



December 1, 2020

Tanya Saporito, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments on Guilford County Fixed MRI Scanner CON Applications

Dear Ms. Saporito:

Enclosed please find written comments prepared by Diagnostic Radiology & Imaging, LLC (doing business as Greensboro Imaging) regarding the competing CON application for a fixed MRI scanner to meet the Guilford County need identified in the *2020 State Medical Facilities Plan*. Thank you for the opportunity to submit these comments for consideration regarding this important community need.

If you have any questions about the information presented here, please contact me at 336.207.2712.

Sincerely,

Kelli Collins

Kelli Collins
Chief Operating Officer
Greensboro Imaging

**COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATION
GUILFORD COUNTY FIXED MRI SCANNER NEED DETERMINATION**

**Submitted by Greensboro Imaging
December 1, 2020**

Two applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2020 State Medical Facilities Plan (SMFP)* for one fixed MRI scanner in Guilford County:

G-11981-20 Diagnostic Radiology & Imaging, LLC d/b/a Greensboro Imaging

G-11986-20 Southeastern Orthopaedic Specialists, P.A. (hereinafter referred to as SOS)

In accordance with N.C.G.S. §131E-185(a1)(1), Diagnostic Radiology & Imaging, LLC (Greensboro Imaging) submits these written comments which offer a comparative analysis of the two applications, and also address representations in the competing application, and a discussion about whether the material in the SOS application complies with the relevant Certificate of Need review criteria, plans and standards. Greensboro Imaging organized its discussion first with a summary of comparative factors the Agency typically considers, and then by reviewing the competing application according to the general CON statutory review criteria. These comments illuminate why the application submitted by Greensboro Imaging represents the most effective alternative for development of a new fixed MRI scanner in Guilford County. These comments are not intended to include any additional information that would represent an amendment to Greensboro Imaging's application.

These comments discuss the deficiencies in the SOS application that necessitate its denial, and combined with an overall comparison of the two applications, Greensboro Imaging believes demonstrate the superiority of its proposed project versus the competing application. Greensboro Imaging is Guilford County's preeminent imaging provider. Because of its long history of providing imaging services in the Piedmont Triad, and its history of service to Guilford County residents, Greensboro Imaging has established a significant level of support and coordination with other healthcare providers in Guilford County. On pages 79 - 81 of its application, and in the hundreds of letters of support included in Exhibit I.2, Greensboro Imaging summarizes its extensive outreach and engagement with the local healthcare provider community. Greensboro Imaging is committed to Guilford County, and such a demonstration of broad coordination is a critical leading indicator of which applicant represents the greatest access by a diverse patient population and meets the broadest range of clinical needs, and therefore, the most effective alternative for Guilford County residents.

The Agency typically performs a comparative analysis when evaluating competing fixed MRI scanner applications in a need determination batch review. The purpose is to identify which

proposal would bring the greatest overall benefit to the community. The following table summarizes objective metrics that the Agency should use for comparing the two applications in this Guilford County MRI batch review, based on the comparative factors the Agency applied in the 2019 Forsyth County and Wake County fixed MRI batch reviews, which are the two most recent competitive batch fixed MRI scanner Agency Findings.

2020 Guilford County Fixed MRI Scanner Batch Review Comparative Analysis

	Greensboro Imaging	Southeastern Orthopaedic Specialists
Conformity with Review Criteria & Rules	Yes	No
Scope of Services	Most Effective	Least Effective
Historical Utilization	Most Effective	Least Effective
Competition/Access to New Provider	Equally Effective	Equally Effective
Geographic Accessibility	Most Effective	Least Effective
Access by Service Area Residents	Effective	Not approvable
Access by a Diverse Patient Population/Broad Range of Clinical Needs	Most Effective	Least Effective
Projected Charity Care	Effective	Not approvable
Projected Medicare	Most Effective	Least Effective
Projected Medicaid	More Effective	Not approvable
Projected Average Net Revenue per Scan less Professional Fee	Most Effective	Least Effective
Projected Average Operating Expense per Scan less Professional Fee	Effective	Not approvable

As the table portrays objectively, the Greensboro Imaging application is the most effective alternative. In other words, the Agency will enable the greatest benefit to local residents by approving the Greensboro Imaging application. Specifically:

Conformity with Review Criteria. The Greensboro Imaging application is conforming to all CON review criteria. In contrast, SOS fails to conform to all statutory review criteria, and its application is not approvable.

Scope of Services. Both applicants propose to acquire and operate a 1.5T fixed MRI scanner in a freestanding outpatient setting. However, SOS proposes to acquire and operate a Siemens Espree MRI scanner, while Greensboro Imaging proposes to acquire and operate a Siemens Aera MRI scanner. A comparison of the two shows that the SOS choice is clinically less effective than the Greensboro Imaging magnet. Both the Espree and the Aera have 70cm bores offering patient comfort, and both utilize Total Imaging Matrix technology that allows providers to combine coils to image multiple regions of the body simultaneously. Both the Espree and Aera run on the Syngo platform, which Siemens uses across all its modalities. While these features represent common ground, the Espree and Aera have more differences than similarities. Here are a few that stand out, and highlight how the Aera is a higher quality option than the Espree:

- **Radio Frequency Hardware:** All the Aera's components for transmitting and receiving RF signal are mounted right at the magnet, while the Espree's are in the equipment room. This means the Aera has less cabling (a fiber optic cable between the magnet and equipment room) and less noise, which improves signal quality.
- **TIM 4G:** Both systems feature TIM, but the Aera has the latest iteration, TIM 4G. TIM 4G offers added coil elements and exceptional signal to noise ratio (SNR).
- **Table Configuration:** The Aera comes in two table configurations: roll-away or floor-mounted. The Espree has just one table type, a fixed table that hangs off the front of the gantry, which thus provides less flexibility for accommodating patient needs.
- **Gradients:** The Aera has a higher gradient class. Gradients are loops of wire or thin conductive sheets on a cylindrical shell that lies just inside the bore of an MRI Scanner. When an electrical current passes through these coils, the result is a secondary magnetic field. This gradient field distorts the main magnetic field in a slight but predictable pattern. This causes the resonance frequency of protons to vary in a function of position. Gradients' job is to modify the magnetic field in the area being scanned so the system can "listen" for the resonance and create an image. It is difficult work to modify a magnetic field strong enough to lift a car, so the coils in these smaller magnets move and stress, literally vibrating. These vibrations are the source of the sound. For the best performance concerning peak gradient strength, bigger is better.

- Magnet Field Homogeneity: The Aera shims to a spherical magnetic field, as opposed to the elliptical field found on the Espree. This field shape better suits the Aera for full-body scanning, as the field more closely aligns with the overall shape of the human body.
- Coils: The coil options of these two systems differ substantially. While both use TIM, the Espree uses an older version of the technology. The TIM 4G Aera uses coils with up to 64 independent RF channels. That goes up to 204 when a provider combines coils. The increase in channels allows for faster acquisition and better image quality.

Historical Utilization. The following table illustrates historical utilization of each applicant, as shown in the 2020 State Medical Facilities Plan (SMFP) and the Proposed 2021 SMFP.

Weighted MRI Procedures in Guilford County, FY2018-FY2019

Provider	FY2018	FY2019	FY2019 Weighted MRI Procedures/Scanner
Greensboro Imaging	16,438	17,676	5,892
SOS	5,139	5,147	5,147

Source: 2020 & Proposed 2021 SMFPs

As shown in the table, Greensboro Imaging historically provides more than three times the number of weighted MRI procedures than does SOS, and also operates at a higher capacity per scanner than does SOS. Therefore, from an historical utilization perspective, Greensboro Imaging is the most effective alternative.

Competition/Access to New Provider. Both applicants currently provide MRI services in Guilford County; therefore, neither applicant qualifies as a new or alternative provider in the service area.

Increase Geographic Accessibility. SOS proposes to locate the fixed MRI scanner at its existing office location on N. Church Street in Greensboro, therefore its proposal provides no new benefit to Guilford County residents from the perspective of geographic access. In contrast, Greensboro Imaging proposes to locate the fixed MRI scanner in Summerfield, which represents new geographic access in Guilford County. As shown in the Greensboro Imaging CON application on page 36, the following table identifies the municipal location of the existing fixed MRI scanners in Guilford County.

Guilford County Fixed MRI Scanners by Municipal Location

City/Town	2019 Population	# of Existing & Approved Fixed MRI Scanners	Population/Scanner
Greensboro	293,726	9	32,636
High Point	106,771	3	35,590
Summerfield	11,949	0	
Oak Ridge	7,651	0	
Stokesdale	5,965	0	
Pleasant Garden	4,658	0	
Jamestown	4,362	0	
Gibsonville	3,619	0	
Guilford County	539,666	12	44,972
North Carolina	10,508,254	242	43,423

Source: NCOsBM (2019 municipal population is the most recent available), Proposed 2021 SMFP

Nine fixed MRI scanners are located in Greensboro. The current distribution of fixed MRI scanners in Guilford County is limited to Greensboro and High Point. The population/scanner ratio for both Greensboro and High Point is more favorable than the comparable ratios for both Guilford County and North Carolina. By contrast, northern Guilford County does not host any fixed MRI scanners. It is important from a health planning perspective to improve geographic access to MRI services in Guilford County. As the previous table shows, Summerfield and the neighboring northern Guilford County communities of Oak Ridge and Stokesdale (combine 2019 population of 25,565) are the largest population center in Guilford County that does not host a freestanding fixed MRI scanner. Therefore, Greensboro Imaging’s planned Summerfield location is the most effective alternative for addition of a fixed MRI scanner from a geographic perspective.

Access by Service Area Residents. The following table shows the projected Guilford County patient origin percentage of the competing application. As stated in its application, Greensboro Imaging is an important regional imaging referral center, and serves patients from throughout the Piedmont Triad area.

Projected Guilford County Patient Origin, PY3

Greensboro Imaging	SOS
57.0%	70.8%

Source: CON applications, Section C.3.

However, the SOS application is not conforming to all statutory review criteria, and is therefore not approvable.

Access by a Diverse Patient Population/Broad Range of Clinical Needs. The paucity of physician letters of support for the SOS proposal is indicative of a fundamental weakness of its proposal: the SOS scanner will only serve patients of SOS. SOS is an orthopedic physician practice that relies on its own physicians to support the proposed fixed MRI scanner. Patient referrals from non-SOS physicians will most likely be non-existent. The only clinical letters of support included with the SOS application were from SOS physicians; none were from any other physicians. An MRI scanner located at an orthopedic practice is not designed to be an MRI service that is accessible to the broader community.

By sharp contrast, Greensboro Imaging’s proposal is to offer a fixed MRI scanner that is accessible and welcoming to any local physician who refers patients for MRI scans, regardless of the physician specialty. Greensboro Imaging is a large and experienced local provider of imaging services, with long-standing positive working relationships with the broad referring physician community in Guilford and surrounding counties. The Greensboro Radiology radiologists who diagnose patients at Greensboro Imaging have practiced in Guilford County and surrounding communities for many years, and have during that time developed these long-standing professional relationships with referring physicians and the broader healthcare provider community. As stated in its application, Greensboro Imaging anticipates that its large network of referring physicians will continue to refer patients to Greensboro Imaging for MR imaging services, just as they have been for many years. As stated on page 79 of its application, during 2019, 329 medical offices and 5,029 physicians and providers referred patients to Greensboro Imaging for imaging services, including 1,115 physicians who made MRI referrals. The Greensboro Imaging proposal is well supported by the community, as evidenced by the many letters from physicians documented in its CON application. As evidence of this stark difference between applicants, the SOS application included just 17 provider letters of support, limited solely to the 17 physicians at SOS, whereas the Greensboro Imaging application included over 220 letters of support, including 160 from a wide variety of referring providers.

Therefore, the Greensboro Imaging application is the most effective alternative in terms of providing access to a diverse patient population and broad range of clinical needs.

Access for the Medically Underserved. For access by underserved groups, applications are compared with respect to three underserved groups: charity care patients, Medicare patients and Medicaid patients. Greensboro Imaging projects reasonable charity care/self-pay, Medicare and Medicaid access based on historical experience, as shown in the table below. Greensboro Imaging projects a higher combined medically underserved payor mix than SOS. In addition to projecting lesser medically underserved access, SOS did not reasonably project its underserved access according to its historical access, and is not conforming to Review Criterion 13. Therefore Greensboro Imaging is the more effective alternative as to access for the medically underserved.

Projected Charity Care/Self-Pay, Medicare & Medicaid Payor Mix

Payor Mix Year 3	Greensboro Imaging	SOS
Charity Care/Self-Pay	2.13%	4.25%
Medicare	44.98%	33.25%
Medicaid	4.97%	6.00%
Combined Total	52.08%	43.50%

Source: CON Applications, Section L.3.

Projected Average Net Revenue per MRI Procedure. Greensboro Imaging proposes market-competitive charges for its fixed MRI scanner in Summerfield, including projecting the lowest average net revenue per MRI scan of the two competing applicants. Therefore, the Greensboro Imaging application is the more effective alternative.

Projected Average Net Revenue/MRI Procedure

	Greensboro Imaging	SOS
Average Net Revenue, Year 3	\$320	\$350

Source: CON Applications, Section Q, Form F.2. Excludes professional fees.

Projected Average Total Operating Cost per Procedure. Greensboro Imaging projects a compelling and market-competitive operating expense of \$244/scan (excluding professional fees) for the proposed Summerfield fixed scanner. This represents a modest operating expense/scan in the third project year, even though as a new location it will yet be in the “ramp-up” phase of offering services. The Summerfield operating expense/scan will become even more cost effective beyond the initial three project years as volume increases. The SOS application projects \$198 (excluding professional fees) for its average expense per scan in PY3, but the SOS application is not approvable. The discussion regarding access found in Criterion (13) is incorporated herein by reference. Therefore, the application submitted by Greensboro Imaging is the most effective alternative with regard to projected average total operating expense per MRI scan.

In summary, Greensboro Imaging represents the only approvable application, and is the most effective alternative for development of the need-determined fixed MRI scanner in Guilford County.

Specific comments regarding the Southeastern Orthopaedic Specialists, P.A. application

Criterion (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.*

SOS fails to adequately demonstrate how the proposed project will promote equitable access in meeting the need identified in the 2020 SMFP. The discussion regarding analysis of medically underserved access found in Criterion (13) is incorporated herein by reference. Therefore, SOS is not consistent with Policy GEN-3. The SOS application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (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.”*

SOS does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. See discussion regarding Criterion 13. An application that cannot be approved cannot be the most effective alternative. Therefore, the SOS application is not conforming to Criterion (4).

Criterion (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.”*

The SOS application is not conforming to other statutory and regulatory review criteria, and thus, is not approvable. See discussion regarding Criterion 13. A project that does not reasonably demonstrate the extent to which medically underserved groups will access its services does not demonstrate financial feasibility. Consequently, the application is not conforming to this criterion.

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

SOS fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service because the application is not conforming to all statutory and regulatory review

criteria. See Criterion 13 for additional discussion. Therefore the application is not conforming to Criterion (6).

Criterion (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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:*

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;”

SOS did not reasonably project the extent to which medically underserved groups expect to utilize the proposed services. Specifically, SOS projects an unjustifiably high Medicaid payor mix of 6.0%. SOS attempts to justify this figure by claiming that the COVID-19 pandemic has changed patient practice and referral patterns. However, assuming this were the case, all payor types would be similarly impacted, and therefore the overall SOS payor mix would tend to be the same as the historical mix. Further, SOS references its FFY 2019 Medicaid mix of 5.76% as justification for the 6% Medicaid assumption. This figure is also not the same as the projected Medicaid mix. The more reasonable basis upon which SOS should have developed its payor mix projection is the most recent historical patient origin of the SOS MRI service, which is 4.86% for FFY 2020, as SOS shows on page 90 of its application. Greensboro Imaging's projected Medicaid payor mix is 4.97%, which is based on its CY2019 Medicaid payor mix, is higher than the SOS historical Medicaid payor mix of 4.86%. SOS is simply attempting to manufacture a medically underserved payor mix that it hopes will be considered more favorably in an Agency comparative analysis. Therefore the application is not conforming to Criterion (13).

Criteria (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.”*

SOS's application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will have a positive impact on access to the services proposed. The applicant's projected payor mix is not based on reasonable and adequately supported assumptions. The discussions regarding medically underserved access found in Criterion (13) is incorporated herein by reference.