

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 30, 2016

Findings Date: June 30, 2016

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project I.D. #: J-11173-16

Facility: Wake Radiology Fuquay-Varina

FID #: 160158

County: Wake

Applicants: Wake Radiology Services, LLC

Wake Radiology Diagnostic Imaging, Inc.

Project: Develop a diagnostic center by acquiring a 3D mammography unit to replace existing mammography equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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

Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. (“the applicants”) propose to acquire a new 3D mammography unit to replace existing mammography equipment at Wake Radiology Fuquay-Varina (WRFV). WRFV is a freestanding outpatient imaging center located at 7636 Purfoy Road, Suite 200, in Fuquay-Varina. The value of the new 3D mammography unit (\$333,750), combined with the existing medical diagnostic equipment already being utilized by WRFV, exceeds the statutory threshold promulgated in G.S. 131E-176(7a) of \$500,000 for a diagnostic center; therefore, the acquisition of the proposed equipment requires a certificate of need.

Need Determination

There are no need determinations in the 2016 State Medical Facilities Plan (2016 SMFP) which are applicable to the acquisition of the type of equipment proposed in this application or to the establishment of a diagnostic center.

Policies

There are no policies in the 2016 SMFP which are applicable to this review.

Conclusion

In summary, the applicants do not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2016 SMFP. There are no policies in the 2016 SMFP that are applicable to this review. 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

Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. (“the applicants”) propose to acquire a new 3D mammography unit to replace existing mammography equipment at Wake Radiology Fuquay-Varina (WRFV). WRFV is a freestanding outpatient imaging center located at 7636 Purfoy Road, Suite 200, in Fuquay-Varina. The value of the new 3D mammography unit (\$333,750), combined with the existing medical diagnostic equipment already being utilized by WRFV, exceeds the statutory threshold promulgated in G.S. 131E-176(7a) of \$500,000 for a diagnostic center; therefore, the acquisition of the proposed equipment requires a certificate of need.

Population to be Served

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina; nor does the SMFP specify a service area relative to diagnostic centers. The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1802(3) 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 III.1, page 36, Wake Radiology states that the geographic service area for WRFV is Wake and

Harnett counties. The applicants may also serve residents of counties not included in the service area.

In Section III.1, page 39, the applicants provide the CY 2015 patient origin for mammography services at WRFV, as illustrated in the following table:

WRFV Historical Patient Origin by County – CY 2015		
County of Origin	# of Patients	% of Total
Wake	1,673	87.59%
Harnett	193	10.10%
Johnston	17	0.89%
Lee	5	0.26%
Cumberland	3	0.16%
Durham	2	0.10%
Montgomery	2	0.10%
Sampson	2	0.10%
Carteret	1	0.05%
Chatham	1	0.05%
Vance	1	0.05%
Warren	1	0.05%
NC Subtotal	1,901	99.53%
Out of State	9	0.47%
Grand Total	1,910	100.00%

In Section III.1, pages 39-41, the applicants provide the projected patient origin for WRFV mammography services during the first two operating years following project completion, as shown in the table below.

WRFV Projected Patient Origin by County – OYs 1-3				
County of Origin	% of Total	2Q 2017–1Q 2018 (OY1)	2Q 2018–1Q 2019 (OY2)	2Q 2019–1Q 2020 (OY3)
Wake	87.59%	2,551	2,764	2,994
Harnett	10.10%	294	318	345
Other NC Counties	1.83%	53	58	63
Other States	0.47%	13	16	16
Total	100.00%	2,911	3,156	3,418

On page 39, the applicants state that projected patient origin is based on their 2015 utilization percentages.

The applicants adequately identify the population to be served.

Analysis of Need

In Section III, pages 35-43, and referenced exhibits, the applicants state that the following factors support the need to acquire a new 3D mammography unit to replace an existing unit and develop a new diagnostic center facility at WRFV:

- Breast cancer screening utilizing 3D mammography finds more invasive cancers and results in fewer false alarms than standard mammography.
- Projected population growth in both the overall population as well as the population of women within the service area will exceed the average projected population growth for the state as a whole.
- The proposed project will enhance patient access to the best quality healthcare services within the service area.
- Using 3D mammography results in decreased patient call backs for additional procedures and increased cancer detection rates.
- Doctors believe that 3D mammography will be the standard of care for mammography exams within 10 years.
- Projected utilization at WRFV meets or exceeds Diagnostic Center performance standards.

The applicants adequately demonstrate the need to develop a diagnostic center by replacing the existing mammography system with a new 3D mammography system.

Projected Utilization

In Section IV, page 55, the applicants provide projected utilization for mammography services at WRFV through the first three years of operation following completion of the project, as shown in the following table.

WRFV – Projected Mammography Procedures OYs 1-3			
	OY 1 – 2Q 2017-1Q 2018	OY 2 – 2Q 2018-1Q 2019	OY 3 – 2Q 2019-1Q 2020
Mammography Procedures	2,912	3,155	3,419

In Section III, page 40, the applicants provide their historic mammography utilization from the beginning of 2013 through the end of 2015, as shown below.

WRFV – Historical Mammography Utilization		
Year	Number of patients	Change
2013	1,501	--
2014	1,630	8.6%
2015	1,910	17.2%
AAGR	--	12.9%

The applicants state on page 40 that to be conservative in their estimates, they took the previous average annual change rate, added it the town of Fuquay-Varina’s projected

population growth, and averaged the two out, which resulted in an 8.17 percent growth rate $[(12.9 + 3.43) / 2] = 16.23 / 2 = 8.17$].

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section VI.2, page 62, the applicants state that they provide access without regard to income, ability to pay, racial/ethnic origin, gender, age, physical or mental conditions, or any other type of characteristic that would qualify someone as underserved or medically indigent.

In Section VI, pages 67-68, the applicants provide the projected payor mix for the entire facility and for mammography services only at WRFV (during the second full fiscal year of operation), as shown in the following table:

WRFV – Entire Facility (OY2)	
Self-Pay/Indigent/Charity	0.7%
Medicare/Medicare Managed Care	30.2%
Medicaid	4.6%
Commercial Insurance	0.3%
Managed Care	62.9%
Other	1.3%
Total	100.0%

WRFV – Mammography Services (OY2)	
Self-Pay/Indigent/Charity	0.3%
Medicare/Medicare Managed Care	28.6%
Medicaid	1.0%
Commercial Insurance	0.1%
Managed Care	68.6%
Other	1.3%
Total	100.0%

As shown in the above referenced table, 34.8 percent of the facility’s projected patients will have some or all of their services paid for by Medicare and/or Medicaid.

The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need that population has for the proposed project, and adequately demonstrate the extent to which all residents, including underserved groups, are likely to have access to the proposed services. 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 III.3, pages 44-45, the applicants describe the alternatives considered, which included maintaining the status quo. The applicants discuss the changing standard of care in the industry, quality of care concerns, and concerns about cost-effectiveness. After considering those issues, 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 applicable statutory and regulatory review criteria, and thus, is approvable. An application 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 to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. shall materially comply with all representations made in the certificate of need application and in supplemental information received June 24, 2016. In those instances where representations conflict, Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. shall materially comply with the last made representation.**
- 2. Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. shall acquire no more than one 3D mammography system.**
- 3. Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
- 4. Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, 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

WRFV proposes to acquire a new 3D mammography unit to replace existing mammography equipment. WRFV is a freestanding outpatient imaging center located at 7636 Purfoy Road, Suite 200, in Fuquay-Varina. The value of the new 3D mammography unit (\$333,750), combined with the existing medical diagnostic equipment already being utilized by WRFV, exceeds the statutory threshold promulgated in G.S. 131E-176(7a) of \$500,000 for a diagnostic center; therefore, the acquisition of the proposed equipment requires a certificate of need.

Capital and Working Capital Costs

In supplemental information received June 24, 2016, the applicants project the total capital cost of the project will be \$353,750, which includes \$321,100 for the Hologic Selenia Dimensions Tomo with AWS 5000 (the mammography equipment), \$12,650 in renovation and miscellaneous costs to install the equipment, and \$20,000 for consultant fees. In Section IX, page 86, the applicants state no working capital (start-up and initial operating expenses) is required for the proposed project because no new service is being proposed and the facility has been staffed and operational since 2012.

Availability of Funds

In Section VIII, pages 81-83, the applicants state that the capital costs of the proposed project will be financed through an existing line of credit with Wells Fargo Bank. Exhibit XIII.C on page 390 contains a letter dated March 10, 2016 from a Senior Vice President of Commercial Banking at Wells Fargo Bank. The letter states that the applicants have been customers of Wells Fargo Bank for at least 14 years and that Wells Fargo Bank has extended a \$1 million loan to the company to fund equipment purchases and related expenses, which is to be repaid on a five year amortization schedule.

The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (Form B, page 105) provided in the pro formas section, the applicants project that revenues will exceed operating expenses in each of

the first two Operating Years following completion of the proposed project, as shown in the table below.

Projected Revenues and Operating Expenses		
WRFV	Operating Year 1 4/2017-3/2018	Operating Year 2 4/2018-3/2019
Gross Patient Revenue	\$2,105,144	\$2,185,526
Deductions from Gross Patient Revenue	(\$1,009,614)	(\$1,048,165)
Net Patient Revenue	\$1,095,530	\$1,137,361
Total Operating Expenses	\$1,006,396	\$1,031,290
Net Income/Profit	\$89,134	\$106,072

The assumptions used by the applicants in preparation of the pro formas are reasonable including projected utilization, costs, and charges. See pages 109-111 at the end of the pro formas section for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of 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

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The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina; nor does the SMFP specify a service area relative to diagnostic centers. The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1802(3) defines 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 III.1, page 36, Wake Radiology states that the geographic service area for WRFV is Wake and Harnett counties. The applicants may also serve residents of counties not included in the service area.

The total number of mammography systems in the service area defined by the applicants will not increase as a result of this proposal.

In Section III.6, pages 49-50, the applicants provide a list by name and location of all existing facilities that operate mammography services in the project service area, Wake and Harnett counties, as illustrated in the table below:

Existing Mammography Providers in Wake and Harnett Counties		
Facility	City	County
Valley Radiology	Angier	Harnett
Central Harnett Hospital	Lillington	Harnett
First Choice Community Health Centers	Lillington	Harnett
Duke Raleigh Hospital Outpatient Imaging	Raleigh	Wake
Duke Raleigh Hospital	Raleigh	Wake
North Carolina Correctional Institute	Raleigh	Wake
Raleigh Radiology Blue Ridge	Raleigh	Wake
Raleigh Radiology Breast Center	Raleigh	Wake
Raleigh Radiology Brier Creek	Raleigh	Wake
Raleigh Radiology Cary	Raleigh	Wake
Raleigh Radiology Cedarhurst	Raleigh	Wake
Rex Breast Care Center	Raleigh	Wake
Rex Diagnostic Imaging of Knightdale	Knightdale	Wake
Rex Diagnostic Imaging of Wakefield	Raleigh	Wake
Rex Healthcare of Holly Springs	Holly Springs	Wake
Rex Primary Care and Wellness Center	Cary	Wake
WakeMed Cary Hospital	Cary	Wake
WakeMed North	Raleigh	Wake
WakeMed Raleigh Medical Park	Raleigh	Wake
Women's Health Alliance Mammography	Raleigh	Wake

On page 50, the applicants state that the CON Section does not maintain any inventory of mammography units or their utilization and there is insufficient publicly available data to quantify the number of units in the area and the utilization of those units. The applicants state that there will be a growing demand for 3D mammography services in the area as the technology becomes standard within the industry.

The discussions regarding analysis of need, alternatives, and competition found in Criteria (3), (4), and (18a), respectively, are incorporated herein by reference.

The applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved mammography in the proposed service area. 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

WRFV's mammography services are open Monday through Friday from 8:00 a.m. to 5:00 p.m., with one hour each day where the office is closed for lunch. In Section VII, pages 70-71, the applicants state that WRFV's mammography services staffs 2.0 Full Time Equivalent (FTE) radiology technologists, including 1.0 FTE mammography technologist, and that the replacement equipment will not result in the addition of any FTEs. In Section VII.8, page 77, the applicants identify Kerry Eileen Chandler, M.D., as the Medical Director WRFV. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in the pro forma financial statements. 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 II.2, pages 18-19, the applicants describe the ancillary and support services that will be provided by the facility. Exhibit II.E contains a letter dated April 1, 2016, from the Chief Medical Officer of Wake Radiology Services, LLC, verifying the availability of all necessary ancillary and support services. Exhibit V.B contains copies of letters from other health care providers expressing support for the proposed project. In Section V.2, page 57, the applicants state that:

"Wake Radiology exclusively provides outpatient radiology services and therefore is not required to have formal transfer agreements with area hospitals and providers."

The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care 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

The applicants propose to acquire a new 3D mammography unit to replace existing mammography equipment and establish a new diagnostic center. In Section XI, pages 96-99, the applicants state that only minor renovations are needed to replace the existing mammography unit with a new 3D mammography unit and that no construction will take place. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. Therefore, this criterion is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Sections VI.12 and VI.13, pages 66 and 67, respectively, the applicants provide the historical payor mix for the entire Wake Radiology practice and for mammography services at WRFV for CY2015, as shown in the following tables.

Wake Radiology – Entire Facility Historical Payor Mix As % of Total Utilization (CY2015)	
Self-Pay/Indigent/Charity	0.92%
Medicare/Medicare Managed Care	30.94%
Medicaid	5.28%
Commercial Insurance	0.32%
Managed Care	61.04%
Other – Military	1.30%
Other – Workers Comp.	0.19%
Total	100.00%

WRFV – Mammography Service Component Historical Payor Mix As % of Total Utilization (CY2015)	
Self-Pay/Indigent/Charity	0.3%
Medicare/Medicare Managed Care	28.6%
Medicaid	1.0%
Commercial Insurance	0.1%
Managed Care	68.6%
Other	1.3%
Total	100.0%

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 applicants’ service area.

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%
Harnett	11%	51%	37%	21%	10%	19%
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 demonstrate that they currently provide adequate 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 VI.11, page 66, the applicants state that they have no obligation to provide uncompensated care or community service under federal regulations. In Section VI.10, page 66, the applicants state that there have been no civil rights access complaints filed within the last five years against Wake Radiology. Therefore, 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 Sections VI.14 and VI.15, pages 67 and 68, respectively, the applicants provide the projected payor mix for the entire Wake Radiology practice and for mammography services at WRFV for the second full year of operation (4/1/2017-3/31/2018), as shown in the following tables.

Wake Radiology – Entire Facility Projected Payor Mix As % of Total Utilization (OY2)	
Self-Pay/Indigent/Charity	0.7%
Medicare/Medicare Managed Care	30.2%
Medicaid	4.6%
Commercial Insurance	0.3%
Managed Care	62.9%
Other	1.3%
Total	100.0%

WRFV – Mammography Service Component Projected Payor Mix As % of Total Utilization (OY2)	
Self-Pay/Indigent/Charity	0.3%
Medicare/Medicare Managed Care	28.6%
Medicaid	1.0%
Commercial Insurance	0.1%
Managed Care	68.6%
Other	1.3%
Total	100.0%

As shown in the above referenced table, 34.8 percent of the projected payor mix for Wake Radiology is Medicare and/or Medicaid. In Section VI.2, page 62, the applicants state: *“Wake Radiology ensures access to all health agencies 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 medical [sic] indigent.”*

The applicants demonstrate that medically underserved populations would have adequate 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 V.4(c), page 59, and Section VI.5, page 63, the applicants describe the range of means by which a person will have access to WRFV’s services. The applicants adequately demonstrate that they will provide a range of means by which a person can access the diagnostic imaging 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 V.1, page 57, the applicants state the following about how the facility will accommodate the clinical needs of area health professional training programs:

“Wake Radiology partners with area organizations to offer technical and physician training programs at its North Hills office as well as the Raleigh MRI Center. While Wake Radiology remains committed to exploring new opportunities to offer training programs at other locations, such as at the Fuquay Varina Office, there is no immediate demand or need to do so at this specific location. Nonetheless, as a

practice serving all of Wake County and surrounding counties, Wake Radiology is very supportive of the training programs it currently offers.”

Exhibit V.A contains copies of existing agreements for providing educational and training opportunities with Edgecombe Community College and Wake Technical Community College. 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

Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc. (“the applicants”) propose to acquire a new 3D mammography unit to replace existing mammography equipment at Wake Radiology Fuquay-Varina (WRFV). WRFV is a freestanding outpatient imaging center located at 7636 Purfoy Road, Suite 200, in Fuquay-Varina. The value of the new 3D mammography unit (\$333,750), combined with the existing medical diagnostic equipment already being utilized by WRFV, exceeds the statutory threshold promulgated in G.S. 131E-176(7a) of \$500,000 for a diagnostic center; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina; nor does the SMFP specify a service area relative to diagnostic centers. The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1802(3) defines 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 III.1, page 36, Wake Radiology states that the geographic service area for WRFV is Wake and Harnett counties. The applicants may also serve residents of counties not included in the service area.

The total number of mammography systems in the service area defined by the applicants will not increase as a result of this proposal.

In Section III.6, pages 49-50, the applicants provide a list by name and location of all existing facilities that operate mammography services in the project service area, Wake and Harnett counties, as illustrated in the table below:

Existing Mammography Providers in Wake and Harnett Counties		
Facility	City	County
Valley Radiology	Angier	Harnett
Central Harnett Hospital	Lillington	Harnett
First Choice Community Health Centers	Lillington	Harnett
Duke Raleigh Hospital Outpatient Imaging	Raleigh	Wake
Duke Raleigh Hospital	Raleigh	Wake
North Carolina Correctional Institute	Raleigh	Wake
Raleigh Radiology Blue Ridge	Raleigh	Wake
Raleigh Radiology Breast Center	Raleigh	Wake
Raleigh Radiology Brier Creek	Raleigh	Wake
Raleigh Radiology Cary	Raleigh	Wake
Raleigh Radiology Cedarhurst	Raleigh	Wake
Rex Breast Care Center	Raleigh	Wake
Rex Diagnostic Imaging of Knightdale	Knightdale	Wake
Rex Diagnostic Imaging of Wakefield	Raleigh	Wake
Rex Healthcare of Holly Springs	Holly Springs	Wake
Rex Primary Care and Wellness Center	Cary	Wake
WakeMed Cary Hospital	Cary	Wake
WakeMed North	Raleigh	Wake
WakeMed Raleigh Medical Park	Raleigh	Wake
Women's Health Alliance Mammography	Raleigh	Wake

On page 50, the applicants state that the CON Section does not maintain any inventory of mammography units or their utilization and there is insufficient publicly available data to quantify the number of units in the area and the utilization of those units. The applicants state that there will be a growing demand for 3D mammography services in the area as the technology becomes standard within the industry.

In Section V.7, page 60, the applicants discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicants state that 3D mammography will provide enhanced quality and better overall outcomes to patients and that it is more cost-effective than conventional screening equipment.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 to acquire the proposed replacement equipment and become a diagnostic center and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicants adequately demonstrate that WRFV will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants adequately demonstrate WRFV will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are 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

In Section II.7, pages 19-29, and Exhibits II.F and II.I, the applicants describe the methods used by WRFV to ensure and maintain quality care, including statements that no licenses or Medicare or Medicaid provider agreements associated with any of Wake Radiology's facilities have ever been revoked. On page 20, the applicants state:

“Wake Radiology – Fuquay Varina will comply with all relevant facility, programmatic, and service-specific North Carolina and federal licensure, certification, North Carolina Department of Environment and Natural Resources [currently the Department of Environmental Quality] regulation and accreditation standards associated with the project. This includes the North Carolina Building Code, FDA, OSHA, ADA, Medicaid, Medicare, CPR and basic cardiac life support (“BCLS”) training law, rules and requirements.”

The information provided by the applicants is reasonable and supports the determination that 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

The application is conforming to all applicable Criteria and Standards for Diagnostic Centers promulgated by 10A NCAC 14C Section .1800. See discussion 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- The applicants propose to acquire a new 3D mammography unit to replace existing mammography equipment. In Section II, page 25, and Section III, page 50, the applicants identify other health service facilities that operate or have been approved to operate similar medical diagnostic equipment. However, the applicants correctly note that there is insufficient publicly available data to determine if the similar medical diagnostic 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 submittal of the application.
- (2) *documentation that all existing and approved medical diagnostic equipment and services of the type proposed in the 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 II, pages 30-31, the applicants state that due to the lack of publicly available data, the applicants cannot determine if the existing and approved medical diagnostic equipment and services of the type proposed in this CON application are projected to be utilized at 80 percent of the maximum number of procedures that the equipment is capable of performing at any time for other providers. In Section II, pages 30-31, and Section IV, pages 53-54, the applicants state that WRFV's mammography services will be utilized at 88.1 percent 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.
- (3) *documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and*

- C- In Section II.3, page 31, Section III, pages 39-42, and Section IV, pages 53-54, the applicants document that their utilization projections are based on their experience providing mammography services at WRFV and on epidemiological studies. See also Section III.1 of the application.
- (4) *all the assumptions and data supporting the methodologies used for the projections in this Rule.*
- C- In Sections II, III, IV, and Exhibits II.B and II.C, the applicants provide the assumptions and data supporting the methodologies used to project utilization.