

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-11290-17

Facility: Browning Breast Care Center

FID #: 170022

County: Wake

Applicants: Browning Equipment SPE, LLC

Rex Hospital, Inc.

Project: Develop a new diagnostic center at the same site as an existing provider-based outpatient imaging center

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 new diagnostic center at the same site as an existing provider-based outpatient imaging center currently owned and operated by Rex Hospital, and known as Rex Breast Care Center, through the contribution of the existing medical diagnostic equipment 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 the type of equipment proposed in this application 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- (2) Repealed effective July 1, 1987.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 new diagnostic center at the same site as an existing provider-based outpatient imaging center currently owned and operated by Rex Hospital, and known as Rex Breast Care Center, through the contribution of the existing medical diagnostic equipment to a newly formed joint venture entity, Browning Equipment. The existing medical diagnostic equipment is currently operational.

In Section C.1, pages 32-33, the applicants describe the project as follows:

“As noted above, all of the equipment to be located in the proposed diagnostic center already exists and is currently being operated by Rex Hospital, Inc., an applicant. As such, the proposed project is not for the acquisition of additional medical 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 Breast Care Center, which is currently operated as a department of UNC REX Hospital and provides outpatient mammography, ultrasound, and bone density services. With this project, Rex Hospital, Inc. proposes to contribute the existing medical diagnostic equipment at REX Breast Care Center to Browning Equipment SPE, LLC, which will operate the facility as a diagnostic center.”

Designation as a Diagnostic Center

In Section C.1, page 33, the applicants list the current fair market value (FMV) and original purchase price of the existing diagnostic equipment at Rex Breast Care Center (RBCC), which is summarized below:

Existing Medical Diagnostic Equipment at Rex Breast Care Center

SERVICE	EQUIPMENT	CURRENT FMV	ORIGINAL PURCHASE PRICE
Mammography	Hologic Dimensions 3D	\$381,000	\$381,000
Mammography	Hologic Selenia	\$167,474	\$453,508
Mammography	Hologic 3D 6000	\$445,092	\$445,092
Mammography	Hologic Stereo Affirm Biopsy	\$86,750	\$86,750
Ultrasound	Siemens Acuson S-1000	\$76,908	\$76,908
Ultrasound	Siemens Acuson S-2000	\$75,075	\$100,000
Bone Density	Hologic Horizon	\$56,500	\$56,500
Subtotal Existing Medical Diagnostic Equipment		\$1,288,799	\$1,599,758
Existing Essential Non-Medical Equipment Assets*		\$29,888	\$29,888
Total		\$1,318,687	\$1,629,646

Source: Section C.1, page 33, of the application.

*The applicants state this category includes supplies.

The total cost of the existing medical diagnostic equipment utilized by RBCC 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 36-37, the applicants provide the historical patient origin (FY2015) for Rex Breast Care Center (RBCC) and the projected patient origin for the medical diagnostic services at Browning Breast Care Center (BBCC) through the first three operating years (CY2018-CY2020), which is summarized in the table below:

Historical RBCC and Projected BBCC Patient Origin

County	RBCC Historical Patient Origin FY2015	BBCC Projected Patient Origin CY2018-2020
Wake	80.5%	80.5%
Other*	19.5%	19.5%
TOTAL	100.0%	100.0%

*The applicants list the counties included in the *“Other”* category on pages 36 and 37 of the application.

In Section C.3, page 38, the applicants state, *“Projected patient origin for Browning Breast Care Center is based on the historical patient origin for REX Breast Care Center applied to total projected procedures.”* 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 which are the ability to joint venture (pages 38-43), improved access (pages 43-44), and alignment with Federal health reform and payment policies (pages 44-45). 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 the UNC REX imaging center, 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 facility, with the existing medical diagnostic equipment contributed to the joint venture entity, Browning Equipment SPE, LLC, will facilitate this collaboration. ... The proposed project will also benefit patients through a broader, more expansive network of facilities through the joint venture, which will provide care closer to home....”

Another driver of need for the proposed project is the improvement of financial access to the existing services. Since REX Breast Care Center is hospital-based, patients receiving services there 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 freestanding facility, the proposed diagnostic center 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 facility 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.”

The applicants’ statements are reasonable and adequately supported. See also Exhibit C.4 of the application.

Projected Utilization

RBCC currently operates four units of mammography equipment, two units of ultrasound equipment, and one unit of bone density 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 mammography equipment at the imaging facility through the first three years of operation following completion of the project, which is summarized below.

Operating Year	# of Units	Total Mammography Procedures	Procedures Per Unit	Annual Percent Increase
FY2014 Actual	4	10,790	2,698	---
FY2015 Actual	4	11,157	2,789	3.4%
FY2016 Actual	4	14,872	3,718	33.3%
FY2017 Projected*	4	15,017	3,754	1.0%
CY2018 Project Year 1	4	15,243	3,811	1.5%
CY2019 Project Year 2	4	15,396	3,849	1.0%
CY2020 Project Year 3	4	15,550	3,888	1.0%

*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 15,550 mammography procedures on the four mammography units at BBCC in the third year of operation following completion of the project, or 3,888 procedures per mammography unit per year. In Section C.7, page 47, the applicants state the maximum annual capacity of the mammography equipment is 4,250 procedures. Therefore, the applicants project the four units of mammography equipment at BBCC will operate at 91 percent of capacity in the third year of operation [$3,888/4,250 = 0.91$].

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

Operating Year	# of Units	Total Ultrasound Procedures	Procedures Per Unit	Annual Percent Increase
FY2014 Actual	2	1,428	714	---
FY2015 Actual	2	1,425	713	-0.2%
FY2016 Actual	2	1,918	959	34.6%
FY2017 Projected*	2	2,168	1,084	13.0%
CY2018 Project Year 1	2	2,200	1,100	1.5%
CY2019 Project Year 2	2	2,222	1,111	1.0%
CY2020 Project Year 3	2	2,245	1,123	1.0%

*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 2,245 ultrasound procedures on the two ultrasound units at BBCC in the third year of operation following completion of the project, or 1,123 procedures per ultrasound unit per year. In Section C.7, page 47, the applicants state that *“the utilization and capacity of Browning Breast Care Center’s ultrasound service is entirely contingent on its mammography service and driven by the number of abnormal mammograms, which differs from year to year.”*

In Section Q, the applicants provide the historical and projected utilization for the bone density equipment at the imaging facility through the first three years of operation following completion of the project, which is summarized below.

Operating Year	# of Units	Total Bone Density Procedures	Annual Percent Increase
FY2014 Actual	1	923	---
FY2015 Actual	1	957	3.7%
FY2016 Actual	1	810	-15.4%
FY2017 Projected*	1	807	-0.4%
CY2018 Project Year 1	1	807	0.0%
CY2019 Project Year 2	1	807	0.0%
CY2020 Project Year 3	1	807	0.0%

*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 807 bone density procedures at BBCC in the third year of operation following completion of the project. In Section C.7, page 48, the applicants state the maximum annual capacity of the bone density equipment is 1,000 procedures. Therefore, the applicants project the bone density equipment at BBCC will operate at 81 percent of capacity in the third year of operation [$807/1,000 = 0.81$].

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 mammography and ultrasound equipment has grown significantly over this time period and the utilization of the existing bone density equipment has declined, but leveled off. Based on the benefits of the proposed project, as described in Section C.4, as well as population growth in the service area, 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], the proposed service area population is expected to grow 1.7 percent annually through 2021. ... Based on the factors described above, mammography and ultrasound utilization 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 service area. ... Bone density utilization is conservatively projected to remain at SFY17 levels based on recent fluctuation in

utilization, but given the proposed change from hospital-based to freestanding, it is likely that the lower cost structure will attract more patients in the future.”

As shown above, the applicants’ utilization projections are based on their historical experience providing these diagnostic imaging services and projected service area 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 50, 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 87, the applicants report that 33% of patients who received diagnostic imaging services at RBCC had some or all of their services paid for by Medicare or Medicaid in FY2015. In Section L.3(a), page 88, the applicants project that 33% of BBCC’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 proposed diagnostic center, 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.

NA

- (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 60, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Develop a Diagnostic Center without a Joint Venture –The applicants state that developing a 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 consolidation of existing equipment and the benefits of a single standard of care.
- Develop the Diagnostic Center at Another Location – The applicants state that developing the diagnostic center at another location would not be an effective alternative because the existing location is in close proximity to other healthcare services, and developing a new location would result in higher capital costs.
- Develop the Diagnostic Center with Additional or Replacement Equipment– The applicants state that developing the diagnostic center with additional or replacement equipment is less effective because the condition and capacity of the existing equipment is adequate to meet the needs of the population they propose to serve.

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 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 expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 3. Browning Equipment SPE, LLC and Rex Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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 63, the applicants state that they will incur \$48,000 in capital costs to develop this project. In Section F.3, pages 64-66, 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 63, the applicants state they 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 Diagnostic Procedures	18,251	18,425	18,602
Total Gross Revenues (Charges)	\$11,208,059	\$11,654,685	\$12,119,158
Total Net Revenue	\$2,867,894	\$2,982,369	\$3,101,424
Total Operating Expenses (Costs)	\$2,255,067	\$2,321,017	\$2,389,116
Net Income	\$612,827	\$661,352	\$712,308

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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 capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable 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 new diagnostic center at the same site as an existing provider-based outpatient imaging center currently owned and operated by Rex Hospital, and

known as Rex Breast Care Center, through the contribution of the existing medical diagnostic equipment 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 patients to be served will be the same as the patients currently served in the existing location. No new services will be offered. In Section G, pages 71-72, the applicants state:

“As noted in the response to Section C.3, Browning Breast Care Center’s service area is defined as Wake County which comprises over 75 percent of its patients. Browning Breast Care Center is not aware of a public inventory of diagnostic centers which would identify facilities located in the service area. ... As noted throughout this application, the proposed project is to develop a new freestanding diagnostic center at the same site as an existing provider-based outpatient imaging center. The proposed project does not include the acquisition of new or additional units of equipment. All of the proposed equipment is currently owned by 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, no public data is available regarding the capacity and utilization of mammography, breast-only ultrasound or bone density equipment.”

The applicants adequately demonstrated 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 demonstrated that the proposal would not result in unnecessary duplication of existing or approved diagnostic centers providing mammography, breast-only ultrasound and bone density services. 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 12.35 full-time equivalents (FTE) to staff the diagnostic services at RBCC, and they project to staff BBCC with the same number of FTEs following completion of the proposed project. In Section H.2, page 74, 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 BBCC. 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 77, 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 87, the applicants report the following payor mix percentages for diagnostic services at RBCC for FY2015.

Payor Category	Procedures as Percent of Total
Medicare	31.7%
Medicaid	1.3%
Commercial/Managed Care	59.4%
Other	0.7%
Self Pay	7.0%
Total	100.0%

Source: Table on page 87 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, page 88, 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 88, 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 88, the applicants project the following payor mix for BBCC's diagnostic services during the second operating year (CY2019):

Payor Category	Procedures as Percent of Total
Medicare	31.5%
Medicaid	1.3%
Commercial/Managed Care	59.4%
Other	0.7%
Self Pay	7.2%
Total	100.0%

Source: Table on page 88 of the application.

On page 88, the applicants state, *“Projected payor mix is expected to remain consistent with the historical experience of the provider-based outpatient imaging center (currently known as REX Breast Care Center) that is located at the same site of the proposed new freestanding diagnostic center, Browning Breast Care Center, adjusted to reflect the impact of the projected growth for each imaging modality.”* 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.

C

In Section L.5, page 89, the applicants describe the range of means by which a person will have access to BBCC 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.

C

In Section M.1, page 90, 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.

C

The applicants propose to develop a new diagnostic center at the same site as an existing provider-based outpatient imaging center currently owned and operated by Rex Hospital, and known as Rex Breast Care Center, through the contribution of the existing medical diagnostic equipment 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 projected patient origin for the patients to be served at BBCC will be the same as the patient origin for patients currently served in the existing RBCC location. No new services will be offered.

In Section N.2, pages 92-93, 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 diagnostic center, 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 diagnostic center, 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 diagnostic center, 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.

C

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 96, 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 94, 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.

C

Certificate of Need (Agency) proposed to repeal the Criteria and Standards for Diagnostic Centers (10A NCA 14C .1801-.1806) on July 21, 2016. The Rules were repealed effective March 16, 2017, during the time this application was under review. The Rules would have been repealed before this application was submitted had the Rules Review Commission not received 10 or more objections from interested parties. Nonetheless, the application is conforming to all applicable Criteria and Standards for Diagnostic Centers. The specific criteria are discussed below.

SECTION .1800 CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS
10A NCAC 14C .1804 PERFORMANCE STANDARDS

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

- (1) documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;*
- C- In Section C.11, page 53, the applicants state that *“there is insufficient publicly available data to determine if mammography, breast-only ultrasound, or bone density equipment was operating at 80 percent of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submission of the application.”*
- (2) documentation that all existing and approved medical diagnostic equipment and services of the type proposed in this CON application are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services;*
- C- In Section Q, the applicants project that utilization of the mammography and bone density equipment will exceed 80 percent of the maximum number of procedures the equipment is capable of performing by the third year of operation. In Section C.7, page 47, the applicants state that *“the utilization and capacity of Browning Breast Care Center’s ultrasound service is entirely contingent on its mammography service and driven by the number of abnormal mammograms, which differs from year to year.”* In Section C.11, pages 53-54, the applicants state that there is insufficient publicly available data to determine if the other existing and approved mammography, breast-only ultrasound, or bone density equipment will be operating at 80 percent of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation.
- (3) documentation that the applicants utilization projections are based on the experience of the provider and on epidemiological studies; and*
- C- In Section Q, the applicants state that all utilization projections are based on the applicant’s experience providing diagnostic imaging services at RBCC, and on the projected growth in the service area population. The applicants do not specifically cite epidemiological studies as a basis for their utilization projections. However, publicly available data on female breast cancer incidence rates in Wake County (169.7 cases per 100,000 population) and North Carolina (157.1 cases per 100,000 population) support the applicants’ utilization projections for the mammography services at BBCC.

(4) all the assumptions and data supporting the methodologies used for the projections in this Rule.

-C- In Section Q, the applicants provide the assumptions and data supporting the methodologies used to project utilization.