

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 16, 2026

Findings Date: January 16, 2026

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: P-12700-25

Facility: Wayne MRI

FID #: 250960

County: Wayne

Applicant: Wayne MRI, LLC

Project: Acquire no more than one fixed MRI scanner pursuant to the 2025 SMFP need determination

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.

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Wayne MRI, LLC , herein after referred to as “the applicant” or “Wayne MRI,” proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 State Medical Facilities Plan (SMFP).

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 Wayne County. The application was submitted in response to the need determination in the 2025 SMFP for one fixed MRI scanner in Wayne County. Therefore, the application is consistent with the need determination in the 2025 SMFP.

Policies

There are two policies in the 2025 SMFP, on pages 30-31, that are applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Services Facility and Policy GEN-5: Access to Culturally Competent Healthcare.

Policy GEN-4: Energy Efficiency and Sustainability for Health Services Facility

“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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.

The proposed capital expenditure for this project is greater than \$4 million. In Section B, pages 27-28, the applicant provides a written statement describing the project’s plan to assure improved energy efficiency and water conversation.

Policy GEN-5: Access to Culturally Competent Healthcare

“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.

Item 1 – Demographics

In Section B, page 30, the applicant states,

“In Wayne County, there are cultural, linguistic, economic, and physical challenges that may prevent some community members from accessing adequate medical care. Understanding and addressing these barriers is essential for ensuring equitable healthcare services for all residents.”

The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will provide services to members of all demographics.

Item 2 - Culturally Competent Services

In Section B, page 31, the applicant states:

“Wayne MRI, through its association and collaboration with UNC Health Wayne, a nonprofit affiliate of UNC Health, is committed to ensuring equitable healthcare access for all, implementing a variety of strategies to respond to the unique needs of the community and provide culturally competent services to the medically underserved.”

The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will provide culturally competent services to members of the medically underserved community.

Item 3- Reflect Cultural Competence

In Section B, page 33, the applicant states,

“While cultural competence is not specifically defined, UNC Health Wayne believes that the awards and recognition it has received by organizations focused on improving healthcare equity, including through culturally competent care, are an indication that its strategies are reflective of cultural competence. UNC Health continues to be recognized locally and nationally for its commitment to culturally competent care.”

The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will reflect cultural competence services to members of the medically underserved community.

Item 4 - Reducing Health Disparities

In Section B, page 34, the applicant states,

“UNC Health Wayne utilizes internal practices and policies to ensure the provision of accessible care, which in turn works to reduce health disparities.”

The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will help reduce health disparities, increase health equity and improving the health outcomes to members of the medically underserved community.

Item 5 – Measure and Assess Increase Equitable Access

In Section B, page 35, the applicant states,

“UNC Health Wayne has integrated many strategies for building cultural competence with these best practices and evidence-based studies in mind. UNC Health Wayne will continue to measure and periodically assess equitable access to healthcare services in underserved communities through comprehensive program evaluations and community health monitoring systems. The hospital tracks key performance indicators across its chronic disease management programs, including diabetes prevention, cardiovascular health, and hypertension management, with particular attention to measuring participation rates and outcomes among Wayne County's diverse communities.

Through its school-based health programs, UNC Health Wayne evaluates the effectiveness of provided resources by monitoring the number of health screenings completed and overall student engagement. Maternal health program assessment includes tracking enrollment in digital health education platforms and provider participation in cultural competency training while mental health and substance use prevention programs are evaluated by community awareness campaign reach and event participation. Following the development of its Community Health Needs Assessment every three years, UNC Health Wayne establishes a Community Health Improvement Plan, with measurable objectives specifically designed to address the needs of underserved populations. Collectively, these qualitative and quantitative measures enable UNC Health Wayne and facilities in which it is a member, such as Wayne MRI, to determine progress in improving healthcare access and outcomes for Wayne County's underserved populations and identify areas for continued enhancement of culturally competent care delivery.”

The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal will measure and assess increase equitable access to the underserved community.

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 based on the following:

- The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* based on the proposed incorporation with written statement of improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the application is consistent with *Policy GEN-5* based on the proposed incorporation of access to culturally competent healthcare.

(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.

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 State Medical Facilities Plan (SMFP) to be located at a medical office building in Goldsboro. The applicant operates two hospital -based fixed MRI scanners at UNC Health Wayne.

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

Wayne MRI is not an existing facility and therefore no historical patient origin exists. In Section C, page 42, the applicant provides projected patient origin for the first three full fiscal years, FYs 2027-2030, for the proposed fixed MRI services, as summarized below:

Wayne MRI						
County	1st Full FY 7/1/27 to 6/30/28		2nd Full FY 7/1/28 to 6/20/29		3rd Full FY 7/1/29 to 6/30/30	
	# of Patients	%of Total	# of Patients	% of Total	# of Patients	% of Total
Wayne	3,810	80.3%	3,973	81.3%	4,143	82.3%
Lenior	277	5.8%	236	4.8%	193	3.8%
Duplin	192	4.0%	197	4.0%	203	4.0%
Johnston	183	3.9%	189	3.9%	195	3.9%
Sampson	74	1.6%	76	1.6%	78	1.6%
Other^	209	4.4%	215	4.4%	222	4.4%
Total	4,745	100.0%	4,887	100.0%	5,034	100.0%

In Section C, page 42, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the following:

- The applicant states that projected patient origin for Wayne MRI is based on the historical patient origin for outpatient MRI procedures performed in FY2025 on Wayne MRI’s two existing scanners located at UNC Health Wayne, assuming a one-to-one ratio of MRI scans to patients.
- The applicant states that Wayne MRI projects a one percent reduction in Lenior County patients each year and a corresponding one percent increase of patients from Wayne County.
- The applicant states that given the availability of the first freestanding MRI scanner in Wayne County, which is likely to mitigate outmigration of Wayne County residents.

Analysis of Need

In Section C, pages 44-58, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed fixed MRI services as summarized below:

- **2025 (State Medical Facilities Plan (SMFP) Need Determination:** The applicant states the proposed project is in response to a need determination identified in the 2025 SMFP for one additional fixed MRI scanner in Wayne County. The current inventory of fixed MRI scanners in Wayne County consists of two hospital-based scanners located at UNC Health Wayne, both owned by Wayne MRI.
- **Population growth:** The applicant states Wayne County, the service area for the proposed project, has historically experienced modest growth, with this growth projected to continue in future years. This expanding population base will drive demand for additional healthcare resources, including additional fixed MRI capacity.
- **Aging in Wayne County:** The applicant states that the growth of Wayne County's senior population, the second largest in the region, is another important factor contributing to the need for the proposed project. At 1.8 percent, the historical rate of aging in Wayne County is significantly higher than that associated with overall population growth during the same timeframe. While Wayne County did not experience the highest rate of aging compared to surrounding counties, its 1.8 percent CAGR nonetheless translated to adding the second highest number of residents aged 65 or older. As a result, nearly one-in-five Wayne County residents belong to this age cohort.
- **Demographic Factors:** The applicant states that demographic factors in Wayne County further contribute to the need to develop additional fixed MRI capacity. Specifically, these include the county's elevated incidence rates for disease and other adverse events as well as the presence of communities that are historically more vulnerable to the negative health outcomes associated with these issues. This is directly evidenced by primary and secondary data reported in Wayne County's 2024 Community Health Needs Assessment (CHNA), which identifies chronic health conditions as one of several important factors negatively impacting the wellbeing of the overall community. Moreover, the most recent available data compiled by the North Carolina Division of Health Service Regulation (NC DHRS) demonstrate that Wayne County's mortality rate for heart disease is significantly higher than that reported for the state, exceeding the North Carolina figure by over 32 percent in 2022.
- **Increasing Use Rates for MRI Services:** The applicant states that along with data related to the development and makeup of Wayne County's population, historical and projected utilization patterns for the service area's existing fixed MRI scanners also emphasize the need for the proposed project. Use rates per 1,000 population increased for both total MRI scans and for adjusted scans using the 2025 SMFP methodology for weighting procedures. In FFY 2023, the use rates for Wayne County MRI scanners were 69.6 MRI scans per 1,000 population or 83.0 adjusted MRI scans per 1,000 population. Applying these historical use rates to projected future utilization still produces growth in MRI procedures due to increases in population alone, with adjusted scans rising to an estimated 9,982 procedures in FFY 2029.

- **Need for freestanding fixed MRI resources in Wayne County:** The applicant states that Wayne County’s two existing fixed MRI scanners are both hospital-based and perform inpatient, emergent, and outpatient procedures. While these two existing scanners have experienced an overall increase in their utilization, as represented by the unadjusted total of MRI scans performed. outpatient procedures make up the majority of the two scanners’ overall procedure volume, more than 80 percent of total volume since FFY 2021. However, growth in inpatient procedures has significantly outpaced growth in outpatient procedures, increasing at a CAGR of nearly 35 percent compared to just 3.0 percent for the latter type. This changing composition of procedure volume has a direct impact on the actual capacity of these two existing scanners due to the greater complexity of inpatient and complex procedure types, which require a correspondingly longer period of time to perform.

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

- The applicant proposes to develop Wayne County’s first freestanding fixed MRI scanner pursuant to the need determination in the 2025 SMFP for one additional fixed MRI scanner in Wayne County.
- The applicant provides demographic data to support Wayne County’s continued population growth, aging population, and adverse health outcomes such as higher rates of mortality for heart disease, Alzheimer’s Disease, and certain cancers.
- The applicant historical utilization data for the existing hospital-based MRI scanners to support the need for the additional fixed MRI scanners in a freestanding imaging center.

Projected Utilization

In Section Q, Form C.2b page 121 the applicant provides projected utilization for MRI services at Wayne MRI the first three project years (FY 2028-2030), as illustrated in the following table:

Wayne MRI	Projected Utilization		
	1 st Full FY 7/1/27 to 6/30/28	2 nd Full FY 7/1/28 to 6/30/29	3 rd Full FY 7/1/29 to 6/30/30
# of Units	1	1	1
MRI Procedures	4,745	4,887	5,034
Adjusted MRI Procedures	5,035	5,194	5,359

In Section Q, pages 124-125, the applicant provides the assumptions and methodology used to project utilization , which is summarized below:

On page 124, the applicant states Wayne MRI, through a joint venture with UNC Health Wayne owns two hospital-based MRI scanners located on the main campus of UNC Health Wayne. Wayne MRI is the only provider of fixed MRI services in Wayne County. The procedures performed on Wayne MRI’s two existing scanners are reported under Wayne UNC Health Care in the SMFP and included on UNC Health Wayne’s License Renewal Application

(LRA) due to the scanners’ location at the hospital. Wayne MRI modeled its projections for the number of procedures to be performed on the proposed freestanding MRI scanner after historical growth in the number of procedures performed on the two existing fixed MRI scanners at UNC Health Wayne.

The applicant states that the total number of MRI procedures performed on Wayne MRI’s two hospital-based scanners has grown significantly, increasing from 7,215 unadjusted MRI scans in FY 2022 to 8,872 unadjusted MRI scans in FY 2025, representing a compound annual growth rate (CAGR) of 7.1 percent. When converted to adjusted scans to account for the performance of more complex, time-intensive procedures, Wayne MRI performed 8,239 adjusted MRI scans in FY 2022, rising to 10,471 adjusted MRI scans in FY 2025, representing a CAGR of 8.3 percent, which is demonstrated in the table below:

Wayne MRI Historical MRI Volume by Procedure Type						
	FY22	FY23	FY24	FY25	Weight[^]	FY22-25 CAGR
Base Outpatient	4,908	5,395	5,309	5,493	1.00	3.8%
Complex Outpatient	1,566	1,971	2,039	2,160	1.21	11.3%
Base Inpatient	458	487	641	745	1.82	17.6%
Complex Inpatient	283	328	346	474	2.12	18.8%
Total Unadjusted MRI	7,215	8,181	8,335	8,872		7.1%
Total Adjusted MRI	8,239	9,365	9,680	10,471		8.

Source: Section Q, page 126 of the application

Source: UNC Health Wayne Internal data

[^] Weight values indicate the ratios used to convert unadjusted MRI scans to adjusted MRI scans and are based on the 2025 SMFP methodology for determining relative resource utilization by scan type and complexity.

Projected MRI Utilization at UNC Health Wayne

In Section Q, pages 125-126, the applicant states the resulting projected MRI volumes, including both the unadjusted and adjusted volume totals. In FY 2028, the first full project year, the two existing hospital-based MRI scanners are expected to perform a total of 9,942 unadjusted scans, increasing to 10,340 unadjusted scans in FY 2029, the second project year, and 10,761 unadjusted scans in FY 2030, the third project year. The applicant states using the 2025 SMFP methodology to multiply unadjusted scans by the appropriate weight and convert to adjusted scans, projected volumes for these two hospital-based units will rise from a total of 11,963 adjusted scans in FY 2028 to 12,526 adjusted scans in FY 2029, and 13,126 adjusted scans in FY 2030. These projections are prior to any shifts from UNC Health Wayne to the proposed scanner, discussed later in the methodology. The applicant states that the weight column indicates the weighted ratios used to convert unadjusted scans to adjusted scans that are based on the 2025 SMFP methodology for determining relative resource utilization by scan type.

Projected UNC Health Wayne MRI Utilization Prior to Shift								
	FY25	FY26	FY27	FY28 (PY1)	FY29 (PY2)	FY30 (PY3)	FY25-FY30 CAGR	Weight [^]
Base Outpatient	5,493	5,598	5,705	5,814	5,925	6,039	1.9%	1.00
Complex Outpatient	2,160	2,282	2,411	2,548	2,692	2,844	5.7%	1.21
Base Inpatient	745	811	882	960	1,044	1,136	8.8%	1.82
Complex Inpatient	474	518	567	620	678	742	9.4%	2.12
Total Unadjusted MRI	8,872	9,209	9,565	9,942	10,340	10,761		
Total Adjusted MRI	10,471	10,938	11,434	11,963	12,526	13,126		

Source: Section Q, page 126 of the application

[^] Weight values indicate the ratios used to convert unadjusted MRI scans to adjusted MRI scans and are based on 2025 SMFP methodology for determining relative resource utilization by scan type and complexity.

Projected Utilization at Wayne MRI

In Section Q, page 126, the applicant states Wayne MRI isolated historical volumes for base outpatient and complex outpatient MRI scans. From this subset of historical outpatient volumes, Wayne MRI separated out the volumes associated with emergency department patients, in keeping with the reasonable assumption that the facility will only perform scans that would not need to be performed at the hospital, such as scans for ED patients. Table 3 compares the total number of base and complex scans performed on ED patients to those performed on non-ED outpatients in FY 2025, thereby identifying the percentages of ED outpatient volume that would be ineligible to shift from the hospital-based scanners to the proposed scanner at Wayne MRI.

Emergent and Non-Emergent Outpatient MRI Utilization by Procedure Type, FY 2025				
	ED	OP	Total	% of Total Excluded from Shift
Base	177	5,316	5,493	3.2%
Complex	226	1,934	2,160	10.5%
Total Outpatient Procedures	403	7,250	7,653	

Source: Section Q, page 126 of the application

In Section Q, page 126, the applicant states to calculate the number of ED procedures that would be excluded from the shift to the proposed scanner in Project Years 1 through 3, Wayne MRI multiplied the projected base and complex outpatient scans by the corresponding percentages of base and complex ED scans that were performed in FY 2025. The applicant states that the resulting number of base and complex ED scans projected for FY 2026 through FY 2030, providing both unadjusted and adjusted scan totals.

Projected Emergent Outpatient MRI Utilization by Procedure Type					
	FY26	FY27	FY28 (PY1)	FY29 (PY2)	FY 30 (PY3)
Base Outpatient	180	184	187	191	195
Complex Outpatient	239	252	267	282	298
Total Unadjusted MRI	419	436	454	473	492
Total Adjusted MRI	470	490	510	532	555

Source: Section Q, page 127 of the application

In Section Q, page 127, the applicant states that totals from the overall base and complex outpatient scans projected for FY 2026 to FY 2030. The remaining eligible base and complex outpatient scans projected for FY 2026 to FY 2030.

Projected UNC Health Wayne Outpatient MRI Utilization Eligible to Shift					
	FY26	FY27	FY28 (PY1)	FY29 (PY2)	FY30 (PY3)
Base Outpatient	5,418	5,521	5,627	5,734	5,844
Complex Outpatient	2,043	2,159	2,281	2,410	2,547
Total Unadjusted MRI	7,461	7,680	7,908	8,145	8,391
Total Adjusted MRI	7,895	8,138	8,392	8,656	8,931

Source: Section Q, page 127 of the application

In Section Q, page 127, the applicant states that Wayne MRI assumes that a portion of these eligible outpatient MRI scans will shift from the two existing hospital-based MRI scanners at UNC Health Wayne to the proposed freestanding fixed MRI scanner. The applicant states that given the numerous cost and convenience benefits associated with a freestanding setting and the proposed scanner’s location directly across the street from UNC Health Wayne, Wayne MRI believes that it is reasonable to assume that 60 percent of the eligible volume will shift to the proposed MRI unit. The applicant states that shift in volume will offer outpatients enhanced access to lower-cost services while enabling the two existing hospital-based scanners at UNC Health Wayne to better accommodate increasing inpatient MRI volumes and continue to perform outpatient scans for more acute patients or as schedule/capacity warrants.

Projected Adjusted MRI Utilization at Wayne MRI			
	FY 28 (PY1)	FY29 (PY2)	FY30 (PY3)
Base Outpatient	3,376	3,441	3,506
Complex Outpatient	1,369	1,446	1,528
Total Unadjusted OP MRI Shift	4,745	4,887	5,034
Total Adjusted Procedures	5,035	5,194	5,359

Projected Utilization at UNC Health Wayne After Shift

In Section Q, page 128, the applicant states that following this 60 percent shift of site-appropriate MRI procedures to the proposed freestanding fixed MRI scanner, Wayne MRI projects that the two existing hospital-based scanners at UNC Health Wayne will collectively perform 6,928 adjusted procedures in Project Year 1, increasing to 7,767 adjusted procedures in Project Year 3. The applicant states that the proposed scanner, the shift in outpatient volume will result in the new unit performing 5,035 adjusted procedures in Project Year 1, increasing to 5,359 adjusted procedures in Project Year 3.

Projected Adjusted MRI Utilization at UNC Health Wayne After Shift					
	FY26	FY27	FY28 (PY1)	FY29 (PY2)	FY30 (PY3)
Total UNC Health Wayne Projected MRI Volume (Unadjusted)	9,209	9,565	9,942	10,340	10,761
Total Shifted Volume (Unadjusted)			4,745	4,887	5,034
Total After Shift (Unadjusted)	9,209	9,565	5,197	5,453	5,727
Total UNC Health Wayne Projected MRI Volume (Adjusted)	10,938	11,434	11,963	12,526	13,126
Total Shifted Volume (Adjusted)			5,035	5,194	5,359
Total After Shift (Adjusted)	10,938	11,434	6,928	7,332	7,767
# of MRI Units	2	2	2	2	2
Adjusted Procedures per Unit	5,469	5,717	3,464	3,666	3,884

Section Q, page 128 of the application

The following table shows the utilization projections of the two existing hospital-based fixed MRI scanners and the proposed freestanding MRI scanner through the first three project years.

Projected Adjusted MRI Utilization			
	FY28 (PY1)	FY29 (PY2)	FY30 (PY3)
Wayne MRI Adjusted Procedures	5,035	5,194	5,359
# of MRI Units	1	1	1
Wayne MRI Adjusted Procedures (Scanner#1)	5,035	5,194	5,359
UNC Health Wayne Adjusted Procedures	6,928	7,332	7,767
# of MRI Units	2	2	2
UNC Health Wayne Adjusted Procedures (Scanner #1)	3,464	3,666	3,884
UNC Health Wayne Adjusted Procedures (Scanner #2)	3,464	3,666	3,993

Section Q, page 129 of the application

As shown in the table above the applicant projects that its existing and proposed fixed MRI scanners will 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).

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

- The applicant’s projections of the number of procedures to be performed on the proposed freestanding MRI scanner are supported by the historical growth in the number of procedures performed on the two existing fixed MRI scanners at UNC Health Wayne.
- The applicant projects that a portion of the eligible outpatient MRI scans will shift from the two existing hospital-based MRI scanners at UNC Health Wayne to the proposed freestanding fixed MRI scanner based on its historical experience providing MRI services.

Access to Medically Underserved Groups

In Section C, page 65, the applicant states:

“As shown in table above, all these MRI scanners are projected to perform. As noted in its Financial Assistance policy, Exhibit C.6-3, “[a]s part of its mission, UNC Health

provides care for residents of North Carolina who are uninsured or underinsured and do not have the ability to pay for medically necessary health care services. The purpose of this policy is to use financial assistance resources available to UNC Health to maximize the availability of health care services to the people of North Carolina in a consistent, equitable and effective manner.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	N/A*
Racial and ethnic minorities	32.9%
Women	58.1%
Persons with Disabilities	N/A*
Persons 65 and older	41.1%
Medicare beneficiaries	43.4%
Medicaid recipients	11.8%

Source: Section C, page 66 of the application

*N/A – The applicant states it does not maintain data on low income or persons with disabilities.

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

- The applicant states that it will provide access to all underserved groups.
- The applicant states the percentages of patients in each group listed above are based on recent facility experience.
- The applicant provides supporting documentation of the access it provides and programs to assist the underserved in Exhibit C.6.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

In Section E, pages 78-79, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Develop the proposed MRI as a hospital-based service The applicant states that Wayne MRI considered locating the proposed fixed MRI scanner as a hospital-based service. However, those services are associated with higher charges and facility fees than the same services performed in a freestanding setting, regardless of physical location or whether the service itself is designated as inpatient or outpatient. The proposed fixed MRI scanner at Wayne MRI will also represent the first freestanding fixed MRI scanner in Wayne County, addressing the current lack of existing freestanding fixed MRI capacity and offering patients more choices for where they receive their MRI procedures. The applicant states that the patients who prefer a freestanding MRI facility must travel outside the county for these services. Thus, the applicant states this is not the most effective alternative.

Develop the proposed MRI at another freestanding location in Wayne County The applicant states that the proposed location in Goldsboro, directly across from UNC Health Wayne, offers significant operational and patient care advantages that would not be available at alternative sites within the county. The applicant states that the selected location provides close proximity to the hospital campus where Wayne MRI's two existing hospital-based scanners are located, facilitating care coordination between the freestanding facility and the hospital-based services. The applicant states that the co-location of the proposed MRI scanner with Wayne Radiologists promotes more efficient and comprehensive care delivery, allowing patients to potentially consolidate multiple visits. The existing infrastructure at the selected site also minimizes the capital investment and development time required compared to new construction at an alternative location. Thus, the applicant states an alternative location is not the most effective alternative to meet patient needs.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Wayne MRI, LLC. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP to be located at Wayne MRI.**
- 3. 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**
- 4. 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.**
- 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holders shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on July 1, 2026.**

6. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 130, the applicant projects the total capital cost of the project as shown in the table below.

Wayne MRI Projected Capital Costs	
Construction/Renovation Contract(s)	\$2,149,686
Architect/Engineering Fees	\$200,000
Medical Equipment	\$1,851,000
Non Medical Equipment	\$10,076
Furniture	\$34,000
Other (Contingency)	\$600,000
Total Capital Cost	\$4,844,762

In Section Q, page 131, 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 projects construction, architect and engineering costs are based on the experience of UNC Health Wayne with similar projects.
- The cost of medical equipment cost (including MRI scanners and injectors), non-medical equipment costs (including audio system and MRI wheelchairs), and furniture costs are based on vendor estimates and Wayne MRI's experience with similar projects.
- The other costs includes contingency costs and are based on the experience of Wayne MRI with similar projects.

In Section F.3b, page 82, the applicant states there will be start-up cost in the amount of

\$75,373. This amount includes the cost of paying for hiring staff, mortgage or rent, utilities, purchasing supplies and equipment. In Section F.3c, page 83, the applicant states that there will be initial operating costs in the amount of \$301,492, for a total working capital cost of \$376,865.

The applicant adequately demonstrates the working capital needs of the project based on the following:

- The applicant projects the start-up cost based on one month of supplies, utilities, staffing, and all other non-depreciation expenses.
- The applicant projects the initial operating period cost number of months during which cash outflow (operating costs) for the entire facility exceeds cash inflow (revenues) for the entire facility; that period ends for Wayne MRI after three months.
- The applicant projects include all non-depreciation expenses, calculated as the difference between the total cash outflow (operating costs) during the initial operating period for the entire facility and total cash inflow (revenues) during the initial operating period for the entire facility.

Availability of Funds

In Section F, page 83, the applicant states the capital cost will be funded through the accumulated reserves of UNC Health Wayne. Exhibit F.2.1 contains a letter signed William Thoma, Senior Vice President, Finance and CFO of UNC Health Wayne, documenting the availability of accumulated reserves to fund the proposed project. Exhibit F.2.3 the applicant provides a copy of the most recent audited financials for Wayne Heath Corporation and Affiliates.

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

- The applicant provides documentation of UNC Health Wayne's commitment to use the necessary funding toward development of the proposed project.
- The applicant documents the availability of sufficient financial resources to fund the proposed capital cost.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, page 132, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years (FY) following project completion, as shown in the table below:

Wayne MRI	1 st Full FY SFY 2028	2 nd Full FY SFY 2029	3 rd Full FY SFY 2030
# of Scans (Adjusted)	4,745	4,887	5,034
Total Gross Revenues (Charges)	\$7,113,789	\$7,546,490	\$8,007,682
Total Net Revenue	\$1,842,957	\$1,955,056	\$2,074,536
Average Net Revenue per MRI Scan	\$388	\$400	\$412
Total Operating Expenses (Costs)	\$1,273,524	\$1,508,293	\$1,553,146
Average Operating Costs per MRI Scan	\$268	\$309	\$309
Net Income	\$569,432	\$446,763	\$521,390

Source: Section Q, Form F.2b , page 132 of the application

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 131 and 134. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant’s patient services gross revenue is based on projected payor mix and average charge. Average charge is based on FY 2024 average charge at UNC Health Wayne adjusted from outpatient hospital-based MRI services to freestanding MRI services based on a weighted Medicare reimbursement adjustment and applied proportionally to other payors. Projected payor mix is based on FY 2025 payor mix of UNC Health Wayne's outpatient MRI services.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital cost is based on reasonable and adequately supported assumptions
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

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

The following table identifies the two existing fixed MRI scanner located in the Wayne County service area, summarized from Table 15E-1, page 356 of the 2025 SMFP:

Location	Fixed MRI Scanners	Total MRI Scans	Adjusted MRI Scans
Wayne UNC Health Care	2	8,173	9,745

Source: Table 15E-1, page 356 2025 SMFP

In Section G, page 90, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Wayne County. The applicant states:

“The proposed project involves the development of a freestanding fixed MRI scanner in response to a need determination in the 2025 SMFP for one additional fixed MRI scanner to be located in Wayne County. As discussed in Section C.4, the growth and aging of the communities in the service area are driving increased demand for MRI services, highlighting a corresponding need for enhanced access to lower-cost, high-quality imaging resources closer to home. The service area’s two existing fixed MRI scanners are both hospital-based and located at UNC Health Wayne, which is experiencing rapid growth in the utilization of these scanners for inpatient procedures.”

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 the need for the proposed fixed MRI scanner at Wayne MRI in addition to the existing MRI scanners in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

In Section Q, Form H, page 136, the applicant provides projected full-time equivalent (FTE) staffing for its MRI services, as illustrated in the following table:

Staffing	1st Full FY SFY2028	2nd Full FY SFY2029	3rd Full FY SFY2030
MRI Technologists	2.0	2.0	2.0
Supervisor, MRI -Imaging Clerical	0.5	0.5	0.5
MRI Receptionist	1.0	1.0	1.0
Total	3.5	3.5	3.5

The assumptions and methodology used to project staffing are provided in Section Q, page 137. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 92-93, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant states that the project will be all staff will be employed and trained by UNC Health Wayne and leased to the applicant to staff Wayne MRI.
- The applicant states that UNC Health Wayne’s employment offices use a variety of venues to recruit new staff and hire the best applicant considering job fit and organization fit.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

Ancillary and Support Services

In Section I, page 94, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section I, pages 94-95 the applicant explains how each ancillary and support service is and will be available and supporting documentation is provided in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services are and will be made available.

Coordination

In Section I, page 95, the applicant describes that although the facility will be new freestanding diagnostic center, Wayne MRI will benefit from existing relationships with UNC Health Wayne's relationships with local health care and social service providers. The applicant provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

In Section K, page 98, the applicant states that the project involves renovating 1,609 square feet of existing space. Line drawings are provided in Exhibit C.1.

In Section K, pages 98-99, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal because the design and means of the proposed renovation, were developed to minimize the cost of the project by renovating existing space rather than constructing new space.

In Section K, page 99, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that the proposed costs are necessary to ensure the proposed project can be developed, which in turn will increase access to convenient, lower cost MRI services in the service area.

- The applicant states the proposed fixed MRI scanner at Wayne MRI will have lower fixed expenses than the existing hospital-based MRI service at UNC Health Wayne
- The applicant states that outpatient MRI procedures performed at a freestanding facility also have a lower reimbursement level than those performed at a hospital, resulting in lower costs to patients and insurers.

In Section B.19, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 102, the applicant states that they are not an existing facility, therefore historical payor sources do not exist. The applicant, however, does provide the historical payor mix during for UNC Health Wayne for its existing fixed MRI services, as shown in the table below:

UNC Health Wayne Last Full FY before Submission of Application 7/1/2024 to 6/30/2025	
Payor Source	MRI Services as Percent of Total
Self-Pay	1.5%
Medicare	43.4%
Medicaid	11.8%
Insurance	20.1%
Other(Other Govt, Worker’s Comp)^^	23.7%
Total	100.0%

Source: Section L, page 103 of the application

*Including any managed care plans.

^^Workers Compensation, TRICARE, and other payors are included in the Other payor category.

Wayne MRI Last Full FY before Submission of the Application		
	% of Total Patients Served	% of the Population of the Service Area*
Female	58.1%	50.7%
Male	41.9%	49.3%
Unknown	0.0%	0.0%
64 and Younger	58.9%	82.3%
65 and Older	41.1%	17.7%
American Indian	0.5%	0.6%
Asian	0.3%	1.4%
Black or African-American	28.5%	32.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	66.7%	56.9%
Other Race	3.6%	8.3%
Declined / Unavailable	0.4%	0.0%

Source: Section L, page 104 of the application

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 105, the applicant states it has no such obligation.

In Section L, page 105, the applicant states that Wayne MRI is not an existing facility and there have been no patient civil rights equal access complaints filed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, pages 106, the applicant projects the following payor mix for MRI services at Wayne MRI for the third full fiscal year of operation (SFY2030), as shown in the table below:

Wayne MRI Projected Payor Mix during the 3rd Full FY 7/1/2029 to 6/30/2030	
Payor Source	Percentage of Total Patients Served
Self-Pay	0.9%
Medicare*	43.4%
Medicaid *	11.8%
Insurance*	20.1%
Other(Other Govt, Worker's Comp)^	23.7%
Total	100.0%

Source: Section L, page 106 of the application

*Including any managed care plans.

^^Workers Compensation, TRICARE, and other payors are included in the Other payor category.

In Section L, page 105, the applicant provides the assumptions used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the UNC Health Wayne most recent historical payor mix for outpatient MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 107, the applicant describes the means by which a person will have access to the proposed fixed MRI services at Wayne MRI.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

In Section M, page 109, 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 and will continue to have access to the facility for training purposes based on the following:

- The applicant states the proposed freestanding fixed MRI services at Wayne MRI will be accessible to the existing professional training programs affiliated with UNC Health Wayne.
- UNC Health Wayne has a long history of supporting health professional training programs in the community at large.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the need determination in the 2025 SMFP.

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

The following table identifies the two existing fixed MRI scanners located in the Wayne County service area, summarized from Table 15E-1, page 356 of the 2025 SMFP:

Location	Fixed MRI Scanners	Total MRI Scans	Adjusted MRI Scans
Wayne UNC Health Care	2	8,173	9,745

Source: Table 15E-1, page 356 2025 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 111, the applicant states

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to freestanding MRI services, which are currently unavailable in the service area. As discussed in Section C.1, the proposed MRI scanner at Wayne MRI will be the first freestanding fixed MRI scanner in Wayne County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home. The proposed MRI scanner will not only introduce lower cost, freestanding fixed MRI services to Wayne County, but it will also create additional capacity that, in turn, will enhance timely access to the existing hospital-based MRI services provided at UNC Health Wayne.”

Regarding the expected effects of the proposal on cost effectiveness, in Section N, pages 111-112, the applicant states that Wayne MRI will be the first freestanding fixed MRI scanner in Wayne County and will operate five days per week, providing a lower cost, convenient option for MRI services close to home. The proposed MRI scanner will not only introduce lower cost, freestanding fixed MRI services to Wayne County, but it will also create additional capacity that, in turn, will enhance timely access to the existing hospital-based MRI services provided at UNC Health Wayne.

Regarding the expected effects of the proposal on quality in the service area, in Section N, pages 112-114, the applicant states,

“Wayne MRI believes that the proposed project will provide high quality healthcare services to patients in the service area. Through its two hospital-based MRI scanners at UNC Health Wayne, Wayne MRI has a proven record of offering high quality services to the patients it serves. As discussed in Section C.4, the proposed project will expand the accessibility of advanced imaging services in Wayne County by increasing the total MRI capacity available in the service area and freeing up hospital-based capacity to perform inpatient and higher complexity scans.”

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

Regarding the expected effects of the proposal on access by medically underserved groups in the service area, in Section N, page 114, the applicant states that UNC Health Wayne is committed to promoting equitable access in the provision of MRI services and the positive impact the proposed project will have on access by medically underserved groups to the proposed services.

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section Q, Form O, page 138, the applicant identifies the health service facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of one hospital located in North Carolina.

In Section O, page 117, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at that facility. After reviewing and considering information provided by the applicant and the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at that facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

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

-C- In Section C, page 68, the applicant states Wayne MRI owns two existing fixed hospital-based MRI scanners located at UNC Health Wayne. There are no related entities that own or operate a fixed MRI in the proposed fixed MRI scanner service area (Wayne County) .

(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- In Section C, page 68, the applicant states that there are no approved fixed MRI scanners that are owned or operated by Wayne MRI or related entities located in the proposed fixed MRI scanner service area (Wayne County).

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

-NA- In Section C, page 68, the applicant states that there are no existing mobile MRI scanners owned or operated by Wayne MRI or related entities that provides 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.

(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- In Section C, page 68, the applicant states that there are no approved mobile MRI scanners that it or any related entity owns or operates 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- In Section Q, page 124, the applicant provides projected utilization for both its existing and proposed fixed MRI scanners during each of the first three full fiscal years of operation following completion.

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

-C- In Section Q, pages 124-128, 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 completion of the project.

(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) *3,494 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) *3,058 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or*

(c) *1,310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and*

There is currently two existing fixed MRI scanners in Wayne County at UNC Health Wayne; thus, Subparagraph (a) applies to this review.

-C- In Section Q, page 129, the applicant projects to provide more than 3,494 adjusted MRI procedures per fixed MRI scanner during the third full fiscal year of operation following project completion for each of its existing and proposed fixed MRI scanners. The full methodology and assumptions are provided in Section Q. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(8) *Project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operation following completion of the proposed project.*

-NA- In Section C, page 69, the applicant states, there are no mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites in the Wayne County proposed fixed MRI scanner service area during the 12 months before the application deadline for this review.

(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 (1) and (2) of this Paragraph and the proposed mobile MRI scanner;*
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (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 (6) of this Paragraph;*
- (8) project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and*
- (9) project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:*
 - (a) 3,494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;*
 - (b) 3,058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area;*
 - (c) 1,310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area*

-NA- In Section C, page 70, the applicant states that it 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.