac MRI scans require specialized MRI technologists trained specifically to perform these cardiovascular examinations. The proposed cardiac MRI equipment is specifically needed to support grant-funded research and clinical trials conducted by Duke's faculty as well as support clinical procedures for patients referred to DUH for cardiology services. Lastly, the applicant states on page 17, that DUH does not have any other dedicated cardiac MRI units within 20 miles of DUH other than the two scanners identified in the application which are fully utilized and do not have sufficient excess capacity to accommodate the planned faculty recruitment and expansion of research activities.

The applicant adequately demonstrates the proposed project will accommodate patients and staff research activities, that there are no other non-AMCTH within 20 miles of DUH that

currently offer dedicated cardiac MRI services, that the cardiac MRI equipment is needed to support granted-funded research and clinical trials, support clinical patient procedures and that DUH does not have any other dedicated cardiac MRI scanners within 20 miles of Duke University Hospital other than the two discussed in this application. Therefore, the application is consistent with Policy AC-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states**:**

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is 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.*

The proposed capital expenditure for this project is greater than $2 million, but less than $5 million. In Exhibit B.11, the applicant provides a letter dated March 24, 2017 from Isley Hawkins architecture which outlines the steps that will be taken to ensure the project provides energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the NC State Building Code. The letter states the project will include the upfit of existing space, the current HVAC system will be modified to accommodate additional offices, patient care and support space, adjustments for increased water usage due to additional fixtures, and replacement of existing lighting fixtures with energy efficient LED fixtures.

The applicant adequately demonstrates that the application includes a written statement describing the projects plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy AC-3 and Policy GEN-4 in the 2017 SMFP. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

DUH currently operates two cardiac MRI scanners, one is located in the Duke South Orange Zone and the other one is located on the seventh floor of Duke North. In this application, DUH proposes to acquire one additional dedicated cardiac MRI scanner to be located on the Duke University Hospital campus in the Duke Medicine Pavilion pursuant to Policy AC-3 in the 2017 SMFP for a total of three dedicated cardiac MRI scanners upon project completion.

Patient Origin

In Section B.3(e), page 16, the applicant states DUH is an Academic Medical Center Teaching Hospital, as such, DUH provides services for patients from multiple counties in North Carolina and patients from Virginia. The applicant identifies 22 counties as its primary and secondary service area.

In Section C.2, page 25 and C.3, pages 26-27, the applicant provides its historical and projected cardiac MRI patient origin for the first three operating years. The table below illustrates the historical and projected patient origin for 19 of the 22 counties that DUH states make up its primary and secondary service area, as summarized below.

County	Historical (FY2016)		OY1 (FY2019)		OY2 (FY2020)		OY3 (FY2021)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	85	3.72%	88	3.50%	93	3.53%	99	3.58%
Caswell	8	0.35%	16	0.64%	17	0.65%	18	0.65%
Chatham	17	0.74%	24	0.95%	26	0.99%	27	0.98%
Cumberland	109	4.77%	143	5.68%	152	5.78%	163	5.90%
Durham	439	19.21%	471	18.72%	502	19.07%	536	19.40%
Franklin	14	0.61%	20	0.79%	22	0.84%	23	0.83%
Granville	50	2.19%	58	2.30%	61	2.32%	66	2.39%
Guilford	59	2.58%	54	2.15%	58	2.20%	63	2.28%
Harnett	31	1.36%	38	1.51%	41	1.56%	44	1.59%
Johnson	29	1.27%	22	0.87%	24	0.91%	26	0.94%
Lee	28	1.23%	18	0.72%	19	0.72%	20	0.72%
Nash	27	1.18%	24	0.95%	26	0.99%	28	1.01%
Orange	121	5.30%	125	4.97%	134	5.09%	144	5.21%
Person	54	2.36%	69	2.74%	73	2.77%	78	2.82%
Robeson	39	1. 71%	45	1.79%	48	1.82%	51	1.84%
Vance	32	1.40%	26	1.03%	27	1.03%	29	1.05%
Wake	402	17.59%	452	17.97%	485	18.42%	522	18.89%
Warren	16	0.70%	13	0.52%	14	0.53%	15	0.54%
Wilson	8	0.35%	11	0.44%	11	0.42%	12	0.43%
Other NC Counties	461	20.17%	499	19.83%	499	18.96%	499	18.06%
Virginia	123	5.38%	151	6.00%	151	5.74%	151	5.47%
Other States	133	5.82%	149	5.92%	149	5.66%	149	5.39%
Total	**2,285**	**100.00%**	**2,516**	**100.00%**	**2,632**	**100.00%**	**2,763**	**100.00%**

On page 27, the applicant states the counties not included in its historical and projected patient origin individually that make up its 22-county primary and secondary service area are Halifax, Pittsylvania and Mecklenburg counties in Virginia. The applicant provides the assumptions and methodology for the projections above on page 27. Additional assumptions regarding projected utilization are in Section Q, pages 69-74.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section C.4, pages 28-33, the applicant describes the factors which it states support the need for the proposed project, including:

- The applicant reports that more than 65,000 people with heart disease are treated at DUH (page 28).

- The Duke Cardiovascular Magnetic Resonance Center (DCMRC) is one of the largest in the world performing more than 4,000 clinical procedures a year (page 28).

- DCMRC provides post-doctoral fellows in basic MR physics, clinical fellows, and physicians interested in cardiovascular MRI (page 28). DCMRC plans to expand its academic research activities by recruiting an additional specialist (page 32).

- DCMRC experienced a 17% increase in clinical volumes between FY2014 and FY2016. This growth was primarily in outpatient/ambulatory procedures with inpatient procedures remaining consistent (page 29).

- Various analytics used by DUH project a growth of 26.3% in Cardiovascular Magnetic Resonance Imaging (CMRI) between 2015 and 2020, and 54.1% between 2015 and 2025 in the 22 counties in DUH's primary and secondary service area (page 29).

- DUH projects a population increase of 7.2% for Durham County, 8.6% for Wake County and 4.9% for North Carolina by 2020 (page 29).

- DUH reports lengthy wait times of approximately six weeks or longer for pediatric and adult patients to be scheduled for a CMRI. Additionally, availability is also limited for DUH's congenital heart patients (page 30).

- The scan times for patients requiring CMRI can range from 1.5 to 2 hours followed by image post processing, report entry and preparation for the next test all of which limits patient throughput. The addition of a third CMRI would improve wait times (page 30).

- The current volume and capacity at DUH of CMRI services is operating above 80% capacity (page 30).

- Planned research activities including animal research on Mondays on the CMRI scanner located at Duke South, research with human subjects and research time without patients to develop novel imaging procedures place restraints on the scanners availability. Exhibit B-3, contains a letter from the Dean of the School and Vice Chancellor for Academic Affairs which states that DUH "*is planning to expand, significant research activities that require access to specialized cardiac MRI equipment.*" Exhibit B-3, pages 3-4, contains a list of the research activities planned for DCMRC.

In Section B, page 15, the applicant states DUH qualifies for Policy AC-3 based on prongs 2 and 3. In Exhibit B.3, the applicant provides a letter dated April 10, 2017 from the Dean of the School of Medicine and the Vice Chancellor for Academic Affairs, stating DUH's plans to recruit an additional faculty member whose primary focus will be cardiac magnetic resonance imaging to begin in January 2018. The applicant further states on page 16, that the existing cardiac MRI scanners do not have sufficient capacity to accommodate the additional procedures projected to be performed by the new faculty member, for both the faculty member's research and clinical activities. The applicant also states that additional capacity is also necessary to allow the existing faculty who depend on this equipment to continue their research, teaching and clinical activities. The applicant further states on page 16 that DUH

anticipates *"significant expansion of research activities"*. Exhibit C.4 contains letters of support for the proposed project.

In summary, the applicant adequately demonstrates the need for one additional cardiac MRI scanner for a total of three scanners at DUH pursuant to Policy AC-3.

Projected Utilization

On page 34, the applicant states the proposed cardiac MRI scanner is projected to operate Monday through Friday from 7:00 to 5:30, for 62.5 hours/week. The applicant reports that cases can take up to two hours per case for an annual maximum capacity of 1,625 scans per year (31.25/week x 52 weeks), assuming 100% use of the CMRI scanners for procedures. However, in addition to being used for cardiac MRI procedures the applicant states that the equipment will be used for teaching and research purposes. Thus, DUH calculates that the capacity of each of the three CMRI scanners operated would be used as follows: two scanners (one existing scanner and the proposed scanner) will be available five days per week for clinical and research needs for a total of 1,302 cases per year and that the other existing scanner would have one dedicated day per week for research (including animal research), for a total of 1,042 cases per year. In Section Q, the applicant provides the following table which illustrates the current and projected utilization for its cardiac MRI scanners, as illustrated below.

	Historical	**Interim**		**Projected**		
	FFY 2016	**FFY 2017**	**FFY 2018***	**OY1 FFY 2019**	**OY2 FFY 2020**	**OY3 FFY 2021**
#of MRI Scanners	2	2	3	3	3	3
# of Cases	2,285	1,167**	2,421	2,521	2,641	2,776
# of Procedures	4,290	4,538	4,698	4,901	5,147	5,424
# of Weighted Procedures	6,161	6,529	6,752	7,036	7,379	7,766

Note*: In Section Q, the applicant projects the proposed cardiac MRI equipment will be operational on February 1, 2018. **Reflects year-to-date (YTD) cases.

The applicant states that projected utilization is based on inpatient, outpatient and research cases. In Exhibit C.9, DUH provides the market data projections from Sg2, a nationally recognized marketing and research company. The Sg2 tool projects that CMRI ambulatory volume will grow by 26.3% between 2015 and 2020 and 54.1% between 2015 and 2025 in DUH's primary and secondary service areas. The data presented by Sg2 factors in the projected growth and aging of the population comprising DUH's proposed 22-county service area. By 2020, the population of Durham County is projected to increase by 7.2%, Wake County by 8.6% and North Carolina, as a whole, by 4.9%. The applicant provides its assumptions regarding projected utilization in Section Q, which is based on the data comprised by Sg2, as follows:

"*Inpatient*

[I]*npatient volumes have remained relatively flat in recent years. … Duke conservatively projects no increase in inpatient case volumes and hold volumes constant at FY 17 annualized case volumes of 365 cases and 488 procedures.*

Outpatient

Duke (sic) *historical growth in CMRI procedures has resulted from outpatient growth … all future clinical growth is projected to be outpatient …. DUH projects the following year-to-year growth in outpatient clinical (non-research) cardiac MRI cases by year … The total cases are projected to be performed across the 2 existing and 1 proposed new scanner. …* [T]*he total capacity of the equipment of the three machines is assumed to be 3646 cases per year.*

FY17: annualized based on 6 months [CMRI outpatient and impatient volumes are reported in Section Q (YTD) and projected volume is reported in Exhibit C.9, page 8.]
FY18 – 4.0%
FY19 – 4.5%
FY20 – 5.2%
FY21 – 5.6%
FY22 – 5.6%
FY23 – 5.6%
FY24 – 2.4%
FY25 – 1.4%
…

Duke has adjusted its projected growth rates each year based on ramp-up and capacity. First, Duke assumes that growth will be faster in the first half of the next decade than the second half, following the Sg2 projections, and consistent with adding capacity, which allows for significant growth as scheduling constraints on the existing highly utilized equipment are eased. However, Duke also assumes that there will be a ramp-up period typical when adding capacity and adding additional providers (with the recruitment of an additional facility member in 2018). Based on these assumptions, Duke assumes growth in initial project years of 4-4.5%, ultimately ramping up to 5.6% in FY21-23. After FY23, growth is projected to continue, but at a much slower rate. This slow-down is projected as the additional machine reaches capacity and cannot easily support further volumes. … .

The projected growth is consistent with the historical growth Duke has experienced in the past 3 years … This growth is supported by Duke's plans not only to expand capacity but to create new treatment protocols for implant patients and to recruit another CMRI provider.

Research

Separately, Duke projects that research case volumes may increase by up to 100% by FY23. Approximately half of the increase can be attributed to the additional approved research expansion activities … Additional increases in research case volumes would be expected with the recruitment of an additional facility member to practice with the DCMRC and with

future research activities by existing faculty. … These research volumes are projected to reach the FY23 total at the same rate as outpatient clinical volumes, reflecting the same ramp-up assumption."

In Section Q, the applicant provides data on its inpatient and outpatient utilization procedures. The table below summarizes the number of DUH's historical and projected weighted and unweighted CMRI procedures.

Unweighted CMRI Procedures								
	2014	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Inpatient								
With contrast/sedation	514	437	428	242	486	486	486	486
Without contrast/sedation	10	8	2	1	2	2	2	2
Outpatient								
With contrast/sedation	3,175	3,397	3,685	1,924	4,018	4,198	4,417	4,662
Without contrast/sedation	77	41	40	23	48	50	53	56
Estimated Research	145	137	135	70	144	165	189	218
Total	**3,921**	**4,020**	**4,290**	**2,260**	**4,698**	**4,901**	**5,147**	**5,424**
Weighted CMRI Procedures								
	2014	**2015**	**2016**	**2017***	**2018**	**2019**	**2020**	**2021**
Inpatient								
With contrast/sedation	925	787	770	436	875	875	875	875
Without contrast/sedation	14	11	3	1	3	3	3	3
Outpatient								
With contrast/sedation	4,445	4,756	5,159	2,694	5,625	5,878	6,184	6,527
Without contrast/sedation	77	41	40	23	48	50	53	56
Estimated Research	202	191	188	98	202	230	265	305
Total	**5,664**	**5,786**	**6,161**	**3,252**	**6,752**	**7.036**	**7,379**	**7,766**

*Projected weighted CMRI utilization as reported on the first page of Section Q for 2017 is 6,529, which is based on annualized volumes. The third CMRI scanner is projected to become operational on February 1, 2018, thus the difference of 3,277 weighted scans, as reported in Section Q, page 69 of the application.

Based on DUH's internal data, the applicant demonstrates that the three CMRI scanners will do a total of 7,766 weighted CMRI procedures by OY3 (2021). Pursuant to Policy AC-3, the applicant adequately demonstrates that the proposed additional cardiac MRI scanner will be used to accommodate the recruitment of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching and research within the academic medical center teaching hospital. Additionally, the applicant adequately demonstrates that DUH will accommodate research activities.

Therefore, the applicant adequately demonstrates the need to acquire one additional cardiovascular MRI scanner for a total of three CMRI scanners upon project completion.

The proposed project was filed pursuant to Policy AC-3 in the 2017 SMFP to acquire a 3rd unit of cardiac MRI equipment. Due to the specialized purposes for which the equipment is being used by the Academic Medical Teaching Center Hospital, the inventory is reported in a separate table that is not included in the calculation of the need methodology. Policy AC-3 MRI scanners used exclusively for cardiovascular research are reported in Chapter 9 Table 9Q(1) in the 2017 SMFP. Therefore, the performance standards found in 10A NCAC 14C .2703 for magnetic resonance imaging scanners are not applicable to this review.

Access

In Section C.10, page 35, the applicant states DUH is opened to all residents and non-area residents of North Carolina and surrounding areas. The applicant states DUH does not discriminate based on race, ethnicity, age, gender, or disabilities. In Section L, page 59, the applicant provides a table which illustrates that DUH provided CMRI services to women (51.5%), those 65+ (13.5%) and racial minorities (35.9%) during the last fiscal year. In Section L.3, page 61, the applicant projects that 44.48 percent of patients will have some or all of their CMRI scanner services paid for by Medicare and/or Medicaid during the second FY (2020).

Conclusion

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

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

NA

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

CA

In Section E, page 41, the applicant discusses the alternatives considered for meeting the needs for the proposed project. The applicant states that because of the specialized cardiac imaging equipment, hardware, software, staffing, and physician coverage required to provide cardiac

MRI scans for specialized use as a AMCTH that no other alternative was considered other than applying for the equipment pursuant to Policy AC-3. The applicant further states on page 41, that the two existing CMRI scanners are highly utilize and do not have the capacity to accommodate significant additional clinical and research activities. Therefore, the proposed alternative is the most effective alternative.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. 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 one cardiovascular MRI scanner to be located in the Duke Medicine Pavilion on the Duke University Hospital campus for a total of no more than three cardiovascular MRI scanners.**

3. **Duke University Health System, Inc. d/b/a Duke University Hospital as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**

4. **Duke University Health System, Inc. d/b/a Duke University Hospital shall report Policy AC-3 assets, (including beds, operating rooms and equipment) and the annual volume of days, cases or procedures performed for the reporting year on the Policy AC-3 approved asset on the annual license renewal application.**

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.

C

DUH proposes to acquire one additional dedicated cardiac MRI scanner to be located on the Duke University Hospital campus in the Duke Medicine Pavilion pursuant to Policy AC-3 in the 2017 SMFP for a total of three dedicated cardiac MRI scanners upon project completion.

Capital and Working Capital Costs

In Form F.1a in Section Q, the applicant projects the total capital cost of the proposed project to be $4,793,318, as follows:

Projected Capital Costs

Renovation Contract	$2,066,299
Architect/Engineering Fees	$199,305
Medical Equipment	$2,350,000
Non-medical Equipment	$145,313
Furniture	$1,563
Other	$30,908
Total	**$4,793,388**

In Section F.3(a) and (b), pages 43-44, the applicant projects no start-up or initial operating expenses for the proposed project.

Availability of Funds

In Section F.2, page 42, the applicant states the capital cost of the project will be funded with accumulated reserves or owner's equity. Exhibit F.2 contains a letter dated April 10, 2017 from the Senior Vice President, Chief Financial Officer and Treasurer of DUHS committing up to $5,000,000 in accumulated reserves to the capital costs of the proposed project. Exhibit F.2 also contains the Duke University Health System, Inc. and Affiliates consolidated balance sheets for the years ending June 30, 2016 and 2015. As of June 30, 2016, DUHS had $281,143,000 in cash and cash equivalents, $5,164,925,000 in total assets, and $2,394,892,000 in net assets. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project on Form F.2. In the pro forma financial statements (Form F.4), the applicant projects that operating expenses will exceed revenues in the first three operating years of the proposed project, as shown in the table below.

DUH CMRI Scanner Projected Revenues & Expenses – FYs 2019-2021			
	OY 1 – FY 2019	**OY 2 – FY 2020**	**OY 3 – FY 2021**
Total CMRI Cases	2,521	2,641	2,776
Total Gross Revenues (Charges)	$16,094,115	$16,827,213	$17,651,824
Total Net Revenue	$4,484,999	$4,687,428	$4,693,696
Total Operating Expenses (Costs)	$5,682,733	$5,890,607	$6,040,326
Projected Average Charge per Case	$6,594	$6,603	$6,611
Average Operating Expense per Case	$2,254	$2,231	$2,176
Net Income	($1,197,734)	($1,203,179)	($1,076,629)

However, the applicant projects in Form F.2 that revenues will exceed operating expenses in the first three operating years of the project for DUHS as a whole. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates 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

In Section B.3(e), page 16, the applicant states DUH is an Academic Medical Center Teaching Hospital, as such, DUH provides services for patients from multiple counties in North Carolina and patients from Virginia. The applicant identifies 22 counties as its primary and secondary service area.

On page 168, in Table 9Q of the 2017 SMFP, is a list of the inventory of MRI scanners for cardiovascular clinical research pursuant to Policy AC-3, as illustrated below:

Service Area	County	Provider	MRI Scanners
	Durham	Duke University Hospital	2
A certificate of need (J-006511-01) was issued on April 30, 2002 to Duke University Hospital. The certificate of need states that Duke University Health Systems, Inc. shall, pursuant to Policy AC-3 in the 2001 SMFP, convert a research only MRI scanner to clinical research use and acquire a second MRI scanner for clinical research use by the Cardiovascular and Magnetic Resonance Center. These MRI scanners shall only be used for cardiovascular purposes and shall not be counted in the inventory of fixed MRI scanners.			

In Section B.3(e), page 16, the applicant states there are no other hospitals that have dedicated cardiovascular MRI equipment. The applicant further states on page 16, that *"cardiac MRI requires unique hardware and software specific to cardiovascular applications."* DUH provides services for patients from multiple counties in North Carolina and patients from Virginia. The applicant adequately demonstrates in its application that it is in conformity with Policy AC-3. The applicant adequately demonstrates that its projected utilization is based on

reasonable and adequately supported assumptions. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved cardiac MRI scanners services in its proposed service area. Therefore, the application is conforming to this criterion.

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

C

In Section Q, on Form H, the applicant states that it currently employs 8.75 FTE positions for its CMRI services. The applicant projects to hire one additional registered nurse in October 2017 and two MRI technicians in July 2017 for a total of 11.75 FTE positions. The applicant states in its assumptions on page 90, that the new FTE positions have to be hired in advance of the project to provide specialized training and ensure staff readiness. The applicant does not anticipate needing any other additional staff. In Section H.2, page 49, the applicant discusses its process for recruiting staff. In Section H.4, the applicant states that Dr. Lisa Pickett is the Medical Director for DUH and that Dr. Raymond Kim and Dr. Robert M. Judd serve as co-directors for the Duke Cardiac MRI Center. 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 I, pages 52-53, the applicant states that as an Academic Medical Center Teaching Hospital the necessary ancillary and support services are currently available including DUH's clinical engineering and radiation safety personnel. On page 52, the applicant discusses DUH and WakeMed Health and Hospitals recent agreement to combine their heart programs into a single heart service in Wake County. Both hospitals will continue to operate independently with the exception of the Heart Care Plus+ program. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare 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

DUH purposes the addition of one CMRI in the Duke Medicine Pavilion, adjacent to two other CMRI scanners. In Section K, page 55, the applicant states the existing space proposed for the renovations is not currently in use. The applicant further states that the proposed project does not entail the upfit of newly leased spaced, but rather the renovation of existing leased space. DUH leases space from Duke University. The applicant states on page 56, that placing the equipment together will maximize construction and operational efficiencies. In Exhibit K.2, the applicant provides a line drawing depicting the spaced proposed. Therefore, the application is conforming to this criterion.

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

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

C

In Section L.1(b), page 60, the applicant provides the payor source for DUH and for its CMRI services for FY 2016, as follows.

DUH Historical Payor Mix FY 2016		
Payor Source	**Entire Facility**	**CMRI Service**
Private Pay/Managed Care*	39.73%	51.69%
Medicare	41.26%	33.47%
Medicaid	13.11%	7.46%
TRICARE	1.67%	4.93%
Worker Comp.	0.14%	0.09%
Other** Manage Care Plans	1.75%	0.89%
Self-Pay	2.33%	1.48%
Total	**100.0%**	**100.0%**

*Includes Commercial (DUH 1.09%), (CMRI 1.85%), Duke Select (DUH 3.15%), (CMRI 3.72%) and Managed Care (DUH 35.49%), (CMRI 46.12%). **Includes out of state Medicaid, VA, International, other Government and non-specified payor sources.

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

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Durham	11%	52%	58%	17%	7%	18%
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

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

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

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.2, page 60, the applicant states DUH has satisfied its requirements of applicable federal regulations for uncompensated care in return for the Hill-Burton funds previously received. The applicant states on page 60, that DUH has no obligation under applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons other than those obligations which apply to private, not-for-profit, acute care hospital which participate in Medicare, Medicaid and Title V programs. On page 61, the applicant states no civil rights access complaints were filed against the hospital in the last 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 L.3, page 61, the applicant projects its payor mix for the second operating year following project completion (FY2020) for the entire hospital and its CMRI services, as shown below.

DUH Projected Payor Mix FY 2020		
Payor Source	**Entire Facility**	**CMRI Service**
Private Pay/Managed Care*	38.04%	48.14%
Medicare	42.68%	37.03%
Medicaid	12.76%	7.45%
TRICARE	1.75%	5.00%
Worker Comp.	0.16%	0.00%
Other** Manage Care Plans	1.97%	0.91%
Self-Pay	2.64%	1.47%
Total	**100.0%**	**100.0%**

*Includes Commercial (DUH 1.03%), (CMRI 1.85%), Duke Select (DUH 3.23%), (CMRI 3.72%) and Managed Care (DUH 33.78%), (CMRI 42.57%). **Includes out of state Medicaid, VA, International, other Government and non-specified payor sources.

The applicant projects that 44.48 percent of its CMRI services patients will have all or some of their services paid for by Medicare and/or Medicaid. The applicant provides its assumptions and methodology used for the projected payor mix on page 62. The applicant demonstrates that medically underserved populations will continue to have adequate access to the CMRI services offered at DUH. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 63, the applicant states that patients are referred for CMRI services by physician or are admitted through the emergency department. 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 M, page 64, the applicant states that as an Academic Medical Teaching Hospital, DUH serves as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals. The applicant further states on page 64, that the proposed project will enhance DUH's ability to fulfill its educational mission. The applicant states that members of Duke University Schools of Medicine and Nursing and DUH's staff work closely with faculties of other schools and universities, community colleges and clinics in the area to provide health professional training programs including specialized training. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

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

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

C

In Section B.3(e), page 16, the applicant states DUH is an Academic Medical Center Teaching Hospital, as such, DUH provides services for patients from multiple counties in North Carolina and patients from Virginia. The applicant identifies 22 counties as its primary and secondary service area.

On page 168, in Table 9Q of the 2017 SMFP, is a list of the inventory of MRI scanners for cardiovascular clinical research pursuant to Policy AC-3, as illustrated below:

Service Area	County	Provider	MRI Scanners
	Durham	Duke University Hospital	2
A certificate of need (J-006511-01) was issued on April 30, 2002 to Duke University Hospital. The certificate of need states that Duke University Health Systems, Inc. shall, pursuant to Policy AC-3 in the 2001 SMFP, convert a research only MRI scanner to clinical research use and acquire a second MRI scanner for clinical research use by the Cardiovascular and Magnetic Resonance Center. These MRI scanners shall only be used for cardiovascular purposes and shall not be counted in the inventory of fixed MRI scanners.			

In Section B.3(e), page 16, the applicant states there are no other hospitals that have dedicated cardiovascular MRI equipment. The applicant further states on page 16, that "*cardiac MRI requires unique hardware and software specific to cardiovascular applications.*" As an Academic Medical Center Teaching Hospital, DUH provides services for patients from multiple counties in North Carolina and patients from Virginia. The applicant identifies 22 counties as its primary and secondary service area.

On page 34, the applicant states the proposed cardiac MRI scanner is projected to operate Monday through Friday from 7:00 to 5:30, for 62.5 hours/week. The applicant reports that cases can take up to two hours per case for an annual maximum capacity of 1,625 scans per year (31.25/week x 52 weeks), assuming 100% use of the CMRI scanners for procedures. However, in addition to being used for cardiac MRI procedures the equipment will be used for teaching and research purposes. Thus, DUH calculates that the capacity of each of the three CMRI scanners operated would be used as follows: two scanners (one existing scanner and the proposed scanner) will be available five days per week for clinical and research needs for a total of 1,302 cases per year and that the other existing scanner would have one dedicated day per week for research (including animal research), thus the third scanner would perform 1,042 cases per year. See the discussions regarding projected utilization found in Criterion (3) and incorporated herein by reference.

In Section N, page 65, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

> *"This project will not directly affect the cost effectiveness of services, as it is an expansion of existing services for which charges will not change. However, it may improve the quality and access for patients, including medically underserved groups, by reducing capacity constraints and wait times, which can currently be as much as 6 weeks. In addition, by expanding research as well as training opportunities for practitioners, this project will enhance quality and access across the service area."*

See also Sections C, E, F, G, H, I, L, and O, where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

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

- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.

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

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

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

C

In Section O, page 66 and Exhibits O.1, the applicant describes the methods used by DUH to insure and maintain quality care. In Section O.3, page 66, the applicant lists the eight facilities owned by Duke University Health System, which includes:

- DUH
- Duke Raleigh Hospital
- Duke Home Health
- Duke Home Infusion
- Duke Hospice (Durham)
- Duke Hospice (Raleigh)
- Hock Family Pavilion
- Duke Hospice at the Meadowlands

Additionally, DUHS also leases and operates Duke Regional Hospital. On page 67, the applicant states that of those facilities only one facility, Duke Raleigh Hospital, received a conditional deficiency in December 2015. The hospital submitted a plan of correction in February 2016 and is back in compliance with Medicare Conditions of Participation. After reviewing and considering information provided by the applicant and considering the quality of care provided at DUHS facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The proposed project was filed pursuant to Policy AC-3 in the 2017 SMFP to acquire a 3rd unit of cardiac MRI equipment. Due to the specialized purposes for which the equipment is being used by the Academic Medical Teaching Center Hospital, the inventory is reported in a separate table that is not included in the calculation of the need methodology. Policy AC-3 MRI scanners used exclusively for cardiovascular research are reported in Chapter 9 Table 9Q(1) in the 2017 SMFP. Therefore, the performance standards found in 10A NCAC 14C .2703 for magnetic resonance imaging scanners are not applicable to this review.