

May 2, 2016

Celia Inman, 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 CON Applications

Dear Ms. Inman:

Enclosed please find comments prepared by Wake Forest Baptist Imaging, LLC regarding the competing CON applications for one fixed MRI scanner for Guilford County, to meet the need identified in the *2016 State Medical Facilities Plan*. We trust that you will take these comments into consideration during your review of the applications.

If you have any questions about the information presented here, please feel free to contact me at 336.608.3082. I look forward to seeing you at the public hearing.

Sincerely,

*Jo Ellen Lucas*

Jo Ellen Lucas  
Administrator

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

**Submitted by Wake Forest Baptist Imaging, LLC  
May 2, 2016**

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Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2016 State Medical Facilities Plan (SMFP)* for one fixed MRI scanner in Guilford County. In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by the other applicants, and a discussion about whether the material in each application complies with the relevant review criteria, plans, and standards. These comments also address the issue of which of the competing proposals represents the most effective alternative for development of an additional fixed MRI scanner in Guilford County.

Specifically, the CON Section, in making the decision, should consider several key issues, including the extent to which the proposed projects:

- (1) enhance competition for MRI services in Guilford County;
- (2) demonstrate improved access for the medically underserved;
- (3) represent the most effective alternative for developing a fixed MRI program, with competitive charges and costs;
- (4) improve geographic access to fixed MRI services in Guilford County; and
- (5) document abundant support from local referring physicians.

The Agency typically performs a comparative analysis when evaluating competing fixed MRI applications in a need determination batch review. The purpose is to identify the applicant that would bring the greatest overall benefit to the community. The table below summarizes 12 objective metrics that the Agency should use for comparing the three applications in this Guilford County MRI batch review.

It is important to note that the comparative analysis for costs is based on Project Year 3 for each of the applicants. This is the most reasonable comparison given that two of the applicants are existing providers, and WFBI will be a new provider, with a volume ramp-up; thus Project Year 3 provides the most representative comparison.

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## Guilford County Fixed MRI Applicant Comparative Analysis

Metrics			
Comparative	WFBI	SOS/AHS	Cone Health
Enhance Market Competition	Yes	No	No
Improve Geographic Access	Yes	No	No
Operational Date	1/1/2017	10/1/2017	10/1/2017
Project Capital Cost	\$ 2,310,432	\$ 710,000	\$ 3,559,980
PY3 Gross Revenue/Scan	\$ 1,579	\$ 1,391	\$ 3,173
PY3 Net Revenue/Scan	\$ 468	\$ 379	\$ 560
PY3 Operating Cost/Scan, excluding professional fees	\$ 384	\$ 315	\$ 229
Self-Pay/Charity Care %	1.8%	1.0%	8.2%
Medicare %	31.0%	27.0%	46.3%
Medicaid %	5.9%	5.8%	11.3%
Guilford County Patient Origin %	85.6%	86.9%	74.6%
Physician Support Letters	115	20	19

Rankings			
Comparative	WFBI	SOS/AHS	Cone Health
Enhance Market Competition	1	2	2
Improve Geographic Access	1	2	2
Operational Date	1	2	2
Project Capital Cost	2	1	3
PY3 Gross Revenue/Scan	2	1	3
PY3 Net Revenue/Scan	2	1	3
PY3 Operating Cost/Scan, excluding professional fees	3	2	1
Self-Pay/Charity Care %	2	3	1
Medicare %	2	3	1
Medicaid %	2	3	1
Guilford County Patient Origin %	2	1	3
Physician Support Letters	1	2	3
<b>Average</b>	<b>1.75</b>	<b>1.91</b>	<b>2.08</b>
<b>Total</b>	<b>21</b>	<b>23</b>	<b>25</b>

For each of the comparative metrics shown in the first table, WFBI ranked the providers in terms of effectiveness, as shown in the second table. A rank of “1” indicates the most effective applicant, with “3” indicating the least effective of the three applications. As the second table portrays objectively, the WFBI application is the most effective alternative because WFBI offers the lowest total and average scores. In other words, the Agency will enable the greatest overall benefit to local residents by approving the WFBI application. Specifically:

- SOS/AHS and Cone Health are existing MRI providers in Guilford County. WFBI is the only applicant that offers the benefit of being a new provider and enhancing competition for MRI services.
- SOS/AHS and Cone Health both propose to locate the fixed MRI scanner at their existing place of business where they already offer MRI services. Neither offers any geographic access benefit. WFBI is the only new provider applicant, and thus, clearly, the WFBI proposal provides the greatest benefit to Guilford County residents from the perspective of improved geographic access.
- WFBI projects to make operational its fixed MRI scanner nine months earlier than both SOS/AHS and Cone Health.
- WFBI projects a reasonable capital cost for adding a new fixed MRI scanner to the Guilford County market place. Cone Health projects the highest project capital cost, which is not unusual for a hospital-based project. As discussed later in these comments, the Cone Health project does not bring any new benefit that it does not already offer in the community, and therefore is not the most effective capital investment. By contrast, SOS/AHS has the lowest projected capital cost, but this is because it doesn't plan to make any substantive change to the MRI service it already offers. In fact, as described later in these comments, SOS/AHS doesn't even need a CON to enact the change it proposes.
- WFBI proposes market-competitive charges for its fixed MRI scanner in Guilford County, and projects competitive operating costs for a new fixed scanner. Cone Health projects the highest gross revenue/scan, as well as the highest reimbursement/scan, which, again, is not surprising for a hospital-based service. SOS/AHS is an existing provider, and therefore does not offer the benefit of new competition in the Guilford County marketplace.

- WFBI offers a competitive operating cost/scan in the third project year, even though as a new provider it is still in the “ramp-up” phase of offering services. Its operating cost/scan will only become even more competitive beyond the initial three project years.
- As a new provider, WFBI projects to offer wide access to services for all local residents, including the medically underserved. WFBI’s projected combined Medicare/Medicaid/Charity Care mix is 38.7%, which is higher than the 33.8% projected by SOS/AHS. Cone Health’s underserved access is to be expected for an institution that is tax-exempt and, thus, financially supported and obligated to provide such access.
- The SMFP MRI need determination is for Guilford County; therefore, access for Guilford County residents is paramount. WFBI projects a much higher Guilford County patient origin percentage than Cone Health, and is comparable to SOS/AHS.
- An important factor to consider when evaluating the competing proposals is the extent to which the local community supports each proposed project; particularly the extent to which referring physicians will sustain the project. Physicians refer patients for MRI services, so physician support for an MRI scanner application is essential. WFBI’s application evidenced significantly more project support from the MRI referral community, with 115 physician letters of support, which is three times the combined letters of support from SOS/AHS and Cone Health. This is a significant statement made by local referring physicians who are indicating their strong desire for and support of a new proposed MRI provider in this marketplace.

## **Specific comments regarding the Southeastern Orthopaedic Specialists/Alliance HealthCare Services application**

- SOS/ AHS is not proposing any change from the status quo. SOS/ AHS plan to upgrade the existing MRI scanner and trailer currently located at the SOS medical clinic. Fundamentally, this project does not require a CON. AHS already owns the scanner, which is grandfathered from the CON law. Upgrading or even replacing this medical diagnostic equipment is exempt from CON review, regardless of the project capital cost, and certainly as long as the equipment remains located on the main campus. It would appear that the sole purpose of the SOS/ AHS application is to seek to eliminate the MRI need determination in Guilford County by trying to declare its mobile MRI scanner to be a fixed MRI scanner. This is simply gamesmanship, trying to perform an end-run around the 2016 SMFP need determination, and provides no incremental benefit to the residents of Guilford County. This is clearly not the most effective alternative of the competing applications.
- Recently Southeastern Orthopaedic Specialists has significantly contracted in size, decreasing from 26 physicians down to 18. Since 2013, 10 physicians have left SOS for other practices. (in fact, one of the departing physicians, Dr. Stephen Lucey, provided a letter of support in the WFBI application). This 30% shrinkage in the SOS physician staff is significant, as it is indicative of historical instability in the partnership, and the possibility of future staff fracturing. A further decline in the number of SOS physicians would render meaningless the MRI projections in the SOS/ AHS application. As it is, because the SOS/ AHS scanner only treats SOS patients, one can reasonably question the likelihood of the volume projections, given that 100% of the projected patient scans are based on SOS physician referrals.
- The relative lack of physician letters of support for the SOS/ AHS proposal is indicative of a fundamental weakness of the proposal. SOS/ AHS scanner will only serve patients of SOS. An MRI scanner located at an orthopedic practice is not designed to be an MRI service that is accessible to the broader community. By comparison, WFBI'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. The WFBI proposal is well supported by the community, as evidenced by the many letters from physicians and community leaders documented in its CON application.

- On page 42 of its application, SOS/AHS states that Alliance operates two mobile MRI scanners in the service area (Guilford County). However, Exhibit 4 of the application includes a table listing all the mobile MRI scanners that Alliance owns and operates in North Carolina. Six of the listed scanners include Guilford County as their service location. On pages 42-43, SOS/AHS provided historical utilization for two mobile MRI scanners serving Guilford County, but not all six units. Therefore, SOS/AHS did not demonstrate how it is conforming to the MRI Performance Standards (10A NCAC 14C .2703(b)(2), and thus is not approvable.
- SOS/AHS is currently an existing MRI location in Greensboro, and thus the SOS/AHS proposal provides no benefit to Guilford County residents from the perspective of geographic access.
- As shown on the following table, WFBI projects to provide greater Medicare/Medicaid/Charity Care access than SOS/AHS, the other non-hospital applicant.

**Projected MRI Medically Underserved Payor Mix**

Payor Mix Year 2	WFBI	SOS/AHS
Self-Pay/ Charity Care	1.8%	1.0%
Medicare	31.0%	27.0%
Medicaid	5.9%	5.8%
<b>Total</b>	<b>38.7%</b>	<b>33.8%</b>

Source: CON Applications

Further, as documented in its application, if WFBI is awarded a fixed MRI scanner, WFBI has offered to partner with the Guilford County Health Department, and specifically Triad Adult and Pediatric Medicine, to provide up to 52 charitable scans each year to local patients who are uninsured or underinsured. By comparison, SOS/AHS proposes to offer 12 free scans per year to students of Guilford County Public Schools.

- On page 76 of its application, SOS/AHS states it has “working relationships with several local health professional training programs”. However, the

application includes no documentation to support this claim, nor does SOS/ AHS specifically name a health professional training program with which it works. Therefore, the SOS/ AHS application is non-conforming to Review Criterion 14.

- Exhibit 23 of the SOS/ AHS application includes a quote from GE for the MRI scanner. However, this quotation expired December 31, 2015, nearly 3 months prior to the submission of the SOS/ AHS CON application. SOS/ AHS tries to mitigate this problem by referencing an email from a GE sales representative, saying Alliance has an upgrade order backlog. However, the upgrades need to be completed by August 31, 2016. This will not be possible because the 150-day CON review period does not end until August 28, 2016, and is followed by a 30-day appeal period. SOS/ AHS's own application confirms this, where on page 122 it lists October 3, 2016 as the CON issuance date. Until a CON is issued, AHS is not authorized to contract for or expend funds. Therefore, the project capital cost is not reliable, and the SOS/ AHS funding may not be sufficient for the project needs. Therefore, the application is non-conforming to Review Criterion 5.

## Specific comments regarding the Cone Health application

- Guilford County is currently host to 11 fixed MRI scanners. As documented in its application, Cone Health currently controls six (6) of the 11 scanners, because it owns and operates three scanners at Moses Cone and Wesley Long Hospitals, and it also is a member of Diagnostic Radiology and Imaging, LLC (DRI) which operates three fixed scanners in Guilford County. This represents 55% (6/11) of the fixed inventory in the county. In terms of volume, Cone Health controls over 45% of the market share in Guilford County. Therefore, the Cone Health proposal is the least effective alternative from a perspective of enhancing competition. Award of a 7<sup>th</sup> fixed scanner to Cone Health would only serve to increase its dominance in the Guilford County MRI marketplace. This is not the most effective alternative for local residents given the higher MRI charge structure for Cone Health.
- As Cone Health includes Rockingham and Alamance counties in its service area in Exhibit 13, it is reasonable to also consider the MRI resources Cone Health already operates in those adjacent counties. In Rockingham County, Cone Health owns and operates one of the two fixed MRI scanners, and in Alamance County, Cone Health owns and operates both of the fixed scanners, plus one mobile MRI scanner based in the county. Clearly, Cone Health is a dominant local MRI provider, and this CON batch review would be most beneficial by awarding the fixed MRI CON to a new provider.
- Cone Health is not proposing the most effective alternative it has available. Cone Health is proposing to add a third fixed scanner at Moses Cone Hospital, to be located adjacent to the two existing scanners within the hospital. A more effective option would be to locate the proposed scanner in a dedicated outpatient setting, with a freestanding, not hospital-based charge structure. Cone Health describes the need to make MRI services available for cardiac imaging, as well as neurological and neonatal MRI. However, Cone Health is creating a false choice by saying that a freestanding outpatient alternative can't treat emergency, inpatient, and complex cardiac, neuro and neonatal patients. In fact, Cone Health can already treat those patients with its existing hospital-based scanners.
- Data on pages 46-47 are telling. Outpatient scans are steadily declining, decreasing from 58.3% of scans in FY2010, to 53.3% of scans in FY2015. And only 33.2% were scheduled outpatients. This indicates that the marketplace is voting with its feet, and seeking a less expensive setting for elective

outpatient MRI scans. Cone Health’s proposal to develop another hospital-based MRI service will not increase access to cost effective MRI services sought by Guilford County residents.

- Cone Health projects by far the highest project capital cost. In the current economic climate, effective initiatives to contain unnecessary costs and expenditures are especially important to promote value in healthcare. Declining reimbursement rates and increased government regulations are increasingly placing downward pressure on healthcare providers to effectively do more with less. Thus, efficient management of project capital costs is crucial to providing value. Cone Health does not satisfy this objective as measured against the competing applicants.
- Another issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for provision of MRI services. In the current healthcare marketplace, where cost of care is a major concern with payors and the public, the projected average procedure charge is an important measure of consumer value. WFBI proposes lower charges and lower reimbursement than Cone Health for all three project years.

**Proposed Average Charge per Procedure\***

	WFBI	Cone Health
Project Year 1	\$1,580	\$3,053
Project Year 2	\$1,579	\$3,112
Project Year 3	\$1,579	\$3,173

**Proposed Average Reimbursement per Procedure\***

	WFBI	Cone Health
Project Year 1	\$455	\$550
Project Year 2	\$464	\$555
Project Year 3	\$468	\$560

Source: CON Applications  
\*Reflects only technical charges, PY1-3

- Cone Health's Moses Cone Hospital is currently an existing fixed MRI location, and thus the Cone Health proposal provides no benefit to Guilford County residents from the perspective of geographic access.
- Cone Health by nature, as a not-for-profit hospital provider, provides extensive care to the medically underserved. WFBI is also committed to providing the medically underserved with quality healthcare services. Because of the distinctly different tax statuses of WFBI and Cone Health, the two entities are not directly comparable in terms of expanding access to the local medically underserved population.
- The Cone Health MRI income statement appears to significantly underestimate the expenses associated with offering MRI services. Specifically, on Form C Cone estimates that its "operational support" will decrease 62% in FY2016, decreasing from \$338K in FY2015 to \$130K in FY2016. Also, Cone projects a 4% decrease of medical supplies and pharmaceuticals. It is counterintuitive that these expenses will decrease when Cone Health proposes to increase its inventory of hospital-based MRI scanners and increase their charges each project year. Neither of these decreases is explained or justified in the application. Therefore, the projected expenses are not reasonable or reliable, and the application is not conforming to Review Criterion 5.
- Cone Health does not include any G&A expenses. The only indirect expense listed in Form C is "Billing Service". This is not reasonable, and in fact, contradicts the information provided in Exhibit 6, where a letter from the President of Moses Cone Hospital itemizes the many ancillary and support services that are available at the hospital and are necessary to support MRI services. Therefore, the projected expenses are not reasonable or reliable, and the application is not conforming to Review Criterion 5.