



May 2, 2016

Via email and USPS

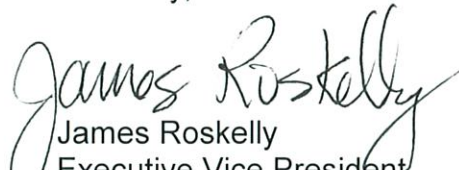
Ms. Martha J. Frisone, Assistant Chief, Certificate of Need
Ms. Celia Inman, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Written Comments on CON Project ID# G-11149-16

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-11149-16, an application filed by Wake Forest Baptist Imaging, LLC 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 Wake Forest Baptist Imaging, LLC
Fixed MRI CON Application, Project I.D. #G-11149-16**

Introduction

The following comments are filed by Cone Health (CH) in response to the competing CON application filed by Wake Forest Baptist Imaging, LLC (WFBI) 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.

The WFBI project is non-conforming with several CON review criteria for the reasons detailed below, and Cone Health contends that the Agency must disapprove the pending CON application for the following reasons:

- WFBI fails to reasonably identify the population to be served and to demonstrate the need that this population has for the services proposed
- WFBI fails to substantiate its assumptions
- WFBI's proposed project does not adequately ensure access for medically indigent and underserved persons

Even if the Agency determines that WFBI's application conforms with all relevant criteria, Cone Health's application is superior and should be approved for the reasons detailed below.

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 WFBI’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 WFBI and CH MRI Proposed Project Payor Mix

Payor	WFBI	CH	Difference
Self-Pay	1.8%	8.2%	(6.4%)
Medicare	31.0%	46.3%	(15.3%)
Medicaid	5.9%	11.3%	(5.4%)
Commercial	59.8%	31.6%	28.2%
Other	1.5%	2.6%	(1.1%)
Total	100.0%	100.0%	

Source: Cone Health Project ID #G-11147-16 and Wake Forest Baptist Imaging Project ID #G-11149-16 CON applications

Additionally, a comparison of WFBI 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 WFBI and CH Charity Care and Bad Debt In Project Years 1 and 2

	WFBI (1 MRI scanner)	CH (average per MRI scanner for 4 scanners)	Difference
Charity care/bad debt in dollars, year 1	\$154,002	\$1,206,973	(\$1,052,971)
Charity care/bad debt in dollars, year 2	\$180,936	\$1,251,263	(\$1,070,327)

Source: Cone Health Project ID #G-11147-16 and Wake Forest Baptist Imaging Project ID #G-11147-16 CON applications

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.

WFBI does not adequately identify the population to be served by the proposed project, does not demonstrate the need that this population has for the proposed services, and does not demonstrate that all residents of the area, in particular low income and medically underserved groups will have access to the services proposed.

WFBI states that more than 300 Guilford County residents utilized MRI services at WFBI last year, demonstrating a “strong referral base” and established relationships with referral sources and patients in Guilford County.¹ However, if each patient receives one scan, 300 scans represents just 0.5% of scans performed in Guilford County, based on published volume data from the 2016 SMFP. Although not all the scans performed in Guilford County were for Guilford County residents, 300 scans for Guilford County patients is not indicative of a strong referral base.

WFBI states that it will be a cost effective alternative for Medicare, Medicaid, and uninsured patients as compared to a hospital outpatient department.² However, WFBI projects that Medicare, Medicaid, or self-pay patients will only make up 38.7% 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 scans to, and Cone Health projects to continue to serve that level of medically underserved patients. Also on p. 21, WFBI states, for information purposes, that there are 874 WFBH employees (not including their spouses and/or dependents) that reside in Guilford County. However, WFBI does not provide any relevant information projecting how many of these employees and/or family members might require scans and might be served on the proposed scanner annually.

WFBI states that the proposed project will be available to all patients, regardless of ability to pay. The applicant also states that “WFBI will provide up to 52 charitable scans each year in the local community.”³ This paltry level of charitable care is insufficient to meet need in the community. Additionally, WFBI does not propose to increase the volume of charitable scans each year. In contrast, in FY 2015, Cone Health provided 1,094 MRI scans to self-pay/medically indigent patients in Guilford County. Cone Health’s proposed project expects to provide approximately 1,191 MRI scans to self-pay/medically indigent patients in FY 2020 to patients, or 298 per scanner for four (4) scanners.

WFBI relies on its proposed purchase of Cornerstone Health Care as a primary source of referrals for the proposed project. As the map included as Exhibit 1 demonstrates, only four Cornerstone practices with 12 physicians are located within 5 miles of the proposed site. In fact, the majority of Cornerstone practices are located in High Point, more than 20 miles from the proposed site. There are 11 existing fixed or mobile scanners located in closer proximity to the Cornerstone High Point-based practices than the proposed location.

¹ WFBI CON Application for Project ID #G-11149-16, p. 11

² Ibid, p. 21

³ Ibid, p. 22

Additionally, Triad Imaging, a freestanding, fixed outpatient MRI provider, which was utilized at 53.5% in FY 2014 per the 2016 SMFP, is located just 2.7 miles from the proposed WFBI site.

WFBI also relies on its network of physicians located in Guilford County, including the consolidation and relocation of several of its physician specialty practices in a Medical Plaza on N. Elm Street in Greensboro. However, WFBI does not provide any detail regarding the number of physicians practicing in this location, the associated patient visits or MRI referrals from this location, or where those practices are currently referring MRI patients.

WFBI references more than 100 letters of support from local referring physicians provided in Exhibit 19 of the application. Of those 100 letters, 32 are from physicians located at Miller Plaza in Winston-Salem, more than 32 miles from the proposed MRI location, and nine are from providers located in Kernersville, more than 21 miles from the proposed MRI location. There is no detail provided to explain why these physicians would refer patients to an outpatient MRI scanner in Guilford County at such a distance, and no detail regarding the specific number of scans these physicians project to refer to the proposed project.

WFBI projects that the proposed project will garner 5.0% Guilford County market share in FY 2017, growing to 9.0% market share in FY 2019.⁴ However, there is no quantitative detail provided to demonstrate that a 5.0% market share, growing to 9.0%, is reasonable. There are no detailed projections of volume from the physician letters of support. For these reasons, WFBI's projected volumes are unreasonable and unsupported.

WFBI projects that the existing Cornerstone fixed MRI scanner will continue to operate above the administrative performance standard of 4,805 weighted MRI procedures and that Cornerstone will no longer have access to a mobile MRI scanner.⁵ WFBI states that Cornerstone can effectively decompress capacity constraints on its existing service by referring patients to WFBI's proposed fixed MRI scanner in Guilford County. However, more than three dozen Cornerstone physicians have left the practice and are now employed by other practices including UNC Regional Physicians, Novant Health, and other practices in the past two (2) years. Therefore, it is difficult to determine if that high utilization of Cornerstone's existing fixed MRI scanner will continue.

WFBI states that patients desire increased access to cost effective MRI services. However, WFBI does not demonstrate that freestanding, outpatient services are needed. In fact, the last three (3) fixed MRI scanners awarded in Guilford County were for freestanding outpatient settings, as provided in the table below.

⁴ Ibid, p. 49

⁵ Ibid, 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 4 – NCGS § 131E-183(a)(4)

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

WFBI notes that an alternative to the proposed project is to develop it in another geographic area of Guilford County. WFBI reviewed the distribution of population and existing fixed MRI scanners in Guilford County, determining that both population centers of High Point/Jamestown and Greensboro are equitably served. However, WFBI states that WFBI's proposed location in Greensboro is in close proximity to referring physicians. As demonstrated in the map in Exhibit 3, the proposed location is not in close proximity to most physicians who submitted letters of support for the proposed project. In fact, 55, or 48.7%, of the letters of support are from providers who are not located in Guilford County. Therefore, WFBI has not demonstrated that the proposed location is the most effective alternative.

WFBI states that "with its proposal to acquire and install a fixed MRI scanner in Guilford County, WFBI will establish a local cost effective provider of fixed MRI services, and will greatly improve access to MRI services for the residents of Greensboro and surrounding communities."⁶ However, WFBI's proposed project only improves access to MRI services for outpatients. It does not improve access to MRI services for inpatients. There are currently 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 WFBI'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. WFBI has not demonstrated that the need in the community is for freestanding outpatient scans. As demonstrated in Cone Health's application, there is adequate freestanding outpatient capacity in Guilford County, but there is not adequate capacity for inpatient and complex outpatient scans.

⁶ Ibid, p. 66

WFBI is non-conforming to multiple criteria and therefore, cannot be approved. An application that cannot be approved is not an effective alternative, and therefore cannot conform to this criterion.

Criterion 5 – NCGS § 131E-183(a)(5)

Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

As described in detail under Criterion 3, WFBI's projected volumes are unreasonable and unsupported, and therefore cannot be used to demonstrate the immediate and long-term financial feasibility of the proposed project.

WFBI states that provision of outpatient MRI services in a freestanding facility is more cost effective than MRI services provided in a hospital setting because the outpatient facility does not experience the operational overhead costs associated with a hospital. However, a freestanding outpatient facility is also more limited in its services to the community than a hospital. A hospital serves not only low acuity outpatients, but also inpatients and complex, high acuity outpatients. Freestanding outpatient facilities are often limited in the types of specialties they are able to serve. Hospitals serve all types of specialties. Finally, a freestanding outpatient facility is not subject to EMTALA and does not serve all patients presenting to an emergency department with a clinical need for an MRI scan. A hospital setting serves all these patients, regardless of ability to pay, as demonstrated by our payor mix. Therefore, CH's proposed project serves a broader segment of the community than the one proposed by WFBI.

Also, their total Net Revenue on Form E does not match their total Net Revenue on Form C. This inconsistency casts doubt on the accuracy of their financial statements.

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.

WFBI states that the proposed project will establish a new, cost-effective provider of fixed MRI services in Guilford County. However, WFBI does not demonstrate that its proposed project does not duplicate existing freestanding outpatient health service capabilities or facilities.

WFBI states that many of their referrals will come from Cornerstone HealthCare physicians, which is being purchased by Wake Forest Baptist Health. However, Cornerstone is, and has been, an existing provider of MRI services in Guilford County for many years. Therefore, WFBI is not really a new entrant into the market. WFBI is relying on existing

providers in the county. WFBI states that the proposed location is in close proximity to multiple medical facilities, including Wake Forest Baptist.⁷ In fact, the proposed location is over 30 miles from a Wake Forest Baptist acute care facility.

In response to Question III.6.(b), WFBI states that existing providers do not currently have the capacity to meet the growing need for MRI services, resulting in a need determination.⁸ However, WFBI does not explain or provide specific documentation of the inadequacy or inability of existing providers to meet the identified need and does not explain why its proposed project is superior. In fact, the last three (3) MRI scanners awarded in Guilford County were for freestanding outpatient settings, and it has been sixteen (16) years since an MRI CON was awarded to serve an acute care facility in Guilford County.

Criterion 8 – NCGS § 131E-183(a)(8)

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

In Section II of the application, WFBI identifies the ancillary and support services that will be required for the proposed project and notes which entity will provide those services.⁹ However, no documentation is provided supporting the availability of these ancillary and support services.

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 noted previously, a comparison of WFBI'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.

⁷ Ibid, p. 18

⁸ Ibid, p. 71

⁹ Ibid, p. 19-20

Comparison of WFBI and CH MRI Payor Mix

Payor	WFBI	CH	Difference
Self-Pay	1.8%	8.2%	(6.4%)
Medicare	31.0%	46.3%	(15.3%)
Medicaid	5.9%	11.3%	(5.4%)
Commercial	59.8%	31.6%	28.2%
Other	1.5%	2.6%	(1.1%)

Source: Cone Health Project ID #G-11147-16 and Wake Forest Baptist Imaging Project ID #G-11147-16 CON applications

Comparison of WFBI and CH Charity Care and Bad Debt In Project Years 1 and 2

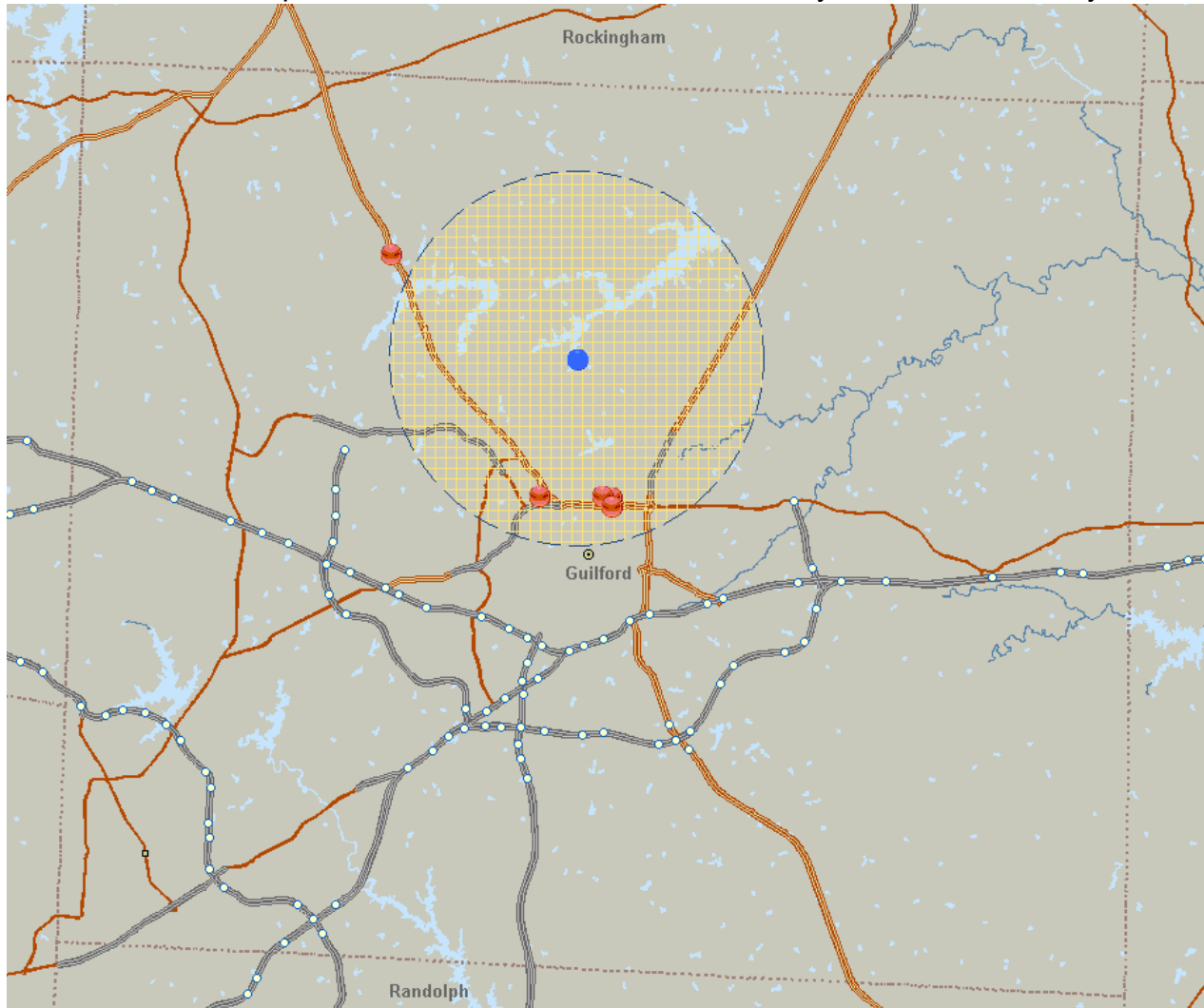
	WFBI (1 MRI scanner)	CH (average per MRI scanner for 4 scanners)	Difference
Charity care/bad debt in dollars, year 1	\$154,002	\$1,206,973	(\$1,052,971)
Charity care/bad debt in dollars, year 2	\$180,936	\$1,251,263	(\$1,070,327)

Source: Cone Health Project ID #G-11147-16 and Wake Forest Baptist Imaging Project ID #G-11149-16 CON applications

Exhibit 1

Map of WFBI's North Elm Street
Proposed Fixed MRI Location with
Proximity to Cornerstone Physicians

Map of WFBI's North Elm Street Proposed Fixed MRI Location with Proximity to Cornerstone Physicians



Map illustrates a 5 mile radius from the proposed fixed MRI scanner placement location on North Elm St, and Cornerstone practices within the five mile radius

Source: Cornerstone Healthcare website, find a provider, accessed 5/2/16.

Exhibit 2

Letters of Support and Distance from
Proposed Site

Letters of Support and Distance from Proposed Site

Practice Name	City	Number of Letters	Miles from Proposed Site
Wake Forest Baptist Urgent Care Mocksville	Mocksville	1 - PA	55.1
Davie Medical Center	Bermuda Run	2 - PA	44.4
Wake Forest Baptist Miller Plaza	Winston-Salem	32 - MD	32.8
Wake Forest School of Medicine	Winston-Salem	1 - MD	32.6
Cornerstone Internal Medicine	High Point	4 - MD	24.6
Cornerstone Foot & Ankle Specialists at Westchester	High Point	4 - MD	24.6
Triad Adult and Pediatric Medicine - Family Medicine at Commerce	High Point	1 - MD	24.5
Cornerstone Health Care Administration	High Point	1 - MD	23.8
Wake Forest Baptist Health - Laurel Creek	Kernersville	1 - PA; 2 - NP;	22.4
Cornerstone Pediatric Associates of Kernersville	Kernersville	1 - MD; 2 - NP; 1 - PA	21.4
Wake Forest Baptist Health Pediatrics - Kernersville	Kernersville	1 - MD; 1 - NP	21.4
Cornerstone Pediatrics at Premier	High Point	6 - MD; 1 - NP; 1 - PA	15.1
Cornerstone Endocrinology	High Point	2 - MD; 1 - NP; 1 - PA	15.1
Cornerstone Nephrology	High Point	3 - MD	15.1
Cornerstone Internal Medicine at Premier	High Point	1 - MD	15.1
Cornerstone Family Medicine at Premier	High Point	5 - MD; 2 - PA	15.1
Cornerstone Family Practice at Summerfield	Summerfield	2 - MD; 2 - PA	9.0
Wake Forest Baptist Health - Summerfield Family	Summerfield	1 - NP	5.8
Triad Adult and Pediatric Medicine Pediatrics at Wendover	Greensboro	1 - MD	5.1
Triad Internal Medicine	Greensboro	2 - MD; 1 - NP	4.1
Sports Medicine & Joint Replacement of Greensboro	Greensboro	1 - MD; 2 - PA	4.0
Carolina Bone & Joint	Greensboro	3 - MD	3.6
Guilford Medical Associates	Greensboro	5 - MD	2.7
Orthopedic & Hand Specialists	Greensboro	1 - MD	2.2
Wake Forest Baptist Medical Plaza - North Elm	Greensboro	12 - MD; 1 - NP; 1 - PA	0.0

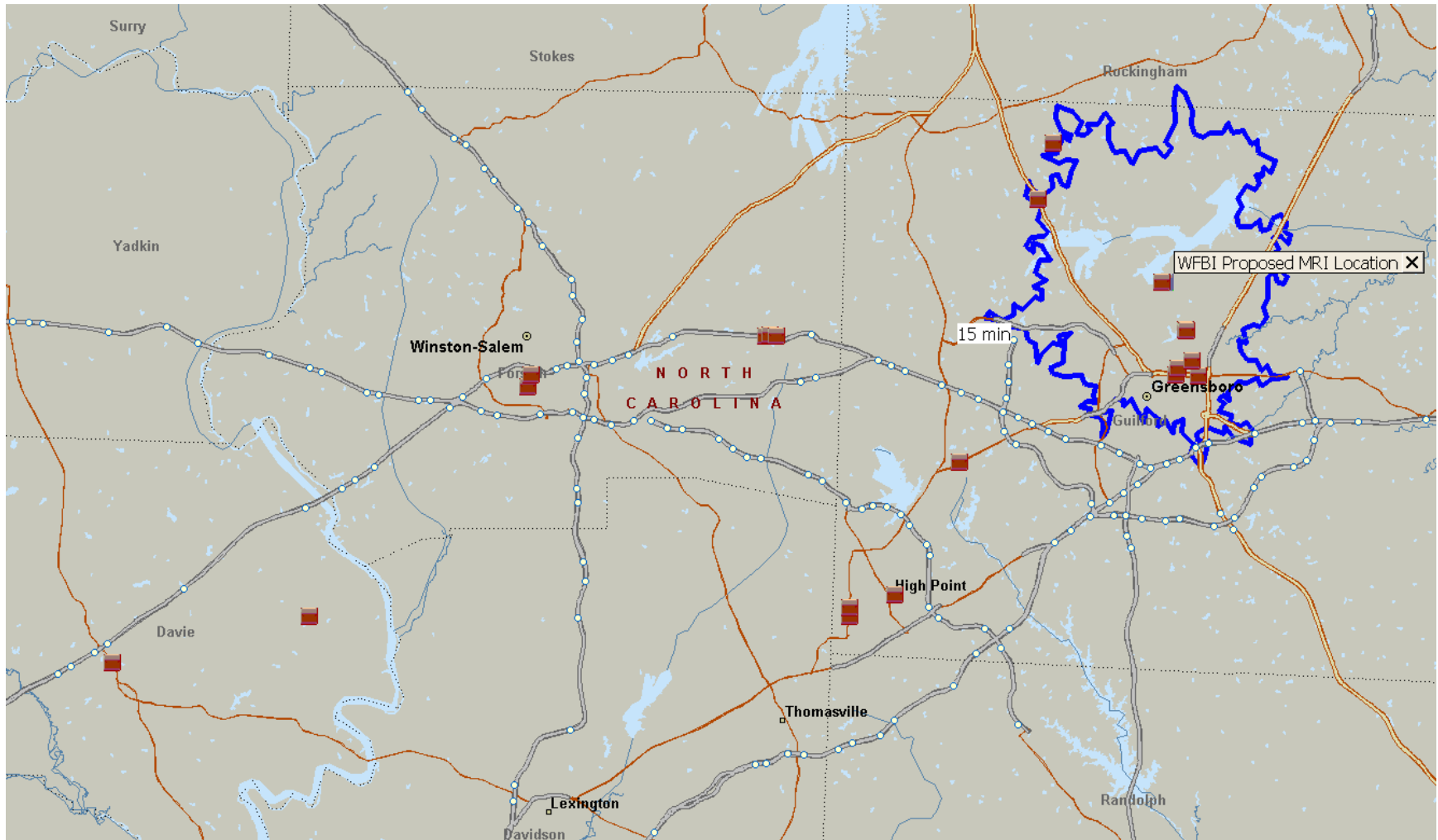
Source: WFBI CON application, Project ID #G-11149-16

Please note that not all letters contained information identifying the practice name and address. In those cases, CH researched the names provided to determine a location, and verified through provider websites when possible. When the signatures were unclear, or the roles not stated, CH assumed that the signer was a physician provider. Two duplicate letters were deleted from the totals.

Exhibit 3

Map of Practices Providing a Letter of
Support for WFBI MRI CON
Application and 15 Minute Drive Time
Radius from Proposed North Elm
Street Location

Map of Practices Providing a Letter of Support for WFBI MRI CON Application and 15 Minute Drive Time Radius from Proposed North Elm Street Location



Source: WFBI CON application, Project ID #G11149-16