

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 19 2017
Findings Date: April 19, 2017

Project Analyst: Mike McKillip
Team Leader: Lisa Pittman
Assistant Chief: Martha Frisone

Project ID #: J-11291-17
Facility: Browning Mobile MRI
FID #: 170021
County: Wake
Applicants: Browning Equipment SPE, LLC
Rex Hospital, Inc.

Project: Develop a new freestanding diagnostic center through the contribution of an existing provider-based mobile MRI unit

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

Browning Equipment SPE, LLC [**Browning Equipment**] and Rex Hospital, Inc. [**Rex Hospital**] propose to develop a freestanding diagnostic center through the contribution of an existing provider-based mobile MRI unit currently owned and operated by Rex Hospital (Rex Mobile MRI) to a newly formed joint venture entity, Browning Equipment.

Need Determination and Policies

There are no need determinations or policies in the 2017 State Medical Facilities Plan (SMFP) applicable to the acquisition of existing equipment or to the establishment of a diagnostic center. Therefore, this criterion 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- (2) Repealed effective July 1, 1987.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

The applicants, Browning Equipment and Rex Hospital, propose to develop a freestanding diagnostic center through the contribution of an existing provider-based mobile MRI unit currently owned and operated by Rex Hospital (Rex Mobile MRI) to a newly formed joint venture entity, Browning Equipment.

In Section C.1, pages 31-32, the applicants describe the project as follows:

“As noted above, the mobile MRI equipment to be operated as the proposed diagnostic center already exists and is currently being operated by Rex Hospital, Inc., one of the applicants. As such, the proposed project is not for the acquisition of additional medical diagnostic equipment, but for the reorganization of an existing provider-based imaging center into a non-provider based imaging center, which will result in the creation of a diagnostic center as defined in G.S. 131E-176(7a) ... Rex Hospital, Inc. owns and operates REX Mobile MRI, which is currently operated as a department of UNC REX Hospital and provides outpatient MRI services. With this project, Rex Hospital, Inc. proposes to contribute the existing medical diagnostic equipment to Browning Equipment SPE, LLC, which will operate the mobile scanner as a mobile diagnostic program....”

Rex Hospital, Inc. acquired the existing mobile MRI scanner pursuant to previously approved Project ID #J-7284-05, which granted approval to operate the mobile MRI scanner at Rex Hospital, Inc. and Rex Family Practice of Wakefield. ... As part of the joint venture initiative between UNC REX and Wake Radiology, Browning Equipment SPE, LLC wishes to provide mobile MRI services at three outpatient sites to be owned by the joint venture, including Browning Diagnostic Imaging of Wakefield, Browning Diagnostic Imaging of Knightdale, and Browning Diagnostic Imaging of Holly Springs.”

Rex Hospital received Declaratory Rulings (DRs) from DHSR in 2009 and 2011 allowing the addition of mobile MRI sites at Rex Knightdale and Rex Holly Springs outpatient facilities. However, Rex is not required by the DRs to utilize those additional sites. On the other hand,

Condition #2 of the Certificate of Need for Project I.D. # J-7284-05 requires that *“the mobile MRI scanner be moved each week to provide MRI services to at least two host sites and shall not, at any time, serve less than two host sites each week.”* In its 2017 Hospital License Renewal Application (LRA), Rex Hospital reports that its existing mobile MRI scanner served only the Wakefield site during the FFY2016 reporting period. Therefore, based on the data in the 2017 LRA, Rex Hospital did not serve at least two host sites each week as required. However, any failure by Rex to comply with Condition #2 of the certificate issued for a different project is not material to the Agency’s review of this proposal as there are no statutory or regulatory review criteria related to past compliance with conditions imposed on certificates of need issued to the same or different applicants for other projects.

Designation as a Diagnostic Center

In Section C.1, page 32, the applicants list the current fair market value (FMV) and original purchase price of the existing mobile MRI scanner, which is summarized below:

Existing Medical Diagnostic Equipment at Rex Mobile MRI

SERVICE	EQUIPMENT	CURRENT FMV	ORIGINAL PURCHASE PRICE
Mobile MRI	Mobile Siemens Espree	\$387,295	1,679,046
Subtotal Existing Medical Diagnostic Equipment		\$387,295	\$1,679,046
Existing Essential Non-Medical Equipment Assets*		\$157,766	\$157,766
Total		\$545,061	\$1,836,812

Source: Section C.1, page 32, of the application.
 *The applicants state this category includes supplies.

The total cost of the existing medical diagnostic equipment utilized by Rex Mobile MRI which cost \$10,000 or more exceeds \$500,000. Therefore, the acquisition of the existing diagnostic medical equipment by Browning Equipment will result in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

Patient Origin

The 2017 SMFP does not define a service area for diagnostic centers. However, 10A NCAC 14C .1802 does define the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section C.2, pages 34-35, the applicants provide the historical (FY2015) patient origin for Rex Mobile MRI and the projected patient origin for the proposed Browning Mobile MRI scanner through the first three operating years (CY2018-CY2020), which is summarized in the table below:

Historical Rex Mobile MRI and Projected Browning Mobile MRI Patient Origin

County	Rex Mobile MRI Historical Patient Origin FY2015	Browning Mobile MRI Projected Patient Origin CY2018-2020
Wake	71.1%	76.6%
Other*	28.9%	23.4%
TOTAL	100.0%	100.0%

*The applicants list the counties included in the “Other” category on page 35 of the application.

In Section C.3, page 36, the applicants state, “*Projected patient origin for Browning Mobile MRI is based on the historical patient origin for patients served by the existing equipment at Rex Family Practice of Wakefield adjusted for proposed patients to be served at the Holly Springs and Knightdale locations based on the historical patient origin for patients served by REX Diagnostic Imaging of Holly Springs and REX Diagnostic Imaging of Knightdale.*” The applicants adequately identify the population to be served.

Analysis of Need

In Section C.4, pages 38-45, the applicants describe the factors which they state support the need for the proposed project are the ability to joint venture (pages 36-38), improved access (pages 38-39), and alignment with Federal health reform and payment policies (pages 39-40). The applicants state:

“The first factor driving the need for the proposed project is that the conversion of the existing imaging center from hospital-based to freestanding will allow it to be joint ventured. As discussed in more detail below, UNC REX and Wake Radiology have decided to collaborate by forming a joint venture. The existing structure of UNC REX’s mobile MRI, as provider-based to the hospital and as part of the hospital’s billing structure, is not conducive to joint venture due to multiple federal laws and regulations. Thus, the proposed change to a freestanding diagnostic center, with the existing medical diagnostic equipment contributed to the joint venture entity, Browning Equipment SPE, LLC, will facilitate this collaboration....

Another driver of need for the proposed project is the improvement of financial access to the existing services. Since the REX Mobile MRI is required by the conditions of its current certificate of need to be hospital-based, patients receiving its services are subject to the higher copays and coinsurance amounts associated with hospital-based care, compared to freestanding facilities. In addition, some private insurance plans restrict ‘in-network’ access to one hospital system to the exclusion of the other (e.g. Duke Health could be ‘in-network,’ while UNC Health Care System would not be.) Out-of-network status effectively restricts access or increases costs to patients through higher coinsurance payments and deductibles for such facilities. As a mobile diagnostic program providing MRI services to outpatient sites, the mobile MRI would not be considered part of one of these more limited networks, and could separately negotiate

with payors. Given the lower charge structure of the freestanding setting and the experience of the applicants successfully negotiating with payors, the applicants believe that the proposed conversion from hospital-based status is likely to expand the number of patients for whom the facility is ‘in-network’, lowering the cost of care for them....

The proposed project will enable the existing hospital-based equipment to better align with federal policies, including newly-enacted payment policies regarding off-campus hospital departments. The Bipartisan Budget Act of 2015, specifically Section 603, included language that indicated Congress’ desire to reduce payments to off-campus hospital departments, also known as the ‘site-neutral’ provisions. ... While the existing UNC REX outpatient imaging facilities would meet the grandfathering provisions, it is clear from these actions that CMS intends to curtail hospital-based payments for hospital-owned facilities that are not located on the hospital campus.”

This mobile MRI already exists and is serving patients; however, a condition was imposed on the certificate of need which requires the mobile MRI to be hospital or provider-based. Approval of this application would allow it to be non-hospital based, which has the potential to lower the cost to the patients currently using the MRI scanner. The applicants’ statements are reasonable and adequately supported. See also Exhibit C.4 of the application.

Projected Utilization

Rex Mobile MRI currently operates this unit of mobile MRI equipment. The applicants do not propose to acquire any additional equipment as part of proposed project.

In Section Q, the applicants provide the historical and projected utilization for the mobile MRI equipment through the first three years of operation following completion of the project, which is summarized below.

Operating Year	# of Units	Unweighted MRI Procedures	Weighted MRI Procedures	Annual % Increase (Weighted Procedures)
FY2014 Actual	1	905	1,070	---
FY2015 Actual	1	758	896	-16.3%
FY2016 Actual	1	796	956	6.7%
FY2017 Projected*	1	1,025	1,190	24.5%
CY2018 Project Year 1	1	1,451	1,684	41.5%
CY2019 Project Year 2	1	1,461	1,696	0.7%
CY2020 Project Year 3	1	1,472	1,708	0.7%

*The applicants change the annual basis for reporting utilization from fiscal year (July 1 – June 30) to calendar year in the first operating year of the project (CY2018).

As shown in the above table, the applicants project they will perform 1,708 weighted MRI procedures on the mobile MRI scanner unit in the third year of operation following completion of the project. The Criteria and Standards for Magnetic Resonance Imaging Scanner, 10A NCAC

14C .2701(3), defines the capacity of a mobile MRI scanner as 4,160 weighted MRI procedures per unit per year. However, the target utilization is 80% or 3,328 weighted MRI procedures [$3,328/4,160 = 0.8$]. Therefore, the applicants project the Browning Mobile MRI equipment will operate at 51.3 percent of the target in the third year of operation [$1,708/3,328 = 0.513$].

The applicants describe the assumptions and methodology used to project utilization in Section Q of the application as follows:

“As shown above, utilization of the existing mobile MRI has grown significantly over this time period. Based on the benefits of the proposed project, as described in Section C.4, as well as population growth in Wake County, the utilization of the equipment is expected to grow in the future or remain at current levels. As shown [in the table in Section Q, page 1], Wake County’s population is expected to grow 1.7 percent annually through 2021. ... Based on the factors described above, historical mobile MRI utilization at Browning Diagnostic Imaging of Wakefield is conservatively projected to grow 1.0 percent annually through the project years. This projected growth rate is less than the equipment’s historical utilization growth and less than projected population growth in the county....

The following table provides project year utilization for Browning Mobile MRI at the Wakefield location.

	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
<i>MRI Procedures</i>	<i>1,041</i>	<i>1,051</i>	<i>1,062</i>
<i>MRI Weighted Procedures</i>	<i>1,208</i>	<i>1,220</i>	<i>1,232</i>

In addition to the Wakefield site, the applicants propose to provide mobile MRI services to Browning Diagnostic Imaging of Knightdale and Browning Diagnostic Imaging of Holly Springs. In Section Q, page 2-5, the applicants state:

“As discussed above, the proposed project also involves the addition of two host sites at joint venture outpatient sites at Knightdale and Holly Springs. In order to project utilization at these two host sites, historical utilization data for each of UNC REX’s provider-based and Wake Radiology’s imaging centers was considered.... Browning Mobile MRI has used a conservative methodology based on an estimated number of scans per day of mobile MRI service. The number of scans per day of mobile MRI service among UNC REX and Wake Radiology sites varied from 4.1 to 7.0. ... In order to remain conservative, Browning Mobile MRI assumed that the Knightdale and Holly Springs sites would have 4.1 scans per day of mobile MRI service, which is equivalent to the lowest rate among these UNC REX and Wake Radiology sites. Based on this assumption, the following table provides projected mobile MRI utilization for the Knightdale and Holly Springs sites.

	<i>Knightdale</i>	<i>Holly Springs</i>
<i>Days of Service per Week</i>	<i>1</i>	<i>1</i>
<i>Weeks per Year</i>	<i>50</i>	<i>50</i>
<i>Scans per Day of Service</i>	<i>4.1</i>	<i>4.1</i>
<i>Projected Mobile MRI Scans</i>	<i>205</i>	<i>205</i>

...The following table provides project year utilization for Browning Mobile MRI at the Knightdale and Holly Springs locations based on the above analysis. Weighted MRI procedures are calculated based on the REX Mobile MRI historical ratio of weighted to unweighted procedures.

	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
<i>Knightdale</i>	<i>205</i>	<i>205</i>	<i>205</i>
<i>Holly Springs</i>	<i>205</i>	<i>205</i>	<i>205</i>
<i>MRI Procedures</i>	<i>410</i>	<i>410</i>	<i>410</i>
<i>MRI Weighted Procedures</i>	<i>476</i>	<i>476</i>	<i>476</i>

The projected utilization for Browning Mobile MRI at all three proposed sites, Knightdale, Holly Springs, and Wakefield, is shown below.

	<i>PY1</i>	<i>PY2</i>	<i>PY3</i>
<i>MRI Procedures</i>	<i>1,451</i>	<i>1,461</i>	<i>1,472</i>
<i>MRI Weighted Procedures</i>	<i>1,684</i>	<i>1,696</i>	<i>1,708</i>

As shown above, the applicants' utilization projections are based on their historical experience providing mobile MRI services and projected Wake County population growth. Exhibit I.2 contains letters of support for the proposed project from physicians and other healthcare providers in the proposed service area. Projected utilization is based on reasonable and adequately supported assumptions.

Access

In Section C.10, page 44, the applicants state, "Wake Radiology Services, LLC and Rex Hospital, Inc. – the entities that are, or will be, members of Browning Equipment SPE, LLC – each ensures access to care for all patients regardless of income, status, ability to pay, racial/ethnic origin, gender, age, physical or mental conditions, or any other characteristics that would classify a person as underserved or medically indigent." In Section L.1(b), page 77, the applicants report that 46.9% of patients who received mobile MRI services from Rex Mobile MRI had some or all of their services paid for by Medicare or Medicaid in FY2015. In Section L.3(a), page 78, the applicants project that 44.3% of Browning Mobile MRI's patients will be Medicare or Medicaid recipients. The applicants adequately demonstrate the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicants adequately identify the population to be served, demonstrate the need the population has for the mobile MRI scanner to become non-hospital based, and demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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.

C

On August 4, 2006, Rex Hospital was approved (Project I.D. #J-7284-05) to acquire one mobile MRI scanner to provide mobile MRI services at two host sites, Rex Hospital's main campus in Raleigh, and Rex Family Practice of Wakefield. In this application, the applicants propose to discontinue mobile MRI services to the Rex Hospital main campus host site, and add two new mobile MRI host sites in Knightdale and Holly Springs. In Section D.2, pages 49-50, the applicants state:

“UNC REX Hospital currently operates two fixed MRI scanners on its main campus (a 3rd fixed MRI scanner is located at its Cary campus), which provided 9,496 weighted MRI scans in SFY 2016. According to the MRI section of Chapter 9 of the 2017 SMFP, the capacity of a single fixed MRI is 6,864 procedures annually. Thus, the combined capacity of the two fixed scanners is 13,728, and the two scanners operated at approximately 69 percent of maximum capacity in SFY 2016. As such, UNC REX has sufficient fixed MRI capacity to meet the needs of its current patients as well as sufficient capacity to allow growth in MRI volume in the future, without the capacity of the mobile MRI service.”

Moreover, the mobile MRI scanner has not been serving patients on the Rex Hospital main campus based on the information provided by Rex Hospital in its 2017 LRA.

In Sections L.1 and L.3, pages 77-78, the applicants provide the historical (FY2016) and projected (CY2019) payor sources for mobile MRI services, as shown in the table below.

Historical Rex Mobile MRI and Projected Browning Mobile MRI Payor Sources

Payor Source	Rex Mobile MRI Historical Procedures as Percent of Total	Browning Mobile MRI Projected Procedures as Percent of Total
Medicare	45.0%	42.1%
Medicaid	1.9%	2.2%
Commercial/Managed Care	49.4%	50.8%
Other	1.4%	1.9%
Self Pay	2.4%	3.0%
TOTAL	100.0%	100.0%

Source: Tables on pages 77 and 78 of the application.

As shown in the table above, the applicants project that 44.3 percent of their mobile MRI services will be for patients who will have some or all of their care paid for by Medicare or Medicaid. The applicants adequately demonstrate that discontinuation of mobile MRI services at the Rex Hospital main campus will not have a negative effect 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.

In summary, the applicants adequately demonstrate that the needs of the population presently served by Rex Mobile MRI will be adequately met following the proposed acquisition of the mobile MRI unit by Browning Mobile MRI. Therefore, the application is conforming to this criterion.

- (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 Section E.2, page 52, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Develop a Mobile Diagnostic Center without a Joint Venture –The applicants state that developing a mobile diagnostic center without a joint venture partner was not an effective alternative because it would forgo the benefits of a collaboration between the two joint venture partners, including the benefits of a single standard of care.
- Develop the Mobile Diagnostic Center with Different Host Sites – The applicants state that developing the mobile diagnostic center at different host sites would not be an effective alternative due to the geographic distribution of existing fixed MRI scanners operated by the applicants.

After considering those alternatives, the applicants state the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Browning Equipment SPE, LLC and Rex Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Browning Mobile MRI shall provide mobile MRI services one day per week at Browning Diagnostic Imaging of Knightdale, as one host site, and one day per week at Browning Diagnostic Imaging of Holly Springs, as the second host site. Browning Mobile MRI shall provide mobile MRI service the remaining operating days per week at Browning Diagnostic Imaging of Wakefield, as the third host site.**
- 3. The mobile MRI scanner shall be moved each week to provide MRI services to at least two host sites and shall not, at any time, serve less than two host sites each week.**
- 4. For a period of three years from the date on which Browning Mobile MRI commences to provide the services authorized by this certificate of need, Browning Mobile MRI shall make quarterly reports for the first year and annual reports for the second and third years of operation, due within 15 days after the end of the period, to the Healthcare Planning and Certificate of Need Section, containing the following information: The identity of each host site served weekly and the number of procedures performed at each host site each week.**
- 5. Browning Mobile MRI shall not change or add host sites unless it first obtains a material compliance determination authorizing the change in location of the equipment.**
- 6. The mobile MRI scanner shall not, at any time, be converted to a fixed MRI scanner without first obtaining a new certificate of need for a fixed MRI scanner.**
- 7. Browning Equipment SPE, LLC and Rex Hospital, Inc. shall not acquire as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section Q of the application and that would otherwise require a certificate of need.**
- 8. Browning Equipment SPE, LLC and Rex Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 Section F.2, page 55, the applicants state that they will incur \$47,000 in capital costs to develop this project. In Section F.3, pages 56-57, the applicants state there will be no start-up expenses or initial operating expenses incurred for this project.

Availability of Funds

In Section F.2, page 55, the applicants state Rex Hospital will finance the capital costs with accumulated reserves. Exhibit F-1 contains a letter dated January 17, 2017 from the Chief Financial Officer for Rex Hospital, Inc. which states it has adequate funds for the capital costs for the proposed project. Exhibit F-2 contains the Combined Financial Statements for Rex Healthcare, Inc. and Subsidiaries which indicates that it had \$91 million in cash and cash equivalents as of June 30, 2016. The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicants provided pro forma financial statements for the first three years of the project. In the pro forma financial statement (Form F.3), the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	CY2018 Operating Year 1	CY2019 Operating Year 2	CY2020 Operating Year 3
Total MRI Procedures	1,451	1,461	1,472
Total Gross Revenues (Charges)	\$4,734,803	\$4,911,830	\$5,095,577
Total Net Revenue	\$1,124,725	\$1,166,776	\$1,210,425
Total Operating Expenses (Costs)	\$454,662	\$466,377	\$478,444
Net Income	\$670,063	\$700,399	\$731,980

The assumptions used by the applicants 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. The applicants adequately demonstrate 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.

Conclusion

In summary, the applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable and

adequately supported assumptions regarding projected costs and charges. Therefore, the application is conforming to this criterion.

- (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

The applicants propose to develop a freestanding diagnostic center through the contribution of a provider-based mobile MRI unit currently owned and operated by Rex Hospital (Rex Mobile MRI) to a newly formed joint venture entity, Browning Equipment.

The 2017 SMFP does not define a service area for diagnostic centers. However, 10A NCAC 14C .1802 does define the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

The applicants do not propose to acquire any new or additional medical diagnostic equipment and no new services will be offered. In Section G, page 63, the applicants state:

“As noted throughout this application, the proposed project is to develop a mobile diagnostic program with existing mobile MRI equipment currently operated as a department of UNC REX Hospital. The proposed project does not include the acquisition of new or additional units of equipment. The proposed equipment is currently owned by Rex Hospital, Inc., an applicant. There will be no change in services provided in the service area, nor will any additional facilities be constructed, and, therefore, the proposed project will not result in any unnecessary duplication of services. Further, the proposed project would add two host sites for the existing mobile MRI scanner, both of which are located in areas of Wake County which currently have no or limited access to MRI services.”

The applicants adequately demonstrate the need to establish the proposed diagnostic center. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Therefore, the applicants adequately demonstrate that the proposal would not result in unnecessary duplication of existing or approved diagnostic services or facilities. Consequently, the application is conforming to this criterion.

- (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 Section Q, the applicants provide staffing tables that indicated they currently employ 2.5 full-time equivalents (FTE) to staff the mobile MRI services at Rex Mobile MRI, and they project to staff Browning Mobile MRI with the same number of FTEs following completion of the proposed project. In Section H.2, page 66, the applicants state that they do not anticipate any difficulty hiring and retaining staff. In Section H.4, page 75, the applicants identify William Way, M.D. as the Medical Director for Browning Mobile MRI. Exhibit I.2 of the

application contains copies of letters from other physicians expressing support for the proposed project. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (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 Section I.1, page 69, the applicants describe the manner in which they will provide the necessary ancillary and support services. Exhibit I.2 contains letters of support from physicians. The applicants adequately demonstrate that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, 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

- (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

- (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

- (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 Section L.1, page 77, the applicants report the following payor mix percentages for Rex Mobile MRI for FY2015.

Payor Category	Procedures as Percent of Total
Medicare	45.0%
Medicaid	1.9%
Commercial/Managed Care	49.4%
Other	1.4%
Self Pay	2.4%
Total	100.0%

Source: Table on page 77 of the application.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the Wake County service area and statewide.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants adequately demonstrate that they currently provide access to medically underserved populations. 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 Section L.2, pages 77, the applicants report the facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. In Section L.2, page 78, the applicants state that no civil rights access complaints have been filed against Wake Radiology or Rex Hospital in last five years. 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 Section L.3, page 78, the applicants project the following payor mix for Browning Mobile MRI during the second operating year (CY2019):

Payor Category	Procedures as Percent of Total
Medicare	42.1%
Medicaid	2.2%
Commercial/Managed Care	50.8%
Other	1.9%
Self Pay	3.0%
Total	100.0%

Source: Table on page 78 of the application.

On page 78, the applicants state, “*Projected payor mix is based on the historical payor mix for patients served by the existing equipment at Rex Family Practice of Wakefield adjusted for proposed patients to be served at the Holly Springs and Knightdale locations based on the historical payor mix for outpatient MRI patients served by UNC REX originating from the Holly Springs and Knightdale service areas....*” The applicants adequately demonstrate that the medically underserved population will have access to the proposed services. Therefore, 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.

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In Section L.5, page 79, the applicants describe the range of means by which a person will continue to have access to Browning Mobile MRI services. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, 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.

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In Section M.1, page 80, the applicants state that Wake Radiology and Rex Hospital have established relationships with area health professional training programs, and the applicants will continue to offer the same opportunities to these programs following completion of the proposed project. Exhibit M.2 contains copies of examples of existing health professional training agreements and a list of training programs with which the applicants have relationships. The information provided is reasonable and adequately supports a determination that 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.

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The applicants propose to develop a freestanding diagnostic center through the contribution of a provider-based mobile MRI unit currently owned and operated by Rex Hospital (Rex Mobile MRI) to a newly formed joint venture entity, Browning Equipment.

The 2017 SMFP does not define a service area for diagnostic centers. However, 10A NCAC 14C .1802 does define the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section N.2, pages 82-83, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants state:

“The proposed project will positively impact the cost effectiveness of the services offered in the proposed mobile diagnostic program, primarily in that the development of a diagnostic center will allow the existing services to continue to be provided, but in a freestanding setting, which will have a lower charge structure than the existing hospital-based facility. ... The proposed project will positively impact the quality of the services offered in the proposed mobile diagnostic program, as they will be managed by Wake Radiology and will maintain ACR accreditation, the industry’s highest quality standard. ... The proposed project will positively impact access by medically underserved groups to the services offered in the proposed mobile diagnostic program, as the lower charge structure will allow the medically indigent and other medically underserved groups to better access the services compared to the existing hospital-based services.”

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants adequately demonstrate that they will provide access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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.

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The University of North Carolina Health Care System owns or manages nine licensed healthcare facilities in North Carolina, including Rex Hospital. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Rex Hospital, Caldwell Memorial Hospital and Wayne Memorial Hospital are currently awaiting final determinations from CMS regarding their compliance with a CMS Condition of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, none of the other facilities is currently out of compliance with a CMS Condition of Participation, nor have any other incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by The University of North Carolina Health Care System.

In Section O.3, page 86, Wake Radiology provides a list of diagnostic imaging facilities it currently operates. None of the facilities are licensed by the Acute and Home Care Licensure and Certification Section, DHSR. In Section O.1, page 84, the applicants state that Wake Radiology has *“internal policies, processes and procedures to maintain quality care,”* and that *“the practice voluntarily embraces the rigorous standards set by the American College of Radiology (ACR) for each modality across all of its offices.”*

After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at UNC Health Care System facilities and Wake Radiology, the applicants 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

The Criteria and Standards for Diagnostic Centers, promulgated in 10A NCAC 14C .1800, are not applicable to this proposal. Pursuant to 10A NCAC 14C .1801 PURPOSE AND SCOPE, *“The rules set forth in this Section shall apply to applications for diagnostic centers for which specific criteria and standards have not otherwise been promulgated in 10A NCAC 14C.”* The only item of medical diagnostic equipment proposed in this application is the existing mobile MRI scanner, which is a type of equipment for which criteria and standards have been promulgated in 10A NCAC 14C. The Criteria and Standards for Magnetic Resonance Imaging Scanner, promulgated in 10A NCAC 14C .2700, are not applicable to the proposal because Rex Hospital is contributing an existing mobile MRI scanner to the newly formed joint venture entity, Browning Equipment. The proposal does not result in the addition of a new MRI scanner to the inventory. Rather, as part of a new diagnostic center, the existing mobile MRI scanner will no longer be provider or hospital based which has the potential to lower the cost to the patient and third party payors.