

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 4, 2015

Findings Date: September 4, 2015

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11048-15

Facility: Raleigh Radiology Wake Forest

FID #: 090950

County: Wake

Applicant: Pinnacle Health Services of North Carolina, LLC

Project: Acquire 3D mammography equipment to replace existing mammography equipment and establish a new diagnostic center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

The applicant, Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Wake Forest [RRWF] proposes to acquire a 3D mammography unit to replace its existing mammography equipment and establish a new diagnostic center. RRWF is a freestanding outpatient imaging center located at 839 Durham Road, Suite A, in Wake Forest. The acquisition of the replacement diagnostic equipment results in the development of a diagnostic center as that term is defined in G.S. 131E-176(7a). It is the development of a new diagnostic center that is subject to review.

The total cost or fair market value of the proposed 3D mammography equipment is \$367,339. However, when combined with the existing medical diagnostic equipment utilized by the

facility which costs \$10,000 or more, the total capital cost exceeds \$500,000 and therefore, pursuant to G.S. 131E-176(7a), acquisition of the proposed equipment results in the development of a diagnostic center, which requires a certificate of need. In Section XI.4, page 115, the applicant states that there will be no new construction or renovation of existing space at RRWF for the proposed project. The following table shows the capital cost of the existing diagnostic equipment and the proposed equipment, as described by the applicant on page 96 of the application.

COST OF EXISTING EQUIPMENT	COST
Existing Ultrasound & X-ray Equipment*	\$199,154
COST OF PROPOSED EQUIPMENT	
3D Mammography Equipment Purchase/Installation	\$367,339
Total Projected Capital Costs	\$566,493

* RRWF already owns and operates this equipment (sunk cost). From page 96 of application.

There are no need determinations or policies in the 2015 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 applicant, RRWF, is a freestanding outpatient imaging center which is located at 839 Durham Road in Wake Forest, and currently offers digital mammography, ultrasonography, x-ray, and mobile MRI scanner services. In this application, RRWF proposes to purchase a 3D mammography machine to replace its existing 2D digital mammography machine, which will result in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

Designation as a Diagnostic Center

In Exhibit 3, the applicant lists the costs of acquisition and installation of the existing diagnostic equipment at RRWF, which is summarized below:

COST OF EXISTING RRWF DIAGNOSTIC EQUIPMENT	COST
Hologic 2D digital mammography/CAD license	\$187,995
Ultrasound System/Table	\$91,751
Triangle X-ray Radiographic System	\$31,491
Konica Minolta Nano CR Reader	\$34,694
Construction/Electrical Work (X-ray and mammography rooms)	\$40,036
Total Cost of Existing Diagnostic Equipment	\$385,967

Source: Exhibit 3 of the application.

The total project capital cost for the proposed 3D mammography equipment is \$415,339. The proposed new equipment plus the equipment currently in use at the RRWF exceeds the \$500,000 threshold.

In Section II.1, page 14, the applicant describes the project as follows:

“PHS [Pinnacle Health Services] proposes to replace its existing 2D digital mammography machine at RRWF with a 3D breast tomosynthesis mammography machine. This replacement equipment increases the total cost of medical diagnostic equipment at RRWF above \$500,000, which will result in RRWF being designated as a diagnostic center, according to CON Statute. Please refer to Exhibit 3 for the inventory and valuation of RRWF’s existing medical diagnostic equipment, and to Section VIII regarding replacement equipment costs....

The existing digital mammography system at RRWF has been in continuous operation since 2008. It is fully depreciated and is at the end of its useful life. Downtime and maintenance expenses have increased in the last year, and the vendor has recently stopped manufacturing the equipment model. Therefore, in addition to the clinical benefits of 3D, from a productivity and asset-management standpoint, now is an appropriate time to replace the RRWF mammography equipment with a 3D breast tomosynthesis mammography machine.

As previously stated, the 3D mammography procedure is nearly identical to a 2D digital mammogram, except that in mammography the machine is stationary, while a tomosynthesis system moves around the breast. Also called 3D mammography, the test takes many X-rays at different angles to create a three-dimensional image of the breast.”

Population to be Served

The 2015 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 III.5, page 58, the applicant projects the patient origin for mammography services at RRWF during the first two operating years following project completion, which is summarized in the table below:

**RRWF Mammography Services
Projected Patient Origin (CY2016-CY2017)**

County	Percent of Total Patients
Wake	74.0%
Franklin	26.0%
TOTAL	100.0%

In Section III.5, pages 56-58, the applicant describes its assumptions regarding projected patient origin as follows:

“The primary service area for RRWF’s mammography service area includes Wake County zip codes 27587, 27596 and 27614. The secondary service area for RRWF’s mammography services includes the following [Wake and Franklin County] zip codes: 27549, 27525, 27616, 27571, 27597, and 27615. The rationale for defining this service area is based on the historical patient origin for mammography patients at RRWF. During the most recent 12 months (June 2014-May 2015), patients from the identified zip codes comprised 91.2% of RRWF’s mammography patient origin. ...

Based on historical patient origin information, PHS currently provides mammography services to patients in this identified service area, and thus does not anticipate a significant change in patient origin for the proposed project.”

The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, pages 44-53, the applicant describes the factors which it states support the need for the proposed project, including:

- The projected overall service area population growth in Wake County and Wake Forest, and projected service area population growth among women age 40 and older (pages 45-49).
- Higher than average breast cancer incidence rates for Wake County from 2008 to 2012 (pages 49-50).
- Increasing demand for 3D mammography services because of its “superior image quality and ability to better detect invasive cancers compared to a traditional mammogram” (pages 50-52).
- The need to replace the existing 2D digital mammography equipment, which has reached the end of its useful life (pages 51-52).

In Section IV.1, pages 63-65, the applicant provides the historical and projected utilization for mammography services at RRWF through the first three years of operation following completion of the project, which is summarized below.

Operating Year	Total Mammography Procedures	Annual Percent Increase
CY2011 Actual	4,008	---
CY2012 Actual	4,212	5.1%
CY2013 Actual	4,864	15.5%
CY2014 Actual	5,384	10.7%
CY2015 Annualized*	5,460	1.4%
CY2016 Project Year 1	5,609	2.7%
CY2017 Project Year 2	5,762	2.7%
CY2018 Project Year 3	5,919	2.7%

*The applicant states projected CY2015 mammography procedures are based on five months of actual volumes (January-May) annualized.

As shown in the above table, the applicant projects it will perform 5,609 mammography procedures on the proposed equipment in the first year of operation, and 5,919 mammography procedures in the third operating year. In Section IV.2, page 67, the applicant states the maximum annual capacity of the proposed mammography equipment is 6,129 procedures. Therefore, the applicant projects the mammography equipment will operate at 97 percent capacity in the third year of operation [$5,919/6,129 = 0.97$].

The applicant describes the assumptions and methodology used to project utilization in Section IV.1(d), pages 64-66, as follows:

“The following table provides historical utilization for RRWF’s existing mammography machine.

**Raleigh Radiology Wake Forest
 Mammography Procedures**

	CY2011	CY2012	CY2013	CY2014	CY2015*	4-Yr CAGR
Mammography Procedures	4,008	4,212	4,864	5,384	5,460	8.0%

*Annualized based on five months data (Jan-May).

As indicated by the four-year compound annual growth rate of 8 percent, the demand for mammography at RRWF has consistently increased. In addition, patients from the RRWF service area are travelling to Raleigh Radiology Cedarhurst for 3D mammography services. Based on CY2014 patient origin by zip code, 1,772 patients from the RRWF primary and secondary service area received 3D mammography services at RRC.

To project mammography procedures during the initial three project years, RRWF conservatively projects utilization to increase based on the projected population growth rate for women age 40+ in the identified service area (2.7%, see Section

III.1). ... The projected annual growth rate of 2.7% is approximately one-third of the 4-year compound annual growth rate for mammography services at RRWF.

As described previously, the proposed replacement equipment can perform both digital 2D mammography procedures and 3D breast tomosynthesis mammography procedures, therefore, RRWF patients who do not elect 3D mammography will continue to have access to the same 2D digital mammography services currently provided at RRWF.”

As shown above, the applicant’s utilization projections are based on its historical experience providing mammography services and projected service area population growth for women age 40 and older. Exhibit 15 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. Therefore, the applicant adequately demonstrated the need to acquire the proposed 3D mammography equipment to replace the existing 2D mammography equipment, and to establish a diagnostic center.

Access

In Section VI.2, pages 76-78, the applicant states RRWF will continue to provide services to all patients regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. The applicant adequately demonstrates 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 applicant adequately identified the population to be served by the proposed project, demonstrated the need the population has for the services proposed, and demonstrated the extent to which all residents of the area, 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 53-54, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative due to need for mammography services in the community, as demonstrated by the historical utilization of the existing mammography services at RRWF, and the fact that the existing mammography equipment at RRWF has reached the end of its useful life.
- Replace the Existing 2D Mammography Equipment with Another 2D Mammography Unit – The applicant states this alternative was rejected because, each year, more and more women are electing to have 3D mammography, as demonstrated by the historical growth in utilization of the 3D mammography services currently offered at the applicant’s Cedarhurst location.

After considering those alternatives, the applicant states 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 applicant adequately demonstrates 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. Pinnacle Health Services of North Carolina, LLC shall materially comply with all representations made in the certificate of need application.**
 - 2. Pinnacle Health Services of North Carolina, LLC shall not acquire, as part of this project, any equipment that is not included in the project’s proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
 - 3. Pinnacle Health Services of North Carolina, LLC 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.

In Section VIII.1, page 98, the applicant states the total project capital cost is projected to be \$415,339. In Section VIII.3, the applicant states \$48,720 will be financed with accumulated reserves and \$366,619 will be financed with a bank equipment lease. In Section IX.1, page 106, the applicant states there will be no start-up expenses or initial operating expenses associated with the proposed project.

In Exhibit 13, the applicant provides a letter dated June 9, 2015, from the Chief Financial Officer for PHS, which states,

“Pinnacle Health Services of North Carolina, LLC (Pinnacle) is seeking to replace the 2D digital mammography system at our Raleigh Radiology Wake Forest outpatient imaging center. The addition of 3D breast tomosynthesis digital mammography will result in the value of all existing medical diagnostic equipment at the facility to exceed \$500,000, and thus constitute a diagnostic center.

Pinnacle is planning to fund the medical equipment technology upgrade through an operating lease with 5th/3rd Bank. The operating lease will be paid through patient revenues and recorded as an operating expense.

Pinnacle will fund the estimated \$60,000 associated with the consultant and application fees and space renovation through its accumulated reserves. The financial statements included in our application show that Pinnacle has these funds currently available. Please accept this letter as confirmation of Pinnacle’s intention to use the funds for the proposed CON project.”

Exhibit 13 also contains a letter dated June 12, 2015 regarding the “*Letter of Intent-CON Application for Pinnacle Health Services,*” from a Vice President of Fifth Third Bank, which states,

“Fifth Third Bank would like to finance your project for the Hologic [3D mammography] imaging system once the CON is approved. We hope you will consider us for that opportunity. As usual, we would expect a 5 year Finance Lease based on the current rates at the time of installation of the Hologic system.”

Exhibit 13 also contains a letter dated June 12, 2015 regarding the “*Funding Availability for Proposed 3D Mammography System,*” from a Vice President of Fifth Third Bank, which states,

“We understand that Pinnacle plans to fund the remaining CON project capital costs (estimated at less than \$60,000) with its own cash reserves. PHS has asked that I provide you this letter to confirm that PHS has a significant banking relationship with 5th/3rd Bank, including deposit and investment accounts. I can confirm that as of June 12, 2015, PHS has sufficient funds between cash balances in their checking account

and access to a line of credit to cover the anticipated costs associated with the CON consultant and CON application fees and the facility electrical system up fit.”

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In the pro forma financial statement (Form B) for RRWF, the applicant projects that revenues will exceed operating expenses in each of the first three years of operation of the project, as shown in the table below.

	CY2016	CY2017	CY2018
Total Operating Revenue	\$4,508,659	\$4,565,328	\$4,636,391
Total Operating Expenses	\$2,205,502	\$2,282,773	\$2,325,725
Net Income	\$2,303,157	\$2,282,554	\$2,310,666

The assumptions used by the applicant 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 applicant adequately demonstrates 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

The 2015 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 applicant, RRWF, proposes to acquire a 3D mammography unit to replace its existing 2D mammography equipment, and establish a new diagnostic center. The patients to be served will be the same as the patients currently serviced in the existing location. No new services will be offered.

In Section II.8, page 30, the applicant provides a table listing the existing and approved providers of the types of diagnostic equipment proposed for the facility that are located in the proposed service area, as shown below:

Health Service Facility	Provider	Location	Type
Hospital	Novant Franklin Medical Center	100 Hospital Drive Louisburg NC 27549	Digital Mammo
Hospital Department	Rex Diagnostic Imaging of Wakefield	11200 Governor Manly Way, Ste 106 Raleigh NC27614	Digital Mammo
Hospital	WakeMed North Family Health & Women's Hospital	10000 Falls of Neuse Rd Raleigh NC 27614	Digital Mammo

Source: Application page 30.

However, on page 36, the applicant states there is no publicly available data which identifies the number of existing mammography machines located in health service facilities in RRWF's proposed service area that also includes the hours of operation for the facility, the hours of staffing radiology technicians, or the hours that a physician is available to perform interpretations, all of which would be necessary to determine the percentage of capacity at which the equipment was operating.

The applicant states the existing mammography equipment at RRWF has reached the end of its useful life, and that patients are referred to other locations for 3D mammography services, which the existing mammography equipment cannot perform. The applicant adequately demonstrated the need to replace the existing 2D mammography equipment with 3D mammography equipment. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved mammography 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 VII.1, page 89, the applicant provides the current staffing for the mammography services at RRWF, as shown in the table below.

RRWF Mammography Staffing	Number of Staff (FTE)
Administrator	0.10
Mammography Technologist	1.22
Registration Supervisor	0.46
Registration Staff	0.73
Clinical Supervisor	0.16
Marketing Liaison	0.24
TOTAL	2.91

Source: Table VII.1 page 89.

In Section VII.2, page 90, the applicant does not project any changes in staffing associated with the proposed project. In Sections VII.3, pages 91-92, and Section VII.6, page 93, the applicant describes its experience and process for recruiting and retaining staff. In Section VII.8, the applicant identifies Jeffrey Browne, M.D., as the Medical Director for RRWF. Exhibit 11 contains a copy of a letter from Dr. Browne expressing his interest in continuing as the Medical Director for the facility. The applicant adequately demonstrates 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 17-18, the applicant states that, as a current provider of mammography services, it already provides the necessary ancillary and support services. In Section V.2, page 69, the applicant states,

“In an outpatient facility, the patient remains under the care of his/her personal physician. PHS has no authority to ‘transfer’ patients to another healthcare facility, and thus no formal transfer agreements between PHS facilities and the local hospitals and nursing homes are required. ... In case of an emergency, all patients will be transported to the nearest available hospital by either Wake or County Emergency Medical Services (EMS).”

Exhibit 15 of the application contains copies of letters from physicians and other healthcare providers expressing support for the proposed project. The applicant adequately demonstrates 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 VI.12, page 85, and Section VI.13, page 86, the applicant reports the following payer mix for the entire facility and for mammography services at RRWF for CY2014:

Payer Category	Entire Facility Procedures as Percent of Total	Mammography Procedures as Percent of Total
Self Pay/Indigent/Charity	1.4%	1.0%
Medicare	16.9%	16.0%
Medicaid	2.7%	1.3%
Commercial Insurance	77.6%	81.7%
Worker's Compensation	1.4%	0.1%
Total	100.0%	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY2008-2009 (Estimate by Cecil G. Sheps Center)
Wake	10%	3.3%	18.4%
Franklin	18%	7.4%	19.7%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the mammography services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually

receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer 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 applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 84, the applicant states, "*PHS is a recipient of federal funds, and is compliant with all applicable federal regulations to insure continued access to these funds. PHS does not discriminate based on race, color, religion, gender, national origin, age, handicap, or ability to pay.*" In Section VI.10 (a), page 83, the applicant states that no civil rights complaints have been filed against it 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 VI.14, page 87, and Section VI.15, page 88, the applicant projects the following payer mix for the entire facility and for mammography services at RRWF during the second operating year (CY2017):

Payer Category	Entire Facility Procedures as Percent of Total	Mammography Procedures as Percent of Total
Self Pay/Indigent/Charity	1.4%	1.0%
Medicare	16.9%	16.0%
Medicaid	2.7%	1.3%
Commercial Insurance	77.6%	81.7%
Worker's Compensation	1.4%	0.1%
Total	100.0%	100.0%

Source: Application pages 87-88.

On page 87, the applicant states, “Based on its current referral sources, PHS does not anticipate any significant difference in the payor mix from that of its current diagnostic imaging service for the second year of operation following completion of the mammography equipment replacement project.” The applicant demonstrated that the medically underserved population will have adequate access to the services offered at RRWF. 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 VI.9, pages 82-83, the applicant describes the range of means by which a person will have access to RRWF’s services, including self-referral and physician referral. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to 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 69, the applicant states that it already has an established relationship with Wake Technical Community College (WTCC). Exhibit 10 contains a copy of a clinical training agreement between the applicant and WTCC. The information provided is reasonable and credible and supports a finding of conformity 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

RRWF proposes to replace existing 2D mammography equipment with 3D mammography equipment in the same location. Therefore, this project will not increase the inventory of mammography equipment in the proposed service area.

The 2015 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 V.6, pages 72-74, the applicant discusses how any enhanced competition in the service area would have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“PHS proposes to replace the 2D digital mammography machine with a 3D breast tomosynthesis mammography machine.... In summary, recent research has demonstrated a positive correlation associated with 3D breast tomosynthesis mammography and breast cancer detection rates, and reduced call-back rates. Therefore, the proposed equipment replacement project will implement state-of-the-art mammography technology with the intent of improving the quality of care provided at RRWF.

The proposed project will improve access to 3D breast tomosynthesis mammography for RRWF patients. As described previously, many patients are traveling from the Wake Forest area to RRC to receive 3D mammography. PHS’s proposal to replace the 2D mammography equipment at RRWF with a 3D breast tomosynthesis mammography machine will enhance the quality of care at RRWF and improve access to state-of-the-art mammography services for residents of Wake Forest and surrounding communities. Significantly, the proposed replacement equipment can perform both 2D digital mammography procedures and 3D breast tomosynthesis mammography procedures, therefore, RRWF patients who do not elect 3D mammography will continue to have access to the 2D digital mammography services currently provided at RRWF.

...

There is an economic benefit for payers and patients when using 3D breast tomosynthesis mammography to screen women for breast cancer. According to a January 2015 study in the Journal of ClinicoEconomics and Outcomes Research, commercial insurers may save at least \$28 for every patient screened with 3D mammography compared to using only traditional mammography. That's based on the benefits of reductions in follow-up diagnostic screening and improved detection of invasive cancers...."

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

The information provided by the applicant in the application is reasonable and adequately demonstrates that any enhanced competition in the service area would have 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 applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that it will provide adequate 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

In Section II.7, pages 22-24, the applicant describes the methods used by RRWF to insure and maintain quality care. The information provided by the applicant is reasonable and supports the determination that the applicant 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. The specific criteria are discussed below.

SECTION .1800 CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANTS

(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the correct application form.

(b) An applicant shall also provide the following additional information:

(1) the number, type, cost, condition, useful life and depreciation schedule of all medical diagnostic equipment that either is proposed to be acquired or is currently owned or operated by the applicants, and will be part of the diagnostic center following completion of the project;

-C- In Section II.8, page 27, the applicant identifies the existing medical diagnostic equipment at RRWF, the proposed medical diagnostic equipment to be located at the diagnostic center and the number, type, cost, condition, useful life, and depreciation schedule for each piece of equipment.

(2) other than the equipment listed in Subparagraph (b) (1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;

-C- In Exhibit 4, the applicant provides a list equipment and related components for the proposed mammography equipment which are necessary to perform the proposed procedures and services.

(3) the maximum number of procedures that each piece of medical diagnostic equipment in the diagnostic center is capable of performing and the assumptions used to project capacity;

-C- In Section II.8, page 28, the applicant provides the assumptions it used to project capacity for the service component, and the projections, as shown below.

EQUIPMENT	WEEKS / YEAR	HOURS / WEEK	MACHINE DOWN TIME	PROCEDURES / HOUR	TOTAL PROCEDURE CAPACITY
Mammography	50	43	5%	3.0	6,129

(4) a list of all existing and approved health service facilities that operate or have been approved to operate medical diagnostic equipment and diagnostic suites by type and location in the proposed medical diagnostic equipment service area;

-C- In Section II.8, page 30, the applicant provides a table listing the existing and approved providers of the types of diagnostic equipment proposed for the facility that are located in the proposed service area, which is shown below:

Health Service Facility	Provider	Location	Type
Hospital	Novant Franklin Medical Center	100 Hospital Drive Louisburg NC 27549	Digital Mammo
Hospital Department	Rex Diagnostic Imaging of Wakefield	11200 Governor Manly Way, Ste 106 Raleigh NC27614	Digital Mammo
Hospital	WakeMed North Family Health & Women's Hospital	10000 Falls of Neuse Rd Raleigh NC 27614	Digital Mammo

Source: Application page 30.

(5) the hours of operation of the proposed diagnostic center and each proposed diagnostic service;

-C- In Section II.8, page 30, the applicant states the diagnostic center is open from 8:00 AM to 5:00 PM, Monday-Friday.

(6) the patient origin by percentage by county of residence for each diagnostic service provided by the applicants in the 12 month period immediately preceding the submittal of the application;

-C- In Section III.4(b), page 55, the applicant provides the patient origin by percentage by county of residence for mammography services provided by RRWF from June 2014 to May 2015.

(7) the projected patient origin by percentage by county of residence for each service proposed, and all the assumptions and data supporting the methodology used for the projections;

-C- In Section III.5, page 58, the applicant provides projected patient origin by percentage by county of residence for the proposed service as well as the assumptions and data which support the methodology.

- (8) *drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and*
- C- In Exhibit 12, the applicant provides a line drawing of the diagnostic center that identifies a distinct, identifiable area for the mammography service.
- (9) *a three year capital budget.*
- C- In Section II.8, page 31, the applicant states, *“This proposed 3D mammography system acquisition represents the capital budget for RRWF for the next three years.”*
- (c) *An applicant proposing to establish a new mobile diagnostic program shall also provide the following information:*
- (1) *the number, type and cost of all proposed mobile medical diagnostic equipment including the cost of the transporting equipment;*
 - (2) *other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;*
 - (3) *the number and type of all existing and approved mobile diagnostic equipment in the proposed mobile diagnostic center service area;*
 - (4) *the maximum number of procedures that each proposed piece of medical diagnostic equipment is capable of performing and the assumptions used to project capacity;*
 - (5) *the name, address and hours of service at each host facility that is proposed to be served by the mobile diagnostic program; and*
 - (6) *copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the mobile diagnostic program.*
- NA- The applicant does not propose to establish a mobile diagnostic program.
- (d) *An applicant shall demonstrate that all equipment, supplies and pharmaceuticals proposed for the diagnostic center have been certified for clinical use by the U.S. Food and Drug Administration or will be operated or used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.*
- C- In Section II.8, page 32, the applicant provides documentation that the equipment proposed for the diagnostic center has been certified for clinical use by the U.S. Food and Drug Administration.
- (e) *An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:*
- (1) *the projected number of patients to be served, classified by diagnosis for each of the first twelve calendar quarters following completion of the project; and*

- C- In Section II.8, page 33, the applicant provides the projected number of patients to be served, classified by diagnosis (CPT code), for each of the first twelve calendar quarters following project completion.
 - (2) *the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following completion of the project; and*
- C- In Section II.8, page 34, the applicant provides the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following project completion, for the mammography equipment.
 - (3) *the projected number and type of diagnostic procedures proposed to be provided by CPT code or ICD-9-CM procedure code for each of the first twelve calendar quarters following completion of the project.*
- C- In Section II.8, page 33, the applicant provides the projected number and type of diagnostic procedures by CPT code to be provided for each of the first twelve calendar quarters following project completion.

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 II.8, page 36, the applicant identifies three existing health service facilities providing digital mammography services in the defined service area. However, on page 36, the applicant states there is no publicly available data which identifies the number of existing mammography machines located in health service facilities in RRWF's proposed service area that also includes the hours of operation for the facility, the hours of staffing radiology technicians, or the hours that a physician is available to perform interpretations, all of which would be necessary to determine the percentage of capacity at which the equipment was operating.
 - (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 II.8, page 39, the applicant projects that utilization for the proposed 3D mammography equipment will exceed 80 percent (96.6%) of the maximum number of procedures the proposed replacement equipment is capable of performing by 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 II.8, page 40, the applicant states that all utilization projections are based on the applicant's experience providing mammography services at the RRWF location and other sites in Wake County, and on the breast cancer incidence rates provided by the North Carolina State Center for Health Statistics.
 - (4) *all the assumptions and data supporting the methodologies used for the projections in this Rule.*
- C- In Section III.1, pages 44-53, and Section IV.1, pages 64-67, the applicant provides the assumptions and data supporting the methodologies used to project utilization.

10A NCAC 14C .1805 REQUIRED SUPPORT SERVICES

An applicant shall provide documentation showing the proximity of the proposed diagnostic center to the following services:

- (1) emergency services;*
 - C- In Section II.8, page 40, the applicant states that emergency services are available at WakeMed North Healthplex, which is approximately nine miles from RRWF.
- (2) support services;*
 - C- In Section II.8, page 40, the applicant states that support services, including administration, business office, information technology and medical records are currently provided at RRWF, and will continue to be provided upon implementation of the mammography equipment project.
- (3) ancillary services; and*
 - C- In Section II.8, page 41, the applicant states that it is an existing outpatient imaging center which provides medical diagnostic services, and that the necessary ancillary services are currently in place at RRWF. Lab and other diagnostic services are available at Rex Healthcare at Wakefield and WakeMed North HealthPlex.
- (4) public transportation.*

- C- In Section II.8, pages 41-42, the applicant states that patients in Wake County have access to public transportation via TRACS and Triangle Transit.

10A NCAC 14C .1806 STAFFING AND STAFF TRAINING

- (a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall identify the number of radiologists, radiation physicists, other physicians, laboratory staff, radiologic technologists and support staff that are projected to be involved in providing each of the proposed diagnostic services.*
- C- In Section II.8, page 42, and in Section VII.1, page 89, the applicant identifies the number of staff by type projected to provide the proposed services.
 - (b) An applicant proposing to provide ionizing and nonionizing radiation procedures shall demonstrate that a physician, licensed to practice medicine in North Carolina shall be available to perform and supervise all radiation procedures and shall document the qualifications of this physician to perform radiation procedures.*
- C- In Section II.8, page 42, the applicant states that all of Raleigh Radiology's physicians are licensed to practice medicine in North Carolina and have the qualifications necessary to perform radiation procedures, and shall be available to perform and supervise all mammography procedures.
 - (c) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall document that a program of continuing education shall be available for technologists and medical staff.*
- C- In Section II.8, page 43, and Exhibit 8, the applicant provides documentation of its program of continuing education for technologists and medical staff.