

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 28, 2018

Findings Date: February 28, 2018

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: F-11440-17

Facility: Carolinas HealthCare System Imaging-Denver

FID #: 170522

County: Lincoln

Applicants: Union Medical Services, LLC

The Charlotte-Mecklenburg Hospital Authority

Project: Acquire a fixed MRI scanner

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

Union Medical Services, LLC and The Charlotte-Mecklenburg Hospital Authority propose to acquire one fixed MRI scanner to be developed in a freestanding MRI facility, Carolinas HealthCare System Imaging-Denver [**CHSI-Denver**] in Denver, which is located in Lincoln County.

Need Determination

The 2017 State Medical Facilities Plan (SMFP) includes a need determination for one additional fixed MRI scanner for the Lincoln County service area. CHSI-Denver proposes to acquire one fixed MRI scanner to be located in Denver (Lincoln County). Therefore, the applicants' proposal is consistent with the need determination in the 2017 SMFP.

Policies

There are two policies in the 2017 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3

Policy GEN-3 states:

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

CHSI-Denver addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section B.10, pages 27-28, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access – The applicants describe how they believe the proposed project would promote equitable access in Section B.10, pages 28-29, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value – The applicants describe how they believe the proposed project would maximize healthcare value in Section B.10, page 29. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

The applicants adequately demonstrate how their projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. The application is consistent with Policy GEN-3.

Policy GEN-4

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, 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 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 \$2 million but less than \$5 million. In Section B.11, page 30, the applicants state:

“CHS will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed upfit. The design team has Energy Star, Leadership in Energy and Environmental Design (LEED) and Hospitals for a Healthy Environment Green Guide for Healthcare (GGHC) experience.”

The applicants adequately demonstrate that the application 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.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supports the applicants’ conformity with Policy GEN-3 and Policy GEN-4.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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 applicants, Union Medical Services, LLC (UMS) and The Charlotte-Mecklenburg Hospital Authority (CMHA) propose to acquire one fixed MRI scanner to be developed in a freestanding MRI facility, Carolinas HealthCare System Imaging-Denver (CHSI-Denver) in Denver, which is located in Lincoln County. In Section A.1, pages 9-10, the applicants state UMS is a wholly owned subsidiary of CMHA, and that CMHA d/b/a Carolina HealthCare System (CHS) is *“included as a co-applicant to the extent that it is the owner and lessor of the property where the proposed project will be developed and it will fund the capital costs associated with the proposed project.”* Carolinas HealthCare System Lincoln (CHS Lincoln) currently operates one fixed MRI scanner in Lincoln County. In Section C.1, pages 32-33, the applicants describe the proposed project as follows:

“UMS proposes to acquire one fixed MRI scanner to be operated at CHSI-Denver, a new freestanding MRI facility, to meet the need identified in the 2017 SMFP for one fixed MRI scanner in Lincoln County. ... The proposed freestanding MRI facility will be developed in Denver, which is the fastest growing region within Lincoln County, in space that is currently vacant in an existing medical office building owned by CMHA. The proposed site is easily accessible from NC Highway 16, which is a main thoroughfare that runs north-south through east Lincoln County. The proposed project can be operationalized with upfit to 2,250 square feet of existing, unoccupied space, which represents a cost effective alternative to new construction. ... As shown on the project line drawings in Exhibit C.1, the MRI scanner will be co-located with all necessary on-site support space, including a control room and equipment room; patient waiting, toilet, dressing, and staging areas; clean and soiled utility; a radiologist reading room; and staff toilets and break room.”

Patient Origin

On page 146, the 2017 SMFP defines the service area for MRI scanners as *“the same as an Acute Care Bed Service Area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.”* Figure 5.1 on page 42 of the 2017 SMFP indicates that Lincoln County is a single county service area. Thus, the service area for this project consists of Lincoln County. Facilities may also serve residents of counties not included in their service area.

In Section C.3, page 36, the applicants provide the projected patient origin for the proposed MRI scanner for the first three operating years (CY2020-CY2022), as shown in the table below.

CHSI-Denver Projected Patient Origin

County	Project Year 1	Project Year 2	Project Year 3
Lincoln	75.0%	75.0%	75.0%
Gaston	12.6%	12.6%	12.6%
Catawba	8.0%	8.0%	8.0%
Cleveland	2.0%	2.0%	2.0%
Mecklenburg	0.7%	0.7%	0.7%
Other*	1.7%	1.7%	1.7%
TOTAL	100.0%	100.0%	100.0%

Source: Table on page 36 of the application.

*The applicants list the counties included in the "Other" category on page 36 of the application.

In Section C.3, page 36, the applicants state,

"As stated in the Form C assumptions and methodology, CHS expects that 75 percent of CHSI-Denver's patients will originate from Lincoln County and that the remaining 25 percent of patients will be the result of immigration from other counties. CHS assumes that the composition of these immigration patients will be consistent with the distribution by county of CHS Lincoln's scheduled outpatient, non-Medicaid MRI patients in CY 2016."

The applicants adequately identified the population proposed to be served.

Analysis of Need

In Section C.4 of the application, the applicants describe the factors which they state supports the need for the proposed project, including:

- The historical and projected growth in MRI scanner utilization at CHS Lincoln (p. 37-44).
- The advantages and benefits of freestanding, outpatient MRI scanner services for Lincoln County residents (p. 44-45).
- Historical population growth and aging in Lincoln County and the Denver area (p. 45-47).

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

Projected Utilization

In Section Q, Form C, the applicants provide CHSI-Denver’s projected MRI scanner utilization through the first three full fiscal years of operation following completion of the proposed project, as summarized in the table below.

	Partial Fiscal Year CY2019*	1st Full Fiscal Year CY2020	2nd Full Fiscal Year CY2021	3rd Full Fiscal Year CY2022
Fixed MRI Units	1	1	1	1
MRI Procedures	326	2,344	3,135	3,546
Weighted MRI Procedures	362	2,605	3,484	3,942

*Applicants project the CHSI-Denver MRI scanner will become operational on October 1, 2019.
Source: Form C, Section Q of the application.

As shown in the table above, CHSI-Denver projects the proposed MRI scanner will perform 3,942 weighted MRI scanner procedures in the third operating year of the project (CY2022), which exceeds the performance standards promulgated in 10A NCAC 14C .2703(b)(3). In Section Q, the applicants describe their assumptions and methodology for projecting utilization of the proposed fixed MRI scanner, as summarized below.

Step 1: Review Historical Utilization of CHS Lincoln MRI Scanner

The applicants reviewed the historical utilization growth of the existing CHS Lincoln MRI scanner from FFY2011 to FFY2016 and determined that utilization increased at an average annual rate of 4.7 percent during the time period. Also, the applicants reviewed patient origin for the existing CHS Lincoln MRI scanner, and determined that 65.9 percent of Lincoln County residents received MRI services from out-of-county providers in FFY2016. See tables in Section Q, pages 1 and 2.

Step 2: Project Patients Expected to Shift from CHS Lincoln to CHSI-Denver

Based on ZIP Code of origin, payor source, and inpatient/outpatient status, the applicants projected the number of patients that have historically received MRI services at CHS Lincoln who would shift to CHSI-Denver through the first three full operating years of the project. See table in Section Q, page 3.

Step 3: Project Patients Expected to Shift from CHS Hospitals to CHSI-Denver

Based on historical internal data, the applicants projected the number of patients that have historically received MRI services at out-of-county CHS hospitals who would shift to CHSI-Denver through the first three full operating years of the project. See table in Section Q, page 4.

Step 4: Project Patients Expected to Shift from Other Freestanding Imaging Centers to CHSI-Denver

Based on data reported on license renewal application forms, the applicants projected the number of patients that have historically received MRI services at out-of-county freestanding imaging centers who would shift to CHSI-Denver through the first three full operating years of the project. See table in Section Q, page 5.

Step 5: Project Patients Expected to Shift from Novant Hospitals to CHSI-Denver

Based on data reported on license renewal application forms, the applicants projected the number of patients that have historically received MRI services at out-of-county Novant hospitals, including Novant Health Huntersville Medical Center and Novant Health Presbyterian Medical Center, who would shift to CHSI-Denver through the first three full operating years of the project. See table in Section Q, page 6.

Step 6: Project Patients Expected to Shift from Catawba and Gaston County Hospitals to CHSI-Denver

Based on data reported on license renewal application forms, the applicants projected the number of patients that have historically received MRI services at Catawba and Gaston Hospitals who would shift to CHSI-Denver through the first three full operating years of the project. See tables in Section Q, pages 7 and 8.

Step 7: Project Ramp-Up Period

The applicant projects total Lincoln County patients to shift to CHSI-Denver through the first three operating years based on the assumption that 60 percent will shift in the first operating year, 90 percent in the second operating year, and 100 percent by the third operating year, as shown in the table below:

CHSI-Denver Projected Lincoln County MRI Patients

	FFY2020	FFY2021	FFY2022	FFY2023
Shift from CHS Lincoln	1,077	1,128	1,182	1,238
Shift from CMC	85	89	93	97
Shift from Imaging Centers outside Lincoln Co.	311	326	341	357
Shift from Novant Health Hospitals	277	290	304	319
Shift from Catawba and Gaston Hospitals	315	330	346	362
Total Patients Shifted to CHSI-Denver	2,066	2,164	2,266	2,373
Ramp-up Percentages	60.0%	90.0%	100.0%	100.0%
Total Projected Lincoln County MRI Patients	1,239	1,947	2,266	2,373

Source: Table in Section Q, page 8.

Step 8: Project In-migration

Based on data reported on license renewal application forms for freestanding MRI facilities in the Charlotte region, the applicants projected that an additional 25 percent of patients originating from outside of Lincoln County will seek services at CHSI-Denver through the first three full operating years of the project, as shown in the table below:

CHSI-Denver Projected MRI Patients

	FFY2020	FFY2021	FFY2022	FFY2023
Total Projected Lincoln County MRI Patients	1,239	1,947	2,266	2,373
Percent of In-migration	25%	25%	25%	25%
Total Patients from In-migration	413	649	755	791
CHSI-Denver Total Patients	1,653	2,596	3,021	3,165

Source: Table in Section Q, page 9.

Step 8: Project Unweighted and Weighted MRI Procedures

Based on data reported on license renewal application forms for freestanding MRI facilities in the Charlotte region, the applicants project an average of 1.16 unweighted MRI procedures per patient, and 1.29 weighted MRI procedures per patient at CHSI-Denver through the first three full operating years of the project, as shown in the table below:

CHSI-Denver Projected Weighted and Unweighted MRI Procedures

	FFY2020	FFY2021	FFY2022	FFY2023
Patients	1,653	2,596	3,021	3,165
Unweighted MRI procedures	1,917	3,011	3,505	3,671
Weighted MRI procedures	2,131	3,347	3,895	4,080

Source: Table in Section Q, page 10.

The applicants then convert the CHSI-Denver MRI scanner utilization projections from a federal fiscal year basis to calendar years to correspond to the CHS fiscal year, as shown in the table below:

CHSI-Denver Projected Weighted and Unweighted MRI Procedures

	CY2019	CY2020	CY2021	CY2022
Patients	281	2,021	2,703	3,057
Unweighted MRI procedures	326	2,344	3,135	3,546
Weighted MRI procedures	362	2,605	3,484	3,942

Source: Table in Section Q, page 11.

As discussed above, the applicants project utilization of the proposed MRI scanner based on historical utilization of the existing MRI scanner at CHS Lincoln, as well as MRI utilization at out-of-county providers by Lincoln County residents who are projected to shift to the proposed CHSI-Denver MRI scanner. Exhibit I.2 contains letters from physicians expressing support for the proposed project. Projected utilization of CHSI-Denver's MRI scanner is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need for one fixed MRI scanner.

Access

In Section C.10, page 50, the applicants state their commitment to provide services to all patients who need the services regardless of income, payer status, gender, race, ethnicity or physical handicap or other conditions that would classify them as underserved. In Section L.3, page 89, the applicants project that 47.9 percent of CHSI-Denver's MRI services will be provided to Medicare recipients in the second year of operation (CY2021) following completion of the project. The applicants note that Medicaid does not reimburse for MRI services provided at independent diagnostic testing facilities (IDTFs) like CHSI-Denver. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants use historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicants use established methodologies and uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicants use historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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

The applicants do not propose the reduction or elimination of a service, or the relocation of a facility or service.

- (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.

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In Section E.2, pages 63-64, the applicants describe the following alternatives:

- Maintain the status quo – The applicants state this was not an effective alternative due to the fact that it would not meet the need for additional freestanding MRI services in Lincoln County.
- Develop a hospital-based MRI scanner – The applicants considered developing the MRI scanner at the hospital location, however the applicants determined that another hospital-based MRI scanner would not meet the needs of patients currently leaving the county to seek freestanding MRI services.
- Develop a freestanding MRI scanner in another location – The applicant states this was not an effective alternative due to the fact that the Denver area is the fastest growing area in Lincoln County and is in easy travel distance from Lincolnton, which is the largest population center in Lincoln County.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants use reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicants with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Union Medical Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**

2. **Union Medical Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall acquire no more than one fixed MRI scanner.**
 3. **Union Medical Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 4. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Union Medical Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
 5. **Union Medical Services, LLC and The Charlotte-Mecklenburg Hospital Authority 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.

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CHSI-Denver proposes to acquire one fixed MRI scanner to be developed in a freestanding MRI facility to be located in an existing medical office building owned by CHS.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant states the total capital cost for the proposed project is projected to be as follows:

CHSI-Denver MRI Scanner Capital Cost

Cost Category	Projected Capital Cost
Construction/Renovation	\$1,174,000
Medical Equipment	\$1,570,000
Nonmedical Equipment	180,000
Furniture	\$27,000
Consultant Fees	\$210,400
Other (Contingency)	\$720,000
TOTAL CAPITAL COST	\$3,881,400

Source: Section Q, Form F.1a of the application.

In Section F.3, pages 67-68, the applicants state that the project will require \$69,666 in start-up expenses and \$58,272 in initial operating expenses for total working capital required of \$127,938.

Availability of Funds

In Section F.2, page 66, and Section F.3, page 68, the applicants state the capital and working capital costs for the proposed project will be funded by the accumulated reserves of CMHA d/b/a CHS. In Exhibit F.2, the applicants provide a letter dated November 15, 2017, from the Executive Vice President and Chief Financial Officer for CHS documenting their intention to provide \$3,881,400 in funds for capital costs and \$200,000 for working capital costs for the proposed project. Exhibit F.2 also contains the audited financial statements for CHS that indicate it had \$143 million in cash and cash equivalents and \$1.2 billion in current assets as of December 31, 2016. The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

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

Projected Revenue and Expenses for CHSI-Denver

	PY1 CY2020	PY2 CY2021	PY3 CY2022
MRI Procedures	2,344	3,135	3,546
Total Gross Revenue (Charges)	\$3,857,407	\$5,313,905	\$6,191,641
Total Net Revenue	\$1,450,699	\$1,805,650	\$2,088,347
Net Revenue Per Procedure	\$619	\$576	\$589
Total Operating Expenses	\$1,353,294	\$1,664,520	\$1,880,515
Operating Expenses Per Procedure	\$577	\$531	\$530
Net Income (Loss)	\$97,405	\$141,130	\$207,833

Source: Section Q, Form F.3 and F.4

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate 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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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

CHSI-Denver proposes to acquire one fixed MRI scanner to be developed in a freestanding MRI facility to be located in an existing medical office building in Denver (Lincoln County).

On page 146, the 2017 SMFP defines the service area for MRI scanners as “*the same as an Acute Care Bed Service Area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” Figure 5.1 on page 42 of the 2017 SMFP indicates that Lincoln County is a single county service area. Thus, the service area for this project consists of Lincoln County. Facilities may also serve residents of counties not included in their service area.

There is one existing fixed MRI scanner in Lincoln County, as shown in the table below:

Lincoln County MRI Scanners	Fixed MRI Scanner Units	Total MRI Scans	Total Weighted MRI Scans
Carolina HealthCare System Lincoln	1	3,931	4,639

Source: 2018 State Medical Facilities Plan, Table 9P: MRI Fixed and Mobile Procedures by MRI Service Area

In Section G.3, page 73, the applicants state,

“The proposed project involves the development of a freestanding fixed MRI scanner in Lincoln County in response to the need identified in the 2017 SMFP and the growing demand for MRI services in Lincoln County. The proposed project will provide a local, convenient, and cost-effective alternative that will meet the needs of many patients who have historically left the county for care and address the needs of the county’s only existing MRI facility, CHS Lincoln.”

The applicants adequately demonstrate the need the population proposed to be served has for the fixed MRI scanner, and adequately demonstrates that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants use established methodologies and assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicants provide adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed MRI scanner at CHSI-Denver for each of the first three operating years, as summarized in the table below.

Position	CY2020 FTE	CY2021 FTE	CY2022 FTE
MRI Technician	1.0	1.0	1.2
Registrar	1.0	1.0	1.2
TOTAL	2.0	2.0	2.4

Source: Form H in Section Q of the application.

In Section H.2, pages 75-76, the applicants describe their experience and process for recruiting and retaining staff. In Section H.4, page 76, the applicants identify Ramesh Avva, M.D., as the Medical Director for the CHSI-Denver. The applicants adequately demonstrate 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.1, page 78, the applicants identify and describe the manner in which they will provide the necessary ancillary and support services. Exhibit I.2 of the application contains copies of letters from physicians expressing support for the proposed project.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of necessary ancillary and support services.
- The applicant provides documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

The applicants do not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicants do not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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

The applicant is not an HMO. Therefore Criterion (10) is not applicable.

- (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

CHSI-Denver proposes to upfit 2,250 square feet of vacant office space in an existing medical office building owned by CHS to accommodate the fixed MRI scanner. Exhibit F.1 contains a certified cost estimate from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section Q, Form F.1a of the application. In Section K.4, page 82, the applicants describe how the cost, design, and means of construction proposed represent the most reasonable alternative, and how the construction project will not increase the costs of providing health services. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides a certified cost estimate for the upfit costs and a line drawing of the proposed MRI facility.
- The applicant describes how the design and construction will not increase the costs of providing health services.

This determination is based on a review of the:

- information in the application, including any exhibits
- information which was publicly available during the review and used by the Agency

Therefore, the applicant adequately demonstrates that 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

CHSI-Denver is a new facility and does not have historical payment source data. The table below shows the historical (FY2016) payment source for the outpatient services at CHS Lincoln:

Payment Source	Outpatient Visits as Percent of Total
Self Pay/Indigent/Charity	3.3%
Medicare/Medicare Managed Care	44.9%
Medicaid	14.5%
Commercial Insurance	1.0%
Managed Care	33.4%
Other	3.0%
Total	100.0%

Source: 2017 Hospital Licensure Renewal Application, Section F.

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 service area, Lincoln County, and statewide.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Lincoln	17%	50%	15%	13%	12%	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 applicants' current payer 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 information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants' historical payor mix is adequate documentation that they currently provide services to medically underserved populations.
- The applicants' historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicants' existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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 88, the applicants states that UMS does not have obligations to provide uncompensated care. In Section L.2, page 88, the applicants state that no civil rights access complaints have been filed against any affiliate of UMS in the last five years.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants provide credible information about their lack of obligation to provide any uncompensated care or community service under any federal regulations.
- The applicants states they have not had any civil rights access complaints filed against it within the last five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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 89, the applicants project the following payment sources for CHSI-Denver's MRI services during the second operating year (CY2021):

Payment Source	MRI Services as Percent of Total
Medicare	47.9%
Medicaid	0.0%
Commercial/Managed Care	47.2%
Other (Government, other payors)	1.7%
Self Pay	3.2%
Total	100.0%

Source: Table on page 89 of the application.

On page 89, the applicants state projected payment sources are based on the historical payment sources for MRI services at CHS Lincoln. The applicants note that freestanding MRI facilities are not eligible for reimbursement from Medicaid.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicants' projected payor mix adequately demonstrates that medically underserved populations will have access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits.

- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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 90, the applicants describe the range of means by which a person will have access to CHSI-Denver.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicants adequately demonstrate that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that 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.1, page 91, the applicants state that CHSI-Denver, through CHS, will have extensive relationships with local health professional training programs. Exhibit M.1 contains copies of sample training agreements between CHS and area health professional training programs, and a list of institutions with which the applicants have established relationships.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicants adequately document that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate 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

CHSI-Denver proposes to acquire one fixed MRI scanner to be developed in a freestanding MRI facility to be located in an existing medical office building in Denver (Lincoln County).

On page 146, the 2017 SMFP defines the service area for MRI scanners as “*the same as an Acute Care Bed Service Area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.*” Figure 5.1 on page 42 of the 2017 SMFP indicates that Lincoln County is a single county service area. Thus, the service area for this project consists of Lincoln County. Facilities may also serve residents of counties not included in their service area.

There is one existing fixed MRI scanner in Lincoln County, as shown in the table below:

Lincoln County MRI Scanners	Fixed MRI Scanner Units	Total MRI Scans	Total Weighted MRI Scans
Carolina HealthCare System Lincoln	1	3,931	4,639

Source: 2018 State Medical Facilities Plan, Table 9P: MRI Fixed and Mobile Procedures by MRI Service Area

In Sections N.1 and N.2, pages 93-94, the applicants describe the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

On pages 93-94, the applicants state:

“CHS believes the proposed project will promote safety and quality in the delivery of healthcare services. ... The proposed freestanding fixed MRI scanner will be developed in a dedicated outpatient facility designed to optimize patient convenience and comfort. Patients will have easy access to the facility and convenient parking. .. As a freestanding

facility, CHSI-Denver will provide services at a lower out-of-pocket cost to most patients.”

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

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate the need for the proposal and that it is a cost-effective alternative.
- The applicants adequately demonstrate that they will provide quality services.
- The applicants adequately demonstrate that they provide access to medically underserved groups.

This determination is based on a review of:

- the information in the application, including any exhibits
- information which was publicly available during the review and used by the Agency

(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

CHS owns or manages 23 hospitals in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, none of the CHS facilities is currently out of compliance with a CMS Condition of Participation, nor have any other 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 CHS.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicants provide adequate and credible documentation of their current policies with regard to providing quality care.
- The applicants provide accurate information regarding their history of compliance with CMS Conditions of Participation.

This determination is based on a review of the:

- Information in the application, including any exhibits.

- Information which was publicly available during the review and used by the Agency.

Therefore, the applicants adequately demonstrate that the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application submitted by CHSI-Denver is conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner promulgated in 10A NCAC 14C .2700 and all applicable. The specific criteria are discussed below.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*
 - (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
 - (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- CHSI-Denver does not propose to acquire a mobile MRI scanner.

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;

-C- CHS Lincoln operates the only existing fixed MRI scanner in the proposed MRI service area. In Section C.11, page 55, the applicants report the MRI scanner at CHS Lincoln performed 5,032 weighted MRI procedures in the most recent 12 months of operation (August 2016 to July 2017) for which data was available.

(2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

-NA- The applicants do not operate any mobile MRI scanners in the proposed MRI service area.

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

- (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-C- There is one fixed MRI scanner located in Lincoln County. In Section C.11, page 56, the applicants project the existing fixed MRI scanner at CHS Lincoln will perform 4,106 weighted MRI procedures, and the proposed fixed MRI at CHSI-Denver will perform 3,985 weighted MRI procedures, in the third year of operation (FFY2022).

(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to

perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-C- In Section C.11, page 56, the applicants project the proposed fixed MRI at CHSI-Denver will perform 3,985 weighted MRI procedures in the third year of operation (FFY2022).

- (5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

-NA- The applicants do not operate any mobile MRI scanners in the proposed MRI service area.

- (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-C- The applicants provide documentation of its assumptions and provides data supporting its methodology in Section Q of the application.

(c) An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- CHSI-Denver does not propose to acquire a fixed dedicated breast MRI scanner.

(d) An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- CHSI-Denver does not propose to acquire a fixed extremity MRI scanner.

(e) An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:

- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- CHSI-Denver does not propose to acquire a fixed multi-position MRI scanner.