

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF FACILITIES SERVICES  
RALEIGH, NORTH CAROLINA**

IN RE: REQUEST FOR DECLARATORY )  
RULING BY BLUE RIDGE ) **DECLARATORY RULING**  
RADIOLOGY ASSOCIATES, P.A. )  
PROJECT I.D. No. E-7066-04 )

I, Robert J. Fitzgerald, as Director of the Division of Facility Services, North Carolina Department of Health and Human Services (“Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A N.C.A.C. 14A.0103 under the authority granted me by the Secretary of the Department of Health and Human Services. This new Declaratory Ruling is issued in response to the ruling made by the Honorable Richard D. Boner (“Judge Boner”) on February 13, 2007 and filed in Lincoln County Superior Court on February 19, 2007, pursuant to which Judge Boner reversed and remanded this matter to the Agency to make specific findings of fact based upon substantial evidence regarding whether Blue Ridge Radiology Associates, P.A.’s (“BRRRA”) request to change host sites for its mobile MRI from Catawba Valley Medical Center in Hickory, North Carolina (“CVMC”) to a physician’s office, Blue Ridge Radiology Associates, P.A. in Lincolnton, North Carolina (“Blue Ridge Lincolnton”) constitutes a material change in the physical location or scope of the project.

This new Declaratory Ruling contains specific findings of fact based upon substantial evidence which support both the Agency’s original Declaratory Ruling and this new Declaratory Ruling’s determination that BRRRA’s requested change in host site from CVMC to Blue Ridge Lincolnton is not a material change in the physical location or scope of the project. This Declaratory Ruling is issued after a thorough analysis of the following documents: BRRRA’s

original Declaratory Ruling Request dated November 22, 2005; the January 26, 2007 and February 27, 2007 letters from BARRA's counsel; BARRA's Certificate of Need application and progress reports in Project I.D. # E-7066-04; the Required State Agency Findings approving BARRA's Certificate of Need application in Project I.D. # E-7066-04; agency files related to other MRI Certificates of Need; the applicable State Medical Facilities Plans; the Petition for Judicial Review filed by Lincoln Medical Center and Lincoln Health System (collectively, "Lincoln Medical") in Lincoln County Superior Court, 06 CVS 00565; BARRA's Answer to Petition for Judicial Review; Lincoln Medical's Memorandum of Law in Support of Petition for Judicial Review; BARRA's Memorandum of Law in Opposition to Petition for Judicial Review; the Agency's Brief in Response to Petitioners' Petition for Judicial Review; Lincoln Medical's Proposed Order submitted to Judge Boner via letter dated February 12, 2007; BARRA's Proposed Order submitted to Judge Boner via letter dated February 12, 2007; the ruling issued by Judge Boner on February 13, 2007 and filed on February 19, 2007; and the January 29, 2007 and February 23, 2007 letters from counsel for Lincoln Medical Center and Lincoln Health System.

On January 26, 2007, through counsel, BARRA requested a second declaratory ruling allowing for a change in host sites for Project I.D. # E-7066-04 on grounds that the change in host sites did not constitute a material change in physical location nor a failure to materially comply with the representations made by BARRA in its Certificate of Need ("CON") application for its project per N.C.G.S. §§ 131E-181(a) and (b). This ruling will be binding upon the Agency and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Agency expressly reserves the right to make a prospective change in the interpretation of the statutes and

regulations at issue in this Declaratory Ruling. BARRA has requested this ruling and has provided the material facts upon which this ruling is based.

### **STATEMENT OF THE FACTS**

On May 17, 2004, BARRA filed a CON application, designated Project I.D. # E-7066-04, to acquire a mobile MRI scanner to serve Health Service Areas I, II, and III; specifically, the primary service area of Alexander, Burke, Caldwell, Catawba and Lincoln Counties. BARRA proposed the following host sites: (1) Blue Ridge Radiology Associates, P.A., Morganton, Burke County (“Blue Ridge Morganton”) and (2) CVMC; or (3) “other host sites should the above hosts obtain new fixed MRI units.” (See CON Application, Project I.D. # E-7066-04, at p. 3.)

On October 27, 2004, the North Carolina Department of Health and Human Services, Division of Facility Services, Certificate of Need Section (the “CON Section”) conditionally approved the application as required by N.C.G.S. § 131E-186(a). The CON Section issued a CON to BARRA for the project on January 18, 2005, authorizing mobile MRI service at the first two host sites, stating in Condition #4: “Blue Ridge Radiology Associates, P.A. shall not change or add host sites unless it first obtains a declaratory ruling authorizing the change in location of the equipment pursuant to North Carolina Statute 150B-4 and the rules of the Department of Health and Human Services, Division of Facility Services.” (See Certificate of Need, Condition 4.).

On August 12, 2005, the CON Section conditionally approved Project I.D. # E-7270-05, a CON application for a fixed MRI scanner at CVMC, and issued the CON on September 13, 2005. As required by Condition #4 to its CON, BARRA filed a request for a declaratory ruling on November 22, 2005 that a change in host sites within BARRA’s service area from CVMC to Blue Ridge Lincolnton was not a material change in BARRA’s CON application. The Agency

approved BRRRA's request and issued a Declaratory Ruling on January 23, 2006 ("BRRRA's January Declaratory Ruling"). BRRRA began providing mobile MRI service in Lincoln on March 1, 2006. BRRRA now provides mobile MRI service to fourteen people per day at Blue Ridge Lincoln.

Lincoln Medical Center and Lincoln Health System (the "Petitioners") filed a Petition for Judicial Review in Lincoln County Superior Court on April 17, 2006, seeking review of BRRRA's January Declaratory Ruling. The Honorable Richard D. Boner reversed and remanded BRRRA's January Declaratory Ruling in an Order dated February 13, 2007 and filed on February 19, 2007. In the Order, Judge Boner gave the Agency the following directions: "If the Agency issues a new ruling in this matter, it shall make specific findings based upon substantial evidence regarding whether Blue Ridge's request to substitute Blue Ridge Lincoln for CVMC constitutes a material change in the physical location or scope of the project." Judge Boner further ordered: "To the extent the Agency does not have sufficient evidence to make that determination or to support the required findings of fact, the Agency is ordered to obtain and carefully evaluate such evidence before it makes its decision."

BRRRA clearly identified to the Agency on page 3 of its CON application BRRRA's intent to change host sites within its service area as circumstances changed. On page 62 of its CON application, BRRRA also noted: "Should [CVMC] obtain a fixed [MRI scanner] and not need the mobile capacity, Blue Ridge has had expression of interest from other providers in Western North Carolina, including a physician practice in Lincoln County[.]"

In accordance with N.C.G.S. § 131E-183(a)(3), BRRRA identified "the population to be served by the proposed project" and demonstrated "the need that this population has for the services proposed." The population to be served specifically included Lincoln County and the

need was developed accordingly for the five-county service area. (See CON Application at pp. 37-59.)

In its CON application, BARRA proposed to provide mobile MRI service at Blue Ridge Morganton four and one-half days per week and CVMC one and one-half days per week. Pursuant to the conditions placed on the CON, BARRA has identified a substitute location at a physician's office, Blue Ridge Radiology Associates, P.A., Lincolnton (200 N. Grove Street, Lincolnton, North Carolina). BARRA represents that its provision of mobile MRI services at Blue Ridge Radiology Lincolnton instead of CVMC is not a material change in physical location and will not materially increase the capital costs, the operating costs, or the charges from the amounts proposed in BARRA's application.

Blue Ridge Lincolnton is located in Lincoln County, within BARRA's proposed service area. The cost to operate the mobile MRI scanner is materially the same whether it is transported to CVMC or Blue Ridge Lincolnton. The scope of services provided by BARRA will not change, nor will the availability of ancillary and support services. BARRA also states that use of the Alternative Site will not adversely affect the services to be provided at Blue Ridge Morganton. BARRA further represents that the route for the mobile MRI scanner, as modified to include Blue Ridge Lincolnton, meets the CON criteria and standards under which BARRA's application was approved and is consistent with the representations in the application, as required by N.C.G.S. § 131E-181(a). BARRA represents that the financial arrangements with the Blue Ridge Lincolnton host site will be identical to those with Blue Ridge Morganton.

## ANALYSIS

Under N.C.G.S. § 131E-181(a), the CON law would require a full review of BRRRA's proposed change of host site if the proposed change represented a material change in the physical location or scope of the project. Since BRRRA's proposed change does not represent a material change, a full review of BRRRA's request is not required.

BRRRA's proposed change does not constitute a material change in the physical location or the scope of the proposed project because the use of Blue Ridge Lincolnton as a host site will not change the identified service area, affect the scope of services offered or increase the costs and charges to BRRRA or to the public for the provision of the mobile MRI services. Further, ancillary and support services are available to Blue Ridge Lincolnton in the same manner they are available to Blue Ridge Morganton as outlined in BRRRA's CON application. Finally, there is no proposed change in the person named in the application such that a violation of N.C.G.S. § 131E-181(a) would result.

One of the objectives of mobile technology is to make a service accessible within a reasonable distance and travel time to all of the population of North Carolina, including populations that cannot obtain full-time (fixed) technology. Several mobile sites in operation for the entire 2004-05 period reported less than 200 procedures. The 2004 State Medical Facilities Plan (the "2004 SMFP"), which applied in this case, provided a single application batch for development of new mobile MRI scanners in the Western HSAs I, II and III. (See 2004 SMFP at pp. 12-13.)

N.C.G.S. §131E-183 (a)(1) states: "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.” The 2004 SMFP does not define or otherwise limit the number of mobile MRI scanners. Hence, the statute permits the applicant to identify and demonstrate the need for the services it proposes. The Agency affirmed this in Required State Agency Findings for the BRRRA CON Application: “There are no policies in the 2004 SMFP applicable to the review of applications for mobile MRI scanners. Further, because the 2004 State Medical Facilities Plan (SMFP) does not contain a methodology for determining need for a mobile MRI scanner, there is no applicable need determination for mobile MRI scanners.” (See Required State Agency Findings, Project ID # E-7066-04, at p.1.)

BRRRA based the need for its proposed mobile MRI scanner on a primary service area within Health Service Areas I, II, and III in Western North Carolina, specifically Alexander, Burke, Caldwell, Catawba and Lincoln Counties. In its CON application, BRRRA established the need in its primary service area based on the projected population, aging and health status of this five-county service area. (See CON Application at Section III, p. 37.) BRRRA projected that by 2007, the population residing in Alexander, Burke, Caldwell, Catawba and Lincoln Counties will have enough need for MRI procedures to justify as many as 13 fixed equivalent MRI scanners. BRRRA stated, “Today, the service area has three operational fixed MRI scanners, one recently awarded (April 2004) fixed scanner that is not yet operational, and mobiles equivalent to almost three more fixed scanners. Thus, the area will need as many as six additional fixed equivalent MRI scanners three years after the proposed mobile comes on line.” (CON Application at p. 38.) This projection took into account Carolinas Imaging Services, LLC’s mobile MRI scanner, which was awarded a CON in October 2004 and for which Lincoln Medical Center was named as a host site. (See CON Application at pp. 50 - 52.) The 2007 State Medical Facilities Plan

Table 90 reports only 10.52 fixed equivalent MRI scanners in the five-county service area, which is fewer than BARRA's projection of a need for 13.

BARRA acknowledged that as a mobile provider, it "has no control over placement of other scanners in the service area. Should the need arise to rebalance service area capacity, [BARRA] may move the scanner to another underserved community." (CON Application at p. 19.) In fact, BARRA stated that in the event CVMC did not need the mobile capacity, "Blue Ridge has had expressions of interest from other providers in Western North Carolina, including a physician practice in Lincoln County and the hospital in Alexander County." (CON Application at p. 62.)

A review of official State information regarding available MRI services in Lincoln County<sup>1</sup> reveals no existing or approved fixed MRI scanners in Lincoln County. At the time of BARRA's first Request for Declaratory Ruling, as well as at present, the only provider of MRI services in Lincoln County is Lincoln Medical Center, which does not have its own MRI scanner, but serves as a mobile host site for Carolinas Imaging Associates and InSight Health Corp. Lincoln Medical Center reported only 1,307 unweighted MRI procedures in 2003, 1,337 unweighted MRI procedures in 2004, 1,429 unweighted MRI procedures in 2005 and 1,900 unweighted MRI procedures in 2006 on its respective 2004, 2005, 2006 and 2007 Hospital License Renewal Applications. Lincoln Radiology Associates, which was a mobile MRI host site in 2003, reported no MRI procedures in 2005.

Because BARRA projected the need for its mobile MRI service based upon the need, demand and utilization of the entire five-county service area, changing host sites within the proposed service area does not constitute a material change in physical location. (See CON Application at pp. 37-53.) In the CON application on page 50, BARRA both justified the need for

---

<sup>1</sup> See 2005 and 2007 State Medical Facilities Plans Table 90 and DFS 2006 Registration and Inventory of Medical Equipment for Mobile Magnetic Resonance Imaging (MRI) Equipment Reports.



mobile services and addressed N.C.G.S. §131E-183(a)(6) regarding unnecessary duplication within the five-county service area. BARRA even referenced Lincoln County as a possible alternative site. (See CON Application at p. 62.)

BARRA's cost of providing MRI services to Blue Ridge Lincolnton instead of CVMC will change only slightly with the change in host site. Transport costs will increase, but this does not constitute a material change for the reasons stated below. Blue Ridge Lincolnton's charges will not exceed charges to patients in Blue Ridge Morganton. Also, BARRA's projected patient charges are lower than CVMC's projected hospital-based charges. (See CON Application at pp. 131-32.)

In its CON application, BARRA reasonably projected that its agreement with CVMC would result in a cost of \$117 per move of the mobile MRI scanner in 2006. When CVMC declined to transport the mobile unit, CVMC forced BARRA to contract with another company to transport the unit at a higher cost per move. These events were beyond BARRA's control. BARRA contracts with InSight Health Corp. to transport the mobile MRI scanner at a cost of \$500 per move for a move of up to 60 miles. This results in an increased cost of \$39,832 for 2006. The InSight fee would be the same whether the mobile MRI scanner serves Catawba or Lincoln County because both sites are within the 60-mile, \$500 minimum fee range. The change in transport companies rather than the change in host site caused the increase. BARRA's CON proforma reflected an adequate net income to cover this increased amount. In fact, as can be determined from assumptions provided in the CON application at Tab 13, BARRA's net revenue will be higher, because the added cost of the transport is less than the revenue increase that results when BARRA bills direct for services provided at the second host site. Therefore, the project is still financially feasible and the increase does not result in a material change in operating costs.

BARRA also stated that, as a freestanding imaging center, it did not offer the support services listed in 10A N.C.A.C. 14C .2704, as it was written at the time of the application, and that the physician who referred the patient to BARRA for the MRI scanner would continue to supervise the patient's care and would be the one to refer the patient for further treatment. (CON Application at p. 32.) However, this particular provision of the regulation was deleted in January 2005 and effective November 1, 2005, applicants for a MRI scanner are no longer required to meet this standard.

Finally, BARRA represents that the Blue Ridge Lincolnton host site satisfies all requirements for mobile MRI host sites.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw BARRA's CON if BARRA either fails to develop the service in a manner consistent with representations made in the application or with any conditions that were placed on the CON. Based on the findings of fact outlined above and the substantial evidence upon which they are based, BARRA will be developing its project in a manner that is not materially different from the representations made in its application, and with this ruling, BARRA will be developing its project in a manner that is consistent with all of the conditions that were placed on its CON.

### **CONCLUSION**

For all the foregoing reasons, assuming the statements of fact in the CON application and the Request for Declaratory Ruling to be true, I conclude that BARRA's request to change its host site from CVMC to the Blue Ridge Lincolnton for BARRA's mobile MRI scanner (Project I.D. # E-7066-04) will not constitute a material change in the physical location or scope of the project, will not violate the N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the CON in violation of N.C.G.S. § 131E-189(b). I further conclude that this Declaratory Ruling is

deemed to be in the public interest and will not result in the unnecessary duplication of health services.

This the \_\_\_\_ day of March, 2007.

---

Robert J. Fitzgerald, Director  
Division of Facility Services  
N. C. Department of Health and Human Services

**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

**CERTIFIED MAIL**

Lee M. Whitman  
Sarah M. Johnson  
Wyrick Robbins Yates & Ponton LLP  
4101 Lake Boone Trail, Suite 300  
Raleigh, NC 27607

With a courtesy copy to:

William R. Shenton  
Louis B. Meyer III  
Poyner & Spruill, LLP  
3600 Glenwood Avenue  
Raleigh, NC 27612

This the \_\_\_\_\_ day of March, 2007.

---

Jeff Horton  
Chief Operating Officer