

March 3, 2017

Pinnacle Health Services of North Carolina, LLC
166 Springbrook Avenue, Suite 103
Clayton, NC 27520

Ms. Martha Frisone, Assistant Section Chief
Mr. Mike McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699

Re: Comments on Application for a Certificate of Need for establishment of a new diagnostic center in Wake County, HSA IV; CON Project ID Number:

J-011291-17, Browning Equipment SPE, LLC, Browning Mobile MRI

Dear Ms. Frisone and Mr. McKillip,

On behalf of Pinnacle Health Services of North Carolina, LLC, thank you for the opportunity to comment on the above referenced application for a new diagnostic center in Wake County. I recognize the Agency's burden of fair and careful review of applications and appreciate the difficulty of the task.

CONTEXT

This application came on the heels of an announced business and clinical relationship between Wake Radiology and UNC Rex Healthcare. According to these CON filings and press releases, the two organizations plan to form a joint venture to operate imaging centers currently owned by Wake Radiology and UNC Rex. This application states that a new organization, called Browning Equipment SPE, LLC, will operate existing imaging services currently owned by Rex Hospital, Inc.

The proposed joint venture between Wake Radiology and Rex Hospital, Inc. ("UNC Rex") will reduce access to affordable imaging services in Wake County. The proposed joint venture "diagnostic center MRI" will affect access to an existing Rex Hospital, Inc. mobile MRI scanner. For the purposes of these comments, we refer to the existing equipment as the "Mobile MRI." Contrary to what the application states, the proposal will increase costs and therefore reduce access to the MRI service. The application proposes to keep the Mobile MRI service at an existing location at Rex Wakefield, but also expand service to imaging centers in Holly Springs and Knightdale.

As noted in the Findings of Fact, intent of the CON statute (NCGS 131E-175 – 192) is to prevent unrestrained growth in North Carolina’s healthcare system. NCGS 131E-175 (1) states that

“the financing of health care, particularly the reimbursement of health services rendered by health service facilities, limits the effect of free market competition and government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities”

Design of this application appears to be an administrative move to enable significant expansion at the proposed location. A true diagnostic center as defined in GS 131E-176 (7a) is a “health care facility” (NCGS 131E-176(9b)). A “health care facility” can expand without additional CON approvals (NCGS 131E-184(g)).

The requirement that applicants demonstrate need is not only a statutory requirement, in this case it is especially critical because the proposed project establishes a new “health service facility.” Yet the applicant fails to demonstrate need for the proposed “diagnostic center MRI” in Wake County. In fact, as demonstrated in the attached document, Browning Mobile MRI also fails to meet four statutory criteria, specifically #3, #4, #5, and #13 and should be denied.

Thank you for taking time to consider the attached observations.

Sincerely,



W. Cannon King
President

Outpatient Imaging Affiliates, Inc., parent company of Pinnacle Health Service of North Carolina, LLC

Attachment

NON-CONFORMANCE WITH REVIEW CRITERIA

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.**

The Applicants Do Not Adequately Demonstrate Need

The applicants, Browning Equipment SPE, LLC and Rex Hospital, Inc., do not adequately demonstrate that the population to be served *needs* the proposed project. The application contains three arguments for need, all of which are subjective and none of which relate to actual needs of the population.

The first, the “Ability to Joint Venture,” does not address needs of the population. Rather, it is an argument for needs of the applicants, and their related organizations, Wake Radiology and UNC Rex. It is a financial arrangement that will benefit providers, but not patients. The applicants’ supporting rationale for the joint venture are that it will allow for sub-specialization, provide care closer to home, allow for the use of a PACS system, and lower costs.

- **Sub-specialization:** These are *existing* providers. Nothing in the structure will change sub-specialization. Residents of Wake County and patients of Rex Hospital currently have access to a broad set of radiology subspecialists from Wake Radiology and other radiology providers.
- **Care closer to home:** The application proposes to expand the Mobile MRI service to Holly Springs and Knightdale. Both Wake Radiology and Rex, Hospital, Inc. own mobile MRI services. Rex Hospital could have filed a material compliance request or a certificate of need application to serve these additional sites. However, the application requests to establish the mobile MRI as a “diagnostic center.” Rex Hospital or Wake Radiology could extend its existing mobile MRI services to Holly Springs and Knightdale without designating the Mobile MRI as a “diagnostic center.” The application provides no qualitative justification of the need of the population to be served for the “diagnostic center” designation.
- **PACS:** The major providers of imaging services in Wake County including acute care hospitals, Wake Radiology, and Raleigh Radiology have PACS today. Organization as a diagnostic center does not, in and of itself, enable use of PACS. That technology has been in use for decades.
- **Lower costs:** Evidence in the application does not support that the new designation of the Mobile MRI from hospital-based to non-hospital-based status will truly reduce costs. In fact, there is public evidence to the contrary.

The second argument, “Improved Access,” focuses on reduced costs and improved financial access because of the Mobile MRI’s change from hospital-based billing to non-hospital-based billing status. The application states Wake Radiology, an existing provider and operator of imaging services in Wake County, will manage the Mobile MRI. Table 1 compares Blue Cross

rates for Wake Radiology's MRI services to other providers. Table 1 also includes the year two average commercial MRI reimbursement reported for the proposed project. The application does not indicate what portion of its commercial revenues are from Blue Cross, however Blue Cross is a major commercial payer in North Carolina and likely represent a sizable share of Wake Radiology and UNC Rex's commercial payer mix. As such, the prices in Table 1 are comparable.

Table 1 – Comparison of Blue Cross Reimbursement for Selected MRI Procedures

| Provider | MRI Brain w/o contrast | MRI Lower Limb Joint w/o Contrast | MRI Pelvis w/o Contrast | Average MRI |
|--|------------------------|-----------------------------------|-------------------------|-----------------|
| Raleigh Radiology | \$ 736 | \$ 726 | \$ 744 | n/a |
| Raleigh Rad/ Pinnacle | \$ 747 | \$ 737 | \$ 756 | n/a |
| Triangle Orthopedic | \$ 783 | \$ 968 | \$ 779 | n/a |
| Raleigh Orthopedic | n/a | \$ 788 | n/a | n/a |
| UNC Rex | \$ 1,267 | \$ 1,217 | \$ 1,087 | n/a |
| WakeMed Raleigh | \$ 1,062 | \$ 1,212 | \$ 1,046 | n/a |
| Wake Radiology | \$ 1,192 | \$ 1,163 | \$ 1,180 | n/a |
| Duke Raleigh | \$ 1,769 | \$ 1,713 | \$ 1,477 | n/a |
| Average Payment Year Two of Project¹ | n/a | n/a | n/a | \$ 1,219 |

Source: Blue Cross Treatment Estimator (Blue Value). Accessed 2/27/2017. Data for a 12-month period. Actual year of data not identified in tool.

Note: Average MRI costs not available in Blue Cross tool. Browning application did not provide costs for specific MRI procedure types.

As the table shows, Wake Radiology's historical Blue Cross reimbursement is substantially higher than the other non-hospital-based providers in the county and very close to UNC Rex. The application projects MRI costs for commercial payers in year two (2019) at an average of \$1,219 per procedure, higher than Wake Radiology's historical rates *and* higher or at least comparable to UNC Rex's historical rates. Therefore, these publicly available data appear to show that the proposed MRI service will cost patients and payors more. In fact, because the application provides no data on specific procedures, as would be necessary to make the case that patient costs under the JV will be less, one could speculate that the average cost presented was selectively chosen to represent procedures on the lower end of the charge spectrum.

The application also states, without documentation, that hospital-based patients have higher copays and coinsurance. This is entirely up to individual insurance plans. Also, a large percentage of today's health plans are high deductible, meaning patients often carry the full financial burden out-of-pocket. A higher price structure will mean higher out of pocket costs. The applicants also suggest that the Mobile MRI and other imaging facilities owned by the JV will

¹ The Application pro formas did not breakout reimbursement by procedure type, so the cost listed is the average reported on FORM F.6

not be excluded from certain narrow network plans, thereby improving access. This is entirely speculative. The application provides no evidence that the Mobile MRI service nor any other service owned by the JV will be included or excluded from any particular health plan. The application fails to mention that by moving the Mobile MRI out of the UNC network, the MRI may fall *out* of narrow networks in which UNC is a part. Clearly, the application fails to demonstrate that the proposed project, and the JV as a whole, will improve access. If anything, available data indicate that it will increase costs and thereby reduce access.

Finally, the applicants cite “Alignment with Federal Health Reform” as a reason the project is needed, citing the Bipartisan Budget Act of 2015’s (“Act”) provisions around site-neutral payments. UNC Rex could have completed the same proposed project years ago, before the Act. The Act’s provisions restricting development of new hospital-based outpatient departments have nothing do with the Browning proposal.

The applicants have not demonstrated need of the population to be served. The application’s need rationale is insufficient. As such, the applicants do not conform to CON Criterion 3.

- 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.**

The Applicants did not Demonstrate The Proposed Project is the Least Costly Alternative

As the discussion above shows, leaving the Mobile MRI under a hospital-based billing structure with UNC Rex appears to be a less costly alternative to the proposed project.

Because the application does not demonstrate that the proposed project is the least costly alternative, the applicants do not conform to CON Criterion 4.

- 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.**

The Applicants Do Not Provide Reasonable Projections of Costs and Charges

The pro forma assumptions provided by the applicants provide no supporting information for projected charges. Regarding charges, the application simply states, “*Projected average charge is based on projected average charge for the service...*” The assumptions contain no basis, such as historical charges or payor requests or even a proposed charge schedule. The amounts appear to be sheer speculation about “averages.” This is clearly not sufficient or reasonable.

Regarding net revenue per procedure, the application states:

“Net revenue figures on FORM F.6 are equal to gross revenue from Form F.5, reduced to account for deductions by payor (including charity care and bad debt). Deductions, charity care, and bad debt by payor are projected forward based on the historical experience of UNC Rex Hospital.”

However, Wake Radiology is the sole member of Browning Equipment SPE, LLC at the time of the application². Wake Radiology, not UNC Rex, will provide management services for the MRI service. As such, Wake Radiology’s historical financial information would be the logical basis for assumptions, for the alternative would require a substantial change in the manager’s billing program. Wake Radiology did not provide historical financial information regarding its operation of mobile MRI scanners. Similarly, though Rex Hospital, Inc., the co-applicant, currently operates the Mobile MRI, the application does not contain **any** historical financial information from the Mobile MRI. Because the application contains no information to show why UNC Rex Hospital charges and not Wake Radiology charges will prevail and provides no information about the former, accepting the financial assumptions would require the Agency to rely on pure speculation.

Regarding capital cost, the applicants appear to show that \$1.7M worth of imaging equipment will transfer from Rex Hospital, Inc., a 501(c)(3) nonprofit hospital, to Browning Equipment SPE, LLC. According to the application, Browning Equipment, LLC is fully owned by a for-profit organization, Wake Radiology. The application presents the transaction as a cashless transaction in which UNC Rex will give the equipment to Browning Equipment SPE, LLC without receiving any payment or equal value in return. The application calls into question how a tax-exempt nonprofit hospital can provide income-producing assets to a for-profit entity without violating IRS inurement rules.

Because of the unreasonable charge and net revenue projections, the applicants fail to conform to CON Criterion 5. In addition, the nature of the capital cost transaction between the two applicants is questionable. If such a “contribution” arrangement is not permissible under IRS rules, then the project would also fail to conform to Criterion 5 on the basis that its necessary capital would not be available.

² Of note: the application states that UNC Rex will become a member of Browning Equipment SPE, LLC, but provides no documentation from UNC Rex confirming this assertion.

- 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:**

The Applicants Do Not Properly Demonstrate How the Proposed Facility Will Meet the Needs of Medically Indigent and Low Income Persons

As described above, the proposed “diagnostic center MRI” will increase costs for patients. As a result, financially vulnerable groups, such as the medically indigent or low-income persons, will suffer an adverse impact from the proposal. As such, the applicants do not conform with the core requirements of CON Criterion 13, which asks that applicants demonstrate the contribution to meeting the health care needs of these groups.

- (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;**

The Applicants Do Not Properly Describe Historical Requirements to Meet Charitable Obligations

In Section A, the application identifies Rex Hospital, Inc., a nonprofit hospital, as an applicant. The application also clearly states that UNC Rex will become a member of Browning Equipment SPE, LLC upon issuance of the CON related to the Mobile MRI application. The IRS requires nonprofit hospitals to provide some amount of community benefit to justify their tax-exempt status. This generally means the provision of charity care, uncompensated care to persons with means tested health plans, and other benefits provided to the community either free or at discounted rates. All nonprofit hospitals are required to demonstrate compliance with these federal requirements to the IRS in Form 990, Schedule H. In Section L, Question 2 (a), the applicants checked “No” in regards to the question of whether the facility has an obligation under federal regulation to provide uncompensated care, community service, or access to minorities and handicapped persons. Rex Hospital, Inc. is an applicant and, presumably, carries the referenced obligations under its tax-exempt status. As such, the Browning Mobile MRI will also be required to provide uncompensated care or other community benefits to comply with the same IRS regulations to which Rex Hospital, Inc. is obligated to meet.

As such, the applicants do not comply with CON Criterion 13b, which requires applicant facilities to show past performance in meeting federal requirements around uncompensated care and community service.

NON-CONFORMANCE WITH ADMINISTRATIVE RULES

The application incorrectly states that the MRI performance standards in 10A NCAC 14C. 2703 do not apply. The applicants cite another CON from Granville Health System (K-10064-12) involving a leased MRI scanner. That application is not relevant to the Browning Mobile MRI scanner. The new entity, Browning Equipment SPE, LLC does not currently lease the proposed MRI scanner from UNC Rex or any other party at the proposed locations.

10A NCAC 14C. 2703 (a) requires an applicant to meet the MRI performance standards if the applicant is “proposing to acquire a mobile magnetic resonance imaging (MRI) scanner.” The application states that UNC Rex will “contribute” its mobile MRI to Browning Equipment SPE, LLC. At the time of the application, Browning Equipment SPE, LLC did not include Rex Hospital, Inc. as a member. The CON Statute includes in its definition of “New institutional health services”: “The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person...Magnetic resonance imaging scanner” (NCGS 131E-176 (16).f1.7). The applicants were careful to use the word “contribute” when possible. Regardless of the language used, the “contribution” of an MRI from one entity to the next is clearly either a donation or a transfer. The CON statute defines those as an acquisition. As such, the performance standards apply.

The applicants fail to meet 10A NCAC 14C. 2703 (a) for the following reasons:

- 10A NCAC 14C. 2703 (a) (1) requires that applicants demonstrate that each existing mobile MRI owned by a related entity performed 3,328 weighted MRIs in the most recent 12 month period. Wake Radiology, a related entity, performed 1,890 on its mobile scanner in the most recent reported year. UNC Rex, a related entity, performed 847. Table 2 summarizes.

Table 2 – 2015 Utilization of Mobile MRIs, UNC Rex and Wake Radiology

| Operator | Equipment Type | Weighted Scans | Sites |
|----------------|---------------------|----------------|------------------------------|
| Wake Radiology | Siemens Avanto 1.5T | 1,890 | WR Wake Forest, Fuquay, Cary |
| UNC Rex | Unknown | 847 | Rex Wakefield |

Source: 2016 Hospital License Renewal Applications and 2016 Registration and Inventory of Medical Equipment Forms

- 10A NCAC 14C. 2703 (a) (2) requires that applicants demonstrate projected third year utilization of at least 3,328 weighted scans on each of the existing or proposed mobile MRI scanners owned by the applicant or a related entity. The applicants do not attempt to show how the existing Wake Radiology mobile scanner listed above could achieve those volumes by year three of the proposed project. The Browning Mobile MRI project itself, which is the existing UNC Rex mobile MRI scanner, proposes to do only 1,472 weighted scans by year three.

Clearly, the applicants do not meet the MRI performance standards in 10A NCAC 14C. 2703 (a) and therefore the application should be denied.

CONCLUSION

Although diagnostic centers are not governed by a determinative need projection in the State Medical Facilities Plan, the certificate of need law only allows the Agency to approve regulated projects for which applicants demonstrate need of the population to be served, and increase access, lower cost, and/or improve quality. The proposed Browning Mobile MRI does not comply with the CON statute or CON performance standards governing proposals for the acquisition of mobile MRI scanners. Given the facts stated above, the application for the Browning Mobile MRI “diagnostic center” should be denied.