

March 3, 2017

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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-011290-17, Browning Equipment SPE, LLC, Browning Breast Care Center**

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. We believe the application should be denied.

## **CONTEXT**

This application came on the heels of an announced business and clinical relationship between Wake Radiology and UNC Rex Healthcare. According to the 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 own and operate existing mammography, ultrasound, and bone density imaging services currently owned and operated by Rex Hospital, Inc. at this same address.

The proposed joint venture between Wake Radiology and Rex Hospital, Inc. ("UNC Rex") will increase cost, thus reduce access to affordable imaging services in Wake County. For the purposes of these comments, we refer to the existing center as the "Breast Care Center." Contrary to what the application states, the proposal will increase costs and therefore reduce access to existing mammography, ultrasound, and bone density imaging equipment. The application proposes to convert diagnostic imaging equipment from hospital-based status to freestanding status, without any change in the location of the equipment. But, the ownership will change from non-profit tax-exempt to limited liability and currently taxable.

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 CON requirement that applicants demonstrate need is important. As noted in the Application on page 71, there are 13 diagnostic centers in Wake County. These centers adequately meet the needs of Wake County residents. There is no need to add an additional “diagnostic center” designated service to the inventory in Wake County. As we will discuss, the proposed application does not adequately demonstrate that the population to be served will benefit from or needs the new arrangement. Moreover, based on information presented, the application for Browning Breast Care Center also fails to meet four statutory criteria, specifically #3, #4, #5, and #13. For these reasons, it should be denied.

The attached document describes in more detail why the application falls short.

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 why 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 relates 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 joint venture (JV) will not bring care closer to home. The project does not propose any new brick and mortar facilities. Therefore, how can care become closer to anyone? In fact, according to the application, the JV plans to close some of other facilities currently owned or operated by one of the applicants.
- **PACS:** The major providers of imaging services in Wake County including the acute care hospitals, Wake Radiology, and Raleigh Radiology, use PACS today. A JV alone does not enable the 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 Breast Care Center from hospital-based to freestanding status will truly reduce costs. In fact, there is public evidence to the contrary. There is no evidence that the service will operate at lower cost under the proposed JV.

The second argument, “Improved Access,” focuses on reduced costs and improved financial access because of the Breast Care Center’s change from hospital-based to freestanding status. The application states Wake Radiology, an existing radiology provider and operator of imaging centers in the county, will manage the facility. Table 1 compares Blue Cross rates for Wake Radiology’s mammogram services to other providers. Table 1 also includes the year two average commercial mammogram 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 would 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: Blue Cross Reimbursement by Provider for Mammograms**

Provider	Mammo - Digital One Breast	Mammo - Digital Two Breasts	Mammo - Screening Two Breasts	Average Mammogram
Raleigh Radiology	\$ 163	\$ 202	\$ 191	n/a
Raleigh Rad/ Pinnacle	\$ 166	\$ 205	\$ 194	n/a
UNC Rex	\$ 163	\$ 206	\$ 190	n/a
WakeMed	\$ 190	\$ 218	\$ 191	n/a
Wake Radiology <sup>1</sup>	\$ 255	\$ 325	\$ 295	n/a
<b>Average Payment Project Year Two</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>\$ 241</b>

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

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

As the table shows, Wake Radiology's historical Blue Cross reimbursement is more than \$100 higher than any other provider, *including* UNC Rex. The application projects mammogram costs for commercial payers in year two (2019) at an average of \$234 per procedure, lower than Wake Radiology's historical rates, but still higher than UNC Rex's historical rates. These publicly available data demonstrate that the proposed 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. Many plans require 20 percent coinsurance at both hospital-based and freestanding facilities. For example, Medicare requires 20 percent coinsurance from the patient for diagnostic mammograms regardless of whether the procedure occurs in a freestanding center or in a hospital outpatient department<sup>2</sup>. 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 Breast Care Center and the other services owned by the JV will not be excluded from certain narrow network plans, thereby improving access. This is entirely speculative. The application provides no evidence that the Breast Care

<sup>1</sup> The Application pro formas did not breakout reimbursement by procedure type, so the cost listed is the average reported on FORM F.6 for commercial payers.

<sup>2</sup> <https://www.medicare.gov/coverage/mammograms.html>

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Center 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 Breast Care Center out of the UNC network, it may fall *out* of narrow networks that include UNC facilities. 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.

Moreover, the applicants' need methodology (application Section C) contains no quantitative data describing the need for mammogram, ultrasound, and bone density imaging services in the service area. Therefore, nothing in the application would allow the Agency to judge whether the basis of the proposed utilization is actual epidemiological need of the population to be served.

The applicants have not demonstrated need for the project. The application's need rationale is insufficient. It includes neither quantitative documentation nor qualitative data supporting population need. The application does not conform to statutory 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 Breast Care Center under a hospital-based billing structure with UNC Rex is 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 contain no information to substantiate 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 only:

*“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 application<sup>3</sup>. Wake Radiology, not UNC Rex, will provide management services for the imaging center 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. For example, Wake Radiology recently filed a CON application for a diagnostic center primarily consisting of mammography in 2016 (J-011174-16). In that application, Wake Radiology explained its charge assumptions by stating:

*“Gross revenue and charges are based on the current charges by payor type and are not expected to change over the projection period.”*

That same application explains its net revenue assumptions by stating:

*“Net revenue and projected reimbursement per procedure are based on the current levels by payor type and are not expected to change over the projection period.”*

As part of that application, Wake Radiology provided its historical charge and reimbursement information. Yet, Wake Radiology elected **not** to provide historical financial information in the Browning Breast Care Center application. Similarly, though Rex Hospital, Inc., the co- applicant, currently operates the Breast Care Center, the application does not contain **any** historical financial information from the Breast Care Center. Hence, accepting the pro forma assumptions in the application would require the Agency to rely on pure speculation.

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<sup>3</sup> 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.

Regarding capital cost, the applicants appear to show that \$1.2M 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.

- 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, publicly available data suggest that the proposed freestanding diagnostic center will increase costs for patients. As a result, the proposed project will adversely affect financially vulnerable groups, such as the medically indigent or low-income persons. As such, the applicants do not conform with the requirements of CON Criterion 13, which requires 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 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 Breast Care Center application. The IRS requires nonprofit hospitals to provide some amount of

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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 Breast Care Center 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 states, incorrectly, that the performance standards in 10A NCAC 14C .1804 do not apply to the Breast Care Center application. The application is for a “new diagnostic center.” As such, these rules, collectively, apply. However, the application reasonably argues that standards 10A NCAC 14C .1804 (1) and 10A NCAC 14C .1804 (2) require information not publicly available and therefore the applicants cannot comply with those rules.

The applicants **do not**, however, describe how and why 10A NCAC 14C .1804 (3), a requirement that utilization projections be based upon epidemiologic studies, does not apply. 10A NCAC 14C .1804 (3) does apply in this case. The applicant contains no evidence that the utilization projections in the Breast Care Center application are based on epidemiological studies, as required by 10A NCAC 14C .1804 (3). As such, the applicants do not meet the diagnostic center performance standards.

## **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 Breast Care Center does not comply with the CON statute or CON performance standards governing proposals for new diagnostic centers. Given the facts stated above, the application for the Browning Breast Care Center should be denied.