

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 29, 2023

Findings Date: March 29, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: Q-12286-22

Facility: Orthopaedics East and Sports Medicine Center

FID #: 220733

County: Pitt

Applicant(s): Orthopaedics East and Sports Medicine Center, Inc. and Orthopaedics East Properties, LLC

Project: Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

Project ID #: Q-12294-22

Facility: Greenville MRI, LLC

FID #: 30544

County: Pitt

Applicant(s): Greenville MRI, LLC

Project: Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of no more than three fixed MRI scanners upon project completion

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

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
Both Applications

Need Determination

The 2022 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed Magnetic Resonance Imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in the 2022 SMFP identified a need for one fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) with each proposing to acquire one fixed MRI scanner. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

Policies

Policy GEN-3: Basic Principles of the 2022 SMFP is applicable to both applications.

Policy GEN-3

Policy GEN-3 on page 30 of the 2022 SMFP states:

“A certificate of need applicant applying to develop or offer 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 promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination
Orthopaedics East and Sports Medicine Center, Inc. and Orthopaedics East Properties, hereinafter referred to as “the applicant” or “OrthoEast”, proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination. The applicant is proposing to add an addition to the medical clinic to house the proposed fixed MRI scanner. The clinic currently offers MRI services via a leased mobile MRI scanner.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Pitt/Greene/Hyde/Tyrrell County service area.

Policy GEN-3. In Section B.2, pages 25-26, the applicant explains why it believes its application is conforming to Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing
- 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 does not propose to acquire 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-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the Pitt/Greene/Hyde/Tyrrell County service area.
 - The applicant adequately documents how the project will promote equitable access to MRI services in Pitt County; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

Greenville MRI, LLC, hereinafter referred to as “the applicant” or “Greenville MRI,” proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners, located at Greenville MRI, a physician practice.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Pitt/Greene/Hyde/Tyrrell County service area.

Policy GEN-3. In Section B.2, pages 28-30, the applicant explains why it believes its application is conforming to Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing
- 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 does not propose to acquire 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-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the Pitt/Greene/Hyde/Tyrrell County
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

The applicant is proposing to acquire a fixed MRI scanner and add an addition to the medical clinic to house the proposed scanner. In Section C, page 27, the applicant states that the projected total capital cost will be \$2,313,519.

Designation as a Diagnostic Center

N.C. Gen. Stat. 131E-176(7a) states:

“Diagnostic center. – a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds one million five hundred dollars (\$1,500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than exceeds one million five hundred dollars (\$1,500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater...”

In Section Q, page 114, the applicant projects that the total cost of the proposed medical diagnostic equipment which costs \$10,000 or more, and the cost of the addition to the medical clinic to house the scanner exceeds the statutory threshold of \$1,500,000. Therefore, Orthopaedics East and Sports Medicine Center qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

Patient Origin

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

The following tables illustrate historical and projected patient origin.

County	OrthoEast Fixed MRI scanner Historical Patient Origin Last Full FY 01/01/2021-12/31/2021	
	Patients	% of Total
	Pitt	1,394
Beaufort	222	9.1%
Lenoir	131	5.4%
Martin	113	4.6%
Wilson	81	3.3%
Greene	65	2.7%
Edgecombe	56	2.3%
Bertie	49	2.0%
Craven	46	1.9%
Wayne	41	1.7%
Nash	39	1.6%
Hertford	30	1.2%
Other NC Counties*	160	6.6%
Other States	7	0.3%
Total	2,434	100.0%

Source: Section C, page 31

*Includes all other North Carolina counties, each of which represents <1% of total patient origin.

OrthoEast Fixed MRI scanner Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	CY2024		CY2025		CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Pitt	1,755	57.3%	1,787	57.3%	1,820	57.3%
Beaufort	279	9.1%	284	9.1%	289	9.1%
Lenoir	165	5.4%	168	5.4%	172	5.4%
Martin	141	4.6%	143	4.6%	146	4.6%
Wilson	101	3.3%	103	3.3%	105	3.3%
Greene	83	2.7%	84	2.7%	86	2.7%
Edgecombe	70	2.3%	72	2.3%	73	2.3%
Bertie	61	2.0%	62	2.0%	64	2.0%
Craven	58	1.9%	59	1.9%	60	1.9%
Wayne	52	1.7%	53	1.7%	54	1.7%
Nash	49	1.6%	50	1.6%	51	1.6%
Hertford	37	1.2%	37	1.2%	38	1.2%
Other NC Counties*	202	6.6%	206	6.6%	210	6.6%
Other States	9	0.3%	9	0.3%	10	0.3%
Total	3,063	100.0%	3,119	100.0%	3,177	100.0%

Source: Section C, page 33

Totals may not foot due to rounding. Note: this table represents patients, not procedures.

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

“OrthoEast projects the fixed MRI scanner patient origin based on its historical mobile MRI scanner patient origin.”

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 35-45, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The 2022 SMFP need methodology determined a need for one fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area (page 36).
- The number of weighted procedures performed on the existing fixed and mobile MRI scanners located in Pitt County has consistently grown over the last five fiscal years (pages 36-38).
- Based on OrthoEast’s internal data, the facility experienced a 3-year (CY 2018 – CY 2021) Compound Annual Growth Rate (CAGR) of 8.30% of weighted and

unweighted MRI procedures performed on the existing mobile MRI scanner and a 4-year (CY 2018 – CY 2022) CAGR of 6.56% (page 38).

- The existing mobile MRI scanner limits access to MRI services due to the location of the scanner and the limitations for obese and claustrophobic patients (page 39).
- The applicant is proposing to offer MRI services in a freestanding location which will provide services at a lower cost as opposed to MRI services performed in a hospital, which can incur hospital-based costs (pages 40-41).
- The projected population growth in the service area, particularly among the age cohort more likely to utilize healthcare services, drives the need to increase access to MRI services. Additionally, the health status and risk factors of Pitt County residents supports the need expand MRI capacity (pages 41-45).
- OrthoEast's support of physicians and referring providers from Pitt County and surrounding counties (page 45).

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the bullets points listed below:

- The 2022 SMFP identifies the need for one additional fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area.
- Historical utilization and MRI use rates of the existing MRI scanners in Pitt County.
- Population growth, particularly among the elderly is occurring in the service area.
- The applicant uses clearly cited and reasonable historical and demographic data to identify the population to be served, its projected growth, and the need for the proposed services.
- A letter from Eastern Radiologists expressing their support for the proposed project. See Exhibit I.2.

Projected Utilization

In Section Q, pages 107-108, the applicant provides historical and projected utilization, as illustrated in the following tables.

OrthoEast Fixed MRI Scanner Historical and Projected Utilization						
	Last Full FY CY 2021	Interim Full FY CY 2022	Interim Full FY CY 2023	1st Full FY CY 2024	2nd Full FY CY 2025	3rd Full FY CY 2026
# of Units	1	1	1	1	1	1
Unweighted Procedures	2,732	2,773	2,834	3,438	3,501	3,566
Weighted Procedures	2,763	2,801	2,865	3,476	3,540	3,605

In Section Q, pages 110-113, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Examine historical utilization of OrthoEast’s existing mobile MRI scanner.

OrthoEast Historical Fixed MRI Scanner Utilization, CY2018 – CY 2022*							
	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022**	3-Yr CAGR	4-Yr CAGR
Unweighted Mobile MRI Scans	2,151	2,255	2,246	2,732	2,080	8.30%	6.56%

Source: Section Q, page 110

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

**Nine months (January – September) year-to-date actual utilization

To estimate the number of MRI scans performed during CY 2022, the applicant annualized the actual utilization for the initial nine months of 2022. OrthoEast experienced a 3-year (CY 2018 – CY 2021) CAGR of 8.30% of unweighted MRI scans performed on the existing mobile MRI scanner and a 4-year (CY 2018 – CY 2022) CAGR of 6.56%.

Step 2: Project fixed MRI scanner utilization for the first three years of the project.

The applicant projects utilization using one third of the historical 3-year CAGR of 6.56%. The applicant states that using a CAGR of 2.19% is conservative and reasonable based on OrthoEast’s plan to expand the scope of services and the addition of two new surgeons. The following table illustrates projected utilization.

OrthoEast						
Projected Fixed MRI Scanner Utilization, CY2022 – CY 2026						
Unweighted	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	4-Yr CAGR
Fixed MRI Scans	2,773	2,834	2,896	2,959	3,024	2.19%

Source: Section Q, page 110

Step 3: Project utilization of patients previously not accommodated by OrthoEast

OrthoEast cannot accommodate claustrophobic and/or obese patients on the existing mobile scanner. These patients were referred to other providers. The applicant assumes that these patients will be recaptured once the proposed MRI scanner becomes operational. Based on the number of these patients that were referred to other providers during CY 2021, the applicant projects the total number of unweighted scans.

OrthoEast					
Total Projected Fixed MRI Scanner Utilization, CY2022 – CY 2026					
Unweighted	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026
Organic Growth	2,773	2,834	2,896	2,959	3,024
Claustrophobic/Obese			518	518	518
HealthAssist Charity Care			24	24	24
Total	2,773	2,834	3,438	3,501	3,566

Source: Section Q, page 111

Step 4: Project adjusted fixed MRI scanner utilization

The applicant projects adjusted fixed MRI scanner utilization using the historical five-year average weighting ratio of 1.011 and projects that it will remain constant through the third operating year. The applicant projects that OrthoEast will perform 3,605 weighted MRI scans by the third operating year. The following tables illustrate the historical weighting ratio (CY 2021 – CY 2022 and the projected adjusted utilization using the applicable weighting ratio.

OrthoEast					
Historical Fixed MRI Scanner Adjusted Utilization, CY 2021 – CY 2022					
	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Unweighted MRI Scans	2,151	2,255	2,246	2,732	2,080
Weighted MRI Scans	2,175	2,277	2,275	2,763	2,101
Weighting Ratio	1.011	1.010	1.013	1.011	1.011

Source: Section Q, page 111

OrthoEast					
Total Projected Adjusted Fixed MRI Scanner Utilization, CY2022 – CY 2026					
	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026
Organic Growth	2,773	2,834	2,896	2,959	3,024
Claustrophobic/Obese			518	518	518
HealthAssist Charity Care			24	24	24

Unweighted MRI Scans	2,773	2,834	3,438	3,501	3,566
Weighted MRI Scans	2,801	2,865	3,476	3,540	3,605
Weighting Ratio	1.010	1.011	1.011	1.011	1.011

Source: Section Q, page 112

Step 5: Project OrthoEast MRI service market share in Pitt County

To project OrthoEast’s market share in Pitt County, the applicant begins with the Pitt County market share using Pitt County’s five-year (FY 2017 – FY 2021) average MRI use rate of 193.5. The projected Pitt County population was multiplied by the average use rate to project the number of Pitt County procedures. The applicant states that using the 5-year average MRI use rate is conservative considering that actual Pitt County MRI use rate was 222.1 in 2021. The applicant projects that OrthoEast will have a 10.61% market share by the third operating year. The applicant states that the projections are conservative and reasonable because OrthoEast would have an inventory of one MRI scanner out of the 9.52 Pitt County inventory which would result in an MRI use rate of 10.50% (1/9.52).

OrthoEast MRI Service Market Share in Pitt County							
	2020	2021	2022	2023	2024	2025	2026
MRI Procedures	2,246	2,732	2,773	2,834	3,438	3,501	3,566
Pitt County Procedures	32,610	37,821	32,945	33,039	33,186	33,376	33,603
Market Share %	6.89%	7.22%	8.42%	8.58%	10.36%	10.49%	10.61%

Source: Section Q, page 112

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need determination in the 2022 SMFP for a fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area. The proposed project will meet that need determination by developing a fixed MRI scanner in Pitt County.
- Population is growing in Pitt County, particularly among the 65+ age group, the primary users of imaging services. There is a projected 2.8% annual growth rate from 2022 to 2026.
- To project utilization the applicant utilized an MRI use rate per 1,000 people of 193.5 which is conservative as it is below the Pitt County MRI use rate in the most recent full year of MRI utilization.
- The methodology and assumptions utilized by the applicant were reasonable, conservative and well supported. The applicant’s projected total unweighted Pitt County MRI procedures combined with its projected market share of those MRI procedures combined with projected number of recaptured procedures is reasonable.
- MRI scans performed in a freestanding facility are generally less costly than MRI scans performed in a hospital licensed facility.

- The applicant’s expansion of services and the MRI physician/provider referral base.

Access to Medically Underserved Groups

In Section C, page 50, the applicant states:

“Patients obtain access to OrthoEast MRI services through physician/provider referral, and OrthoEast does not discriminate based on income, race, ethnicity, creed, color, gender, age, physical or mental handicap, religion, national origin, sexual orientation, or any other factor that would classify a patient as underserved.”

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	13.0%
Racial and ethnic minorities	34.6%
Women	60.6%
Persons with Disabilities	9.7%
Persons 65 and older	36.7%
Medicare beneficiaries	31.2%
Medicaid recipients	5.6%

Source: Section C, page 51

*OrthoEast does not track income demographics or disability. Estimates are based on the most recent available U.S. Census Bureau demographics for Pitt County. Because the OrthoEast historical MRI patient origin is primarily derived from Pitt County, OrthoEast considers the estimated percentage of low-income persons and persons with disabilities will each appropriate the respective Pitt County population percentage.

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 facility has historically provided services to Medicaid and Medicare recipients.
- As required by the Americans with Disabilities Act, the proposed new space will be accessible to persons with disabilities.
- OrthoEast will continue to provide communication services to the hearing impaired and non-English speaking patients.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

Patient Origin

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

The following tables illustrate historical and projected patient origin.

County	Greenville MRI Fixed MRI scanner Historical Patient Origin	
	Last Full FY 01/01/2021-12/31/2021	
	Patients	% of Total
Pitt	4,075	48.6%
Greene	218	2.6%
Hyde	36	0.4%
Tyrrell	12	0.1%
Beaufort	798	9.5%
Martin	498	5.9%
Lenoir	446	5.3%
Wilson	355	4.2%
Edgecombe	285	3.4%
Wayne	268	3.2%
Craven	186	2.2%
Bertie	158	1.9%
Nash	154	1.8%
Washington	153	1.8%
Hertford	93	1.1%
Halifax	88	1.0%
Duplin	78	0.9%
Onslow	74	0.9%
Carteret	52	0.6%
Northampton	51	0.6%
Other*	314	3.7%
Total	8,392	100.0%

Source: Section C, page 36

*Includes 38 other North Carolina counties and other States.

Greenville MRI Fixed MRI scanner Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	CY2024		CY2025		CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Pitt	4,528	48.6%	4,802	48.6%	4,828	48.6%
Greene	242	2.6%	257	2.6%	258	2.6%
Hyde	40	0.4%	42	0.4%	43	0.4%
Tyrrell	13	0.1%	14	0.1%	14	0.1%
Beaufort	887	9.5%	940	9.5%	945	9.5%
Martin	553	5.9%	587	5.9%	590	5.9%
Lenoir	496	5.3%	526	5.3%	528	5.3%
Wilson	394	4.2%	418	4.2%	421	4.2%
Edgecombe	317	3.4%	336	3.4%	338	3.4%
Wayne	298	3.2%	316	3.2%	318	3.2%
Craven	207	2.2%	219	2.2%	220	2.2%
Bertie	176	1.9%	186	1.9%	187	1.9%
Nash	171	1.8%	181	1.8%	182	1.8%
Washington	170	1.8%	180	1.8%	181	1.8%
Hertford	103	1.1%	110	1.1%	110	1.1%
Halifax	98	1.0%	104	1.0%	104	1.0%
Duplin	87	0.9%	92	0.9%	92	0.9%
Onslow	82	0.9%	87	0.9%	88	0.9%
Carteret	58	0.6%	61	0.6%	62	0.6%
Northampton	57	0.6%	60	0.6%	60	0.6%
Other	349	3.7%	370	3.7%	372	3.7%
Total	9,324	100.0%	9,889	100.0%	9,943	100.0%

Source: Section C, page 39

In Section C, pages 37-38, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- Projected patient origin is based on the historical (CY 2021) patient origin for MRI services at Greenville MRI.
- To project patient origin, the applicant relied on the historical average number of scans per patient performed in 2021.

Analysis of Need

In Section C, pages 41-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The aging and growth in population in the Greene/Pitt/Hyde/Tyrrell County service area (pages 42-43).
- The growth in the number fixed MRI patients in the service area (page 43).
- Need to expand access to MRI services in Pitt County, the most populous and fastest growing county in the service area (pages 44-45).
- The increase in MRI Use Rate as the service area continues to age demonstrates the need to meet future demand for MRI services (pages 45-46).
- Greenville MRI's two existing fixed MRI scanners have consistently performed above the performance standard for fixed MRI scanners (pages 46-47).
- In response to the growing demand for MRI services, Greenville MRI implemented strategies to improve access to MRI services. Efforts included, expanding hours, adding breast MRI services and upgrading equipment (pages 47-49).
- Greenville MRI's relationship with referring providers that have a wide range of specialties. (pages 49-51).
- The applicant is proposing to provide MRI services using state-of-the-art equipment and software that would improve the patient's experience (pages 51-53).

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2022 SMFP identifies the need for one additional fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area.
- Aging and growth of the population in the service area.
- MRI use rates of the existing MRI scanners in Pitt County.
- Historical utilization of the two existing fixed MRI scanners located at Greenville MRI.

Projected Utilization

In Section Q, pages 114 and 116, the applicant provides historical and projected utilization, as illustrated in the following table.

Greenville MRI Fixed MRI Scanner Historical and Projected Utilization						
	Last Full FY CY 2021	Interim Full FY CY 2022	Interim Full FY CY 2023	1st Full FY CY 2024	2nd Full FY CY 2025	3rd Full FY CY 2026
# of Units	2	2	2	3	3	3
Unweighted Procedures	10,124	10,598	10,800	11,248	11,930	11,996
Weighted Procedures	11,626	12,262	12,432	12,948	13,733	13,809

In Q, pages 119-123, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify last full fiscal year volume (2021)

The applicant begins with the Greenville MRI historical utilization. The applicant states that according to internal data, the facility performed 10,124 MRI scans during CY 2021 which equates to 11,626 weighted scans.

Step 2: Project interim Year 2022 Volume

The applicant projects 2022 volume by annualizing the number of scans performed from January to August.

Annualization of 2022 Data for Form C.2a			
		Total Scans	Weighted Scans
A	January to August	7,065	8,175
B	Months in Period	8	8
C = A/B	Per Month	883	1,022
D = C x 12	Times 12	10,598	12,262

Source: Section Q, page 121

Step 3: Project interim year 2023 volume

The applicant states that following Greenville MRI’s expanded hours of services beginning in March 2021, the facility experienced an increase in scans in 2022. In March, June, July, and August, the facility performed more than 900 scans per month. The applicant assumes that 900 scans per month is the maximum sustainable number on the existing scanners and expects it will perform an average of 900 scans per month or a total 10,800 unweighted scans in 2023.

The applicant applied the average scan weight from 2019-August 2022 (1.151), to project the total number of weighted scans. The following table illustrates the applicant’s calculation.

Weighted Scan Calculation					
	2019	2020	2021	2022*	Total
Unweighted	9,891	8,890	10,124	7,065	35,970
Weighted Scans	11,378	10,228	11,626	8,175	41,407
Average Weight	1.150	1.150	1.148	1.157	1.151

*January-August

Source: Section Q, page 122

Step 4: Project first full project year volume (2024)

The applicant intends to expand hours of services once the proposed MRI scanner becomes operational in 2024. Greenville MRI previously expanded hours of operation in March 2021.

To project the first project year, the applicant compared the average monthly scans performed prior to the first expansion (March 2019-February 2020 (822 scans)) to the average monthly scans performed after the expansion and the height of the pandemic (March 2021-February 2022 (856 scans)).

Time Periods Based on Hour Expansion	Average Scans/Month
March 2019 – February 2020	822
March 2020 – February 2021	734
March 2021 – February 2022	856
March 2022 – August 2022	908

Source: Section Q, page 122

The average monthly scans increased by 4.136%. The applicant projects that the average monthly scans will increase by 4.136% from interim year (2023) through the first full project year (2024). The applicant projects that Greenville MRI will perform 11,248 unweighted scans and 12,948 weighted scans in the first project year. See calculation below. Totals may not foot due to rounding.

$$10,800 \text{ (2023 unweighted scans)} \times 104.14\% = 11,248 \text{ (2024 unweighted scans)}$$

$$11,248 \text{ (2024 unweighted scans)} \times 1.151 \text{ (average weight)} = 12,948 \text{ (2024 weighted scans)}$$

Step 5: Project second full project year volume (2025)

The applicant states that the average monthly scans continued to increase after the first full year after the facility expanding their hours of operation. The average monthly scans increased by 6.064% from the period of March 2021-February 2022 (856 scans) to March 22-August 2022 (908 scans). The applicant projects that the average monthly scans will increase by 6.064% from the first full project year (2024) through the second full project year (2025). The applicant projects that Greenville MRI will perform 11,930 unweighted scans and 13,733 weighted scans in the second project year. See calculation below. Totals may not foot due to rounding.

$$11,248 \text{ (2024 unweighted scans)} \times 106.06\% = 11,930 \text{ (2025 unweighted scans)}$$

$$11,930 \text{ (2025 unweighted scans)} \times 1.151 \text{ (average weight)} = 13,733 \text{ (2025 weighted scans)}$$

Step 6: Project third full project year volume (2026)

The applicant projects that the number scans will increase by 0.55% from 2025 to 2026, which is equal to NCOSBM's actual projected population growth rate in the Pitt/Greene/Hyde/Tyrrell County service area. See table below.

Service Area Population Growth, 2025-2026			
	2025 Population	2026 Population	2025-2026 Growth
Pitt	172,501	173,675	0.68%
Greene	20,352	20,351	0.00%
Hyde	4,249	4,194	-1.29%
Tyrrell	2,994	2,969	-0.84%
Grand Total	200,096	201,189	0.55%

Source: Section Q, page 123

The applicant projects that Greenville MRI will go from 11,626 weighted scans in 2021 to 13,809 weighted scans in 2026, a 19% growth. The applicant states that the projections are conservative because the number of weighted scans in the service area grew 22% in the most recent five fiscal years, as shown in the table below.

Adjusted Service Area MRI Scans, FY 2016-2021						
	2016	2017	2018	2019	2020	2021
Scans on Service Area MRIs	37,659	34,215	37,333	39,796	41,218	45,889

Source: Section Q, page 123; NCOSBM; SMFPs 2019-2023

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a need determination in the 2022 SMFP for a fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area. The proposed project will meet that need determination by developing a fixed MRI scanner in Pitt County.
- Population growth and increasing MRI use rate in the service area demonstrates the need to meet the future demand for MRI services.
- Historical utilization of the two existing fixed MRI scanners located at Greenville MRI.
- The methodology and assumptions utilized by the applicant were reasonable, conservative and well supported. The applicant’s projections were based on the actual percentage of growth in average monthly scans performed before and after the facility expanded hours of operation. The applicant is proposing to expand hours once the proposed scanner becomes operational in 2024.

Access to Medically Underserved Groups

In Section C, page 58, the applicant states:

“Greenville MRI has a long history of meeting the needs of low-income individuals. Around 18 percent of Greenville MRI’s service area is at or below the poverty level. Greenville MRI services all patients, regardless of payor.”

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*	n/a
Women	61.4%
Persons with Disabilities*	n/a
Persons 65 and older	32.7%
Medicare beneficiaries	28.0%
Medicaid recipients	8.0%

Source: Section C, page 59

*Greenville MRI does not track information on patients' income Level, disability status, race, or ethnicity.

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:

- Greenville MRI will serve both Medicaid and Medicare recipients.
- The applicant has policies designed to ensure access to services, including financial assistance.
- The applicant states that the proposal will be accessible to persons with disabilities as required by the American with Disabilities Act.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

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

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

NA
Both Applications

Neither of the applicants in this review propose to reduce or eliminate a service, or to 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
Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section E, pages 61-64, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain Status Quo-Doing nothing would not meet the need for one additional fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area identified in the 2022 SMFP. Furthermore, maintaining the status quo would not address the growing need for MRI services as the population grows and the limitations of the existing mobile MRI scanner.

Develop the Proposed Diagnostic Center in Another Service Area Location-The applicant considered developing the MRI scanner in another area in Pitt County, or in Greene, Hyde, or Tyrrell Counties. However, the applicant determined that Greenville was the best location because the city is the hub of Pitt County healthcare infrastructure. The applicant states that Greenville has the only acute care hospital and ambulatory surgery center in Pitt County and OrthoEast serves residents of Pitt County and surrounding counties.

Acquire Different MRI Equipment-The applicant is proposing to acquire a 1.5T MRI scanner. The applicant considered acquiring a 3.0T MRI scanner, however, it was determined to be a more costly alternative.

On page 64, the applicant states that its proposal is the most effective alternative because the proposed MRI scanner will increase access to convenient, high quality and cost-effective freestanding MRI services.

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

- Developing the proposed fixed MRI scanner expands access to a cost-effective alternative for MRI services in the Pitt/Greene/Hyde/Tyrrell County service area.

- Maintaining the status quo would not address the need in the 2022 SMFP for an additional fixed MRI scanner in the service area.
- 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section E, pages 71-72, 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:

Status Quo-Doing nothing would not meet the need for one additional fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area identified in the 2022 SMFP. Furthermore, maintaining the status quo would not address the need to expand MRI capacity at Greenville MRI.

Locate an MRI in Another Service Area County-The applicant considered developing the MRI scanner in another county in the service area. However, this alternative was dismissed because Green, Hyde or Tyrrell do not have the necessary population base to support a fixed MRI scanner.

Build a New Freestanding Diagnostic Center in Pitt County-The applicant dismissed this alternative as not cost-effective. Additionally, building a new freestanding diagnostic center would not allow for the sharing of staff and existing infrastructure.

On page 72, the applicant states that its proposal is the most effective alternative because it would meet the identified need and respond to the projected growth in the community while minimizing capital costs.

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

- Maintaining the status quo would not address the need in the 2022 SMFP for an additional fixed MRI scanner in the Pitt/Greene/Hyde/Tyrrell County service area.
- The applicant's proposal will expand MRI capacity as a response to the projected growth in the community.
- 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

- (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

Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

Capital and Working Capital Costs

In Section Q, page 114, the applicant projects the total capital cost of the project, as shown in the table below.

OrthoEast Capital Costs			
	Othopaedics East and Sports Medicine Center, Inc.	Orthoedics East Properties, LLC	Total
Construction/Renovation Contract(s)		\$1,093,025	\$1,093,025
Architect/Engineering Fees		\$40,000	\$40,000
Medical Equipment (includes sales tax, freight and installation)	\$1,055,876		\$1,055,876
Furniture	\$5,000		\$5,000
Consultant Fees (CON-related)	\$50,500		\$50,500
Financing Costs	\$11,359	\$11,630	\$22,989
Interest during Construction		\$8,628	\$8,628
Other (IT, rigging overage. Misc. sales. Tax. Contingency)	\$25,000	\$12,500	\$37,500
Total	\$1,147,735	\$1,165,784	\$2,313,519

The applicant provides its assumptions and methodology for projecting capital cost in Forms F.2 and F.3 in Section Q and Exhibits F.1 and K.3. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the information provided in Forms F.2 and F.3 in Section Q and in Exhibits F.1 and K.3.

In Section F, pages 67-68, the applicant projects that start-up costs will be \$8,701. On page 67, the applicant states that there will be no initial operating costs because the current MRI services offered at OrthoEast provides sufficient revenue and cash inflow to exceed the cash outflow. On page 68, 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 reasonable and supported by the expenses related to clinical staffing, inventory, and other expenses related to prepping the equipment for service.

Availability of Funds

In Section F, page 65, the applicant states that the capital cost will be funded, as shown in the tables below.

Sources of Capital Cost Financing

Orthopaedics East and Sports Medicine Center, Inc.		Total
Loans	\$1,147,735	\$1,147,735
Cash and Cash Equivalents, Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$1,147,735	\$1,147,735

* OE = Owner's Equity

Sources of Capital Cost Financing

Orthopaedics East Properties, LLC		Total
Loans	\$1,165,784	\$1,165,784
Cash and Cash Equivalents, Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$1,165,784	\$1,165,784

* OE = Owner's Equity

In Section F, page 68, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Orthopaedics East and Sports Medicine Center, Inc.	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$8,701
Lines of credit	\$0
Bonds	\$0
Total *	\$8,701

In Section F, page 66, the applicant states that the capital costs for the project will be funded by loans and working capital costs will be funded by OrthoEast. Exhibit F.2.1 contains a letter dated September 28, 2022, from Eric S. Clark, First Citizens Bank, documenting that \$1.14 million will be available to fund the proposed project. Exhibit F.2.2 contains a letter from Jesiah W. Duke, MD, president of Orthopaedics East and Sports Medicine Center, Inc., documenting OrthoEast's commitment to fund the working capital costs of the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based the information provided in Section F and Exhibit F.2.1 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

OrthoEast Fixed MRI Scanner	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	CY 2024	CY 2025	CY 2026
Total Weighted Procedures	3,476	3,540	3,605
Total Gross Revenues (Charges)	\$4,219,611	\$4,297,322	\$4,376,733
Total Net Revenue	\$1,127,494	\$1,148,259	\$1,169,477
Average Net Revenue per Procedure	\$324	\$324	\$324
Total Operating Expenses (Costs)	\$823,075	\$922,650	\$958,020
Average Operating Expense per Procedure	\$237	\$261	\$266
Net Income	\$304,419	\$225,609	\$211,457

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:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- 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
- Written comments
- Responses to comments
- Remarks made at the public hearing

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.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

Capital and Working Capital Costs

In Section Q, page 125, the applicant projects the total capital cost of the project, as shown in the table below.

Greenville MRI Capital Cost		
	Greenville MRI, LLC	Total
Construction/Renovation Contract(s)	\$160,950	\$160,950
Architect/Engineering Fees	\$15,000	\$15,000
Medical Equipment (includes sales tax)	\$1,588,022	\$1,588,022
Non-Medical Equipment PC and Injector	\$42,775	\$42,775
Consultant Fees (CON App. Prep)	\$75,000	\$75,000
Interest during Construction	\$13,598	\$13,598
Contingency	\$189,578	\$189,578
Total	\$2,084,923	\$2,084,923

In Section Q, page 126, 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:

- Vendor quotes for construction, architectural and engineering, and non-medical equipment.
- The applicant assumes interest for the first two months of room renovation and the initial 80% of total equipment cost upon delivery and the remaining 20% upon operation.

In Section F, page 75, the applicant states there will be no start-up costs or initial operating expenses because the proposed MRI scanner will be placed in an existing facility.

Availability of Funds

In Section F, page 73, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Greenville MRI, LLC	Total
Loans	\$2,071,325	\$2,071,325
Cash and Cash Equivalents, Accumulated reserves or OE *	\$13,598	\$13,598
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,084,923	\$2,084,923

* OE = Owner's Equity

In Section F, page 74, the applicant states that the capital costs for the project will be funded by a loan and accumulated reserves. Exhibit F.2.1 contains a letter dated October 6, 2022, from Eric S, Clark, First Citizens Bank, documenting that up to \$3 million will be available to fund the proposed project. Exhibit F-2.2 contains a letter dated October 10, 2022, from Lesli Mayberry, Eastern Radiologists, Inc., owner of Greenville MRI, authorizing the use of accumulated reserves to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based the information provided in Section F and Exhibits F.2.1 and F.2.1 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Greenville MRI (Entire Facility)	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
	CY 2024	CY 2025	CY 2026
Total Weighted Procedures	12,948	13,733	13,809
Total Gross Revenues (Charges)	\$15,846,094	\$16,912,954	\$17,006,521
Total Net Revenue	\$5,717,282	\$6,063,938	\$6,097,485
Average Net Revenue per Procedure	\$442	\$442	\$442
Total Operating Expenses (Costs)	\$3,436,668	\$3,864,699	\$3,814,805
Average Operating Expense per Procedure	\$265	\$261	\$276
Net Income	\$2,280,614	\$2,199,239	\$2,282,680

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:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.

- 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
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C Both Applications

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

The following table identifies the existing and approved fixed and mobile MRI scanners located in the Pitt/Greene/Hyde/Tyrrell County service area, summarized from Table 17E-1 of 2022 SMFP.

Fixed MRI Scanners in Pitt County				
Provider	# of Fixed MRI Scanners	# of Mobile MRI Scanners	Total MRI Scans	Adjusted Total
Vidant Medical Center	4	0	13,847	20,078
ECU Physicians MRI	1	0	3,880	4,503
Greenville MRI, LLC	1	0	5,278	6,112
Greenville MRI, LLC	1	0	3,685	4,241
Physicians East P.A. (King's Medical Group)	1	0	3,684	4,023
OrthoEast	0	0.47	2,236	2,265
Totals	8	0.47	32,610	41,222

Source: 2022 SMFP, Table 17E-1, pages 356-357.

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section G, page 75, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Pitt County. The applicant states:

“OrthoEast’s proposed project will improve local access for Pitt County resident to high quality and cost-effective outpatient MR imaging in a lower cost, geographically convenient, easily accessible freestanding diagnostic imaging setting.

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

- The applicant is proposing to provide quality MRI services in the Pitt/Greene/Hyde/Tyrrell County service area at a lower cost in comparison to hospital-based MRI services.
- There is a need determination in the 2022 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
- Written comments
- Responses to comments

- Remarks made at the public hearing
- 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.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section G, page 84, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Pitt County. The applicant states:

“This CON application responds to a published need for an additional fixed MRI scanner in the service area in the 2022 SMFP. This need is shown in Chapter 17, Table 17E-3, page 364, Pitt/Greene/Hyde/Tyrrell, 1 MRI Scanner...Greenville MRI needs an additional scanner to meet the needs of the aging population and to meet the growing demand for MRI services that are expected to accompany the aging demographics in the service area.”

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 2022 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
- Written comments
- Responses to comments
- Remarks made at the public hearing
- 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
 Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section Q, page 119, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff		
	As of 01/01/2022	1 st Full Fiscal Year (CY 2024)	2 nd Full Fiscal Year (CY 2025)	3 rd Full Fiscal Year (CY 2026)
Radiology Technologists	0.00	1.33	1.33	1.50
Administrator/CEO	0.05	0.05	0.05	0.50
Business Office	0.20	0.20	0.20	0.20
Clerical (Scheduler)	1.00	1.00	1.00	1.00
Other (Clinical Supervisor)	0.25	0.25	0.25	0.25
Other (MRI Tech Asst.)	0.00	1.33	1.33	1.50
Total	1.50	4.16	4.16	4.50

The assumptions and methodology used to project staffing are provided in Section H, page 77. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Section H, pages 77-79, 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 is a well-established employer in North Carolina with extensive experience in recruiting appropriate staff.
- The applicant offers competitive salaries and generous benefits and recruit staff through traditional means.
- Staff is required to provide evidence of continued competency and maintaining appropriate licensure requirements and certifications.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section Q, page 145, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff		
	As of 09/04/2022	1 st Full Fiscal Year (CY 2024)	2 nd Full Fiscal Year (CY 2025)	3 rd Full Fiscal Year (CY 2026)
Radiology Technologists	8.00	9.00	9.50	10.00
Business Office	2.00	2.00	2.00	2.50
Clerical	2.33	3.00	3.00	3.00
Other (Clinical Assistant)	3.33	5.00	5.00	6.00
Total	16.00	19.00	20.00	22.00

The assumptions and methodology used to project staffing are provided in Section Q, page 146. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 85-86, 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:

- Greenville MRI is an existing imaging center operating two existing MRI scanners with appropriate staff already in place.
- The applicant states that staff is recruited through ER Imaging, the facility’s management company and provides supporting documentation in Exhibit I-1.1.
- In Exhibit M-1.4, the applicant provides documentation of the orientation process for new staff and annual education requirements.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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
Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

Ancillary and Support Services

In Section I, page 81, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 81-82, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1.1, I.1.2, and I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is an existing facility in the service area with ancillary and support services already in place.
- Eastern Radiologists and the facility's director will continue to service the facility. The applicant provides supporting documentation.

Coordination

In Section I, pages 82-83, 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 OrthoEast's long-established relationships with the physician and provider community, the facility's medical staff privileges at local hospitals, and its network of physicians/providers and their intention to continue to refer MRI patients to OrthoEast.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

Ancillary and Support Services

In Section I, page 88, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 88-90, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.1 and I-1.3. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Greenville MRI has existing ancillary and support services in place that support the two existing MRI scanners and will support the proposed MRI scanner.
- The applicant provides supporting documentation of its management agreement with ER Imaging and the Clinical Laboratory Improvement Amendments (CLIA) waiver allowing the facility to perform lab test without meeting full laboratory requirement and certifications of certain services.

Coordination

In Section I, page 90, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Greenville MRI's extensive experience providing MRI services to service area residents.
- Greenville MRI is a participating provider in a program that assist qualified uninsured residents of Beaufort, Greene, Edgecombe, Hertford, Martin, and Pitt counties.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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
Both Applications

Neither applicant projects 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
Both Applications

Neither applicant is an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section K, page 85, the applicant states that the project involves constructing 2,235 square feet of new space. Line drawings are provided in Exhibit K.1.

On pages 87-89, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.4. The applicant is the building owner; therefore, re-zoning or special permits are not required.

On page 85, 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 states that the proposal will be directed by an experienced architect and construction professionals.
- The applicant projects a reasonable capital cost based on what is required to construct an additional space to house the proposed MRI scanner.

On page 86, 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. OrthoEast provides MRI services on a mobile scanner located outside of the building. The applicant is proposing to develop a fixed MRI scanner that will provide faster image acquisition in a more convenient location. Additionally, the proposal will provide an additional, low-cost option to residents of the multicounty service area.

On page 86, 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
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section K, page 94, the applicant states that the project involves renovating 384 square feet of existing space. Line drawings are provided in Exhibits K-2.1 and K-2.3.

On page 94, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant is proposing to develop the MRI scanner in an existing space at Greenville MRI that does not require costs associated with additional space footage which, minimizes downtime on the two existing fixed MRI scanners.

On page 95, 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. The applicant does not project any change to payor source or payment rates resulting from the acquisition of a third fixed MRI scanner.

On page 95, the applicant identified any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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
 Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section L, page 90, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

OrthoEast (MRI Services) Historical Payor Mix 01/01/2021-12/31/2021	
Payor Category	Percent of Total
Self-Pay	0.36%
Charity Care^	
Medicare*	31.17%
Medicaid*	5.60%
Insurance*	61.69%
Workers Compensation	0.43%
TRICARE	0.50%
Other (government)	0.25%
Total	100.00%

*Including any managed care plans.

^Included in Self-Pay.

In Section L, page 91, the applicant provides the following comparison.

OrthoEast	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	60.6%	53.0%
Male	39.4%	47.0%
Unknown	0.0%	0.0%
64 and Younger	63.3%	85.7%
65 and Older	36.7%	14.3%
American Indian	.03%	0.6%
Asian	0.2%	2.1%
Black or African American	30.0%	36.5%
Native Hawaiian or Pacific Islander	.02%	0.2%
White or Caucasian	65.4%	53.7%
Other Race	.02%	6.9%
Declined / Unavailable	4.4%	0.0%

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

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section L, page 97, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

Greenville MRI Historical Payor Mix 01/01/2021-12/31/2021	
Payor Category	Percent of Total
Self-Pay	3%
Charity Care^	
Medicare*	30%
Medicaid*	6%
Insurance*	55%
Workers Compensation	5%
TRICARE	1%
Other	1%
Total	100%

*Including any managed care plans.

^The applicant does not classify charity care patients as a payor type.
 Charity care can be provided to patients in any payor type.

In Section L, page 98, the applicant provides the following comparison.

Greenville MRI	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	61.4%	52%
Male	38.5%	48%
Unknown	0.1%	N/A
64 and Younger	67.3%	85%
65 and Older	32.7%	15%
American Indian	N/A	1%
Asian	N/A	2%
Black or African American	N/A	36%
Native Hawaiian or Pacific Islander	N/A	0%
White or Caucasian	N/A	59%
Other Race	N/A	2%
Declined / Unavailable	N/A	N/A

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

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing
- Information which was publicly available during the review and used by the Agency

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

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

C

Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 92, the applicant states:

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

In Section L, page 92, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section L, page 99, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

On page 99, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

C
Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section L, page 93, 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.

OrthoEast (MRI Services) Projected Payor Mix CY 2026	
Payor Category	Percent of Total
Self-Pay	0.36%
Charity Care^	1.00%
Medicare*	31.17%
Medicaid*	5.60%
Insurance*	60.69%
Workers Compensation	0.43%
TRICARE	0.50%
Other (government)	0.25%
Total	100.00%

*Including any managed care plans.

^Included in Self-Pay

As shown in the table above, during the third fiscal year of operation, the applicant projects that 0.36% of total services will be provided to self-pay patients, 1.0% to charity care patients, 31.17% to Medicare patients and 5.60% to Medicaid patients.

On page 92, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Projected payor mix is based on the facility’s historical CY 2021 payor mix.
- The applicant does not anticipate a change to the existing physician/provider referral relationships.
- The facility’s affiliation with a local not-for-profit organization will allow OrthoEast to provide charity care access to MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section L, page 100, 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.

Greenville MRI (MRI scans) Projected Payor Mix CY 2026	
Payor Category	Percent of Total
Self-Pay	3%
Charity Care [^]	
Medicare*	28%
Medicaid*	8%
Insurance*	55%
Workers Compensation	4%
TRICARE	1%
Other	1%
Total	100%

*Including any managed care plans.

[^]The applicant does not classify charity care patients as payor type.
 Charity care can be provided to patients in any payor type.

As shown in the table above, during the third fiscal year of operation, the applicant projects that 3% of total services will be provided to self-pay patients, 28% to Medicare patients and 8% to Medicaid patients.

On page 100, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Projected payor mix is based the facility’s historical payor mix percentages for the first eight months of 2022.
- The applicant does not anticipate any change to the payor mix because MRI services is the only service component offered by Greenville MRI and will not change upon project completion.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

C
Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section L, pages 94-95, 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
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section L, page 102, 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
- Written comments
- Responses to comments
- Remarks made at the public hearing

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
Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section M, page 96, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility based on the facility's affiliation with East Carolina University and Pitt Community College.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section M, page 104, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility based on the facility's Memorandum of Understanding with Edgecombe Community College.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

Both Applications

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

The following table identifies the existing and approved fixed and mobile MRI scanners located in the Pitt/Greene/Hyde/Tyrrell County service area, summarized from Table 17E-1 of 2022 SMFP.

Fixed MRI Scanners in Pitt County				
Provider	# of Fixed MRI Scanners	# of Mobile MRI Scanners	Total MRI Scans	Adjusted Total
Vidant Medical Center	4	0	13,847	20,078
ECU Physicians MRI	1	0	3,880	4,503
Greenville MRI, LLC	1	0	5,278	6,112
Greenville MRI, LLC	1	0	3,685	4,241
Physicians East P.A. (King's Medical Group)	1	0	3,684	4,023
OrthoEast	0	1	2,236	2,265
Totals	8	1	32,610	41,222

Source: 2022 SMFP, Table 17E-1, pages 356-357.

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 97, the applicant states:

“Pitt County has MRI competition, with existing hospital and freestanding fixed MRI scanners. However, four of the fixed MRI scanners in Pitt County are owned and operated by ECU Health Medical Center. OrthoEast is the only MRI service provider in Pitt County that does not currently own a fixed MRI scanner. With this project to acquire one fixed MRI scanner, OrthoEast, as an experienced diagnostic imaging provider, expects to improve competition in the service area by enhancing the medical diagnostic imaging services it currently offers in Pitt County, and promoting improved local patient access to quality, cost-effective, an accessible diagnostic imaging.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 97, the applicant states:

“The proposed Siemens 1.5T MRI scanner represents modern technology, with ease of operation, excellent imaging quality, patient comfort, high throughput and dependability, cost-effective capital and operating costs, and energy efficiency capabilities. These will combine to accommodate a high volume of MRI procedures per day, thus containing the cost per procedure.”

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

Regarding the impact of the proposal on quality, in Section N, pages 98-99, the applicant states:

“Patient safety and quality will be incorporated into all aspects of the fixed MRI scanner project, including equipment selection and installation, facility construction, staff credentialing and education, patient selection and scheduling, and continuous quality measures and patient satisfaction surveys.

...

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

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 99, the applicant states:

“Diagnostic MRI services at OrthoEast will continue to be available to and accessible by any patient having a clinical need for those services.”

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 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
- Written comments
- Responses to comments
- Remarks made at the public hearing
- 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.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 105, the applicant states:

“To compete in the future, Greenville MRI must have the capacity to perform more scans than it does now. Current utilization and expected growth of Greenville MRI show the capacity of its existing machines is fully utilized. To compete, Greenville MRI must be able to schedule scans without unreasonable delays. To compete in the future, Greenville MRI needs a third machine.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 105-106, the applicant states:

“Greenville MRI is paid by Medicare under the physician fee schedule. Medicare payments for most scans under the physician fee schedule are less than payments made for the same services to a hospital outpatient department...Placing an additional scanner in a freestanding diagnostic center will lower costs to Medicare, Medicare beneficiaries (in the form of lower copays), and other insurers who base their negotiated rates on Medicare payment.”

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

Regarding the impact of the proposal on quality, in Section N, page 106, the applicant states:

“Both of Greenville MRI’s scanners are accredited by the American College of Radiology (ACR) for head, spine, body, musculoskeletal, and magnetic resonance angiography (MRI scans). The proposed third scanner will receive ACR accreditation for head, spine, body, musculoskeletal, and MRA scans.”

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 106, the applicant states:

“The additional scanner will be available to all patients referred by their treating physician or practitioner.”

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 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
- Written comments
- Responses to comments
- Remarks made at the public hearing
- Information publicly available during the review and used by the Agency

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

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

C Both Applications

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner to the existing medical clinic in Pitt County, pursuant to the 2022 SMFP need determination.

In Section Q, page 130, the applicant identifies the facility that will become a diagnostic center with approval of this MRI, located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 103, the applicant states that, OrthoEast's has provided quality care and operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding submission of this application. Diagnostic centers are not subject DHSR license requirements. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners.

In Section Q, page 148, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of two of this type of facility located in North Carolina.

In Section O, page 109, the applicant states that, during the 18 months immediately preceding the submittal of the application, Greenville MRI has not been subject to any state or federal complains, citations, findings of noncompliance, or similar quality-of care violations or complaints. Diagnostic centers are not subject to DHSR license requirements. After reviewing and considering information provided by the applicant, 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

Both Applications

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- **OrthoEast**-Neither the applicant nor any related entities own or operate fixed MRI scanners in the proposed fixed MRI scanner service area.
 - C- **Greenville MRI**-The applicant owns and operates two fixed MRI scanners located at Greenville MRI in Pitt 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- **Both applications**-Neither applicant nor their related entities own or operate an approved fixed MRI scanner 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- **Both applications**-Neither applicant nor their related entities own or operate a mobile MRI scanner 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- **Both applications**-Neither applicant nor their related entities own or operate an approved mobile MRI scanner that provides 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- **OrthoEast**-Neither the applicant nor any related entity own or operate fixed MRI scanners in the proposed fixed MRI scanner service area. In Section Q, page 108, the applicant provides the projected utilization of the proposed fixed

MRI scanner during the first three full fiscal years of operation following the completion of the project, as illustrated below.

OrthoEast Fixed MRI Scanner Projected Utilization			
	1st Full FY CY 2024	2nd Full FY CY 2025	3rd Full FY CY 2026
# of Units	1	1	1
Unweighted Procedures	3,438	3,501	3,566
Weighted Procedures	3,476	3,540	3,605

The applicant projects to perform 3,476 weighted MRI procedures on the proposed fixed scanner in the first full fiscal year following project completion, an average of 3,540 weighted procedures in the second full fiscal year, and 3,605 weighted procedures in the third full fiscal year.

- C- **Greenville MRI**-The applicant owns and operates two fixed MRI scanners located in the Pitt/Greene/Hyde/Tyrell County service area. In Section Q, page 116, the applicant provides the projected utilization of the existing MRI scanners and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following the completion of the project, as illustrated in the table below.

Greenville MRI Fixed MRI Scanner Projected Utilization			
	1st Full FY CY 2024	2nd Full FY CY 2025	3rd Full FY CY 2026
# of Units	3	3	3
Unweighted Procedures	11,248	11,930	11,996
Weighted Procedures	12,948	13,733	13,809

The applicant projects to perform an average of 4,316 weighted MRI procedures on the two existing MRI scanners and the proposed fixed scanner in the first full fiscal year following project completion, an average of 4,578 weighted procedures in the second full fiscal year, and 4,603 weighted procedures in the third full fiscal year.

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

-C- OrthoEast-The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.

C- Greenville MRI- The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.

(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) *3,364 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) *3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;*

(C) *2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;*

(D) *2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or*

(E) *1,201 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and*

-C- OrthoEast-The applicant does not own or operate an existing fixed MRI scanner in the service area. The applicant is proposing to acquire one fixed MRI scanner. The applicant projects an average of 3,605 adjusted procedures in the third full fiscal year, which exceeds the performance standard of 3,364 or more adjusted MRI procedures per fixed MRI scanner.

C- Greenville MRI-The applicant owns two existing fixed MRI scanners and proposes to acquire one fixed MRI scanner, for a total of three fixed MRI scanners. The applicant projects an average of 4,603 adjusted procedures in the third full fiscal year, which exceeds the performance standard of 3,364 or more adjusted MRI procedures per fixed MRI scanner.

(8) *project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,328 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operation following completion of the project.*

NA- Both applications-Neither applicant nor any related entities own or operate mobile MRI scanners 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 (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 3,328 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operation 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 operation following completion of the project as follows:

(A) 3,364 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) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;

(C) 2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;

(D) 2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or

(E) 1,201 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.

NA- Both applications-Neither applicant proposes to acquire a mobile scanner pursuant to a need determination in the annual State Medical Facility Plan in effect as of the first day of the review period.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2019 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for Pitt County in this review. Because the two applications in this review collectively propose to develop two additional fixed MRI scanners to be located in Pitt County, all the applications cannot be approved for the total number of fixed MRI scanners proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination
Orthopaedics East and Sports Medicine Center, Inc. and Orthopaedics East Properties, hereinafter referred to as “the applicant” or “OrthoEast”, proposes to add one fixed MRI scanner to its existing medical clinic located at 810 WH Smith Boulevard in Pitt County, pursuant to the 2022 SMFP need determination. The applicant is proposing to add an addition to the medical clinic to house the fixed MRI scanner.

Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination
Greenville MRI, LLC, hereinafter referred to as “the applicant or Greenville MRI,” proposes to add one fixed MRI scanner pursuant to the 2022 SMFP need determination for a total of three MRI scanners at Greenville MRI, a physician practice located at 2101 W. Arlington Boulevard in Pitt County.

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, the applications submitted by **OrthoEast** and **Greenville MRI** are equally effective alternatives.

Scope of Services

Generally, the application proposing to provide the broadest scope of services is the more effective alternative with regard to this comparative factor. With regard to scope of services, both applications submitted are in response to the 2022 State Medical Facilities Plan (SMFP) which includes a need determination for one fixed MRI scanner. Both applicants propose to acquire and operate a fixed MRI scanner in a freestanding outpatient setting. Therefore, regarding this comparative factor, the applications submitted by **OrthoEast** and **Greenville MRI** are equally effective alternatives.

Historical Utilization

Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that that provider has a greater need for the proposed fixed MRI scanner in order to serve its projected patients. Each of the applicants have a history of providing MRI services in Pitt County. The following table illustrates historical utilization of each applicant as provided in the 2022 SMFP representing FY2020 reported utilization.

Fixed MRI Scanners in Pitt County (FY2020)				
Provider	# of Fixed MRI Scanners	# of Mobile MRI Scanners	Total MRI Scans	Adjusted Total
Vidant Medical Center	4	0	13,847	20,078
ECU Physicians MRI	1	0	3,880	4,503
Greenville MRI, LLC	1	0	5,278	6,112
Greenville MRI, LLC	1	0	3,685	4,241
Physicians East P.A. (King’s Medical Group)	1	0	3,684	4,023
OrthoEast	0	0.47	2,236	2,265
Totals	8	0.47	32,610	41,222

Source: 2022 SMFP, Table 17E-1, pages 356-357.

OrthoEast has historically provided MRI services on a leased mobile MRI scanner. **Greenville MRI** owns two fixed MRI scanners. The 2022 SMFP identifies **OrthoEast’s** MRI scanner as a leased mobile MRI scanner that is not included in the Pitt County inventory of fixed MRI scanners. **OrthoEast** does not own a fixed MRI scanner. Therefore, there is no historical fixed MRI utilization to compare. Thus, the result of this analysis is inconclusive.

Geographic Accessibility (Location within the Service Area)

The following table illustrates where in the service area each applicant proposes to develop its proposal.

	Proposed Locations
OrthoEast	810 WH Smith Blvd, Greenville
Greenville MRI	2101 W. Arlington Blvd. Greenville

Each application is proposing to locate the fixed MRI scanner in Greenville. Per Google Maps the locations are less than a mile apart (4 min drive). Thus, with respect to geographic accessibility, **OrthoEast** and **Greenville MRI** are equally effective alternatives.

Access by Service Area Residents

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

The following table illustrates access by service area residents during the third full fiscal year following project completion.

**Pitt County Residents
 Projected to be Served Project Year 3**

Residents Served as a % of Total Patients					
Applicant	Pitt	Greene	Hyde	Tyrell	Total
OrthoEast	57.3%	2.7%	0.0%	0.0%	59.7%
Greenville MRI	48.6%	2.6%	0.4%	0.1%	51.7%

Source: Section C of the respective applications

As shown in the table above, Pitt County residents are projected to represent a significant portion of each applicant’s total utilization. **OrthoEast** is projected to serve the highest percentage of service area residents. Therefore, regarding projected service to residents of the service area, **OrthoEast’s** proposal is the more effective alternative.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, 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 access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Upon project completion **OrthoEast** will have one fixed MRI scanner and **Greenville MRI** will have a total of three fixed MRI scanners. It is important to note that both applicants include “professional fees” in their pro formas. Each applicant states in their application that “professional fees” are not billed to the patient. Only the technical component is billed to the patient.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion of each facility using the following metrics: Medicare dollars and Medicare dollars as a percentage of total gross revenues.

Applicant	Gross Revenue	MRI Scans*	Medicare	Medicare as a % of Gross Revenue
OthoEast	\$4,376,733	3,605	\$1,364,228	31.17%
Greenville MRI	\$17,006,521	13,809	\$5,017,804	29.5%

Source: Section Q, Form F.2b of the respective applications

*Weighted scans

As shown in the table above, **Greenville MRI** projects the largest dollar amount of Medicare revenue, an average of \$1,672,601 per scanner. **OrthoEast** projects the highest Medicare revenue as a percent of gross MRI patient revenue in the third full fiscal year following project completion. Therefore, with respect to Medicare, the applicants are equally effective.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion of each facility using the following metrics: Medicaid dollars and Medicaid dollars as a percentage of total gross revenues.

Applicant	Gross Revenue	MRI Scans*	Medicaid	Medicaid as a % of Gross Revenue
OthoEast	\$4,376,733	3,605	\$245,097	5.6%
Greenville MRI	\$17,006,521	13,809	\$1,322,166	7.8%

Source: Section Q, Form F.2b of the respective applications

*Weighted scans

As shown in the table above, **Greenville MRI** projects the largest dollar amount of Medicaid revenue, an average of \$440,772 per scanner. **Greenville MRI** projects the highest Medicaid revenue as a percent of gross MRI patient revenue in the third full fiscal year following project completion. Therefore, with respect to Medicaid, **Greenville MRI** is the more effective alternative.

Competition (Access to a New or Alternate Provider)

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. Although, **OrthoEast** does not own a fixed MRI scanner, both applicants are existing providers of MRI services in the service area of Pitt, Green, Hyde and Tyrrell Counties; therefore, neither of the applicants would qualify as a new or alternative provider in the service area. Thus, with regard to this comparative factor, the proposals are equally effective.

Projected Average Net Revenue per MRI Procedure

Upon project completion **OrthoEast** will have one fixed MRI scanner and **Greenville MRI** will have a total of three fixed MRI scanners. It is important to note that both applicants include “professional fees” in their pro formas. Each applicant states in their application that “professional fees” are not billed to patient. Only the technical component is billed to the patient.

The following table compares the projected average net revenue per weighted MRI procedure (scan) for the third year of operation following project completion for both of the applicants, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally regarding this factor, the application proposing the lowest average net revenue per MRI scan is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

Applicant	Net Revenue	# of MRI Scans*	Average Net Revenue per MRI Scan
OthoEast	\$1,169,477	3,605	\$324.40
Greenville MRI	\$6,097,485	13,809	\$441.55

Source: Section Q, Form F.2b of the respective applications

*Weighted scans

As shown in the table above, **OrthoEast**, projects the lowest average net revenue per MRI scan in the third full fiscal year following project completion. Therefore, with respect to projected average net revenue per MRI scanner, **OrthoEast** is the more effective alternative.

Projected Average Operating Expense per MRI Procedure

Upon project completion **OrthoEast** will have one fixed MRI scanner and **Greenville MRI** will have a total of three fixed MRI scanners. It is important to note that both applicants include “professional fees” in their pro formas. Each applicant states in their application that “professional fees” are not billed to patient. Only the technical component is billed to the patient.

The following table shows the projected average operating expense per weighted MRI scan in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per MRI scan is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Applicant	Total # of Weighted MRI Scans	Operating Expense MRI Services	Average Operating Expense per Weighted MRI Scan
OthoEast	3,605	\$958,020	\$265.74
Greenville MRI	13,809	\$3,814,805	\$276.25

Source: Section Q, Form F.2b of the respective applications

As shown in the table above, **OrthoEast** proposes a lower average operating expense per weighted MRI scan. Therefore, regarding average operating expense per MRI scan, the proposal by **OrthoEast** is the more effective alternative.

SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	OrthoEast	Greenville MRI
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes
Scope of Services	Equally Effective	Equally Effective
Historical Utilization of the Facility	Inconclusive	Inconclusive
Geographic Accessibility	Equally Effective	Equally Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Medicare Patients	Equally Effective	Equally Effective
Access by Medicaid Patients	Less Effective	More Effective
Competition (Access to New or Alternative Provider)	Equally Effective	Equally Effective
Projected Average Net Revenue per MRI procedure	More Effective	Less Effective
Projected Average Operating Expense per MRI procedure	More Effective	Less Effective

The **OrthoEast** and **Greenville MRI** applications are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of two fixed MRI scanners in Pitt, Green, Hyde and Tyrrell Counties, but the need determination is for only one fixed MRI scanner in the Pitt, Greene, Hyde and Tyrrell County service area. Therefore, only one fixed MRI scanner can be approved.

As shown in the table above, **OrthoEast** was determined to be a more effective alternative for the following factors:

- Access by Service Area Residents
- Projected Average Net Revenue per MRI procedure
- Projected Average Operating Expense per MRI procedure

As shown in the table above, **Greenville MRI** was determined to be a more effective alternative for the following factors:

- Access by Medicaid Patients

DECISION

Each application is individually conforming to the need determination in the 2022 SMFP for one additional fixed MRI scanner in the Pitt, Greene/Hyde/Tyrrell County fixed MRI scanner service area as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states

that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following application is conditionally approved as submitted:

- Q-12286-22/ Orthopaedics East and Sports Medicine Center / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination.

And the following two applications are denied:

- Q-12294-22/ Greenville MRI / Acquire no more than one fixed MRI scanner pursuant to the 2022 SMFP need determination

The application submitted by **OrthoEast (Project ID #Q-12286-22)** is approved subject to the following conditions:

- 1. Orthopaedics East and Sports Medicine Center, Inc. (hereinafter certificate holders) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holders shall acquire no more than one fixed MRI scanner to be located at Orthopaedics East and Sports Medicine Center.**
- 3. Upon completion of the project, Orthopaedics East and Sports Medicine Center shall be licensed for no more than one fixed MRI scanner.**
- 4. 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 holders shall complete all sections of the Progress Report form.**
 - c. The certificate holders 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 August 1, 2023.**
- 5. The certificate holders 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.**
- 6. 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.**

- 7. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holders shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

- 8. The certificate holders 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.**