

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 22, 2024

Findings Date: January 22, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

Project ID #: C-12413-23

Facility: Atrium Health Imaging Shelby

FID #: 230717

County: Cleveland

Applicant: Union Medical Services, LLC

Project: Acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination and develop a freestanding diagnostic center

REVIEW CRITERIA

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

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

C

Union Medical Services, LLC, herein after referred to as “the applicant,” proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 State Medical Facilities Plan (SMFP). The applicant currently operates a hospital-based outpatient imaging center, Atrium Health Cleveland Imaging, in Shelby. Upon project completion, Atrium Health Cleveland Imaging will combine its existing units of operational diagnostic equipment with the proposed fixed MRI scanner and develop a new freestanding diagnostic center, Atrium Health Imaging Shelby (Atrium Shelby), with one fixed MRI scanner and other diagnostic equipment. The applicant states Atrium Health Cleveland Imaging currently has two non-operational units of fluoroscopic x-ray equipment that will not be a part of the new diagnostic center.

Need Determination

The 2023 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2023 SMFP identified a need for one fixed MRI scanner in Cleveland County. This application was submitted in response to the need determination in the 2023 SMFP for one fixed MRI scanner in Cleveland County. Therefore, the application is consistent with the need determination in the 2023 SMFP.

Policies

Two policies in Chapter 4 of the 2023 SMFP are applicable to this application: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3

Policy GEN-3 on page 30 of the 2023 SMFP 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 28-31, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states it is committed to providing high quality imaging services in a cost-effective freestanding facility to persons in need of those services. The applicant states the proposed fixed MRI services will be accessible to all persons, including those in underserved groups, and the proposal will maximize healthcare value by developing the proposed fixed MRI scanner at a freestanding center as part of the larger Carolinas Mecklenburg Hospital Authority (CMHA), the applicant’s ultimate parent company, thereby improving economies of scale in the delivery of fixed MRI and other diagnostic imaging services to its patients.

Policy GEN-4

Policy GEN-4 on page 30 of the 2023 SMFP states:

“Any person proposing a capital expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall

include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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

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

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 32-33, the applicant describes the project's plan to improve energy efficiency and water conservation. The applicant states,

"CMHA employs a Facility Management Group with experienced, highly trained, and qualified architects, engineers, project managers, tradesmen, and technicians, who oversee the design, construction, operation, and maintenance of CMHA's facilities.

CMHA has demonstrated its commitment to a higher standard of excellence and will continue to do so relative to the proposed project. CMHA 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 possible with this limited renovation of leased space. The design team has Energy Star and Hospitals for a Healthy Environment Green Guide for HealthCare (GGHC) experience."

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to develop 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 and Policy GEN-4 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed MRI services in Cleveland County.
 - The applicant adequately documents how the project will promote equitable access to fixed MRI services in Cleveland County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately documents that it has a plan in place to ensure water and energy conservation in the development of the proposed project.
- (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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant is a subsidiary of CMHA and Wake Forest University Baptist Medical Center, which are managed and operated by Advocate Aurora Health, Inc, and Atrium Health, Inc (collectively “Advocate Health”). In this proposal, the applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP to be located at an existing hospital-based outpatient imaging center. Following acquisition of the proposed fixed MRI scanner, the existing diagnostic imaging equipment will be combined with the proposed fixed MRI scanner to create a new freestanding diagnostic center at the same location, Atrium Shelby, in Cleveland County. The existing imaging center currently provides CT, x-ray, fluoroscopy, ultrasound, mammography and bone density imaging services.

Designation as a Diagnostic Center

N.C. Gen. Stat. §131E-176(7a) states, as amended by Session Law 2023-7, effective March 27, 2023, and which includes a cost threshold adjustment in effect at the time this application was received:

“Diagnostic center” means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds one million five hundred and eighty-one dollars (\$1,581,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than one million five hundred and eighty-one dollars (\$1,581,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”

The applicant notes that the 2023 SMFP incorrectly identifies an existing fixed MRI scanner and associated volume in Cleveland County as being located at Cleveland Advanced Imaging Center. The applicant states Atrium Health Cleveland Imaging does not currently operate a fixed MRI scanner; the fixed MRI scanner referenced in the 2023 SMFP is located on the Atrium Health Kings Mountain campus, which is located in Kings Mountain, a metropolitan area that spans two counties, Cleveland and Gaston. In Exhibit G.1-2, the applicant provides a copy of the 2023 License Renewal Application for Atrium Health Cleveland, that confirms the fixed MRI scanner is located on the Atrium Health Kings Mountain campus. The applicant also notes that two existing units of fluoroscopic x-ray equipment at Atrium Health Cleveland Imaging have not been operational since October 2020 due to insufficient physician coverage. The applicant states that prior to installation of the proposed fixed MRI scanner, both unutilized fluoroscopic x-ray units will be removed from the facility, and the space will be used to install the proposed fixed MRI scanner. The applicant states UMS will acquire the existing diagnostic equipment from CMHA and become the new owner/operator of the equipment.

Upon project completion, UMS will operate one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner) at Atrium Health Imaging Shelby.

In Section A, page 17, the applicant states the total cost of the proposed project is \$5,517,000, which exceeds the statutory threshold of \$1,581,000. Therefore, Atrium Health Imaging Shelby qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

Patient Origin

Diagnostic Center Service Area

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2023 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. The applicant states the service area for the proposed diagnostic center will be the same as the

historical patient origin for the existing Atrium Health Cleveland Imaging facility. Facilities may also serve residents not included in their service area.

Fixed MRI Scanner Service Area

On page 331, the 2023 SMFP defines the fixed MRI scanner service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*”. Therefore, for the purpose of this review, the fixed MRI scanner service area is Cleveland County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 37, the applicant states the proposed diagnostic center does not yet exist and thus has no historical patient origin to report. The following table illustrates historical patient origin for existing diagnostic imaging services at Atrium Health Cleveland Imaging for the last full fiscal year (FY), calendar year (CY) 2022:

Atrium Health Cleveland Imaging Historical Patient Origin, CY 2022

COUNTY	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	12,367	76.8%
Rutherford	1,830	11.4%
Gaston	1,146	7.1%
Cherokee, SC	300	1.9%
Other*	468	2.9%
Total	16,111	100.0%

*On page 37, the applicant lists the other counties in North Carolina that it includes in “*other*”, and states it also includes other states.

The applicant states the proposed diagnostic center will be developed with the proposed fixed MRI scanner and existing diagnostic equipment that will be acquired from Atrium Health Cleveland Imaging. The following tables, from pages 40-42, illustrate projected patient origin for the first three full FYs, CYs 2026-2028, for both fixed MRI services and for all diagnostic services that will be offered at Atrium Cleveland:

Atrium Health Imaging Shelby Projected Patient Origin, MRI Services

COUNTY	1 ST PY (CY 2026)		2 ND PY (CY 2027)		3 RD PY (CY 2028)	
	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	1,677	71.4%	1,694	71.4%	1,712	71.4%
Rutherford	388	16.5%	392	16.5%	396	16.5%
Gaston	166	7.1%	168	7.1%	170	7.1%
Cherokee, SC	40	1.7%	40	1.7%	41	1.7%
Other*	78	3.3%	79	3.3%	80	3.3%
Total	2,349	100.0%	2,373	100.0%	2,398	100.0%

*On page 40, the applicant lists the other counties in North Carolina that it includes in “*other*”, and states it also includes other states.

Atrium Health Imaging Shelby Projected Patient Origin, Mammography

COUNTY	1 ST PY (CY 2026)		2 ND PY (CY 2027)		3 RD PY (CY 2028)	
	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	7,569	76.2%	7,607	76.2%	7,645	76.2%
Rutherford	1,173	11.8%	1,179	11.8%	1,185	11.8%
Gaston	764	7.7%	767	7.7%	771	7.7%
Cherokee, SC	205	2.1%	206	2.1%	207	2.1%
Other*	229	2.3%	230	2.3%	231	2.3%
Total	9,939	100.0%	9,989	100.0%	10,039	100.0%

*On page 40, the applicant lists the other counties in North Carolina that it includes in "other", and states it also includes other states.

Atrium Health Imaging Shelby Projected Patient Origin, X-ray

COUNTY	1 ST PY (CY 2026)		2 ND PY (CY 2027)		3 RD PY (CY 2028)	
	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	3,109	80.3%	3,124	80.3%	3,140	80.3%
Rutherford	305	7.9%	306	7.9%	308	7.9%
Gaston	261	6.7%	262	6.7%	263	6.7%
Cherokee, SC	65	1.7%	66	1.7%	66	1.7%
Other*	130	3.4%	131	3.4%	132	3.4%
Total	3,870	100.0%	3,889	100.0%	3,908	100.0%

*On page 41, the applicant lists the other counties in North Carolina that it includes in "other", and states it also includes other states.

Atrium Health Imaging Shelby Projected Patient Origin, DEXA, Bone Density

COUNTY	1 ST PY (CY 2026)		2 ND PY (CY 2027)		3 RD PY (CY 2028)	
	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	915	80.3%	919	80.3%	924	80.3%
Rutherford	90	7.9%	90	7.9%	91	7.9%
Gaston	77	6.7%	77	6.7%	78	6.7%
Cherokee, SC	19	1.7%	19	1.7%	19	1.7%
Other*	38	3.4%	39	3.4%	39	3.4%
Total	1,139	100.0%	1,144	100.0%	1,150	100.0%

*On page 41, the applicant lists the other counties in North Carolina that it includes in "other", and states it also includes other states.

Atrium Health Imaging Shelby Projected Patient Origin, CT Services

COUNTY	1 ST PY (CY 2026)		2 ND PY (CY 2027)		3 RD PY (CY 2028)	
	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	1,693	72.8%	1,701	72.8%	1,710	72.8%
Rutherford	366	15.7%	368	15.7%	370	15.7%
Gaston	146	6.3%	146	6.3%	147	6.3%
Cherokee, SC	38	1.6%	38	1.6%	38	1.6%
Other*	83	3.6%	84	3.6%	84	3.6%
Total	2,325	100.0%	2,337	100.0%	2,349	100.0%

*On page 42, the applicant lists the other counties in North Carolina that it includes in “other”, and states it also includes other states.

Atrium Health Imaging Shelby Projected Patient Origin, Ultrasound

COUNTY	1 ST PY (CY 2026)		2 ND PY (CY 2027)		3 RD PY (CY 2028)	
	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Cleveland	1,163	74.3%	1,169	74.3%	1,175	74.3%
Rutherford	218	13.9%	219	13.9%	220	13.9%
Gaston	95	6.1%	96	6.1%	96	6.1%
Lincoln	39	2.5%	39	2.5%	40	2.5%
Cherokee, SC	25	1.6%	25	1.6%	25	1.6%
Other*	25	1.6%	25	1.6%	25	1.6%
Total	1,565	100.0%	1,573	100.0%	1,581	100.0%

*On page 42, the applicant lists the other counties in North Carolina that it includes in “other”, and states it also includes other states.

In Section C, page 40, the applicant provides the assumptions and methodology used to project its patient origin, which it states is based on the historical patient origin of existing diagnostic imaging patients served at Atrium Health Cleveland Imagin. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical experience providing diagnostic imaging services to patients in the service area.

Analysis of Need

In Section C, on pages 45-49, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- **Need in Cleveland County for freestanding fixed MRI services** - There is increasing demand for MRI services in Cleveland County as demonstrated by the need for an additional fixed scanner published in the 2023 SMFP. The applicant states that currently, there are two fixed scanners and one mobile MRI provider in the service area. The applicant examined MRI utilization in Cleveland County from FFY 2018-2021 and calculated a compound annual growth rate (CAGR) of 8.9% during that time, which the

applicant states is due to the hospital-based fixed MRI scanners. The applicant examined inpatient MRI scan volume between FFY 2018-2021 and calculated a 10.3% CAGR of total weighted scans during that time. The applicant states many patients who seek outpatient MRI services at the hospital would shift to a freestanding facility if one were available in the county.

- **Need for Freestanding Fixed MRI Capacity at Atrium Health Shelby** - The applicant states the proposed project introduces the county's first freestanding fixed MRI scanner in Cleveland County, which will provide lower-cost options for patients who seek MRI services. The applicant states offering fixed MRI services in a freestanding setting will also create additional capacity for the hospital-based MRI services, thus providing for timely access to those services. Currently, the wait times for a scheduled MRI scan is up to two weeks, despite the availability of the existing MRI scanners from 6:30 AM to 10:30 PM five days per week. Additionally, the applicant states Atrium Health Kings Mountain is expanding its spine program, which will likely result in an increase in the need for MRI scans in the county.
- **Growth and Aging of Population Residing in Cleveland County** - The applicant cited the North Carolina Office of State Budget and Management data that shows the population in the proposed service area is growing and aging. The applicant notes that, while the total projected population growth in Cleveland County is lower than that for the state as a whole, the projected growth in persons age 65 and older is higher than both the County and state growth projections. The older population cohorts typically utilize diagnostic imaging services, including MRI services, more than younger population groups.
- The applicant summarizes its need for the proposed fixed MRI scanner by stating on page 49:

“In summary, the project proposed in this application is in response to the overall need for additional fixed MRI capacity to be located in Cleveland County. This need can best be met with the proposed fixed MRI scanner at Atrium Health Imaging Shelby given its freestanding setting and the significant growth and demonstrated need for additional MRI capacity at CMHA-related facilities in Cleveland County. Further, population growth in the county supports additional MRI capacity. Finally, the proposed project will create a new freestanding diagnostic center, allowing patients to access multiple imaging modalities in a lower cost, more convenient setting.”

The information is reasonable and adequately supported based on the following:

- Cleveland County's weighted threshold, based on the SMFP need determination methodology, is 4,992 procedures per fixed equivalent MRI scanner. The 2023 SMFP identified the need for an additional fixed MRI scanner to be located in Cleveland

County, and the applicant projects to exceed that threshold in FFY 2024 based on historical utilization.

- The applicant provides documented and reasonable data to show fixed MRI services in Cleveland County are increasing, even through the COVID-19 pandemic.
- The applicant provides reasonable and documented data to show the population, particularly in the older age cohorts, is projected to increase in Cleveland County.
- The applicant provides reasonable information to show that there is a need for freestanding fixed MRI services in Cleveland County. Access to freestanding MRI services is significant because the patient's out-of-pocket expenses are higher when receiving hospital-based care, regardless of whether the service is classified as inpatient or outpatient care. The proposed project will increase access to high-quality, affordable fixed MRI services in Cleveland County by offering a convenient, freestanding alternative to the existing hospital-based MRI scanners.

Projected Utilization

In Section Q, Forms C.2a and C.2b, pages 1-4, the applicant provides historical utilization for MRI services at Atrium Health Imaging Cleveland and Atrium Health Kings Mountain for CYs 2022-2024.

In Section Q, Form C.2b, page 5, the applicant provides interim and projected utilization for Atrium Health Shelby for all diagnostic and MRI services, in all three project years (CYs 2026-2028), as illustrated in the following table:

Atrium Health Imaging Shelby - Interim and Projected Diagnostic Imaging Utilization

EQUIPMENT	PARTIAL FY (3/1/25- 12/31/25)	1 ST PY CY 2026	2 ND PY CY 2027	3 RD PY CY 2028
CT Scanner				
# Units	1	1	1	1
# Scans	2,191	2,642	2,656	2,669
# HECT Units	3,618	4,363	4,385	4,407
Fixed X-ray				
# Units	1	1	1	1
# Procedures	4,495	5,421	5,448	5,475
Mammography				
# Units	2	2	2	2
# Procedures	16,396	19,774	19,873	19,973
MRI Scanner				
# Units	1	1	1	1
# Procedures	2,619	3,175	3,207	3,241
# Wtd Procedures	2,856	3,463	3,499	3,535
Ultrasound				
# Units	2	2	2	2
# Procedures	2,818	3,399	3,416	3,433
Bone Density				
# Units	1	1	1	1
# Procedures	1,323	1,595	1,603	1,611

Source: Section Q, Forms C.2a and C.2b, pages 1-5.

In Section Q, Form C.2b, page 2, the applicant provides interim and projected utilization for Atrium Health Cleveland for MRI services for CYs 2025-2028, as illustrated in the following table:

Atrium Health Cleveland Interim and Projected MRI Utilization

MRI SCANNER	INTERIM FULL FY CY 2025	1 ST FULL FY CY 2026	2 ND FULL FY CY 2027	3 RD FULL FY CY 2028
# Units	1	1	1	1
# Procedures	3,907	3,631	3,825	4,032
# Weighted Procedures	6,293	6,136	6,499	6,886

In Section Q, Form C.2b, page 4, the applicant provides interim and projected utilization for Atrium Health Kings Mountain for MRI services for CYs 2025-2028, as illustrated in the following table:

Atrium Health Kings Mountain Interim and Projected MRI Utilization

MRI SCANNER	INTERIM FULL FY CY 2025	1 ST FULL FY CY 2026	2 ND FULL FY CY 2027	3 RD FULL FY CY 2028
# Units	1	1	1	1
# Procedures	1,686	1,690	1,768	1,849
# Weighted Procedures	2,152	2,184	2,296	2,415

In Section Q, pages 1-7, “*Form C Utilization - Methodology and Assumptions*”, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- The applicant examined historical MRI utilization at Atrium Health Cleveland and Atrium Health Kings Mountain from CY 2019-2023 (annualized based on January-April utilization) and calculated a 6.5% CAGR in total weighted MRI utilization at Atrium Health Kings Mountain and a 6.2% CAGR in total weighted MRI utilization at Atrium Health Cleveland during that time. The applicant performed the same calculations for inpatient and outpatient MRI utilization at each facility for the same time period. See the tables that illustrate the historical utilization and CAGRs on pages 1-2 of the *Assumptions* in Section Q.
- The applicant projects future outpatient MRI utilization at both Atrium Health Cleveland and Atrium Health Kings Mountain by applying the historical CAGR to the CY 2023 utilization data. The applicant projects future inpatient MRI utilization at Atrium Health Cleveland and Atrium Health Kings Mountain by applying one-half of the historical CAGR to CY 2023 utilization data. The applicant states this projection is reasonable, given the historical trends at Atrium Health Cleveland, the desire of Cleveland County patients to remain in county for their inpatient imaging needs and the addition of spine surgical services at Atrium Health Kings Mountain. See the tables that illustrate these projections on pages 2-3 of the *Assumptions* in Section Q.
- The applicant states Atrium Health Shelby will represent the county’s first freestanding fixed MRI scanner, providing a lower cost, convenient option for patients seeking MRI services. The applicant states the closest CMHA facility that offers freestanding fixed MRI services is in Mecklenburg County, approximately one hour away, and the closest non-CMHA freestanding facility that offers fixed MRI services is approximately 40 minutes away in Gastonia, in Gaston County. The proposed location of Atrium Health Shelby is across the street from Atrium Health Cleveland hospital and will operate five days per week. Based on these factors, the applicant projects that 75% of patients seeking outpatient MRI scans at Atrium Health Cleveland will shift to Atrium Health Shelby when that facility is operational in CY 2025. See the table that illustrates the projected shift on page 3 of the *Assumptions* in Section Q.

Similarly, the applicant states that, based on patient origin data at Atrium Health Kings Mountain, approximately one-third of patients seeking outpatient MRI services in CY 2022 lived in areas geographically closer or equidistant to the proposed location of Atrium Health Shelby. The applicant therefore projects that 25% of those patients seeking outpatient MRI services at Atrium Health Kings Mountain would shift to Atrium Health Shelby when the facility becomes operational. See the tables that illustrate the projected utilization at Atrium Health Cleveland and Atrium Health Kings Mountain, as well as projected utilization at Atrium Health Shelby following the shift in patients on pages 4-5 of the *Assumptions* in Section Q.

- Atrium Health Shelby will also offer x-ray, mammography, ultrasound, CT and DEXA imaging services. To project utilization of the other diagnostic equipment at Atrium Health Shelby, the applicant examined historical utilization of those imaging services at Atrium Health Cleveland, where those imaging services have historically been offered, from CY 2019-2023 (annualized). The applicant calculated a CAGR for each type of imaging equipment during that time. See the table that illustrates the calculations on page 6 of the *Assumptions* in Section Q.

The applicant states CT utilization at Atrium Health Cleveland decreased as a result of staffing and supply chain issues during the COVID-19 pandemic and later downtime when the existing unit was replaced. The applicant projects that CT utilization will return to pre-COVID-19 levels by the end of CY 2024. The applicant projects the other diagnostic imaging equipment at Atrium Health Shelby will increase at a rate consistent with projected population growth in Cleveland County from CY 2023-2028.

The following table, from page 7 of the *Assumptions* in Section Q, summarizes projected utilization of all imaging services at Atrium Health Shelby from CY 2025-2028. The applicant states CY 2025 represents a partial year, as the facility is projected to become operational on March 1, 2025:

Atrium Health Shelby Projected Utilization

EQUIPMENT	CY 2025*	CY 2026	CY 2027	CY 2028
MRI (Weighted Scans)	2,856	3,463	3,499	3,535
Diagnostic X-ray	4,495	5,421	5,448	5,475
Diagnostic Mammogram	16,396	19,774	19,873	19,973
Diagnostic Ultrasound	2,818	3,399	3,416	3,433
CT (Procedures)	2,191	2,642	2,656	2,669
CT HECTs	3,618	4,363	4,385	4,407
DEXA (Bone Density)	1,323	1,595	1,603	1,611

*Represents a partial year, from March 1, 2025 – December 31, 2025.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant relied on its historical MRI utilization at Atrium Health Cleveland and Atrium Health King’s Mountain to project future utilization.
- The applicant relied on population growth projections from reliable sources to determine population growth in the service area.
- The applicant reasonably projected a shift of MRI outpatients from its existing facilities to Atrium Shelby based on proximity, scheduling availability, and preference for a lower cost, freestanding facility.

Access to Medically Underserved Groups

In Section C, page 56, the applicant states:

“Consistent with all CMHA facilities, UMS will provide services at Atrium Health Imaging Shelby to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment...”

... CMHA will continue to serve this population as dictated by the mission of CMHA, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved.”

On page 57, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	% OF TOTAL PATIENTS
Low-income persons	--
Racial and ethnic minorities	20.6%
Women	82.3%
Persons with disabilities	--
Persons 65 and older	43.5%
Medicare beneficiaries	50.0%
Medicaid recipients	8.9%

*The applicant states UMS and CMHA do not maintain data that includes the number of low-income persons or persons with disabilities served.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant documents that it has historically provided access to its diagnostic imaging services to underserved groups.
- The applicant states that all patients, including those in underserved groups, will continue to receive access to MRI and all diagnostic imaging services that Atrium Shelby will offer.

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 all 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, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or 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.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

In Section E, pages 70-71, 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:

- Develop the proposed fixed MRI scanner at Another Location – The applicant states existing MRI services in Cleveland County consist of one hospital-based fixed MRI scanner at Atrium Health Cleveland Hospital and one hospital-based fixed MRI scanner at Atrium Health Kings Mountain Hospital. The applicant states this proposal, for a fixed MRI scanner in a freestanding facility, will introduce lower cost fixed MRI services to Cleveland County patients who need MRI services. Therefore, this is a less effective alternative.
- Maintain the proposed fixed MRI scanner as a hospital-based unit – The applicant states the proposed fixed MRI scanner will combine with other existing diagnostic imaging equipment from Atrium Health Cleveland Imaging to create a new freestanding diagnostic center in existing space, which is a cost-effective choice that will also increase access to other freestanding imaging services for its patients. The applicant states the proposed fixed MRI scanner will also be the first freestanding MRI scanner in the county, operating five days per week, which will provide lower-cost convenient diagnostic imaging for patients close to home. Therefore, developing the proposed fixed MRI scanner as a hospital-based scanner was determined to be a more costly and less effective alternative for patients.

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 provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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 all the reasons described above. Therefore, the application is approved subject to the following conditions:

- 1. Union Medical Services, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2023 SMFP to be located at Atrium Health Imaging Shelby.**
- 3. Upon project completion, Atrium Health Imaging Shelby shall be licensed for no more than one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).**
- 4. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holders shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**

- b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on July 1, 2024.**
- 6. **The certificate holder 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.**
 - 7. **The certificate holder 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

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

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:

Construction/Renovation Costs	\$1,601,000
Medical Equipment	\$2,717,000
Non-Medical Equipment	\$5,000
Miscellaneous Costs	\$1,194,000
Total	\$5,517,000

In Section Q, *Form F.1a Assumptions*, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Construction and renovation costs are based on the project architect's experience with similar projects.
- Medical equipment costs are based on vendor estimates and the experience of CMHA, the parent entity, with similar projects.
- Non-medical, furniture and miscellaneous costs, including information systems and security, are based on the experience of CMHA, the parent entity, with similar projects.
- In Exhibit F.1, the applicant provides a construction cost estimate signed by the project architect which includes a cost break down that matches the construction cost listed on Form F.1a.

In Section F.3, page 74, the applicant projects that start-up costs will be \$204,309 and initial operating expenses will be \$1,051,027 for a total working capital of \$1,255,336. On page 75, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The initial operating period for Atrium Health Shelby is assumed to be the first six months of operation during which cash outflow exceeds cash inflow, which represents initial operating expenses.
- The applicant assumes a 75-day period with no payments before the facility is certified and then a 75-day period of delayed payment following certification.
- Total estimated start-up costs are based on one month of supplies, rent, utilities, staffing and other costs necessary for operation, excluding depreciation.

Availability of Funds

In Section F, page 72, the applicant states Union Medical Services, LLC, which is wholly owned by CMHA, will fund the capital cost through accumulated reserves provided by CMHA.

In Section F, page 76, the applicant states Union Medical Services, LLC, which is wholly owned by CMHA, will fund the working capital cost through accumulated reserves provided by CMHA.

Exhibit F.2-1 contains a letter signed by the Chief Financial Officer of The Charlotte-Mecklenburg Hospital Authority (CMHA), which commits to funding the capital and working capital costs from accumulated reserves of CMHA. Exhibit F.2-2 contains the most recent CMHA audited financial statements documenting the availability of the necessary funds for the capital and working capital needs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides documentation of CHMA’s commitment to use the necessary funding toward development of the proposed project, including capital and working capital costs.
- The applicant documents the availability of sufficient financial resources to fund the proposed capital and working capital costs.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion. In Section Q Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years (FY), calendar years (CY) 2026-2028 for MRI services following project completion, as shown in the following table:

Atrium Health Imaging Shelby			
MRI SERVICES ONLY	1ST FY CY 2026	2ND FY CY 2027	3RD FY CY 2028
# of Scans (Weighted)	3,463	3,499	3,535
Gross Revenue	\$11,305,984	\$11,724,494	\$12,158,884
Net Revenue	\$4,349,001	\$4,507,865	\$4,672,643
Average Net Revenue per Weighted MRI Scan	\$1,256	\$1,288	\$1,322
Operating Costs	\$3,142,045	\$3,229,009	\$3,310,908
Average Operating Costs per Weighted MRI Scan	\$907	\$923	\$937
Net Income	\$1,206,956	\$1,278,856	\$1,361,735

Source: Section Q, Forms C and F.2b

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 11-12. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant explains how it accounts for projected operating expenses and explains its revenue projections, which are based on its experience with other diagnostic centers and imaging equipment, including MRI scanners.
- Projected utilization is based on reasonable and adequately supported assumptions. 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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

On page 331, the 2023 SMFP defines the fixed MRI scanner service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*”. Therefore, for the purpose of this review, the fixed MRI scanner service area is Cleveland County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Cleveland County service area, summarized from Table 17E-1, pages 338-339 of the 2023 SMFP:

CLEVELAND COUNTY FIXED MRI SCANNERS			
FACILITY	# OF FIXED MRIS	TOTAL # OF MRI SCANS	AVERAGE # OF SCANS/UNIT
Atrium Health Cleveland	1	5,236	5,236
Cleveland Advanced Imaging Center*	1	1,819	1,819
Total	2	7,055	7,055

Source: Table 17E-1, pages 338-339, 2023 SMFP

*The 2023 SMFP erroneously states the fixed MRI is located at Cleveland Advanced Imaging Center. The fixed MRI scanner is located at Atrium Health Kings Mountain.

There are also two mobile MRI scanners in Cleveland County, one of which is a legacy MRI scanner¹, owned by Alliance Healthcare Services.

In Section G, page 82, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Cleveland County. The applicant states:

“The 2023 SMFP includes a need determination for one fixed MRI scanner in Cleveland County. The proposed MRI scanner at Atrium Health Imaging Shelby will be the first freestanding fixed MRI scanner in Stanly County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home. Moreover, the proposed project will develop the county’s first freestanding diagnostic center, providing a lower cost option for a broad range of imaging modalities. These modalities are currently provided by the existing hospital-based outpatient imaging center and the proposed project will not change the inventory of these items of equipment. Thus, the proposed project will not result in any unnecessary duplication.”

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

- There is a need determination in the 2023 SMFP for the proposed fixed MRI scanner in the Cleveland County fixed MRI scanner service area.
- The applicant adequately demonstrates the need for the proposed fixed MRI scanner at Atrium Shelby in addition to the existing MRI scanners in the service area.

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 all the reasons described 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

¹ A “legacy” MRI scanner is one that is “grandfathered” prior to CON regulation of MRI scanners.

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

In Section Q, Form H, page 25, the applicant provides projected full-time equivalent (FTE) positions for its proposed fixed MRI services, as illustrated in the following table:

POSITION	ATRIUM SHELBY PROJECTED STAFFING			
	PARTIAL FY CY 2025	1 ST FY CY 2026	2 ND FY CY 2027	3 RD FY CY 2028
MRI Technologist	1.7	2.0	2.0	2.0
Mammography Technologist	3.8	4.6	4.6	4.6
Radiology Technologist DEXA	0.2	0.3	0.3	0.3
Ultrasound Technologist	0.9	1.1	1.1	1.1
CT Technologists	1.8	0.3	0.3	0.3
Mammography Technologist	1.8	2.2	2.2	2.2
Radiology Technologists x-ray	0.8	1.0	1.0	1.0
Registrar	2.8	3.3	3.3	3.3
Total	12.1	14.5	14.5	14.5

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 84-86, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant bases projected FTE staff on existing positions for similar services at Atrium Health Cleveland Imaging Center, Atrium Health Imaging Kannapolis, and the experience of the parent company, CMHA.

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 all the reasons described 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

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

Ancillary and Support Services

In a table in Section I, page 87, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section I, pages 87-88 the applicant explains how each ancillary and support service is and will be available and supporting documentation is provided in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services are and will be made available because these services are currently provided for patients of Atrium Health Imaging at its other locations, either onsite or through centralized services of CMHA.

Coordination

In Section I, page 88, the applicant describes its existing and proposed relationships with other local health care and MRI providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant currently coordinates its services with the existing health care system and will continue to do so following the acquisition of the proposed fixed MRI scanner.

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 all the reasons described above.

- (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. Therefore, Criterion (9) is not applicable to this review.

- (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 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

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

In Section K, page 91, the applicant states that the project involves renovating 1,094 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

In Section K, pages 91-92, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal by renovating existing space rather than constructing new space.

In Section K, page 92, 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. The applicant states costs are minimized by renovation of existing space rather than new construction. Additionally, the applicant states it has revenues set aside from previous years that enable it to fund projects such as this one without necessitating an increase in charges to its patients.

In Exhibit B.21 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 for all the reasons described above.

- (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 persons with disabilities, 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 states the proposed project will combine existing equipment from the hospital-based Atrium Health Cleveland Imaging with the proposed fixed MRI scanner to develop a new diagnostic center and thus has no historical patient origin to provide. However, the applicant provides historical payor

mix during CY 2022 for its existing imaging services at Atrium Health Cleveland Imaging, as shown in the following table:

Atrium Health Cleveland Imaging HISTORICAL PAYOR MIX, CY 2022	
PAYOR CATEGORY	SERVICES AS % OF TOTAL
Self-Pay	2.0%
Charity Care [^]	--
Medicare*	49.3%
Medicaid*	8.8%
Insurance*	38.3%
Other (Workers Comp/TRICARE)	1.6%
Total	100.0%

[^]The applicant states on page 96 that CMHA and UMS internal data do not include *charity care* as a payor source for patients.

*Includes managed care plans

In Section L, pages 96-97, the applicant provides the following comparison:

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	84.3%	51.6%
Male	15.6%	48.4%
Unknown	0.1%	0.0%
64 and Younger	56.5%	80.9%
65 and Older	43.5%	19.1%
American Indian	0.2%	0.5%
Asian	0.5%	1.2%
Black or African American	19.9%	20.8%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	78.5%	75.4%
Other Race	0.3%	2.1%
Declined / Unavailable	0.7%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 persons with disabilities 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 97, the applicant states it has no such obligation.

In Section L, page 98, the applicant states that Atrium Health Imaging Shelby is not an existing facility and thus has no civil rights complaints that have been filed against it.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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, pages 99-101, the applicant projects payor mix for Atrium Health Shelby as a whole and for each imaging component during the third full fiscal year of operation (CY 2028) following project completion of the project. The following tables, from page 99 illustrate projected payor mix for the entire facility and for MRI services:

Atrium Health Shelby Projected Payor Mix, CY 2028

PAYOR CATEGORY	ENTIRE FACILITY AS % OF TOTAL
Self-Pay	1.9%
Charity Care^	--
Medicare*	50.0%
Medicaid*	8.9%
Insurance*	37.6%
Other (Workers Comp/TRICARE)	1.6%
Total	100.0%

^The applicant states on page 99 that CMHA and UMS internal data do not include *charity care* as a payor source for patients.
 *Includes managed care plans

**Atrium Health Shelby Projected Payor Mix
 MRI Services FY 2028**

PAYOR CATEGORY	MRI SERVICES AS % OF TOTAL
Self-Pay	1.8%
Charity Care^	--
Medicare*	55.8%
Medicaid*	11.5%
Insurance*	29.3%
Other (Workers Comp/TRICARE)	1.6%
Total	100.00%

^The applicant states on page 99 that CMHA and UMS internal data do not include *charity care* as a payor source for patients.
 *Includes managed care plans

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 1.9% of total services provided by Atrium Shelby will be provided to self-pay patients, and 50.0% and 8.9% of total services will be provided to Medicare and Medicaid patients, respectively.

Additionally, during the third full fiscal year of operation, the applicant projects that 1.8% of MRI services provided by Atrium Shelby will be provided to self-pay patients, and 55.8% and 11.5% of total MRI services will be provided to Medicare and Medicaid patients, respectively.

On page 98, the applicant provides the assumptions used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix for all of its imaging and MRI services, including outpatient MRI services at Atrium Health Kings Mountain that are expected to shift to Atrium Shelby.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 102, the applicant describes the means by which a person will have access to the proposed additional fixed MRI services at Atrium Shelby.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

In Section M, page 103, 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-1. The applicant adequately demonstrates that health professional training programs in the area have and will continue to have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

On page 331, the 2023 SMFP defines the fixed MRI scanner service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*”. Therefore, for the purpose of this review, the fixed MRI scanner service area is Cleveland County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Cleveland County service area, summarized from Table 17E-1, pages 338-339 of the 2023 SMFP:

CLEVELAND COUNTY FIXED MRI SCANNERS			
FACILITY	# OF FIXED MRIs	TOTAL # OF MRI SCANS	AVERAGE # OF SCANS/UNIT
Atrium Health Cleveland	1	5,236	5,236
Cleveland Advanced Imaging Center*	1	1,819	1,819
Total	2	7,055	7,055

Source: Table 17E-1, pages 338-339, 2023 SMFP

*The 2023 SMFP erroneously states the fixed MRI is located at Cleveland Advanced Imaging Center. The fixed MRI scanner is located at Atrium Health Kings Mountain.

There are also two mobile MRI scanners in Cleveland County, one of which is a legacy MRI scanner.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 105, the applicant states:

“... the proposed MRI scanner at Atrium Health Imaging Shelby will be the first freestanding fixed MRI scanner in Cleveland County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home. ... As a freestanding facility, Atrium Health Imaging Shelby provides its existing mobile MRI services at a lower out-of-pocket cost to most patients. The proposed fixed MRI scanner at Atrium Health Imaging Shelby will promote competitive access to lower cost MRI services not currently available in Cleveland County and for which many hundreds of residents each year travel outside the county to freestanding facilities some distance away.”

Regarding the expected effects of the proposal on cost effectiveness, in Section B.20.c, page 31, the applicant states:

“As a freestanding facility, Atrium Health Imaging Shelby will provide services at a lower out-of-pocket cost to most patients. Insurance companies categorize hospital-based services in a higher tier than they do freestanding services, meaning that the patient’s out-of-pocket expenses typically are lower when receiving non-hospital-based care. As the first freestanding diagnostic center in Cleveland County with the first freestanding fixed MRI, the proposed project will promote competitive access to lower cost imaging services.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the expected effects of the proposal on quality in the service area, in Section B.20.a, page 28, the applicant states:

“CMHA’s commitment to providing quality care is further demonstrated by its Performance Improvement and Risk Management Plans included in Exhibits B.20-1 through B.20-2. As the services at Atrium Health Imaging Shelby expand, these plans will continue to ensure that quality care is provided to all patients.”

See also Sections C and O of the application and any exhibits.

Regarding the expected effects of the proposal on access by medically underserved groups in the service area, in Section B.20.b, pages 28-29, the applicant states:

“CMHA has long-promoted economic access to its services as it historically has provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay as demonstrated in CMHA’s Non-Discrimination Policies provided in Exhibit B.20-3.”

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

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 all the reasons described 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

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP and develop a diagnostic center, Atrium Imaging Shelby in Cleveland County, for a total of one fixed MRI scanner, one CT scanner, one unit of fixed X-ray equipment, two diagnostic ultrasounds, two units of mammography equipment, and one unit of bone density equipment (DEXA scanner).

In Section Q Form O, the applicant identifies the health service facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant

identifies a total of 38 hospitals, imaging centers and diagnostic centers located in North Carolina.

In Section O, page 108, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected and the facility was back in compliance as of April 25, 2023. According to the files in the Acute and Home Care Licensure and Certification 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 one of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 38 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.

G.S. 131E-183 (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 Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*

-C- In Section C, page 59 that applicant states it owns and operates two fixed MRI scanners in Cleveland County: one fixed MRI scanner at Atrium Health Cleveland and one fixed MRI scanner located at Atrium Health Kings Mountain.

(2) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*

-NA- There are no approved fixed MRI scanners owned or operated by the applicant or a related entity located in the Cleveland County fixed MRI scanner service area.

(3) *identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;*

-NA- In Section C, page 60 the applicant states there are no existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located within the proposed fixed MRI scanner service area during the 12 months before the application deadline for this review period.

(4) *identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;*

-NA- Neither the applicant nor a related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.

(5) *provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;*

-C- In Section Q, Forms C.2b pages 2-5, the applicant provides projected utilization for all of its existing and proposed fixed MRI scanners identified in Subparagraphs (a)(1) through (a)(4) of the Rules during each of the first three full fiscal years of operation following project completion.

(6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (a)(5) of this Paragraph;*

-C- In Section Q, “Form C Utilization – Assumptions and Methodology”, the applicant provides assumptions and methodology for all of its existing and proposed fixed MRI scanners during each of the first three full fiscal years of operation following project completion.

(7) *project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project:*

(a) *3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanner in the fixed MRI scanner service area;*

- (b) *3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or*
- (c) *1,310 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;*

There are currently two existing fixed MRI scanners in the Cleveland County fixed MRI scanner service area; thus, Subparagraph (a) applies to this review.

- C- In Section Q, “*Form C Assumptions and Methodology*”, pages 1-7, the applicant projects to provide 4,279 adjusted MRI procedures per fixed MRI scanner during the third full fiscal year of operation following project completion. This exceeds 3,494 adjusted MRI procedures per fixed MRI scanner in the fixed MRI scanner service area. The full methodology and assumptions are provided in Section Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (8) *project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operations following completion of the project.*
- NA- Neither the applicant nor any related entity owns or operates a mobile MRI scanner in the service area.
- (b) *An applicant proposing to acquire a **mobile MRI** scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*
 - (1) *identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
 - (2) *identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
 - (3) *identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
 - (4) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;*
 - (5) *identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;*
 - (6) *provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;*
 - (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

- (8) *project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and*
 - (9) *project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:*
 - (a) *3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;*
 - (b) *3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area;*
 - (c) *1,310 or more adjusted MRI procedures per fixed MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.*
- NA- The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.