

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 26, 2016

Findings Date: August 26, 2016

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

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COMPETITIVE REVIEW

Project ID #: G-11147-16

Facility: Cone Health

FID #: 943494

County: Guilford

Applicant(s): The Moses H. Cone Memorial Hospital
The Moses H. Cone Memorial Hospital Operating Corporation

Project: Acquire a fourth fixed MRI scanner

Project ID #: G-11148-16

Facility: Southeastern Orthopaedic Specialists

FID #: 090353

County: Guilford

Applicant(s): Southeastern Orthopaedic Specialists, P.A.
Alliance HealthCare Services, Inc.

Project: Acquire a fixed MRI scanner

Project ID #: G-11149-16

Facility: Wake Forest Baptist Imaging, LLC

FID #: 160116

County: Guilford

Applicant(s): Wake Forest Baptist Imaging, LLC

Project: Acquire a fixed MRI scanner

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C- Cone Health
NC-SOS
C-WFBI

The 2016 State Medical Facilities Plan (2016 SMFP) includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2016 SMFP identified a need for one additional fixed MRI scanner in the Guilford County MRI Service Area. Three applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to acquire a fixed MRI scanner for Guilford County.

Need Determination

The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation, collectively referred to as Cone Health or “the applicants”, propose to add one fixed MRI scanner for a total of three MRI scanners to be located on the main campus of Moses Cone Hospital in Greensboro in Guilford County. Cone Health does not propose to acquire more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Guilford County. Therefore, the application is consistent with the need determination.

Southeastern Orthopaedic Specialists, P.A. (SOS) and Alliance HealthCare Services, Inc. (AHS), collectively referred to as SOS or “the applicants”, propose to upgrade one existing AHS-owned mobile MRI scanner to a fixed MRI scanner to be permanently located in a renovated imaging trailer on a concrete pad adjacent to Southeastern Orthopaedic Specialists at 1130 N. Church Street in Greensboro in Guilford County. The applicants do not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Guilford County. Therefore, the application is consistent with the need determination.

Wake Forest Baptist Imaging, LLC (WFBI), the applicant, proposes to acquire one fixed MRI scanner to be located in a new freestanding imaging facility in leased medical office space at 3623 N. Elm Street in Greensboro in Guilford County. WFBI does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2016 SMFP for Guilford County. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2016 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3: Basic Principles, 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 applicants respond to Policy GEN-3 as follows:

Cone Health.

Promote Safety and Quality - In Section 1, pages 11-12, Sections II.5, II.6 and II.7, pages 23-24, Section III.2, pages 54-55, Section V.7, page 94, and Exhibits 10, 11 and 12, the applicants describe how they believe the proposed project would promote safety and quality. Exhibits 10, 11 and 12 contain copies of Cone Health’s Quality Excellence Plan, Policies and Procedures for MRI, and Risk Management Plan. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - In Section III.2, pages 54-55, Section VI, pages 79-88, and Exhibit 21, the applicants describe how they believe the project would promote equitable access to MRI scanner services. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal will promote equitable access.

Maximizing Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section III.2, page 54, stating:

“The proposed project promotes cost effective approaches by utilizing efficiencies from an existing MRI service to provide more technologically advanced care with minimal price increases to patients. The ability to provide a higher level of

complex care in a more efficient manner presents the opportunity to deliver the best value for patients and Cone Health.”

The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

The applicants adequately demonstrate how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.

Therefore, the application is consistent with Policy GEN-3.

SOS.

Promote Safety and Quality - In Section 1, pages 16-21, Sections II.1, pages 30-31, II.5, II.6 and II.7, pages 34-37, Section III.2, page 57, and Section V.7, pages 81-83, the applicants describe how they believe the proposed project would promote safety and quality. Exhibits 6, 9, 10, 12, and 13 contain information on the proposed scanner, safety policies, ACR MRI Accreditation requirements, quality and safety related policies and procedures, and SOS’s existing ACR Accreditation, respectively. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - In Section III.2, page 57, Section V.7, page 85, Section VI, pages 89-92, and Exhibits 16 and 20, the applicants describe how they believe the project would promote equitable access to MRI scanner services. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal will promote equitable access.

Maximizing Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section V.7, page 87, stating the average charge and cost per scan of providing the proposed service; the applicants’ belief that non-hospital based charges lead to decreased insurer payments, patient deductibles and copayments, lower healthcare expenditures and hopefully lower health insurance premiums; and the total cost of implementing the proposed project.

The applicants adequately demonstrate how the projected volumes incorporate the concepts of quality and equitable access. However, the applicants do not adequately demonstrate how the projected volumes incorporate the concept of maximum value for resources expended. The applicants do not adequately demonstrate the need to acquire a fixed MRI scanner to replace the existing mobile MRI service, which operates more hours and performs more scans on the mobile than are projected to be performed on the

proposed fixed scanner. Therefore the applicants fail to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.

Therefore, the application is not consistent with Policy GEN-3.

WFBI.

Promote Safety and Quality - In Section 1, pages 10-16, Sections II.5, II.6 and II.7, pages 21-25, Section III.2, pages 62-63, Section V.7, pages 79-80, and Exhibit 5, the applicant describes how it believes the proposed project would promote safety and quality. Exhibit 5 contains copies of WFBI's Quality Assurance and Process Improvement Plan, Online Incident Reporting, Patient Identification, Patient Education, Patient Screening, Critical Results Reporting, Risk Management and Utilization Review. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - In Section II.5, page 22, Section III.2, page 61, Section VI, pages 82-97, and Exhibit 18, the applicant describes how it believes the project would promote equitable access to MRI scanner services in Guilford County. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access.

Maximizing Healthcare Value - The applicant describes how it believes the proposed project would maximize healthcare value in Section III.2, pages 60-61, and Section V.7, page 78. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.

Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The applicants respond to Policy GEN-4 as follows:

Cone Health. The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section III.2, page 55, the applicants state:

"As part of its commitment to energy efficiency and sustainability in all construction projects, Cone Health will utilize appropriate energy efficient and water conservation components in the proposed project."

Exhibit 15 contains the architect's documentation regarding strategies to ensure the project's energy efficiency and water conservation. The applicants adequately demonstrate that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

SOS. The proposed capital expenditure for this project is less than \$2 million. Therefore, Policy GEN-4 does not apply to the review of this application.

WFBI. The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section III.2, page 72, the applicant states:

"WFBI has designed the proposed fixed MRI project to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including 2016 SMFP Policy GEN-4. ... The primary site was constructed to ensure energy efficiency and cost effective utilities, including water conservation. WFBI will closely monitor its utility

usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations.”

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, all three applications adequately demonstrate that their proposals are consistent with the need determination in the 2016 SMFP for one fixed MRI scanner for Guilford County. However, the limit on the number of MRI scanners that may be approved in this review is one MRI scanner. Collectively, the three applicants propose a total of three MRI scanners. Therefore, even if all applications were conforming to all statutory and regulatory review criteria, all three applications cannot be approved.

The applications submitted by Cone Health and WFBI are conforming to Policy GEN-3. The application submitted by SOS is not conforming to Policy GEN-3. The applications submitted by Cone Health and WFBI are conforming to Policy GEN-4. Policy GEN-4 is not applicable to SOS’s application. Therefore, the applications submitted by Cone Health and WFBI are conforming to this criterion and the application submitted by SOS is not conforming to this criterion. See the Summary following the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C-Cone Health
NC-SOS
C-WFBI

Cone Health. The applicants propose to add one fixed MRI scanner for a total of three MRI scanners to be located on the main campus of Moses Cone Hospital in Greensboro in Guilford County. The Cone Health system includes the following separately licensed hospitals:

- The Moses H. Cone Memorial Hospital in Greensboro (Guilford County); and
- Annie Penn Hospital in Reidsville (Rockingham County).

Per Cone Health’s 2015 License Renewal Application (LRA), License #H0159, The Moses H. Cone Memorial Hospital in Guilford County consists of five campuses and seven entities doing business as “facilities.” The five campuses and seven facilities are:

1. The Moses H. Cone Memorial Hospital and Moses Cone Surgery Center;
2. Wesley Long Hospital and Wesley Long Surgery Center;
3. MedCenter High Point (emergency services, urgent care, and imaging)
4. Women’s Hospital; and
5. The Behavioral Health Hospital.

In addition, there are other facilities that are part of Cone Health, but under individual licenses (i.e., Alamance Regional Medical Center). The applicants provide a full listing of owned and leased facilities in Exhibit 5 of the application.

Cone Health owns and operates the following fixed MRI scanners:

Location	#	County	City
Moses Cone Hospital	2	Guilford	Greensboro
Wesley Long Hospital	1	Guilford	Greensboro
Annie Penn Hospital	1	Rockingham	Reidsville

In addition, through subsidiary corporations, Cone Health owns, in whole or part, five additional fixed MRI scanners in North Carolina. Moses Cone Medical Services, Inc. is a member of Diagnostic Radiology & Imaging, LLC d/b/a Greensboro Imaging, which owns three fixed MRI scanners in North Carolina. Alamance Regional Medical Center owns and operates two fixed MRI scanners in Alamance County. Alamance Regional Medical Center also owns and operates one mobile MRI scanner, currently serving Alamance and Forsyth counties.

At project completion, Cone Health, License #H0159, will be licensed for four MRI scanners; three on the Moses Cone Hospital main campus and one at Wesley Long.

Population to be Served

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area for this project consists of Guilford County. Providers may serve residents of counties not included in their service area.

Cone Health currently owns and operates two fixed MRI scanners on the Moses Cone Hospital main campus and one fixed MRI scanner at Wesley Long, in Guilford County. The application refers to these two hospitals on Cone Health License #HO159 as Cone

Health-Greensboro. In Section III.4, the applicants refer to Exhibit 13 for patient origin by county of residence for MRI services by Cone Health-Greensboro’s fixed MRI services. Exhibit 13 contains patient origin data for the most recent calendar year, from January 1, 2015 through December 31, 2015 and projected patient origin for the first two operating years after project completion, FFY2018 and FFY2019, as summarized below.

**Cone Health-Greensboro (License #HO159)
 MRI Patient Origin by County of Residence**

County	Historical	Projected			
	CY2015	FFY2018		FFY2019	
	% Scans	# Scans	% Scans	# Scans	% Scans
Guilford	74.6%	10,451	74.6%	10,631	74.6%
Rockingham	8.9%	1,247	8.9%	1,268	8.9%
Randolph	6.1%	855	6.1%	869	6.1%
Alamance	3.3%	462	3.3%	470	3.3%
Forsyth	1.3%	182	1.3%	185	1.3%
Caswell	0.4%	56	0.4%	57	0.4%
Davidson	0.7%	98	0.7%	100	0.7%
Virginia	1.5%	210	1.5%	214	1.5%
Other*	3.2%	448	3.2%	456	3.2%
Total	100.0%	14,010	100.0%	14,251	100.0%

Source: Cone Health

*Other is identified in Exhibit 13 as 47 additional North Carolina counties, South Carolina, Georgia, Tennessee and other states

In Section III.5(d), page 58, with regard to assumptions for projected patient origin, the applicants state, “*The proposed project will serve an existing, well-established patient population. Therefore, patient origin for MRI services is not expected to change.*” The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicants state the identified need is to reduce Cone Health-Greensboro’s capacity constraints for advanced MRI scans for inpatients and complex outpatients in a growing and aging service area. The applicants describe the factors which they state result in the need for the proposed project, including:

- Growth and aging of the Guilford County population is expected to increase demand for healthcare services, including MRI procedures (pages 34-39).
- Consistent, significant historical growth in MRI procedures at Cone Health’s existing fixed MRI scanners has led to high levels of utilization, supporting the need to add capacity (pages 40-47).
- Growing demand for advanced capabilities to perform more advanced cardiac, neurological, and neonatal MRI studies that require longer than average scanning

times (pages 47-52). The applicants state that the Moses Cone main campus provides Cone Health's most advanced MRI studies because of patient comorbidities, the need for sedation, scans for Emergency Department patients, and the increased complexity of scans in a tertiary care hospital providing cardiovascular, neuroscience and neonatal services.

In summary, the applicants state that the multiple factors discussed in detail on pages 34 through 52 indicate a need for additional MRI capacity at Moses Cone to serve a large and growing patient need for advanced MRI scans that can only be performed in an acute care setting. On page 58, the applicants state:

“As demonstrated throughout this Section, the identified need is to reduce capacity constraints at Cone Health hospitals for advanced MRI scans for inpatients and complex outpatients in a service area that is growing and aging. These advanced MRI services are not able to be performed in a freestanding outpatient setting. Therefore, freestanding outpatient providers and physician practices are unable to meet the need.”

The applicants' representations regarding the need for another fixed MRI scanner to serve existing and projected patients are reasonable and adequately supported.

Projected Utilization

In Section IV.1, pages 61-62, the applicants provide the historical and projected utilization of the Cone Health-Greensboro's fixed MRI scanners. The applicants discuss the assumptions and methodology used to project MRI utilization at Cone Health-Greensboro, summarized as follows:

- Historical FFY2014 and FFY2015 reflect actual MRI utilization at Moses Cone Hospital and Wesley Long.
- MRI scans for FFY2016 through FFY2020, the third full fiscal year following completion of the proposed project, are projected forward at an annual growth rate of 2.5% for inpatient MRI scans and 1.0% for outpatient MRI scans, for an average annual growth rate of 1.7%. The applicants state this is a reasonable assumption because:
 - Guilford County represents 74.6% of the patient origin for Cone Health and the Guilford County population is projected to grow an average of 1.1% annually from 2015 to 2020. Furthermore, the 65+ age cohort is projected to grow 3.8% annually and Cone Health's data reveals that 38.2% of MRI patients are over age 65. Cone Health's broader market, including Randolph, Rockingham, Alamance and Eastern Forsyth counties, is projected to grow at 0.8% and 3.4% for total population and the 65+ cohort, respectively (Section III.1, page 38).
 - Cone Health-Greensboro's fixed MRI services have increased an average of 3.9% annually from 2010 to 2015. MRI procedures performed at Moses

Cone Hospital main campus have increased 5.4% annually during the same time period (Section III.1, page 40).

- Moses Cone Hospital main campus inpatient MRI procedures increased an average of 8.3% annually from 2010 to 2015, while outpatient MRI procedures grew at an average rate of 2.4% (Section III.1, page 44).
 - Inpatient discharges are projected to increase at an average annual rate of 1.6% through FFY2020, based on market population growth. This rate is less than the projected 2.5% increase in inpatient scans, however, the applicants state this is reasonable based on the use rates for inpatient scans over the past five years, as shown in Table III-8, page 45 of the application.
 - Table III-5 in Section III.1, page 41, shows Cone Health-Greensboro's fixed MRI scanners performed an average of 5,905 weighted scans per scanner in FFY2015, well exceeding the 4,805 weighted scan threshold used to trigger a new need determination. The two fixed scanners at Moses Cone Hospital main campus performed 6,329 weighted scans per scanner.
 - On pages 44 and 66, the applicants provide a table of the historical growth rates reviewed, as discussed above, in determining the projected growth rate.
- MRI scans are weighted using the weighting system described on page 156 of the 2016 SMFP, resulting in an average factor of 1.3 based on FFY 2014 and FFY 2015 actual data.

On page 66, the applicants state:

“After reviewing these growth rates and current levels of utilization at Cone Health-Greensboro hospitals' fixed MRI services, Cone Health decided to apply growth rates of 2.5% annually for inpatient scans and 1.0% annually for outpatient scans for FY 2016 through FY 2020, equating to a 1.7% total annual increase. Although the historical growth rate for MRI scans, particularly inpatient scans at Moses Cone Hospital, has exceeded this projected growth rate, Cone Health believes that this conservative projection is reasonable and appropriate.”

Table IV-5, page 67, shows Cone Health-Greensboro's historical and projected fixed MRI utilization, based upon the above assumptions and methodology, as summarized below.

Type of Scan	Historical		Interim		Project Years 1-3		
	FFY2014	FFY2015	FFY2016	FFY2017	FFY2018	FFY2019	FFY2020
OP W/O Contrast	4,230	4,022	4,062	4,103	4,144	4,185	4,227
OP W/ Contrast	2,335	3,071	3,102	3,133	3,164	3,196	3,228
IP W/O Contrast	3,864	4,526	4,639	4,755	4,874	4,996	5,121
IP W/ Contrast	1,715	1,698	1,740	1,784	1,829	1,874	1,921
Totals	12,144	13,317	13,544	13,775	14,010	14,251	14,497
% Change		9.7%	1.7%	1.7%	1.7%	1.7%	1.7%
Weighted Scans	15,996	17,714	18,032	18,357	18,689	19,027	19,373
# Scanners	3	3	3	3	4	4	4
Weighted Scans/Scanner	5,332	5,905	6,011	6,119	4,672	4,757	4,843
% Capacity	77.7%	86.0%	87.6%	89.1%	68.1%	69.3%	70.6%

The applicants adequately demonstrate projected utilization of the existing and proposed fixed MRI scanners is based upon reasonable and adequately supported assumptions.

Access

In Section VI.2, page 79, the applicants state:

“Cone Health does not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured. In general, the health services of Cone Health are available to any patient in need without restriction of any kind.”

The applicants further address access to Cone Health’s MRI services in Sections VI.13 and VI.15. On pages 87 and 88, the applicants provide the FFY2015 payor mix and the projected payor mix for the MRI service component for the second full fiscal year of the proposed project.

**Cone Health-Greensboro MRI Services
Procedures as a Percent of Total Utilization**

Payor Category	Actual FFY2015	Projected FFY2019
Self Pay/ Indigent /Charity	8.2%	8.2%
Medicare/ Medicare Managed Care	46.3%	46.3%
Medicaid	11.3%	11.3%
Managed Care / Commercial Insurance	31.6%	31.6%
Other (Champus, Workers Comp)	2.6%	2.6%
Total	100.0%	100.0%

Exhibit 21 contains copies of Cone Health’s non-discrimination, patient admitting, and payment policies.

The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicants adequately identify the population to be served; adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner; and demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion.

SOS.

The applicants, SOS and AHS, propose to upgrade an existing AHS-owned mobile GE Signa Excite 1.5T MRI scanner and operate it as a fixed GE Signa HDxt 1.5T MRI scanner, to be permanently housed in a renovated imaging trailer on a reinforced concrete pad located adjacent to the SOS medical practice at 1130 N. Church Street in Greensboro. The proposed fixed MRI service will share the pre-certification area, patient reception, and patient waiting area/restroom with SOS. SOS currently provides MRI services with Alliance Imaging mobile MRI scanners located in an imaging trailer on a concrete pad. Per the Registration and Inventory of Medical Equipment (RIME) forms submitted to the Agency by AHS, there were three different MRI scanners serving SOS during FFY2015. A total of 5,496 procedures and hours of service were reported by AHS. AHS reports that each procedure is equal to one hour and one patient.

Population to be Served

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area for this project consists of Guilford County. Providers may serve residents of counties not included in their service area.

SOS is currently served by AHS’ mobile MRI scanners which the applicants state performed more than 5,800 weighted MRI scans during the past 12-month period (page 42). In Section III.4 and III.5, pages 60 and 62, the applicants provide the current patient origin by county for the existing mobile MRI services at SOS and the projected patient origin by county for the proposed fixed scanner, as summarized below.

**Southeastern Orthopaedic Specialist
Mobile MRI Scanner
Patient Origin**

County	FFY2015	FFY2019
Guilford	86.9%	86.9%
Secondary Service Area		
Randolph	3.6%	3.6%
Rockingham	2.1%	2.1%
Other NC County In-migration	3.0%	3.0%
Other State In-migration	4.4%	4.4%
Total	100.0%	100.0%

In Section III.5, page 62, with regard to the assumptions for projected patient origin, the applicants state, “SOS and AHS expect projected patient origin to be similar to historical patient origin because MRI patients receiving an MRI scan at SOS will now receive their MRI scan on the fixed MRI scanner at SOS.” The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III.1(c), page 55, the applicants state, “The need for the project is primarily based on the internal need for SOS to replace its mobile MRI service with a fixed MRI scanner to more effectively serve its patients” In Section III.1(b), pages 48-54, the applicants describe the factors they believe influence the demand for the proposed project, including:

- Service area population growth trends (pages 49-50),
- SOS Physician referrals and support (page 51), and

- MRI utilization (pages 52-54), which the applicants project will increase annually with the growth and aging of the service area population, the implementation of the Affordable Care Act and physician referrals.

Projected Utilization

In Section IV.1, page 66, the applicants provide the historical and projected utilization for what the applicants identify as the existing AHS-owned mobile MRI scanners serving Guilford County facilities and the proposed fixed MRI scanner through the first three years of operation following completion of the project (FFY2018-FFY2020), which is summarized below.

AHS-Owned MRI Scanners Historical and Projected Unweighted MRI Scans

	Historical		Interim		Projected		
	FFY2014	FFY2015	FFY2016	FFY2017	FFY2018	FFY2019	FFY2020
CNSA Mobile	-	2,196	3,050	3,099	3,147	3,194	3,238
SOS Mobile	4,628	5,341	5,016	5,062			
SOS Fixed					5,110	5,155	5,196

The CNSA mobile MRI scanner, identified as Signa 451 on AHS’ 2016 Registration and Inventory of Medical Equipment (RIME), provides services at Carolina Neurosurgery and Spine Associates (CNSA) in Guilford and Cabarrus counties. The SOS mobile MRI scanner, identified as Signa 447, a 1.5T GE Horizon on AHS’ 2016 RIME, provides MRI services only at SOS in Guilford County and reported 5,341 procedures in FFY2015. The AHS mobile MRI scanner that the applicant proposes to upgrade to provide fixed MRI services at SOS in Guilford County is the mobile scanner identified on AHS’ 2016 RIME as Signa 407, a 1.5T GE Excite scanner. During FFY2015, per AHS’ 2016 RIME, this scanner served Moses Cone (49 procedures) and SOS (124 procedures) in Guilford County, as well as providers in Alamance, Cleveland, Yadkin, Forsyth, Davie, Scotland, Mecklenburg and Union counties. The applicant did not address the total utilization of this scanner.

Per the applicants and as shown in the table above, SOS performed 5,341 unweighted scans on AHS mobile MRI scanners in FFY2015 and the applicants project the proposed fixed MRI scanner will perform 5,196 unweighted MRI scans in the third operating year. However, AHS’ 2016 RIMEs show 5,496 scans performed at SOS during the same time period. It is not clear why the applicants under-report SOS’ utilization.

In Section III.1, page 74, the applicants project the proposed fixed MRI scanner will perform 5,409 weighted MRI scans in the third operating year (FFY2020), which exceeds the utilization standards required in 10A NCAC 14C .2703(b). The applicants describe the assumptions and methodology used to project utilization in Section IV.1(d), pages 67-74, which are summarized below.

Step 1. The applicants identified the utilization of the two AHS-owned mobile MRI scanners it identifies as currently operating at CNSA and SOS. The applicants state that they use the reported volumes in the 2015 and 2016 RIME forms for the FFY2014 and FFY2015 historical MRI scans, respectively and the annualized five-month 2016 (pages 67-68) utilization, resulting in a two-year compound annual growth rate (CAGR) of 32% (page 68), as shown below.

Unweighted MRI Scans

	Historical		Annualized
	FFY2014	FFY2015	FFY2016
CNSA Mobile MRI Scans	-	2,196	3,050
SOS Mobile MRI Scans	4,628	5,341	5,016
Total	4,628	7,537	8,066
Annual Change		62.9%	7.0%
Average Change over Two Years			34.9%
Two-Yr CAGR			32.0%

On page 69, the applicants discuss the exclusion of the MRI scans that originated from the smaller orthopedic practice that has since left the SOS referral network, resulting in a change rate for the SOS physician MRI scans of 22.1% and a change rate for the Non-SOS physician MRI scans of 23.4% from FFY2014 to FFY2015. The applicants state:

“However, as AHS presents in the following Step, AHS utilizes much more conservative annual MRI scan change rates based on the change rate of the over 19 year old population in the service area. This results in less than a 1.0 percent annual MRI scan volume increase at SOS.”

Exhibit 14 contains the applicants’ utilization documentation and projection worksheets. In analyzing the population worksheets and the applicants’ population calculations, it becomes apparent that the applicants used population figures for the population 18 years of age and older, as opposed to the applicants’ quoted “over 19 year old population”.

On page 53, the applicants provide SOS’s MRI utilization FFY2010 through FFY2015, which results in a one-year increase of 15.4% from FFY2014 to FFY2015 and a compound annual growth rate (CAGR) for the five-year period of 3.2%.

Step 2. On page 70, the applicants provide tables presenting the “over 19 year old population” [18 and older] in Guilford, Randolph, Rockingham and Cabarrus counties (Table 1) and the annual change rate (Table 2). Tables 3 and 4, page 71 show the SOS and CNSA patient origin percentages by county. Table 5, page 71, is the Adjusted Annual Change for FFY2017 through FFY2020, which weighted patient origin by the county population change rate for each facility. The applicants state, “AHS utilized the over 19 years old [18 and older] population change rate to project MRI scans as a more

conservative alternate than utilizing the other calculated MRI scan change rates in Step 1.”

The applicants provide the following table as the result of Step 2.

	Interim		Projected		
	FFY2016	FFY2017	FFY2018	FFY2019	FFY2020
SOS Unweighted MRI Scans	5,016	5,062	5,110	5,155	5,196
86.9% of Guilford + 3.6% of Randolph + 2.1% or Rockingham Annual Change		0.93%	0.94%	0.88%	0.80%
CNSA Unweighted MRI Scans	3,050	3,099	3,147	3,194	3,238
64.0% of Guilford + 36.0% of Cabarrus Annual Change		1.60%	1.55%	1.48%	1.40%

Step 3. On page 72, the applicants calculate the MRI scan breakdown by type for annualized FFY2016 scans, which results in 10.2% with contrast and 89.8% without contrast for SOS and 26.4% with contrast and 73.6% without contrast for CNSA.

Step 4. The applicants apply the annualized FFY2016 MRI scan by type breakdown percentages calculated in Step 3 to the projected total utilization, which results in the following projected MRI utilization by type, as summarized from page 73.

	Interim		Projected		
	FFY2016	FFY2017	FFY2018	FFY2019	FFY2020
SOS	5,016	5,062	5,110	5,155	5,196
With Contrast	10.20%	518	523	528	532
W/o Contrast	89.80%	4,544	4,587	4,627	4,664
CNSA	3,050	3,099	3,147	3,194	3,238
With Contrast	26.40%	817	830	842	854
W/o Contrast	73.60%	2,282	2,318	2,352	2,385

Totals may not sum due to rounding

Step 5. The applicants apply the weighting factors identified in 10A NCAC 14C .2701(18), 1.0 for outpatient MRI procedures without contrast and 1.4 for outpatient MRI procedures with contrast, to the projected MRI utilization by scan type breakdown in Step 4, which results in the projected weighted MRI scans provided by the applicants on page 74 and summarized below.

	Interim	Projected		
	FFY2017	FFY2018	FFY2019	FFY2020
SOS Unweighted	5,062	5,110	5,155	5,196
With Contrast	726	733	739	745
W/o Contrast	4,544	4,587	4,627	4,664
SOS Weighted	5,270	5,319	5,366	5,409
CNSA Unweighted	3,099	3,147	3,194	3,238
With Contrast	1,144	1,161	1,179	1,195
W/o Contrast	2,282	2,318	2,352	2,385
CNSA Weighted	3,426	3,479	3,531	3,580

Totals may not sum due to rounding

As shown above, the applicants’ utilization projections are based on the historical utilization of SOS’ and CNSA’s existing mobile MRI scanners from FFY2014 through annualized FFY2016, increased by the projected increase in the population aged 18 and older, and supported by the projected growth and aging of the service area population, expanded health insurance coverage resulting from implementation of the Affordable Care Act, and physician referrals. Exhibit 27 contains letters from physicians in the proposed service area expressing support for the proposed project and their intention to refer patients to the proposed service.

However, the applicants fail to adequately demonstrate the need to acquire a fixed MRI scanner to be located in Guilford County, as explained in the following discussion.

The applicants discuss the utilization of AHS’ existing mobile scanners at SOS and CNSA, each performing greater than 3,328 weighted MRI scans in the most recent 12-month period for which the applicants had data available (3/1/2015-2/29/2016). However, the applicants fail to discuss the utilization of the AHS mobile scanner that served Cone Health’s MedCenter High Point in Guilford County in the last reporting period and which is the scanner that is proposed to be upgraded from mobile to fixed and identified on AHS’ 2016 RIME as Signa 407. Furthermore, the applicant provides a table with a list of AHS-owned mobile MRI scanners, along with counties in which they operate, in Exhibit 4. The list, though not dated, shows that AHS operates six mobile scanners in Guilford County: ESP 27, Signa 294, Signa 413, Signa 447, Signa 451, and Signa 470. Furthermore, the 2016 RIME for AHS’s Signa 407 shows that scanner also operated in Guilford County, in addition to the counties listed in the applicant’s table in Exhibit 4. Therefore, there appear to be seven AHS mobile MRI scanners which served host sites in Guilford County in the last reporting period. The applicant discussed only two of the seven. The applicant fails to discuss the utilization of the other five scanners listed as operating in Guilford County.

The Healthcare Planning and Certificate of Need Section (Agency) has a record of AHS’ submitting the 2016 RIME forms on only three of the seven scanners listed above: Signa 407, Signa 447, and ESP 27.

The RIME which AHS submitted for its Signa 447 reported 5,341 unweighted procedures for FFY2015 at SOS in Greensboro, Guilford County, which is above the 3,328 weighted scan threshold, as required in 10A NCAC 14C .2703(b)(2). The following tables show the utilization reported for the scanners identified as Signa 407 and ESP 27.

SIGNA 407
10/1/2014-9/30/2015

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Inpt w Contrast	Inpt w/o Contrast	Weighted Procedures
UNC	Alamance	272	60	212			296
MRI Specialists of the Carolinas	Cleveland	266	42	224			283
Yadkin Valley Community Hospital	Yadkin	57	7	49		1	60
WFBH Med Plaza	Forsyth	206	21	185			214
Moses Cone MedCenter High Point	Guilford	49	10	39			53
SOS	Guilford	124	1	123			124
Davie County Hospital	Davie	751	193	556	1	1	829
OrthoCarolina PA	Scotland	19	0	19			19
Randolph Spine Center	Mecklenburg	16	1	15			16
OrthoCarolina PA	Union	21	0	21			21
Total Procedures Reported on Signa 407 and Weighted		1,781					1,917

Source: January 2016 Registration and Inventory of Medical Equipment and 2016 SMFP Methodology
 Totals may not sum due to rounding

ESP 27
10/1/2014-9/30/2015

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Weighted Procedures
Moses Cone MedCenter High Point	Guilford	645	152	493	706
UNC	Alamance	343	81	262	375
Carolina Neurosurgery & Spine	Guilford	194	64	130	220
Cone Health MedCenter-Kernersville	Forsyth	95	11	84	99
Wake Radiology Services	Wake	7	0	7	7
Onslow Memorial Hospital	Onslow	9	0	9	9
SOS	Guilford	31	0	31	31
Triangle Orthopedic	Wake	404	8	394	405
Duke Health Raleigh	Wake	188	90	98	224
Wake Radiology Services	Johnston	119	0	119	119
Total Procedures Reported on ESP 27 and Weighted		2,035			2,195

Source: January 2016 Registration and Inventory of Medical Equipment and the 2016 SMFP Methodology
 Totals may not sum due to rounding

As the tables above show, per the January 2016 RIME, both the Signa 407 and ESP 27 scanners performed below the 3,328 weighted scan threshold required in 10A NCAC 14C .2703(b)(2). It appears that AHS did not submit the 2016 RIME forms for the other AHS scanners listed in Exhibit 4 as serving Guilford County.

The applicants fail to demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating at host sites in Guilford County performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data.

Furthermore, as discussed above, the applicants state that the existing AHS mobile scanner serving SOS performed 5,341 unweighted scans at SOS in FFY2015. The applicants project the proposed fixed MRI scanner will perform 5,196 unweighted MRI scans in the third operating year, which is 145 fewer scans than the existing mobile scanner provided at SOS in FFY2015. The applicants do not adequately demonstrate how upgrading an existing AHS-owned mobile MRI scanner to a fixed MRI scanner to be permanently housed in an imaging trailer on a concrete pad at SOS will “*more effectively serve*” (page 55 of the application) the proposed patient population.

In addition, on its 2016 RIMEs, AHS reports each procedure as one hour of service and one patient. The proposed fixed scanner is projected to perform 5,196 unweighted procedures. In Section VII.5, page 102, the applicants state that the fixed scanner will be staffed and operational only 4,100 hours in FFY2020 (82 hours per week x 50 weeks). Thus, it appears the applicants are projecting to serve fewer patients and proposing to offer

less hours of service with the proposed fixed scanner than currently offered at SOS on the mobile equipment.

Therefore, the applicants fail to adequately demonstrate the need to acquire the proposed fixed MRI scanner to be located in Guilford County.

Access

In Section VI, pages 89-90, the applicants state that SOS and AHS are committed to providing care for the under/uninsured, charity patients and the elderly; SOA and AHS guarantee access to MRI services by racial and ethnic minorities, women, and handicapped and disabled persons; medically indigent persons needing MRI services will have access to the MRI service; and SOS and AHS will render appropriate medical care to all persons in need of care regardless of their ability to pay. In Section VI.15, page 96, the applicants project that 27 percent of patients to be served will be Medicare beneficiaries and 5.8 percent will be Medicaid recipients. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served and demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services. However, the applicants fail to adequately demonstrate the need to acquire a fixed MRI scanner to be located in Guilford County because they do not demonstrate how SOS' patients will be more effectively served by the fixed scanner and fail to demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating at host sites in Guilford County performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data.

Therefore, the application is nonconforming to this criterion.

WFBI. The applicant proposes to acquire one fixed MRI scanner to be located in a new freestanding outpatient imaging facility in leased medical office space at 3623 N. Elm Street in Greensboro in Guilford County. WFBI currently operates one fixed MRI at its freestanding imaging facility in Winston-Salem in Forsyth County, where it offers a full complement of screening, diagnostic and interventional radiologic technologies, as described by the applicant in Section I, pages 10-11.

WFBI is a joint venture between North Carolina Baptist Hospital (NCBH), Wake Forest University Health Sciences (WFUHS), and Outpatient Imaging Affiliates, LLC (OIA).

NCBH d/b/a Wake Forest Baptist Health (WFBH) comprises an extensive inpatient and outpatient network that serves the residents of multiple counties through acute care and rehabilitation beds, a comprehensive mix of outpatient services and physician practices, as

discussed by the applicant in Section I, pages 12-13. WFBH recently signed a letter of intent to purchase Cornerstone Health Care (Cornerstone), a physician-owned practice with more than 80 locations throughout central North Carolina, which also owns and operates a fixed MRI scanner in Guilford County.

OIA will manage the proposed WFBI MRI services. OIA, via its wholly-owned subsidiary Pinnacle Health Services of North Carolina, LLC (PHS), owns or has an ownership interest in the following diagnostic imaging facilities in North Carolina:

- Raleigh Radiology Clayton,
- Raleigh Radiology Cedarhurst,
- Raleigh Radiology Wake Forest, and
- Raleigh Radiology Brier Creek.

The applicant's representations regarding the need for a fixed MRI scanner to serve existing and projected patients are reasonable and adequately supported.

Population to be Served

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as *"a single county, except where there is no licensed acute care hospital located within the county."* Thus, the service area for this project consists of Guilford County. Providers may serve residents of counties not included in their service area.

WFBI is proposing a new facility in Guilford County and provides the projected patient origin in Section III.5, page 69, as shown in the table below.

County	CY2017	CY2018
Guilford	86.0%	85.6%
Forsyth	6.0%	6.5%
Randolph	2.3%	2.5%
Rockingham	3.0%	2.6%
Davidson	2.7%	2.8%
Total	100.0%	100.0%

In Section III.5(d), pages 69-70, with regard to its assumptions for projected patient origin, the applicant states that the patient origin is based on the methodology discussed in Section III.1, specifically on the projected market share of MRI services described on pages 48-50. The applicant further states:

"Based on a review of patient origin for WFBH's patient visits at its Greensboro Medical Plaza, patients indeed travel to Greensboro from adjacent counties

including Davidson, Forsyth, Randolph, and Rockingham Counties. Therefore, WFBH included these counties in its methodology for projecting MRI utilization.”

The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(b) of the application, the applicant discusses the factors which it states support the need for the proposed project, including:

- Service area demographics and population growth trends (pages 36-40),
- MRI utilization rates (pages 40-43), and
- Referring physician relationships (43-45).

Projected Utilization

In Section IV.1, page 73, the applicant provides the projected utilization for its proposed new fixed MRI scanner through the first three years of operation following completion of the project (CY2017-CY2019), which is summarized below.

**Wake Forest Baptist Imaging
Fixed MRI Scanner**

	CY2017	CY2018	CY2019
Unweighted MRI Scans	2,509	3,533	4,569
Weighted MRI scans	2,901	4,084	5,282

As shown in the above table, the applicant projects the proposed fixed MRI scanner will perform 4,569 unweighted and 5,282 weighted MRI scans in the third operating year (CY2019), which exceeds the utilization standards required in 10A NCAC 14C .2703(b). The applicant describes the assumptions and methodology used to project utilization in Section III.1(b), pages 45-58, which are summarized below, step by step.

1. Population Projection

Based on its projected patient origin for the proposed MRI services, the applicant provides population projections (page 46) for Guilford, Forsyth, Randolph, Rockingham and Davidson counties through 2019, as shown below.

Projected Population

County	CY2016	CY2017	CY2018	CY2019
Guilford	520,398	524,226	527,911	531,454
Forsyth	371,646	375,559	379,554	383,601
Randolph	144,254	144,841	145,429	146,020
Rockingham	92,543	92,543	92,545	92,543
Davidson	165,399	165,873	166,345	166,815

Source: NCOSBM

2. MRI Use Rate

The applicant states (pages 46-47) that although Guilford County has historically had a higher MRI utilization rate than the State as a whole, for conservatism it will project procedures using the FFY2014 North Carolina Statewide use rate, held constant at 80.4 through 2019.

3. Projected Total MRI Procedures

The applicant applies the FFY2014 North Carolina MRI use rate of 80.4 scans per 1,000 persons to the projected population calculated in Step 1 (page 48).

Total Area Projected MRI Procedures

County	CY2016	CY2017	CY2018	CY2019
Guilford	41,835	42,143	42,439	42,724
Forsyth	29,877	30,191	30,513	30,838
Randolph	11,597	11,644	11,691	11,739
Rockingham	7,440	7,440	7,440	7,440
Davidson	13,297	13,335	13,373	13,410

4. MRI Patient Market Share

The applicant projects its MRI market share based on its established referral physician relationships in Forsyth County, the WFBH network, and Cornerstone, as shown below (page 49).

Projected MRI Market Share

County	CY2017	CY2018	CY2019
Guilford	5.0%	7.0%	9.0%
Forsyth	0.5%	0.8%	1.0%
Randolph	0.5%	0.8%	1.0%
Rockingham	1.0%	1.3%	1.5%
Davidson	0.5%	0.8%	1.0%

On pages 49-50, the applicant states that the market share projections for Guilford County are reasonable based upon the 2016 SMFP identified need; the Guilford County population growth, distribution and aging; referral physician support letters; and its own experience with fixed MRI services at WFBI in Forsyth County and OIA's experience developing fixed MRI services in urban markets. To further demonstrate the reasonableness of its projected market share, the applicant examined the historical utilization of existing MRI providers located in Guilford County and calculated each provider's market share, as presented on page 52 of the application, showing the average market share for fixed MRI providers in Guilford County was 13.47%.

In reference to its market share projections for the adjacent counties, the applicant states that the market share is modest considering the historical patient origin for its referring physicians, including WFBH physicians located in Guilford County and Cornerstone physicians, and increased geographic access for residents in proximate areas of contiguous counties.

5. WFBI's Projected MRI Procedures

The applicant calculates WFBI's projected MRI procedures by applying the market share percentages in Step 4 to the total MRI procedures calculated in Step 3, as shown on page 53. In addition, WFBI has offered to partner with the Guilford County Health Department and Triad Adult and Pediatric Medicine, Inc. to provide one free MRI scan each week to local patients who are uninsured or underinsured, adding 52 free Guilford County MRIs, resulting in the following total WFBI projected MRI procedures.

WFBI Projected MRI Procedures

County	CY2017	CY2018	CY2019
Guilford	2,107	2,971	3,845
Forsyth	151	229	308
Randolph	58	88	117
Rockingham	74	93	112
Davidson	67	100	134
Free Scans	52	52	52
Total	2,509	3,533	4,569

Totals may not sum due to rounding

6. Projected Weighted MRI Procedures

The applicant projects weighted MRI procedures based on WFBI's experience with its existing fixed MRI service in Forsyth County. For FFY2015, WFBI performed

5,547 unweighted scans and 6,413 weighted MRI scans for a weighting factor of 1.16 ($6,416 / 5,547 = 1.157$).

WFBH Projected MRI Utilization

	CY2017	CY2018	CY2019
Unweighted Scans	2,509	3,533	4,569
Weighted Scans	2,901	4,084	5,282

Totals may not foot due to rounding

As of March 15, 2016, neither the applicant nor any related entity owns a controlling interest in any fixed MRI scanners in Guilford County. However, the applicant expects WFBH will acquire Cornerstone, gaining control of Cornerstone’s existing assets, including its existing fixed MRI scanner in Guilford County, during the review of this application. Therefore, as a related entity, the applicant provides projected utilization for Cornerstone’s fixed MRI scanner, as shown on page 58 of the application, and in the following table.

Cornerstone Projected MRI Utilization

	CY2017	CY2018	CY2019
Unweighted Scans	4,581	4,613	4,645
Weighted Scans	5,228	5,265	5,302

Totals may not foot due to rounding

The applicant discusses the assumptions and methodology for Cornerstone’s projected MRI scans on pages 55-58. On page 56, the applicant provides a table with Cornerstone’s historical fixed MRI utilization, showing 4,208, 6,022 and 5,146 weighted MRI scans for FY2013, FY2014, and FY2015, respectively. Cornerstone’s utilization exceeds the 4,805 scan threshold required in 10A NCAC 14C .2703(b)(4) for the historical and projected operating years. The applicant states that during FY2015, Cornerstone also performed 416 MRI procedures on a mobile MRI scanner to relieve capacity constraints on the fixed scanner.

Labeling in the applicant’s utilization tables on page 57 is in error, with the labels listing FY2018 twice. The second FY2018 label should be FY2019 and the FY2019 label should be FY2020. However, the error does not impact the calculations presented for the second and third operating years in the CY utilization table on page 58.

Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire the proposed fixed MRI scanner.

Access

In Section VI.2, page 82, the applicant states that consistent with its current business practice in Winston-Salem, WFBI's Greensboro MRI service will have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved. In Section VI.15, page 97, the applicant projects that 31% of its patients will be Medicare beneficiaries and 5.9% will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA- Cone Health and WFBI
NC-SOS

The applicants state on page 22 of the application that they propose to upgrade an existing AHS-owned mobile GE Signa Excite 1.5T MRI scanner to a fixed scanner. According to the list of AHS' mobile MRI scanners provided by the applicants in Exhibit 4 and AHS' January 2016 Registration and Inventory of Medical Equipment filed with DHSR Healthcare Planning, AHS has only one existing GE Signa Excite 1.5T mobile MRI scanner operating in North Carolina. This machine is identified as SIGNA 407 and serves the following sites:

**SIGNA 407
 10/1/2014-9/30/2015**

Sites Served	County	Unweighted Procedures
UNC	Alamance	272
MRI Specialists of the Carolinas	Cleveland	266
Yadkin Valley Community Hospital	Yadkin	57
WFBH Med Plaza	Forsyth	206
Moses Cone MedCenter High Point	Guilford	49
SOS	Guilford	124
Davie County Hospital	Davie	751
OrthoCarolina PA	Scotland	19
Randolph Spine Center	Mecklenburg	16
OrthoCarolina PA	Union	21
Total Unweighted Procedures Reported on Signa 407		1,781

Source: January 2016 Registration and Inventory of Medical Equipment

The applicants do not discuss how the above sites will be served when the mobile scanner currently serving them is removed from mobile service to be upgraded to a fixed MRI scanner. Therefore, the applicants do not demonstrate that the needs of the population presently served will be adequately met by the proposed project.

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

C-Cone Health
 NC-SOS
 C-WFBI

Cone Health. In Section III.3, pages 55-56, the applicants discuss the alternatives considered prior to the submission of this application, which include:

- Maintain the Status Quo – The applicants state that maintaining the status quo would not increase MRI capacity at Moses Cone Hospital. The applicants further state that the addition of a third shift to meet the need for inpatient MRI scans is a less than optimal solution, resulting in patient, nurse and physician dissatisfaction. Therefore this alternative was rejected.
- Addition of a Fixed MRI Scanner at Wesley Long Hospital - The applicants state that the MRI scanners at Moses Cone Hospital are more heavily constrained with a higher utilization percentage than at Wesley Long. In addition, the increased demand for more complex cardiovascular and neurological scans is at Moses Cone Hospital, the location of the Heart and Vascular center and Neurosciences and

Stroke Centers. Further, beginning in 2020, neonatal patients will be located at Moses Cone Hospital. Therefore, this alternative was rejected.

- Locate a Fixed MRI Scanner in a Freestanding Outpatient Setting – A large component of the need for additional MRI capacity was identified for Moses Cone Hospital inpatients, emergency department patients, and complex cardiac and neurological patients, none of whom can be treated in a freestanding outpatient setting. On page 46, the applicants state,

“However, not all outpatient scans can be provided in a freestanding setting because of patient co-morbidities, the need for sedation, scans for Emergency Department patients, and the increased complexity of scans. These scans will continue to be performed at MCH for patient safety reasons, including the need for anesthesia staff and services.”

Therefore, this alternative was rejected.

- Proposed Project – Locate an Additional Fixed MRI Scanner at Moses Cone Hospital – The applicants state that the project as proposed provides the best option for meeting Moses Cone Hospital’s patients’ need for additional MRI services.

After considering the above alternatives, the applicants state the proposed alternative represents the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

SOS.

In Section III.3, pages 58-59, the applicants discuss the alternatives considered prior to the submission of this application, which include:

- Maintain the Status Quo – The applicant states that maintaining the status quo does not address the additional need for fixed MRI capacity in the service area or the growing outpatient MRI needs for non-hospital based MRI access. The applicants state maintaining the status quo is not the best alternative at this time and therefore this alternative was rejected.
- Acquire New MRI Scanner - The applicants state that neither SOS nor AHS consider spending over \$1 million for a new MRI scanner to be reasonable when a

mobile MRI scanner can be upgraded to the specifications of a new fixed 1.5T MRI scanner for approximately \$500,000. Therefore, the applicants rejected this alternative because it was not the most cost effective alternative.

- Locate the Fixed MRI in Another Location in Guilford County – The applicants state that neither SOS nor AHS provide mobile MRI services at another single location in Guilford County that could support the fixed MRI scanner and therefore it is unreasonable to project a high enough MRI utilization at another location in Guilford County. Therefore, this alternative was rejected.
- Build a New Freestanding Imaging Center –The applicants state that constructing new space to develop a new freestanding service and hiring more support staff when SOS already has space and support staff would not be financially or operationally cost efficient. Therefore, this alternative was rejected.
- Locate the Upgraded Fixed MRI Scanner at SOS – The applicants state that the project as proposed, upgrade an existing mobile MRI scanner to a fixed MRI scanner, provides the most cost effective alternative to meeting the need for additional fixed MRI services.

After considering the above alternatives, the applicants state the proposed alternative represents the most effective alternative to meet the identified need.

However, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. The applicants do not adequately demonstrate the need for the proposed fixed MRI scanner given the access to MRI services already being provided at SOS and the additional capacity available on the mobile MRI scanners owned and operated by the applicant or a related entity in Guilford County.

In summary, the applicants do not adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is nonconforming to this criterion.

WFBI.

In Section III.3, pages 63-66, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- Maintain the Status Quo – The applicant states that maintaining the status quo, providing MRI services utilizing the existing WFBI fixed MRI scanner in Forsyth County, would not meet the need identified in the SMFP. The applicant further states that WFBI's existing Forsyth scanner is very well-utilized and currently providing more than 4,805 weighted MRI procedures per unit; therefore, the

applicant states this alternative is not the most effective at this time and therefore this alternative was rejected.

- Develop the Proposed Project in Another Area of Guilford County - The applicant states that WFBI reviewed the distribution of population and existing fixed MRI scanners in Guilford County, determining that there are two primary population centers in Guilford County, Greensboro and High Point/Jamestown, with both areas having essentially equal access to fixed MRI services. The applicant further states that WFBI's proposed location in Greensboro is in close proximity to existing medical services and is easily accessible from major thoroughfares and traffic arteries in Guilford County. Also given the prospective business transaction with WFBH and Cornerstone, WFBI's proposed location will ensure that WFBH-affiliated fixed MRI services are available in both primary population centers in Guilford County. Therefore, the applicant rejected the alternative of proposing a different area in Guilford County for the project.
- Develop a Mobile MRI Service in Guilford County – The applicant states that it researched the possibility of contracting for mobile MRI services to serve Guilford County and determined that this alternative would be *“inconsistent with WFBI's goal to provide cost effective imaging services to the patients of Guilford County.”* Therefore, this alternative was rejected.
- Develop the Project as Proposed –The applicant states that the project as proposed, acquire a fixed MRI Scanner and locate it in leased medical office space in Greensboro, provides the most cost effective alternative to meeting the need for additional MRI services, as identified in Section III.1.

After considering the above alternatives, the applicant states the proposed alternative represents the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this 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.

Cone Health.

Capital and Working Capital Costs

In Section VIII.1, page 97, the applicants state the total capital cost of the proposed project is projected to be \$3,559,980, comprised of the following costs:

Construction Contract	\$1,315,677
Equipment/Furniture	\$1,936,203
Consultant Fees	\$156,600
Contingency	\$151,500
TOTAL CAPITAL COST	\$3,559,980

Source: Table on page 99 of the application.

In Section IX.1, page 104, the applicants state there will be no start-up expenses and no initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 100, the applicants state that the total capital cost will be funded with \$3,559,980 in Cone Health accumulated reserves. Exhibit 26 contains a letter from the Chief Financial Officer of Cone Health which documents its commitment to fund the proposed project and the availability of funds. Exhibit 27 contains the audited consolidated financial statements for The Moses H. Cone Memorial Hospital and Affiliates for years ending September 30, 2015 and 2014. According to the financial statements, as of September 30, 2015, Cone Health had \$27,152,000 in cash and cash equivalents, \$343,386,000 in total current assets, \$2,335,481,000 in total assets and \$1,462,635,000 in total net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements (Form C), the applicants project a positive net income for the proposed Cone Health-Greensboro (Moses Cone Hospital and Wesley Long) MRI service component in each of the first three operating years of the project, as shown in the table below.

MRI Service	Project Year 1 FFY2018	Project Year 2 FFY2019	Project Year 3 FFY2020
Projected # of MRI Scans	14,010	14,251	14,497
Projected Average Charge	\$3,053	\$3,112	\$3,173
Gross Patient Revenue	\$42,771,575	\$44,354,921	\$45,999,354
Deductions from Gross Patient Revenue	\$35,071,473	\$36,449,848	\$37,883,451
Net Patient Revenue	\$7,700,102	\$7,905,073	\$8,115,903
Total Expenses	\$3,132,914	\$3,227,776	\$3,323,672
Net Income	\$4,567,188	\$4,677,297	\$4,792,231

Furthermore, The Moses H. Cone Memorial Hospital Forecasted Consolidated Income Statement (Form B) projects that revenues will exceed operating expenses in each of the first three operating years of the project. The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

SOS.

Capital and Working Capital Costs

In Section VIII, page 106, the applicants state the total capital cost is projected to be \$710,000, as shown below:

Project Capital Cost	
Equipment /Trailer Upgrade	\$612,620
Consultant Fees	\$32,000
Sales Tax	\$49,010
Contingency	\$16,370
TOTAL CAPITAL COST	\$710,000

Source: Table on page 106 of the application.

In Section IX.1, page 111, the applicants state there will be no start-up or initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 107, the applicants state that the total capital cost of the project will be funded through AHS Owner’s Equity. In Exhibit 24, the applicant provides a letter dated March 10, 2016, from the Chief Financial Officer of AHS documenting its intention to fund the capital costs for the proposed project. Exhibit 25 contains AHS’ Form 10-K which indicates that as of December 31, 2014, AHS had \$33,033,000 in cash and cash equivalents. The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements for SOS’ MRI services (Form C), the applicants project that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

MRI Service	Project Year 1 FFY2018	Project Year 2 FFY2019	Project Year 3 FFY2020
Projected # of MRI Scans	5,110	5,155	5,196
Projected Average Charge	\$ 1,391	\$ 1,391	\$ 1,391
Gross Patient Revenue	\$ 7,107,780	\$ 7,170,164	\$ 7,227,654
Deductions from Gross Patient Revenue	\$ 5,169,719	\$ 5,215,093	\$ 5,256,908
Net Patient Revenue	\$ 1,938,061	\$ 1,955,071	\$ 1,970,746
Other Revenue	\$ 602,041	\$ 607,325	\$ 612,194
Total Expenses	\$ 1,606,300	\$ 1,620,897	\$ 1,635,486
Net Income	\$ 933,801	\$ 941,499	\$ 947,454

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

WFBI.

Capital and Working Capital Costs

In Section VIII.1, page 106, the applicant states the total capital cost is projected to be \$2,310,432, comprised of the following costs:

Construction Contract	\$550,985
Equipment/Furniture	\$1,705,247
Consultant Fees	\$54,200
TOTAL CAPITAL COST	\$2,310,432

In Section IX.1, page 112, the applicant states start-up expenses and initial operating expenses associated with the project will total \$200,000.

Availability of Funds

In Section VIII.3, page 108 and Section IX.2, page 112, the applicant states that \$54,200 of the capital costs and \$110,000 of the working capital will be funded with WFBI accumulated reserves and \$2,256,232 of the capital costs and \$90,000 of the working capital will be funded by a capital lease. In Exhibit 12, the applicant provides a letter dated March 11, 2016, from the Chief Financial Officer of WFBI documenting its intention to fund the capital and working capital costs for the proposed project through accumulated reserves and a GE capital lease. Exhibit 12 also contains the proposed lease which will finance \$2,346,232 for the equipment (which includes \$90,000 of working capital) and an amortization table. Exhibit 13 contains the WFBI financial statements which indicate that as of December 31, 2014, WFBI had \$376,733 in cash and \$1,542,156 in member's equity (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the pro forma financial statements for WFBI's MRI services (Form C), the applicant projects that revenues will exceed operating expenses in the second and third operating years of the project, as shown in the table below.

WFBI MRI Services

	Project Year 1 CY2017	Project Year 2 CY2018	Project Year 3 CY2019
Projected # of MRI Scans	2,511	3,535	4,571
Projected Average Charge (Gross Patient Revenue / Projected # of Scans)	\$1,879	\$1,879	\$1,879
Gross Patient Revenue	\$4,718,314	\$6,642,140	\$8,590,207
Deductions from Gross Patient Revenue	\$3,358,490	\$4,692,007	\$6,042,328
Net Patient Revenue	\$1,359,824	\$1,950,132	\$2,547,879
Total Expenses	\$1,453,472	\$1,904,533	\$2,162,134
Net Income	-\$93,648	\$45,600	\$385,744

Note: The projected number of MRI scans as shown in Form C and above differ from the projected number of MRI scans as calculated in the utilization methodology on page 54 by two scans each year. The difference is immaterial and is assumed to be due to rounding.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this 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.

C-Cone Health
 NC-SOS
 C-WFBI

The 2016 SMFP includes a methodology for determining the need for additional fixed MRI scanners by service area. Step 12, on page 157 of the 2016 SMFP, states:

“If the area average procedure per magnet is greater than or equal to the service area threshold, a need is determined for one additional MRI scanner in the service area.”

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Thus, the service area for this project consists of Guilford County. Providers may serve residents of counties not included in their service area.

The 2016 SMFP identifies the need for one fixed MRI scanner in Guilford County, based on the following data presented on page 165 of the 2016 SMFP.

Service Type	Service Site	Provider	# Fixed and Fixed Equiv	Total Scans	Weighted Scans	Avg Scans / Magnet
Hosp Fixed	Cone Health	Cone Health	3	12,144	15,996	5,332
Hosp Fixed	HPRHS	HPRHS	2	5,893	7,902	3,951
FS Fixed^	Cornerstone Imaging	Cornerstone HC, PA	1	5,405	6,022	6,022
FS Fixed	Greensboro Imaging	Diag Rad & Imaging	1	5,248	6,044	6,044
FS Fixed	Greensboro Imaging	Diag Rad & Imaging	1	1,515	1,742	1,742
FS Fixed	Greensboro Imaging	Diag Rad & Imaging	1	5,543	6,385	6,385
FS Fixed	Greensboro Ortho	Greensboro Ortho	1	5,495	5,654	5,654
FS Fixed	Triad Imaging	Triad Imaging	1	3,407	3,671	3,671
Mobile	Carolina Neuro & Sp	Alliance	0.18	851	940	
Mobile	Cornerstone	Insight Imaging	0.34	1,640	1,823	
Mobile	Greensboro Sp & Sc	Alliance	0.05	219	225	
Mobile	Guilford Neuro Asso	Kings Med Group	0.21	1,003	1,214	
Mobile	MedCenter HP	Alliance*	0.13	646	705	
Mobile	Cone Health	Alliance	0.14	654	710	
Mobile	Premier Imaging	HPRHS	0.19	893	958	
Mobile	Reg Phys Neuro Ctr	HPRHS	0.01	48	55	
Mobile	SE Ortho Specs	Alliance	0.86	4,632	4,826	
Mobile	SE Ortho Specs	Alliance	0	15	15	
Total Fixed Scanners and Scans			11	44,650	53,416	4,856
Total Mobile Fixed Equivalents and Scans			2.11	10,601	11,471	5,436
Total Guilford Co Fixed Scanners and Fixed Equiv Scanners and Scans Performed			13.11	55,251	64,887	4,949
Threshold for Scans per Scanner						4,805

*SMFP shows service site and provider/owner as MedCenter High Point (a Cone Health subsidiary); however, Alliance Healthcare provides mobile MRI service to MedCenter High Point, as documented in AHS' 2016 Registration and Inventory of Medical Equipment.

^FS = Free-Standing

As the table above shows, the average procedure per fixed and mobile fixed equivalent scanner (4,949) is greater than the Guilford County service area threshold of 4,805, indicating a need for one additional fixed MRI scanner in Guilford County.

There are 11 existing fixed MRI scanners in Guilford County. There are no approved fixed MRI scanners in Guilford County, as defined in 10A NCAC 14C .2701(1). The following table identifies the provider, the number of scanners, and average weighted scans per fixed MRI scanner, summarized from Table 9P of the 2016 SMFP, based on 2014 utilization data submitted by the providers.

Provider	Number of Fixed MRIs	Total Number of Weighted Scans	Average Weighted Scans per Scanner
Cone Health - Main and Wesley Long	3	15,996	5,332
High Point Regional Health	2	7,902	3,951
Cornerstone Imaging	1	6,022	6,022
DRI - Greensboro Imaging	3	14,171	4,724
Greensboro Orthopaedics	1	5,654	5,654
Triad Imaging	1	3,671	3,671
Total	11	53,416	4,856

Source: 2016 SMFP, 2015 License Renewal Applications and 2015 Equipment and Inventory of Medical Equipment (FFY2014 data)

Cone Health. In Section III.6(b), pages 58-59, the applicants state that Cone Health’s identified need is to reduce Cone Health-Greensboro’s capacity constraints for advanced MRI scans for inpatients and complex outpatients in a growing and aging service area. The applicants further state that these advanced MRI services are not able to be performed in a freestanding outpatient setting; therefore, the freestanding outpatient providers and physician practices are unable to meet the need. The applicants also state that High Point Regional Health System is the only other acute care hospital in Guilford County; is not a trauma center; does not treat the same level of volume or acuity of cardiovascular, neurological, or neonatal patients as Cone Health; and as shown in the table above, performed an average of 3,951 weighted scans per fixed MRI scanner. However, Cone Health is not required to demonstrate that High Point Regional Health System is operating at or above any minimum threshold in order to demonstrate that its proposal would not result in an unnecessary duplication.

On page 59, the applicants state:

“Finally, Cone Health provides MRI services to all [emphasis in original] patients, regardless of their ability to pay. Other existing providers do not provide the same level of charity care to the underserved and medically indigent.”

The applicants adequately demonstrate in the application that the fixed MRI scanner they propose to develop in Guilford County is needed in addition to the existing fixed MRI scanners in Guilford County. The applicants adequately demonstrate that their projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved MRI services in Guilford County. Therefore, the application is conforming to this criterion.

SOS. The applicants propose to upgrade an existing mobile MRI scanner to a fixed MRI scanner and operate the scanner in a renovated imaging trailer, permanently positioned on a concrete pad located at the SOS medical practice in Greensboro. In Section II.5, page 34, the applicants state:

“The fixed MRI scanner at SOS will increase the fixed MRI scanner capacity in Guilford County and assure that fixed MRI services are always available at SOS, which cannot be said for a mobile MRI scanner.”

The applicants further state that SOS is the only location in Guilford County served by an existing mobile MRI scanner that can meet the performance standards for a fixed scanner based on existing volumes. However, the applicants do not adequately demonstrate in the application that replacing the mobile MRI service with the fixed MRI scanner they propose to develop in Guilford County is needed in addition to the existing fixed MRI scanners in Guilford County, given the additional capacity available on the mobile MRI scanners owned and operated by the applicant or a related entity in Guilford County.

The applicants discuss the utilization of AHS’ existing mobile scanners at SOS and CNSA, each performing greater than 3,328 weighted MRI scans in the most recent 12-month period for which the applicants had data available (3/1/2015-2/29/2016). However, the applicants do not discuss the utilization of the AHS mobile scanner that served Cone Health’s MedCenter High Point in Guilford County in the last reporting period and which is the scanner that is proposed to be upgraded from mobile to fixed and identified on AHS’ 2016 RIME as Signa 407. Furthermore, the applicant provides a table with a list of AHS-owned mobile MRI scanners, along with counties in which they operate, in Exhibit 4. The list, though not dated, shows that AHS operates six mobile scanners in Guilford County: ESP 27, Signa 294, Signa 413, Signa 447, Signa 451, and Signa 470. Furthermore, the 2016 RIME for AHS’s Signa 407 shows that scanner also operated in Guilford County, in addition to the counties listed in the applicant’s table in Exhibit 4. Therefore, there appear to be seven AHS mobile MRI scanners which served host sites in Guilford County in the last reporting period. The applicants discussed only two of the seven. The applicants do not discuss the utilization of the other five scanners listed as operating in Guilford County.

The Healthcare Planning and Certificate of Need Section (Agency) has a record of AHS submitting the 2016 RIME forms on only three of the seven scanners listed above: Signa 407, Signa 447, and ESP 27.

The RIME which AHS submitted for its Signa 447 reported 5,341 procedures for FFY2015 at SOS in Greensboro, Guilford County, which is above the 3,328 scan threshold, as required in 10A NCAC 14C .2703(b)(2). However, two other mobile scanners operated at SOS during the same time frame, performing a total of 5,496 scans at

SOS. The following tables show the utilization reported for the scanners identified as Signa 407 and ESP 27, adjusted to reflect the methodology for weighting MRI scans.

SIGNA 407
10/1/2014-9/30/2015

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Inpt w Contrast	Inpt w/o Contrast	Weighted Procedures
UNC	Alamance	272	60	212			296
MRI Specialists of the Carolinas	Cleveland	266	42	224			283
Yadkin Valley Community Hospital	Yadkin	57	7	49		1	60
WFBH Med Plaza	Forsyth	206	21	185			214
Moses Cone MedCenter High Point	Guilford	49	10	39			53
SOS	Guilford	124	1	123			124
Davie County Hospital	Davie	751	193	556	1	1	829
OrthoCarolina PA	Scotland	19	0	19			19
Randolph Spine Center	Mecklenburg	16	1	15			16
OrthoCarolina PA	Union	21	0	21			21
Total Procedures Reported on Signa 407 and Weighted		1,781					1,917

Source: January 2016 Registration and Inventory of Medical Equipment and 2016 SMFP Methodology
 Totals may not sum due to rounding

ESP 27
10/1/2014-9/30/2015

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Weighted Procedures
Moses Cone MedCenter High Point	Guilford	645	152	493	706
UNC	Alamance	343	81	262	375
Carolina Neurosurgery & Spine	Guilford	194	64	130	220
Cone Health MedCenter-Kernersville	Forsyth	95	11	84	99
Wake Radiology Services	Wake	7	0	7	7
Onslow Memorial Hospital	Onslow	9	0	9	9
SOS	Guilford	31	0	31	31
Triangle Orthopedic	Wake	404	8	394	405
Duke Health Raleigh	Wake	188	90	98	224
Wake Radiology Services	Johnston	119	0	119	119
Total Procedures Reported on ESP 27 and Weighted		2,035			2,195

Source: January 2016 Registration and Inventory of Medical Equipment and the 2016 SMFP Methodology
 Totals may not sum due to rounding

As the tables above show, per the January 2016 RIME, both the Signa 407 and ESP 27 scanners performed below the 3,328 weighted scan threshold required in 10A NCAC 14C .2703(b)(2). It appears that AHS did not submit the 2016 RIME forms for the other AHS scanners listed in Exhibit 4 as serving Guilford County.

The applicants do not demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating at host sites in Guilford County performed at least 3,328 weighted MRI scans in the most recent 12 month period for which the applicant has data. Therefore, the applicants fail to adequately demonstrate the need to acquire the proposed fixed MRI scanner to be located in Guilford County.

Thus, the applicants fail to adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved MRI services in Guilford County. Therefore, the application is nonconforming to this criterion.

WFBI. The applicant, WFBI, proposes to acquire one fixed MRI scanner to be located in leased medical office space in Greensboro. In Section III, page 64, the applicant states:

“WFBI’s proposal to install a fixed MRI scanner in Guilford County will greatly increase access to high-quality, cost-effective MRI services for all patients in the local service area, and will establish a new, cost-effective provider of fixed MRI services in Guilford County.”

The applicant adequately demonstrates in its application that the fixed MRI scanner it proposes to develop in Guilford County is needed in addition to the existing fixed MRI scanners in Guilford County. The applicant adequately demonstrates that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved MRI services in Guilford County. Therefore, the application is conforming to this criterion.

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

C-All Applications

Cone Health. In Section VII.1, pages 89-90, the applicants provide Cone Health-Greensboro's current and projected MRI staffing, which shows they currently employ 10.6 full-time equivalent (FTE) MRI technologists and 2.0 FTE MRI Supervisor positions for a total of 12.6 FTE MRI positions to staff the existing MRI service, and that they project to employ a total of 13.3 FTE MRI technologists to staff the existing fixed scanners and the proposed fixed MRI scanner in the second year of the project. In Section VII, pages 91-93, the applicants describe their experience and process for recruiting and retaining staff. Mark E. C. Shogry, M.D., serves as the Medical Director for MRI services. Exhibit 22 of the application contains a copy of job descriptions for MRI techs and supervisors. Exhibit 18 contains copies of letters from area physicians expressing support for the proposed project. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

SOS. In Section VII.1, pages 97-98, the applicants provide the current and proposed staffing for the fixed MRI scanner in operating year two for SOS and AHS, as shown in the table below.

Position	Number FTE Positions	
	FFY2016	FFY2019
SOS Staffing		
Front Office Coordinator	1.5	1.5
MRI Scheduler/Precertification	3.0	3.0
Total	4.5	4.5
AHS Staffing		
MRI Technologist	2.9	2.9
Patient Coordinator	2.9	2.9
Manager of Operations	0.1	0.1
Total	5.9	5.9
Total Service FTE Positions	10.4	10.4

In Section VII, pages 100-102, the applicants describe their experience and process for recruiting and retaining staff. Job descriptions and staff education materials are in Exhibits 21 and 22, respectively. Greensboro Radiology physicians interpret MRI scans for SOS. Exhibit 8 contains a letter from the CEO of Greensboro Radiology stating that physicians given privileges to provide MRI interpretation services at SOS will be active members, in good standing, on the Cone Health medical staff. The applicants state that F. Mark Gallerani, MD is the Medical Director for the service and Exhibit 18 contains a letter from Dr. Gallerani documenting his intent to continue to serve as Medical Director. Exhibit 27 of the application contains copies of letters from area physicians expressing support for the proposed project. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

WFBI. In Section VII.1, page 99, the applicant provides the proposed staffing for the fixed MRI scanner in operating year 2 (CY2018), as shown in the table below.

Position	Number FTE Positions
Administrator	0.50
Assistant Manager	0.50
Chief MRI Technologist	1.00
MRI Technologist	0.60
MRI Tech Assistant	1.00
Registration/Scheduler	1.60
Marketing Liaison	1.00
TOTAL FTE Positions	6.20

Source: Table VII.1, page 99.

In Section VII, pages 100-102, the applicant describes its experience and process for recruiting and retaining staff. In Section II.1, page 18, the applicant states that Annette Johnson, MD, MS, will serve as Medical Director for the proposed fixed MRI service.

Exhibit 3 contains a letter dated February 23, 2016 from Dr. Johnson documenting her intent to serve as Medical Director for the proposed service. Exhibit 14 contains a copy of an existing professional services agreement between WFBI and WFUHS which the applicant states will fully satisfy the physician needs of the MRI service at WFBI's Greensboro location. Exhibit 19 of the application contains copies of letters from area physicians and other healthcare providers expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C-All Applications

Cone Health. In Section II.2, page 21, the applicants describe the necessary ancillary and support services and state that all necessary ancillary and support services are currently provided to the radiology department at Moses Cone Hospital. Exhibit 6 contains a letter from Moses Cone Hospital President and Cone Health Senior Vice President documenting the availability of the necessary ancillary and support services. Exhibit 18 contains letters of support from physicians. The applicants adequately demonstrate that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

SOS. In Section II.2, page 33, the applicants describe the necessary ancillary and support services required to operate the proposed MRI service and state that all necessary ancillary and support services are currently provided by SOS or through an MRI Service Agreement with AHS. Exhibit 2 contains a copy of the MRI Service Agreement. Exhibit 7 contains a letter from the SOS President documenting the availability of the necessary ancillary and support services. Exhibit 27 contains letters of support from physicians. The applicants adequately demonstrate that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

WFBI. In Section II.2, pages 19-20, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 19 contains letters of support from physicians and other health care providers. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in

adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

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

C-All Applications

Cone Health. The applicants propose to develop the fixed MRI scanner in a newly constructed MRI suite (1,431 square feet of space) adjacent to the existing fixed MRI scanners on the first floor of Moses Cone Hospital at 1200 North Elm Street in Greensboro. An additional 772 square feet of existing space that currently houses storage rooms and a partial corridor will be renovated as part of the proposed new suite. Exhibit 25 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 99 of the application. In Section XI.7, page 114, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

SOS. The applicants propose that the fixed MRI scanner will be permanently housed in a renovated imaging trailer on a reinforced concrete pad located adjacent to the SOS medical practice at 1130 N. Church Street in Greensboro. The proposed fixed MRI service will share the pre-certification area, patient reception, and patient waiting area/restroom inside the SOS facility. Exhibit 5 contains line drawings of the MRI trailer and SOS facility. The quotes to upgrade the mobile MRI and the trailer are provided in Exhibit 23. In Section XI.7, page 121, the applicants state that the upgrading of the mobile MRI scanner and the renovation of the existing imaging trailer will improve energy efficiency. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

WFBI. The applicant proposes to develop the fixed MRI scanner in 5,170 square feet of leased medical office building space at 3623 N. Elm Street in Greensboro. The applicant will upfit the space to include MRI shielding. Exhibit 11 contains the line drawings and a quote for the construction and shielding. The costs are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 106 of the application. In Section XI.7, page 123, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this 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:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C-All Applications

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the service area and the entire state.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014_Estimate_as_of_December_22_2015.

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

Cone Health. In Section VI.12 and VI.13, pages 86-87, the applicants provide the payor mix during FFY2015 for the entire Cone Health facility, and the fixed MRI service component for Cone Health-Greensboro, as illustrated in the tables below:

**Cone Health
 Patient Days as a Percent of Total Days
 FFY2015 (10/1/14-9/30/15)**

	Patient Days
Self-Pay / Indigent / Charity	6.6 %
Medicare/Medicare Managed Care	45.1%
Medicaid	14.8%
Managed Care/Commercial Insurance	29.9%
Other (Champus, Workers Comp)	3.5%
Total	100.0%

Totals may not sum due to rounding

**Cone Health-Greensboro Fixed MRI Services
 Procedures as a Percent of Total Procedures
 FFY2015 (10/1/14-9/30/15)**

	MRI Procedures
Self-Pay / Indigent / Charity	8.2%
Medicare/Medicare Managed Care	46.3%
Medicaid	11.3%
Managed Care/Commercial Insurance	31.6%
Other (Champus, Workers Comp)	2.6%
Total	100.0%

Totals may not sum due to rounding

The applicants demonstrate that medically underserved populations currently have adequate access to the applicants' existing services and are conforming to this criterion.

SOS.

In Section VI.13, page 94, the applicants provide the payor mix during FFY2015 for the SOS MRI service, as illustrated in the table below:

**SOS MRI Service
 Procedures as a Percent of Total Procedures
 FFY2015 (10/1/14-9/30/15)**

	MRI Procedures
Self-Pay / Charity	1.0%
Medicare/Medicare Managed Care	27.0%
Medicaid	5.8%
Commercial Insurance	41.4%
Managed Care	15.2%
Other (Government)	9.6%
Total	100.0%

Totals may not sum due to rounding

The applicants demonstrate that medically underserved populations currently have adequate access to the applicants' existing services and are conforming to this criterion.

WFBI. In Section VI.12 and VI.13, page 90, the applicant states that WFBI is proposing a new fixed MRI scanner in Guilford County and is not an existing facility. On page 92, the applicant provides WFBI's Winston-Salem MRI payor mix for FFY2015, as shown below.

**WFBI Winston-Salem Fixed MRI Service
 Procedures as a Percent of Total Procedures
 FFY2015 (10/1/14-9/30/15)**

	Procedures
Self-Pay / Indigent / Charity	1.0%
Medicare	19.0%
Medicaid	4.0%
Commercial/ Managed Care/ BCBS	64.0%
Workers Compensation	12.0%
Total	100.0%

Totals may not sum due to rounding

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services in a different service area and is conforming to this criterion.

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

C-All Applications

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons.

Cone Health. In Section VI.11, page 86, the applicants state,

“Cone Health has no obligation under applicable Federal regulations to provide uncompensated care, community service, or access to care by minorities and handicapped persons.”

The applicants state that they are dedicated to providing care to all members of the community, regardless of ability to pay. See Exhibit 21 for Cone Health's Non-discrimination, Patient Admission, Payment, Coverage Assistance and Financial Assistance, Hardship policies. In Section VI.10(a), page 85, the applicants state

that they are not aware of any civil rights access complaints or violations filed against Cone Health in the last five years. The application is conforming to this criterion.

SOS. In Section VI.11, page 93, the applicants state,

“Neither SOS nor AHS has any public obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, as previously stated, SOS and AHS do and will provide equal access to MRI services through uncompensated care (charity) and bad debt write-offs, as well as guaranteeing physical access to the MRI Service.

SOS has pledged to perform 12 MRI scans per year for three years at no cost to Guilford County School System students that are in need of an MRI scan, but whose families lack the funds to obtain an MRI scan.”

In Section VI.10(a), page 92, the applicants state that they are not aware of any civil rights access complaints or violations filed against SOS or AHS in the last five years. The application is conforming to this criterion.

WFBI. In Section VI.11, pages 89-90, the applicant states,

“WFBI is a recipient of federal funds, and is compliant with all applicable federal regulations to insure continued access to these funds. WFBI does not discriminate based on race, color, religion, gender, national origin, age, or handicap.”

In Section VI.10 (a), page 89, the applicant states that WFBI is not aware of any civil rights access complaints having been filed against it in last five years. The application is conforming to this criterion.

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

C-All Applications

Cone Health. The applicants address access to services in Section VI. On pages 87-88, the applicants provide the following payor mix for the second full fiscal year of the proposed project.

**Cone Health (Entire Facility)
 Projected Patient Days/Procedures as a Percent of Total
 FFY2019**

Payor Category	Patient Days
Self Pay/ Indigent	6.6 %
Medicare/ Medicare Managed Care	45.1%
Medicaid	14.8%
Managed Care / Commercial Insurance	29.9%
Other (Champus, Workers Comp)	3.5%
Total	100.0%

Totals may not sum due to rounding

**Cone Health-Greensboro Fixed MRI Services
 Procedures as a Percent of Total Procedures
 FFY2019**

	MRI Procedures
Self-Pay / Indigent / Charity	8.2%
Medicare/Medicare Managed Care	46.3%
Medicaid	11.3%
Managed Care/Commercial Insurance	31.6%
Other (Champus, Workers Comp)	2.6%
Total	100.0%

Totals may not sum due to rounding

On page 87, the applicants state, “*Projected payor mix is based on FY 2015 actual payor mix percentages under the assumption that payor mix will not change significantly.*” The applicants demonstrate that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

SOS. In Section VI.15, page 96, the applicants project the following payor mix for SOS’s MRI services during the second operating year (FY2019):

**SOS MRI Service
 Procedures as a Percent of Total Procedures
 FFY2019 (10/1/18-9/30/19)**

	MRI Procedures
Self-Pay / Charity	1.0%
Medicare/Medicare Managed Care	27.0%
Medicaid	5.8%
Commercial Insurance	41.4%
Managed Care	15.2%
Other (Government)	9.6%
Total	100.0%

Totals may not sum due to rounding

On page 96, the applicants state, “SOS and AHS assume that payer mix will remain relatively consistent with historical payer mix.” The applicants demonstrate that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

WFBI. The applicant addresses access to services in Section VI. The applicant provides the following payor mix for the facility (page 91) and for the MRI service (page 97) for the second full fiscal year of the proposed project.

**WFBI-Greensboro Fixed MRI Services
 Procedures as a Percent of Total Procedures
 CY2018**

	WFBI Facility	Fixed MRI Scanner
Self-Pay / Indigent / Charity*	1.8%	1.8%
Medicare	31.0%	31.0%
Medicaid	5.9%	5.9%
Commercial/ Managed Care/ BCBS	59.8%	59.8%
Workers Compensation	1.5%	1.5%
Total	100.0%	100.0%

Totals may not sum due to rounding

*On page 54, the applicant discusses performing 52 charitable scans in each of the first three project years.

On pages 91-92, the applicant states that there is a scarcity of publically available data for MRI payor mix information in Guilford County; however, it was able to obtain limited information and further states:

“Therefore, WFBI projects its Greensboro MRI payor mix for the initial three project years based on a weighted average of the: 1) 2015 payor mix at WFBI’s Winston-Salem MRI scanner for patients originating from Guilford County, 2) Cornerstone Imaging’s 2015 MRI payor mix, and 3) Triad Imaging’s 2015 MRI payor mix.”

On page 94, the applicant provides a table showing the weighted average of the above listed facilities. The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C-All Applications

Cone Health. In Section VI.9, page 84, the applicants document the range of means by which patients have access to the proposed services. The applicants state that patients typically are referred by area physicians and other hospitals. The applicants further state that patients may self-refer to the emergency department and, depending on their clinical diagnosis, may then be referred for primary or specialty services, including MRI services, as needed. The applicants state, "*Cone Health accepts referrals from a variety of organizations and will not turn patients away.*" The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

SOS. In Section VI.9, page 92, the applicants document the range of means by which patients have access to the proposed services. The applicants state, "*Access to SOS, including the proposed fixed MRI scanner is by physician's order; however, patients have the ability to choose where they receive their MRI scan.*" The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

WFBI. In Section VI.9, pages 88-89, the applicant describes the range of means by which a person will have access to WFBI's MRI services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C- All Applications

Cone Health. In Section V.1, pages 68-70, the applicants document that Cone Health accommodates the clinical needs of health professional training programs in the service area and that they will continue to do so. The applicants provide a list of the health professional training programs that currently utilize the training opportunities at Cone Health on pages 68-69. The information provided is reasonable and supports a finding of conformity with this criterion.

SOS. In Section V.1, page 76, the applicants state that SOS and AHS already have working relationships with local health professional training programs, are committed to accommodating the needs of those programs, and will make the fixed scanner available to students in the training programs, as appropriate. Exhibit 17 contains a copy of the policy providing guidelines for the provision of student affiliated training programs. The

information provided is reasonable and supports a finding of conformity with this criterion.

WFBI. In Section V.1, page 75, the applicant states that it already has established relationships with health professional training programs. Exhibit 8 contains a letter to Forsyth Technical Community College offering the proposed facility as a training site for MRI services. It also contains a list of the existing training agreements in place at WFBI. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

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

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

C- Cone Health
NC-SOS
C-WFBI

The 2016 SMFP includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2016 SMFP identified a need for one additional fixed MRI scanner in the Guilford County MRI Service Area.

On page 154, the 2016 SMFP defines the service area for fixed MRI scanners as *“a single county, except where there is no licensed acute care hospital located within the county.”* Thus, the service area for this project consists of Guilford County. Providers may serve residents of counties not included in their service area.

There are 11 existing fixed MRI scanners in Guilford County. There are no approved fixed MRI scanners in Guilford County, as defined in 10A NCAC 14C .2701(1). The following table identifies the provider, number of scanners, and average weighted scans per fixed MRI scanner, summarized from Table 9P of the 2016 SMFP, based on 2014 utilization data submitted by the providers.

Provider	Number of Fixed MRIs	Total Number of Weighted Scans	Average Weighted Scans per Scanner
Cone Health - Main and Wesley Long	3	15,996	5,332
High Point Regional Health	2	7,902	3,951
Cornerstone Imaging	1	6,022	6,022
DRI - Greensboro Imaging	3	14,171	4,724
Greensboro Orthopaedics	1	5,654	5,654
Triad Imaging	1	3,671	3,671
Total	11	53,416	4,856

Source: 2016 SMFP and 2015 Registration and Inventory of Medical Equipment (FFY2014 data)

Cone Health. The applicants propose to add one additional fixed MRI scanner on the Moses Cone Hospital main campus. In Section V.7, pages 75-77, the applicants discuss how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services, stating:

“Cone Health is a leader in the cost effectiveness and quality of hospital-based inpatient and outpatient services delivered to the residents of its service area as demonstrated by its recognition as a Community Value Five-Star Hospital by Cleverly & Associates. The proposed project, as an expansion of an existing service, will continue to foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area.

...

Cone Health is dedicated to providing high quality care services to all its patients. ... As was discussed in Section II, Cone Health’s Heart and Vascular Center and Neurosciences Center of Excellence promote competition by providing the highest quality care for those services in the community, as evidenced by numerous honors and awards...

...

Although Cone Health’s costs for hospital-based MRI services may be higher than those of freestanding outpatient MRI competitors, Cone Health’s MRI service covers a broader patient population with many types of conditions. ... Moses Cone Hospital’s MRI service treats patients with complex cardiovascular and neurological conditions who often require sedation or anesthesia, which increases costs. Moreover, Cone Health, as a fundamental part of its community service mission, makes these services available to all [emphasis in original] community residents.”

See also Sections II, III, V, VI, VII and XI where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicants in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicants demonstrate that they will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

SOS. The applicants propose to upgrade an existing mobile MRI scanner to a fixed MRI scanner to be located in a renovated imaging trailer permanently positioned on a concrete pad adjacent to SOS. The applicants currently provide MRI services on AHS mobile MRI scanners parked on a concrete pad adjacent to SOS. In Section V.7, pages 80-87, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants state:

“SOS and AHS are committed to developing and carrying out a quality improvement plan to ensure safety and quality.

...

Neither SOS nor AHS discriminates against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. Additionally, SOS has pledged to perform 12 MRI scans per year for three years at no cost to Guilford County School Systems students that are in need of an MRI scan, but whose families lack the funds to obtain an MRI scan. [emphasis in original]

...

The non-hospital based MRI charge leads to decreased insurer payments, patient deductible payments and copayments. Lower freestanding-based charges also leads to lower healthcare expenditure and hopefully result in lower health insurance premiums. [emphasis in original]

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

However, the applicants do not adequately demonstrate how any enhanced competition includes a positive impact on the cost effectiveness of the proposed services. Specifically, the applicants do not adequately demonstrate that their proposal is cost effective given that the applicant or a related entity operates mobile MRI scanners in Guilford County with capacity to meet the identified need. This determination is based on the information in the application and the determination that the applicants did not adequately demonstrate the need to acquire the proposed fixed MRI scanner or that their proposal is the most cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

Therefore, the application is not conforming to this criterion.

WFBI. The applicant, WFBI, proposes to acquire one fixed MRI scanner to be located in leased medical office space in Greensboro. In Section V.7, pages 78-80, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“WFBI proposes to establish a new, non-hospital based fixed MRI service in Guilford County. This is particularly important from a cost perspective because there is an economic benefit for payers and patients that choose a non-hospital based provider.

...

The proposed project will ensure future access to fixed MRI services for medically underserved patients, specifically Medicare and Medicaid patients.

...

The guiding principle of WFBI is to provide the comfort and convenience of outpatient care, while delivering the highest possible quality of care in a manner that is consistent with our Policies and Procedures, Mission and Values.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and

alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1), (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C- All Applications

Cone Health. In Section II.7, pages 24-25, and Exhibits 10 and 12, the applicants describe the methods used to insure and maintain quality care. On page 23, the applicants state that all Cone Health facilities, including Moses Cone Hospital, are accredited by the Joint Commission. In Exhibit 4, the applicants provide a list of Cone Health-owned health care facilities in North Carolina. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System manages Cone Health. Exhibit 5 contains a list of Carolinas HealthCare System owned and/or managed healthcare facilities in North Carolina. In Section II.7, pages 24-25, the applicants state that none of the licensed health service facilities owned or operated by the applicant, as identified by the applicant in Section I.12, pages 7-9, have had their licenses revoked or had their Medicare or Medicaid provider agreements revoked. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, one incident occurred at two of the 22 Cone Health/CHS owned or managed facilities within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems had been corrected. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Cone Health and Carolinas HealthCare System facilities, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

SOS. In Section II.7, pages 36-37, and Exhibits 12 and 13, the applicants describe the methods used by SOS and AHS to insure and maintain quality care. SOS is an American College of Radiology (ACR) accredited facility. In Section II.7(c), page 37, the applicant indicates that there have been no quality of care issues at the healthcare facilities identified in Section I.12. The information provided by the applicants is reasonable and supports the

determination that the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

WFBI. In Section II.6 and 7, pages 22-25, and Exhibit 8, the applicant describes the methods used by WFBI to insure and maintain quality care. In Section I.12, page 12, the applicant describes WFBH's acute care network as including Brenner Children's Hospital, Wake Forest Baptist Medical Center, Davie Medical Center and Lexington Medical Center. On page 12, the applicant states, "*WFBH also holds the Gold Seal of Approval from the Joint Commission, the nation's esteemed standards-setting and accrediting body for health care quality.*" In Section II.7(c), page 25, the applicant states that no license has ever been revoked for any of the healthcare facilities identified in Section I.12. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, two incidents occurred at North Carolina Baptist Hospital and one at Lexington Medical Center within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems had been corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at WFBH System facilities, WFUHS, and OIA, the applicant provided sufficient evidence that quality care has been provided in the past. The information provided by the applicant is reasonable and supports the determination that the applicant is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C- Cone Health and WFBI
NC- SOS

The applications submitted by Cone Health and WFBI were determined to be conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The application submitted by SOS was found not to be conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*
 - (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
 - (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- **All Applicants.** The applicants do not propose the acquisition of a mobile MRI scanner.

- (b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*
- (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-C- **Cone Health.** Cone Health owns and operates three existing fixed MRI scanners located in Guilford County. Diagnostic Radiology and Imaging,

LLC (DRI) is a joint venture between Cone Health and Greensboro Radiology P.A. and, therefore, is a related entity. DRI owns and operates three fixed MRI scanners in Guilford County. In Section II.8, page 29, the applicants provide the following table and state that Cone Health and DRI performed an average of 5,367 weighted scans per machine in FY2015, well in excess of the required average of 3,328 scans.

	# Scanners	Outpatient		Inpatient		Total Weighted Scans *	Average Weighted Scans
		W/O Contrast	W/ Contrast	W/O Contrast	W/ Contrast		
Moses Cone	2	3,128	1,234	4,008	1,217	12,657	6,329
Wesley Long	1	894	1,837	518	481	5,057	5,057
DRI	3	7,627	4,899	0	0	14,486	4,829
Total	6	11,649	7,970	4,526	1,698	32,200	5,367

*The applicants state that scans are weighted per the weighting system described on page 156 of the 2016 SMFP

- NA- **SOS.** In Section II.8, page 41, the applicants state that neither SOS nor AHS owns a controlling interest in a fixed MRI scanner in the proposed service area.
- C- **WFBI.** In Section II.8, page 29, the applicant states that neither WFBI nor a related entity owns a controlling interest in any fixed MRI scanners.

As of March 15, 2016, neither the applicant nor any related entity owned a controlling interest in any fixed MRI scanners in Guilford County. However, on page 30, the applicant states that it expects WFBH will acquire Cornerstone, gaining control of Cornerstone’s existing assets, including its existing fixed MRI scanner in Guilford County during the review of this application. Therefore, as WFBH is a related entity, the applicant provides the relevant historical utilization for Cornerstone’s fixed MRI scanner, stating:

“During FY2015, Cornerstone’s fixed MRI scanner performed 4,509 unweighted MRI procedures (1,593 procedures with contrast + 2,916 procedures without contrast), or 5,146 weighted MRI procedures.”

- (2) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

- NA- **Cone Health.** In Section II.8, page 29, the applicants state that neither Cone Health nor any related entities operate a mobile MRI scanner in Guilford County, the proposed service area.

- NC- **SOS.** In Section II.8, pages 42-43, the applicants state that AHS currently operates two mobile MRI scanners in the service area, one at SOS (Signa 447) and one at CNSA (Signa 451). The applicants provide spreadsheets in Exhibit 14 showing both scanners performed over 3,328 weighted MRI scans in the most recent 12-month period for which their data was available, March 1, 2015 through February 29, 2016. However, the applicant provides a table in Exhibit 4 identifying AHS-owned North Carolina MRI scanners, which shows that AHS operates six mobile scanners in Guilford County: ESP 27, Signa 294, Signa 413, Signa 447, Signa 451, and Signa 470. Furthermore, the 2016 Registration and Inventory of Medical Equipment for AHS's Signa 407 shows that scanner also operated in Guilford County, in addition to the counties listed in the applicant's table in Exhibit 4. Therefore, there appear to be seven AHS mobile MRI scanners which served host sites in Guilford County in the last reporting period. The applicant discussed only two of the seven. Nothing in the application as submitted documents that five of the seven mobile MRI scanners are no longer operating in Guilford County.

The Project Analyst was able to access the 2016 RIME submitted to the Healthcare Planning and Certificate of Need Section (Agency) by AHS on only three of the seven scanners listed above: Signa 407, Signa 447, and ESP 27.

On its 2016 RIME for Signa 447, AHS reported 5,341 procedures at SOS in Greensboro, Guilford County, which is above the 3,328 scan threshold, as required in 10A NCAC 14C .2703(b)(2). The following tables show the utilization reported for Signa 407 and ESP 27, as adjusted by the 2016 SMFP methodology for weighting MRI scans.

SIGNA 407
10/1/2014-9/30/2015

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Inpt w Contrast	Inpt w/o Contrast	Weighted Procedures
UNC	Alamance	272	60	212			296
MRI Specialists of the Carolinas	Cleveland	266	42	224			283
Yadkin Valley Community Hospital	Yadkin	57	7	49		1	60
WFBH Med Plaza	Forsyth	206	21	185			214
Moses Cone MedCenter High Point	Guilford	49	10	39			53
SOS	Guilford	124	1	123			124
Davie County Hospital	Davie	751	193	556	1	1	829
OrthoCarolina PA	Scotland	19	0	19			19
Randolph Spine Center	Mecklenburg	16	1	15			16
OrthoCarolina PA	Union	21	0	21			21
Total Procedures Reported on Signa 407 and Weighted		1,781					1,917

Source: January 2016 Registration and Inventory of Medical Equipment and 2016 SMFP Methodology
 Totals may not sum due to rounding

ESP 27
10/1/2014-9/30/2015

Sites Served	County	Unweighted Procedures	Outpt w Contrast	Outpt w/o Contrast	Weighted Procedures
Moses Cone MedCenter High Point	Guilford	645	152	493	706
UNC	Alamance	343	81	262	375
Carolina Neurosurgery & Spine	Guilford	194	64	130	220
Cone Health MedCenter-Kernersville	Forsyth	95	11	84	99
Wake Radiology Services	Wake	7	0	7	7
Onslow Memorial Hospital	Onslow	9	0	9	9
SOS	Guilford	31	0	31	31
Triangle Orthopedic	Wake	404	8	394	405
Duke Health Raleigh	Wake	188	90	98	224
Wake Radiology Services	Johnston	119	0	119	119
Total Procedures Reported on ESP 27 and Weighted		2,035			2,195

Source: January 2016 Registration and Inventory of Medical Equipment and the 2016 SMFP Methodology
 Totals may not sum due to rounding

As the tables above show, both the Signa 407 and ESP 27 scanners performed below the 3,328 weighted scan threshold, per the January 2016 RIME. It appears AHS did not submit the 2016 RIME forms for the other AHS scanners reported in Exhibit 4 as operating in Guilford County.

The applicant does not demonstrate that each existing mobile MRI scanner owned by the applicant or a related entity and operating in Guilford County performed at least 3,328 weighted scans during the most recent 12-month period for which the applicant has data. Therefore, the application is not conforming with this Rule.

-NA- **WFBI.** In Section II.8, page 30, the applicant states that neither WFBI nor any related entities have ownership in a mobile MRI scanner that operates in Guilford County.

(3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

(A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

(B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

(C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

(D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

(E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The 2016 SMFP shows that there are more than four (4) fixed MRI scanners located in the MRI service area of Guilford County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Guilford County is reasonably expected to perform 4,805 weighted MRI procedures in the third operating year.

C- **Cone Health.** In Section II.8, page 30, the applicants provide tables showing Cone Health's and DRI's projected MRI utilization for the proposed project's first three project years, FFY2018 through FFY2020, as shown below. Cone Health-Greensboro will own and operate four fixed

MRI scanners: Moses Cone Hospital main campus - two existing fixed scanners and one proposed fixed scanner; and Wesley Long – one existing fixed scanner. DRI will own and operate three existing fixed MRI scanners.

Cone Health Projected MRI Scans

Type of Scan	FFY2018	FFY2019	FFY2020
OP W/O Contrast	4,144	4,185	4,227
OP W/ Contrast	3,164	3,196	3,228
IP W/O Contrast	4,874	4,996	5,121
IP W/ Contrast	1,829	1,874	1,921
Total Scans	14,010	14,251	14,497
Weighted Scan Totals*	18,689	19,027	19,373
Average Weighted Scans	4,672	4,757	4,843

*The applicants state that scans are weighted per the weighting system described on page 156 of the 2016 SMFP.

Diagnostic Radiology and Imaging Projected Scans

Type of Scan	FFY2018	FFY2019	FFY2020
OP W/O Contrast	7,858	7,937	8,016
OP W/ Contrast	5,047	5,098	5,149
Totals	12,905	13,035	13,165
Weighted Totals*	14,925	15,074	15,225
Average Weighted Total	4,975	5,025	5,075

*The applicants state that scans are weighted per the weighting system described on page 156 of the 2016 SMFP

The applicants state that the average annual weighted MRI scan volume for Cone Health’s four fixed MRI scanners is projected to be 4,843 weighted MRI procedures per MRI scanner in the third operating year. The applicants further state that DRI, a related entity is projected to provide 5,075 weighted MRI scans per fixed MRI scanner in the proposed project’s third operating year. The application is conforming to this Rule.

- C- **SOS.** In Section II.8, page 44, the applicants state the annual weighted MRI scan volume for SOS’s proposed, and only, fixed MRI scanner is projected to be 5,409 weighted MRI procedures in the third operating year. The application is conforming to this Rule.
- C- **WFBI.** In Section II.8, page 31, the applicant states WFBI projects to perform 5,282 weighted MRI procedures during the third year of the proposed project. The applicant further states that Cornerstone will perform 5,302 weighted MRI procedures during CY2019, the proposed project’s third project year. The application is conforming to this Rule.

(4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

(A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

(B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

(C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

(D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

(E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-NA- **Cone Health.** In Section II.8, page 31, the applicants state that the proposed scanner will be located on the Moses Cone Hospital main campus with the existing fixed MRI service.

-NA- **SOS.** In Section II.8, page 45, the applicants state that the proposed fixed MRI scanner will be located at SOS, which is currently serviced by the AHS mobile MRI scanner.

-C- **WFBI.** In Section II.8, page 31, the applicant refers to 10A NCAC 14C .2703(b)(3), where it projects WFBI will perform 5,282 weighted MRI procedures and Cornerstone will perform 5,302 weighted procedures in CY2019, the third project year. The application is conforming with this Rule.

(5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

- NA- **Cone Health.** In Section II.8, page 31, the applicants state that neither Cone Health nor any related entities currently operate a mobile MRI scanner in Guilford County, the proposed MRI service area.
- NC- **SOS.** In Section II.8, page 46, the applicants state that AHS's mobile scanner at CNSA (Signa 451) will perform 3,580 weighted scans in FFY2020, the proposed project's third year of operation. The applicants are proposing that the Signa 407 mobile MRI will be upgraded to fixed; and correctly do not provide utilization for that scanner in response to this question. However, the applicants fail to discuss the utilization for the mobile scanner currently serving SOS (Signa 447) and the other AHS-owned mobile scanners that operate in Guilford County, as identified in the applicants' table in Exhibit 4 of the application. The applicants provide projections for the proposed fixed and only one mobile. Therefore the application is not conforming to this Rule.
- NA- **WFBI.** In Section II.8, page 32, the applicant states that neither WFBI nor any related entities have ownership in a mobile MRI scanner that operates in Guilford County.
 - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- C- **Cone Health.** The applicants' methodology and assumptions used for the above Cone Health projections are described in Section IV.1, pages 61-67. The applicants state on page 32, that the DRI projections are based on a 1.0% annual growth rate, which the applicants state essentially mirrors projected population growth in Guilford County from 2015 to 2020.
- NC- **SOS.** The applicants' methodology and assumptions used for these projections are described in Section IV.1(d), pages 67-74. However, the applicants fail to discuss the utilization for the mobile currently serving SOS (Signa 447) and the other AHS-owned mobile scanners that operate in Guilford County, as identified in Exhibit 4 of the application. The applicants provide projections for the proposed fixed and only one mobile. Therefore the application is not conforming to this Rule.
- C- **WFBI.** The applicant describes the methodology and assumptions used for its projections in Section III.1, pages 35-59.
 - (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- **All Applicants.** The applicants do not propose the acquisition of a fixed dedicated breast MRI scanner.

- (d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*
- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
 - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- **All Applicants.** The applicants do not propose the acquisition of a fixed extremity MRI scanner.

- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
 - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- **All Applicants.** The applicants do not propose the acquisition of a fixed multi-position MRI scanner.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2016 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for Guilford County. Because the three applications in this review collectively propose to acquire three additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Cone Health, is approved and the other applications, submitted by SOS and WFBI, are denied.

Demonstration of Need

WFBI and Cone Health adequately demonstrate the need for their respective proposals. In contrast, SOS does not adequately demonstrate the need for its proposal. Furthermore, SOS does not adequately demonstrate the need to upgrade the MRI service provided at SOS from mobile to fixed for the following reasons:

- The MRI services will still be located in a imaging trailer on a mobile pad adjacent to the SOS facility, and
- The applicants project to serve fewer patients on the proposed fixed scanner than were served in FFY2015 on the AHS mobile scanners at SOS.

SOS does not adequately explain why a fixed MRI scanner is needed to replace the mobile service given the level of service already available at SOS. On its 2016 RIMES, AHS reported a total of 5,496 hours of service and unweighted procedures at SOS in FFY2015. AHS reports each procedure as one hour of service and one patient. The proposed fixed scanner is projected to perform only 5,196 unweighted procedures and staffed to operate only 4,100 hours at SOS in FFY2020 (Section VII.5, page 102). Thus, it appears the applicants are proposing to serve fewer patients and offer less hours of service with the proposed fixed scanner than currently offered at SOS on the mobile equipment.

See the discussions regarding need found in Criterion (3). Therefore, the proposals submitted by WFBI and Cone Health are more effective alternatives than the proposal submitted by SOS.

Geographic Accessibility

The following table identifies the location of the existing fixed MRI scanners in Guilford County.

Facility	City/Town	Number of Fixed MRIs	Number of Scans
Cone Health - Moses Cone Main	1200 N. Elm St., Greensboro 27401	2	8,660
Cone Health – Wesley Long	501 N. Elm St., Greensboro 27403	1	3,484
High Point Regional Health	601 N. Elm St., High Point 27262	2	5,893
Cornerstone Imaging*	1814 Westchester Dr., High Point 27262	1	4,509
DRI - Greensboro Imaging	315 Wendover Ave., Greensboro 27408	2	10,791
DRI - Greensboro Imaging	3801 W. Market St., Greensboro 27407	1	1,515
Greensboro Orthopaedics	3200 Northline Ave., Greensboro 27408	1	5,495
Triad Imaging	2705 Henry St., Greensboro 27405	1	3,407
Total		11	43,754

Source: 2016 SMFP and 2015 Registration and Inventory of Medical Equipment

*2015 Registration and Inventory of Medical Equipment was not available, reflects 2016 Registration and Inventory of Medical Equipment scans

As shown in the table above, there are eleven existing fixed MRI scanners located in Guilford County, eight in Greensboro and three in High Point. All three applicants propose to locate the fixed MRI scanner in Greensboro. All three proposed sites are located in Central Greensboro, north of E. Wendover Avenue and between Battleground Avenue and N. O’Henry Blvd, within four miles of one another. Therefore, with regard to improving geographic accessibility to fixed MRI scanner services in Guilford County, the three proposals are comparable.

Ownership of Fixed MRI Scanners in Guilford County

There are eleven existing fixed MRI scanners in Guilford County, owned by six different providers. The following table identifies the provider, number of MRI scanners, and average utilization of each of the fixed MRI scanners, summarized from Table 9P of the 2016 SMFP.

Provider	Number of Fixed MRIs	Total Number of Weighted Scans	Average Weighted Scans per Scanner
Cone Health - Main and Wesley Long	3	15,996	5,332
High Point Regional Health	2	7,902	3,951
Cornerstone Imaging	1	6,022	6,022
DRI - Greensboro Imaging	3	14,171	4,724
Greensboro Orthopaedics	1	5,654	5,654
Triad Imaging	1	3,671	3,671
Total	11	53,416	4,856

Source: 2016 SMFP and 2015 Registration and Inventory of Medical Equipment

As shown in the table above, five of the 11 existing Guilford County fixed MRI scanners are hospital-based and six are in freestanding outpatient imaging centers. Hospital-based MRI scans are provided at three different hospital sites and freestanding outpatient scans are provided at five different sites. In addition, mobile MRI services are offered at nine outpatient MRI service sites in Guilford County. Moses Cone owns three of the eleven existing fixed MRI scanners located in Guilford County and is a member-owner of the three DRI-Greensboro Imaging scanners.

Cornerstone Imaging, which WFBI expects to take ownership of during this CON review, owns one of the existing fixed scanners. SOS and AHS do not own any of the fixed MRI scanners in Greensboro; however AHS does own existing mobile MRI scanners operating in Guilford County, the Signa 447 at SOS, the Signa 451 at CNSA, the Signa 407 mobile MRI which serves MedCenter High Point and the additional four AHS scanners listed in Exhibit 4 as operating in Guilford County.

Assuming the acquisition of Cornerstone Imaging by WFBI occurs during this CON review, only the proposal submitted by SOS would offer a new provider of fixed MRI services in Guilford County. However, SOS through AHS, already provides MRI services in Guilford County with AHS' mobile MRI services. The change in the actual MRI services being provided at SOS (from mobile to fixed) will be insignificant for all intents and purposes: the machine will be upgraded and the trailer will be renovated; however, the location, management and staffing will remain the same. Therefore, with regard to improving accessibility to an increased number of providers of MRI services in Guilford County, the three proposals are comparable.

Access by a Diverse Patient Population / Broad Range of Clinical Needs and Acuity

Cone Health proposes a need for MRI services to include services for inpatients, observation patients, neonates, emergency department patients and some outpatients, many of whom need contrast and /or sedation services. Moses Cone Hospital's MRI services provide scans for patients with complex cardiovascular and neurological conditions, co-morbidities, and trauma; patients who often require sedation or anesthesia and cannot be scanned in a freestanding outpatient setting.

Outpatient (non-hospital-based) scans are accessible on six fixed freestanding outpatient MRI scanners and another 2.11 fixed equivalent mobile scanners in nine different locations in Guilford County. Hospital-based scans are provided at only three sites in Guilford County. See table in Criterion (6).

SOS and WFBI propose to provide MRI services only to patients appropriately served in a freestanding outpatient setting. Furthermore, SOS does not provide any information on where the mobile scanner being removed from service at SOS will be located; thus, replacing the mobile scanner at SOS with a fixed scanner could effectively reduce access to MRI services in Guilford County if AHS decides to no longer serve Guilford County sites with the scanners currently serving SOS. The applicants do not say what will happen with these scanners, particularly the one that reportedly operated 5,341 hours at SOS during FFY2015.

Therefore, with regard to improving access to a more diverse patient population based on clinical needs and acuity, Cone Health is the most effective alternative.

Access by Underserved Groups

The following table shows each application's projected percentages of MRI procedures to be provided to Medicaid and Medicare recipients, and to self-pay, indigent and charity patients in the

second full fiscal year of operation following completion of the project, based on the information provided by the applicants in Section VI.15(a) of the applications. Generally, the application proposing to serve the higher percentages of underserved groups of patients is the more effective alternative with regard to this comparative factor.

APPLICANT	Projected Percentage of Total Procedures Provided to Medicare Recipients	Projected Percentage of Total Procedures Provided to Medicaid Recipients	Projected Percentage of Total Procedures Provided to Self-Pay/Indigent/Charity
Cone Health	46.3%	11.3%	8.2%
SOS	27.0%	5.8%	1.0%
WFBI	31.0%	5.9%	1.8%

As shown in the table above, Cone Health projects the highest percentage of services to be provided to Medicare recipients, the highest percentage of services to be provided to Medicaid recipients, and the highest percentage of services to be provided to Self-pay/Indigent/Charity. Therefore, the application submitted by Cone Health is the most effective alternative with regard to access by underserved groups.

Projected Average Revenue per MRI Procedure

The following table shows the projected gross and net revenues per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form C). Generally, the application proposing the lowest average gross and net revenues per MRI procedure is the more effective alternative with regard to this comparative factor, assuming all else is equal.

Third Operating Year	Cone Health	SOS	WFBI
Gross Patient Revenue	\$45,999,354	\$7,227,654	\$8,590,207
Deductions from Gross	\$37,883,451	\$5,256,908	\$6,042,328
Net Patient Revenue	\$8,115,903	\$1,970,746	\$2,547,879
Deduct Professional Fees*	N/A	(\$400,093)	(\$407,661)
Net Revenue Less Professional Fees	\$8,115,903	\$1,570,653	\$2,140,218
Adjustment for WFBI Expensed CC/BD^			(\$120,263)
Net Revenue Adjusted for Professional Fees and Expensed CC/BD	\$8,115,903	\$1,570,653	\$2,019,955
Unweighted MRI Procedures	14,497	5,196	4,571
Gross Revenue/Procedure	\$3,173	\$1,391	\$1,879
Net Revenue less Professional Fee /Procedure	\$560	\$302	\$442

Source: Applicants' Form C and accompanying assumptions

*Cone Health - physician fees are contract billed to patient (Section II, page 21)

^WFBI expensed Charity Care and Bad Debt – Analyst deducted from revenue for comparison purposes

As shown in the table above, SOS projects the lowest average gross and net revenues per MRI procedure in the third operating year; however, SOS did not adequately demonstrate the need to

acquire a fixed MRI scanner to be located in Guilford County and therefore cannot be approved. The discussion regarding need found in Criterion (3) is incorporated herein by reference. WFBI projects the second lowest average gross and net revenues per MRI procedure; therefore the application submitted by WFBI is the more effective alternative with regard to projected average gross and net revenues per MRI procedure.

Charges for MRI services provided at a freestanding outpatient facility are typically less than those provided at a hospital. However, a tertiary hospital provides services to a broader patient population, including emergency and inpatients or patients with co-morbidities. Some of these patients may require sedation or anesthesia which cannot be performed in a freestanding outpatient facility. Therefore, a direct comparison of average revenues per procedure between a tertiary hospital and freestanding outpatient facilities may be of little value.

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Generally, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative with regard to this comparative factor, assuming all else is equal.

Third Operating Year	Cone Health	SOS	WFBI
Total Operating Expenses	\$3,323,672	\$1,635,486	\$2,162,134
Deduct Professional Fees*	N/A	(\$400,093)	(\$407,661)
Operating Expenses less Professional Fees	\$3,323,672	\$1,235,393	\$1,754,473
Adjustment for WFBI Charity Care/Bad Debt^			(\$120,263)
Operating Expenses less Professional Fees and Adjustment for CC/BD	\$3,323,672	\$1,235,393	\$1,634,210
Unweighted MRI Procedures	14,497	5,196	4,571
Operating Expense/Procedure	\$229	\$238	\$358

Source: Applicants’ Form C and accompanying assumptions

*Cone Health - physician fees are contract billed to patient (Section II, page 21)

^WFBI expensed Charity Care and Bad Debt – Analyst deducted it for comparison purposes

As shown in the table above, Cone Health projects the lowest average operating expense per MRI procedure in the third operating year. Therefore, the application submitted by Cone Health is the most effective alternative with regard to projected average operating expense per MRI procedure.

SUMMARY

The applications submitted by Cone Health and WFBI were determined to be conforming to all applicable statutory and regulatory review criteria.

In contrast, the application submitted by SOS was determined to be nonconforming to Criteria (3), (4), (6), (18a) and 10A NCAC 14C .2703(b)(2), (5) and (6). Therefore, the application cannot be approved standing alone.

For each of the comparative analysis factors listed below, the application submitted by Cone Health was determined to be the more effective alternative than the application submitted by WFBI:

- Access by patients with diverse clinical needs and acuity, including emergency department and hospital inpatients
- Access by underserved groups
- Operating Expense per Procedure

CONCLUSION

The Agency determined that the application submitted by Cone Health, Project I.D. #G-11147-16, is the most effective alternative proposed in this review for the additional fixed MRI scanner for the Guilford County service area and is approved. The approval of the applications submitted by SOS and WFBI would result in fixed MRI scanners in excess of the need determination for Guilford County. Consequently, the applications submitted by SOS and WFBI are denied.

The application submitted by Cone Health is approved subject to the following conditions.

- 1. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall materially comply with all representations made in the certificate of need application.**
- 2. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall acquire no more than one additional fixed MRI scanner as part of this project, for a total of four fixed MRI scanners on the hospital license.**
- 3. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
- 4. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**