

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 7, 2020

Findings Date: January 7, 2020

Chief: Martha J. Frisone

Project ID #: J-11757-19

Facility: The Bone and Joint Surgery Clinic

FID #: 060621

County: Wake

Applicant(s): The Bone and Joint Surgery Clinic, LLP

Project: Expand the type of procedures that may be performed on the existing MRI scanner acquired pursuant to the demonstration project need determination in the 2006 State Medical Facilities Plan (Project ID #J-7605-06)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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.

NA

The Bone and Joint Surgery Clinic, LLP (Bone & Joint) owns a fixed MRI scanner which has been in use since 2007. The scope of the certificate of need (CON) issued for Bone & Joint's existing MRI scanner states: "*Acquire a fixed extremity MRI scanner resulting in the establishment of a diagnostic center.*" Condition #2 on the CON states: "*Bone and Joint Surgery Clinic, LLC [sic] shall not perform whole body scans on the extremity MRI scanner.*" In the 2019 application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner. That does not result in Bone & Joint proposing to acquire a "new" fixed MRI scanner. The existing MRI scanner is included in the inventory of regular fixed MRI scanners in the 2020 State Medical Facilities Plan (SMFP) and it will continue to be included in the regular inventory even if this application is not approved.

The applicant does not propose to offer or develop a new institutional health service for which there is a need determination in the 2019 SMFP. Moreover, there are no policies in Chapter 4

of the 2019 SMFP that are applicable to the applicant's proposal. Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (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.

C

Bone & Joint owns an existing MRI scanner which has been in use since 2007 or for 12 years. The scope of the CON issued for Bone & Joint's existing MRI scanner states: "*Acquire a fixed extremity MRI scanner resulting in the establishment of a diagnostic center.*" Condition #2 on the CON states: "*Bone and Joint Surgery Clinic, LLC [sic] shall not perform whole body scans on the extremity MRI scanner.*" In the 2019 application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner.

Background

The 2006 SMFP included a demonstration project for a fixed extremity MRI scanner. Bone & Joint, along with five other applicants, submitted a CON application proposing to acquire a fixed extremity MRI scanner pursuant to that need determination. Bone & Joint's 2006 application was identified as Project ID #J-7605-06. After reviewing each application individually against the statutory and regulatory review criteria and conducting a comparative analysis of the six applications, the Healthcare Planning and Certificate of Need Section (Agency) approved the application submitted by Bone & Joint on October 27, 2006. The approval of Bone & Joint's application was appealed. When the litigation was resolved, the CON was issued to Bone & Joint effective March 28, 2007. Bone & Joint acquired the MRI scanner and began using it in 2007. That MRI scanner was replaced in 2016. In late 2017, the Agency was notified that the Bone and Joint Surgery Clinic, including the first replacement MRI scanner, was to be relocated to a new site on Wake Forest Road in Raleigh. However, during the move, the first replacement MRI scanner was damaged beyond repair. Bone & Joint acquired a refurbished 3 Tesla¹ (3T) MRI scanner to replace it (the existing 3T MRI scanner).

In 2019, the State Health Coordinating Council (SHCC), a 25-member body appointed by the Governor, voted to officially end the demonstration project and to move Bone & Joint's existing MRI scanner into the regular inventory of fixed MRI scanners beginning with the Proposed 2020 SMFP. No comments in opposition to this were received by the Agency or the SHCC during the summer comment period. Regardless of whether this proposal is approved, the existing 3T MRI scanner owned by Bone & Joint will remain in the regular inventory of fixed MRI scanners. As a result, the procedures performed on Bone & Joint's existing MRI

¹ Tesla refers to the strength of the magnet.

scanner and the scanner itself will factor into whether the standard need methodology results in a need determination in Wake County in the future.

Patient Origin

On page 149, the 2019 SMFP defines the service area for MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Wake County has more than one licensed acute care hospital located within the county. Thus, the service area for Bone & Joint’s existing 3T MRI scanner consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	2019 (Estimated based on average of 2017 and 2018 utilization)		Third Full Fiscal Year of Operation following Project Completion (Calendar Year 2023)	
	Patients	% of Total	Patients	% of Total
Wake	1,738	76.2%	2,287	76.2%
Other	544	23.8%	716	23.8%
Total	2,282	100.0%	3,002	100.0%

Source: Section C.2(a), page 25, and Section C.3(a), page 26.

In Section C, page 24, the applicant states:

“The existing MRI scanner was only operational for one month in 2018, the last full fiscal year, before it was damaged moving it to a new location. Also, the EMR [electronic medical record] utilized by The Bone and Joint Surgery Clinic aggregates data in a way that makes collection of patient origin data extremely difficult and time consuming. Year to date 2019 was estimated based upon the average of 2017 and 2018 patient origin included in the annual EIFs [Registration and Inventory of Medical Equipment forms] filed by BJSC in 2018 and 2019.”

In Section C, page 26, the applicant states:

“The patient origin for the BJSC MRI is not expected to change. The increased MRI volume from Associated Urology [sic] patients being sent to Duke and UNC for 3T MRIs will represent approximately 16% of future MRI volume. The Associated Urology [sic] market area is comparable to BJSC and therefore patient origin for the new patients will be similar. The addition of the AUNC patients to the MRI volume at BJSC should not result in a significant change in patient origin. Therefore, BJSC assumes the patient origin will remain the same.” (Emphasis added.)

In written comments submitted during the first 30 days of the review cycle, Wake Radiology states:

“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 websites show that the practices have vastly different market areas. BJSC has a single office ... in Raleigh 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.”

In its response to Wake Radiology’s comments, Bone & Joint states:

“BJSC and Associated Urologist [sic] of North Carolina (AUNC) are both regional specialty providers. Over 25% of BJSC patients come from outside Wake County and it is reasonable to assume that a like percentage of AUNC patients come from outside Wake County, especially with location in other counties. Further, as stated on page 24, patient origin data was difficult to collect. As a result, this projection of future patient origin is a reasonable estimate based upon the data that was available.”

Wake Radiology’s comments are not persuasive. The claim that the market areas for Bone & Joint and Associated Urologists of North Carolina (AUNC) are “vastly different” appears to be based solely on a comparison of the number and location of the offices operated by each practice. Wake Radiology fails to explain how that is even remotely relevant to the percentage of each practice’s patients that are Wake County residents.

The applicant’s assumptions regarding patient origin are reasonable and adequately supported based on the following analysis:

- The applicant is required to identify the population to be served. To do that, the Agency requests that the applicant project the number of patients to be served by county of residence or other geographic area. See Section C, Question 3.
- Bone & Joint adequately identifies the number of patients it expects to serve by their county of residence.
- By its very nature, a reasonable projection of the number of patients referred to the existing 3T MRI scanner each year cannot be established with absolute certainty.
- The applicant adequately describes how it determined projected patient origin.
- Patient origin data for AUNC is not publicly available and no evidence was provided by Wake Radiology to support its presumption that the number and location of a physician practice’s offices correlates to patient origin.
- Four of AUNC’s seven offices are in Wake County and AUNC is a specialty practice as is Bone & Joint (though of a different specialty). It was not unreasonable for Bone & Joint to assume that AUNC’s patient origin would be like Bone & Joint’s patient origin, which is approximately 75 percent Wake County residents. Furthermore, only 16 percent of the total projected MRI patients are expected to be patients referred by AUNC.
- There is nothing in the CON Law or rules that requires Bone & Joint to project that a certain number of its patients will be residents of a given county.

Analysis of Need

In Section C.4, pages 28-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

“The existing MRI equipment, an Open Bore Magnetom Verio 3T MRI, is the only operational 3T MRI scanner in Wake County. Physicians and surgeons associated with other Wake County specialty groups have approached BJSC to use the 3T MRI for their patients in need of higher intensity MRI imaging. Associated Urologist [sic] of North Carolina (AUNC) in Wake County currently send nearly 900 patients per year to Durham or Chapel Hill for needed 3T MRI imaging. Many of these patients will be able to be seen locally at the BJSC MRI ... improving access and decreasing cost for these patients. The BJSC 3T MRI is a freestanding outpatient MRI with considerably lower cost and charges than the hospital-based UNC Hospital or Duke University Hospital based 3T MRI [sic] in Chapel Hill and Durham.

The BJSC MRI has available capacity and could perform a greater number of scans annually. Historical utilization of the BJSC MRI is shown in the following table.

The Bone and Joint Surgery Clinic – MRI Utilization

	CY 2017	CY 2018*	2019 Jan-Jun Annualized	Average Annual Growth Rate
Orthopedic MRI Scans - BJSC	1,569	106	2,026	14.6%
Orthopedic MRI Scans – Wake Spine			256	
Percent Contrast	0%	0%	0%	
Percent Sedation	0%	0%	0%	
Total Weighted MRI Scans	1,569	106	2,282	22.7%

Source: Exhibit C.2 for 2017 and 2018; BJSC data for 2019

*Utilization in CY 2018 significantly decreased due to downtime moving and subsequent damage to equipment. Operational time in CY 2018 was 1 month only.

As reflected in the previous table, total MRI procedures performed on the BJSC MRI is expected to increase dramatically in 2019. Estimated MRI volume for 2019 represents actual January to May MRI volume for BJSC patients annualized. The new replacement equipment is faster and more efficient resulting in additional capacity. BJSC has begun ‘renting’ block time to other orthopaedic physician groups interested in 3T MRI services. In May 2019 Wake Spine began utilizing the equipment and staff to perform MRI scans on its patients for four hours per week. ...

In May 2019 Associated Urology [sic] referred 93 patients to the 3T MRIs at Duke and UNC. Over the last two and a half years, 75 patients per month have been referred for 3T MRI outside of Wake County. Of these, Associated Urology [sic] estimates that approximately half of the patients per month could be sent to the BJSC 3T MRI for

prostate imaging in the future. In addition, this number may grow in the future as the standard of care for prostate cancer shift [sic] to 3T MRI imaging. Literature discussing 3T MRI as standard of care for prostate imaging is included in Exhibit C.4.a.

In addition, according to the Advisory Board ‘the tides are beginning to turn for 3T MRI. Enhanced protocols, dedicated coils, new gradients with multi-transmit processing capabilities have enhanced the value of 3T MRI beyond the advanced head and brain studies. Today, benefits are seen across a host of applications, including pediatric imaging, musculoskeletal imaging, small parts imaging, and oncology imaging, among many others.’

...

Please see letters of support from physician [sic] and surgeons in Wake County included in Exhibit C.4.b. Also included in Exhibit C.4.b are letters of support for the project from patients at Associated Urology [sic]. Exhibit C.4.a includes literature discussing 3T MRI as preferred treatment for diagnosing prostate cancer.”

The information is reasonable and adequately supported based on the following analysis:

- In Section C, Question 4, page 29, the applicant states that approximately 75 residents of Wake County are referred by AUNC physicians monthly to have an MRI procedure using a 3T MRI scanner at Duke or UNC Hospitals, which is approximately 900 per year [75 x 12 = 900]. The applicant states that AUNC physicians estimated that half could be scanned on Bone & Joint’s existing 3T MRI scanner, which is approximately 450 per year [900 / 2 = 450].
- At the public hearing, two urologists with AUNC spoke in support of Bone & Joint’s proposal. Marc Benevides, MD stated “*In the last two years the number of patients we refer for 3T MRI has increased dramatically and we now send on average, 75 patients a month to Duke or UNC. We refer our patients there, not because they need the services of a major tertiary care hospital, but because no 3T MRI is available in Wake County.*” Emil Kheterpal, MD stated “*As Dr. Benevides stated we refer around 75 patients monthly to UNC and Duke for 3T MRI of the prostate. This is approximately 900 patients annually and we are not the only Wake County urology practice sending patients out of Wake County.*” Thus, the statements made by the applicant on page 29 were confirmed by the two urologists with AUNC.
- As reported in its 2019 Hospital License Renewal Application (HLRA), in FFY 2018, 3,353 Wake County residents had an MRI procedure at UNC Hospitals. As reported in its 2019 HLRA, in FY 2018, 3,824 Wake County residents had an MRI procedure at Duke. Information is not available on how many of those patients were scanned on a 3T MRI scanner at UNC Hospitals or Duke.
- Bone & Joint’s existing 3T MRI scanner is the only fixed 3T MRI scanner located in Wake County and it is not hospital-based.
- For hospital-based MRI scanners there are two charges: one for interpretation of the images (i.e., the professional fee) and one for use of the facility (i.e., a facility fee).

- The cost to the patient or third-party payor for an MRI scan performed on Bone & Joint’s existing 3T MRI scanner would be lower because Bone & Joint cannot charge a facility fee. At the public hearing, Dr. Kheterpal stated “*The 3T MRI services available at UNC and Duke are not freestanding. They are hospital based, and they are tertiary care hospitals. As a result, our patients are paying substantially more than they would pay for a 3T MRI at a freestanding MRI center.*”
- Bone & Joint adequately documents that it is reasonable to assume that half of AUNC’s patients currently being referred to UNC Hospitals or Duke would utilize Bone & Joint’s existing 3T MRI scanner instead. See the letters of support from AUNC patients in Exhibit C.4.b.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization, as illustrated in the following table.

	Unweighted MRI Procedures	Weighted MRI Procedures²
CY 2017	1,569	1,569
CY 2018 *	106	106
CY 2019 (annualized) **	2,282	2,282
Interim Partial Year (1/1/20 to 3/31/20)	599	599
Operational Partial Year (4/1/20 to 12/31/20)	2,134	2,269
CY 2020	2,733	2,868
1 st Full FY (CY 2021)	2,897	3,080
2 nd Full FY (CY 2022)	2,949	3,136
3 rd Full FY (CY 2023)	3,002	3,192

*The first replacement MRI scanner was damaged beyond repair in January 2018. The second replacement MRI scanner did not begin operating until January 2019.

**CY 2019 is based on actual utilization for January through May of 2019 [$844 / 5 \times 12 = 2,026$; $2,026 + 256$ Wake Spine procedures = 2,282].

In Section Q, page 82, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- 2019 utilization (annualized) was used as the base for projecting utilization through the third full fiscal year (FY) of operation following completion of the project, which is calendar year (CY) 2023. None of these patients would need contrast.
- To project annual utilization by Wake Spine patients, Bone & Joint assumes 2 procedures per hour of block time multiplied by 80 percent. None of these patients would need contrast.
- On average, 75 patients are referred by AUNC to either Duke or UNC Hospitals for an MRI scan using a 3T MRI scanner. That equates to 900 patients annually [$75 \times 12 =$

² The applicant says that it weighted the procedures performed on patients referred by AUNC urologists because 100 percent will require contrast. See 10A NCAC 14C .2701(18). However, the applicant did not multiply its projections by the factor of 1.4. Thus, the weighted number of MRI procedures would be higher than shown in the table. In CY 2023, the weighted number of MRI procedures would be 3,382, not 3,192.

900]. AUNC physicians assume 50 percent could be scanned using Bone & Joint's existing 3T MRI scanner, which would be 450 patients per year. According to the AUNC physicians, 100% of these patients would need contrast.

- Bone & Joint assumes 2019 volumes would increase 1.8% per year, which is the weighted population growth factor shown in Tables 6 and 7 on page 83 of the application.

In its comments, Wake Radiology states that the applicant should not have included non-extremity procedures and procedures to be performed on Wake Spine patients. Furthermore, Wake Radiology asserts that the projected number of AUNC patients is overstated.

Regarding the assertion that Bone & Joint has performed non-extremity procedures with its existing MRI scanner, the CON issued in 2007 prohibits performing whole-body scans. Whether or not Bone & Joint may have performed types of procedures in the past which were not entirely consistent with representations made in its 2006 CON application is not relevant to the analysis of Bone & Joint's projected utilization in the 2019 CON application. G.S. 131E-190 describes how the Agency should enforce the CON Law and what sanctions may be imposed. Denial of a subsequent CON application is not one of the permitted sanctions. Moreover, imposition of sanctions is not mandatory, the Agency has discretion to impose sanctions or not impose them.

Regarding the Wake Spine patients, Wake Radiology incorrectly asserts that the arrangement with Wake Spine is contrary to the CON Law. In Section C, Question 4, page 29, Bone & Joint states it began "*renting* block time" to Wake Spine on Bone & Joint's existing MRI scanner in May 2019. The agreement is for four hours per week for July through December of 2019. In its response to Wake Radiology's comments, Bone & Joint states that the use of the word "*renting*" was in error and that "*no other physician group has ownership or control of the MRI, which is solely owned and controlled by BJSC.*" The arrangement is identical to the arrangement between health care facilities and the owner of a mobile MRI (vendor). In these arrangements, the vendor bills the health care facility a flat fee per patient or per hour and the health care facility bills the patient or third-party payor. There is nothing about the arrangement which violates the CON Law so long as the health care facility does not "acquire" the MRI scanner. Indeed, Wake Radiology operates two health care facilities in Wake County where Alliance owns the MRI scanner, not Wake Radiology. On their respective websites, Wake Radiology states MRI services are available at that location. However, Wake Radiology does not note that it does not own the MRI scanner that would be used to perform the procedure.

Regarding projected utilization by patients referred by AUNC urologists, Wake Radiology incorrectly asserts that the number is overstated because the 10 letters from AUNC physicians do not include estimated referral numbers that add up to 900. Bone & Joint does not represent that the estimated number of referrals in the 10 letters adds up to 900. Furthermore, there is nothing in the CON Law or rules that requires that letters of support include estimated referrals. In fact, there is nothing in the CON Law or rules that requires letters of support.

Moreover, Bone & Joint is not proposing in the 2019 application to acquire an MRI scanner. It already owns the 3T MRI scanner. It has been in use since 2007 or for 12 years. The

Performance Standards, promulgated at 10A NCAC 14C .2703, only apply to proposals to acquire a fixed MRI scanner. Therefore, Bone & Joint is not required to demonstrate that the existing 3T MRI scanner will perform any minimum number of weighted MRI procedures in the third year of operation.

Bone & Joint did project utilization as requested by the application form and the Agency determined that projected utilization is reasonable and adequately supported based on the following analysis:

- Utilization of Bone & Joint's existing 3T MRI scanner in CY 2019 (annualized) is expected to be 2,282 weighted MRI procedures which would be a 45.4 percent increase over the number performed in CY 2017 [$2,282 - 1,569 = 716$; $716 / 1,569 = 0.454$]. CY 2019 is not compared to CY 2018 because the MRI scanner only operated for one month in 2018.)
- According to the copy of Table 17E-1 from the Proposed 2020 SMFP provided in Exhibit C.4.a, there are 19 existing and approved fixed MRI scanners located in Wake County, which includes the 3T MRI scanner owned by Bone & Joint.³ There is a need determination in the 2019 SMFP for one additional fixed MRI scanner to be located in Wake County. It was reasonable for Bone & Joint to assume that the number of procedures to be performed on its existing 3T MRI scanner would increase based on a weighted population growth factor of 1.8 percent per year. See Tables 6 and 7 in Section Q, page 83.
- The applicant states that approximately 75 residents of Wake County are referred by AUNC urologists each month to have an MRI procedure using a 3T MRI scanner at Duke or UNC Hospitals, which is approximately 900 per year. In FFY 2018, 3,353 Wake County residents traveled to UNC Hospitals in Orange County for an MRI procedure on a hospital-based MRI scanner. Information is not available on how many of those patients were scanned on a 3T MRI scanner at UNC Hospitals. In FY 2018, 3,824 Wake County residents traveled to Duke in Durham County for an MRI procedure on a hospital-based MRI scanner. Information is not available on how many of those patients were scanned on a 3T MRI scanner at Duke. It was reasonable for Bone & Joint to assume that 50 percent of AUNC's historical referrals to Duke or UNC Hospitals would be referred to Bone & Joint's existing 3T MRI scanner.
- Bone & Joint's existing 3T MRI scanner is not hospital-based. For hospital-based MRI scanners there are two charges: one for interpretation of the images (i.e., the professional fee) and one for use of the facility (i.e., a facility fee). The cost to the patient or third-party payor for an MRI scan performed on Bone & Joint's existing 3T MRI scanner would be lower because Bone & Joint cannot charge a facility fee. It was reasonable for Bone & Joint to assume that 50 percent of AUNC's patients would prefer the lower cost alternative.

³ The number should be 20 as one of the MRI scanners classified as mobile should have been classified as fixed.

Access

In Section C.11, pages 34-35, the applicant describes how medically underserved groups will have access to the expanded MRI services. In Section L, page 65, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Existing 3T MRI Scanner
Self-Pay	0.9%
Charity Care	0.0%
Medicare *	39.0%
Medicaid *	0.0%
Insurance *	59.5%
Workers Compensation	0.4%
TRICARE	0.0%
Other (Specify)	0.2%
Total	100.0%

* Including any managed care plans

The projected payor mix is reasonable and adequately supported. See the discussion found in Criterion (13) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the expanded MRI services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

CA

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing 3T MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section E, page 43, the applicant states that Bone & Joint has no other alternative to meet the need other than obtaining a CON authorizing the expansion of the types of MRI procedures that can be performed on its existing 3T MRI scanner.

In Section C.4(a), page 27, the applicant states that the existing MRI scanner is the only 3T MRI scanner located in Wake County. The applicant also states that 3T MRI scanners are “capable of providing superior imaging quality for many different types of MRI such as musculoskeletal imaging, small parts imaging, pediatric imaging, and oncology imaging [sic] prostate and brain imaging.” The applicant provides supporting documentation in Exhibit C.4.a. Moreover, the applicant states that “many residents of Wake County are leaving the county to seek 3T MRI imaging at UNC Hospitals or Duke University Hospital.” The applicant notes that those 3T MRI scanners are “hospital-based,” resulting in higher out-of-pocket costs to the patient (i.e., deductibles, co-insurance and co-pays) than what they would be at a diagnostic center like The Bone and Joint Surgery Clinic. The applicant provides supporting documentation in Exhibits C.4.a and C.4.b.

On page 2 of its comments, Wake Radiology states:

“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) [sic], 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. ... The applicant is, and should be, subject to the limitation prohibiting full body scans (non-extremity scans), regardless of the exemption granted 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.” (Emphasis in original.)

Wake Radiology claims that Bone & Joint's 2019 application is not conforming with Criterion (4) because the applicant refers to its proposal as a "modification of scope" but that term is not used in the CON Law. Then Wake Radiology also concludes that the proposal is not a "change in scope" as that term is defined in the CON Law. Based on that, Wake Radiology concludes the proposal cannot be the most effective or least costly alternative.

Wake Radiology's comments are not persuasive. Bone & Joint recognized that it needed a new CON in order to remove the restriction of Condition #2 on the CON issued in 2007, which prohibits Bone & Joint from using the existing 3T MRI scanner to perform whole body scans.⁴ This is the only restriction on the face of the certificate regarding the types of procedures that may be performed on the existing MRI scanner. However, in its 2006 application, Bone & Joint made certain representations about what types of procedures would be performed on the MRI scanner. Before Bone & Joint filed the 2019 application, the Agency discussed with Bone & Joint the need to obtain a new CON in order to remove Condition #2 and to modify the representations about the types of procedures that would be performed.

Moreover, approval of Bone & Joint's 2019 application does not result in approving a new fixed MRI scanner. The SHCC voted to include Bone & Joint's existing 3T MRI scanner in the regular inventory of fixed MRI scanners in Wake County before Bone & Joint filed the 2019 application. Bone & Joint's existing 3T MRI scanner will remain in the regular inventory even if the 2019 application is not approved.

On page 7 of its comments, Wake Radiology states, "*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 place on an extremity MRI scanner.*"

Wake Radiology's assertion that filing an application in response to the need determination in the 2019 SMFP would be a more effective alternative is not persuasive. Bone & Joint already has a fixed MRI scanner, which has been in use since 2007 or for 12 years and Bone & Joint does not want a second fixed MRI scanner.⁵ Moreover, if Bone & Joint had filed an application proposing to expand the types of MRI procedures that could be performed on the existing fixed MRI scanner in response to the need determination in the 2019 SMFP for an additional fixed MRI scanner in Wake County, it would not compare favorably to proposals that would actually increase the inventory of fixed MRI scanners in Wake County.

⁴ The term "whole body scans" is not defined in the CON Law or rules. It has been interpreted by the Agency to mean scanning the whole body (head to toe) in one scan. The Agency does not interpret the term to be equivalent to "non-extremity scans."

⁵ If Bone & Joint had applied for a second fixed MRI scanner pursuant to the need determination in the 2019 SMFP, 10A NCAC 14C .2703(b)(3) would have been applicable and Bone & Joint would have to had to demonstrate that its existing fixed MRI scanner and the second proposed fixed MRI scanner would perform an average of 4,805 weighted MRI procedures per scanner. Utilization increased dramatically between 2017 and 2019 but it is highly unlikely that Bone & Joint could reasonably demonstrate that it would perform 9,610 weighted MRI procedures by the third full year of operation [4,805 x 2 = 9,610]. The alternative suggested by Wake Radiology is no alternative at all for Bone & Joint.

The applicant adequately demonstrates that Bone & Joint has no other alternative to this proposal that would meet the need. Without a new CON, Bone & Joint cannot expand the scope of procedures that may be performed on its existing MRI scanner because of Condition #2 on the CON issued in 2007. The applicant adequately demonstrates the need to expand the scope of procedures that may be performed on its existing 3T MRI scanner. The estimated cost to upgrade the existing MRI scanner is less than \$100,000, which includes medical equipment, consultant fees and a 10 percent contingency.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. The Bone and Joint Surgery Clinic, LLP shall materially comply with all representations made in the certificate of need application identified as Project ID #J-11757-19.**
- 2. The Bone and Joint Surgery Clinic, LLP shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 3. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, The Bone and Joint Surgery Clinic, LLP shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

4. **The Bone and Joint Surgery Clinic, LLP shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (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.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

Capital and Working Capital Costs

In Section Q, page 90, the applicant projects the total capital cost of the project, as shown in the table below.

Medical Equipment	\$60,092
Consultant Fees	\$22,000
Subtotal	\$82,092
Contingency (10% of Subtotal)	\$8,209
Total	\$90,301

In Section Q, page 91, the applicant provides the assumptions used to project the capital cost.

In Section F, page 45, the applicant projects that there will be no start-up costs or initial operating expenses. The applicant correctly notes that the 3T MRI scanner is already operational. Bone & Joint has owned and operated the fixed MRI scanner for 12 years.

Availability of Funds

In Section F, page 45, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total
Loans	\$0
Accumulated reserves or OE *	\$0
Bonds	\$0
Other (Line of Credit)	\$90,301
Total Financing	\$90,301

* OE = Owner's Equity

Exhibit F.2 includes an August 2, 2019 letter signed by Robert Mason, Senior Vice President, Commercial Banking, Capital Bank, which states:

“Capital Bank has had the privilege of working with the physicians of The Bone and Joint Surgical Clinic for many years. We are familiar with their operations and based on the financial condition of their practice and its principals, as well as the long positive banking relationship we have had, we would be willing provide financing for this project.”

Capital Bank proposes a revolving line of credit up to \$150,000 with a variable rate of Prime + 0.00%.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Unweighted MRI Procedures	2,897	2,949	3,002
Total Gross Revenues (Charges)	\$1,839,168	\$1,898,477	\$1,930,852
Total Net Revenue	\$768,033	\$786,182	\$775,816
Average Net Revenue per Procedure	\$265	\$267	\$258
Total Operating Expenses (Costs)	\$510,726	\$510,368	\$508,892
Average Operating Expense per Procedure	\$176	\$173	\$170
Net Income	\$257,306	\$275,813	\$265,924

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

On page 149, the 2019 SMFP defines the service area for MRI scanners as “a single county, except where there is no licensed acute care hospital located within the county.” Wake County has more than one licensed acute care hospital located within the county. Thus, the service area for Bone & Joint consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in Wake County.

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2018 *
Duke Radiology Holly Springs (Duke University Health System) **	1	0
Duke Raleigh Hospital (Duke University Health System)	2	13,892
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,634
Raleigh Neurology Imaging (Alliance)	1	5,988
Raleigh Radiology – Blue Ridge (Alliance)	1	6,004
Raleigh Radiology – Cary (Alliance) ^	1	7,511
Raleigh Radiology – Cedarhurst (Pinnacle)	1	8,111
Rex Hospital – Main (UNC Health System)	2	11,525
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	532
The Bone and Joint Surgery Center (Bone & Joint) ^^	1	106
Wake Radiology – Garner (Alliance)	1	3,300
Wake Radiology (Wake Radiology)	1	3,445
Wake Radiology Diagnostic Imaging (Alliance)	1	4,123
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	3,445
WakeMed (WakeMed)	2	12,949
WakeMed Cary Hospital (WakeMed)	1	4,855
2019 Need Determination #	1	0
Total	20	91,420

Source: Table 17E-1 in the Proposed 2020 SMFP.

* October 1, 2017 to September 30, 2018.

** Under development.

^ In the version of Table 17E-1 posted on the Agency’s website on or about July 1, 2019, this site was incorrectly classified as a mobile site. This MRI scanner is “permanently” installed.

^^ The first replacement MRI scanner was damaged beyond repair in January 2018. Thus, it was only in operation approximately 3 months during FFY 2018 (October through December).

Currently under review. There are six applications, one of which was submitted by Wake Radiology.

The 19 existing and approved fixed MRI scanners are owned by the following entities:

- Alliance (5 scanners)
- Duke University Health System (3 scanners)
- UNC Health System (3 scanners)
- WakeMed (3 scanners)
- Wake Radiology (2 scanners)
- Bone & Joint (1 scanner)
- Raleigh Neurology Associates (1 scanner)
- Pinnacle (1 scanner)

In Section G, page 52, the applicant explains why it believes its proposal to expand the types of procedures performed on its existing fixed MRI scanner would not result in the unnecessary duplication of existing or approved MRI services in Wake County. The applicant states *“The BJSC MRI is an existing MRI scanner and is the only 3T MRI in Wake County.”*

In its comments, Wake Radiology states, *“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 [sic] and rules do not distinguish between types of scanners by Tesla strength.”* In its response to Wake Radiology’s comments, Bone & Joint states, *“BJSC is not acquiring a new MRI. The BJSC MRI is an existing MRI, which is included in the ... SMFP MRI inventory, as such it cannot result in unnecessary duplication of MRI services. It already exists. ... There is no [other] 3T MRI in Wake County.”* Wake Radiology’s comments are not persuasive. Bone & Joint’s is not proposing to acquire a new MRI scanner. Instead, it wants to be able to expand the types of MRI procedures that may be performed on its existing 3T MRI scanner, which will continue to be included in the regular inventory of fixed MRI scanners beginning with the Proposed 2020 SMFP regardless of whether or not this application is approved.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved MRI services in the service area for the following reasons:

- The proposal does not result in an increase in the number of fixed MRI scanners in Wake County. Even if this proposal is not approved, Bone & Joint’s existing 3T MRI scanner will be included in the regular inventory of fixed MRI scanners in Wake County.
- The existing and approved fixed MRI scanners located in Wake County were well utilized in FFY 2017 resulting in a need determination in the 2019 SMFP for one additional fixed MRI scanner. If Bone & Joint’s existing 3T MRI scanner had not been included in the regular inventory, there would have been a need determination for another fixed MRI scanner in Wake County in the 2020 SMFP.
- The applicant adequately demonstrates that urology patients currently utilizing hospital-based 3T MRI scanners in Durham and Orange counties would benefit from access to a lower cost 3T MRI scanner located in Wake County that is not hospital-based.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section Q, Form H, page 98, the applicant provides current and projected full-time equivalent (FTE) staffing for the MRI scanner, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 1/1/19	1 st , 2 nd and 3 rd FFY (CYs 2020, 2021 and 2022)
Radiology Technologists	2.0	2.0
TOTAL	2.0	2.0

The applicant states that “*staffing for the existing MRI will not change as a result of the proposed modification of scope. Existing staffing will be sufficient to handle the additional volume.*” Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007. In Section I, page 56, the applicant states *“No additional ancillary or support services will be necessary with the inclusion of additional types of MRI scans. BJSC currently has an agreement with Raleigh Radiology to interpret the BJSC MRI scan [sic]. This is not expected to change as a result of the project.”* The applicant adequately explains that ancillary and support services are already made available for the existing MRI scanner.

On page 56, the applicant states *“No changes are expected in the coordination with existing health services in the market with the inclusion of additional types of MRI scans at BJSC. Surgeons with BJSC currently have privileges at Duke Raleigh Hospital, WakeMed and Capital City Ambulatory Surgical Facilities.”* In Section L, page 66, the applicant states, *“Both BJSC and AUNC also provide on-call emergency room coverage at Duke Raleigh Hospital, WakeMed and Rex Hospital which carries with it a commitment to provide in-office follow-up to patients served through that call rotation.”*

The applicant adequately describes its existing and proposed relationships with other local health care providers and provides supporting documentation in Exhibit C.4.b.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose any construction as part of the proposal. Therefore, Criterion (12) is not applicable to this review.

- (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:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section L, page 63, the applicant provides the historical payor mix during CY 2019 for the existing MRI services, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	0.9%
Charity Care	0.0%
Medicare *	39.0%
Medicaid *	0.0%
Insurance *	59.5%
Workers Compensation	0.4%
TRICARE	0.0%
Other (specify)	0.2%
Total	100.0%

* Including any managed care plans.

Source: Section L, page 63. "Estimated based on data from January 1, 2019 through May 31, 2019."

In Section L, page 63, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area *
Female		52.0%
Male		48.0%
Unknown		0.0%
64 and Younger **	61%	88.0%
65 and Older	39%	12.0%
American Indian		0.8%
Asian		7.5%
Black or African-American		21.0%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian		59.8%
Other Race		10.3%
Declined / Unavailable		0.5%

*Applicant's Source: "NC OSBM, Age and Sex for 2019, US Census Quickfacts, Race for 2018."

** Calculated by the analyst by subtracting 39% from 100%.

On page 63, the applicant states: “*The Bone and Joint Clinic does not have ready access to demographic information on their patients at [the level of specificity in the table above] for the MRI. ... Patient gender and race data is not easily extracted from the BJSC EMR.*” On page 65, the applicant states:

“BJSC provides care to Medicaid patients in need of wound care, none of whom require MRI services. Medicaid in North Carolina provides coverage predominantly to mothers and children, and chronic disease patients/elderly persons covered by Medicare and Medicaid. ... Patients that would qualify for Medicare/Medicaid are billed under Medicare. ... Therefore, the BJSC MRI historically did not have any Medicaid patients and does not project future Medicaid volume.”

In Section C, Question 11, pages 34-35, the applicant describes how low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare beneficiaries and Medicaid recipients have access to Bone & Joint’s services.

In its written comments, Wake Radiology states:

“In Section L, the application shows that BJSC has historically provided no charity care, served few self-pay patients, and served no Medicaid patients. ... 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.”

In its response to Wake Radiology’s comments, Bone & Joint states:

“Wake Radiology misinterpreted the discussion in Section L in the BJSC application. As stated on pages 65 and 66, BJSC does provide Medicaid and charity care. ...

... Wake Radiology does not provide any documentation or data to support how much charity care or Medicaid they think a small outpatient MRI provider, specializing in orthopedic care provides on average. This information is not provided by MRI providers in the annual Equipment Inventory Form ... so there is no way to determine a comparable payor mix

BJSC treats all patients referred to them and is open to working with all payors and insurance companies. ... BJSC ... recently partnered with the North Carolina State Health Plan as a low-cost provider for state-employees [sic].”

Wake Radiology's comments are not persuasive. There is nothing in the CON Law or rules that requires that a health care facility provide a minimum level of care to specific medically underserved groups. Bone & Joint correctly notes on page 65 of its application that Medicaid is available predominantly to mothers and children and to the elderly. Bone & Joint does treat Medicare patients, some of whom will also have Medicaid coverage.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (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;

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 64, the applicant states that Bone & Joint is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 64, the applicant states that during the last five years no patient civil rights access complaints have been filed against the existing facility.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section L, page 65, the applicant provides the projected payor mix during the third FFY (CY 2023) for the existing MRI services, as shown in the table below.

Payor Category	MRI Services as Percent of Total
Self-Pay	0.9%
Charity Care	0.0%
Medicare *	39.0%
Medicaid *	0.0%
Insurance *	59.5%
Workers Compensation	0.4%
TRICARE	0.0%
Other (specify)	0.2%
Total	100.0%

* Including any managed care plans.

Source: Section L, page 65.

As shown in the table above, during the third FFY (CY 2023), the applicant projects that 0.9% of total services will be provided to self-pay patients and 39.0% to Medicare patients. The projected payor mix is identical to the historical payor mix.

On page 65, the applicant states:

“BJSC provides care to Medicaid patients in need of wound care, none of whom require MRI services. Medicaid in North Carolina provides coverage predominantly to mothers and children, and chronic disease patients/elderly persons covered by Medicare and Medicaid. ... Patients that would qualify for Medicare/Medicaid are billed under Medicare. ... Therefore, the BJSC MRI historically did not have any Medicaid patients and does not project future Medicaid volume.

The new MRI equipment, which became operational in January 2019 has expanded capabilities and is considerably faster and more efficient. The percentage of Medicare and self pay patients, who receive a discount, increased from 2017 as a result. ... Hopefully in the future, as utilization of the MRI equipment increases, and the BJSC MRI breaks even, any losses associated with

scanning Medicaid patients can be absorbed. However, to remain conservative and not overstate payor mix, no Medicaid patients are projected at this point.”

In Section C, Question 11, pages 34-35, the applicant describes how low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare beneficiaries and Medicaid recipients have access to Bone & Joint’s services.

In its written comments, Wake Radiology states:

“In Section L, the application shows that BJSC has historically provided no charity care, served few self-pay patients, and served no Medicaid patients. ... 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.”

In its response to Wake Radiology’s comments, Bone & Joint states:

“Wake Radiology misinterpreted the discussion in Section L in the BJSC application. As stated on pages 65 and 66, BJSC does provide Medicaid and charity care. ...

... Wake Radiology does not provide any documentation or data to support how much charity care or Medicaid they think a small outpatient MRI provider, specializing in orthopedic care provides on average. This information is not provided by MRI providers in the annual Equipment Inventory Form ... so there is no way to determine a comparable payor mix

BJSC treats all patients referred to them and is open to working with all payors and insurance companies. ... BJSC ... recently partnered with the North Carolina State Health Plan as a low-cost provider for state-employees [sic].”

Wake Radiology’s comments are not persuasive. There is nothing in the CON Law or rules that requires that a health care facility provide a minimum level of care to specific medically underserved groups. Bone & Joint correctly notes on page 65 of its application that Medicaid is available predominantly to mothers and children and to the elderly. Bone & Joint does treat Medicare patients, some of whom will also have Medicaid coverage.

The projected payor mix is reasonable and adequately supported based on the following analysis:

- Projected payor mix cannot be known with certainty.

- Relying on historical payor mix is a reasonable method for projecting payor mix in the future.
- Only 16 percent of the projected MRI patients are projected to be referred by AUNC physicians.
- The payor mix for AUNC's existing patients is not publicly available.
- It was reasonable for Bone & Joint to assume that the payor mix would not change as a result of the proposal to expand the types of MRI procedures performed on Bone & Joint's existing 3T MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section L, page 66, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section M, page 67, the applicant describes the extent to which area health professional training programs would have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. There are four documents in Exhibit M.2. Two are from area health professional training programs:

- An August 9, 2019 letter from the Administrative Department Head, Imaging Programs at Wake Technical Community College expressing an interest in a potential relationship with Bone & Joint.
- An August 8, 2019 email from the Clinical Coordinator for Radiography Program Head for Medical Assisting at Vance-Granville Community College expressing an interest in adding Bone & Joint as a clinical site for MRI students.

In its comments, Wake Radiology states, *“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.”* In its response to Wake Radiology’s comments, Bone & Joint states, *“BJSC currently does not provide a full MRI service and as such is not in the position to provide a comprehensive educational opportunity for students.”*

Wake Radiology’s comments are not persuasive. Criterion (14) does not require an applicant to demonstrate that it has accommodated the clinical needs of area health professional training programs in the past. Rather, Criterion (14) requires an applicant to demonstrate that the *“proposed health services”* will accommodate the clinical needs of health professional training programs, *“as applicable.”* An application is conforming if the applicant demonstrates that it is willing to offer its facility as a possible clinical site for training health care providers. The Agency does not require an applicant to demonstrate that it has an executed agreement with one or more area health professional training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, as applicable. Therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

On page 149, the 2019 SMFP defines the service area for MRI scanners as “*a single county, except where there is no licensed acute care hospital located within the county.*” Wake County has more than one licensed acute care hospital located within the county. Thus, the service area for Bone & Joint consists of Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in Wake County.

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2018 *
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Raleigh Radiology – Cedarhurst (Pinnacle)	1	8,111
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Source: Table 17E-1 in the Proposed 2020 SMFP.

* October 1, 2017 to September 30, 2018.

** Under development.

^ In the version of Table 17E-1 posted on the Agency’s website on or about July 1, 2019, this site was incorrectly classified as a mobile site. This MRI scanner is “permanently” installed.

^^ The first replacement MRI scanner was damaged beyond repair in January 2018. Thus, it was only in operation approximately 3 months during FFY 2018 (October through December).

Currently under review. There are six applications.

The 19 existing and approved fixed MRI scanners are owned by the following entities:

- Alliance (5 scanners)
- Duke University Health System (3 scanners)
- UNC Health System (3 scanners)
- WakeMed (3 scanners)
- Wake Radiology (2 scanners)
- Bone & Joint (1 scanner)
- Raleigh Neurology Associates (1 scanner)
- Pinnacle (1 scanner)

In Section C, page 35, the applicant states “*BJSC is NOT acquiring a new MRI. BJSC currently owns and operates the 3T MRI The proposed project is to ... provide access to patients for other Wake County specialties that currently must leave Wake County to receive 3T MRI services.*” (Emphasis in original.) In Section N, pages 69-70, the applicant states:

“All of the MRI scanners in Wake County are 1.5 Tesla scanners. While 1.5 [sic] MRI scanners are the workhorse for MRI imaging for diagnosis and treatment, more and more

often some conditions are better suited for a 3 Tesla (3T) scanner. High field magnetic resonance imaging with a 3T MRI is becoming the standard of care for the prostate

The 3T magnets also improve patient experience. In particular, men undergoing prostate imaging with 3T scanners routinely do not require the use of an endorectal coil which is commonly required in 1.5T scans screening for prostate cancer. In addition, a freestanding outpatient 3T MRI located in Wake County will decrease travel time and expense for patients currently traveling to other counties for MRI procedures requiring a 3T scanner.”

Bone & Joint’s existing 3T MRI scanner has been in operation for 12 years. In 2019, the SHCC voted to include it in the regular inventory of fixed MRI scanners located in Wake County. Even if this proposal were to be denied, Bone & Joint’s existing 3T MRI scanner will continue to be included in the regular inventory of fixed MRI scanners located in Wake County.

Regarding the impact of the proposal on cost effectiveness, on pages 69-70, the applicant states:

“The proposed project will result in making the only 3T MRI in Wake County available to additional patients who currently leave the market to receive 3T MRI imaging at hospital-based MRI locations. The additional cost of hospital-based imaging is well documented. ... Approval of the proposed project will result in a lower-cost alternative available for 3T MRI in Wake County.”

Regarding the impact of the proposal on quality, on page 70, the applicant states:

“The 3T MRI provides twice the signal-to-noise ratio (SNR) compared to 1.5T systems resulting in increased spatial and temporal resolution, which ultimately results in an improvement in image quality. Higher field magnetic resonance imaging available with a 3T MRI has specific advantages for imaging of the brain, spine, liver, pancreas, breast, gallbladder, bile duct system and the prostate, particularly because of its increased spatial resolution. It allows for increased visualization of these structures. ... This more refined information provides a better guide to therapy. The 3T MRI increases visualization of organs and small vessels and improves the interpreter’s ability to evaluate patients.”

Regarding the impact of the proposal on access by medically underserved groups, on page 71, the applicant states:

“The proposed project will result in making the only 3T MRI in Wake County available to additional patients currently leaving the market to receive 3T MRI imaging at hospital-based MRI locations. The additional cost of hospital-based imaging is well documented. As previously discussed, BJSC currently provides access to all persons referred to the group for medical and diagnostic services by any health care or medical provider.

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007.

In Section A, Form A, the applicant states that The Bone and Joint Surgery Clinic is the only facility owned and operated by the applicant or a related entity. In Section O, page 72, the applicant states that the facility is accredited by the Intersocietal Accreditation Commission (IAC), a non-profit organization that accredits facilities that provide diagnostic imaging and procedure-based modalities. ... The applicant states, "*The Bone and Joint Surgery Clinic imaging services have been fully Medicare certified and accredited with no complaints since the equipment became operational.*" The equipment has been in use since 2007.

After reviewing and considering information provided by the applicant and considering the quality of care provided at The Bone and Joint Surgery Center, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

In this application, Bone & Joint proposes to expand the types of MRI procedures that can be performed on its existing MRI scanner, which was acquired pursuant to the certificate of need issued for Project ID #J-7605-06, effective March 27, 2007. The Criteria and Standards for Magnetic Resonance Imaging Scanner, which are promulgated in 10A NCAC 14C .2700, were applicable to the review of the 2006 application and Bone & Joint adequately demonstrated in its 2006 application that its proposal was conforming with those rules.

However, the rules are not applicable to the review of this proposal, which is a different application, because Bone & Joint is not acquiring an MRI scanner as part of this project. Bone & Joint's existing MRI scanner has been in operation for 12 years. In 2019, the SHCC voted to include it in the regular inventory of fixed MRI scanners located in Wake County. Bone & Joint's existing 3T MRI scanner will continue to be included in the regular inventory of fixed MRI scanners located in Wake County even if this application is not approved.