

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 19, 2024

Findings Date: January 19, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Michael J. McKillip

Project ID #: N-12454-23

Facility: Cape Fear Valley-Bladen County Hospital

FID #: 942974

County: Bladen

Applicant: Cumberland County Hospital System, Inc.
Bladen Healthcare, LLC

Project: Acquire no more than one fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP

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

Cumberland County Hospital System, Inc. and Bladen Healthcare, LLC, hereinafter collectively referred to as “the applicant,” proposes to acquire one fixed MRI scanner pursuant to the Policy TE-3 in the 2023 State Medical Facilities Plan (SMFP) to be installed in an outpatient medical office building located on the main campus of Cape Fear Valley-Bladen County Hospital (CFV-Bladen) in Elizabethtown, Bladen County.

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 2023 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

One policy in Chapter 4 of the 2023 SMFP is applicable to this application: *Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners.*

Policy TE-3

Policy TE-3 on page 28 of the 2023 SMFP states:

“The applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner shall demonstrate in its certificate of need (CON) application that it is a licensed North Carolina acute care hospital or a hospital campus:

- 1. that has licensed acute care beds; and*
- 2. that provides emergency care coverage 24 hours a day, seven days a week.*

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The proposed fixed MRI scanner:

- 1. must be located on the main campus of the hospital as defined in G.S. § 131E-176(14n); or*
- 2. must be located at another acute care hospital on a campus that operates under the main hospital’s license.*

The proposed fixed MRI scanner cannot be located at a site where the inventory in the SMFP reflects that there is an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application.

The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed MRI services.”

In Section B, pages 25-27, and in Exhibit B.19, the applicant explains why it believes its application is consistent with Policy TE-3. The applicant adequately demonstrates that CFV-Bladen is a facility with licensed acute care beds that provides an operational emergency department that is open 24 hours a day year-round, does not currently have an existing or approved MRI scanner, and will perform at least 850 weighted MRI procedures during the third full operating year following completion.

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 following:

- The applicant adequately demonstrates that the proposal is consistent with Policy TE-3 based on the following:
 - CFV-Bladen is a licensed North Carolina acute care hospital that provides emergency care coverage 24 hours a day, seven days a week.
 - The applicant does not currently have an existing or approved MRI scanner at the CFV-Bladen location.
 - The proposed fixed MRI scanner will be located in an outpatient building on the main campus of the hospital as that term is defined in N.C. Gen. Stat. 131E-176(14)(n)(a).
 - The applicant demonstrates that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year following project completion.

(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 operates CFV-Bladen, a critical access hospital in Elizabethtown, Bladen County. A critical access hospital is a hospital that has a special designation from the Centers for Medicare and Medicaid Services and operates 25 or fewer beds. In this proposal, the applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen. CFV-Bladen is licensed for 48 acute care beds but operates no more than 25 acute care beds at a given time, consistent with the Critical Access Hospital designation. CFV-Bladen also provides 24-hour emergency services and CT, ultrasound and mammography services. Following acquisition of the proposed fixed MRI scanner, CFV-Bladen will provide fixed MRI services in addition to the existing emergency and imaging services.

Patient Origin

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 Bladen County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 29, the applicant states CFV-Bladen does not currently provide fixed MRI services and thus has no historical fixed MRI patient origin to report. The applicant does provide mobile MRI services through a contract with Mobile Imaging of North Carolina, LLC. The following table illustrates historical patient origin for mobile MRI services for the last full fiscal year (FY), calendar year (CY) 2022:

Cape Fear Valley-Bladen Mobile MRI Historical Patient Origin, CY 2022

COUNTY	# OF PATIENTS	PERCENT OF TOTAL
Bladen	322	82.2%
Sampson	23	5.8%
Columbus	18	4.5%
Robeson	16	4.0%
Cumberland	10	2.7%
Brunswick	1	0.3%
Pender	1	0.3%
Out of State	1	0.3%
Total	392	100.0%

In Section B, page 30 the applicant provides historical patient origin for the entire CFV-Bladen hospital, as shown in the following table:

Cape Fear Valley-Bladen Historical Patient Origin, CY 2022

COUNTY	# OF PATIENTS	PERCENT OF TOTAL
Bladen	79,457	80.4%
Sampson	6,462	6.5%
Columbus	3,971	4.0%
Robeson	3,803	3.9%
Cumberland	2,441	2.5%
Other*	2,643	2.7%
Total	98,777	100.0%

*On page 30 the applicant states "other" includes <1% patient origin from the remaining counties in North Carolina and other states.

The following table, from page 31, illustrates projected patient origin for the first three full FYs, CYs 2025-2027, for fixed MRI services at CFV-Bladen:

Cape Fear Valley-Bladen Projected Patient Origin for Fixed MRI Services

COUNTY	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL	# OF PATIENTS	PERCENT OF TOTAL
Bladen	510	85.0%	610	85.0%	715	85.0%
Sampson	30	5.0%	36	5.0%	42	5.0%
Columbus	23	3.9%	28	3.9%	33	3.9%
Robeson	21	3.4%	25	3.4%	29	3.4%
Cumberland	14	2.3%	16	2.3%	19	2.3%
Other*	3	0.5%	3	0.5%	4	0.5%
Total	600	100.0%	718	100.0%	841	100.0%

*On page 31 the applicant states "other" includes <1% patient origin from the remaining counties in North Carolina and other states.

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin, which it states is based on the historical patient origin of for the entire CFV-Bladen hospital for CY 2022. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical experience and on demographic data regarding projected population growth and MRI utilization.

Analysis of Need

In Section C, on pages 33-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- **Historical MRI use rate** – The applicant examined the state-wide MRI use rate from 2017-2022 and determined that the number of MRI procedures performed during that time increased by a compound annual growth rate (CAGR) of 2.7%. The applicant states the CFV-Bladen currently provides MRI services through a contract with a mobile vendor, but the unit is available only one day per week. CFV-Bladen acquired a physician practice in July 2023 and added a family medicine physician at another affiliated medical clinic in August 2023, which increased MRI referrals. The increasing state-wide use rate, combined with the increase in referral sources substantiate the need for the proposed fixed MRI scanner at CFV-Bladen.
- **Need to enhance access to CFV-Bladen MRI services** – The applicant states the limited availability of the mobile MRI scanner and the limitations inherent in a mobile unit itself create access and imaging challenges that result in patients either needing to wait several weeks for a procedure, or seeking MRI services elsewhere where they can be easily and timely served. The applicant states a wide-bore fixed MRI scanner as proposed in this application would increase availability and more effectively accommodate those obese or claustrophobic patients who cannot be served on a smaller mobile unit. Additionally, the existing mobile cannot perform prostate or breast scans due to poor image quality and the absence of a breast coil. As CFV-Bladen is a critical access hospital with a 24-hour emergency department, it needs a fixed MRI scanner to properly diagnose and treat many emergency patients. The proposed fixed MRI scanner will not only accommodate obese and claustrophobic patients and perform prostate and breast scans, but will also be available for those emergency patients who present to the hospital emergency department.
- **Service area demographics** – The applicant examined population data published by the North Carolina Office of State Budget and Management and determined that, while the overall population in Bladen County is projected to decrease slightly from 2023-2027, the age 18-64 and age 65 + population cohorts are projected to increase by 59.0% and 19.1% respectively during that same time. The applicant states the age 65+ population group accounted for over 58% of total MRI scans performed on the mobile scanner during CY 2022. Thus, despite a projected decrease in Bladen County's total

population from 2023-2027, those age groups most likely to seek MRI services are projected to increase, which supports the need for a fixed MRI scanner at CFV-Bladen.

Additionally, the applicant states the lack of financial resources can create access barriers to healthcare services, which negatively impacts health status. The applicant cites US Census data that shows 21.6% of the Bladen County population live below the poverty line, compared to the national average of 11.6%. As a critical access hospital, CFV-Bladen is specially tasked with improving access to health care for the population it serves. MRI is a critical diagnostic method used to diagnose and treat many diseases, and CFV-Bladen can not effectively serve its patients on a limited capacity mobile unit that is only available one day per week.

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

- The applicant provides documented and reasonable data to show the increasing need at CFV-Bladen for fixed MRI services, particularly in light of CFV-Bladen’s designation as a critical access hospital.
- The applicant provides reasonable and documented data to show the older age population groups are projected to increase in Bladen County.

Projected Utilization

In Section Q, Forms C.2a and C.2b, page 92, the applicant provides historical and interim utilization for mobile MRI services at CFV-Bladen for CYs 2022-2024 and projected utilization for the proposed fixed MRI scanner in all three project years (CYs 2025-2027), as illustrated in the following tables:

Historical and Interim MRI Utilization, Mobile Unit

	CY 2022	CY 2023	CY 2024
# Units	1 Leased Unit	1 Leased Unit	1 Leased Unit
# Procedures	392	492	527
# Adjusted Procedures	426	541	579

Projected Fixed MRI Utilization

	CY 2025	CY 2026	CY 2027
# Units	1	1	1
# Procedures	600	718	841
# Adjusted Procedures	660	790	925

In Section Q, pages 93-98, “*Form C.2b Utilization – Assumptions and Methodology*”, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

Step 1: Identify historical volume of Bladen County patient hospital-based MRI procedures – The applicant analyzed MRI utilization data in Bladen County published by The Hospital Industry Data Institute and determined that MRI procedures at a hospital-based MRI scanner in Bladen County as a whole increased by a CAGR of 5.1% from FFY 2021-2023 (annualized at the time of application submission). The applicant examined only hospital-based MRI services because it states those patients who have historically sought MRI services at a hospital represents the cohort of patients who will likely seek MRI services at CFV-Bladen. See the table on page 93 that illustrates the historical growth.

Step 2: Project Bladen County patient hospital-based MRI procedures – The applicant projects future fixed MRI volume at CFV-Bladen to increase by one-half the historical CAGR calculated in Step 1. The applicant converted the FFY data to correspond to its FY, which is a calendar year, and applied the growth rate of 2.5% to the Bladen County CY 2022 hospital-based MRI utilization. The applicant projected MRI utilization through the third project year, CY 2027, as shown in the following table from page 94:

	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CY 2027
# Procedures	1,577	1,617	1,658	1,700	1,743	1,787

Step 3: CFV-Bladen share of Bladen County hospital-based MRI volume – The applicant calculated its share of Bladen County hospital-based MRI volume based on the number of Bladen County mobile MRI procedures performed at CFV-Bladen in CYs 2022 and 2023 (annualized). The applicant determined that in CY 2022, 20.4% of those patients seeking hospital-based MRI services sought those services at CFV-Bladen. Similarly, in CY 2023, 25.0% of those patients seeking hospital-based MRI services sought those services at CFV-Bladen.

Based on that data, on historical utilization of the mobile MRI service at CFV-Bladen, support letters provided in Exhibit I.2, and the offering of full-time fixed MRI services at CFV-Bladen, the applicant projects an incremental increase in the number of MRI scans it will capture from the total Bladen County hospital-based MRI scans, as shown in the following table from page 95:

	CY 2024	CY 2025	CY 2026	CY 2027
Bladen County Patient MRI Scans	1,658	1,700	1,743	1,787
CFV-Bladen Market Share	27.0%	30.0%	35.0%	40.0%
# Bladen County Patient MRI Scans at CFV-Bladen	448	510	610	715

Step 4: Project CFV-Bladen total MRI procedures – The applicant projected utilization of the mobile MRI scanner during the interim years while the proposed project is developed. See the table that illustrates those projections on application page 96.

Step 5: Project immigration – The applicant projects 15% immigration from other counties for its proposed fixed MRI services for each of the interim and three full project years, based

on its most recent CY 2022 experience, during which approximately 17.8% of its MRI patients came from other counties. See the table that illustrates those projections on application page 97.

Step 6: Determine adjusted MRI procedures – The applicant projected adjusted MRI procedures based on its CY 2022 distribution of MRI procedures by type. The applicant determined it had a 1.1 ratio of unadjusted to adjusted MRI procedures during that time. The applicant notes the historical mix of inpatient MRI procedures was likely suppressed due to the availability of the mobile MRI scanner only one day per week; therefore, the applicant states the ratio it applied is conservative. The applicant projects, in the third project year, to perform in excess of 850 weighted MRI procedures on the proposed fixed MRI scanner, which is consistent with the requirements of Policy TE-3.

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

- The applicant relied on its historical mobile MRI utilization at CFV-Bladen to project future utilization, and accounted for the decreased availability of the mobile MRI scanner.
- The applicant relied on population growth projections from reliable sources to determine population growth in the service area.
- The applicant reasonably projected immigration to CFV-Bladen based on the historical number of patients seeking MRI services at that hospital.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to CFV-Bladen’s MRI services, as clinically appropriate. CFV-Bladen does not and will not discriminate based on race, ethnicity, age, gender, disability, or sexual orientation. Policies to provide access to services by low-income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibits C.6 and L.4.”

On page 46, 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	10.7%
Racial and ethnic minorities	55.1%
Women	51.9%
Persons with disabilities	--
Persons 65 and older	58.4%
Medicare beneficiaries	58.4%
Medicaid recipients	10.7%

*The applicant states on page 46 that CFV-Bladen does not maintain data that includes the number of 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 clinical and MRI services to underserved groups.
- The applicant states that all patients, including those in underserved groups, will continue to receive access to MRI and all clinical services at CFV-Bladen.

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.

- (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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

In Section E, page 54, 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 existing mobile MRI services provided at CFV-Bladen are limited and ineffective to serve all patients at all times who seek MRI services, particularly considering weather limitations, unique conditions of patients, and limited capability of the mobile unit. Therefore, this is a less effective alternative.
- Expand mobile MRI services at CFV-Bladen – The applicant states the mobile unit is provided via a contract over which the applicant has not control regarding scheduling. Service is currently provided one day per week, which is insufficient to meet patient demand. Additionally, the mobile unit is unable to accommodate non-ambulatory patients and often is only available for outpatient scans, leaving inpatient and emergency patients without MRI options. Therefore, expanding existing mobile MRI service is not a reasonable option.

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

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. Cumberland County Hospital System, Inc. and Bladen Healthcare, 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 Policy TE-3 in the 2023 SMFP to be located at Cape Fear Valley-Bladen County Hospital.**
 - 3. 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.**
 - 4. 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.**
 - 5. 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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

Capital and Working Capital Costs

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

Site Costs	\$200,000
Construction/Renovation Costs	\$1,264,847
Medical Equipment	\$1,790,731
Non-Medical Equipment	\$28,762
Miscellaneous Costs	\$257,216
Total	\$3,541,556

In Section Q, *Form F.1a Capital Cost 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 applicant's experience with similar projects.
- Non-medical, furniture and miscellaneous costs, including information systems and security, are based on CFV-Bladen's experience with similar projects.
- In Exhibit K.3, 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 57, the applicant states there will be no start-up costs or initial operating expenses because CFV-Bladen currently offers mobile MRI services, and the proposed fixed MRI scanner will be a natural extension of the hospital's existing radiology department.

Availability of Funds

In Section F, page 56, the applicant states the project capital cost will be funded with the accumulated reserves of Cumberland County Health System, Inc.

Exhibit F.2-1 contains a letter signed by the Chief Financial Officer of the Cape Fear Valley Health System that confirms the availability of sufficient funds to cover the project capital cost and commits the necessary funds from accumulated reserves of CFVHS. Exhibit F.2 also contains the most recent CFVHS audited financial statements documenting the availability of sufficient funds for the 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 CFVHS’s commitment to use the necessary funding for the capital costs.
- The applicant documents the availability of sufficient financial resources to fund the proposed 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 all three full fiscal years (FY), calendar years (CY) 2025-2027 for MRI services following project completion, as shown in the following table:

Cape Fear Valley-Bladen County Hospital			
MRI SERVICES ONLY	1ST FY CY 2025	2ND FY CY 2026	3RD FY CY 2027
# of Scans (Weighted)	660	790	925
Gross Revenue	\$2,591,473	\$3,100,564	\$3,636,428
Net Revenue	\$829,271	\$930,169	\$1,054,564
Average Net Revenue per Weighted MRI Scan	\$1,256	\$1,177	\$1,140
Operating Costs	\$825,572	\$840,200	\$855,393
Average Operating Costs per Weighted MRI Scan	\$1,251	\$1,064	\$925
Net Income	\$3,699	\$89,969	\$199,171

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 104-105. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Revenue projections are based on CY 2022 experience of CFV-Bladen mobile MRI experience, inflated annually.
- The applicant itemizes projected operating expenses and explains its revenue projections, which are based on its experience.
- 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

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 cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

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 Bladen County. Facilities may also serve residents of counties not included in their service area.

According to Table 17E-1, page 336 of the 2023 SMFP, there are no fixed MRI scanners located in the Bladen County fixed MRI service area. There is one mobile MRI scanner owned by Mobile Imaging of North Carolina, LLC that serves Bladen County.

In Section G, page 64, 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, stating that there are currently no fixed MRI scanners in the county. The applicant also states:

“SMFP Policy TE-3 was developed to allow acute care hospitals without a fixed MRI scanner a means to acquire this technology without an SMFP need determination. The development of Policy TE-3 and its inclusion in the annual SMFP is an acknowledgement that fixed MRI is a necessary diagnostic tool that should be available at any North Carolina acute care hospital that provides on-site emergency and surgical services.”

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 currently no fixed MRI scanner in the Bladen County fixed MRI service area.

- The applicant adequately demonstrates the need for the proposed fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP at CFV-Bladen.

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.

- (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 acquire one fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

In Section Q, Form H, page 102, the applicant provides projected full-time equivalent (FTE) positions for its proposed fixed MRI services, as illustrated in the following table:

POSITION	1 ST FY CY 2025	2 ND FY CY 2026	3 RD FY CY 2027
MRI Technologist	2.2	2.2	2.2
Scheduler	1.0	1.0	1.0
Total	3.2	3.2	3.2

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 66-67, 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 fixed MRI services based on its experience as a critical access hospital that provides imaging 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.

- (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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

Ancillary and Support Services

In a table in Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section I, page 68 the applicant explains how each ancillary and support service is and will continue to be available and provides letters of support in Exhibit I.2. 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 CFV-Bladen on the mobile MRI scanner and its other diagnostic imaging services.

Coordination

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care providers and community health organizations. 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

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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

In Section K, page 72, the applicant states that the project involves renovating 1,385 square feet of existing space. Line drawings are provided in Exhibit K.2, and a renovation estimate from a licensed architect are provided in Exhibit K.3.

In Section K, page 73, 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 73, 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.

In Exhibit K.3 the certified construction cost estimate from the project architect 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 765, the applicant provides historical payor mix during CY 2022 for CFV-Bladen hospital, as shown in the following table:

Cape Fear Valley-Bladen County Hospital HISTORICAL PAYOR MIX, CY 2022	
PAYOR CATEGORY	SERVICES AS % OF TOTAL
Self-Pay	2.5%
Charity Care	4.3%
Medicare*	52.0%
Medicaid*	18.6%
Insurance*	19.7%
Other (Workers Comp/TRICARE)	2.9%
Total	100.0%

*Includes managed care plans

In Section L, page 77, 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	51.9%	52.1%
Male	32.9%	47.9%
Unknown	15.2%	---
64 and Younger	61.1%	76.0%
65 and Older	38.9%	24.0%
American Indian	1.7%	3.4%
Asian	0.3%	0.5%
Black or African American	32.2%	33.1%
Native Hawaiian or Pacific Islander	0.5%	0.1%
White or Caucasian	44.9%	54.7%
Other Race	4.6%	2.1%
Declined / Unavailable	15.8%	---

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 78, the applicant states it has no such obligation.

In Section L, page 79, the applicant responded to the question regarding the existence of civil rights equal access complaints that may have been filed against the facility with “*Not applicable*”. The Project Analyst concludes that this response confirms there are no such complaints that have been filed against the facility in the 18 months immediately preceding the application deadline.

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, page 79, the applicant projects payor mix for MRI services at CFV-Bladen during the third full fiscal year of operation (CY 2027) following project completion, as shown in the following table:

CFV-Bladen Fixed MRI Services Projected Payor Mix, CY 2027

PAYOR CATEGORY	ENTIRE FACILITY AS % OF TOTAL
Self-Pay	1.0%
Charity Care^	1.8%
Medicare*	46.8%
Medicaid*	12.2%
Insurance*	34.6%
Other (Workers Comp/TRICARE)	3.6%
Total	100.0%

*Includes managed care plans

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 1.0% of MRI services will be provided to self-pay patients, and 46.8% and 12.2% of total services will be provided to Medicare and Medicaid patients, respectively.

On page 79, 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 mobile MRI 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.

- (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 80, the describes the means by which a person will have access to the proposed additional fixed MRI services at CFV-Bladen.

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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

In Section M, page 81, 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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

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 Bladen County. Facilities may also serve residents of counties not included in their service area.

According to Table 17E-1, page 336 of the 2023 SMFP, there are no fixed MRI scanners located in the Bladen County fixed MRI service area. There is one mobile MRI scanner owned by Mobile Imaging of North Carolina, LLC that serves Bladen County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

“CFV-Bladen expects the acquisition of a new MRI scanner to have a positive effect on competition in the service area because it will increase the current capacity of MRI scanner services in the service area. The current mobile MRI scanner is available at CFV-Bladen only 52 days per year (1 day each week). This creates delays in receiving scans or causes patients and physicians to seek MRI scans at other locations. The proposed 1.5T MRI scanner will enhance access to MRI services at CFV-Bladen and allow more MRI procedures to be performed in the community.”

Regarding the expected effects of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

“This project will not affect the cost to patients or payors for the services provided by CFV-Bladen because reimbursement rates are set by the federal government and commercial insurers regardless of the type of MRI machine. The capital expenditure for this project is necessary to ensure that CFV-Bladen will provide full-time access to fixed MRI services, which are needed for inpatients and emergency department patients.”

See also Sections B, 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 N, pages 84-85, the applicant explains the quality measures taken by CFV-Bladen and the expected effects of the proposed fixed MRI services on quality in the service area.

See also Sections B, 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 N, page 85, the applicant states:

“CFVHS has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. CFV-Bladen will not discriminate in the provision of services on the basis of age, race, religion, disability, or the patient’s ability to pay.”

See also Sections B, 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 fixed MRI 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

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 Policy TE-3 in the 2023 SMFP to be installed in an outpatient medical office building located on the main campus of CFV-Bladen.

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 five hospitals located in North Carolina.

In Section O, page 88, the applicant states that, during the 18 months immediately preceding the submittal of the application, it is not aware of any incidents related to quality of care that occurred in any of these facilities. 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, one incident 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 five 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.

NA

The applicant is submitting this application to obtain a fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP, which states:

“To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and that does [sic] not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The fixed MRI scanner must be located on the hospital’s ‘main campus’ as defined in G.S. 131E-176(14n)a [sic].”

The applicant proposes to add a fixed MRI scanner at CFV-Bladen pursuant to Policy TE-3. The discussion regarding conformity with Policy TE-3 found in Criterion (1) is incorporated herein by reference. There are no administrative rules that are applicable to proposals submitted pursuant to Policy TE-3. Therefore, this criterion is not applicable.