

Comments on The Bone and Joint Surgery Clinic LLP's Application for a New General-Purpose MRI Scanner in Wake County (Project ID # J-11757-19)

submitted by

Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc., (collectively "Wake Radiology") submit the following comments related to the above-referenced application. Wake Radiology's comments on this application include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*" See N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, Wake Radiology has organized its discussion by issue, noting some of the general CON statutory review criteria and regulatory criteria creating the non-conformity in the application.

General Comments

As the Agency is aware, the acquisition of an MRI scanner requires a Certificate of Need, regardless of its cost. The ability to obtain an MRI scanner is further regulated by the *State Medical Facilities Plan ("SMFP")*, which, by statute, is the determinative limitation on the services it regulates, including MRI. The MRI need methodology in the *SMFP* determines need for fixed MRI scanners in each defined service area. In the *2006 SMFP*, Table 9Q(4), there was a need for a "fixed extremity MRI scanner," for which the applicant applied and was approved (See page 114 in the exhibits to the instant application). There was no need for a "fixed MRI scanner" in the Wake County service area in the *2006 SMFP*. Thus, the applicant's opportunity to acquire and operate a fixed extremity MRI scanner is derived solely from a special need determination in the *2006 SMFP*, which included an explicit restriction prohibiting full body scans (scans of body parts other than extremities). At no time has the applicant sought a certificate of need for a "fixed MRI scanner" without limitations, when such a scanner became available through a need determined by the SHCC and listed within the *SMFP*, despite the multiple opportunities it has had since 2006 to do so.

Not only is the applicant's MRI scanner subject to these limitations, in recent litigation over the replacement of its MRI scanner with the 3T scanner that it now operates, the applicant stated that, "*B&J is not performing, and has no intention of performing whole body scans,*" which was a condition of its certificate. See Motion to Dismiss, September 21, 2018. The current proposal is entirely contrary to the demonstration project under which the certificate of need was issued and is contrary to the information provided in the applicant's request for an exemption determination. Of note, if the applicant would have been truthful in its exemption replacement documentation, the proposed 3T MRI would not have met the definition of "replacement equipment" because, inter alia, it would not be comparable equipment since "the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment." (emphasis added) See 10A NCAC 14C .0303 (a), (c), (d)(1) & (2), and (e)(3).

During oral arguments on a Summary Judgment motion in the appeal of the applicant's exemption replacement, Wake Radiology expressed its concerns about the use of the 3T MRI scanner for procedures that are prohibited by the conditions of its CON, to which Counsel for the Respondent (the Agency) replied:

*“There's been some concern also expressed today about that [Intervenor] may enlarge what they do ... [T]here's something in the CON that prohibits and limits what the Bone & Joint Clinic can do with their replacement equipment. ... [I]t clearly says under condition number 2 that they are prohibited from performing whole-body scans. That condition is going to be transferred to the new, ... replacement MRI because all they're doing is replacing what they had with ... comparable equipment. ... [T]hey are clearly bound by the representations [in their project application] except for [reporting results during 3-year period of the study] and they have to follow the conditions that are set forth on their CON. Should they fail to do that, my client has the ability to go after them for violations just like they would anyone who had equipment, had a CON that – under whatever way it got it, they still have the right to force them to follow the conditions that are applicable to that CON. So I think that the concerns about the ... Bone & Joint doing things beyond what it's supposed to do was not really of great concern because the Agency is the one who has the power to go after them under the statute. [I]n the law, CON law, there are certain provisions that the Agency has and is authorized to seek to stop individuals and companies from doing things that are beyond their CON and things that aren't even mentioned in the CON but the law applies to them. So I think the Agency has the power to make sure that the Bone & Joint Clinic continues to follow what it's supposed to do under its CON. ... And they're going to have an MRI, and **they're going to do MRI procedures on what they said they would do, which are the extremities.** (emphasis added) See Page 138, exhibits: Final Decision, Summary Judgment, 18 DHR 03281, 18 DHR 01808.*

In its exemption determination request, the applicant clearly misrepresented its intentions to the Agency when it requested the exemption and is essentially trying to bootstrap its way around the established process for need determination and review. If the State Health Coordinating Council (“SHCC”) determines that another MRI scanner that is not a “fixed extremity MRI scanner” is needed, the applicant should be required to apply under the competitive review process.

Now, the applicant is proposing a “modification of scope;” however, that term does not exist in the NC CON statute. The project clearly cannot be a “change in scope,” as defined at §131E-176(16)(e), as that entails, “*A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.*” Although the project was completed more than one year ago as defined in the original CON, the applicant received approval to replace its existing equipment with the 3T scanner within the last year. NCGS §131E-181(b) states that “*The Department shall require any recipient of a certificate of need, or its successor, whose service is in operation to submit to the Department evidence that the recipient, or its successor, is in material compliance with the representations made in its application for the certificate of need which granted the recipient the right to operate that service.*” The applicant is, and should be, subject to the limitation prohibiting full body scans (non-extremity scans), regardless of the exemption granted by the Agency for the 3T replacement scanner, because allowing the fixed extremity MRI scanner to be utilized without restriction is equivalent to approving a new fixed [non-extremity] MRI scanner.

It is also of concern that the application represents that BJSC is limited to “orthopaedic” MRI scans, as stated on page 27 and elsewhere. By this statement, it appears that BJSC has decided not to operate in material compliance with its representations in its application for the CON it now holds, specifically the following:

“At 22 centimeters, the scanner’s field of view is more than adequate for imaging joints, but not adequate for imaging the cervical, thoracic, and lumbar spine. While an experimental cervical coil does exist, the applicant has written qualifiers in its lease agreements and purchase order to ensure that no spine-based software or coil packages will be acquired. None of the members of the Bone and Joint orthopedic practice performed any spine surgery, which is another reason this proposal is uniquely conforming to both the letter and spirit of the determined need for the demonstration project in the 2006, [sic] SMFP. Bone and joint [sic] fully intends to utilize this equipment solely to image extremities.”

See Exhibit C.4.a, Final Decision Summary Judgment at page 135 et seq.

In contrast to this representation, the applicant now clearly performs non-extremity orthopaedic scans, including spine scans, in direct contradiction of its CON application for the fixed extremity MRI scanner and even more recent representations.

In summary, there is no statutory mechanism to alter the basis of the applicant’s CON, which was issued pursuant to a special need determination for a “fixed extremity MRI scanner.” The applicant has already improperly expanded beyond the limitations of its CON and is now applying for a “fixed MRI scanner,” which can only be approved subject to a need determination in the *SMFP*. Moreover, the application is non-conforming with several statutory and regulatory review criteria, as discussed below, and should be denied.

Issue-Specific Comments

1. The applicant is currently and proposes to continue renting its MRI scanner to other providers in violation of the CON Statute.

The application indicates that the 3T MRI scanner is currently being rented to other orthopaedic providers, and that it intends to rent the scanner to a urology practice following approval of the project. In both cases, the application indicates (page 95) that The Bone and Joint Surgery Clinic, LLP (“BJSC”) bills these other practices a set hourly fee plus supplies, while the practices bill patients and payor directly for the service. Though the application indicates that this arrangement allows another provider to use the MRI “just as it would from a mobile MRI provider,” as the Agency is aware, that is a different arrangement. Specifically, under a contract with a mobile vendor, the owner of the mobile equipment enters into a service agreement with the provider, under which it provides the staff and the other components of the service. Without such an agreement, the provider has acquired an MRI scanner by “purchase, donation, lease, transfer or comparable arrangement,” as per NCGS §131E-176(16)(f1)(7). Moreover, BJSC’s original CON application never proposed or contemplated this arrangement. As such, the application should not be approved to allow BJSC to continue offering services in violation of the CON Statute.

On this basis alone, the application should be denied.

2. The application fails to adequately and reasonably define its patient population.

In Section C.3, the application projects its patient origin to be identical to its historical patient population, despite also projecting that 16 percent of its future patient volume will be Associated

Urologists of North Carolina (“AUNC”) patients. The application asserts on page 26 that “[t]he Associated Urology [sic] market area is comparable to BJSC and therefore patient origin for the new patients will be similar.” However, the application actually projects the patient origin for these patients to be identical, not just similar. Moreover, there is no data or analysis provided to support this assertion. Publicly-available data on their websites¹ show that the practices have vastly different market areas. BJSC has a single office located on Wake Forest Road in Raleigh near Duke Raleigh Hospital. AUNC has seven offices: four in Wake County, one in Johnston County, one in Harnett County and one in Sampson County. Given this substantial difference in clinic locations, and absent any data or analysis, it is unreasonable to believe that the patient population will remain identical to the historical patient population.

As such, the application has failed to reasonably identify the population to be served by the proposed project, and the application should be found non-conforming with Criterion 3.

3. The application fails to demonstrate the need for the proposed project.

a. *No need for another non-extremity MRI scanner in Wake County*

The proposed project involves the development of a new fixed MRI scanner in Wake County, in place of the existing “fixed extremity MRI scanner,” which was approved pursuant to a special need determination in the *2006 SMFP*. The *2019 SMFP* includes a need determination for a one additional fixed MRI scanner in Wake County; however, the applicant has not applied for that review cycle, which begins December 1, 2019. Apart from that need, there is no other need for an additional fixed MRI scanner in Wake County. As such, the application cannot be approved. Moreover, as noted in the application, with the inclusion of the BJSC fixed extremity scanner in the *Proposed 2020 SMFP*, there is no need for another fixed MRI scanner in Wake County. While the application asserts that absent the BJSC in Table 17E-1 in the *Proposed 2020 SMFP*, there would be a need for an additional fixed MRI scanner in the *2020 SMFP*, that is not evident. In particular, had a need been identified by the standard methodology for the *Proposed 2020 SMFP*, that would have been considered by the SHCC among other factors, before it made its final recommendation to the Governor, but the need methodology itself is not determinative. Further, it is notable that BJSC’s fixed extremity MRI scanner is now included in the calculation of need for 2020, yet the SHCC is likely to recommend no need for an additional fixed MRI scanner in the *2020 SMFP*.

b. *Unreasonable and unsupported utilization projections*

First, the historical and projected utilization includes scans performed by non-BJSC providers who are acquiring the MRI scanner without a CON. As such, these scans should not be included in the appropriate utilization of the MRI scanner. In addition, the historical and projected utilization also appears to include non-extremity scans, which is not in material compliance with BJSC’s CON. These scans, which include spine images, should also be excluded from the utilization projections. Moreover, the Wake Spine projections in Step 1 (page 82) are based on only two historical months of data, which is an insufficient foundation to provide a reasonable basis for projecting four and one-half years of volume.

¹ <https://raleighboneandjoint.com/contact-us/>; <https://www.auncurology.com/locations/>

Next, the application provides no basis for its projections of volume for AUNC patients. In Step 2, page 82, the application states that the average monthly referrals from AUNC to UNC/Duke are 75. This number is not supported with any data. While the letters of support from AUNC physicians reference a number of referrals per year, there is no monthly figure, and the annual total for those that provided estimates are fewer than 400 scans, not the 900 estimated in Step 2. As a result, the base number of AUNC scans is overstated. The application then assumes that 50 percent of these inflated scans will shift to the proposed new fixed MRI scanner, which is another assumption without any basis whatsoever. Given the draw of local academic medical centers for patients, as well as the lack of any scans for Medicaid and charity patients, it cannot be reasonably assumed, particularly without any estimates or support from referring physicians, that such a dramatic shift of patients can be achieved. The application then projects these scans to grow, again without any basis such as historical growth trends, or even statements of expected growth from referring physicians—the support letters refer only to the “last twelve months.”

c. *The utilization projections fail to demonstrate the need for the proposed project.*

Notwithstanding the unreasonable utilization methodology discussed above, utilization projections do not support the need for the proposed project.

1) Failure to meet the performance standards

The applicant fails to project sufficient volume to meet the minimum required performance standard in the administrative rules for MRI. While the application states that the rules do not apply, per a discussion with Agency representatives, Wake Radiology believes the rules must apply, for multiple reasons. First, the proposed project most certainly involves the development of a “new fixed MRI scanner” in the service area. Although the application does not propose to acquire a new machine, it does intend to no longer have a “fixed extremity MRI scanner,” which has specified limitations, and instead will operate a “fixed MRI scanner.” These differences are important. For example, if a provider operated peripheral angiography equipment that was capable of performing cardiac procedures, but had no CON to do so, if it proposed using its existing machine for cardiac cases, it would be subject to: a) a need determination in the *SMFP* for cardiac catheterization equipment; b) a CON for cardiac catheterization equipment; and, c) the administrative rules for cardiac catheterization equipment. This assumption is not mere conjecture; it has occurred in the past and should be applied to BJSC’s proposal.

Second, the administrative rules demonstrate that the existing equipment is distinct from the proposed equipment. In particular, the rule at 10A NCAC 14C .2701(6) defines “extremity MRI scanner,” which the applicant currently operates, as “an MRI scanner that is utilized for the imaging of extremities and is of open design with a field of view of no greater than 25 centimeters.” In contrast, an “MRI scanner” has a separate definition at 10A NCAC 14C .2701(9), which refers to the statutory definition. If these two machines were the same in the eyes of the CON statute and rules, there would be no need for separate definitions. Thus, the applicant is proposing a new “MRI scanner,” which is different in definition from the “extremity MRI scanner” it currently owns and the rules must apply.

Third, if the performance standards for an MRI scanner are not applied, then the applicant will have acquired an MRI scanner without ever having the rules applied to it. Though the initial application was subject to performance standards for “fixed extremity MRI” scanners, the minimum number of MRI scans that must be reasonably projected to be approved under those standards are significantly lower than for a “fixed MRI scanner.” Now, the applicant proposes to offer a general MRI scanner, and it must demonstrate the need for its scanner to be operated in this new way, and the performance standards must be applied. If they are not, the applicant will have completely circumvented the same process that anyone else must undergo when obtaining an MRI scanner, and the applicant will have been unfairly advantaged.

2) Failure to demonstrate effective utilization of the proposed MRI scanner

Even if the performance standards in the rules did not apply, the application fails to demonstrate the need for the proposed project based on its utilization projections. Although, as noted previously, it is clear that the applicant is using its MRI scanner for purposes beyond the scope of and out of material compliance with its CON, assuming arguendo that procedures shown on Table 4 on page 82 of the application for BJSC and Wake Spine may all properly be performed on the existing extremity MRI scanner, the only incremental scans proposed by the applicant are those for AUNC. As noted above, these projections are severely overstated based on the actual historical number of referrals from AUNC physicians shown in their letters, and there is no documentation regarding the appropriate percentage of cases that could be redirected to the proposed MRI scanner. Even if the projections were reasonable, however, they show a maximum of only 475 new scans by 2024 that cannot be performed on the existing scanner, which is clearly insufficient to demonstrate the need for the proposed project.

Further, even in instances when the performance standards do not apply, the Agency has used the utilization minimums to gauge the need for the project. In this instance, the application proposes only a modest increase in utilization (even assuming the assumptions are reasonable), and it would fall far short of the minimum 4,805 weighted procedures that applications for new MRI scanners in Wake County must achieve in order to be approved. It should also be noted that the performance standards also require applications for a new MRI scanner to demonstrate that the average utilization of all their existing MRI scanners is also 4,805 by the third project year. Thus, this standard applies not only to the new scanner, but to the existing ones as well. BJSC should not be approved, because it projects to achieve, under the best scenario, 66 percent of the minimum utilization threshold ($3,192 \div 4,805 = 0.66$), which is only 46 percent of the capacity of a fixed MRI scanner ($3,192 \div 6,864 = 0.46$).

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18a.

4. The application fails to demonstrate that the medically underserved will have adequate access to the proposed services.

In Section L, the application shows that BJSC has historically provided no charity care, served few self-pay patients, and served no Medicaid patients. While outpatient providers do generally

experience lower percentages of care to the underserved than hospitals, the complete lack of any charity or Medicaid whatsoever is astounding. The application suggests that the limited procedures it historically performed prevented it from treating these patients; however, no evidence is provided to support the notion that the indigent and Medicaid patients are somehow immune to conditions that require an extremity MRI scan. Even assuming that the limitations on BJSC's MRI scanner prevented it from treating these patients historically, the application continues to project absolutely no service to these patients, even with the projected increase in scans from outside the BJSC practice.

The projected payor mix is also unreasonable because it is not projected to change at all, even though the application proposes to serve a new patient population from AUNC. This issue clearly shows that the applicant has failed to consider what the payor mix of that patient population might be, or how it might be served by the proposed project. It further calls into question the utilization projections, since BJSC does not intend to serve any Medicaid or charity patients from AUNC that might be referred for a 3T MRI scan. Instead, its proposal would require these patients to go elsewhere for care, particularly to hospitals. This has the effect of driving indigent and Medicaid patients to hospitals, allowing the applicant to obtain a more favorable payor mix at the expense of other providers.

Perhaps most astonishing is the notion stated in the application that "to break even on the operation of the MRI, BJSC could not afford to take Medicaid patients...." Yet, according to the financial statements in Section Q, BJSC is projected to realize net income of more than \$14,000 in 2019, which is clearly sufficient to provide some care to Medicaid patients. Further, the pro formas project a significant increase in profitability following development of the proposed project, which would allow the applicant to care for some portion of these patients while still remaining profitable.

This issue is concerning, in that it speaks to a concern raised in the Findings of Fact in the CON law, specifically in §131E-175(3), which states in part, "*[t]hat, if left to the market place to allocate facilities and health care services...less than equal access to all population groups, especially those that have traditionally been medically underserved, would result.*" BJSC's historical and projected payor mix is the quintessential example of a provider giving less than equal access to the medically underserved. As such, the proposed project should not be approved.

Based on these issue, the application should be found non-conforming with Criteria 13(a), 13(c) and 18(a).

5. The application fails to demonstrate that it has chosen the most effective or least costly alternative.

In Section E, the application states that it considered no alternative methods for meeting the need for the proposed project. Since there is no "modification of scope" for a CON, then the proposed project cannot be the most effective or least costly alternative. Further, the application fails to consider the most obvious alternative, which is to apply for the need determination in the 2019 SMFP, which, if approved, would allow it to operate a fixed MRI scanner, without the restrictions placed on an extremity MRI scanner. Moreover, this alternative could have allowed it to continue operating a true "extremity" MRI scanner in addition to the proposed scanner, which would have

allowed the applicant to continue offering lower cost, low field, small bore extremity MRI scans to its patients, on which is what the need for its MRI scanner was based.

Based on the failure to consider these alternatives, the application should be found non-conforming with Criterion 4.

6. The application fails to demonstrate that it would not result in unnecessary duplication.

In Section G, the application fails to provide any evidence that the project would not result in unnecessary duplication. The only discussion relates to the Tesla strength of the MRI scanner and the lack of comparable units in Wake County. However, the CON law and rules do not distinguish between types of scanners by Tesla strength. The application must demonstrate that its proposal does not result in unnecessary duplication of existing resources, including the dozens of MRI scanners that already exist in Wake County. The application fails to even attempt to address how this “modification” in services will not unnecessarily duplicate the existing resources in Wake County. As discussed previously, if the proposed project allows BJSC to achieve its utilization projections, the MRI scanner would still be utilized far below the minimum threshold applied to all fixed MRI scanners. Further, the small number of scans it proposes to perform that it asserts are currently going to UNC or Duke for care does not justify the approval of a new, general use MRI scanner in Wake County. Finally, there is a need determination in the 2019 SMFP, for which BJSC has an opportunity to apply. Approving another new, general use MRI scanner in addition to that allocation will result in unnecessary duplication of existing MRI scanners in Wake County.

Based on this issue, the application should be found non-conforming with Criterion 6.

7. The application fails to reasonable demonstrate that it will provide access to health professional training programs.

In Section M, the application references an exhibit with letters it has recently sent to health training programs. As an existing provider for more than a decade, these relationships should have already been well-established. The application lacks any documentation of any relationships with health professional training programs during the existence of the service. The applicant clearly has no interest in providing access to these programs, or it could have made its existing extremity MRI scanner, a unique service in North Carolina, available to these programs many years ago.

This issue is particularly important given the shortage of trained health professionals—locally, regionally and nationally. As healthcare utilization increases with population growth and aging—at least in some settings—the shortage of healthcare professionals will continue to be an issue unless the number being trained can be increased. The availability of training sites is an essential part of the solution to this problem and BJSC’s historical lack of commitment to this issue should not be ignored.

For these reasons, the application should be found non-conforming with Criterion 14.