

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 20, 2018

Findings Date: November 20, 2018

Project Analyst: Gregory F. Yakaboski

Chief: Martha J. Frisone

Project ID #: F-11536-18

Facility: Carolinas HealthCare System Union

FID #: 923515

County: Union

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Acquire a second 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

The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Atrium Health proposes to acquire a second fixed MRI scanner to be developed Carolinas HealthCare System Union (CHS Union) in Monroe which is located in Union County.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) includes a need determination for one additional fixed MRI scanner for the Union County service area. CMHA proposes to acquire one fixed MRI scanner to be located at CHS-Union in Monroe (Union County). Therefore, the proposal is consistent with the need determination in the 2018 SMFP.

Policies

There are two policies in the 2018 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.”

In Section B, pages 29-31, the applicant explains why it believes its application is conforming to Policy GEN-3. On pages 29-31, the applicant states;

“Atrium Health is dedicated to providing the highest quality care and is continually recognized locally and nationally for its commitment to delivering efficient, quality care. ... Atrium Health has long-promoted economic access to its services as it has historically provided services to all persons in need of medical care.... ... Atrium Health believes the additional MRI capacity is being provided in such a way that will minimize cost while also creating additional capacity to care for the growing number of patients.”

The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2018 SMFP. The discussion regarding projected utilization and access found in Criteria (3) and (13), respectively, are incorporated herein by reference. 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."

In Section B, pages 32-33, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 33, the applicant states

"CHS Union 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 renovations. 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 applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the reasons described above.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 for the reasons described above.
- (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

Atrium Health proposes to acquire a second fixed MRI scanner to be developed at CHS Union in Monroe.

Patient Origin

On page 142, the 2018 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 2018 SMFP indicates that Union County is a single county service area. Thus, the service area for this project consists of Union County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin for MRI services.

County	Current (1/1/17 to 12/31/17)		Second Full FY of Operation following Project Completion (1/1/22 to 12/31/22)	
	Patients	% of Total	Patients	% of Total
Union	3,811	65.3%	5,237	65.3%
Anson	873	15.0%	1,199	15.0%
Chesterfield, SC	543	9.3%	746	9.3%
Lancaster, SC	217	3.7%	298	3.7%
Mecklenburg	151	2.6%	208	2.6%
Other*	243	4.2%	333	4.2%
Total	5,837	100.0%	8,021	100.0%

Source: Section C, pages 37-38

*Other includes other counties in North Carolina as well as other states.

In Section C, page 38, the applicant provides the assumptions and methodology used to project its patient origin. The applicant assumes no change in patient origin for MRI services as a result of adding a second MRI scanner. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 39-51, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 39, the applicant states:

- The need determination in the 2018 SMFP for a fixed MRI scanner in Union County is the reason for the overall need for the proposed project (pages 39-41).
- The applicant states the specific need for the proposed MRI scanner is based on population growth overall and of residents in the 65+ age group (pages 49-51).
- The need for additional fixed MRI scanner capacity in Union County (pages 41-43).
- The need for additional fixed MRI scanner capacity at CHS Union (pages 43-46).
- The need for a hospital-based fixed MRI scanner at CHS Union (pages 46-49).

The information is reasonable and adequately supported for the following reasons:

- The 2018 SMFP includes a need determination for one fixed MRI scanner in Union County.
- The population of Union County is expected to increase.
- The applicant adequately demonstrated there is a need for increased access to hospital based MRI services by patients which include emergency patients, outpatients with comorbidities, inpatients and observation patients as well as outpatients.

Projected Utilization

Atrium Health owns the two existing fixed MRI scanners located in Union County. One fixed MRI scanner is located at CHS Union. The other fixed MRI scanner is located at Carolina HealthCare Imaging Services-Indian Trail (CHSI-Indian Trail), a diagnostic center which only serves outpatients.

In Section Q, the applicant provides historical and projected utilization for MRI utilization at CHS Union, as illustrated in the following table.

CHS Union- Projected MRI Scanner Utilization

	Interim* (CY2018)	Interim (CY2019)	Interim (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
# of Fixed MRI Scanners	1	1	2**	2	2	2
# of Procedures	6,069	6,500	6,966	7,472	8,021	8,618
# of Weighted Procedures	7,558	8,113	8,715	9,370	10,082	10,858

* Annualized based on CHS Union Year to Date (YTD) data as of April.

**The project is proposed to become operational as of July 1, 2020.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Projected MRI Utilization- CHS Union

The applicant calculates MRI scanner growth rates at CHS Union based on historic MRI volumes at CHS Union from CY2015 to CY2018

Historic MRI Utilization- CHS Union

	Historic (CY2015)	Historic (CY2016)	Historic (CY2017)	Annualized (CY2018)	CAGR*
Outpatient w/ No Contrast	2,311	2,541	2,681	2,673	5.0%
Outpatient w/ Contrast	908	973	1,139	1,293	12.5%
Inpatient w/ No Contrast	1,450	1,564	1,674	1,776	7.0%
Inpatient w/ Contrast	294	378	343	327	3.6%
Total	4,963	5,456	5,837	6,069	6.9%
Total Weighted	6,141	6,773	7,237	7,558	7.2%

*Compound Annual Growth Rate (CAGR)

The applicant expects MRI services at CHS Union to continue to grow at the historic growth rates shown in the table above based on following factors:

- The population of Union County is one of the fastest growing in North Carolina.
- CHS Union is offering cancer and neurology/stroke services which require MRI support.
- CHS Union expects to add two neurologists and an advanced care practitioner in CY 2019 plus two additional primary care providers. Further, Atrium expects to add an oncology provider to the Levine Cancer Institute located in Union County.

The following table illustrates how projected utilization was calculated.

Projected MRI Utilization- CHS Union

	Interim* (CY2018)	CAGR Applied	Interim (CY2019)	Interim (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
# of MRI Scanners	1		1	1	2	2	2
Outpatient w/ No Contrast	2,673	5.0%	2,806	2,945	3,092	3,245	3,407
Outpatient w/ Contrast	1,293	12.5%	1,455	1,637	1,841	2,071	2,331
Inpatient w/ No Contrast	1,776	7.0%	1,900	2,033	2,175	2,327	2,490
Inpatient w/ Contrast	327	3.6%	339	351	364	377	390
Total	6,069	6.9%	6,500	6,966	7,472	8,021	8,618
Total Weighted	7,558		8,113	8,715	9,370	10,082	10,858

*annualized based on four months of actual data.

Projected MRI Utilization- CHSI- Indian Trail

The applicant uses the same methodology to project utilization of the fixed MRI scanner located at CHSI-Indian Trail, the results of which are illustrated in the following tables.

Historic MRI Utilization: CHSI-Indian Trail

	Historic (CY2015)	Historic (CY2016)	Historic (CY2017)	Annualized (CY2018)	CAGR
Outpatient w/ No Contrast	1,109	1,245	1,337	1,212	3.0%
Outpatient w/ Contrast	200	321	372	282	12.1%
Total	1,309	1,566	1,709	1,494	4.5%
Total Weighted	1,389	1,694	1,858	1,607	5.0%

Projected MRI Utilization: CHSI- Indian Trail

	Interim* (CY2018)	CAGR Applied	Interim (CY2019)	Interim (CY2020)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
# of MRI Scanners	1		1	1	1	1	1
Outpatient w/ No Contrast	1,212	3.0%	1,248	1,286	1,325	1,364	1,405
Outpatient w/ Contrast	282	12.1%	316	355	398	446	500
Total	1,494	4.5%	1,565	1,641	1,722	1,810	1,905
Total Weighted	1,607	5.0%	1,691	1,782	1,881	1,989	2,105

*annualized based on four months of actual data.

Combined Projected Utilization: CHS Union and CHSI-Indian Trail

The applicant calculates the average number of weighted MRI scans for all of Atrium Health’s fixed MRI scanners in Union County, as shown in the table below.

OY3: Total Projected Combined Weighted MRI Scans at CHS Union and CHSI-Indian Trail

	Interim CY2019	Interim CY2020	OY1 CY2021	OY2 CY2022	OY3 CY2023
CHS-Union	8,113	8,715	9,370	10,082	10,858
CHSI-Indian Trail	1,691	1,782	1,881	1,989	2,105
Total Weighted MRI Scans	9,804	10,497	11,251	12,071	12,963
Total # of MRI Scanners	2	2	3	3	3
Average Weighted MRI Scans per MRI Scanner	4,902	5,249	3,750	4,024	4,321

Projected utilization is reasonable and adequately supported for the following reasons:

- Proposed physician recruitment
- Projected population growth
- Historical growth in MRI volumes which are reasonably expected to continue growing based on the proposed physician recruitment and population growth.

Access

In Section C, page 55, the applicant states “CHS Union provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment.” In Section L, page 97, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

CHS Union- OY2 (CY2022)

Payor Category	MRI Services as Percent of Total
Medicaid*	12.1%
Medicare*	51.4%
Self-Pay	5.3%
Insurance*	29.2%
Other (Other Govt, Workers Comp)***	1.9%
Charity Care**	
Total	100.0%

Source: Table page 95 of the application.

*Including any managed care plans

**Atrium Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Forms F.3&4 for charity care projections.

***Workers Comp and TRICARE are included in the Other payor category.

The projected payor mix is identical to the historical payor mix and is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served for the reasons described above.
- The applicant adequately explains why the population to be served needs the services proposed in this application for the reasons described above.
- Projected utilization is reasonable and adequately supported for the reasons described above.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions for the reasons described above.

- (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 applicant does not propose to reduce, eliminate or relocate a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

- (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

CMHA proposes to acquire a second fixed MRI scanner to be developed at CHS Union in Monroe.

In Section E, pages 69-70, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo- The applicant states that the existing fixed MRI scanner at CHS Union currently has high utilization, is the 6th most highly utilized fixed MRI scanner in the state and continued growth is expected. Due to current high utilization, patients, physicians and staff are being negatively impacted by inefficiencies, increased costs and inconveniences. If a second fixed MRI scanner is not developed, CHS Union

would have to contract for a mobile MRI scanner to address patient need. Therefore the applicant determined that maintaining the status quo is not the least costly or most effective alternative.

- Develop MRI at Another Location- The existing fixed MRI scanner at CHS Union currently has high utilization, is the 6th most highly utilized fixed MRI scanner in the state and continued growth is expected. Therefore, the applicant determined that developing a fixed MRI scanner at another location is not the least costly or most effective alternative.
- Develop a Freestanding MRI- CMHA considered developing a freestanding MRI scanner; however, the existing demand for increased MRI services is based on patients which include emergency patients, outpatients with co-morbidities, inpatients and observation patients as well as outpatients. A freestanding MRI scanner could serve outpatients but would not meet the need of patients best served by a hospital based MRI scanner. Further, CMHA has a freestanding MRI scanner at CHSI-Indian trail to provide appropriate outpatients the opportunity to take advantage of the convenience and cost savings associated with a non-hospital based MRI scanner. Therefore, the applicant determined developing a freestanding MRI scanner was not the least costly or most effective alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The applicant adequately demonstrates that adding a second fixed MRI scanner at CHS Union would most effectively meet both the current and projected needs of the diverse categories of patients, including emergency patients, outpatients with co-morbidities, inpatients and observation patients served by CHS Union.
- The data cited is reasonable and supports the assumptions made with regard to the least costly or most effective alternative for development of the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**

2. **The Charlotte-Mecklenburg Hospital Authority shall acquire one fixed MRI scanner to be located at Carolinas HealthCare System Union for a total of two fixed MRI scanners at Carolinas HealthCare System Union upon project completion.**
 3. **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, 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. **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.

C

CMHA proposes to acquire a second fixed MRI scanner to be developed at CHS Union in Monroe.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	
Construction Costs	\$2,230,500
Architect/Engineering Fees	\$320,000
Medical Equipment	\$2,316,696
Non-Medical Equipment	\$15,000
Furniture	\$15,000
Consultant Fees	\$125,000
Other (IS, Security, Internal Allocation, Contingency)	\$760,100
Total	\$5,782,296

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 73, the applicant projects that there will be no start-up costs or initial operating expenses as the proposed project does not involve a new service and CHS Union is an existing facility.

Availability of Funds

In Section F, page 72, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Atrium Health	Total
Loans	\$	\$
Accumulated reserves or OE *	\$ 5,782,296	\$5,782,296
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$	\$

* OE = Owner's Equity

On page 72, the applicant states that the financing of the proposed project will come from the accumulated reserves of CMHA d/b/a Atrium Health. In Exhibit F.2-1, the applicant provides a letter dated June 15, 2018 from the Executive Vice President and Chief Financial Officer for Atrium Health which states:

“As the Chief Financial Officer of Atrium Health, formerly known as Carolinas HealthCare System, I am responsible for financial operations, and I am very familiar with the organization’s financial position. The capital expenditure associated with this project is estimated to be \$5,782,296. ... Atrium Health will fund the capital costs ... from existing accumulated cash reserves. .. For verification of the availability of funds and our ability to finance these projects internally, please refer to the Line items “Cash and cash equivalents” and “Other assets: designated as funded depreciation,” in the audited financial statements.”

Exhibit F.2-2 includes a copy of the audited Basic Financial Statements and Other Financial Information for The Charlotte-Mecklenburg Hospital Authority (d/b/a Atrium Health) for the period ending December 31, 2017. On page 17 of Exhibit F.2-2, the financial statement shows Atrium Health had \$131,540,000 in “Cash and cash equivalents” as of December 31, 2017.

Financial Feasibility

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

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total MRI Procedures)	7,472	8,021	8,618
Total Gross Revenues (Charges)	\$25,641,445	\$28,351,817	\$31,374,821
Total Net Revenue	\$3,556,384	\$3,807,467	\$4,087,959
Average Net Revenue per MRI Procedure	\$475.96	\$474.69	\$474.35
Total Operating Expenses (Costs)	\$1,549,727	\$1,598,271	\$1,642,127
Average Operating Expense per MRI Procedure	\$207.40	\$199.26	\$190.55
Net Income	\$2,006,657	\$2,209,196	\$2,445,831

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 projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.

- 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.
- 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

CMHA proposes to acquire a second fixed MRI scanner to be developed at CHS Union in Monroe.

On page 142, the 2018 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 2018 SMFP indicates that Union County is a single county service area. Thus, the service area for this project consists of Union County. Facilities may also serve residents of counties not included in their service area.

There are two existing fixed MRI scanners in Union County, as shown in the table below:

Union County MRI Scanners	Fixed MRI Scanner Units	Total MRI Scans	Total Weighted MRI Scans
Carolina HealthCare System Union	1	5,451	6,779
Carolina HealthCare Imaging Services-Indian Trail	1	1,474	1,597

Source: 2018 SMFP, Table 9P, page 159

In Section G, pages 79-80, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Union County. The applicant states:

- The 2018 SMFP has a need determination for one additional fixed MRI scanner in Union County.
- The proposed fixed MRI scanner at CHS Union will serve a broad range of patients including both outpatients and inpatients.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for the proposed fixed MRI scanner in Union County.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved MRI scanners in Union County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 current and projected staffing for the proposed services, as illustrated in the following table.

Position	Current	Projected		
	1/1/17 to 12/31/17	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
MRI Tech	4.39	5.39	5.39	5.39
TOTAL	4.39	5.39	5.39	5.39

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 81-82, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 82, the applicant identifies the current medical director. In Exhibit H.4, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Section H, page 82, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 84, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Registration and billing
- Housekeeping
- Medical records
- Patient scheduling.

On page 84, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 84, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes 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 applicant does 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 applicant does 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 a HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

In Section K, page 88, the applicant states that the project involves renovating 3,214 square feet of existing space. Line drawings are provided in Exhibit C.1.

On pages 34-35 and 89, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposed renovations and provides supporting documentation in Exhibit C.1.

On page 89, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 89-90, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes 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

In Section L, page 95, the applicant provides the historical payor mix during CY2017 for MRI services, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Medicaid*	12.1%
Medicare*	51.4%
Self-Pay	5.3%
Insurance*	29.2%
Other (Other Govt, Workers Comp)***	1.9%
Charity Care**	
Total	100.0%

Source: Table page 95 of the application.

*Including any managed care plans

**Atrium Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Forms F.3&4 for charity care projections.

***Workers Comp and TRICARE are included in the Other payor category.

In Section L, pages 94-95, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY (CY2017)	Percentage of the Population of the Union County Service Area
Female	57.5%	51.0%
Male	42.5%	49.0%
Unknown	0.0%	0.0%
64 and Younger	73.7%	87.6%
65 and Older	26.3%	12.4%
American Indian	1.0%	0.0%
Asian	0.3%	2.6%
Black or African-American	26.3%	12.0%
Native Hawaiian or Pacific Islander	0.0%	0.7%
White or Caucasian	63.6%	82.6%
Other Race	7.8%	2.0%
Declined / Unavailable	0.9%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 96, the applicant states that CHS Union is not obligated to provide such care however, the applicant further states

“CHS Union provides and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment.”

In Section L, page 96, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes 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, page 97, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CHS Union- OY2 (CY2022)

Payor Category	MRI Services as Percent of Total
Medicaid*	12.1%
Medicare*	51.4%
Self-Pay	5.3%
Insurance*	29.2%
Other (Other Govt, Workers Comp)***	1.9%
Charity Care**	
Total	100.0%

Source: Table page 95 of the application.

*Including any managed care plans

**Atrium Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Forms F.3&4 for charity care projections.

***Workers Comp and TRICARE are included in the Other payor category.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.3% of total services will be provided to self-pay patients, 51.4% to Medicare patients and 12.1% to Medicaid patients.

On page 97, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it was based on historical payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

- Remarks made at the public hearing

Based on that review, the Agency concludes 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, page 98, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes 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, pages 99-100, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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

CMHA proposes to acquire a second fixed MRI scanner to be developed at CHS Union in Monroe.

On page 142, the 2018 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 2018 SMFP indicates that Union County is a single county service area. Thus, the service area for this project consists of Union County. Facilities may also serve residents of counties not included in their service area.

There are two existing fixed MRI scanners in Union County, as shown in the table below.

Union County MRI Scanners	Fixed MRI Scanner Units	Total MRI Scans	Total Weighted MRI Scans
Carolina HealthCare System Union	1	5,451	6,779
Carolina HealthCare Imaging Services-Indian Trail	1	1,474	1,597

Source: 2018 SMFP, Table 9P, page 159

In Section N, pages 102-104 the applicant describes 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 102-104, the applicants state

- The proposed project will allow CHS Union to avoid contracting for mobile MRI services and locate the fixed MRI scanner in existing space adjacent to its existing fixed MRI scanner thus increasing MRI capacity while minimizing costs.
- Overall quality will be improved as the proposed fixed MRI scanner will permit CHS Union to meet patient demands in a timely manner as MRI scanner capacity constraints at CHS Union have started to hamper patient service.
- The proposed project will promote completion for MRI services in the Union County MRI service area thus encouraging other MRI providers *“to maximize the level of access to their services, regardless of the patient’s payor source.”* Further, the applicant states *“The proposed project will provide increased access to Medicaid patients, in particular. While Medicaid does reimburse IDTFs for certain imaging procedures including*

ultrasound and mammography, it does not reimburse IDTFs for MRI scans. As a result, hospital-based MRI scanners, like the unit proposed in this application, are an essential source of access for Medicaid patients.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 107, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 24 of this type of facility located in North Carolina.

In Section O, page 107, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. According to the files in the Acute and Home Care Certification and Licensure Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in four of these facilities however, all four of the facilities are back in compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Certification and Licensure Section and considering the quality of care provided at all 24 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

C

SECTION .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- CMHA 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- CMHA owns the only two existing fixed MRI scanners in Union County. In Section C.12, page 59, the applicant reports in the most recent 12 months of operation (May 2017 to April 2018) for which data was available, the fixed MRI scanner at CHS Union performed 7,389 weighted MRI procedures and the fixed MRI scanner at CHSI-Indian Trail performed 1,803 weighted MRI procedures for a total of 9,192 weighted MRI procedures or an average of 4,506 weighted MRI procedures per MRI scanner.

(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 applicant does 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- CMHA owns the only two existing fixed MRI scanners in Union County. Therefore, pursuant to the rule, the applicant must demonstrate that the two existing and one proposed fixed MRI scanners are reasonably expected to perform 4,118 weighted MRI procedures in the third year following completion of the proposed project. The third OY is CY2023. In Section C.12, pages 60-61 and Section Q, the applicant projects the three fixed MRI scanners (two existing and one proposed) will perform 12,963 weighted MRI procedures in the third year of operation (CY2023) for an average of 4,321 weighted MRI procedures which is greater than the 4,118 weighted MRI procedures required by this Rule.

(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;*

-NA- The proposed fixed MRI scanner will be located at the same site as the existing fixed MRI scanner at CHS Union.

- (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 applicant does 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 applicant provides documentation of its assumptions and provides data supporting its methodology in Section Q of the application. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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- CMHA 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- CMHA 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- CMHA does not propose to acquire a fixed multi-position MRI scanner.