



May 2, 2016

Via email and USPS

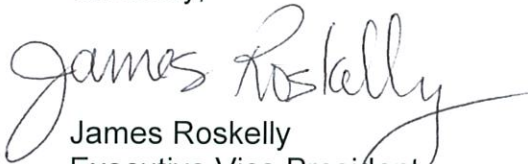
Ms. Martha J. Frisone, Assistant Chief, Certificate of Need
Ms. Celia Inman, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Written Comments on CON Project ID# G-11148-16

Dear Ms. Frisone and Ms. Inman:

In accordance with NCGS § 131E-185(a1)(1), please find enclosed written comments from Cone Health regarding CON Project ID #G-11148-16, an application filed by Southeastern Orthopedic Specialist and Alliance HealthCare Services to acquire a fixed MRI scanner in Guilford County, NC. Please let me know if you have any questions regarding these comments or if I can provide additional information. Thank you for the opportunity to submit these comments.

Sincerely,


James Roskelly
Executive Vice President
Strategic Development

JR/jc

Attachment

**Written Comments regarding Southeastern Orthopaedic Specialists
and Alliance HealthCare Services
Fixed MRI CON Application, Project I.D. #G-11148-16**

Introduction

The following comments are filed by Cone Health (CH) in response to the competing CON application filed by Southeastern Orthopaedic Specialists, P.A. (SOS) and Alliance HealthCare Services, Inc. (AHS) for a fixed MRI scanner in Guilford County, NC. These comments are filed in accordance with NCGS 131E-185(a1)(1). Cone Health's application is the most effective alternative to improve the access and quality of care for MRI services for all residents in Guilford County for the following reasons:

- SOS/AHS's proposed project does not adequately ensure access for medically indigent and underserved persons
- SOS/AHS's proposed project provides services to a limited set of patients, primarily orthopedic patients

The comments below are organized by review criterion, as provided in §131E-183.

Criterion 1 – NCGS § 131E-183(a)(1)

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

Policy GEN-3: Basic Principles in the 2016 State Medical Facilities Plan reads in part:

“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 comparison of SOS/AHS's proposed payor mix and Cone Health's proposed payor mix based on actual historical payor mix demonstrate that Cone Health's proposed project will serve a significantly larger percentage of medically indigent or low income persons and

Medicaid and Medicare recipients. For this reason, Cone Health’s proposed project is superior.

Comparison of SOS/AHS and CH MRI Proposed Project Payor Mix

Payor	SOS/AHS	CH	Difference
Self-Pay	1.0%	8.2%	(7.2%)
Medicare	27.0%	46.3%	(19.3%)
Medicaid	5.8%	11.3%	(5.5%)
Commercial / Managed Care	56.6%	31.6%	25.0%
Other	9.6%	2.6%	(7.0%)
Total	100.0%	100.0%	

Source: Cone Health Project ID #G-11147-16 and Southeastern Orthopaedic Specialists and Alliance HealthCare Services Project ID #G-11148-16 CON applications

Additionally, a comparison of SHS/AHS and CH’s charity care and bad debt amounts, demonstrates that on a per scanner basis, Cone Health projects significantly greater amounts of charity care and bad debt to be provided to the community.

Comparison of SOS/AHS and CH Charity Care and Bad Debt In Project Years 1 and 2

	SOS/AHS (1 MRI scanner)	CH (average per MRI scanner for 4 scanners)	Difference
Charity care/bad debt in dollars, year 1	\$81,993	\$1,206,973	(\$1,124,980)
Charity care/bad debt in dollars, year 2	\$82,712	\$1,251,263	(\$1,168,551)

Source: Cone Health Project ID #G-11147-16 and Southeastern Orthopaedic Specialists and Alliance HealthCare Services Project ID #G-11148-16 CON applications

As demonstrated above, Cone Health’s proposed project is superior to SOS/AHS’s proposed project for promoting equitable access and providing access to services for patients with limited financial resources.

Criterion 3 – NCGS § 131E-183(a)(3)

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

As described above in response to Criterion 1, SOS/AHS’s proposed project does not provide an adequate level of access to the proposed services for all residents of the area, in particular low income and medically underserved patients. SOS/AHS project that Medicare, Medicaid, or self pay patients will only make up 33.8% of the population proposed to be served. In comparison, Medicare, Medicaid, or self pay patients make up 65.8% of the patients Cone Health currently provides MRI scans to, and Cone Health projects to continue to serve that level of medically underserved patients.

The relevant CON criteria and standards for MRI scanners found at 10A NCAC 14C .2703 (b)(2) requires the applicant to:

“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 scanner.]”

AHS states that it operates two mobile MRI scanners in the service area, at Southeastern Orthopaedic Specialists and Carolina Neurosurgery and Spine Associates, and provides unweighted and weighted MRI scans on both scanner from March 1, 2015 to February 29, 2016. In Exhibit 4 of the application, AHS lists six (6) MRI scanners with a Guilford County location. Relevant scanners listed in Exhibit 4 are excerpted below.

Name	Mobile/Fixed	County Location	Vendor	Model	Serial Number
ESP 27	Grandfathered Mobile MRI	Guilford, Alamance, Forsyth, Wake, Onslow, Johnson	Siemens	1.5T Espree	1S9FA4825Y1182327
Signa 294	G-7038-04 Mobile MRI	Avery, Chatham, Henderson, Guilford, Alleghany, Buncombe, Martin, Person	GE	1.5T Horizon ES LX	1S9FA482231182634
Signa 413	Grandfathered Mobile MRI	Guilford, Davie, Cabarrus, Iredell	GE	1.5T Horizon ES LX	1S9FA482451182783
Signa 447	Grandfathered Mobile MRI	Guilford	GE	1.5T Horizon ES LX	1S9FA482171183120
Signa 451	Grandfathered Mobile MRI	Guilford, Cabarrus	GE	1.5T Horizon ES LX	1S9FA482431182635
Signa 470	Grandfathered Mobile MRI	Person, Chatham, Guilford	GE	1.5T Horizon ES LX	1KKVA48283L211004

Source: Exhibit 4; CON Application Project ID #G-11148-16

However, no data are provided verifying whether four of these six scanners were in fact operational in Guilford County for the relevant time period or demonstrating whether these scanners met the required threshold.

In identifying the patient population, SOS/AHS state that “by not submitting a CON application and by allowing another CON applicant to own and operate the available fixed MRI scanner, SOS and AHS do little to address growing outpatient MRI needs and the need to offer a non-hospital based MRI scanner that can offer less expensive, more cost effective services to patients and insurance providers.”¹ Yet, the applicants provide no detail regarding growing outpatient MRI needs and the need to offer a non-hospital based MRI scanner. Currently, there are 11 sites in Guilford County that provide freestanding outpatient services to residents of Guilford and surrounding counties. There are only two (2) sites that provide complex MRI services to inpatients, which SOS/AHS’s proposed project will not be able to provide. Services such as functional MRI (fMRI), cardiac, and neonatal MRI scans cannot be provided in an outpatient setting. SOS/AHS have not demonstrated that the need in the community is for freestanding outpatient scans.

Additionally, the applicants also do not provide any detail regarding the need for orthopedic outpatient scans in the market. SOS/AHS serve primarily orthopedic patients on the existing mobile scanner, and there is no indication that the patient population will be expanded beyond orthopedic patients. Cone Health’s proposed project will serve many specialties, including orthopedic, neurologic, trauma, pediatric, cardiac, and others.

Criterion 6 – NCGS § 131E-183(a)(6)

The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

SOS/AHS state that the proposed project will improve outpatient access and patient wait times. However, the proposed project does not demonstrate that patients do not already have adequate access to outpatient services. In fact, the last three (3) fixed MRI scanners awarded in Guilford County were for freestanding outpatient settings, as provided in the table below.

¹ SOS/AHS CON Application for Project ID #G-11148-16, p. 58

Fixed MRI Scanners Awarded since 2000

CON Project ID	Service Site
G-006952-03	Greensboro Imaging (Diagnostic Radiology & Imaging L.L.C.)
G-007269-05	Cornerstone Imaging (Cornerstone Health Care, P.A.)
G-008347-09	Greensboro Orthopaedics (Greensboro Orthopaedics, P.A.)

Source: 2016 SMFP Table 9P: Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

Criterion 13 - NCGS § 131E-183(a)(13)

The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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.

As discussed under Criterion 1, a comparison of SOS/AHS's proposed payor mix and Cone Health's proposed payor mix based on actual historical payor mix demonstrate that Cone Health's proposed project will serve a significantly larger percentage of medically indigent or low income persons and Medicaid and Medicare recipients. For this reason, Cone Health's proposed project is superior.