Carolina Imaging, LLC's Comments in Opposition to CFVMC's Certificate of Need Application for One Fixed MRI Scanner in Cumberland County March 1, 2024 Review Cycle

INTRODUCTION

The 2024 State Medical Facilities Plan (SMFP) identified a need for one fixed MRI scanner in Cumberland County. In response to the need determination, two applicants have submitted Certificate of Need applications:

Carolina Imaging (Project ID No. M-12485-24), and

Cape Fear Valley Medical Center ("CFVMC") (Project ID No. M-12493-24).

Pursuant to N.C. Gen. Stat. §131E-185(a)(1), Carolina Imaging submits the following comments pertaining to the application filed by CFVMC to acquire one fixed MRI scanner in Cumberland County as identified in the 2024 SMFP. As discussed in the following comments, the application submitted by CFVMC fails to meet all necessary standards and review criteria and should be disapproved. In addition, for the reasons explained in the comparative analysis section below, Carolina Imaging's application is comparatively superior to the other application.

An important consideration in this review is the <u>actual</u> need for the proposed project. Although each applicant is required to demonstrate need for the proposed service, it is critical for the Cumberland County MRI Service Area and this MRI Review. Prior to the 2024 review, the previous MRI need determination for Cumberland County was in the <u>2007</u> SMFP. Mobile MRI services are not readily available to address the high demand in Cumberland County. The Agency has an important to decision to make here to protect the interest of North Carolina residents. Considering all relevant information, Carolina Imaging is the only applicant in this review that can be approved.

CFVMC controls five of the seven fixed MRI scanners in Cumberland County (71%), including two at its joint venture facility, Valley Regional Imaging, which is only three minutes and four-tenths of a mile from the CFVMC main campus. If this project is approved, six of eight (75%) fixed MRI scanners would be under the control of CFVMC or a related entity. This is an extreme competitive imbalance which is not beneficial for consumers or health care payors. As the information in the application shows, CFVMC's project will offer hospital based pricing, which is significantly higher than independent diagnostic testing facility (IDTF) pricing at Carolina Imaging. This is shown in the dramatic difference in projected gross revenues between the two projects:

Comparison of Average Gross Revenue per Procedure – PROJECT YEAR 3

Applicant	Gross Revenue	# of Unweighted	Total Gross
		Procedures	Revenue Per
			Procedure
Carolina Imaging	\$27,245,625	12835	\$2,123
CFVMC	\$46,318,347	11028	\$4,200

Source: Form C and Form F.2 from each application.

CFVMC's average gross revenue is approximately twice that of Carolina Imaging's.

Similarly, the difference in net revenue is compelling:

Comparison of Average Net Revenue per Procedure – Project Year 3

Applicant	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue Per MRI
			Procedure
Carolina Imaging	\$6,781,436	12835	\$528.35
CFVMC	\$7,642,527	11028	\$693.00

Source: Form C and Form F.2 from each application.

Carolina Imaging's average net revenue per procedure is approximately 24% lower than CFVMC's.

A comparison of common MRI charges for each applicant demonstrates that Carolina Imaging is a more cost effective alternative for both patients and third party payors.

MRI CPT Code	CPT Code Description	Carolina Imaging's Charge	CFVMC's Charge	Percentage Difference from Carolina Imaging
72141	Cervical spine without contrast	\$1710	\$5152	+201%
73221	Upper extremity without contrast	\$1650	\$3722	+126%
73721	Lower extremity without contrast	\$1650	\$3559	+116%
72148	Lumbar spine without contrast	\$1840	\$5120	+178%
70551	Brain without contrast	\$1690	\$5461	+223%
70553	Brain with and without contrast	\$3580	\$6281	+75%

Source: <u>Price Transparency | Patients & Visitors | Cape Fear Valley Health</u> <u>www.capefearvalley.com/patients/price-transparency.html</u>; Carolina Imaging internal data

This analysis details the significant price difference between Carolina Imaging's affordable outpatient rates and CFVMC's hospital based pricing for some of the most commonly performed MRI procedures.

These procedures total nearly 80% of the MRI procedures performed at Carolina Imaging. Carolina Imaging's price includes the radiologist reading fees, which provides an added benefit to the patients since they do not receive a separate bill from the radiologist.

CFVMC has more than adequate MRI capacity to address its current and future needs; Carolina Imaging does not. Particular attention should be focused on the provider that is best suited to address the following issues:

Is each applicant fully utilizing its existing MRI resources?

Carolina Imaging	YES	CFVMC	NO
Carolina Imaging operates Saturdays for approximat week.		CFVMC does not schedule phospital based MRI scanner operate on Saturdays, offer of service per week. CFVM MRI scanners in Bladen, Ho Counties that are not fully ucounties account for nearly projected MRI patients.	s past 5pm or ing only 58 hours C also owns fixed ke and Harnett itilized. These

Has each applicant reasonably projected demand based on its current MRI volumes?

Carolina Imaging	YES	CFVMC	NO
Carolina Imaging continue significant growth in MRI vyear.	•	CFVMC's overall MRI volum year. Inpatient MRI volum essentially the same over the CFVMC's outpatient contract 11% over the last year.	e has remained ne last three years.

Does each applicant have a reasonable alternative to address future MRI volumes?

Carolina Imaging	NO	CFVMC	YES
Carolina Imaging currently weighted MRI procedures Carolina Imaging operates units 70+ hours per week. insufficient mobile MRI daprovide Carolina Imaging service per week.	per fixed MRI unit. s its existing fixed MRI There are ays available to	CFVMC's average weighte MRI unit at the hospital is currently owns and/or ope scanners in the service are utilizing existing fixed MRI Cumberland County, incluscanners in Bladen, Hoke, which account for nearly 2 patients.	currently 4,742. CFVMC erates 5 of 7 fixed MRI ea. CFVMC is not fully scanners it owns in ding two at VRI, and and Harnett Counties,

Does each applicant have unique circumstances that require immediate consideration for the development of the proposed fixed MRI scanner?

Carolina	YES	CFVMC	NO		
Imaging					
Carolina Imaging has an owith the Womack Army However	ospital and the oprovide vital MRI sonnel (TriCare ina Imaging's for CFVMC). A 1.5T n scanning patients	of MRI scanners in Cumbe scanners are not fully utili has additional MRI resour County through VRI, and i counties, Harnett, Hoke a account for approximately projected volume in this account in the scanner of the sca	erland County. These ized at this time. CFVMC ces in Cumberland n the contiguous nd Bladen, which y 24% of CFVMC's application. These		
		resources are underutilized. Further, the CFVMC project will not be completed until January 2026 a full year after Carolina Imaging.			

The importance of this MRI review for Cumberland County cannot be understated. Cumberland County requires immediate access to additional fixed MRI service at reasonable prices. As discussed below, the application submitted by CFVMC failed to demonstrate conformity with all applicable review criteria and should be disapproved.

Comments regarding CFVMC's application:

<u>Criterion (1) – Consistency with State Medical Facilities Plan</u>

The CFVMC application should be found not conforming with Criterion (1) and Policy GEN-3 because it fails to demonstrate how its projected utilization incorporates the concept of maximum value for resources expended. There are several reasons why this application fails to meet the requirements of Policy GEN-3. First, there is no need for the project. Second, it unnecessarily duplicates existing and approved resources. Third, CFVMC proposes to spend \$7.2 million to acquire one MRI scanner and build 2,400 square feet of new space. Fourth, the projected gross revenue that CFVMC projects to receive is extraordinarily high (approximately double that of Carolina Imaging's) and its prices for the most commonly performed scans are significantly higher than Carolina Imaging's. Fifth, CFVMC will require a lengthy development period for its proposed project.

CFVMC's application contains unreliable MRI utilization projections, will result in an unnecessary duplication of existing services and provides unsupported financial projections. See additional discussion under Criteria (3), (4), (5), (6), (12) and (18a).

Criterion (3) - Need and Population to be Served

CFVMC currently controls 71% of the fixed MRI scanners in Cumberland County. If this project is approved, CFVMC and its related entity, VRI, will control 75% of the fixed MRI scanners in Cumberland County. In this proposal, CFVMC is requesting a fourth hospital-based MRI unit at an exorbitant capital cost of \$7.2 million for 2,400 square feet of new space. The average gross charge per MRI procedure will exceed \$4,000 at CFVMC, approximately double Carolina Imaging's. As the chart above demonstrates, CFVMC's prices for the most commonly performed MRI scans are significantly higher than Carolina Imaging's.

There are several concerns about the reasonableness of CFVMC's MRI projections and the need the service area has for another CFVMC fixed MRI unit.

1. CFVMC states that it has experienced "robust" growth in its MRI services.

The chart below is an excerpt from page 36 of the CFVMC application.

Cape Fear Valley Medical Center Fixed MRI Scanners

						19-23
MRI Procedure Type	FFY2019	FFY2020	FFY2021	FFY2022	FFY2023	CAGR
Inpatient Scans <u>with</u>						
Contrast or IV Sedation	1,237	1,316	1,313	1,336	1,394	3.0%
Inpatient Scans without						
Contrast or IV Sedation	3,406	3,285	3,343	3,449	3,697	2.1%
Outpatient Scans <u>with</u>						
Contrast or IV Sedation	1,137	1,583	1,706	1,736	1,539	7.9%
Outpatient Scans without						
Contrast or IV Sedation	1,814	2,513	2,858	3,018	3,134	14.6%
Total MRI Scans	7,594	8,697	9,220	9,539	9,764	6.5%
Adjusted MRI Scans	12,009	13,196	13,789	14,227	14,678	5.1%

Source: 2020-2024 CFVMC License Renewal Applications

CFVMC has experienced robust growth in utilization of its fixed MRI scanners across both inpatient and outpatient platforms. CFVMC's fixed MRI utilization (unadjusted) increased by a CAGR of 6.5 percent from FFY2019-FFY2023. CFVMC performed 4,893 adjusted MRI procedures per fixed MRI scanner during FFY2023, which is well above the MRI performance standard of 3,494 set forth in 10A NCAC 14C .2703(7)(a).

CFVMC is mistaken. Its outpatient contrast scans *decreased* by 11% last year. Inpatient scans with contrast have remained essentially the same for the last four years. CFVMC year over year scan volume for adjusted volume are misleading due to changes in the MRI methodology for counting "complex" inpatient and outpatient scans. From FFY 2022 through FFY 2023, unadjusted scan volume increased by only 2.3%. From FFY 2021 to FFY 2022, unadjusted scan volume increased by only 3.4%.

CFVMC is a 50% owner in Valley Regional Imaging (VRI), which currently operates two outpatient fixed MRI scanners. From FY 2022 through FY 2023, VRI's MRI volume *decreased* by 4.2%. The table on page 36 of the CFVMC application is misleading because it *does not include* the 2 scanners at VRI so it creates a false picture of utilization. In fact, VRI's utilization is declining and projected to be flat in PY 1-3. See pages 99-100 and 106-107.

CFVMC's projections, which show an increase of 2,669 adjusted scans over five years, hardly justifies another fixed MRI scanner when those projected scans could readily be absorbed by other scanners, including the underutilized scanners in Hoke, Bladen, and Harnett Counties or at VRI in Fayetteville.

CFVMC points to its planned 92 acute care bed expansion as further support for the fixed MRI project. The Agency should give no weight to this claim. Forty-five of these 92 acute care beds were part of Project ID No. M-8689-11, which means this project is still undeveloped after 13 years. According to the 2024 SMFP, CFVMC Valley is projected to have *surplus* acute care beds in 2026.

Moreover, CFVMC has failed to show, through reasonable and supported assumptions, that the additional beds will have any material bearing on MRI volumes. There is no information in the application showing that inpatient MRI scans have caused or are likely to cause any delays in the delivery of outpatient MRI scans. Though CFVMC mentions Valley Regional Imaging, its joint venture that owns two MRI scanners, it fails to discuss why these two scanners, located in close proximity to the

hospital, cannot absorb more outpatient volume, thus freeing up capacity to handle more inpatient scans, assuming there is any need for additional inpatient scan capacity.

In CFVMC MRI Project Year 1 (FFY 2027), CFVMC projects only <u>124</u> additional inpatient MRI scans from FFY 2026. CFVMC indicates that the proposed acute care expansion will be operational in 2025. By FFY 2027, CFVMC is not expecting significant increases in inpatient MRI procedures. See page 106 of the CFVMC application. These 124 additional inpatient scans could be readily absorbed by CFVMC's existing MRI scanner located inside the hospital. It would hardly appear feasible that such an expensive project represents the best alternative for the development of the fixed MRI scanner in Cumberland County.

Table 9: Cape Fear Valley Medical Center Fixed MRI Utilization

Minus Incremental Bladen County Patient MRI Procedures to be Served at CFV-Bladen

MRI Procedure type	FFY2024	FFY2025	FFY2026	FFY2027	FFY2028	FFY2029
Inpatient Scans <u>with</u>						
Contrast or IV Sedation	1,415	1,437	1,458	1,503	1,548	1,595
Inpatient Scans without						
Contrast or IV Sedation	3,735	3,774	3,813	3,892	3,973	4,055
Outpatient Scans <u>with</u>						
Contrast or IV Sedation	1,562	1,587	1,611	1,660	1,715	1,771
Outpatient Scans without						
Contrast or IV Sedation	3,180	3,233	3,281	3,380	3,491	3,607
Total MRI Scans	9,892	10,031	10,164	10,435	10,727	11,028
Adjusted MRI Scans	14,866	15,066	15,260	15,656	16,077	16,510
Avg Adjusted						
MRI Scans per Unit	4,955	5,022	3,815	3,914	4,019	4,127

2. CFVMC fails to adequately explain why it projects to serve a significant portion of Bladen County residents after the development of the fixed MRI scanner at CFVMC Valley – Bladen County Hospital.

As stated in CFVMC's application on page 107, it filed a CON application to acquire a fixed MRI scanner for Cape Fear Valley – Bladen County Hospital (Project I.D. No. N-12454-23). On page 107 of the CFVMC application, the applicant attempted to explain how it arrived at its Bladen County patient projections. CFVMC has significantly overstated its projections for Bladen County.

Current MRI patient origin data indicates that Bladen County residents represent 14.6% of all patients, or 1,429 patients during FFY 23. See the chart below from CFVMC application, page 30.

The service component included in this proposal is fixed MRI. The following table provides historical patient origin for CFVMC's fixed MRI scanners during FFY2023.

	FFY2023			
	10/01/2022 to 09/30/2023			
County	Patients	% of Total		
Cumberland County	5,959	61.0%		
Bladen County	1,429	14.6%		
Harnett County	695	7.1%		
Sampson County	459	4.7%		
Robeson County	442	4.5%		
Hoke County	314	3.2%		
Lee County	79	0.8%		
Other*	387	4.1%		
Total	9,764	100.0%		

^{*}Other includes <1 percent patient origin from the remaining counties in NC and other states.

The overall patient origin for CFVMC for FFY 2023 is provided below. Bladen County patients represent only 1.7% of CFVMC's patient origin for the entire facility but 14.6% for MRI services. This would be indicative of an accessibility issue to imaging services and likely the reason a fixed MRI scanner was approved for Cape Fear Valley – Bladen County Hospital. For Hoke and Harnett Counties, where Cape Fear Valley operates fixed MRI scanners, the percentages are similar in each category; Hoke County – 3.2% MRI/3.0% overall and Harnett County – 7.1% MRI/6.9% overall.

The following table provides historical patient origin for the entire CFVMC facility during FFY2023.

	FI	FY2023		
	10/01/2022 to 09/30/2023			
County	Patients	% of Total		
Cumberland County	241,907	76.1%		
Harnett County	22,029	6.9%		
Robeson County	17,062	5.4%		
Hoke County	9,657	3.0%		
Sampson County	9,093	2.9%		
Bladen County	5,316	1.7%		
Other*	12,619	4.0%		
Total	317,683	100.0%		

 $^{^*}$ Other includes <1 percent patient origin from each of the remaining counties in NC and other states.

With Cape Fear Valley – Bladen County Hospital approved for a fixed MRI scanner, it would seem reasonable to project a substantial *decrease* in the number of patients from Bladen County, which is nearly 40 miles from CFVMC in Fayetteville. Instead, CFVMC projects that it will serve even more Bladen County MRI patients than it currently does. This is not a reasonable assumption.

The service component included in this proposal is fixed MRI. The following table provides projected patient origin for CFVMC's fixed MRI services during the first three project years.

	Cape Fear Valley Medical Center *						
Fixed MRI	1 st Full FF	1st Full FFY FY2027 2		2 nd Full FY FFY2028		Y FFY2029	
	10/01/2026 to	o 9/30/2027	10/01/2027	to 9/30/2028	10/01/2028	to 9/30/2029	
County	Number of Patients **	% of Total	Number of Patients ** % of Total		Number of Patients **	% of Total	
Cumberland County	6,432	61.6%	6,611	61.6%	6,795	61.6%	
Bladen County	1,439	13.8%	1,480	13.8%	1,524	13.8%	
Harnett County	750	7.2%	771	7.2%	792	7.2%	
Sampson County	495	4.7%	509	4.7%	523	4.7%	
Robeson County	477	4.6%	490	4.6%	504	4.6%	
Hoke County	339	3.2%	348	3.2%	358	3.2%	
Lee County	85	0.8%	88	0.8%	90	0.8%	
Other*	418	4.0%	430	4.0%	441	4.0%	
Total	10,435	100.0%	10,727	100.0%	11,028	100.0%	

^Other includes less than one percent of patients from the remaining North Carolina counties and other states.

As seen in this chart from page 32 of the CFVMC application, CFVMC projects that Bladen County patients will continue to be the second largest patient group for its MRI services well after the development of the fixed MRI unit at Cape Fear Valley – Bladen County Hospital. Inexplicably, CFVMC contends that Bladen County MRI patients will increase as follows:

Bladen County Patients	Historical	CFVMC
	FFY 2023	PY 1 – FFY
		2027
CFV- Bladen County Hospital	405	715
CFVMC – Fayetteville	1429	1439
Bladen County Patient Totals	1834	2154
Projected Increase in Bladen County MRI Patients from FFY 2	17.4%	
2027		

This should match the name provided in Section A, Question 4.

^{**} Home health agencies should report the number of unduplicated clients.

CFVMC fails to adequately explain why the projected number of Bladen County patients are reasonable. According to CFVMC, Bladen County MRI patients will increase by over 17% in the next four years. As noted in CFVMC's population data on page 39, Bladen County's population is expected to *decline* from 2023 through 2028. See the chart below.

CFVMC Catchment Area
Projected Population

Year	Bladen	Cumberland	Harnett	Hoke	Robeson	Sampson	Total
2023	28,902	342,872	141,501	55,417	117,596	59,425	745,713
2024	28,850	343,636	145,438	56,269	118,737	59,770	752,700
2025	28,812	344,230	148,515	57,140	119,873	60,032	758,602
2026	28,781	344,694	151,521	58,023	121,009	60,237	764,265
2027	28,762	345,055	153,541	58,913	122,142	60,393	768,806
2028	28,748	345,336	155,457	59,813	123,270	60,512	773,136

Source: North Carolina Office of State Budget & Management

Thus, CFVMC is asking the Agency to assume: 1) despite the addition of a fixed MRI scanner in Bladen County, Bladen County patients will continue to travel a significant distance to receive MRI scans at CFVMC; and 2) despite a declining population, the number of Bladen County MRI patients will grow. Neither assumption is reasonable nor supported. CFVMC fails to adequately explain the basis for its Bladen County patient projections. As such, the MRI utilization projections are overstated and unreliable.

3. CFVMC operates other fixed MRI scanners that are chronically underutilized in Hoke and Harnett Counties.

CFVMC also owns and operates fixed MRI scanners in Hoke and Harnett Counties. During FFY 2023, CFVMC's MRI patients from Harnett County accounted for 7.1% and 3.2% from Hoke County totaling just over 1,000 patients. According to the 2024 SMFP, CFVMC's fixed MRI scanner in Harnett County performed less than 2,400 adjusted procedures. CFVMC's fixed MRI scanner in Hoke County performed just 691 adjusted procedures.

Table 15E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	В	С	D	E	F	G	Н	I	J	K	L
Service Area	Service Type	CON#	Service Site (Provider/Owner)		Fixed Equiv	Total MRI Scans	Base Outpatient	Complex Outpatient	Base Inpatient	Complex Inpatient	Adjusted Total
							'			·	
Harnett	Hospital Fixed	M-006712-02	Betsy Johnson Hospital		1.00	1,778	466	912	191	209	2,362
Hoke	Hospital Fixed		Cape Fear Valley Hoke - Health Pavilion	1	1.00	690	685	5	0	0	691

CFVMC fails to adequately explain why using all of the fixed MRI scanners available to its patients in Bladen, Hoke and Harnett Counties is not a viable option to address any incremental demand it expects in FFY 2027-2029.

CFVMC fails to demonstrate the need for the proposed project as required by Criterion (3) based on reasonable and supported MRI utilization projections. The Agency should find the CFVMC application non-conforming with Criterion (3).

<u>Criterion (4) –Least Costly, Most Effective Alternative</u>

Criterion (4) requires an applicant to demonstrate that the least costly or most effective alternative has been proposed. CFVMC has failed to do so. The least costly or most effective alternative for CFVMC is to make better use of the scanners it already owns in Cumberland, Bladen, Harnett, and Hoke Counties. As the foregoing discussion illustrates, there is sufficient excess capacity available on the existing MRI scanners that CFVMC can meet patient needs while avoiding an exorbitant \$7.2 million capital cost and lengthy development period to complete its proposed project. In contrast, Carolina Imaging will be able to develop its project for \$2.5 million in a one-year development period, which means services will be available much faster for outpatients. Both applicants propose to purchase a GE Voyager 1.5T MRI scanner. While CFVMC plans to offer the same MRI technology as Carolina Imaging, but at much higher capital cost, higher gross charge per procedure and higher net revenue per procedure.

CFVMC owns and operates five (5) existing fixed MRI scanners in Cumberland County alone. CFVMC owns and operates fixed MRI scanners in Harnett, Bladen and Hoke Counties that are currently underutilized. Patients from these three counties represent more than 24% of CFVMC's projected MRI patients in FFY 2027. CFVMC has alternative methods currently available to it to meet the needs outlined in its proposed project.

Further, CFVMC does not discuss the alternative of replacing one of its three existing inpatient MRI scanners and relocating it to the proposed medical office building. In FFY 2027 (PY1), more than 48% of CFVMC's projected volume will be outpatient MRI scans.

Accordingly, the Agency should find the CFVMC application nonconforming with Criterion (4).

<u>Criterion (5) – Financial Feasibility</u>

As discussed under Criterion (3), CFVMC's MRI utilization projections and assumptions are both unreliable and unsupported. CFVMC fails to adequately explain why it continues to project a significant portion of Bladen County residents after the development of fixed MRI services within Bladen County.

CFVMC states that the project will be operation on January 1, 2026 but uses October 1, 2026 as the beginning of Project Year 1 in its financial proformas.

Form C.2a and C.2b Utilization - Assumptions and Methodology

The following section provides the specific assumptions and methodology used to project fixed MRI procedures at CFVMC.

Historical and projected utilization is based on the federal fiscal year Oct 1 – Sept 30, which is consistent with CFVHS's fiscal year. The project is expected to be complete and operational by January 2026. Therefore, the first three fiscal years of the project will be FY2027-FY2029.

CFVMC's project timetable from page 97:

Milesto	ne	Date mm/dd/yyyy
1	Financing Obtained	
2	Drawings Completed	
3	Land Acquired	
4	Construction / Renovation Contract(s) Executed	
5	25% of Construction / Renovation Completed (25% of the cost is in place)	
6	50% of Construction / Renovation Completed	
7	75% of Construction / Renovation Completed	
8	Construction / Renovation Completed	11/01/2025
9	Equipment Ordered	01/01/2025
10	Equipment Installed	11/15/2025
11	Equipment Operational	12/01/2025
12	Building / Space Occupied	12/01/2025
13	Licensure Obtained	
14	Services Offered *	01/01/2026
15	Medicare and / or Medicaid Certification Obtained	
16	Facility or Service Accredited	
17	First Annual Report Due * ^	01/01/2028

Required

The impact of CFVMC's error in using 10/1/2026 as the beginning of Project Year 1, instead of January 1, 2026, is that it allows CFVMC an additional nine months for utilization and financial projections in order to meet the required MRI levels contained in 10A NCAC.2700. Without the additional time from January 2026-October 2026, it is questionable whether CFVMC would exceed the required MRI threshold of 3,494 adjusted procedures. Coupled with overstated projections as discussed under Criterion 3, it is unlikely that CFVMC has provided reasonable and supported utilization projections.

CFVMC also understated its equipment maintenance each year as it projects an increase of only \$4,000 for a new MRI scanner.

CFVMC fails to identify any rental expenses related to the square footage space for the proposed MRI scanner in the new outpatient building, which further underestimates CFVMC's operating expenses related to the proposed project.

CFVMC has also overestimated the number of Bladen County residents who will utilize the proposed service, and failed to fully utilize fixed MRI services owned by Cape Fear Valley that are available in Harnett, Hoke and Bladen Counties. This calls into question the reasonableness of the financial projections as it is based on the MRI utilization projections.

CFVMC has failed to demonstrate that its financial projections are based on supported and reasonable assumptions and should be found non-conforming with Criterion (5).

Criterion (6) – Unnecessary Duplication of Existing Services

As discussed under Criteria (3) and (5), CFVMC fails to explain why its proposed project will not result in an unnecessary duplication of existing services. CFVMC fails to explain why more efficient utilization of its existing MRI resources, including the two scanners at VRI, are not being considered as viable options. CFVMC has failed to demonstrate that its proposed project will not result in an unnecessary duplication of existing services and should be found non-conforming with Criterion (6).

Criterion (12) - Proposed Construction is Reasonable and Does not Result in Increased Costs

CFVMC has failed to demonstrate that its proposed project is conforming to Criterion (12), which states:

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.

In this proposal, CFVMC is requesting a fourth hospital-based MRI unit at an exorbitant capital cost of \$7.2 million for 2,400 square feet of new space. Under Criterion (5), Carolina Imaging has provided information that details the high price of MRI procedures at CFVMC. See also the chart on page 2 of these comments. CFVMC states numerous times that the proposed project is needed to enhance outpatient MRI accessibility but it already has sufficient outpatient capacity at CFVMC, VRI and its satellite hospitals in Bladen, Hoke, and Harnett Counties.

<u>Page 29</u>- "The proposed project will provide convenient access for service area outpatients needing MRI services. In addition, by redirecting a greater volume of outpatient cases from the MRI scanner from within the hospital to the new ambulatory site, the proposed project will enhance patient convenience."

<u>Page 36</u> – "Developing the proposed fixed scanner in an outpatient setting will enable CFVMC to redirect a greater volume of outpatient cases from the MRI scanner from within the hospital to the new ambulatory site. This approach minimizes the need for outpatients to compete for MRI access with inpatient and emergency cases, thereby improving overall efficiency and access for inpatient and outpatient cohorts."

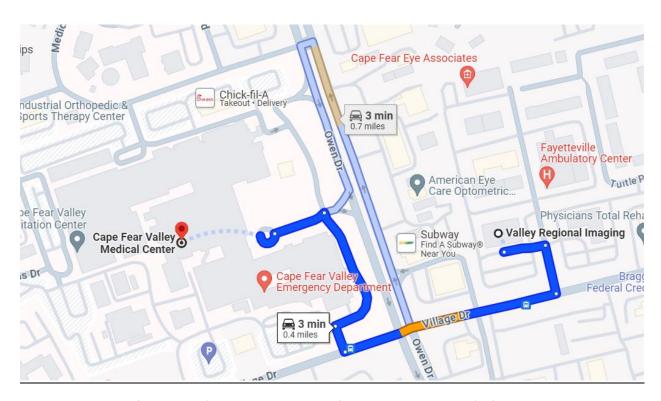
<u>Page 59</u> – "The proposed 1.5T fixed MRI scanner allows CFVMC to diversify its service offerings in the outpatient setting."

However, in Section E, CFVMC dismisses the alternative of developing the proposed fixed MRI at its existing outpatient imaging center citing "significant renovations and construction". CFVMC fails to explain how a \$7.2 million project is the more effective alternative for the development of the proposed MRI.

Develop The Proposed Fixed MRI Scanner At VRI

Cumberland County Hospital System, Inc. is a member of VRI, which is an existing diagnostic center in Cumberland County with two fixed MRI scanners. Thus, another alternative is to develop the proposed fixed MRI scanner at VRI. However, adding capacity at VRI would not provide the same level of coordination of care with other CFVMC campus clinic services compared to the project as proposed. Adding capacity at VRI would not effectively extend training opportunities to the radiology residents onsite at CFVMC. In addition, CFVMC already has plans to develop a new outpatient building in which its existing outpatient diagnostic services will be located. The proposed fixed MRI scanner can be efficiently incorporated into the planned campus project. Development of an additional fixed MRI scanner at VRI would require significant renovations and construction which would interrupt ongoing operations at the busy diagnostic center. For these reasons, CFVMC determined this alternative is not the most effective at this time.

As the following map shows, CFVMC and VRI are 0.4 miles apart in Fayetteville.



The Agency should find CFVMC's application non-conforming with Criterion (12).

<u>Criterion (18a) – Positive Impact on Competition</u>

CFVMC's application will not enhance competition in the service area and will not have a positive impact on cost-effectiveness, quality and access. Currently, CFVMC controls 71% of the fixed MRI scanners (5 out of 7) in Cumberland County. If this project is approved, CFVMC will have a near monopoly with 75% of the fixed MRI scanners in Cumberland County under its control. CFVMC is proposing a \$7.2 million project that will require a two-year development period. Despite its claims that the proposed scanner

is needed due to additional acute care beds, there are only 124additional inpatient scans projected in PY 1. The approval of a sixth fixed MRI scanner for CFVMC at the cost of \$7.2 million that will take approximately two years to complete does not create a positive impact on competition in Cumberland County. Residents of Cumberland County need immediate access to convenient and cost-effective outpatient MRI services. Moreover, as shown on page 2 of these comments, CFVMC's hospital-based pricing for its MRI services does not promote cost effectiveness or access for patients, especially for those who do not have insurance or have high deductible health plans.

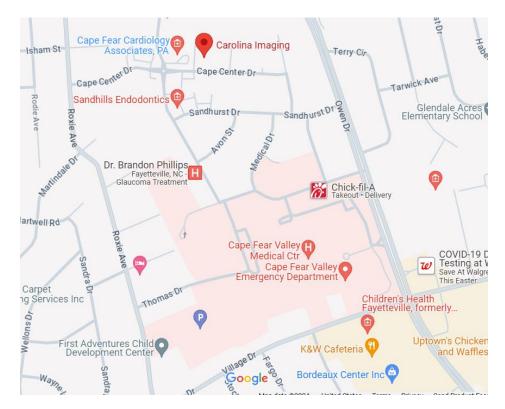
The Agency should find CFVMC's application non-conforming with Criterion (18a).

Comparative Analysis

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2024 SMFP, there is a need for one fixed MRI scanner in Cumberland County. There are two applicants in this review but only one applicant can be approved. The last MRI need determination available in Cumberland County was 2007. It is critical that the proposed MRI scanner is awarded to a provider that can provide high quality scans to the broadest patient population in a cost-effective outpatient setting. The only provider in this review who can do this is Carolina Imaging.

Geographic Accessibility

The primary advantage in terms of accessibility is that Carolina Imaging offers a convenient outpatient location, IDTF pricing, a reasonable development period and a low capital cost. Both applicants are proposing to acquire a 1.5T MRI scanner. CFVMC's proposal will require a lengthy development schedule and a staggering \$7.2 million price tag. As shown on page 2 of these comments, there is a dramatic difference in pricing between these two applicants with Carolina Imaging offering much more patient friendly pricing. Geographic access and financial access go hand in hand. A service that is geographically accessible but financially out of reach does not promote access at all. Both applicants agree that focusing on outpatient MRI services is most needed in Cumberland County. Both applicants propose a location in Fayetteville. Carolina Imaging and CFVMC are approximately 1 mile apart. See the map below.



Carolina Imaging's proposal has the added benefit of serving as a training site for MRI technologists in partnership with Edgecombe Community College. Access for MRI students is vital considering the ongoing critical shortage of MRI technologists in North Carolina and across the country.

Despite superficial similarities, these two proposals are not the same at all. Compared to CFVMC, Carolina Imaging represents the most effective alternative to quickly and cost-effectively deliver additional access to fixed MRI capacity for service area residents and MRI technologists in training.

Access by Underserved Groups

Carolina Imaging's projected payor source is based on its long-standing history of providing high quality MRI services for the community. Carolina Imaging's commitment to provide high-quality MRI services to all patients is reflected in its application and support from the medical community for its project.

The following table provides the payor source data for each applicant.

Payor	Carolina Ima	CI	FVMC – Year 3 11,028	
	Percentages	Patients	Percentages	Patients
Charity Care	1.8%	231	2.4%	265
Self Pay	Included in Charity		2.6%	287
Medicare	36.1%	4633	47.1%	5194
Medicaid	10.2%	1309	16.0%	1764
TriCare	23.7%	3042	6.0%	662

Source: Application Section L for each applicant.

As discussed in Section C of the Carolina Imaging application, Cumberland County has a unique patient population as home to the US Military's largest base in the United States. With active-duty, retired personnel and dependents, the US Military has partnered with Carolina Imaging for more than two decades to provide vital MRI services for its population. This category of patient is not typically seen in most service areas. This special patient population encounters more hazardous conditions conducting their training and service to our nation than the civilian population. As a result, many of these patients have special concerns such as shrapnel or metal medical components. This is one of the primary factors that lead Carolina Imaging to select a state of the art 1.5T MRI scanner for this patient population. A 1.5T MRI scanner is the safer option for patients with non-removable metal in their bodies. As the chart above shows, TriCare patients represent a significant portion of Carolina Imaging's patients.

Carolina Imaging is also the exclusive partner with the US Military for prostate MRI procedures in Cumberland County. Carolina Imaging has installed the necessary software to effectively communicate with the military health system so that the imaging studies can be streamlined between the two healthcare systems.

While TriCare is not on the list of underserved patients found in Criterion (13), members of the military may fall into any of the categories of medically underserved patients listed in Criterion (13). Also, the military is not always able to provide timely and convenient access to services, so providers like Carolina Imaging are critically important in meeting the needs of military members and their families.

Further, as discussed above, there is a dramatic difference in pricing between these two applicants. For patients who are uninsured, underinsured, or have high deductible health plans, a facility's posted charges really matter. The Agency has a statutory duty under Criterion (13) to protect the interests of patients who may not able to pay for their care, and the only way the Agency can discharge that responsibility in this review is to approve the Carolina Imaging application.

With regard to access by the medically underserved, Carolina Imaging is the most effective alternative.

Projected Average Gross Revenue per MRI Procedures

The projected average gross revenue per MRI procedure is a comparative factor used by the Agency. CFVMC is proposing to add a fourth hospital-based fixed MRI scanner, which can be more costly for patients than services provided at a freestanding outpatient facility. CFVMC projects that 48% of its MRI volume will be performed on outpatients. It is important for the Agency to consider such high demand for outpatient MRI services that a freestanding facility offers a more cost-effective option for patients.

Comparison of Average Gross Revenue per Procedure – PROJECT YEAR 3

Applicant	Gross Revenue	# of Unweighted Procedures	Total Gross Revenue Per
			Procedure
Carolina Imaging	\$27,245,625	12835	\$2,123
CFVMC	\$46,318,347	11028	\$4,200

Source: Form C and Form F.2 from each application.

The comparison reveals a dramatic difference between the two applicants, with Carolina Imaging's average gross revenue per procedure approximately 50% that of CFVMC's. Since one of the primary purposes of CON is cost control, the Agency should find this difference compelling.

A comparison of MRI charges for each applicant demonstrates that Carolina Imaging is a more cost effective alternative for both patients and third party payors.

MRI CPT Code	CPT Code Description	Carolina Imaging's Charge	CFVMC's Charge	Percentage Difference from Carolina Imaging
72141	Cervical spine without contrast	\$1710	\$5152	+201%
73221	Upper extremity without contrast	\$1650	\$3722	+126%
73721	Lower extremity without contrast	\$1650	\$3559	+116%
72148	Lumbar spine without contrast	\$1840	\$5120	+178%
70551	Brain without contrast	\$1690	\$5461	+223%
70553	Brain with and without contrast	\$3580	\$6281	+75%

Source: <u>Price Transparency | Patients & Visitors | Cape Fear Valley Health</u> <u>www.capefearvalley.com/patients/price-transparency.html</u>; Carolina Imaging internal data

Patients at Carolina Imaging also benefit from a comprehensive rate for services which includes the radiologist reading fees. Although CFVMC states on page 66 that *it* does not charge reading fees, CFVMC patients can be billed separately by the radiology groups reading their MRI scans. Therefore, the Agency should not assume that there is no reading fee for MRI services performed on CFVMC's

scanners. In fact, it would be highly unusual if there were no reading fee charged by CFVMC's radiology group.

Regarding projected average gross revenue per MRI procedure, Carolina Imaging is the most effective alternative.

Projected Average Net Revenue per MRI Procedures

The following table presents the projected average net revenue per MRI procedures for the third year of operation for the applicants based on the information provided in Form C and Form F.2 of each application.

Comparison of Average Net Revenue per Procedure – Project Year 3

Applicant	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue Per MRI Procedure
Carolina Imaging	\$6,781,436	12835	\$528.35
CFVMC	\$7,642,527	11028	\$693.00

Source: Form C and Form F.2 from each application.

Again, the difference between the two applicants is significant. Carolina Imaging's average net revenue per procedure is approximately 24% lower than CFVMC's. Carolina Imaging is the most effective alternative with regard to projected average net revenue per MRI procedure.

Projected Average Operating Expense per MRI Procedures

The following table presents the projected average operating expense per MRI procedures for the third year of operation for the applicants based on the information provided in Form C and Form F.3 of each application.

Comparison of Average Operating Expense per Procedure – PROJECT YEAR 3

Applicant	Operating Expenses	# of Unweighted MRI Procedures	Average Operating Expense Per MRI
Carolina Imaging	\$4,252,341	12835	Procedure \$331.31
CFVMC	\$3,632,559	11028	\$329.39

Source: Form C and Form F.3 from each application.

While the average operating cost for each applicant varies by only \$1.92 per procedure, there is a critical difference between the two applicants. Currently, Carolina Imaging pays its MRI technologists \$88,555 annually compared to CFVMC's current MRI technologist salary of \$78,820, which is a difference of 12.4%. By FY 2027, Carolina Imaging's technologists will make approximately \$102,660 while CFVMC will pay only \$86,129. Considering the critical shortage of qualified MRI technologists, Carolina Imaging believes it is vital to compensate its staff appropriately. Carolina Imaging also pays for three

radiologists to work on staff, which accounts for an additional \$1,350,000 in salary expense. By keeping radiologists on staff at Carolina Imaging, it reduces the cost to the patient as the patient is not charged separately for radiologist reading fees and it maintains a high standard of care.

Carolina Imaging accurately provides all necessary operating costs associated with the project. It does not appear that CFVMC has accounted for other necessary expenses such as rent expense, PACS and imaging archiving. Without properly applying all operating costs, CFVMC's estimated operating cost per procedure as shown in the previous chart is unreliable. In comparison, Carolina Imaging has accounted for all necessary operating expenses and projected higher salaries for staff, which provides reliable financial pro formas for the proposed project.

With regard to projected average operating expense per MRI procedure, Carolina Imaging is the most effective alternative.

Conclusion

Carolina Imaging's application meets all applicable review criteria and standards for MRI services. Based on the comparative analysis, Carolina Imaging's application is the most effective alternative for the development of the proposed MRI scanner based on the following factors:

- Carolina Imaging is the most effective alternative regarding geographic accessibility. Both applicants agree that a 1.5T MRI scanner is needed to primarily serve outpatient need.
 Carolina Imaging will develop the proposed scanner quickly and at a lower capital cost, which in turn improves access in more timely fashion.
- Carolina Imaging is the most effective alternative regarding average gross revenue per procedure and lower prices for most commonly performed MRI scans.
- Carolina Imaging is the most effective alternative regarding average net revenue per procedure.
- Carolina Imaging is the most effective alternative regarding average operating expense per procedure, as it will offer much higher salaries for its MRI technologists and maintains radiologists on staff.
- Carolina Imaging is the most effective alternative regarding the provision of service to the medically underserved populations, including Charity Care/Self Pay, Medicare and Medicaid patients, and TriCare patients.
- Both applicants are existing providers of fixed MRI services in Cumberland County. CFVMC currently owns and operates the vast majority of fixed MRI units. The approval of a new fixed MRI scanner at Carolina Imaging will have a positive impact on competition.

The outcome of this MRI review is critical for the Cumberland County MRI service area. The last MRI need determination for this service area was in 2007. During the last 17 years, Carolina Imaging has worked nonstop to provide high quality imaging services in a convenient outpatient setting. Each year, Carolina Imaging continues to experience high demand for its MRI services without relief. Carolina

Imaging is the only applicant in this review that has a demonstrated need for additional MRI capacity based on its current operations. The approval of the Carolina Imaging application will benefit the Cumberland County MRI service area by allowing a provider, with a proven track record of high-quality service and outreach to the medically underserved populations, the ability to offer additional fixed MRI services for the community at reasonable costs and charges. The approval of Carolina Imaging's application will provide the greatest good for the greatest number of service area residents and their referring physicians.

The Carolina Imaging application should be approved and the CFVMC application should be denied.

Location	Code Type	Code	Procedure	Procedure Description	Price
10199	EAP	CPT® 70540	32100434	HC MRI Orb/Face/Neck WO Cont Only	5,847.08
10199	EAP	CPT® 70551	32100435	HC MRI Brain W/O Cont Only	5,460.85
10199	EAP	CPT® 72141	32100436	HC MRI Spinal Can/C-Spine W/O Cont	5,152.97
10199	EAP	CPT® 72146	32100437	HC MRI Spinal Can/T-Spine W/O Cont	5,389.94
10199	EAP	CPT® 72148	32100438	HC MRI Spinal Can/L-Spine W/O Cont	5,120.12
10199	EAP	CPT® 73720	32100439	HC MRI Lower Ext Non Jt W/WO Cont Lt	4,704.84
10199	EAP	CPT® 73720	32100440	HC MRI Lower Ext Non Jt W/WO Cont Rt	4,704.84
10199	EAP	CPT® 73221	32100441	HC MRI Upper Ext Any Jt W/O Cont Lt	3,722.16
10199	EAP	CPT® 73221	32100442	HC MRI Upper Ext Any Jt W/O Cont Rt	3,722.16
10199	EAP	CPT® 73721	32100443	HC MRI Lower Ext Any Jt W/O Cont Lt	3,559.17
10199	EAP	CPT® 73721	32100444	HC MRI Lower Ext Any Jt W/O Cont Rt	3,559.17
10199	EAP	CPT® 70553	32100445	HC MRI Brain W/WO Cont	6,884.06
10199	EAP	CPT® 72156	32100446	HC MRI C-Spine W/WO Cont	6,821.13
10199	EAP	CPT® 72157	32100447	HC MRI T-Spine W/WO Cont	7,437.08
10199	EAP	CPT® 72158	32100448	HC MRI L-Spine W/WO Cont	7,065.06
10199	EAP	CPT® 70544	32100449	HC Mra Head W/O Cont Only	5,083.08
10199	EAP	CPT® 70547	32100450	HC Mra Neck W/O Cont Only	4,736.03
10199	EAP	CPT® 70549	32100451	HC Mra Neck W/WO Cont	6,680.97
10199	EAP	CPT® 70543	32100452	HC MRI Orb/Face/Neck W/WO Cont	7,738.10
10199	EAP	CPT® 72195	32100453	HC MRI Pelvis W/O Cont Only	5,055.05
10199	EAP	CPT® 72197	32100454	HC MRI Pelvis W/WO Cont	6,978.92
10199	EAP	CPT® 73218	32100455	HC MRI Up Ext No Jt W/O Cont Only Lt	2,753.59
10199	EAP	CPT® 73218	32100456	HC MRI Up Ext No Jt W/O Cont Only Rt	2,753.59
10199	EAP	CPT® 73223	32100457	HC MRI Upper Ext Any Jt W/WO Cont Lt	4,817.99
10199	EAP	CPT® 73223	32100458	HC MRI Upper Ext Any Jt W/WO Cont Rt	4,817.99
10199	EAP	CPT® 73718	32100459	HC MRI Low Ext No Jt W/O Cont Only Lt	3,498.73