



December 1, 2022

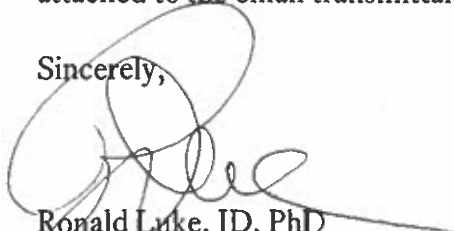
Ena Lightbourne  
North Carolina Division of Health Service Regulation  
Healthcare Planning and Certificate of Need Section  
2704 Mail Service Center  
Raleigh, NC 27699

RE: Comments on CON Project I.D. # Q-012286-22 Orthopaedics East & Sports Medicine Center

Dear Ms. Lightbourne:

I am authorized by Greenville MRI, LLC (Project ID# Q-012294-22) to submit written comments regarding Orthopaedics East & Sports Medicine Center's CON application for a fixed MRI scanner in Pitt County (Project ID# Q-012286-22). Greenville MRI's written comments are attached to the email transmittal.

Sincerely,



Ronald Luke, JD, PhD  
President

**Comments in Opposition to the OrthoEast Certificate of Need Application  
for a Fixed MRI Scanner in Pitt County, October 17, 2022  
Submitted by  
Greenville MRI, LLC**

Greenville MRI, LLC (Greenville MRI), respectfully submits these comments for the Agency’s consideration as part of the 2022 Pitt County Magnetic Resonance Imaging (MRI) review.<sup>1</sup> In this review, two applicants, Orthopaedics East & Sports Medicine Center Inc. and Greenville MRI, LLC, filed certificate of need (CON) applications seeking CON approval to add one fixed MRI in Pitt County. Both applied to meet the need for a fixed MRI machine in the Pitt/Green/Hyde/Tyrrell Service Area found in the 2022 State Medical Facilities Plan (SMFP).

In accordance with N.C. Gen. Stat. § 131E-185, Greenville MRI offers comments on the OrthoEast application with specific attention to:

1. Facts relating to the service area proposed in the application;
2. Facts relating to the representations made by the applicant in its application, and its ability to perform or fulfill those representations; and
3. Discussion of whether the material in the application and other relevant factual material shows the application complies with relevant review criteria and performance standards.

The Agency must review each application independently against the criteria (without considering the competing applications) and determine whether each “is either consistent with or not in conflict with these criteria” (N.C. Gen. Stat. §§ 131E-183[a]). Based on the following, only the Greenville MRI application demonstrated conformity with the applicable criteria, policies and CON rules:

- Criterion (1)
  - Policy GEN-3
- Criterion (3)
  - 10A NCAC 14C .2701
- Criterion (4)
- Criterion (5)
- Criterion (6)
- Criterion (7)
- Criterion (8)
- Criterion (9)

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<sup>1</sup> Nothing in these Comments is intended to amend the Greenville MRI Application, and nothing contained here should be considered an amendment to the Greenville MRI Application.

- Criterion (12)
- Criterion (13)
- Criterion (14)
- Criterion (18a)
- Criterion (20)

Should the Agency find both applications conforming with all relevant criteria, the Agency should find the Greenville MRI application superior to the OrthoEast application overall, based on the factors discussed later in these comments.

## GENERAL COMMENTS

Greenville MRI owns one diagnostic center in Pitt County, North Carolina, which has two MRI scanners at 2101 W Arlington Boulevard in Greenville, North Carolina. Greenville MRI is owned by MRI ERI, LLC, and Eastern Radiologists Inc. (with a very small percentage held by two individual physicians—Dr. Timothy Clark and Dr. Julian Vainright). Greenville MRI has no diagnostic equipment other than its two existing MRI scanners. Related entities own, or partially own, five other diagnostic centers, listed below.

- Breast Imaging Center
- Eastern Radiologist Imaging Center
- Seashore Imaging, LLC
- Kinston Imaging Center
- Washington Imaging Center

Neither the Applicant nor any related entities own any other diagnostic centers in the service area with MRI scanners. Greenville MRI submits global bills that include both the technical and professional components.

Orthopaedics East & Sports Medicine Center Inc. (OrthoEast) is a single-specialty physician practice that calls itself “Eastern North Carolina’s Premier Orthopedic Specialists.”<sup>2</sup> OrthoEast “specializes in comprehensive orthopedic and musculoskeletal care, from joint replacement and regenerative treatments to advanced diagnostics and physical therapy.” The website lists nine surgeons, six physician assistants, and six physical therapists.

OrthoEast is not a CON diagnostic center but is a host site for a mobile MRI scanner leased from Alliance. The only imaging modality it offers now is x-ray. While OrthoEast lists an Imaging Manager as part of its management team, it currently employs no MRI technicians or assistant

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<sup>2</sup> Orthopaedics East & Sports Medicine Center webpage, <https://orthoeast.com/>, accessed November 20, 2022.

technicians.<sup>3</sup> All staff who operate and maintain the leased MRI are recruited, trained, and supervised by Alliance Imaging. While OrthoEast staff schedule MRI procedures, they have no experience *providing* MRI procedures. With respect to MRI services at OrthoEast, Alliance Imaging provides the technical component and OrthoEast bills for it. Eastern Radiologists provides the professional component and bills for it directly.

The OrthoEast application did not include a copy of the current lease with Alliance. That document is necessary for reasonable support of many statements, financial assertions and numbers in the OrthoEast application. The Agency should know what operating and maintenance expenses the lease covers to determine whether all those costs are covered in the project pro forma. The Agency should know the payment formula net revenue OrthoEast receives for each scan now and how this compares to its incentives to order scans when it owns the machine. The Agency should know what arrangements OrthoEast negotiated to allow its physicians to order scans for charity and self-pay patients to determine whether OrthoEast's proposed project improves access to MRI services for charity care patients.

OrthoEast included no comparison of the capabilities of the leased MRI and of the MRI it proposes to buy. Based on OrthoEast's projected scans, the purchased machine will continue to be used almost entirely for orthopedic scans. Therefore, the additional coils and software on the purchased machine would not deliver much, if any, value to the community. OrthoEast has not explained what benefits to orthopedic patients the purchased machine will deliver.

The leased MRI at OrthoEast is a legacy, grandfathered scanner with special privileges under the CON law.<sup>4</sup> CON-approved mobile MRIs must be moved between two or more sites. The legacy MRI does not have this requirement. The MRI at OrthoEast operates as a fixed MRI available seven days a week, with no hours lost to transport. While the SMFP shows the MRI with 0.52 capacity, OrthoEast is free to use it at the same capacity levels as the fixed MRIs in Pitt County.

OrthoEast does not indicate what will happen to the leased MRI if it is awarded a CON.

The proposed fixed MRI scanner is not duplicative of the leased Alliance mobile MRI scanner since that equipment will discontinue serving the OrthoEast facility following implementation of the proposed fixed MRI scanner project. The Alliance mobile MRI scanner will be relocated to serve other host sites; it is a "legacy" scanner authorized for use in North Carolina prior to CON regulation.<sup>5</sup>

Alliance can site the MRI anywhere in North Carolina. It is as likely as not that the MRI will be removed from the Service Area. If so, awarding OrthoEast the CON would not meet the Service Area's need for 1.0 more MRIs because, with the loss of the current 0.52 mobile MRI, the net gain

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<sup>3</sup> OrthoEast Application, Form H, p. 119.

<sup>4</sup> In Table 17E-1 of the 2022 SMFP, the scanner is noted as a "Legacy" scanner. See 2022 SMFP, p. 356.

<sup>5</sup> OrthoEast CON Application, p. 75.

in MRI capacity would be only 0.48 MRIs. The OrthoEast application does not meet the need for an additional MRI in the Service Area.

Given its full-time availability, the leased machine has much unused capacity. The performance standard for a full-time or fixed MRI in Pitt County is 3,364 adjusted procedures. For 2021, OrthoEast reported 2,773 adjusted procedures; for 2022, it estimated an annualized 2,776 adjusted procedures, based on nine months of actual data. Extrapolating its current MRI volume, even with the addition of physicians, OrthoEast would not meet the performance standard for a fixed MRI in the third year of operation.

To project meeting the performance standard, OrthoEast says it referred 518 patients annually to other MRIs in Pitt County due to the needs of claustrophobic and obese patients. It does not say these patients did not receive needed scans in a timely manner or that the scans were not of acceptable quality. Therefore, there is no community need for OrthoEast to be able to do these scans. There is no community need to redistribute the scans from another Pitt County MRI provider to OrthoEast.

The OrthoEast application does not show the purchased MRI will be available to all referring physicians and their patients. Substantially, all MRIs on the leased machine are ordered by OrthoEast practitioners. There is no evidence non-OrthoEast physicians can directly schedule MRIs. It is more likely non-OrthoEast providers can refer patients to OrthoEast physicians who may order scans for those patients. The four non-OrthoEast letters of support for the application are from providers in orthopedic-related specialties who could be expected to refer patients to OrthoEast subspecialists.<sup>6</sup> The current MRI is only ACR accredited for musculoskeletal and spine scans.<sup>7</sup> OrthoEast's application will provide a more limited set of MRI services and will be available to a more limited portion of the Service Area population, as compared to Greenville MRI, which will provide the full array of MRI services. This is evidenced by the language in OrthoEast's application, its referral letters, and the lower average weighted scan 1.011 vs. Greenville MRI's average weight of 1.151.

OrthoEast proposes to operate the purchased MRI with 1.33 full-time equivalent (FTE) technicians and 1.33 FTE technician assistants. It does not explain what full-time and part-time staff it would hire. To reliably staff an MRI scanner eight hours a day, five days a week, OrthoEast would need at least two full-time technicians and a full-time assistant. For extended hours per day or for weekend operations, they would need to hire more staff. Alliance can budget fractional staff for a site because it has a larger pool of technicians and assistants in its staff pool. A single MRI

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<sup>6</sup> These letters are from Cynthia Lopez at Eastern Neurology & NeuroMuscular Center, Deanna Boyette at Boyette Orthopedics & Sports Medicine, Bryan Cooper at Eastern Headache & Spine, and Kyle Harner at Carolina Arthritis Center.

<sup>7</sup> American College of Radiology. Accredited Facility Searched. "Orthopaedics East & Sports Medicine Center, Inc." is only certified for the MSK (musculoskeletal) and spine modules. Available at: <https://www.acraccreditation.org/accredited-facility-search> Accessed November 21, 2022.

operator must have staff redundancy for reliable operations. Without providing sufficient staff, OrthoEast has understated staffing costs and has not provided reliable operating costs in its CON application.

The OrthoEast application does not reasonably support its commitment to provide services to the uninsured and other low-income patients. Its past financial data show zero charity care and very low bad debt write-off. The assumptions on page 120 of the OrthoEast application show bad debt held constant at 0.75% from 2021 (last full year) to 2024, the third project year. In the third project year, OrthoEast projects \$43,767 of bad debt (approximately 1% of its gross revenue of \$4,376,733). This does not seem reasonable. OrthoEast currently refers patients to Greenville MRI for scans. In 2021, the patients OrthoEast referred to Greenville MRI accounted for \$86,187 of bad debt. Presumably, OrthoEast will incur at least as much bad debt as its own patients account for at Greenville MRI.

OrthoEast states it has no charity care policy and does not include in the application any policies or application forms for reduced charges. It says it accepts referrals of uninsured patients from HealthAssist. However, HealthAssist refers patients to specialists. OrthoEast does not document how many referrals its practitioners accepted, how many of these patients received MRIs at their facility, and how many HealthAssist patients they accepted for MRI scans only.

## **THE ORTHOEAST APPLICATION IS NON-CONFORMING WITH RELEVANT CRITERIA**

The following paragraphs explain why the OrthoEast application is nonconforming with multiple CON criteria.

### **Section B - Criterion (1)**

G.S. 131E-183(a)(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.”*

### **Consistency with the State Medical Facilities Plan (SMFP)**

OrthoEast proposes to replace a “mobile” MRI scanner that does not travel to any other sites with a fixed MRI scanner it owns and operates. This will not increase the supply of MRI scanners in the Service Area. The SMFP states:

*A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination to replace the existing contracted service with a fixed MRI scanner under the applicant’s ownership and control. It is consistent with the purposes of the Certificate of Need law and the SMFP*

*for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility's own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility.<sup>8</sup>*

While this language does not “preclude” an application by OrthoEast- meaning the Agency is not required to deny the application if OrthoEast had been the only applicant, replacing a fixed-mobile with a fixed scanner is far from the best option for the service area. According to the forms in Section Q, OrthoEast will have lower operating expenses per scan in year three than it did in 2021 (\$265.75 vs. \$302.26). On its face, this illustrates OrthoEast will “reduce the cost of providing the MRI service.” However, OrthoEast’s application does not provide adequate staffing for the hours and employee benefits it states it will offer in its CON application. OrthoEast also includes very low costs for administrative/central office expenses and provides no explanation for the low cost. As discussed in detail under Criterion (5), OrthoEast has not included sufficient expenses to operate the proposed MRI scanner as described in its application. Those comments are incorporated here by reference. Because it has not included sufficient costs, OrthoEast has not sufficiently demonstrated the operation of the MRI will “reduce the cost of providing the MRI service at that facility.”

OrthoEast’s application also does not “reduce the cost” patients incur for receiving MRI services. OrthoEast states that it “has retained the present charge structure for the proposed fixed MRI scanner.”<sup>9</sup> If the Agency interprets the above-quoted SMFP excerpt as pertaining to patient costs, it should find OrthoEast does not reduce the cost of MRI services and is therefore not “consistent with the purposes of the Certificate of Need law and the SMFP.”

The SMFP language quoted above simply states that a facility proposing to replace a contracted service with a fixed MRI scanner “is not precluded” from applying for an MRI from a fixed need determination. Greenville MRI has demonstrated in the paragraphs above that OrthoEast should be precluded from receiving CON approval because it does not meet the applicable clause about reducing the cost of care.

Greenville MRI also notes the SMFP language above in no way indicates that an applicant proposing to replace a leased scanner with a fixed MRI scanner deserves any preference or comparative advantage over another applicant who does not propose such a project. As discussed throughout these comments, OrthoEast has not demonstrated its project will provide any patient benefit in terms of reduced cost, enhanced access or higher-quality care. OrthoEast’s proposed CON application included no comparison of the capabilities of the leased MRI and of the MRI it proposes to buy. Based on OrthoEast’s projected scans, the purchased machine will continue to be used almost entirely for orthopedic scans. Therefore, the additional coils and software on the

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<sup>8</sup> 2022 SMFP, p. 342.

<sup>9</sup> OrthoEast CON application, page 74.

purchased machine would not deliver much, if any, value to the community. OrthoEast has not explained what benefits to orthopedic patients the purchased machine will deliver.

For these reasons, OrthoEast's CON application is not conforming with the SMFP or with Criterion (1).

**Policy GEN-3: Basic Principles 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.”*

The OrthoEast proposal is not consistent with Policy GEN-3 and therefore does not conform to Criterion (1). The OrthoEast proposal is not consistent with Policy GEN-3 because:

- The leased MRI will likely be removed from the Service Area. If it is, there will be no increase in the number of MRIs in the service area. Even per the SMFP, the increase in capacity would be 0.48 MRI and would not meet the SMFP need for 1.0 additional MRIs.
- The OrthoEast MRI now, and if the proposal is approved, is scheduled to meet the needs of a single orthopedic practice. Regardless of the coils and software, it will not be equally available to all physicians in all specialties and will not maximize healthcare value or address the needs of all residents of the Service Area.
- OrthoEast has no written charity care policy or any written policy for reduced charges for uninsured and low-income patients for its physician services or imaging services. It reports delivering no MRI scans as charity care. Its relationship with HealthAssist appears to be for its physician services and not for imaging services requested by non-OrthoEast physicians.
- Placing an owned MRI with a physician practice that orders scans does not maximize healthcare value. Physicians in the practice have a financial incentive to order scans, regardless of medical necessity.<sup>10</sup> The incentive increases when the practice owns the MRI as opposed to paying a charge per scan, because the MRI owner has increased fixed costs and reduced variable costs.

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<sup>10</sup> See Brian Kouri, R. Gregory Parsons, and Hillel R. Alpert, “Physician Self-Referral for Diagnostic Imaging: Review of the Empiric Literature,” *AJR* 179 (2002): 843–850, <https://www.ajronline.org/doi/10.2214/ajr.179.4.1790843?mobileUi=0>.



- OrthoEast has not demonstrated how it will promote safety and quality. OrthoEast states it “has experience providing MR imaging services in Pitt County for residents from throughout eastern North Carolina.”<sup>11</sup> This is inaccurate. OrthoEast staff have no experience operating or maintaining an MRI. OrthoEast employs no MRI technicians. Alliance is responsible for all operations and maintenance. OrthoEast simply schedules and bills for MRI services. OrthoEast has not included staffing costs for an MRI manager with expertise in operating an MRI scanner. OrthoEast has not included sufficient MRI technician or assistant staffing for its proposed hours of operations in year three or its proposed number of scans. OrthoEast has proposed MRI equipment that utilizes software that runs on an outdated and unprotected operating system.

The OrthoEast application is also not consistent with Policy GEN-3, as its ownership structure incentivizes overutilization which does not maximize “healthcare value.” Overutilization of MRI and other imaging services increases healthcare costs. It is well established that when physician practices that order imaging own or lease imaging equipment, including MRI, they order significantly more scans, and more unnecessary scans, than physicians in the same specialties who do not profit from ancillary revenue.<sup>12</sup> Orthopedic practices that lease or own MRIs are clearly one such specialty.

OrthoEast has a leased MRI that gives it the financial incentive to order unnecessary scans. While OrthoEast has not disclosed the exact terms of that lease, we can discern from the financial and staffing information in the OrthoEast application that Alliance pays all the operating and maintenance expenses of the MRI and charges OrthoEast some unknown amount for use of the scanner.

If the Agency allows OrthoEast to own the MRI, it increases OrthoEast’s incentive to order unnecessary scans. With ownership, OrthoEast has large fixed costs it did not have with the lease. It must order enough scans to cover those fixed costs or, for the first time, risk losing money on the MRI. Because the variable costs per scan are likely to be lower than with the lease, the operating income per scan is higher and the economic incentive to order more scans is much greater.

For the purposes of Policy GEN-3, the Agency can reduce unnecessary imaging costs by having outpatient MRIs owned by organizations with no ability to order scans. Radiologists do not order scans; they only interpret them. The OrthoEast application is not conforming to Policy GEN-3 or to Criterion 1.

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<sup>11</sup> OrthoEast CON application, p. 25.

<sup>12</sup> See Medicare Payment Advisory Commission, “Improving Payment Accuracy and Appropriate Use of Ancillary Services” (2011), pp. 31–32, [https://www.medpac.gov/wp-content/uploads/import\\_data/scrape\\_files/docs/default-source/reports/Jun11\\_Ch02.pdf](https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Jun11_Ch02.pdf). See also: Brian Kouri, Gregory Parsons, and Hillel Alpert, “Physician Self-Referral for Diagnostic Imaging: Review of the Empiric Literature,” *AJR* 179 (2002): 843–850, <https://www.ajronline.org/doi/10.2214/ajr.179.4.1790843?mobileUi=0>.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (1) and should not be approved.

### **Section C - Criterion (3)**

G.S. 131E-183(a)(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.”*

Reasonable and adequately supported utilization projections are required to show need for a proposed project. If projected utilization is not reasonable and adequately supported, the application cannot be approved.

The comments regarding OrthoEast’s nonconformance with Criterion (1) demonstrate that OrthoEast has not adequately demonstrated that the population it intends to serve has an unmet need for the project. Those criticisms are incorporated here by reference.

The need shown in the SMFP is for additional MRI scans across all specialties. Whatever the capabilities of the hardware and software on the purchased MRI, the focus of the staff and OrthoEast will be on orthopedic scans. Placing an MRI machine with a single-specialty physician practice limits its access by physicians in other specialties and by competing orthopedic practices.

The OrthoEast application shows the population that will be served if the application is approved will be patients seen by OrthoEast physicians. Almost all these patients are already being adequately served by the leased MRI. There is much unused capacity for additional scans on the leased machine so it can accommodate growth in OrthoEast’s practice.

The only scans OrthoEast says cannot be conducted on its mobile scanner are the 518 obese or claustrophobic patients it says it refers to other MRI providers in Pitt County. However, OrthoEast does not say those patients are not receiving needed MRI services from other providers. It appears the needs of these patients are being met. There is no evidence their needs would be better met using a purchased machine at OrthoEast, rather than at one of the existing MRI scanners that is currently designed and equipped to meet their needs.

There is no evidence the quality of scans will be better on the purchased machine staffed by OrthoEast. OrthoEast has no experience operating or maintaining an MRI machine, while Alliance staff have extensive experience and Alliance has a staff pool to cover absences and staff turnover. It also has experienced staff to train and supervise new staff.

### Technical Errors in Section C-Criterion (3)

OrthoEast’s CON application had several technical errors in Section C, as outlined below. These issues made OrthoEast’s CON application non-responsive to several of the questions and did not provide the Agency with the information asked for to make a determination on conformity with CON criteria.

#### Patient Origin for the “Entire Facility or Campus” is not provided.

On page 20, OrthoEast states it is currently a “medical clinic,” meaning it provides medical care to patients outside of just x-ray scans. However, OrthoEast failed to provide either current or future patient origin for “the entire facility or campus” as the CON application form requests. Without this information, the Agency does not have patient origin information for all the individuals OrthoEast will see at its facility. Instead, OrthoEast chose to include only “patient origin of all imaging patients (x-ray and mobile MRI) at OrthoEast.”<sup>13</sup>

#### OrthoEast Provides Unsubstantiated Estimates of Patient Demographics.

On page 51 of its application, OrthoEast provides estimates of what percent of its patients in year three will be low-income persons, and what percent will be persons with disabilities. However, the percentages reported for each are not based on historical patient demographics. OrthoEast places a small note that states it “does not track income demographics or disability status of its patients” and that its estimates are based on US Census demographics for Pitt County. While there is a technical error of OrthoEast incorrectly reporting that 13% of Pitt County residents are low-income persons when the census shows 17.1% of residents living “in poverty,” the larger issue is that OrthoEast provides no evidence as to why these two groups of patients would closely mirror Pitt County’s overall demographics. The table below shows the demographics presented in OrthoEast’s CON application and the demographics of Pitt County. Pitt County’s demographics do not closely mirror those of OrthoEast’s patients in terms of race, sex, or age. There is no reason to assume they would in terms of income level or disability status. Moreover, OrthoEast’s extremely low bad debt allowance casts additional doubt on the percent of low-income patients at its facility mirroring Pitt County’s demographics.

	<b>OrthoEast Reported</b>	<b>Pitt County Census</b>
Low-income persons*	13.0%	17.1%
Racial and ethnic minorities	34.6%	47.0%
Women	60.6%	53.0%
Persons with Disabilities*	10.1%	10.1%
Persons 65 and older	36.7%	14.3%

*Sources: US Census Quick Facts for Pitt County, OrthoEast CON Application, p. 51. \*Sourced by OrthoEast as Pitt County’s demographics.*

<sup>13</sup> OrthoEast CON application, pp. 32, 36.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (3) and should not be approved.

#### **Section D - Criterion (3a)**

G.S. 131E-183(a)(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.”*

The OrthoEast proposal implicitly assumes the elimination of mobile MRI services in the Service Area. OrthoEast does not include a copy of the lease arrangement with Alliance Imaging, nor does it provide information on the lease terms that would allow the Agency to discern the exact duration of the lease or any requirements for moving sites. OrthoEast includes no discussion of Alliance’s plans for the existing MRI, should the OrthoEast application be approved. Approval of the OrthoEast application and removal of the existing MRI from the Service Area would not meet the Service Area’s need for an additional MRI. Practically speaking, it would leave the Service Area with no additional MRI capacity. Even accepting the SMFP rating of the mobile as 0.52 MRIs, the Service Area would only gain 0.48 MRIs rather than the 1.0 MRI the SMFP says it needs.

The OrthoEast application does not address the effect of adding no new physical capacity or only 0.48 MRI capacity to the Service Area “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.”

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (3a) and should not be approved.

#### **Section E - Criterion (4)**

G.S. 131E-183(a)(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.”*

The OrthoEast application failed to adequately consider options that generally fall under maintaining the status quo that would make that the preferred alternative:

- There was no discussion of the potential to upgrade hardware and software on the existing MRI to match more closely the capabilities of the MRI OrthoEast proposes to purchase.

- There was no consideration of construction and renovation to provide a waiting area and covered access to the existing MRI at a lower facility improvement cost.
- There was no discussion of amendments to the lease with Alliance to reduce the cost per scan to OrthoEast, or to allow OrthoEast to offer free scans to charity care patients at no cost to OrthoEast or to offer scans to low-income persons at a reduced rate.
- There was no discussion of amendments to the lease to increase operating hours or to provide additional evening or weekend hours to accommodate additional volume from the new providers and potential outside referrals.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (4) and should not be approved.

**Section F - Criterion (5)**

G.S. 131E-183(a)(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.”*

**Projected Staffing Levels**

OrthoEast underestimated the staffing requirements needed to provide the proposed fixed MRI services. Its application is silent with respect to the planned hours of operation during the first two years. OrthoEast states on page 27 that the scanner *may* be available for 60 hours per week by the third year. The OrthoEast application does not include sufficient staffing to operate 60 hours per week.

Form H Staffing presents very different staffing levels for the two applicants. Greenville MRI is an established, experienced provider with onsite fixed MRI services. OrthoEast does not have this knowledge or history. The table below illustrates the difference for each applicant in year three.

<b>Form H Staffing</b>	<b>OrthoEast</b>	<b>Greenville MRI Total</b>	<b>Greenville MRI per Scanner</b>
Radiology Tech	1.5	10	3.33
MRI Tech Assistant	1.5	6	2
Business Office	0.2	2.5	0.83
Clerical	1.3	3	1
<b>Total</b>	<b>4.5</b>	<b>22</b>	<b>7.33</b>

As the table above shows, OrthoEast has fewer FTEs per scanner than Greenville MRI. OrthoEast does not have experience operating a scanner, and it has not provided sufficient FTEs for either a

60-hour week or the number of scans it projects to provide in year three, given the scan times stated in its application. If OrthoEast budgeted the same staffing per scanner as Greenville MRI, an experienced provider, budgeted in its application, it would have an additional \$219,896 in salary costs, as the table below shows. This additional cost likely underestimates the staffing OrthoEast would need to provide the same level of care as Greenville MRI. Because Greenville MRI operates three scanners, it benefits from staffing efficiencies and the flexibility to move staff between scanners, which OrthoEast does not.

	<b>FTEs in Ortho East Application</b>	<b>More (less) FTEs to Match Greenville Staffing Level</b>	<b>YR 3 Salary per FTE (Form H)</b>	<b>Additional Cost</b>
Radiology Tech	1.5	1.83	\$90,131.00	\$164,939.73
MRI Tech Assistant	1.5	0.5	\$75,499.00	\$ 37,749.50
Business Office	0.2	0.63	\$46,821.00	\$ 29,497.23
Clerical	1.3	(0.3)	\$40,969.00	\$ (12,290.70)
<b>Total</b>	<b>4.5</b>	<b>2.66</b>	<b>\$ 253,420.00</b>	<b>\$219,895.76</b>

Sources: OrthoEast CON application, p. 119, Greenville MRI CON application.

OrthoEast’s staffing also appears scant on a per scan basis. Each of the clinical staff at OrthoEast (1.5 Radiology Technicians and 1.5 Clinical Assistants) are forecast to complete 1,202 scans per FTE, whereas the same mix of staff at Greenville are forecast to complete 863 scans per year.

OrthoEast’s lower staffing cannot be attributed to efficiency: 1.5 technicians and 1.5 clinical assistants cannot provide adequate coverage for the 60-hour week OrthoEast claims it may have in year three. Operating 60 hours per week for 50 weeks per year equates to 3,000 hours open per year. On a basic FTE of 2,080 hours per year, assuming a very conservative productivity rate of 49 weeks per year,<sup>14</sup> equates to 1,960 productive hours per employee. This requires 1.53 FTEs just to be onsite and does not address the time required to provide patient care (3,000 operating hours divided by 1,960 hours per FTE = 1.53 FTEs). OrthoEast failed to include sufficient FTEs for these hours, as it only included 1.5 radiology techs and clinical assistants in year three, and 1.3 clerical FTEs.

Moreover, OrthoEast states it has “generous benefits” and will offer “paid time off for vacation/holiday/sick, plus jury duty and bereavement leave.” The calculations above do not provide for a “generous” leave benefit. If OrthoEast’s assertions are correct, an even greater number of FTEs would be required to operate the MRI 60 hours per week. 1.33 FTEs per position, per 40-hour work week, represents a generous allowance for paid time off. The staffing OrthoEast includes is not sufficient to provide “generous benefits” for a 60-hour work week.

OrthoEast’s staffing is insufficient, even if it only operates just the hours required to perform its scans. In its CON application, OrthoEast states its MRI scans “can last anywhere from 30–60

<sup>14</sup> In other words, only allowing for 15 business days of sick leave and vacation (non-productive pay).

minutes.”<sup>15</sup> Taking the median of this range, 45 minutes, OrthoEast needs to run its MRI scanner 10.815 hours a day, five days a week to perform the scans it projects in its CON application in year three. The table below shows this calculation. These are the hours required just to run the scanner, with every patient scheduled back-to-back and with no time between scans.

	Year 1	Year 3
Project number of weighted scan	3,476	3,605
Given average 45 minutes per patient, p. 28		
Total patient minutes	156,420	162,225
Given 8-hour work day		
Patient hours per year	2,607	2,704
Available weeks per year at 50, assumes 10 holidays and days closed	50	50
Patient hours per week	52.14	54.07
Patient hours per day, based on 8-hour workday	10.428	10.815

OrthoEast only includes 1.5 FTE radiology techs and 1.5 FTE clinical assistants in year three. To provide the number of scans in the time indicated, OrthoEast needs 0.8 additional FTEs in year one and 0.6 additional FTEs in year three, as the table below shows. OrthoEast does not have sufficient FTEs for the hours needed to provide the number of scans indicated in its CON application. Moreover, the costs for the required FTEs are not included in the CON application. Therefore, OrthoEast’s application is not “based upon reasonable projections of the costs” and is not conforming with Criterion (5).

	Year 1	Year 3
FTEs for 1 position, using “generous” benefits	1.33	1.33
Hours in standard work day	8	8
FTEs per hour	0.16625	0.16625
Hours needed to perform scans	10.428	10.815
FTEs needed per position, given hours	1.734	1.798
Multiplied by 2 (radiology tech and MRI assistant positions)	3.468	3.596
Budgeted radiology tech and MRI assistant FTEs	2.66	3.0
<b>Daily deficiency in staffing and MRI hours</b>	<b>0.808</b>	<b>0.596</b>

In addition, OrthoEast did not increase its existing FTEs for any of the below-listed positions in any of the project years, despite increasing the number of procedures from 2,801 to 3,605 and allegedly operating up to 60 hours per week. OrthoEast offers no explanation as to why these partial FTE amounts would be sufficient for operating up to 60 hours a week, or up to 10.428 hours per day in year one and 10.815 hours in year two (as calculated in the table above).

<sup>15</sup> OrthoEast CON application, p. 28.

- Administrator/CEO (.05 FTE)
- Business Office (0.2 FTE)
- Scheduler (1.0 FTE)
- Clinical Supervisor (0.25 FTE)

The Agency has previously found applicants nonconforming with Criterion (5) due to insufficient staffing when applicants do “not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs.”<sup>16</sup> The Agency has also found applicants nonconforming with Criterion (5) due to “unreliable” staffing assumptions.<sup>17</sup>

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (4) and should not be approved.

### **Administrative and Central Office Costs**

As presented in the table below, there are vast differences in the costs projected by the applicants for administrative and central support services. OrthoEast has separately reported a Central Office Allocation from Billing and IT services. Greenville MRI has reported all similar services as a single Management Fee. Greenville MRI has a nearly twenty-year history of providing MRI services in the area and has based its future cost on its expertise and historical experience. OrthoEast does not have experience operating an MRI machine. Its administrative costs are half those projected by Greenville MRI, despite not having the economies of scale Greenville MRI has. OrthoEast does not provide detailed information to support that the administrative expenses it includes are sufficient for operating the proposed MRI.

It appears OrthoEast has significantly underestimated the necessary costs for administrative/central office support services, and has included only half the cost per weighted scan that Greenville MRI has included, based on its two decades of experience offering MRI services. This is in addition to potentially underestimating the necessary staff.

### **Difference in Costs in Project Year Three**

	<b>OrthoEast</b>		<b>Greenville MRI</b>	
	Projected Value	Per Weighted Scan	Projected Value	Per Weighted Scan
Total Admin/Central Office	\$79,603	\$22.08	\$609,749	\$44.16
Central Office Allocation	\$25,950	\$7.20	N/A	N/A
Billing and IT	\$53,653	\$14.88	N/A	N/A
Management Fee	N/A	N/A	\$609,749	\$44.16

<sup>16</sup> See Required State Agency Findings 2013 Brunswick County Home Health Review, October 4, 2013, and Required State Agency Findings 2012 Mecklenburg County Home Health Review, December 27, 2012.

<sup>17</sup> See Required State Agency Findings 2013 Forsyth County Home Health Review, December 20, 2013.



OrthoEast did not fully account for all required staffing costs, and its administrative and central office costs are too low. OrthoEast is non-conforming with Criterion (5), because it did not provide “reasonable projections of the costs” of the proposed MRI scans.

### **Potential Ongoing MRI Lease Costs**

OrthoEast did not provide a copy of its lease agreement with Alliance Imaging, nor did it provide any detail in the text of its CON application about the duration of its lease arrangement. There is no detail in Section Q, Form F.3a or F.3b assumptions about the payments made to Alliance Imaging under the current arrangement, or when they will stop. OrthoEast proposes to continue operating the mobile MRI until the fixed MRI opens in January 2024. However, OrthoEast provides no information on whether the terms of the lease will require OrthoEast to provide Alliance Imaging with any compensation during the project years. Without providing the lease, or the duration of the lease and the required payments, OrthoEast has not provided the Agency with enough information to discern whether the proposed project is “based upon reasonable projections of the costs.”

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (5) and should not be approved.

### **Section H - Criterion (7)**

G.S. 131E-183(a)(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.”*

If the OrthoEast application is approved, it will be the first time OrthoEast has been responsible for the operation and maintenance of an MRI scanner. To start up the service, it will need experienced technicians and an imaging manager with MRI experience. It has none of those. It has no existing experienced staff to train new staff. The application does not recognize the need for experienced personnel and gives no reasonable evidence or support for where it will find those people.

Additionally, OrthoEast has not demonstrated adequate health manpower and management personnel. The criticisms of OrthoEast’s staffing discussed under Criterion (5) are incorporated here by reference. Because OrthoEast does not have adequate staffing, it has not shown evidence of the availability of health manpower for the provision of the services it proposes to provide. The

Agency has made determinations of non-conformity with Criterion (7) due to inadequate staffing in a past decision<sup>18</sup> and should do so again with regard to OrthoEast's application.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (7) and should not be approved.

### **Section I - Criterion (8)**

G.S. 131E-183(a)(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.”*

OrthoEast has not demonstrated the proposed service will be coordinated with the existing health care system. Its volume projections are based entirely on scans ordered by OrthoEast physicians. It has identified no existing scans ordered by non-OrthoEast physicians. The 518 scans of obese or claustrophobic patients it says it refers annually were ordered by OrthoEast physicians. The four letters of support from non-OrthoEast physicians appear to be from physicians who do not order scans from OrthoEast but refer patients to OrthoEast physicians who then may order scans.

The application mentions no outreach or advertising program to encourage non-OrthoEast physicians to order scans directly.

OrthoEast indicates it has a relationship with HealthAssist but includes no evidence to support this claim. The HealthAssist website does not list Ortho East as a partner.<sup>19</sup> OrthoEast has no letter of support from HealthAssist or any organization that helps uninsured or low-income people.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (8) and should not be approved.

### **Section K - Criterion (12)**

G.S. 131E-183(a)(12)

*“Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.”*

The comments under Criterion (4) are incorporated by reference to this response.

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<sup>18</sup> See Required State Agency Findings 2013 Brunswick County Home Health Review, October 4, 2013.

<sup>19</sup> HealthAssist webpage, <https://www.accesseast.org/ae-community-partners/>, accessed November 20, 2022.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (12) and should not be approved.

### **Section L - Criterion (13)**

G.S. 131E-183(a)(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;*
- (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) 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*
- (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.”*

The OrthoEast application does not demonstrate the contribution of the proposed service in meeting the health-related needs of medically indigent or low-income persons.

- OrthoEast has no written charity care policy or any written policy for reduced charges for uninsured and low-income patients for its physician services or imaging services.
- It reports delivering no MRI scans as charity care. Evidence of its future commitment of 1% is not supported by its past performance.
- Its relationship with HealthAssist appears to be for its physician services and not for imaging services requested by non-OrthoEast physicians.
- OrthoEast indicates it has a relationship with HealthAssist but includes no evidence to support this claim. The HealthAssist website does not list Ortho East as a partner. OrthoEast has no letter of support from HealthAssist or any organization that helps uninsured or low-income people.

### Payor Mix for the “Facility or Campus” Is Not Provided.

On page 20, OrthoEast states it is a “medical clinic,” meaning it provides medical care to patients outside of just x-rays. However, OrthoEast failed to provide either the current or the future payor mix for “the facility or campus” as the CON application form requests on pages 90 and 92–93. Without this information, the Agency does not have payor mix information for all the individuals OrthoEast will see at its facility. Instead, OrthoEast chose to include only the historical payor mix for “OrthoEast MRI Services”<sup>20</sup> and the year three payor mix for “OrthoEast Combined MRI & X-Ray” patients and MRI patients.<sup>21</sup>

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (13) and should not be approved.

### **Section N - Criterion (18a)**

G.S. 131E-183(a)(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.”*

A new scanner is most likely to have beneficial effects on quality, access, and price when operated by an organization that does not compete with the physician specialists who order most scans, and that charges non-hospital prices.

OrthoEast will not be a new provider in Pitt County, from an economic perspective. It has offered MRI services using its leased MRI for many years. To schedule scans, patients or providers call OrthoEast. The bill for the technical component is an OrthoEast bill. OrthoEast says its charges will stay the same. That OrthoEast would own rather than lease an MRI does not make it a new provider in the market.

The OrthoEast application will not affect competition for MRI services in the Service Area because all projected scans will be self-referred from OrthoEast physicians. Those physicians will not consider other MRI providers when ordering scans.

The OrthoEast MRI and its staff will specialize in orthopedic scans. Therefore, its target market would be other orthopedists in the Service Area. However, competing orthopedists likely will not

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<sup>20</sup> OrthoEast CON application, p. 90.

<sup>21</sup> OrthoEast CON application, p. 93.

order scans from a competing practice when there are other non-hospital MRI providers in Pitt County.

As discussed in the comments under Criterion (5), OrthoEast does not include adequate staffing or projected operating costs associated with staffing. Those comments are incorporated here by reference. In a past review, the Agency used an applicant's failure to "adequately demonstrate that projected operating costs are reliable" to determine it did not demonstrate any enhanced competition would "have a positive impact on the cost effectiveness and quality of the proposed services" and was therefore nonconforming with Criterion (18a).<sup>22</sup> The Agency should make a similar determination regarding OrthoEast's application.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (18a) and should not be approved.

### **Section O - Criterion (20)**

G.S. 131E-183(a)(20)

*"An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past."*

There is no evidence OrthoEast can provide quality MRI services. OrthoEast has no track record in providing quality MRI services because it has had no role in operating or maintaining the existing MRI. OrthoEast has no staff with experience in operating or maintaining an MRI.

For these reasons and others the Agency may discern, the OrthoEast application is nonconforming with Criterion (20) and should not be approved.

### **COMPARING THESE FACTORS, THE GREENVILLE MRI APPLICATION IS SUPERIOR**

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2022 SMFP, no more than one fixed MRI may be approved for the Service Area in this review. Because the two applicants in this review each propose to develop a fixed MRI in Pitt County, both applications cannot be approved.

After considering the information in each application and reviewing each individually against the applicable review criteria, the Agency uses a comparative analysis of the proposals to decide which proposals it should approve. A comparative review is required as part of the Agency findings when the MRI applications found conforming with the applicable review criteria exceed the number of MRIs the SMFP allows the Agency to approve. The Agency must then comparatively review the applications and select one application.

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<sup>22</sup> See Required State Agency Findings 2013 Forsyth County Home Health Review, December 20, 2013, p. 71.

The Agency has developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews, regardless of the type of service or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Competition (Access to a New or Alternate Provider)
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Projected Average Net Revenue per Patient, Procedure, Case or Visit
- Projected Average Total Operating Cost per Patient, Procedure, Case, or Visit

We suggest adding the ability to provide quality services to the comparative review factors in this MRI batching cycle. Project analysts have the discretion to apply additional factors based on the type of proposal.

### **Conformity with Statutory and Regulatory Review Criteria**

The Greenville MRI application conforms with all relevant statutory and regulatory review criteria. The OrthoEast MRI application is nonconforming with Criteria 1, 3, 3a, 4, 7, 8, 12, 13, 18a and 20.

### **Scope of Services**

Both MRI machines are likely capable of performing the same range of scans. However, Greenville MRI is staffed and experienced in delivering the scans required by the full range of physician specialties. OrthoEast is a single-specialty orthopedic physician practice and practically all its scans will be ordered by its orthopedic physicians. The OrthoEast MRI staff will not have experience with the full range of scans. For practical purposes, the scope of services Greenville MRI offers is more effective.

### **Historical Utilization**

The OrthoEast MRI was present at its site continuously in 2021. It was, for all practical purposes, a fixed MRI. The table below shows Greenville MRI and OrthoEast MRI procedures for fiscal year (FY) 2017 to FY 2021. For total procedures and procedures per machine, Greenville MRI has

substantially higher utilization. The higher utilization is because Greenville MRI received orders for scans from 898 different providers in 2021. OrthoEast relies entirely on its one physician practice. The same will be true for both applicants in the future. On historical utilization, Greenville MRI is more effective.

**Greenville MRI and OrthoEast Historical Adjusted Scans, FY 2017–2021**

	2017	2018	2019	2020	2021
Greenville MRI Total	10,533	10,399	10,695	10,353	10,829
Greenville MRI per Scanner	5,267	5,200	5,348	5,177	5,415
OrthoEast Total	2,042	2,188	2,248	2,265	2,594

*Sources: 2019–Draft 2023 State Medical Facilities Plans; Greenville MRI internal data. Note the FY 2019 data are updated from what was published in the 2021 SMFP to provide Greenville MRI’s adjusted scans. The FY 2021 data are updated from what was published in the Draft 2023 SMFP to account for a reporting error which Greenville MRI reported and corrected on September 16, 2022.*

**Geographic Accessibility (Location within the Service Area)**

Both applicants are located in Pitt County and are reasonably and equally accessible to Service Area residents. Geographically, the applicants are equally effective.

**Access by Service Area Residents**

Generally, the application projecting to serve the highest percentage of residents from the four Service Area counties is the more effective alternative with regard to this comparative factor, since the need determination is for an additional MRI to be located in the Service Area. The table below shows the MRI patient origin for Pitt, Greene, Hyde, and Tyrrell Counties.

County	Greenville MRI <sup>1</sup>	OrthoEast MRI <sup>2</sup>
Pitt	48.6	57.3
Greene	2.6	2.7
Hyde	0.4	NA
Tyrrell	0.1	NA
Total Service Area	52.7	60.0

<sup>1</sup> Greenville MRI Application, p. 36.

<sup>2</sup> OrthoEast MRI Application, p. 31. No data for Hyde or Tyrrell Counties

OrthoEast, however, will not improve access to all Service Area residents. OrthoEast’s application illustrates that it will not provide the full array of MRI scans but will instead be limited to orthopedic scans (including musculoskeletal scans and spine scans). The following evidence supports this statement:

- The four non-OrthoEast letters of support for the application are from orthopedic-related specialties.<sup>23</sup>
- OrthoEast maintained its historical five-year average MRI procedure weight (1.011) for projecting future scans.<sup>24</sup> This indicates the expected mix of scans will mirror the current scans provided on the Alliance scanner.
- The current MRI is only ACR accredited for musculoskeletal and spine scans.<sup>25</sup>
- The only discussion of expanded service appears on page 110 of the OrthoEast application, where it says, “OrthoEast is expanding the scope of services of its practice to add and enlarge the services offered to patients in need of orthopaedic care for hand and foot/ankle injuries and conditions.”<sup>26</sup>

This means that, in practice, OrthoEast’s MRI will not be accessible to all Service Area residents in need of MRI scans. Instead, only patients with orthopedic needs, and particularly the patients at OrthoEast, will have access to the MRI. In contrast, Greenville MRI will provide the full array of MRI services and will not be limited to referrals from a specific medical specialty or for scans of particular body parts.

Moreover, Greenville MRI’s proposal will provide MRI services to more additional Service Area patients in year three than OrthoEast’s proposal. The table below calculates the *additional* number of MRI patients served by the third project year over the baseline 2021 patients served, by county. As the table shows, Greenville MRI will provide MRI scans to 802 additional Service Area patients by year three, nearly twice the 447 additional Service Area patients OrthoEast proposes to serve. Therefore, Greenville MRI is the more effective applicant on the access by Service Area residents factor.

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<sup>23</sup> These letters are from Cynthia Lopez at Eastern Neurology & NeuroMuscular Center, Deanna Boyette at Boyette Orthopedics & Sports Medicine, Bryan Cooper at Eastern Headache & Spine, and Kyle Harner at Carolina Arthritis Center.

<sup>24</sup> OrthoEast CON application, p. 111.

<sup>25</sup> According to the American College of Radiology’s Accredited Facility Search, “Orthopaedics East & Sports Medicine Center, Inc.” is only certified for the MSK (musculoskeletal) and spine modules. <https://www.acr.org/accreditation.org/accredited-facility-search>, accessed November 21, 2022.

<sup>26</sup> OrthoEast CON application, p. 110.



**Number of Additional Patients, Project Year Three Over 2021**

County	Greenville MRI		OrthoEast MRI	
	Patients	Percent	Patients	Percent
Pitt	753	48.5%	426	57.3%
Greene	40	2.6%	21	2.8%
Hyde	7	0.5%	0	NA
Tyrrell	2	0.1%	0	NA
Total Service Area	802	51.7%	447	60.2%
Other	749	48.3%	296	39.8%
Total	1,551	100.0%	743	100.0%

*Source: OrthoEast CON Application, p. 31; Greenville MRI application, p. 37. Numbers represent year three projections less last full actual year (2021).*

**Competition (Access to a New or Alternate Provider)**

Both applicants are existing providers of MRI services in the Service Area. OrthoEast has provided services since at least 2008, using a leased machine. Greenville MRI has provided services since 2003. Neither is proposing to provide different services than it provides now. They are equally effective on this factor.

**Access by Underserved Groups: Uncompensated Care – Charity Care and Bad Debt**

Comparing applicants in this cycle based solely on charity care does not provide an accurate assessment of their provision of uncompensated care. As the Greenville MRI CON application explains, because neither Greenville MRI nor Eastern Radiologists refers patients for MRI scans, the MRI scans performed at Greenville MRI are based on referrals from physicians throughout the community. While the majority of patients referred to Greenville MRI are insured (which is logical, given they have seen and presumably paid for a physician visit before the referral), Greenville MRI and Eastern Radiologists accept all referred patients, regardless of ability to pay. Greenville MRI categorizes patients who it knows will not have the ability to pay for services in full as “charity care.” “Bad debt” represents payments Greenville MRI expected to receive but ultimately wrote off, such as payments a patient should have made for a scan to meet their deductible or copay, but did not pay. Both these categories represent care provided at no or reduced cost to the patient.

### Comparison of Year Three Uncompensated Care

	OrthoEast	Greenville MRI
Charity Care	\$ 43,767	\$ 17,867
Bad Debt	\$ 32,825	\$ 960,519
Total	\$ 76,592	\$ 978,386
Total per Machine	\$ 76,592	\$ 326,129
Total Gross Charges	\$ 4,376,733	\$ 17,006,521
Charity + Bad Debt as % of Gross Charges	1.7%	5.8%

Greenville MRI is providing significantly more uncompensated care than OrthoEast, in total, per machine, and as a percent of gross charges. When total uncompensated care is considered, rather than just the “charity care” line, Greenville MRI is the more effective applicant on this factor.

Greenville MRI also works with patients to offer payment plans. These plans are available to both self-pay patients and patients who are unable to pay their entire deductible or copay at the time of service. Greenville MRI provided MRI scans to 8,392 unique patients in 2021 and offered payment plans to 982 patients, or over 10% of patients. Over 75% of these patients pay less than \$100 per payment period. Greenville MRI will continue to provide care regardless of a patient’s ability to pay and will work with all its patients to develop a payment plan, as necessary.

#### Access by Underserved Groups: Medicaid

The table below shows various metrics relating to projected Medicaid revenue and scans during the third full fiscal year following project completion for each applicant. Greenville MRI is more effective on this factor. In an attempt to quantify the number of additional Medicaid *patients* each applicant proposes to serve, the table below also includes a calculation of the incremental scans to be performed on Medicaid patients in year three, above what was provided in 2021 (the last full year). To calculate this, the payor mix percentages from Form F.2a and F.2b were applied to the total volume of procedures for each year. Then, the 2021 Medicaid procedures were deducted from the 2026 procedures, to arrive at the incremental scans. As the table below shows, Greenville MRI will offer scans to more additional Medicaid patients than OrthoEast will. Greenville MRI is the more effective applicant on this factor.

Medicaid	OrthoEast	Greenville MRI
Total Value	\$245,097	\$1,322,166
Percent of Gross Charges	5.6%	7.8%
Incremental Scans (2026 v 2021)	47	150

### Access by Underserved Groups: Medicare

The table below shows various metrics relating to projected Medicare revenue and scans during the third full fiscal year following project completion for each applicant. While OrthoEast projects a higher percentage of its gross charges will be attributable to Medicare, Greenville MRI will serve more Medicare patients than OrthoEast. To calculate the incremental Medicare scans to be performed in year three (over what was performed in 2021), the payor mix percentages from Form F.2a and F.2b were applied to the total volume of procedures for each year. Then, the 2021 Medicare procedures were deducted from the 2026 procedures, to arrive at the incremental scans. As the table below shows, Greenville MRI will offer scans to more additional Medicare patients than OrthoEast will. Greenville MRI is the more effective applicant on this factor.

<b>Medicare</b>	<b>OrthoEast</b>	<b>Greenville MRI</b>
Total Value	\$1,364,228	\$5,017,804
Percent of Gross Charges	31.2%	29.3%
Incremental Scans (2026 v 2021)	260	524

### Projected Average Net Revenue per Patient, Procedure, Case or Visit

The table below shows the projected average net revenue per adjusted MRI procedure in the third full fiscal year following project completion for each applicant. Generally, the application projecting the lowest average net revenue per adjusted MRI procedure is the more effective alternative with regard to this comparative factor, to the extent the average reflects a lower cost to the patient or third-party payor. The table below provides the average net revenue per adjusted MRI scan for each applicant.

<b>Average Net Revenue per Adjusted MRI</b>	
<b>OrthoEast</b>	<b>Greenville MRI</b>
\$324.40	\$441.56

Because Greenville MRI is providing a wider array of MRI services, it is providing more scans with contrast than OrthoEast. Greenville MRI's average scan weight is 1.151, while OrthoEast's is 1.011. Revenue is higher for scans with contrast than scans without contrast. For example, Medicare payment for the technical component of an MRI lumbar spine scan without dye is \$125.17, while payment for MRI lumbar spine with dye is \$192.93.<sup>27</sup> OrthoEast and Greenville MRI are not providing a comparable array of MRI scans. Greenville MRI will provide more scans with

<sup>27</sup> CMS Physician Fee Schedule Lookup Tool, HCPCS Code 72148 and 72149, Specific Locality - 1150200 North Carolina, <https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=1&CT=2&H1=72148&H2=72149&C=90&M=5>.

contrast/dye that garner a higher payment. Therefore, the average net revenue each applicant receives for MRI scans cannot be compared.

**Projected Average Total Operating Cost per Patient, Procedure, Case, or Visit**

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

<b>Average Operating Expense per Adjusted MRI, Year 3</b>		
	<b>OrthoEast</b>	<b>Greenville MRI</b>
As Reported in CON Application	\$265.75	\$276.25
Without Medical Supply Costs	\$264.13	\$257.61
Additional Salary Costs	\$61.00	\$0
Expense-Adjusted for Medical Supplies & Salary, Admin Costs	\$325.13	\$257.61
Additional Costs for Adequate Central Office/Admin Costs	\$22.08	\$0
Expense-Adjusted for Medical Supplies Salary & Admin Costs	\$347.21	\$257.61

The lower operating expenses at OrthoEast are due largely to its offering a more limited range of services and insufficient staffing and administrative overhead costs. OrthoEast projects a total of \$5,383 in medical supplies in year three, or \$1.62 per weighted scan. By comparison, Greenville MRI projects \$257,401 or \$18.64 in medical supplies per weighted scan. The medical supply costs are almost entirely the costs for contrast dye and the accompanying supplies required to administer the dye (such as syringes). Because Greenville MRI provides a wider array of MRI services, it provides more scans with contrast than OrthoEast. An outpatient MRI scan with contrast is weighted at 1.4, while an outpatient MRI scan without contrast is weighted at 1.0. Greenville MRI’s average scan weight is 1.151 (meaning slightly less than half the scans are with contrast), while OrthoEast’s is 1.011 (meaning nearly all scans do not use contrast). If Greenville MRI’s medical supply cost per scan were as low as OrthoEast’s, it would have a lower average operating expense per scan than OrthoEast does, as the table above shows.

As discussed under Criterion (5), OrthoEast appears to have underestimated staffing costs and central support services costs. The additional staffing expenses needed for OrthoEast to staff its MRI scanner at the same per-scanner level as Greenville MRI was calculated on page 13 of these comments. The \$219,895 required to bring OrthoEast’s staffing up to Greenville MRI’s equates to \$61.00 per adjusted MRI scan. As the table above shows, when this \$61.00 is added to the operating expenses, and the medical supply costs are removed, Greenville MRI’s average operating expense (\$257.61) is lower than OrthoEast’s (\$325.13).

As discussed under Criterion (5), OrthoEast also underestimated the cost for administrative and central office costs. The criticisms under Criterion (5) are incorporated here by reference. The table below summarizes the differences in cost per scan for central office and administration between the two applicants. OrthoEast included only half of the cost for administration and central office functions that Greenville MRI did, on a per adjusted scan basis. If OrthoEast had appropriately accounted for administrative costs, it would have a total adjusted operating expense of \$347.21, which is higher than Greenville MRI's \$257.61, as the chart above shows.

**Difference in Costs, Year Three**

	OrthoEast		Greenville MRI	
	Projected Value	Per Weighted Scan	Projected Value	Per Weighted Scan
Total Admin/Central Office:	\$79,603	\$22.08	\$609,749	\$44.16
Central Office Allocation	\$25,950	\$7.20	N/A	N/A
Billing and IT	\$53,653	\$14.88	N/A	N/A
Management Fee	N/A	N/A	\$609,749	\$44.16

OrthoEast and Greenville MRI do not provide a comparable range of MRI scans. When the operating expenses are adjusted to make their services more comparable, Greenville MRI's average operating expense per adjusted MRI scan is lower than OrthoEast's. Moreover, OrthoEast did not reasonably budget all costs of providing its more limited set of MRI services. Therefore, Greenville MRI is the more effective applicant on this factor.

**Ability to Provide Quality Services**

Greenville MRI has nearly two decades of experience providing high-quality MRI services to Service Area residents. Its CON application includes all the required staffing, expenses, and services to continue providing these services on the proposed additional scanner. The Agency can rely on Greenville MRI to continue providing high-quality care to Service Area residents.

OrthoEast states it “has experience providing MR imaging services in Pitt County for residents from throughout eastern North Carolina.”<sup>28</sup> This is inaccurate. OrthoEast has had no role in operating or maintaining the existing MRI. OrthoEast has no staff with experience in operating or maintaining an MRI and does not propose hiring an experienced MRI manager to bring expertise to the project. Additionally, the insufficient staffing and low administrative/central office expenses demonstrate OrthoEast does not know how to properly staff the proposed MRI or account for its

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<sup>28</sup> OrthoEast CON application, p. 25.

expenses. The discussion of these deficits included in Criterion (5) is incorporated here by reference.

The MRI scanner equipment and software OrthoEast included in its application also demonstrate a lack of experience and inability to provide high-quality care to Service Area patients. OrthoEast proposes to purchase a refurbished 2012 Siemens 1.5T Aera scanner. This is not state-of-the-art equipment, as Siemens has introduced three newer models of scanners since the Aera. Moreover, the software capabilities of this scanner are not guaranteed by the seller and may not be properly functional, as evidenced by the following clause in the purchase agreement:

**14. SOFTWARE.**

- (a) PURCHASER acknowledges and agrees that SELLER has no rights, titles, and interest in and to software relating to the Equipment, and that SELLER has no right to grant any licenses thereunder. PURCHASER further acknowledges and agrees that all rights, title and interest in such software remains with the original equipment manufacturer (OEM).
- (b) SELLER makes no representations and warranties to PURCHASER that the software or optional software packages were properly installed in, and licensed for the Equipment, and that it will perform substantially as described in the OEM's specification for the Equipment.

The software proposed for the machine is SYNGO MR D13. This software runs on a Windows 7 operating system.<sup>29</sup> Microsoft no longer supports the Windows 7 operating system and no longer issues security fixes and patches for it. Greenville MRI, like most MRI vendors, has upgraded its systems to use Windows 10-based operating systems and compatible application software. Use of an older Windows 7-based operating system leaves open security vulnerabilities which may put patients' Protected Health Information (PHI) at risk. Greenville MRI understands the system could be operating on Windows XP, rather than Windows 7. If this is the case, the same concerns remain, as Microsoft has stopped providing support for Windows XP and has stated that "running Windows XP will not be secure and will still be at risk for infection."<sup>30</sup> Because it has no history of providing care, OrthoEast may be unaware of this potential quality issue.

There is a significant lack of attention to detail in OrthoEast's choice of equipment, including the age of the equipment and potential security concerns related to installed operating software. Based on Greenville MRI's historical experience, there is a near-term possibility of the equipment vendor declaring the Aera scanner as being at "end of life" in terms of upgradeability. This creates a dead-end to any future path to install and take advantage of new scanning features, which in turn decreases the quality of scans and patient care.

Greenville MRI is the more effective alternative with regard to this comparative factor.

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<sup>29</sup> Siemens SYNGO® MR D13 MR DICOM Conformance Statement, p. 9.

<sup>30</sup> Microsoft, "Windows XP Support Has Ended," <https://support.microsoft.com/en-us/windows/windows-xp-support-has-ended-47b944b8-f4d3-82f2-9acc-21c79ee6ef5e>.

## SUMMARY

The table below lists the comparative factors and states which application is the more effective alternative with regard to each comparative factor. Factors are listed in the order discussed above but not necessarily in the order of importance.

<b>Comparative Factor</b>	<b>Greenville MRI</b>	<b>OrthoEast</b>
Conformity with Statutory and Regulatory Review Criteria	Yes	No
Scope of Services	More Effective	Less Effective
Historical Utilization	More Effective	Less Effective
Geographic Accessibility	Equally Effective	Equally Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Charity Care Patients/Uncompensated Care	More Effective	Less Effective
Access by Medicare Patients	More Effective	Less Effective
Access by Medicaid Patients	More Effective	Less Effective
Competition (Access to New or Alternate Provider)	Equally Effective	Equally Effective
Projected Average Net Revenue per MRI Procedure	Inconclusive	Inconclusive
Projected Average Operating Expense per MRI Procedure	More Effective	Less Effective
Demonstrated Ability to Provide Quality Service	More Effective	Less Effective

Greenville MRI is more effective on eight of the factors listed above. Therefore, the Greenville MRI application is the more effective application.

For all the reasons discussed in these comments and such others as the Agency may discern, the Agency should deny the OrthoEast application and approve the Greenville MRI application.