

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2023

Findings Date: September 27, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: E-12398-23

Facility: EmergeOrtho-Lenoir

FID #: 230543

County: Caldwell

Applicant(s): EmergeOrtho, P.A.

Project: Acquire a fixed MRI scanner pursuant to the 2023 SMFP adjusted need determination

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

EmergeOrtho P.A. (hereinafter referred to as “the applicant” or “EmergeOrtho”) proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP). The applicant will upfit an existing space to install and operate the fixed MRI scanner in a building adjacent to EmergeOrtho-Lenoir’s outpatient clinic. EmergeOrtho-Lenoir serves as one of the host sites for the EmergeOrtho Foothills Region mobile MRI scanner. EmergeOrtho-Lenoir will cease as a host site upon projection completion.

Need Determination

The 2023 SMFP includes an adjusted need determination for one fixed MRI scanner in the Caldwell County MRI Service Area. The applicant submitted an application for one fixed MRI

scanner in response to the adjusted need identified in Table 17E-4, page 358, of the 2023 SMFP. There were no other applications submitted for a fixed MRI scanner in Caldwell County. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area. Thus, the applicant's proposal is consistent with the adjusted need determination in the 2023 SMFP for one fixed MRI scanner in Caldwell County.

Policies

There is one policy in the 2023 SMFP which are applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3: Basic Principles, on page 30 of the 2023 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.”

Policy GEN-3. In Section B, pages 25-26 and Section N, pages 100-103, the applicant explains why it believes its application is conforming to *Policy GEN-3*.

Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed MRI services in Caldwell County; and

- The applicant adequately documents how the project will promote equitable access to fixed MRI services in Caldwell County; and
 - 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

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

Patient Origin

The 2023 SMFP defines the service area for a fixed MRI scanner service area as “...*the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1... Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.*” Figure 5.1 on page 36 of the 2023 SMFP shows Caldwell County as a single service area. Therefore, for the purpose of this review, the fixed MRI service area is Caldwell County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

| County | EmergeOrtho-Lenoir Mobile MRI Services Historical Patient Origin | |
|--------------------|------------------------------------------------------------------------|----------------|
| | Last Full FY 01/01/2022-12/31/2022 | |
| | Patients | % of Total |
| Caldwell | 986 | 70.48% |
| Burke | 125 | 8.93% |
| Catawba | 92 | 6.58% |
| Wilkes | 49 | 3.50% |
| Alexander | 45 | 3.22% |
| Watauga | 40 | 2.86% |
| McDowell | 20 | 1.43% |
| Other NC Counties* | 38 | 2.72% |
| Other States | 4 | 0.28% |
| Total | 1,399 | 100.00% |

Source: Section C, page 31

*Includes other NC counties, each representing less than 1% of total patient origin.

| EmergeOrtho-Lenoir Fixed MRI Services Projected Patient Origin | | | | | | |
|----------------------------------------------------------------------|-------------------------|---------------|-------------------------|---------------|-------------------------|---------------|
| County | 1 st Full FY | | 2 nd Full FY | | 3 rd Full FY | |
| | CY2025 | | CY2026 | | CY2027 | |
| | Patients | % of Total | Patients | % of Total | Patients | % of Total |
| Caldwell | 2,412 | 85.4% | 2,829 | 87.2% | 3,250 | 88.7% |
| Burke | 125 | 4.4% | 125 | 3.9% | 125 | 3.4% |
| Catawba | 92 | 3.3% | 92 | 2.8% | 92 | 2.5% |
| Wilkes | 49 | 1.7% | 49 | 1.5% | 49 | 1.3% |
| Alexander | 45 | 1.6% | 45 | 1.4% | 45 | 1.2% |
| Watauga | 40 | 1.4% | 40 | 1.2% | 40 | 1.1% |
| McDowell | 20 | 0.7% | 20 | 0.6% | 20 | 0.5% |
| Other NC Counties* | 38 | 1.3% | 38 | 1.2% | 38 | 1.0% |
| Other States | 4 | 0.1% | 4 | 0.1% | 4 | 0.1% |
| Total | 2,826 | 100.0% | 3,243 | 100.0% | 3,664 | 100.0% |

Source: Section C, page 33

*Includes other NC counties, each representing less than 1% of total patient origin.

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported by the historical patient origin of EmergeOrtho's mobile MRI patients and the applicant's assumption that Caldwell County patients who obtained MRI services outside Caldwell County will shift to EmergeOrtho-Lenoir upon project completion.

Analysis of Need

In Section C, pages 36-47, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The 2023 SMFP identified an adjusted need for one fixed MRI scanner in Caldwell County. (page 36)
- Caldwell County has one hospital-based fixed MRI scanner and one mobile MRI scanner located in EmERGEOrtho's outpatient clinic. The five-year (FY2017 – FY2022) Compound Annual Growth Rate (CAGR) in MRI utilization and the growing use rate in Caldwell County demonstrates the need for the proposed freestanding fixed MRI scanner. (pages 36-38)
- The lack of fixed MRI scanner competition in Caldwell County does not incentivize providers to be innovated and improve quality outcomes. (pages 38-39)
- There are no cost-effective freestanding MRI services available to Caldwell County patients. (pages 39-41)
- The projected population growth and aging in the Caldwell County service area, particularly among the 65+ age cohort, and the population health characteristics are driving the need to expand access to MRI services. (pages 41-45)
- The annual growth in the number of MRI procedures performed on EmERGEOrtho's mobile MRI scanner. (pages 45-46).
- The existing mobile MRI scanner located outside of the EmERGEOrtho-Lenoir outpatient clinic limits access to MRI services, particularly for patients with physical limitations. (pages 46-47)
- The support of physicians and providers in Caldwell County and surrounding counties that refer patients to EmERGEOrtho-Lenoir for mobile MRI procedures. (page 47)

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

- The lack of a freestanding fixed MRI scanner in the Caldwell County limits access to outpatient MRI procedures.
- The applicant relied on data from the North Carolina Office of State Budget Management (NCOSBM) and other resources related to health statistics, to demonstrate the projected population growth in the Caldwell County and the percentage of risk factors that supports the need for MRI services.
- The growth in utilization of weighted MRI procedures performed in Caldwell County.
- The applicant provides letters of support from referring physicians and providers who support the need for the proposed fixed MRI scanner.

Projected Utilization

In Section Q, pages 110-113, the applicant provides historical and projected utilization, as illustrated in the following tables.

| EmergeOrtho-Lenoir Historical and Interim Utilization | | | |
|------------------------------------------------------------------|------------------------------------|---------------------------------------|---------------------------------------|
| | Last Full FY CY2022 | Interim Full FY CY2023 | Interim Full FY CY2024 |
| X-Ray | | | |
| # of Units | 1 | 1 | 1 |
| # of Procedures | 5,031 | 5,033 | 5,036 |
| Mobile MRI Scanner | | | |
| # of Units | 1 | 1 | 1 |
| Unweighted Procedures | 1,399 | 1,400 | 1,400 |
| Weighted Procedures | 1,417 | 1,427 | 1,428 |

Source: Section Q, page 110

| EmergeOrtho-Foothills Region Historical and Interim Utilization Mobile MRI Scanner | | | |
|---------------------------------------------------------------------------------------------------|------------------------------------|---------------------------------------|---------------------------------------|
| | Last Full FY CY2022 | Interim Full FY CY2023 | Interim Full FY CY2024 |
| # of Units | 1 | 1 | 1 |
| Unweighted Procedures | 5,323 | 5,350 | 5,378 |
| Weighted Procedures | 5,410 | 5,444 | 5,472 |

Source: Section Q, page 111

| EmergeOrtho-Lenoir Projected Utilization | | | |
|-----------------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|
| | 1st Full FY CY2025 | 2nd Full FY CY2026 | 3rd Full FY CY2027 |
| X-Ray | | | |
| # of Units | 1 | 1 | 1 |
| # of Procedures | 5,038 | 5,040 | 5,043 |
| Fixed MRI Scanner | | | |
| # of Units | 1 | 1 | 1 |
| Unweighted Procedures | 2,826 | 3,243 | 3,664 |
| Weighted Procedures | 2,882 | 3,307 | 3,736 |

Source: Section Q, page 112

| EmergeOrtho-Foothills Region Projected Utilization Mobile MRI Scanner | | | |
|--------------------------------------------------------------------------------------|------------------------------------|---------------------------------------|---------------------------------------|
| | Last Full FY CY2025 | Interim Full FY CY2026 | Interim Full FY CY2027 |
| # of Units | 1 | 1 | 1 |
| Unweighted Procedures | 3,873 | 3,863 | 3,853 |
| Weighted Procedures | 3,942 | 3,931 | 3,921 |

Source: Section Q, page 113

In Section Q, pages 115-120, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Historical and Projected MRI Procedures on EmergeOrtho-Foothills Region Mobile MRI Scanner

EmergeOrtho operates a mobile MRI scanner in the Foothills Region and serves four host sites located in Caldwell, Burke, and Catawba counties. EmergeOrtho-Lenoir serves as one of the host sites two days a week. To begin its projections, the applicant examined the historical utilization and weighting ratio of the Foothills Region mobile MRI scanner.

| EmergeOrtho-Foothills Region Historical Mobile MRI Scanner Utilization, CY2019-CY2022* | | | | | |
|---------------------------------------------------------------------------------------------------|-------------|---------------|-------------|-------------|-------------|
| Historical Foothills Mobile MRI | 2019 | 2020** | 2021 | 2022 | CAGR |
| Total Unweighted Procedures | 5,242 | 5,055 | 5,498 | 5,323 | 0.51% |
| Weighted Procedures | 5,338 | 5,153 | 5,587 | 5,410 | |
| Weighted Ratio | 1.018 | 1.019 | 1.016 | 1.016 | |

Source: Section Q, page 115

*Data reported for calendar years.

**Impact of the COVID-19 pandemic.

The applicant will discontinue mobile services at the Lenoir location upon project completion and add the two mobile MRI service days to the two Catawba County host sites. As illustrated in the table above, Foothills Region experienced a 4-year (CY2019-CY2022) CAGR of 0.51% for unweighted mobile MRI procedures. The applicant projects the number of unweighted mobile MRI procedures through CY2027 using the 0.51% growth rate. To project the number of weighted mobile MRI procedures, the applicant applied the Foothills Region 4-year (CY2019-CY2022) average weighting ratio of 1.018 to the projected number of weighted mobile MRI procedures. See table below.

| EmergeOrtho-Foothills Region Projected Mobile MRI Utilization, CY2023-CY2027 | | | | | |
|-----------------------------------------------------------------------------------------|-------------|-------------|-------------|-------------|-------------|
| Projected Foothills Mobile MRI | 2023 | 2024 | 2025 | 2026 | 2027 |
| Unweighted Procedures | 5,350 | 5,378 | 5,405 | 5,433 | 5,461 |
| Weighted Procedures | 5,444 | 5,472 | 5,500 | 5,529 | 5,557 |
| Weighted Ratio | 1.018 | 1.018 | 1.018 | 1.018 | 1.018 |

Source: Section Q, page 116

EmergeOrtho-Lenoir Mobile MRI Procedures

The applicant examined the historical utilization and weighting ratio of mobile MRI procedures at EmergeOrtho-Lenoir. As previously stated, the Lenoir location serves as a host site for mobile MRI services two days a week.

| EmergeOrtho-Lenoir Historical Mobile MRI Scanner Utilization, CY2019-CY2022* | | | | |
|-----------------------------------------------------------------------------------------|-------------|-------------|-------------|-------------|
| Historical Lenoir | 2019 | 2020 | 2021 | 2022 |
| Total Unweighted Procedures | 1,461 | 1,382 | 1,492 | 1,399 |
| Weighted Procedures | 1,500 | 1,421 | 1,509 | 1,417 |
| Weighted Ratio | 1.027 | 1.028 | 1.012 | 1.013 |

Source: Section Q, page 116

*Data reported for calendar years.

The applicant proposes to begin offering fixed MRI services at the Lenoir location beginning January 2025. The host site will continue to offer mobile MRI services through CY2024. The applicant projects the number of unweighted mobile MRI procedures for CY2023 and CY2024, based on projected population data from NCOSBM. The Caldwell County total population is projected to grow 0.05% annually from 2023 to 2027. The applicant applied the 4-year average (CY2019-CY2022) weighting ratio of 1.020 to project the number of weighted mobile MRI procedures, See table below.

| EmergeOrtho-Lenoir Projected Mobile MRI Utilization CY2023-CY2024 | | |
|----------------------------------------------------------------------------------|-------------|-------------|
| Projected Lenoir | 2023 | 2024 |
| Total Unweighted Procedures | 1,400 | 1,400 |
| Weighted Procedures | 1,427 | 1,428 |
| Weighted Ratio | 1.020 | 1.020 |

Source: Section Q, page 116

Recapture Out-Migrated Caldwell County MRI Procedures

The applicant assumes that once EmergeOrtho-Lenoir begins offering MRI services full time, the facility will recapture the Cardwell County residents that have historically traveled outside of the county to access MRI services. The applicant projects that 35% of those patients will

shift during the initial project year, 45% by the second project year, and 55% by the third project year. The applicant’s projections are based on factors such as the availability of full time outpatient MRI services in a convenient location in Caldwell County. The following table illustrates the number of unweighted fixed MRI procedures projected to shift to EmergeOrtho-Lenoir during the first three project years.

| Projected EmergeOrtho Shifting of Out-Migrated Caldwell County Unweighted MRI Procedures | | | |
|-------------------------------------------------------------------------------------------------|--------------|--------------|--------------|
| Shifted to Lenoir | 2025 | 2026 | 2027 |
| Out-Migrated MRI Procedures on Caldwell County Residents* | 4,071 | 4,092 | 4,112 |
| Recapture Percentage | .35 | .45 | .55 |
| Total Shifted Procedures | 1,425 | 1,841 | 2,262 |

Source: Section Q, page 118

*Calculated based on 2021 total of 3,991 (per Exhibit C.4.1), projected to CY2025-CY2027 based on projected annual Caldwell County population growth rate of 0.05%.

Total Projected Lenoir MRI Procedures

Although mobile MRI services will no longer be offered beyond CY2024, the applicant projects utilization for the first three project years for the purpose of determining the total number of fixed unweighted procedures. The applicant assumes the number of procedures will increase by one procedure by the second project year. The applicant combined the projected number of unweighted fixed MRI procedures with the projected number of unweighted fixed MRI procedures projected to shift. The applicant applied the 4-year average (CY2019-CY2022) weighting ratio of 1.020 to project the total number of weighted fixed MRI procedures.

| Total Projected EmergeOrtho-MRI Procedures | | | |
|---------------------------------------------------|-------------|-------------|-------------|
| Lenoir Total After Shift | 2025 | 2026 | 2027 |
| Organic Unweighted Procedures | 1,401 | 1,402 | 1,402 |
| Recapture Caldwell County Outmigration | 1,425 | 1,841 | 2,262 |
| Total Unweighted Procedures | 2,826 | 3,243 | 3,664 |
| Weighted Procedures | 2,882 | 3,307 | 3,736 |
| Weighting Ratio | 1.020 | 1.020 | 1.020 |

Source: Section Q, page 118

Total Projected Foothills Region Mobile MRI Procedures After Shift

To project the total number of Foothills Region mobile MRI procedures after the shift of Caldwell County patients, the applicant subtracted the projected number of unweighted fixed MRI procedures (prorated) projected to shift to EmergeOrtho-Lenoir during the first three project years. The applicant applied the Foothills Region 4-year average (CY2019-CY2022) weighting ratio of 1.018 to project the total number of weighted fixed MRI procedures.

| Total Projected Foothills Region Mobile MRI Procedures | | | | | |
|---------------------------------------------------------------|--------------|--------------|--------------|--------------|--------------|
| Foothills Mobile After Shift | 2023 | 2024 | 2025 | 2026 | 2027 |
| Unweighted Procedures | 5,350 | 5,378 | 5,405 | 5,433 | 5,461 |
| Shifted Lenoir* | | | 131 | 168 | 206 |
| Lenoir Mobile Site Discontinued | | | 1,401 | 1,402 | 1,402 |
| Total Unweighted | 5,350 | 5,378 | 3,873 | 3,863 | 3,853 |
| Weighted Procedures | 5,444 | 5,472 | 3,942 | 3,931 | 3,921 |
| Weighting Ratio | 1.018 | 1.018 | 1.018 | 1.018 | 1.018 |

Source: Section Q, page 119

*Represents prorated share of out-migrated Caldwell County residents shifting to the Lenoir fixed MRI scanner.

Fixed and Mobile MRI Performance Standards

The total projected number of weighted procedures for the proposed fixed MRI scanner exceeds the performance standards of 3,494 weighted MRI procedures for a county with two or more fixed MRI scanner in the service area during the third full fiscal year of operation following completion of the project, as set forth in 10A NCAC 14C .2703. The total projected number of weighted procedures for the existing mobile MRI scanners exceeds the performance standards of 3,120 weighted MRI procedures during the third full fiscal year of operation following completion of the project, as set forth in 10A NCAC 14C .2703.

| Total Projected EmergeOrtho MRI Procedures | | |
|-------------------------------------------------------------------------|-------------|-------------|
| Lenoir Fixed MRI Scanner and Foothills Region Mobile MRI Scanner | | |
| | 2027 | 2027 |
| Weighted Lenoir Fixed Procedures | 3,736 | |
| Fixed Performance Standard | 3,494 | |
| Weighted Foothills Mobile Procedures | | 3,921 |
| Mobile Performance Standard | | 3,120 |

Source: Section Q, page 120

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

- There is an adjusted need determination for one fixed MRI scanner for Caldwell County in the 2023 SMFP.
- The applicant relied on the historical utilization of the existing mobile MRI scanner.
- The applicant’s projections are supported by the projected population growth in Caldwell County.
- Upon project completion, EmergeOrtho-Lenoir will be the only provider of freestanding fixed MRI services in Caldwell County. MRI procedures performed in a freestanding facility are generally less costly and more convenient than MRI procedures performed in a hospital licensed facility.
- The applicant documents out-migration of Caldwell County residents in FY2022 to receive MRI services in surrounding counties and reasonably projects that a portion of these patients will shift to EmergeOrtho upon project completion.

- The applicant’s projected total unweighted MRI procedures combined with projected number of recaptured procedures are reasonable.

Access to Medically Underserved Groups

In Section C, page 53, the applicant states:

“Patients obtain access to EmergeOrtho MRI services through physician/provider referral, and EmergeOrtho 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...MRI imaging services at EmergeOrtho will continue to be available to and accessible by any patient having a clinical need for those services.”

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

| EmergeOrtho-Lenoir 3rd Full FY, CY 2027 | |
|---------------------------------------------------------------|-------------------------------------|
| Medically Underserved Groups | Percentage of Total Patients |
| Low-income persons* | 14.8% |
| Racial and ethnic minorities** | 7.6% |
| Women** | 49.1% |
| Persons with Disabilities* | 14.5% |
| Persons 65 and older** | 47.2% |
| Medicare beneficiaries** | 36.3% |
| Medicaid recipients** | 6.3% |

Source: Section C, page 53

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

**Based on the historical access to MRI services by these medically underserved groups at EmergeOrtho-Lenoir during CY2022.

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

NA

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

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

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

In Section E, pages 63-65, 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-The applicant states that maintaining the status quo is not an effective alternative because the 2023 SMFP has determined an adjusted need for one fixed MRI scanner in Caldwell County. Additionally, Caldwell County does not have a freestanding fixed MRI scanner and only one hospital-based fixed MRI scanner in the county. The applicant states that the majority of similar size counties have at least one fixed MRI scanner. This has resulted in patients leaving the county for MRI services or forgoing services all together.

Develop the Proposed Diagnostic Center in Another Caldwell County Location-The applicant states that Lenoir is the largest municipality in the county, geographically centralized, easily

accessible to major highways, and has the largest concentration of healthcare providers, therefore, making it the most appropriate location for the proposed fixed MRI scanner.

Acquire Different MRI Equipment-The applicant considered obtaining a 3T MRI scanner instead of a 1.5T MRI scanner because it can provide high image quality and faster scan times. The strength of a 3T MRI scanner can produce certain scan types that are not available on a 1.5T MRI scanner. However, this alternative was dismissed because of the higher costs and the limitations for certain orthopedic patients. The applicant also considered obtaining a dedicated extremity scanner, but this alternative was dismissed because of longer scanning durations.

On pages 64-65, the applicant states that its proposal is the most effective alternative because the proposed fixed MRI scanner will enhance access to MRI services in Caldwell County and allow EmmergeOrtho to provide convenient, high quality and cost-effective 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:

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

Conclusion

Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. EmmergeOrtho P.A. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than one fixed MRI scanner pursuant to an adjusted need determination in the 2023 SMFP.**
- 3. Upon completion of the project EmmergeOrtho-Lenoir shall be licensed for no more than one fixed MRI scanner.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with**

the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at:

<https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.

- b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on May 1, 2024.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

Capital and Working Capital Costs

In Section Q, page 121, the applicant projects the total capital cost of the project, as shown in the table below.

| Capital Costs | |
|----------------------------------------------------------------|--------------------|
| Construction/Renovation Contract(s) | \$391,966 |
| Architect/Engineering Fees | \$25,000 |
| Medical Equipment (Includes sales tax, freight & installation) | \$843,325 |
| Furniture | \$4,500 |
| Consultant Fees (CON-related) | \$53,750 |
| Financing Costs | \$15,000 |
| Interest during Construction | \$5,879 |
| Other (IT, contingency, misc. taxes & fees) | \$50,000 |
| Total | \$1,389,420 |

In Section F, page 59, 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:

- Capital costs are based on vendor quotes related to the cost for equipment and facility renovation.
- The applicant provides supporting documentation in Exhibits F.1 and K.3.

In Section F, page 68, the applicant projects that start-up costs will be \$32,000 and initial operating expenses will be \$50,000 for a total working capital of \$82,000. On page 69, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Start-up costs are based on expenses related to clinical staffing, supply inventory, occupying facility space, equipment operation, and incidentals related to preparing the fixed MRI scanner for service.
- Initial operating expenses are associated with transitioning to fixed MRI services.

Availability of Funds

In Section F, page 66, the applicant states that the capital cost will be funded, as shown in the table below.

| Sources of Capital Cost Financing | | |
|------------------------------------------|-------------------------|--------------|
| Type | EmergeOrtho P.A. | Total |
| Loans | \$1,389,420 | \$1,389,420 |
| Accumulated reserves or OE * | \$0 | \$0 |
| Bonds | \$0 | \$0 |
| Other (Specify) | \$0 | \$0 |
| Total Financing | \$1,389,420 | \$1,389,420 |

*OE = Owner's Equity

On page 69, that applicant states that the working capital will be funded from EmergeOrtho P.A accumulated reserves.

In Exhibit F.2, the applicant provides a letter dated June 12, 2023, from the senior vice-president for First Citizen's bank, stating their willingness to further discuss a loan to fund the project based on the EmergeOrtho's financial status and their relationship with the bank. The letter includes the loan amortization schedule. Exhibit F.2 also contains a letter from the chief executive officer for EmergeOrtho authorizing the use of accumulated reserves for the working capital needs of the project.

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

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant 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.

| EmergeOrtho-Lenoir Fixed MRI Services | 1st Full FY CY 2025 | 2nd Full FY CY 2026 | 3rd Full FY CY 2027 |
|--------------------------------------------------|-------------------------------------------|-------------------------------------------|-------------------------------------------|
| Total MRI Procedures (Weighted) | 2,882 | 3,307 | 3,736 |
| Total Gross Revenues (Charges) | \$3,955,822 | \$4,596,230 | \$5,257,954 |
| Total Net Revenue | \$1,212,063 | \$1,408,284 | \$1,611,036 |
| Average Net Revenue per Procedure | \$421 | \$426 | \$431 |
| Total Operating Expenses (Costs) | \$1,109,680 | \$1,241,235 | \$1,339,150 |
| Average Operating Expense per Procedure | \$385 | \$375 | \$358 |
| Net Income | \$102,383 | \$167,049 | \$ 271,886 |

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

The 2023 SMFP defines the service area for a fixed MRI scanner service area as “...the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1... Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.” Figure 5.1 on page 36 of the 2023 SMFP shows Caldwell County as a single service area. Therefore, for the purpose of this review, the fixed MRI service area is Caldwell County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Caldwell County service area, summarized from Table 17E-1 of 2023 SMFP.

| Fixed MRI Scanners in Caldwell County | | | |
|----------------------------------------------|--------------------------------|------------------------|-----------------------|
| Provider | # of Fixed MRI Scanners | Total MRI Scans | Adjusted Total |
| Caldwell Memorial Hospital | 1 | 2,646 | 3,310 |
| Total | 1 | 2,646 | 6,310 |

In Section G, pages 75-76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Caldwell County. The applicant states:

“Caldwell County does not currently host a freestanding fixed MRI scanner, and in this application EmergeOrtho has documented that thousands of MRI scans performed on Caldwell County residents occur in other counties. As described throughout this application... EmergeOrtho’s proposed project will improve local access for Caldwell County residents 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 2023 SMFP has identified an adjusted need determination for one fixed MRI scanner in Caldwell County.
- There is one existing fixed MRI scanner located in a hospital licensed facility. The applicant’s proposal will expand access to MRI services in Caldwell County.

Conclusion

The Agency reviewed the:

- Application

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

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

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

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

In Section Q, page 131, 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 01/01/2023 | 1 st Full FY (CY2025) | 2 nd Full FY (CY2026) | 3 rd Full FY (CY2027) |
| Radiology Technologists (MRI) | 0.35 | 1.25 | 1.75 | 2.00 |
| Administrator/CEO | 0.02 | 0.05 | 0.05 | 0.05 |
| Business Office | 0.2 | 0.75 | 0.75 | 0.75 |
| Clerical (Scheduler/Receptionist) | 0.2 | 1.15 | 1.15 | 1.15 |
| Other (Sales Liaison) | 0.1 | 0.15 | 0.15 | 0.15 |
| Other (MRI Tech Asst) | 0.35 | 1.25 | 1.75 | 2.00 |
| TOTAL | 1.22 | 4.60 | 5.60 | 6.10 |

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 77-80, 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:

- In addition to recruiting staff through internet job search engines and social media, ErmergeOrtho will leverage its presence in the community to recruit the appropriate staff, recruit graduates from training programs, and serve as a clinical training site.
- ErmergeOrtho has training and education for all new employees and staff members are required to maintain competency in their respective job description.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

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 and I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides supporting documentation demonstrating the medical director's commitment to continue to serve and documentation of a service agreement for radiology services.
- The majority of ancillary and support services will be provided by EmergeOrtho staff.

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 the applicant's status as an established provider of mobile MRI services in the service area and its relationships with healthcare providers and referring physicians in Caldwell County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

In Section K, page 85, the applicant states that the project involves renovating 2,200 square feet of existing space. Line drawings are provided in Exhibit K.2.

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 plan to upfit an existing space with minimal renovation and costs.

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. The applicant is proposing to acquire an MRI scanner at a competitive price that will allow EmergeOrtho to offer MRI services using advanced technology resulting in faster image acquisition. The MRI scanner will increase productivity by transporting patients at a shorter distance as opposed to outside of the building where the existing mobile MRI scanner is located. Additionally, freestanding MRI services tend to be offered at a lower price than hospital-based MRI services.

On pages 86-87, 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
- 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.

- (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;

In Section L, page 92, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.

| EmergeOrtho-Lenoir (Mobile MRI Services) Historical Payor Mix 01/01/2022-12/01/2022 | |
|----------------------------------------------------------------------------------------------------|-------------------------|
| Payor Category | Percent of Total |
| Self-Pay | 0.61% |
| Charity Care (included with self-pay) | |
| Medicare* | 36.30% |
| Medicaid* | 6.29% |
| Insurance* | 55.96% |
| Workers Compensation | 0.38% |
| TRICARE | 0.46% |
| Total | 100.00% |

In Section L, page 93, the applicant provides the following comparison.

| EmergeOrtho-Lenoir | Percentage of Total Patients Served by the Facility or Campus during the Last Full FY | Percentage of the Population of the Service Area |
|-------------------------------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Female | 49.1% | 50.3% |
| Male | 50.9% | 49.7% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 52.8% | 79.2% |
| 65 and Older | 47.2% | 20.8% |
| American Indian | 0.0% | 0.7% |
| Asian | 0.1% | 0.8% |
| Black or African American | 6.1% | 5.5% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.1% |
| White or Caucasian | 92.4% | 86.4% |
| Other Race | 0.5% | 6.5% |
| Declined / Unavailable | 0.8% | 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

- 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 94, the applicant states:

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

In Section L, pages 94-95, the applicant states that during the 18 months immediately preceding the application deadline, an adult patient's caretaker filed a civil rights access complaint alleging that EmergeOrtho had denied services to the patient based on disability. The federal Office of Civil Rights (OCR) determined that it was an isolated incident, and no further action was necessary. OCR closed the matter on June 1, 2022.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 95, 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.

| EmergeOrtho-Lenoir (MRI Services) Projected Payor Mix 3rd Full FY, CY 2027 | |
|------------------------------------------------------------------------------------------------------|-----------------------------|
| Payor Category | Percent of Total |
| Self-Pay | 0.61% |
| Charity Care | 0.50% |
| Medicare* | 36.30% |
| Medicaid* | 6.29% |
| Insurance* | 55.46% |
| Workers Compensation | 0.38% |
| TRICARE | 0.46% |
| Total | 100.00% |

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.61% of total services will be provided to self-pay patients, 0.50% to charity care patients, 36.30% to Medicare patients and 6.29% to Medicaid patients.

On page 95, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects its payor mix based on the historical payor mix of mobile MRI services offered at EmergeOrtho's existing outpatient clinic.
- The applicant assumes there will be no change to EmergeOrtho's existing referral relationships with physicians and other providers.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 97, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

In Section M, pages 98-99, 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 for training purposes based on the following:

- EmergeOrtho has an existing clinical training affiliation agreement with Wake Forest University Baptist Medical Center and provides supporting documentation in Exhibit M.1.
- The applicant has existing relationships with several colleges and universities' health professional training programs throughout North Carolina.
- The applicant will offer the proposed fixed MRI scanner to area schools and clinical training programs for clinical training rotations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop no more than one fixed MRI scanner in Caldwell County pursuant to an adjusted need determination in the 2023 State Medical Facilities Plan (SMFP).

The 2023 SMFP defines the service area for a fixed MRI scanner service area as “...*the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1... Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.*” Figure 5.1 on page 36 of the 2023 SMFP shows Caldwell County as a single service area. Therefore, for the purpose of this review, the fixed MRI service area is Caldwell County. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 100, the applicant states:

“Caldwell County currently has limited local MRI competition, with only one existing fixed MRI scanner in Caldwell County, owned and operated by UNC Health Caldwell. With this project to acquire a fixed MRI scanner, EmergeOrtho, as an experienced diagnostic imaging provider, is expected to enhance competition in the service area by augmenting the part-time MRI imaging services it currently offers in Caldwell County, and promoting improved patient access to quality, cost-effective, and accessible diagnostic imaging.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 100-101, the applicant states:

“The proposed fixed MRI scanner is modern technology and offers ease of operation, excellent imaging quality, patient comfort, along with high throughput and dependability, cost-effective capital and operating costs, and energy efficiency capabilities.

...

The development of the fixed MRI service in Lenoir represents an efficient use of an existing building that can be accomplished in a timely and cost-effective manner.

...

EmergeOrtho is committed to and will continue to be actively involved in efforts to contain costs in its MRI service.”

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

Regarding the impact of the proposal on quality, in Section N, pages 101-102, the applicant states:

“EmergeOrtho’s will pursue ACR accreditation for the Lenoir fixed MRI scanner within one year of commencement of services.

...

MRI exams performed at EmmergeOrtho are interpreted by radiologists. ProScan’s board-certified radiologists provide specialized reads for many sub-specialties, including musculoskeletal radiology, and are well respected healthcare providers with a commitment to ensuring quality and patient safety.

...

EmergeOrtho will utilize its existing quality-related policies and procedures, which serve well in operating existing EmmergeOrtho MRI services.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 102, the applicant states:

“EmergeOrtho has historically provided care and services to all medically underserved populations.”

See also Sections B, 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
- 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

In Section Q, page 132, 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 five of these types of facility located in North Carolina.

In Section O, page 106, the applicant states that physician offices are not licensed facilities and are not subject to DHSR licensing requirements. The applicant states that during the 18 months immediately preceding the submittal of the application, all of the facilities listed have provided quality care and operated in compliance with Medicare Conditions of Participation. 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

The application is conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER 10A NCAC 14C

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- The proposed fixed MRI scanner service area is Caldwell County. Neither EmurgeOrtho nor a related entity owns or operates a fixed MRI scanner in Caldwell 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- Neither EmurgeOrtho nor a related entity owns or operates an approved fixed MRI scanner in Caldwell County.

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

-C- EmurgeOrtho owns and operates an existing mobile MRI scanner in the fixed MRI scanner service area and provides mobile MRI services at a host site 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- Neither EmurgeOrtho nor a related entity has been approved for a mobile MRI scanner in the proposed fixed MRI scanner service area nor does EmurgeOrtho or a related entity own or operate an approved mobile MRI scanner in the proposed fixed MRI scanner service area.

(5) provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;

-C- In Section Q, Form C.2b, pages 112-113, the applicant provided projected utilization for the proposed fixed MRI scanner and the existing mobile MRI scanner during each of the first three full fiscal years of operation following completion of this project. The existing mobile MRI scanner will cease to operate at EmurgeOrtho-Lenoir upon project completion.

| EmergeOrtho-Lenoir Projected Utilization | | | |
|-----------------------------------------------------|----------------------------------------------|----------------------------------------------|-----------------------------------|
| | 1st Full FY CY2025 | 2nd Full FY CY2026 | 3rd Full FY CY2027 |
| X-Ray | | | |
| # of Units | 1 | 1 | 1 |
| # of Procedures | 5,038 | 5,040 | 5,043 |
| Fixed MRI Scanner | | | |
| # of Units | 1 | 1 | 1 |
| Unweighted Procedures | 2,826 | 3,243 | 3,664 |
| Weighted Procedures | 2,882 | 3,307 | 3,736 |

Source: Section Q, page 112

| EmergeOrtho-Foothills Region Projected Utilization Mobile MRI Scanner | | | |
|--------------------------------------------------------------------------------------|------------------------------------|---------------------------------------|---------------------------------------|
| | Last Full FY CY2025 | Interim Full FY CY2026 | Interim Full FY CY2027 |
| # of Units | 1 | 1 | 1 |
| Unweighted Procedures | 3,873 | 3,863 | 3,853 |
| Weighted Procedures | 3,942 | 3,931 | 3,921 |

Source: Section Q, page 113

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

-C- In Section Q, Form C-*Assumptions and Methodology*, pages 115-120, the applicant provides the assumptions and methodology used to project utilization for the proposed fixed MRI scanner and the existing mobile MRI scanner during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(7) *project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(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:*

- (a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
- (b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
- (c) 1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and

-C- There is one existing fixed MRI scanner and one proposed fixed MRI scanner in the fixed MRI scanner service area. In Section Q, Form C.2b, page 112, the applicant projects that the proposed fixed MRI scanner shall perform 3,736 adjusted MRI procedures during the third full fiscal year of operation following completion of the project which exceeds the 3,494 adjusted MRI procedures per fixed MRI scanner required by this Rule.

(8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operations following completion of the project.

-C- There is one existing mobile MRI scanner in the fixed MRI scanner service area owned or operated by the applicant or a related entity. In Section Q, Form C.2b, page 113, the applicant projects that the existing mobile MRI scanner shall perform 3,921 adjusted MRI procedures during the third full fiscal year of operation following completion of the project which exceeds the 3,120 adjusted MRI procedures per mobile MRI scanner required by this Rule.

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

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

(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;

(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;

(4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;

(5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;

(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;

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

(8) project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and

(9) project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:

(a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;

(b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
(c) 1310 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.

-NA- The applicant is not proposing to acquire a mobile MRI scanner.