

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 14, 2022

Findings Date: December 14, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Mike Mckillip

Project ID #: E-12275-22

Facility: Catawba Valley Imaging Center

FID #: 220671

County: Catawba

Applicant(s): County of Catawba

Project: Replace an existing MRI scanner

### 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.

NA

The County of Catawba (“applicant”) proposes to replace one fixed MRI scanner located at Catawba Valley Imaging Center (CVIC). CVIC is a facility located off Catawba Valley Medical Center’s (CVMC) main hospital campus. CVMC is licensed for two fixed MRI scanners. The second MRI scanner is located on the main hospital campus of CVMC.

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

#### **Policies**

There are no policies in the 2022 SMFP applicable to this review. Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 proposes to replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

**Patient Origin**

The 2022 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.”* Therefore, for the purpose of this review, the fixed MRI service area is Catawba County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	Catawba Valley Imaging Center MRI Services Historical Patient Origin	
	Last Full FY 10/01/2020-09/30/2021	
	Patients	% of Total
Catawba	1,596	67.2%
Alexander	223	9.4%
Lincoln	195	8.2%
Caldwell	150	6.3%
Burke	111	4.7%
Iredell	24	1.0%
Watauga	14	0.6%
Cleveland	9	0.4%
Other NC Counties*	40	1.7%
Other States	14	0.6%
<b>Total</b>	<b>2,375</b>	<b>100.0%</b>

Source: Section C, page 30

\*Includes other NC counties, each representing less than 1% of total patient origin

<b>Catawba Valley Imaging Center MRI Services Projected Patient Origin</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY</b>		<b>2<sup>nd</sup> Full FY</b>		<b>3<sup>rd</sup> Full FY</b>	
	<b>FY2024</b>		<b>FY2025</b>		<b>FY2026</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Catawba	1,898	67.2%	1,921	67.2%	1,944	67.2%
Alexander	265	9.4%	269	9.4%	272	9.4%
Lincoln	232	8.2%	234	8.2%	237	8.2%
Caldwell	178	6.3%	180	6.3%	182	6.3%
Burke	133	4.7%	134	4.7%	136	4.7%
Iredell	28	1.0%	29	1.0%	29	1.0%
Watauga	17	0.6%	17	0.6%	17	0.6%
Cleveland	11	0.4%	11	0.4%	12	0.4%
Other NC Counties*	48	1.7%	49	1.7%	49	1.7%
Other States	14	0.6%	14	0.6%	14	0.6%
<b>Total</b>	<b>2,824</b>	<b>100.0%</b>	<b>2,858</b>	<b>100.0%</b>	<b>2,892</b>	<b>100.0%</b>

Source: Section C, page 32

\*Includes other NC counties, each representing less than 1% of total patient origin

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin. On page 32, the applicant states:

*“CVMC projects the MRI patient origin based on the historical CVMC MRI patient origin.”*

The applicant’s assumptions are reasonable and adequately supported. The applicant is proposing to replace an existing fixed MRI scanner, thus, not changing the patient origin.

**Analysis of Need**

In Section C, pages 34-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The need to replace an aging and obsolete fixed MRI scanner that has exceeded its useful life (pages 34-35)
- The projected population growth and aging in the Catawba County service area, particularly among the 65+ age cohort, and the population health characteristics driving need for MRI scans (pages 36-39)
- Historical utilization of the two existing fixed MRI scanners (pages 39-40)
- The support of physicians/providers in Catawba County and surrounding counties that refer patients to CVMC and CVIC for MRI procedures (pages 40-41)

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

- The applicant is proposing to replace the existing fixed MRI scanner with an updated model that can provide higher resolution images and more efficient scanning which will allow shorter patient visit time.
- The applicant relied on data from the North Carolina Office of State Budget Management (NCOSBM) and other resources related to health statistics, to demonstrate the projected population growth in the Catawba County service area and the percentage of risk factors that supports the need for MRI services.
- The growth in the number of unweighted MRI scans performed on the two existing fixed MRI scanners.
- The applicant provides letters of support from referring physicians/providers who support the need for the replacement fixed MRI scanner.

Projected Utilization

In Section Q, pages 99-102 the applicant provides historical and projected utilization, as illustrated in the following tables.

<b>Catawba Valley Imaging Center Historical and Projected Utilization</b>						
	<b>Last Full FY CY 2021</b>	<b>Interim Full FY CY 2022</b>	<b>Interim Full FY CY 2023</b>	<b>1<sup>st</sup> Full FY CY 2024</b>	<b>2<sup>nd</sup> Full FY CY 2025</b>	<b>3<sup>rd</sup> Full FY CY 2026</b>
# of Units	1	1	1	1	1	1
Unweighted Procedures	2,069	2,758	2,791	2,824	2,858	2,892
Weighted Procedures	2,690	3,585	3,629	3,672	3,716	3,761

Source: Section Q, pages 99 and 101

<b>Catawba Valley Medical Center Historical and Projected Utilization</b>						
	<b>Last Full FY CY 2021</b>	<b>Interim Full FY CY 2022</b>	<b>Interim Full FY CY 2023</b>	<b>1<sup>st</sup> Full FY CY 2024</b>	<b>2<sup>nd</sup> Full FY CY 2025</b>	<b>3<sup>rd</sup> Full FY CY 2026</b>
# of Units	1	1	1	1	1	1
Unweighted Procedures	3,460	3,386	3,426	3,467	3,509	3,551
Weighted Procedures	4,499	4,403	4,455	4,509	4,562	4,617

Source: Section Q, pages 100 and 102

In pages 104-107, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: Examine the historical utilization to project utilization of MRI Procedures*

The applicant examines the historical utilization of the two existing fixed MRI scanners located at CVMC and CVIC.

<b>Catawba Valley Medical Center/Catawba Valley Imaging Center Historical Fixed MRI Scanner Utilization, CY 2018 – CY 2022*</b>						
Unweighted	CY 2018	CY 2019	CY 2020**	CY 2021**	CY 2022***	4-YR CAGR
Fixed MRI Scans	5,337	5,998	5,551	5,529	3,072	3.58%

Source: Section Q, page 104

\*Data reported for calendar years, which differs from federal fiscal year data shown SMFPs.

\*\*This data reflects the anomalous impact of the COVID-19 pandemic, which is temporarily negatively impacted utilization.

\*\*\*Six months (January-June) year-to-date actual utilization.

As illustrated in the table above, the number of fixed MRI scans grew annually 3.58 percent from CY 2018 to CY 2022 (annualized). The applicant considered the impact of the pandemic temporary and did not factor it in when projecting utilization. To project utilization, the applicant applied a conservative CAGR that is equivalent to one-third of the historical growth of MRI scans, as illustrated in the table below.

<b>Catawba Valley Medical Center/Catawba Valley Imaging Center Projected Fixed MRI Scanner Utilization, CY 2022 – CY 2026</b>						
Unweighted	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	4-YR CAGR
Fixed MRI Scans	6,144	6,217	6,292	6,367	6,443	1.19%

Source: Section Q, page 104

The applicant states that during the most recent five years, an overall average of 48.89 percent of MRI scans were performed on the scanner located at CVMC and 55.11 percent was performed at CVIC. See table below.

<b>Catawba Valley Medical Center/ Catawba Valley Imaging Center Historical Fixed MRI Scanner Utilization by Site, CY 2018 – CY 2022</b>							
Unweighted	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022*	Combined Total	Average %
Fixed MRI Scans	5,337	5,998	5,551	5,529	3,072	25,487	100.0%
Main Campus	2,689	3,140	2,867	3,460	1,889	14,045	55.11%
CVIC	2,648	2,858	2,684	2,069	1,183	11,442	44.89%

Source: Section Q, page 105

\*January - June year-to-date totals.

To project utilization of each MRI scanner, the applicant assumed that the percentage of scans performed on each MRI scanner will be equivalent to the historical percentage during the most recent five years, as stated above. The following table illustrates the projected utilization for each MRI scanner.

<b>Catawba Valley Medical Center/ Catawba Valley Imaging Center Projected Fixed MRI Scanner Utilization by Site, CY 2022 – CY 2026</b>						
Unweighted	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	4-YR CAGR
CVIC	2,758	2,791	2,824	2,858	2,892	1.19%
Main Campus	3,386	3,426	3,467	3,509	3,551	1.19%
<b>Combined</b>	<b>6,144</b>	<b>6,217</b>	<b>6,292</b>	<b>6,367</b>	<b>6,443</b>	<b>1.19%</b>

Source: Section Q, page 105

*Step 2: Project the Total Adjusted (Weighted) Utilization*

The following table illustrates the historical weighting ratio from CY 2021 to CY 2022.

<b>Catawba Valley Medical Center/ Catawba Valley Imaging Center Historical Fixed MRI Scanner Adjusted Utilization, CY 2021 – CY 2022</b>					
	CY 2021 Unweighted Scans	CY 2022 Unweighted Scans*	Weighting Factor	Weighted Scans	Overall Weighting Ratio
IP no contrast/sedation	1,028	545	1.4	2,202	
IP with contrast/sedation	497	263	1.8	1,368	
OP no contrast/sedation	1,994	910	1	2,904	
OP with contrast/sedation	2,010	1,354	1.4	4,710	
<b>Total</b>	<b>5,529</b>	<b>3,072</b>		<b>11,184</b>	

Source: Section Q, page 106

\*January - June year-to-date totals.

The applicant applied the historical weighting ratio of 1.300 and assumed that it will remain constant through CY 2026. The following table illustrates the projected weighted fixed MRI scanner utilization from CY 2022 to CY 2026.

<b>Catawba Valley Medical Center/ Catawba Valley Imaging Center Projected Weighted Fixed MRI Scanner Utilization, CY 2022 – CY 2026</b>						
Weighted	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	4-YR CAGR
CVIC	3,586	3,629	3,672	3,716	3,761	1.19%
Main Campus	4,403	4,455	4,509	4,562	4,617	1.19%
<b>Combined</b>	<b>7,989</b>	<b>8,084</b>	<b>8,181</b>	<b>8,279</b>	<b>8,378</b>	<b>1.19%</b>

Source: Section Q, page 106

Although the scope of this project does not require the applicant's projections meet the Performance Standards, the applicant projects the average weighted MRI scans per fixed MRI scanner.

<b>Total Projected CVMC Fixed MRI Weighted Procedures Combined Main Campus and CVIC</b>					
Weighted	<b>CY 2022</b>	<b>CY 2023</b>	<b>CY 2024</b>	<b>CY 2025</b>	<b>CY 2026</b>
CVIC	3,586	3,629	3,672	3,716	3,761
Main Campus	4,403	4,455	4,509	4,562	4,617
Combined	7,989	8,084	8,181	8,279	8,378
<b>Average weighted procedures/scanner</b>	<b>3,994</b>	<b>4,042</b>	<b>4,090</b>	<b>4,139</b>	<b>4,189</b>

Source: Section Q, page 107

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

- The applicant relied on the historical utilization of the existing fixed MRI scanners.
- The applicant’s projections are supported by the projected population growth and aging in the proposed service area.

**Access to Medically Underserved Groups**

In Section C, page 45, the applicant states:

*“Patients obtain access to CVMC MRI services through physician/provider referral, and CVMC does not discriminate based on income, race, ethnicity, creed, color, gender, age, physical or mental handicap, religion, national origin, sexual orientation, or any other factor that would classify a patient as underserved...CVMC will continue to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions ,age, or any other factor that classify a patient as underserved. MR imaging services at CVMC will continue to be available to and accessible by any patient having clinical need for those services.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	11.6%
Racial and ethnic minorities	17.6%
Women	66.2%
Persons with Disabilities	9.7%
Persons 65 and older	38.4%
Medicare beneficiaries	46.6%
Medicaid recipients	7.0%

Source: Section C, page 46

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's proposal to replace an existing fixed MRI scanner will not affect the needs of medically underserved groups currently served by CVIC.
- CVIC is an established facility in the service area currently serving patients defined as medically underserved.

### **Conclusion**

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 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 the reduction or elimination of 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.

C

The applicant proposes to replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

In Section D, pages 57-58, 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 maintaining the status quo was not an option because the existing fixed MRI scanner is operating beyond the average age of MRI equipment. Additionally, operating an MRI scanner beyond its useful life would not be efficient nor cost effective.

Acquire Different MRI Equipment-The applicant considered acquiring a 1.5T scanner as opposed to a 3T scanner. However, this alternative was dismissed because a 3T MRI scanner can provide more scanning options for doctors, produce more detailed images in less time, and lower the risk for distorted images. Additionally, the cost for the 3T scanner is approximately the same for the 1.5T scanner; therefore, not driving up any costs for patients or insurance plans.

On page 58, the applicant states that its proposal is the most effective alternative because of the age of the existing scanner and due to the 1.5T scanner located on the CVMC campus, the replacement MRI scanner will offer patients and referring providers a choice of equipment.

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

- The applicant is proposing to replace an aging piece of equipment with an updated model that will allow CVIC to provide higher quality service to patients and referring providers.
- The applicant provides reasonable 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

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 County of Catawba (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall replace one fixed MRI scanner located off Catawba Valley Medical Center main hospital campus at Catawba Valley Imaging Center.**
- 3. Upon completion of the project, Catawba Valley Medical Center shall be licensed for no more than two fixed MRI scanners.**
- 4. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder 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 May 1, 2023.
5. The certificate holder, as part of this project, shall not acquire 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.
6. 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 certificate holder 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.
7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

#### **Capital and Working Capital Costs**

In Section Q, page 108, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Capital Costs</b>	
Construction/Renovation Contract(s)	\$400,681
Architect/Engineering Fees	35,464
Medical Equipment (Includes freight & Installation)	\$1,693,000
Consultant Fees (CON-related)	\$36,738
Other (temporary mobile scanner lease contingency)	\$186,470
<b>Total</b>	<b>\$2,352,353</b>

In Section F, page 59, 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:

- Capital costs are based on vendor estimates related to the cost to purchase the replacement equipment and the construction cost for demolishing then renovating the existing space that will accommodate the new MRI scanner.
- The applicant provides supporting documenting in Exhibits F.1 and K.3.

On page 61, the applicant states that there will be no start-up or operating costs associated with this project because CVMC is a licensed facility currently operating fixed MRI scanners.

**Availability of Funds**

In Section F, page 58, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
Type	County of Catawba	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$2,352,353	\$2,352,353
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$2,352,353</b>	<b>\$2,352,353</b>

\*OE = Owner's Equity

In Exhibit F.2, the applicant provides a letter dated August 4, 2022, from the vice-president/chief financial officer of CVMC, authorizing the use of accumulated reserves for the capital needs of the project. The applicant provides the 2022 consolidated balance sheets for CVMC, which states over \$159 million in "Cash in Bank and on Hand" to fund the capital cost of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

**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.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

<b>Catawba Valley Medical Center</b>	<b>1<sup>st</sup> Full FY CY 2024</b>	<b>2<sup>nd</sup> Full FY CY 2025</b>	<b>3<sup>rd</sup> Full FY CY 2026</b>
Total MRI Procedures (Weighted)*	8,181	8,278	8,378
Total Gross Revenues (Charges)	\$25,326,433	\$25,628,916	\$25,935,011
Total Net Revenue	\$5,020,316	\$5,080,275	\$5,140,951
Average Net Revenue per Procedure	\$614	\$614	\$614
Total Operating Expenses (Costs)	\$2,740,486	\$2,933,924	\$3,001,467
Average Operating Expense per Procedure	\$335	\$354	\$358
Net Income	\$2,279,830	\$2,146,351	\$2,139,484

\*Includes weighted MRI scans at Catawba Valley Imaging Center.

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

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 for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- 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 replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

The 2022 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.*” Therefore, for the purpose of this review, the fixed MRI service area is Catawba 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 Catawba County service area, summarized from Table 17E-1 of 2022 SMFP.

<b>Fixed MRI Scanners in Catawba County</b>			
<b>Provider</b>	<b># of Fixed MRI Scanners</b>	<b>Total MRI Scans</b>	<b>Adjusted Total</b>
Catawba Valley Medical Center-Imaging Center	1	2,745	3,268
Catawba Valley Medical Center-Main Campus	1	3,011	3,992
Frye Regional Medical Center-Tate Campus	1	2,078	2,314
Frye Regional Medical Center-Main	1	2,462	3,305
<b>Totals</b>	<b>4</b>	<b>10,296</b>	<b>12,879</b>

In Section G, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Catawba County. The applicant states:

*“...CVMC is simply proposing to replace a fixed MRI scanner that has reached the end of its useful life; CVMC’s fixed MRI scanner inventory count of two will not change...CVMC’s equipment replacement project will maintain local access for Catawba County residents to high quality and cost-effective outpatient MR imaging in a geographically convenient, easily accessible freestanding diagnostic imaging setting.”*

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:

- The proposal would not result in an increase in fixed MRI scanners in the services area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners.
- Replacing the outdated MRI scanner will allow the facility to provide higher quality MRI services to patients in the service area.

**Conclusion**

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 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

The applicant proposes to replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

In Section Q, page 114, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 01/01/2022	2nd Full Fiscal Year (CY 2025)
Radiology Technologists (MRI)	5.0	5.0
Administrator/CEO	0.124	0.124
Business Office (coder)	0.50	0.50
Clerical (Scheduler)	0.50	0.50
Other (Transporter)	0.124	0.124
Other (Clinical Supervisor)	0.50	0.50
<b>TOTAL</b>	<b>6.75</b>	<b>6.75</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 69-71, 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 staff required to operate the replacement MRI scanner is already in place at CVIC.
- CVMC’s affiliation with local clinical health training programs to recruit future staff.
- CVMC is an established employer in the service area offering competitive pay and “generous” benefits.
- CVMC requires all clinical staff to meet continuing educations requirements.

**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.

- (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 replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

#### **Ancillary and Support Services**

In Section I, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 73-74, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits F.1, I.1.1 and I.1.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides supporting documentation demonstrating the medical director's commitment to continue to serve and the support from referring physicians and advance practice providers.
- The majority of ancillary and support services will be provided by CVMC staff.

#### **Coordination**

In Section I, pages 74-75, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.1. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the applicant's status as an established healthcare provider in the service area and its relationships with the healthcare provider community, including referring physicians.

#### **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.

- (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 replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

In Section K, page 77, the applicant states that the project involves renovating 933 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 77-78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The project's construction plan will be directed by experienced architect and construction professionals.
- The construction involves renovating an existing facility space which will avoid costs associated with constructing or upfitting a new space.

On page 78, 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 based on the following:

- The applicant is proposing to replace the existing MRI scanner with an updated model than can provide higher quality images, which will allow the facility to provide higher quality service.
- The proposed project will allow CVIC to maintain access, convenience, and time efficiency to patients in the service area without increasing costs.

On pages 78-79, 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

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 81, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

<b>Catawba Valley Medical Center (MRI Services) Historical Payor Mix 01/01/2021-12/01/2021</b>	
<b>Payor Category</b>	<b>Percent of Total</b>
Self-Pay	3.1%
Charity Care (included with self-pay)	
Medicare*	46.6%
Medicaid*	7.0%
Insurance*	40.5%
Workers Compensation	0.4%
TRICARE	0.7%
Other	1.6%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, page 82, the applicant provides the following comparison.

<b>Catawba Valley Medical Center (Imaging)</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	66.1%	50.8%
Male	33.9%	49.2%
Unknown	0.0%	0.0%
64 and Younger	61.6%	81.5%
65 and Older	38.4%	18.5%
American Indian	0.0%	0.6%
Asian	1.6%	4.8%
Black or African American	8.4%	9.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	82.4%	74.9%
Other Race	5.6%	10.5%
Declined / Unavailable	2.0%	0.0%

\*The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

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

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 83, the applicant states:

*“CVMC has no requirements to provide uncompensated care, community service, or access by minorities and persons with disabilities.”*

In Section L, page 82, the applicant states that during the 18 months immediately preceding the application deadline, 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

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 84, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Catawba Valley Imaging Center (MRI Services) Historical Payor Mix 3<sup>rd</sup> Full FY, CY 2024</b>	
<b>Payor Category</b>	<b>Percent of Total</b>
Self-Pay	3.1%
Charity Care (included with self-pay)	
Medicare*	46.6%
Medicaid*	7.0%
Insurance*	40.5%
Workers Compensation	0.4%
TRICARE	0.7%
Other	1.6%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.1% of total services will be provided to self-pay patients, 46.6% to Medicare patients and 7.0% to Medicaid patients.

On page 84, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of

the project. The projected payor mix is reasonable and adequately supported based on CVMC's historical MRI payor mix and the existing referring physicians/providers that continue to be the source of referrals to CVMC.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated 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 85, 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

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 replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

In Section M, page 87, 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 access to the facility for training purposes based on the following:

- CVMC has an existing clinical training affiliation agreement with Lenoir-Rhyne University and provides supporting documentation in Exhibit M.1.

- The applicant states that CVMC facilities will continue to be available for students training in clinical services.

### **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 replace one fixed MRI scanner located off CVMC main hospital campus at CVIC.

The 2022 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.*” Therefore, for the purpose of this review, the fixed MRI service area is Catawba 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 Catawba County service area, summarized from Table 17E-1 of 2022 SMFP.

<b>Fixed MRI Scanners in Catawba County</b>			
<b>Provider</b>	<b># of Fixed MRI Scanners</b>	<b>Total MRI Scans</b>	<b>Adjusted Total</b>
Catawba Valley Medical Center-Imaging Center	1	2,745	3,268
Catawba Valley Medical Center-Main Campus	1	3,011	3,992
Frye Regional Medical Center-Tate Campus	1	2,078	2,314
Frye Regional Medical Center-Main	1	2,462	3,305
<b>Totals</b>	<b>4</b>	<b>10,296</b>	<b>12,879</b>

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

*“Catawba County currently has MRI competition, with existing fixed and mobile MRI scanners. With this project to replace one of its fixed MRI scanners, CVMC, as an experienced diagnostic imaging provider, will have a positive impact on competition in the service area by enhancing the medical diagnostic imaging services it currently offers in Catawba County, and maintaining patient access to quality, cost-effective, and accessible diagnostic imaging.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 88, the applicant states:

*“CVMC has a reputation for delivering high quality diagnostic imaging services in a cost-effective manner. The CVMC fixed MRI scanner replacement project will enhance the scope of high quality, low cost healthcare services available to the community.*

*The proposed Siemens 3T open MRI scanner is modern technology and offers ease of operation, excellent imaging quality, patient comfort, along with high throughput and dependability, cost-effective capital and operating costs, and energy efficiency capabilities. These will combine to enable a high volume of MRI procedures per day, thus containing the cost per procedure.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 89-90, the applicant states:

*“...CVMC’s proposal to obtain a replacement 3T fixed scanner will be of great benefit to the local community from a quality perspective, offering several advantages, including:*

- 3T MRIs provide more scanning options for doctors, with sophisticated imaging procedures not available in lower-power models of MRI scanners...*
- higher resolution which produces more detailed images, which are beneficial when diagnosing pathological conditions...*
- provide higher detailed images in less time...*
- a lower risk of distorted images, which lessens the need for repeated scans...*

*CVMC will continue to maintain the highest standards and quality of care, consistent with the standards that it has sustained throughout its many years of providing patient care in Catawba County.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 90, the applicant states:

*“CVMC has historically provided care and services to medically underserved populations. CVMC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, or any other factor that would classify a patient as underserved. CVMC will continue to provide all services to all patients of regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.”*

See also Section L and C 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
- 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 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

In Section Q, page 115, the applicant identifies the facilities offering MRI services located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 95, the applicant states that, during the 18 months immediately preceding the submittal of the application, situations resulting in a finding immediate jeopardy had not occurred in this facility. 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 had not occurred in this facility. 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 this facility, 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.

NA

The applicant is proposing to replace one fixed MRI scanner located off CVMC main hospital campus at CVIC. The applicant is not proposing to acquire a fixed MRI scanner pursuant to a need determination in the 2022 SMFP. There are no administrative rules that are applicable to this proposal. Therefore, this Criterion is not applicable.