REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: July 23, 2025 Findings Date: July 30, 2025

Project Analyst: Ena Lightbourne Co-Signer: Micheala Mitchell

Project ID #: G-12608-25

Facility: Duke Imaging Mebane

FID #: 250156 County: Alamance

Applicant(s): Duke University Health System, Inc.

Project: Acquire a fixed MRI scanner pursuant to the 2025 SMFP need determination to be

located at Duke Imaging Mebane.

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

Duke University Health System, Inc., hereinafter referred to as "the applicant", or "DUHS", proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be upfitted in a medical office building that will be developed at as an Independent Diagnostic Testing Facility (IDTF) in Mebane of Alamance County. The facility will be named Duke Imaging Mebane.

Need Determination

The 2025 SMFP includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2025 SMFP identified a need for one fixed MRI scanner in Alamance County. The application was submitted in response to the need determination in the 2025 SMFP for one fixed MRI

scanner in Alamance County. Therefore, the application is consistent with the need determination in the 2025 SMFP.

Policies

There are two policies in the 2025 SMFP that are applicable to this review, *Policy GEN-4:* Energy Efficiency and Sustainability for Health Service Facilities and Policy GEN-5: Access to Culturally Competent Healthcare.

Policy GEN-4 on page 30 of the 2025 SMFP states:

"Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

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

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

Policy *GEN-4*. The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 27, the applicant describes the project's plan to improve energy efficiency and water conservation.

Policy GEN-5: Access to Culturally Competent Healthcare states:

"A certificate of need (CON) applicant applying to offer or develop a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will provide culturally competent healthcare that integrates principles to increase health equity and reduce health disparities in underserved communities. The delivery of culturally competent healthcare requires the implementation of systems and training to provide responsive, personalized care to individuals with diverse backgrounds, values, beliefs, customs, and languages. A certificate of need applicant shall identify the underserved

populations and communities it will serve, including any disparities or unmet needs of either, document its strategies to provide culturally competent programs and services, and articulate how these strategies will reduce existing disparities as well as increase health equity.

CON applications will include the following:

The applicant shall, in its CON application, address each of the items enumerated below:

- Item 1: Describe the demographics of the relevant service area with a specific focus on the medically underserved communities within that service area. These communities shall be described in terms including, but not limited to: age, gender, racial composition; ethnicity; languages spoken; disability; education; household income; geographic location and payor type.
- *Item 2:* Describe strategies it will implement to provide culturally competent services to members of the medically underserved community described in Item 1.
- *Item 3:* Document how the strategies described in Item 2 reflect cultural competence.
- **Item 4:** Provide support (e.g., best-practice methodologies, evidence-based studies with similar communities) that the strategies described in Items 2-3 are reasonable pathways for reducing health disparities, increasing health equity and improving the health outcomes to the medically underserved communities within the relevant service area.
- Item 5: Describe how the applicant will measure and periodically assess increased equitable access to healthcare services and reduction in health disparities in underserved communities.

In approving an application, Certificate of Need shall impose a condition requiring the applicant to implement the described strategies in a manner that is consistent with the applicant's representations in its CON application."

Policy *GEN-5*. In Section B, pages 28-31, the applicant explains why it believes its application is conforming to Policy *GEN-5*.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2025 SMFP.
- The applicant adequately demonstrates that the application is consistent with Policies *GEN-4* and *GEN-5* based on:
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to ensure improved energy efficiency and water conservation.
 - o The applicant states it will develop and implement an Energy Efficiency and Sustainability Plan for the project as required by the CON Section, that will not adversely affect patient or resident health, safety, or infection control.
 - O The applicant adequately describes the demographics of Alamance County, the proposed service area for the proposed fixed MRI scanner. The applicant provides demographic data, that includes age, racial composition, disability spoken language, education and household income.
 - The applicant adequately describes its strategies to provide culturally competent services to all patients, including medically underserved groups. As an existing health care system, DUHS has Health Equity, and Inclusion (HEDI) liaisons in place across the system to provide guidance on inclusive and equitable health care for all patients. Additionally, all clinical staff are required to complete training in cultural competence, gender identity, biases and discrimination and harassment compliance.
 - The applicant adequately describes one of DUHS and Duke School of Medicine's initiatives, Collaborate to Advance Clinical Health Equity (CACHE), to eradicate disparities in health outcome.
- (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.

 \mathbf{C}

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

Patient Origin

On page 334, the 2025 SMFP defines the fixed MRI 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 service area Alamance County. Facilities may also serve residents of counties not included in their service area.

The applicant does not own or operate a fixed MRI scanner in Alamance County, therefore, there is no historical patient origin to report. The following table illustrates projected patient origin.

Duke Imaging Mebane MRI Services						
		Projected	Patient Ori	gin		
	1 st Full FY 2 nd Full FY 3 rd Full FY					
	07/01/2026- 07/01/2027-			07/01/2028-		
County	06/30	/30/2027 06/30/2028		06/30/2029		
County	FY 2	2027	FY 2028		FY 2029	
	# of	% of	# of	% of	# of	% of
	Patients	Total	Patients	Total	Patients	Total
Alamance	942	85.0%	1,960	85.0%	3,057	85.0%
Other^	166	15.0%	346	15.0%	540	15.0%
Total	1,108	100.0%	2,306	100.0%	3,597	100.0%

Source: Section C, page 33

In Section Q, pages 100-105, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported that are based on population growth, MRI use rate, and historical patient origin of MRI services in the Alamance County. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Analysis of Need

In Section C, pages 35-46, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The SMFP change to the fixed MRI scanner methodology in 2023 has resulted in identifying a need for one fixed MRI scanner in Alamance County in the 2025 SMFP. (pages 35-37)
- The statewide increase in the MRI use rate is an indicator of the overall growing demand for MRI services. (pages 37-38)
- The percentage of county residents leaving the county for MRI services (outmigration), demonstrates the need to expand access to services in Alamance County. (pages 38-40)
- Alamance County residents would benefit from the first freestanding fixed MRI provider since most MRI scans performed in the county are outpatient. (pages 40-41)
- The applicant's proposal will serve as a possible lower-cost alternative to hospital-based MRI services. (page 41)

[^]Other include <1 percent patient origin from the remaining counties in Health Service Area (HSA) II and adjacent HSAs.

- The applicant is proposing to develop the fixed MRI scanner in a medical office building that will include other medical services such as specialty physician clinics and possibly a primary care practice. This will allow DUHS to enhance access and align services to its patient population. (pages 41-42)
- The applicant demonstrates the need to expand MRI services in Alamance County based on the projected population growth and aging in Alamance County, according to data from the North Carolina office of State Budget and Management (NCOSBM). (pages 43-44)
- The applicant determined that locating the proposed fixed MRI scanner in Mebane is the best option due to its rapid population growth and geographical accessibility, further demonstrating the need for proposal. (pages 44-45)
- The applicant's proposal will enhance access to MRI services to the medically underserved, who account for a significant percentage of the Alamance County population. (pages 45-46)

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

- The 2025 SMFP identifies the need for one additional fixed MRI scanner in the Alamance County fixed MRI scanner service area.
- The applicant provides information and data to support its assertions regarding service area population growth and aging and the need to expand capacity in Alamance County.
- The applicant is proposing to develop the IDTF alongside other specialty services to align healthcare for its patient population.
- As the first freestanding MRI provider in the service area, the applicant will introduce a possible lower cost option for MRI services.

Projected Utilization

In Section Q, page 98, the applicant provides projected utilization, as illustrated in the following table.

Duke Imaging Mebane MRI Services					
1 st Full FY 2 nd Full FY 3 rd Full FY					
FY 2027 FY 2028 FY 20					
# of Units	1	1	1		
# of Procedures	1,108	2,306	3,597		
# of Adjusted Procedures	1,214	2,526	3,940		

In Section Q, pages 99-105, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify the service area projected population growth

Table 1: Alamance County Population Growth						
	2025 2026 2027 2028 2029					
Alamance	185,255	187,282	189,311	191,339	193,364	

Source: Section Q, page 100; NCOSBM, Vintage 2024

Step 2: Identify the historical MRI Use Rate in Alamance County and statewide and the ratio of population per fixed MRI scanner

Т	Table 2: Alamance County MRI Procedure Rate				
Year	County Population	Alamance County MRI Procedures	Alamance County MRI Use Rate per 1,000		
FFY2018	166,638	11,264	67.60		
FFY2019	170,483	12,231	71.74		
FFY2020	172,348	11,936	69.26		
FFY2021	175,114	13,368	76.34		
FFY2022	178,334	13,496	75.68		
FFY2023	181,097	16,233	89.64		
5-Year CAGR	1.7%	7.6%	5.8%		

Source: Section Q, page 100; NCOSBM, Vintage 2024; FY2018-FY2023 MRI Patient Origin Reports, Patient County of Residence (Reflects the number of MRI procedures performed on Alamance County residents.)

	Table 3: North Carolina MRI Procedure Rate					
	Statewide	Statewide	Statewide MRI Use			
Year	Population	MRI Procedures	Rate per 1,000			
FFY2018	10,389,148	905,378	87.15			
FFY2019	10,508,254	939,196	89.38			
FFY2020	10,472,893	885,496	84.55			
FFY2021	10,573,149	975,892	92.30			
FFY2022	10,702,014	1,021,998	95.50			
FFY2023	10,846,274	1,104,821	101.86			
5-Year CAGR	0.9%	4.1%	3.2%			

Source: Section Q, page 101; NCOSBM, Vintage 2024; FY2018-FY2023 MRI Patient Origin Reports, Patient County of Residence (Reflects the number of MRI procedures performed on Alamance County residents.)

Table 4: Ratio of Population Per Fixed MRI Scanner					
2020 Total Fixed Ratio of Population Area Population MRI Scanners per Fixed MRI Scanner					
Alamance County	185,255	3	61,752		
North Carolina	11,107,246	287	38,701		

Source: Section Q, page 101

The applicant projects the MRI use rate in Alamance County forward using one half of the Alamance County MRI use rate 5-year CAGR (5.8% / 2 = 2.9%), as illustrated in *Table 2* above.

Table 5: Alamance County MRI Use Rate						
FFY2024 FFY2025 FFY2026 FFY2027 FFY2028 FFY2029						
Alamance County MRI						
Use Rate per 1,000 92.24 94.92 97.67 100.51 103.43 106.43						

Source: Section Q, page 102

Step 3: Project Alamance County MRI procedures for the first three project years using population projections (Step 1) and projected MRI Use Rate (Step 2)

Table 6: Alamance County MRI Procedures						
FFY2025 FFY2026 FFY2027 FFY2028 FFY2029						
Alamance County						
MRI Procedures 17,584 18,293 19,028 19,790 20,580						

Source: Section Q, page 102

The applicant converts the Alamance County MRI procedure projections (*Table 6*) to State Fiscal Years (SFY). The applicant provides the following example:

 $SFY2027 (Jul\ 26 - Jun\ 27) = .25 x FFY2026\ 18,293 + .75 x FFY2027\ 19,028 = 18,844$

Table 7: Alamance County MRI Procedures (Converted to SFY)					
SFY2027 SFY2028 SFY2029					
Alamance County					
MRI Procedures 18,844 19,599 20,382					

Source: Section Q, page 102

Step 4: DUHS Service Area Share of Projected MRI Procedures

The applicant assumes that some Alamance County patients will choose Duke Imaging Mebane for reasons such as DUHS' reputation, patient's preference for an outpatient setting or geographical accessibility. Therefore, the applicant projects that the proposed facility will capture a share of the Alamance County projected MRI procedures. Based on factors such as the projected population growth, DUHS' existing provider network, and patient origin utilization patterns, the applicant projects that Duke Imaging Mebane will capture 5.0% of the MRI market share in the first project year and increase by 5.0% in the second and third project years.

Table 8: Duke Imaging Mebane					
Service Area Share of Projected MRI Procedures					
SFY2027 SFY2028 SFY2029					
Alamance County					
MRI Market Share 5.0% 10.0% 15.0%					

Source: Section Q, page 103

The applicant states that projections are also supported by actual lives of Alamance County residents touched by DUHS facilities. The following table illustrates lives touched by DUHS historically as a percentage of the Alamance County population.

Table 9: Lives Touched by DUHS: Alamance County					
% of					
Year	Lives Touched	Population	Population		
FY2023	67,761	181,097	37.4%		
FY2024	68,168	183,229	37.2%		

Source: Section Q, page 103; NCOSBM, Vintage 2024; DUHS Internal Data

Step 5: Duke Imaging Mebane Alamance County MRI Procedures

The applicant applies the projected percentage of the Alamance County market share (*Table 8*) to the projected Alamance County MRI procedures (*Table 7*).

Table 10: Duke Imaging Mebane Alamance County Fixed MRI Procedures (Unadjusted)						
SFY2027 SFY2028 SFY2029						
Alamance County						
MRI Procedures	·					

Source: Section Q, page 104

Step 6: Service Area MRI In-Migration

The applicant states that patients residing outside of Alamance County have historically traveled to the county for healthcare services, including Duke Health physicians. The applicant states that FY2023 MRI patient origin report, which included Duke Health physicians, reflected that 26% of MRI procedures performed in Alamance County originated from outside the county. The applicant projects that the proposed Duke Imaging Mebane facility will experience similar in-migration. The applicant projects a 15% annual in-migration for the proposed facility.

Table 11: Duke Imaging Mebane Fixed MRI Procedures (Unadjusted)					
SFY2027 SFY2028 SFY2029					
Alamance County MRI Procedures	942	1,960	3,057		
In-Migration (15%)	166	346	540		
Total MRI Procedures	1,108	2,306	3,597		

Source: Section Q, page 105

Step 7: Adjusted MRI Procedures

To project adjusted MRI procedures, the applicant examined the most recent utilization of an existing IDTF with one fixed MRI scanner; Duke Imaging Holly Springs.

Table 12: DUHS MRI Utilization By Type					
Complex					
	Base OP OP Total Adjusted Ratio				
Duke Imaging Holly Springs 1,442 1,316 2,758 3,037 1.10					

Source: Section Q, page 105; 2025 SMFP

The applicant assumes that Duke Imaging Mebane's experience will be similar to Duke Holly Springs.

Table 13: Duke Imaging Mebane Fixed MRI Procedures				
PY1 PY2 PY3				
SFY2027 SFY2028 SFY2029				
Total MRI Procedures	1,108	2,306	3,597	
Adjusted MRI Procedures	1,220	2,539	3,961	

Source: Section Q, page 105

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

- The applicant reasonably projects utilization based on population projection data from the NCOSBM and statewide and service area historical MRI scanner utilization, including in-migration and MRI use rates, and patient encounters with DUHS providers.
- The applicant provides reasonable assumptions regarding expansion of geographical accessibility, a cost-effective alternative provider of freestanding MRI services, and DUHS' growing provider network and support in the service area.
- The applicant adequately demonstrates that its proposed fixed MRI scanner is reasonably expected to perform more than 3,494 adjusted MRI procedures in the third full fiscal year of operation following the project completion, as required by 10A NCAC 14C .2703(a)(7)(a).

Access to Medically Underserved Groups

In Section C, page 50, 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 have access to Duke Imaging Mebane's MRI services, as clinically appropriate. DUHS 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..."

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

Medically Underserved Groups	Estimated % of Total Patients in 3 rd Full FY
Low-income persons	12.2%*
Racial and ethnic minorities	28.8%
Women	52.1%
Persons with disabilities	N/A
Persons 65 and older	34.4%
Medicare beneficiaries	34.4%
Medicaid recipients	9.0%

Source: Section C, page 51

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 information provided in Section C, pages 50-51, and Exhibits C.6 and L.4.

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.

^{*}Calculated as patients with Medicaid and/or charity or reduced care discounts.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

In Section E, pages 62-63, 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:

No New MRI Services-The applicant states that not expanding MRI services in Alamance County would not meet the growing demand for services or improve access for DUHS patients. Also, in Project ID# J-12378-23, the applicant was approved for a mobile MRI scanner for host sites in Alamance, Durham and Wake counties, that would have included one day every other week at Duke Imaging Mebane. However, the applicant projected that this would not meet the growing demand for MRI services.

<u>Develop MRI Services at a Different Location</u>-The applicant states that this alternative was less effective because the proposed location was chosen based on geographical need, population growth, and access to existing services. Moreover, the proposed medical office building will accommodate primary care, urgent care, and physician specialty services in one location as part of DUHS' efforts to coordinate services for its patient population.

Acquire Different MRI Equipment-The applicant is proposing to acquire a 1.5T MRI scanner as opposed to a 3.0T MRI scanner. The applicant determined that a 1.5T MRI scanner would be more appropriate in an outpatient setting. Additionally, the applicant determined that a 3.0T MRI scanner may be inappropriate for certain situations such as implanted metallic devices, prior surgery in the target area, or fluid in the abdomen.

Contract with Mobile Provider-The applicant states that this alternative is not the most efficient or cost effective. As stated above, in Project ID# J-12378-23, the applicant was approved for a mobile MRI scanner to host sites in Alamance, Durham and Wake counties, that included one day every other week at Duke Imaging Mebane. However, the Mobile MRI scanner is operating at full capacity. Also, contracting with a mobile MRI scanner would require a provider fee and DUHS would be subject to the vendor's contractual terms and availability.

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

- The applicant's proposal will meet the growing need to expand MRI services in Alamance County, as demonstrated by the need determination identified in the 2025 SMFP.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.

• The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP for a total of one fixed MRI scanner at Duke Imaging Mebane.

3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
- b. The certificate holder shall complete all sections of the Progress Report form.
- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
- d. The first progress report shall be due on March 1, 2026.
- 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 develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 6. The certificate holder shall execute or commit to a contract for design services for the project no later than two years following the issuance of this certificate of need.

- 7. The certificate holder shall develop and implement strategies to provide culturally competent services to members of its defined medically underserved community that are consistent with representations made in the certificate of need application.
- 8. 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.

 \mathbf{C}

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

Capital and Working Capital Costs

In Section Q, page 106, the applicant projects the total capital cost of the project, as shown in the table below.

Duke Imaging Mebane		
Construction Contract	\$2,269,613	
Architecture/Engineering Fees	\$590,000	
Medical Equipment	\$3,026,700	
Non-Medical Equipment	\$170,000	
Furniture	\$100,000	
Other (Contingency)	\$1,231,687	
Total	\$7,388,000	

In Section Q, page 110, 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:

- The applicant's recent experience in developing similar projects and the architect's construction cost estimate.
- The applicant assumes a 20% increase to the quoted amount to account for market fluctuations.
- In supporting documentation in Exhibit F.1., the applicant provides an equipment quote from a recent MRI project.

In Section F, page 66, the applicant projects that start-up costs will be \$50,000 and initial operating expenses will be \$350,000 for a total working capital of \$400,000. On pages 66-67, the applicant provides the assumptions and methodology used to project the working capital

needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant reasonably projects start-up costs based on half of a month of onboarding time and expenses related to staff, accreditation training, and contingency during that period.
- The applicant assumes a 12-month initial operating period when a cash outflow for the facility exceeds cash inflow.

Availability of Funds

In Section F, pages 64 and 67, the applicant states that the capital and working capital cost will be funded by Duke University Health System, Inc. through accumulated reserves.

In Exhibit F-2, the applicant provides a letter dated February 6, 2025, from the Chief Financial Officer for DUHS, documenting \$10,000,000 in accumulated reserves available to fund the capital and working capital costs of the project. Exhibit F-2 includes DUHS' June 30, 2023 financial statements documenting over \$3.5 million in cash and cash equivalents and over \$9 billion in total assets.

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

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant does not project that revenues will exceed operating expenses in the first three full fiscal years for the fixed MRI scanner. However, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years for the entire Duke University Health System, following completion of the project, as shown in the tables below.

Duke Imaging Mebane	1 st FFY FY 2027	2 nd FFY FY 2028	3 rd FFY FY 2029
Total Procedures (Adjusted)	1,214	2,526	3,940
Total Gross Revenues (Charges)	\$1,139,071	\$2,370,667	\$3,697,870
Total Net Revenue	\$571,058	\$1,230,749	\$1,988,174
Average Net Revenue per Procedure	\$470	\$487	\$505
Total Operating Expenses (Costs)	\$1,711,342	\$2,053,201	\$2,276,993
Average Operating Expense per			
Procedure	\$1,410	\$813	\$578
Net Income	(\$1,140,284)	(\$822,452)	(\$288,819)

Note: In Section Q, Form F.2b, page 107, the applicant identifies the project years as interim years. However, based on the information provided throughout the application, the Project Analyst assumes that this is a typographical error.

Duka University Usalth Custom	1 st FFY	2 nd FFY	3 rd FFY
Duke University Health System	FY 2027	FY 2028	FY 2029
Total Procedures (Adjusted)	1,214	2,526	3,940
Total Gross Revenues (Charges)	\$23,256,834	\$24,611,796	\$25,055,629
Total Net Revenue	\$7,733,876	\$8,170,487	\$8,316,668
Average Net Revenue per Procedure	\$6,371	\$3,235	\$2,111
Total Operating Expenses (Costs)	\$7,385,876	\$7,691,488	\$7,842,231
Average Operating Expense per			
Procedure	\$6,084	\$3,045	\$1,990
Net Income	\$348,000	\$479,000	\$474,437

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

- The applicant explains how it accounts for projected operating expenses and explains its revenue projections.
- The assumptions used by the applicant are reasonable, including projected utilization, costs and charges, and net reimbursement.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

On page 334, the 2025 SMFP defines the fixed MRI 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 service area Alamance County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners currently located in the Alamance County fixed MRI scanner service area.

Alamance County Fixed MRI Scanners				
# of Fixed Total MRI Adjus				
Scanners Scans				
Alamance Regional Medical Center	2	9,345	12,443	
Diagnostic Radiology and Imaging	1	1,762	1,870	

Source: 2025 SMFP, Table 15E-1, page 338

In Section G, pages 73-74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Alamance County. The applicant states:

"The 2025 SMFP has identified a need for one additional fixed MRI scanner in the service area because MRI utilization in the service area is projected to exceed the capacity of the existing and approved providers.

...DUHS demonstrates the need the population has for the proposed project based on demographic data, historical service area utilization, and qualitative benefits...

DUHS owns and operates a mobile MRI scanner (Project ID # J-12378-23), which proposed locating the unit at Duke Imaging Mebane one day every other week (Project ID # J-12378-23). DUHS determined this limited mobile MRI access is insufficient to meet the projected demand for MRI services at Duke Imaging Mebane."

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

- There is a need determination in the 2025 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

Conclusion

The Agency reviewed the:

Application

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

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

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

In Section Q, page 109, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

	Projected FTE			
Position	1 st 2 nd 3 rd Full FY Full FY Full FY 2027 FY 2028 FY 2			
MRI Technologists	2.24	2.24	3.36	
Financial Care Counselor	1.12	2.24	2.24	
Nursing Practitioner	1.12	1.12	1.12	
Imaging Manager	1.12	1.12	1.12	
Total	5.60	6.72	7.84	

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 75-76, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- DUHS utilizes methods such as the internet, social media, job fairs, and advertisements to recruit staff and adheres to changing market demands to recruit and retain high quality staff.
- All clinical staff are required to maintain licensure and certification appropriate to the position and attend continuing education programs.

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.

 \mathbf{C}

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

Ancillary and Support Services

In Section I, page 77, the applicant identifies the necessary ancillary and support services for the proposed services. On page 78, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 78, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- As an established healthcare system in North Carolina, DUHS has existing relationships and collaborations with local health care and social service providers for services such as outpatient surgery, psychiatric, and primary care.
- DUHS will leverage its association with Duke University School of Medicine faculty practice and its specialty program affiliations such as Duke Heart Network and Duke Cancer Network.

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.

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

In Section K, page 81, the applicant states that the project involves renovating 3,900 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 82, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant relied on the experience of the project managers and the architect to develop the most cost-effective way to upfit the IDTF in the existing medical office building.
- The architect based the design and estimated cost of the project on its experience with similar projects.
- In Exhibit K.3, the applicant provides a letter from the architect documenting the cost estimate of the project.

On page 82, 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 because the applicant is proposing to develop the project as a IDTF by upfitting an existing building. This will allow the applicant to provide cost-effective care without increasing the cost and charges to the public as reimbursement rates are already established.

On page 82, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

(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 87, the applicant states:

"DUHS has no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons, other than those obligations which apply to private, not-for-profit, acute care hospitals that participate in the Medicare, Medicaid, VA, TRICARE, and Title V programs."

In Section L, page 88, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina because Duke Imaging Mebane is not an existing facility.

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

In Section L, page 88, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Duke Imaging Mebane Projected Payor Mix 3 rd Full FY, FY 2029		
Payor Category	Entire Facility	
Self-Pay	2.1%	
Charity Care	1.1%	
Medicare* 34.49		
Medicaid*	9.0%	
Insurance*	51.8%	
Workers Compensation 0.4%		
Other (other govt) 1.2%		
Total	100.0%	

^{*}Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.1% of total services will be provided to self-pay patients, 1.1% to charity care patients, 34.4% to Medicare patients and 9.0% to Medicaid patients.

On page 89, the applicant provides the assumptions and methodology used to project payor mix during the third of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant reasonably projects payor mix based on the DUHS' historical MRI payor mix of MRI patients originating from Alamance County, excluding inpatient and emergency department patients.
- The applicant's proposal to enhance access to freestanding MRI services in the service area supports the applicant's projected utilization and/or payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

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

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

In Section L, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

 \mathbf{C}

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- DUHS has existing residency and fellowship programs in Diagnostic Radiology at Duke University School of Medicine that require radiology rotations.
- The applicant proposes to extend its existing training opportunities for radiology technician students to Duke Imaging Mebane.

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.

 \mathbf{C}

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2025 SMFP, to be located at Duke Imaging Mebane.

On page 334, the 2025 SMFP defines the fixed MRI 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 service area Alamance County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners currently located in the Alamance County fixed MRI scanner service area.

Alamance County Fixed MRI Scanners				
# of Fixed Total MRI Adjus				
Scanners Scans				
Alamance Regional Medical Center	2	9,345	12,443	
Diagnostic Radiology and Imaging	1	1,762	1,870	

Source: 2025 SMFP, Table 15E-1, page 338

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 92, the applicant states:

"This project will benefit competition by creating additional capacity for outpatient/non-hospital based MRI services in Alamance County, increasing choice for patients and providers. DUHS does not provide fixed MRI services within Alamance County. As a result, the proposed project will increase competition while expanding patient choice."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 92, the applicant states:

"The proposed IDTF structure typically has lower reimbursement than hospital facilities and is more cost effective for many payors and patients depending on their plan terms. Also, DUHS intends to develop the proposed fixed MRI service in space within a medical office building. This represents an efficient use of planned medical office space for development of the proposed services."

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

Regarding the impact of the proposal on quality, in Section N, page 92, the applicant states:

"DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care. DUHS has quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 93, the applicant states:

"The proposed project will improve access to fixed MRI services in the service area. As previously stated, DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. Duke's financial assistance policy will apply to these services. With the availability of Medicaid reimbursement for IDTF services, this will provide an attractive option for Medicaid patients as well as other underserved groups."

See also Sections and 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 services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

 \mathbf{C}

In Section Q, page 121, the applicant identifies the hospitals and diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 hospitals and four diagnostic centers located in North Carolina. Diagnostic centers are not subject to DHSR license requirements.

In Section O, pages 95-96, the applicant states that, during the 18 months immediately preceding the submittal of the application, two Duke Lifepoint hospitals, not directly operated by DUHS, had findings resulting in immediate jeopardy. Maria Parham Hospital was cited for immediate jeopardy on July 24, 2024. Wilson Medical Center was cited for immediate jeopardy on August 28, 2024. The applicant states that all the problems have been corrected. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care had not occurred in any 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 12 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.

 \mathbf{C}

The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
 - (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -NA- **Duke Imaging Mebane.** In Section C, page 53, the applicant states that the applicant does not currently own or operate any fixed MRI scanners in the fixed MRI scanner service area.
 - (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -NA- **Duke Imaging Mebane.** In Section C, page 53, the applicant states that there are no approved fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.
 - (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;
- -NA- **Duke Imaging Mebane.** In Section C, page 53, the applicant identified one existing mobile MRI scanner operating at host sites located in Durham and Wake counties that was approved to operate at a host site located in Alamance County. However, the applicant determined it would not meet the growing need in the service area. Therefore, neither the applicant nor any related entity owns or operates a mobile MRI scanner at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period.
 - (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;
- -NA- **Duke Imaging Mebane.** In Section C, page 53, the applicant states that neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
 - (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- -C- **Duke Imaging Mebane.** In Section Q, page 98, the applicant provides projected utilization for its proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.

Duke Imaging Mebane MRI Services				
1 st Full FY 2 nd Full FY 3 rd Full FY				
FY 2027 FY 2028 FY 2029				
# of Units	1	1	1	
# of Procedures	1,108	2,306	3,597	
# of Adjusted Procedures	1,214	2,526	3,940	

- (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;
- -C- **Duke Imaging Mebane.** In Section Q, pages 99-105, the applicant provides the assumptions and methodology used to projected utilization of the proposed fixed MRI scanner through the first three full fiscal years of operation following project completion.
 - (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:
 - (a) 3494 or more adjusted MRI procedures per MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
 - (b) 3058 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
 - (c) 1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and

According to Table 15E-1, page 338 of the 2025 SMFP, there are currently three existing fixed MRI scanners in the Alamance County fixed MRI scanner service area. Therefore, Subparagraph (a) applies to this review.

- -C- **Duke Imaging Mebane.** In Section Q, page 98, the applicant projects to provide 3,940 adjusted MRI procedures on the proposed fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - (8) Project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operation following completion of the proposed project.
- -NA- **Duke Imaging Mebane.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.

- (b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
 - (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;
 - (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;
 - (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
 - (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;
 - (5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;
 - (6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;
 - (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;
 - (8) project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and
 - (9) project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:
 - (a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
 - (b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;
 - (c) 1310 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;
- -NA- **Duke Imaging Mebane.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.