ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	January 28, 2016
Findings Date:	January 28, 2016
Project Analyst:	Gregory F. Yakaboski
Team Leader:	Fatimah Wilson
Assistant Chief:	Martha J. Frisone
Project ID #:	J-11058-15
Facility:	Raleigh Radiology Clayton
FID #:	150392
County:	Johnston
Applicant:	Pinnacle Health Services of North Carolina, LLC
Project:	Develop a diagnostic center by acquiring a Digital X-Ray/Fluoroscopy System to replace the existing X-Ray/Fluoroscopy 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

Pinnacle Health Services of North Carolina, LLC (PHS) d/b/a Raleigh Radiology Clayton (RRC), also referred to throughout these findings as "the applicant," proposes to acquire a refurbished Digital X-Ray/Fluoroscopy System (R&F system) to replace its existing R&F equipment at RRC. RRC is a freestanding outpatient imaging center located at 166 Springbrook Avenue, Suite 103, in Clayton. The value of the R&F System ($229,995) combined with the existing medical diagnostic equipment already being utilized by RCC, exceeds the statutory threshold for a diagnostic center of $500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

Need Determination

There are no need determinations in the 2015 State Medical Facilities Plan (2015 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 2015 SMFP which are applicable to this review.

Conclusion

In summary, the applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2015 SMFP. There are no policies in the 2015 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

RRC proposes to acquire a refurbished R&F System to replace its existing R&F equipment at RRC. RRC is a freestanding outpatient imaging center located at 166 Springbrook Avenue, Suite 103, in Clayton. The value of the R&F System ($229,995) combined with the existing medical diagnostic equipment already being utilized by RCC, exceeds the statutory threshold for a diagnostic center of $500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

RRC currently has the following equipment: 2D mammography, ultrasound machines, x-ray units and a bone densitometer

In supplemental information, the applicant describes the project as follows:

> *"PHS intends to replace its existing x-ray/fluoroscopy machine in Clayton with a digital x-ray/fluoroscopy (R&F) system. Specifically, PHS intends to acquire a Refurbished GE Precision 500D R&F Unit. … The replacement R&F equipment will afford a faster serial operation and will also streamline workflow. PHS will continue to provide the same scope of procedures that are currently offered at RRC…"*

Population to be Served

The 2015 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. 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."*

On pages 57-58 and in supplemental information, the applicant identifies RRC's R&F service area by Zip code area. On page 58, the primary and secondary service areas are illustrated by a color coded map.

The historical patient origin for existing R&F services for the twelve-month period prior to submission of the application is provided in supplemental information, as illustrated in the table below.

RRC- R&F Services
December 2014 – November 2015

County	Projected % of Total
Johnston	63.9%
Wake	28.5%
Harnett	3.2%
Other*	4.4%
Total	100.0%

*Other includes less than 1 percent patient origin from each of the following counties in North Carolina: Nash, Wayne, Cumberland, Sampson, Wilson, Durham, Franklin, Edgecombe, Onslow, Vance Alamance, Halifax, Craven, Orange, Duplin, Lenoir, Greene, Mecklenburg, Moore, New Hanover, Robeson, Rockingham, Pitt, and Pamlico counties, and other states.

In supplemental information, the applicant provides the projected patient origin for R&F services at RRC during the first two operating years following project completion, as shown in the table below.

RRC- R&F Services
CY2016-CY2017

County	Projected % of Total
Johnston	67.0%
Wake*	29.5%
Harnett*	3.5%
Total	100.0%

*In supplemental information the applicant identifies the primary service area for RRC's R&F services as including the following zip codes: 27520, 27527, 27529, 27577, and 27603. The secondary service area includes the following zip codes: 27576, 27592, 27504, 27591, and 27524. The applicant states *"The rationale for defining this service area is based on the historical patient origin for R&F patients at RRC. During the most recent 12 months (December 2014-November 2015), patients from the identified zip codes comprised over 80 percent of RRC's R&F patient origin."*

In supplemental information, the applicant states that RRC currently provides R&F services in the service area and the projected patient origin information is based on this historical data. Furthermore, in supplemental information, the applicant states, *"PHS has historically served some patients (approximately 4.4%) from North Carolina counties other than the counties identified … above. These patients are intermittent, and the number of patients from each of these counties is less than 1%. Therefore, these counties are not included in PHS' projected patient origin, as PHS does not expect to receive any statistically significant number of patients from them. In order to reflect a total projected patient origin of 100%, the percentage of patients from each county was proportionally increased by 4.4%."*

The applicant adequately identified the population to be served.

Analysis of Need

In supplemental information, the applicant states that the need for the proposed project is based on quantitative and qualitative factors, which are summarized below.

- The existing R&F system in at the end of its useful life and fully depreciated.
- The R&F system is experiencing unscheduled downtime and interrupting patient care. Numerous specific instances are detailed in the supplemental information.
- As of December 31, 2015, the applicant has been notified by the manufacturer of the existing R&F system that the R&F unit at RCC has reached "end-of-support (EOS) status". See supplemental information.
- Projected population growth presumes continued increased demand for healthcare.
- The R&F equipment is integral to the continuum of radiographic services provided at RCC.
- Further, the proposed replacement R&F equipment will: 1) afford a faster serial operation; and 2) streamline workflow.

The applicant adequately demonstrates the need to develop a diagnostic center by replacing the existing R&F equipment with a refurbished digital R&F system at the existing RRC facility.

Projected Utilization

In supplemental information, the applicant provides projected utilization for R&F services at RRC through the first three years of operation following completion of the project, as shown in the following table.

	CY2016	CY2017	CY2018
R&F Procedures	4,297	4,358	4,421

In supplemental information, the applicant provided the capacity (with assumptions) of the proposed digital R&F equipment, as illustrated in the table below.

Equipment	Days per Week	Hours per Week	Machine Down Time	Procedures/Hour	Equipment Capacity (procedures)
R&F Unit	5	40	5%	2.85	5,423

The table below illustrates at what capacity the proposed digital R&F equipment is projected to operate for the first three years following project completion.

	CY2016	CY2017	CY2018
R&F Procedures	4,297	4,358	4,421
# of R&F Systems	1	1	1
% of Capacity	79.2%	80.4%	81.5%

As shown above, for each of the first three project years following completion of the proposed project the digital R&F equipment is projected to operate at over 79.0% of capacity. By the third project year the applicant projects the digital R&F equipment to be operating at over 81.0% capacity.

In supplemental information, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- Calculated the projected population growth for the RRC R&F service area for 2015 through 2020.
- The 5 year Compound Annual Growth Rate (CAGR) was 1.4% for the total service area.
- RRC then applied the 1.4% growth rate to the annualized R&F utilization for CY2015 to project utilization for the first operating year (CY2016).
- The 1.4% growth rate was also used to project utilization for the second and third operating yeas (CY2017 and CY2018).

RRC began offering R&F services in the fall of 2012. The table below summarizes RRC's historic and projected utilization of its R&F services including year over year percentage growth.

	CY2012*	CY2013	CY2014	CY2015**	CY2016	CY2017	CY2018
R&F Procedures	314	2,408	3,377	4,236	4,297	4,358	4,421
Annualized Increase %	-na-	-na-	40.1%	25.4%	1.4%	1.4%	1.4%

*Services started in CY2012.
**Based on annualized data (11 months: January-November)

It is noted that the applicant is only projecting an increase of 185 R&F procedures from CY2015 to CY2018 [4,421 – 4,236 = 185].

An increase of 185 R&F procedures from CY2015 to CY2018 is a conservative projection based on RRC's historical experience providing R&F services, projected service area population growth, and the increase in efficiency and reliability of providing Digital R&F services.

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. Therefore, the applicant adequately demonstrates the need for the development of a diagnostic center by acquiring the proposed digital R&F equipment to replace the existing R&F equipment.

Access

In Section VI.2, pages 80-81 and supplemental information, the applicant states, *"PHS has historically provided care and services to medically underserved populations. … Consistent with its current business practice, PHS has a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. …"*

In Section VI.15, page 92 and supplemental information, the applicant provides the projected payor mix for all diagnostic imaging services and R&F services only for CY2017 (the second full fiscal year of operation), as shown in the following tables:

RRC- Entire Facility
Second Full Fiscal Year (CY2017)
Procedures as Percent of Total Utilization

Self Pay/ Indigent/ Charity	3.25%
Medicare	18.47%
Medicaid	4.82%
Commercial/ BCBS/ SEHP	68.77%
Workers Compensation	4.69%
Total	100%

RRC- R&F Services Only
Second Full Fiscal Year (CY2017)
Procedures as Percent of Total Utilization

Self Pay/ Indigent/ Charity	3.3%
Medicare	18.5%
Medicaid	4.8%
Commercial/ BCBS/ SEHP	68.8%
Workers Compensation	4.7%
Total	100.0%

As shown in the table above, 23.3% of the payor mix is Medicare and Medicaid.

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 identifies the population to be served, adequately demonstrates the need that population has for the proposed project and adequately demonstrates 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 supplemental information, the applicant describes the alternatives considered, which included maintaining the status quo or replace the R&F equipment with a new digital R&F system or replace the R&F equipment with a refurbished R&F system. The applicant discusses the fact the existing R&F equipment is fully depreciated, at the end of its useful life, is encountering unexpected downtime and has reached its end-of-support status. Furthermore, the applicant states that purchasing a new R&F system was not cost-effective. After considering those alternatives, the applicant states the alternative represented in the application and supplemental information 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 applicant adequately demonstrates 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. **Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Clayton shall materially comply with the representations made in the certificate of need application and in supplemental information provided. In those instances where representations conflict, Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Clayton shall materially comply with the last made representation.**

2. **Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Clayton shall acquire no more than one Digital X-Ray/Fluoroscopy System.**

3. **Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Clayton 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 and which would otherwise require a certificate of need.**

4. **Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology Clayton 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

RRC proposes to acquire a refurbished R&F System to replace its existing R&F equipment at RRC. RRC is a freestanding outpatient imaging center located at 166 Springbrook Avenue, Suite 103, in Clayton. The value of the R&F System ($229,995) combined with the existing medical diagnostic equipment already being utilized by RCC, exceeds the statutory threshold for a diagnostic center of $500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

Capital and Working Capital Costs

In supplemental information, the applicant projects the total capital cost of the project will be $286,420, which includes:

Construction costs	$1,900
Movable Equipment`	$245,520
Consultant Fees	$38,000
Other (Freight)	$1,000
Total	$286,420

In supplemental information, the applicant states no working capital (start-up and initial operating expenses) is required for the proposed project because no new service is being proposed, but replacement of RRC's existing R&F equipment.

Availability of Funds

In supplemental information, the applicant states that the capital costs of the proposed project will be financed by accumulated reserves and a bank equipment lease.

In Attachment 3 of the supplemental information, the applicant provides a letter dated December 17, 2015 from Lance Waller, Vice President of Fifth Third Bank which states that Fifth Third Bank would like to finance the proposed equipment utilizing a five year Finance Lease based on current rates.

In Attachment 3 of the supplemental information, there is also a letter dated December 17, 2015 from Megan Brearey, Vice President of Fifth Third Bank which states that PHS has sufficient funds in its checking account to cover the capital costs outside of the equipment lease.

Furthermore, Attachment 3 of the supplemental information also contains a letter dated December 17, 2015 from Perry Baker, CPA Chief Financial Officer and Vice President of Finance stating that PHS has the accumulated reserves to cover the capital costs outside of the proposed equipment lease and intends to use those accumulated reserves for that stated purpose and that the operating lease will be paid through patient revenues.

The applicant adequately demonstrated that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In projected revenue and expense statement (Form B) provided in supplemental information, RCC projects revenues will exceed operating expenses in both of the first two Operating Years following completion of the proposed project, as shown in the table below.

	CY 2016 (1st Operating Year)	CY 2017 (2nd Operating Year)
Net Revenues	$2,960,183	$3,008,773
Total Operating Expenses	$2,089,328	$2,126,425
Net Profit	$870,855	$882,386

The assumptions used by the applicant in preparation of the pro formas are reasonable including projected utilization, costs and charges. See the financial section in the supplemental information 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 applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, 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

RRC proposes to acquire a refurbished R&F System to replace its existing R&F equipment at RRC. RRC is a freestanding outpatient imaging center located at 166 Springbrook Avenue, Suite 103, in Clayton. The value of the R&F System ($229,995) combined with the existing medical diagnostic equipment already being utilized by RCC, exceeds the statutory threshold for a diagnostic center of $500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2015 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. 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 supplemental information, the applicant provides the projected patient origin for R&F services at RRC during the first two operating years following project completion, as shown in the table below.

RRC- R&F Services
CY2016-CY2017

County	Projected % of Total
Johnston	67.0%
Wake*	29.5%
Harnett*	3.5%
Total	100.0%

*In supplemental information the applicant identifies the primary service area for RRC's R&F services as including the following zip codes: 27520, 27527, 27529, 27577, and 27603. The secondary service area includes the following zip codes: 27576, 27592, 27504, 27591, and 27524. The applicant states *"The rationale for defining this service area is based on the historical patient origin for R&F patients at RRC. During the most recent 12 months (December 2014-November 2015), patients from the identified zip codes comprised over 80 percent of RRC's R&F patient origin."*

The total number of R&F systems in the service area defined by the applicant will not increase as a result of this proposal.

In supplemental information, the applicant provides a list of all existing and approved health service facilities that operate or have been approved to operate medical diagnostic suites by type and location in the proposed project service area, as illustrated in the table below:

Health Service Facility	Provider	Location	Type
Hospital Department	Wakemed Clayton	555 Medical Park Pl Ste 107, Clayton, NC 27520	Radiography Equipment
Hospital Department	Johnston Medical Center Clayton	2138 NC Highway 42, Clayton, NC 27520	Radiography Equipment
Diagnostic Center	Wake Radiology Diagnostic Imaging	300 Health Park Dr Ste 100, Garner, NC 27529	Radiography Equipment
Hospital Department	Johnston Memorial Hospital	509 N. Brightleaf Blvd, Smithfield, NC 27577	Radiography Equipment
Hospital Department	Johnston Health Ambulatory Imaging	514 Brightleaf Blvd, Smithfield, NC 27577	Radiography Equipment

However, the applicant correctly notes that there is no publically available data which provides sufficient information to determine if the similar medical diagnostic equipment was operating at 80.0% 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.

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

The applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved R&F System services 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

RRC's x-ray/fluoroscopy services are open five days per week, Monday through Friday, 8:00am to 5:00pm. In supplemental information, the applicant states that it staffs 1.0 Full Time Equivalent (FTE) radiology technologist and that the replacement equipment will not result in the addition of any FTEs. In Section VII.8, page 98 and supplemental information, the applicant identifies Jeffrey Browne, M.D., as the Medical Director for RRC. Exhibit 11 contains a copy of a letter from Dr. Browne expressing his interest in continuing as the Medical Director for the facility. In Section VII.8(b), page 99, the applicant states, *"Professional services at RRC will continue to be provided by Raleigh Radiology Associates via a professional business services agreement."* See also supplemental information pages 16-17. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financial statements. 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, page 17, the applicant describes the ancillary and support services that will be provided by the facility. Exhibit 2 contains a copy of the management agreement. Exhibit 15 contains copies of letters from other health care providers expressing support for the proposed project. In Section V.2, page 73, 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 Johnston County Emergency Medical Service (EMS)."*

The applicant adequately demonstrates 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

(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 supplemental information, the applicant provides the payor mix during the last full fiscal year (CY2014) for all diagnostic imaging services at RRC and for just R&F services, as illustrated in the tables below.

RRC- Entire Facility
Last Full Fiscal Year (CY2014)
Procedures as Percent of Total Utilization

Self Pay/ Indigent/ Charity	3.25%
Medicare	18.47%
Medicaid	4.82%
Commercial/ BCBS/ SEHP	68.77%
Workers Compensation	4.69%
Total	100%

RRC- R&F Services Only
Last Full Fiscal Year (CY2014)
Procedures as Percent of Total Utilization

Self Pay/ Indigent/ Charity	3.3%
Medicare	18.5%
Medicaid	4.8%
Commercial/ BCBS/ SEHP	68.8%
Workers Compensation	4.7%
Total	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 the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following table illustrates those percentages for Johnston, Wake and Harnett counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	**2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population ***	**2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) ***
Johnston County	17.5%	6.7%	20.0%
Wake County	9.8%	3.3%	18.4%
Harnett County	16.9%	6.2%	20.3%
Statewide	16.5%	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 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 and gender. However, a direct comparison to the applicant's 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, handicapped persons or women utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the services offered at RCC. 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 88, that applicant states, "*PHS is a recipient of federal funds, and is compliant with all applicable federal regulations to insure continued access to these funds."* In Section VI.2, pages 80-81, the applicant states, *"PHS has historically provided care and services to medically underserved populations. ..."*

In Section VI.10(b), page 88, the applicant states that PHS has *"not had any civil rights complaints filed against it during the last five years."* Therefore, 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 supplemental information, the applicant provides the projected payor mix for all diagnostic imaging services and for only R&F services at RRC for CY2017 (the second full fiscal year of operation), as shown in the following table:

RRC- Entire Facility
Second Full Fiscal Year (CY2017)
Procedures as Percent of Total Utilization

Self Pay/ Indigent/ Charity	3.25%
Medicare	18.47%
Medicaid	4.82%
Commercial/ BCBS/ SEHP	68.77%
Workers Compensation	4.69%
Total	100%

RRC- R&F Services Only
Second Full Fiscal Year (CY2017)
Procedures as Percent of Total Utilization

Self Pay/ Indigent/ Charity	3.3%
Medicare	18.5%
Medicaid	4.8%
Commercial/ BCBS/ SEHP	68.8%
Workers Compensation	4.7%
Total	100.0%

As shown in the above referenced table, 23.3% of the payor mix is Medicare and Medicaid. In Section VI.2, page 80 and supplemental information, the applicant states, "*PHS has a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.*"

The applicant demonstrated 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.2(d), page 74, Section VI.9, page 87 and supplemental information, the applicant describes the range of means by which a person will have access to RRC's services. Referrals from all physicians, regardless of affiliation, will be accepted at RRC. 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 73, the applicant describes how the facility will accommodate the clinical needs of area health professional training programs, as follows:

> *"PHS already has established relationships with area training programs. For example, PHS has a positive working relationship with Wake Technical Community College (WTCC) for training students form the Radiography Program. ... Please refer to Exhibit 10 for a copy of the existing training agreement with WTCC. RRC is under the purview of this agreement."*

Exhibit 10 contains a copy of the existing training agreement between Wake Technical Community College and Raleigh Radiology Associates, Inc. which provides for clinical learning experiences for the students.

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

RRC proposes to acquire a refurbished R&F System to replace its existing R&F equipment at RRC. RRC is a freestanding outpatient imaging center located at 166 Springbrook Avenue, Suite 103, in Clayton. The value of the R&F System ($229,995) combined with the existing medical diagnostic equipment already being utilized by RCC, exceeds the statutory threshold for a diagnostic center of $500,000; therefore, the acquisition of the proposed equipment requires a certificate of need.

The 2015 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. 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 supplemental information, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

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 applicant adequately demonstrates 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 applicant adequately demonstrates that RRC will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicant adequately demonstrates RRC 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 22-24, the applicant describes the methods used by RRC to insure and maintain quality care including stating that PHS has never had the license revoked for any of its facilities in North Carolina nor has it ever had the Medicare/Medicaid provider agreement terminated for any of its facilities in North Carolina. 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 promulgated by 10A NCAC 14C Section .1800. See discussion below.

SECTION .1800 - CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANT

(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 utilized the Acute Care Facility/Medical Equipment 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 applicant, and will be part of the diagnostic center following completion of the project;

-C- In supplemental information, the applicant provides a table setting forth 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 RRC, and will be part of the diagnostic center following completion of the project. Furthermore, on pages 26-27, the applicant states that all of the existing equipment was purchased and made operational more than 12 months prior to the submission of the application for the proposed project.

(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 3 of the application and supplemental information Attachment 1, the applicant provides a list of all equipment and related components 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 supplemental information, the applicant provides the maximum number of procedures that the proposed R&F equipment in the diagnostic center is capable of performing and the assumptions used to project capacity.

(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, pages 29-30 and supplemental information, the applicant provides 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. In supplemental information the applicant identifies the primary service area for RRC's R&F services as including the following zip codes: 27520, 27527, 27529, 27577, and 27603. The secondary service area includes the following zip codes: 27576, 27592, 27504, 27591, and 27524. The applicant states, *"The rationale for defining this service area is based on the historical patient origin for R&F patients at RRC. During the most recent 12 months (December 2014-November 2015), patients from the identified zip codes comprised over 80 percent of RRC's R&F patient origin."*

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

-C- In supplemental information, the applicant states that the R&F equipment will be available up to 40 hours each week and that the proposed diagnostic center's hours of operation will be Monday thru Friday 8:00am to 5:00 pm.

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

-C- In supplemental information, the applicant provides the patient origin by percentage by county of residence for the R&F services provided by RRC in the 12 month period immediately preceding the submittal of the application.

(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 supplemental information, the applicant provided the projected patient origin by percentage by county of residence for RRC's proposed R&F service, and all the assumptions and data supporting the methodology used for the projections.

(8) drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and

-C- Exhibit 12 contains a line drawing of the proposed diagnostic center that identifies a distinct, identifiable area for the proposed R&F equipment.

(9) a three year capital budget.

-C- In supplemental information, the applicant states that *"This proposed R&F system acquisition will be an operating expense, not a capital expenditure. However, for information purposes, please refer to Attachment 1 for the equipment the equipment vendor quotation and the contractor flooring quote."*

(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- PHS does not propose to establish a new 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 supplemental information, the applicant states that the proposed R&F equipment, was approved by the U.S. Food and Drug Administration in 2008. (See also Attachment 5 of the supplemental information)

(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 supplemental information and Attachment 6, the applicant provides the projected number of patients to be served, classified by diagnosis for each of the first twelve calendar quarters following completion of the project.

(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 supplemental information, the applicant provides 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, for the proposed R&F 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 Attachment 6 of supplemental information, the applicant provides a table that provides the projected number and type of diagnostic procedures proposed to be provided by CPT code for each of the first twelve calendar quarters following completion of the project

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 applicant is proposing to replace its existing R&F equipment with a refurbished digital R&F System. In supplemental information, the applicant identifies other health service facilities that operate or have been approved to operate similar medical diagnostic equipment. However, the applicant correctly notes that there is no publically available data which provides sufficient information to determine if the similar medical diagnostic equipment was operating at 80.0% 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 supplemental information, the applicant states that due to the lack of publically available data, the applicant 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% 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. In supplemental information, the applicant documents that the RRC's proposed Digital R&F System will 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. The applicant projects utilization of the Digital R&F System at 81.5% of capacity in Project Year 3 (CY2018) as illustrated in the following tables.

Equipment	Days per Week	Hours per Week	Machine Down Time	Procedures/Hour	Equipment Capacity (procedures)
R&F Unit	5	40	5%	2.85	5,423

	CY2016	CY2017	CY2018	Project Year 3 Operating Capacity
R&F Procedures	4,297	4,358	4,421	81.5%

(3) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and

-C- In supplemental information, the applicant documents that the applicant's utilization projections are based on the applicant's experience providing R&F services at RRC and in Johnston County 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 Section III.1 and supplemental information, the applicant provides all the assumptions and data supporting the methodologies used to project utilization.

10A NCAC 14C .1805 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, page 41, the applicant states that Johnston Medical Center Clayton offers emergency services and is less than one mile from the RRC facility.

(2) support services;

-C- RRC is an existing facility. In Section II., page 42, the applicant states that support services will continue to be offered after project completion.

(3) ancillary services; and

-C- In Section II, page 42 and in supplemental information, the applicant states that RCC is an existing facility already providing R&F services with all necessary ancillary services already in place. Lab work and similar diagnostic services are available at WakeMed Clayton and Johnston Medical Center Clayton.

(3) public transportation.

-C- On page 42 the applicant states that Johnston County Area Transportation (JCATS) provides public transportation to patients in Johnston County.

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 VII, pages 93-94 and supplemental information, the applicant provides the number of radiologists, radiation physicists, other physicians, laboratory staff, radiologic technologists and support staff for the current and proposed staffing for R&F services at RRC. The proposed replacement of R&F equipment with refurbished digital R&F equipment is projected to result in no change in FTEs. In addition, in supplemental information, the applicant states that Raleigh Radiology Associates has 25 radiologists on staff and many are involved in providing the R&F services at RRC.

(*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 supplemental information, the applicant documents that a physician, licensed to practice medicine in North Carolina shall be available to perform and supervise all radiation procedures. Exhibit 11 contains a letter from Jeffrey Brown, MD, stating

that he is the current medical director of RRC and that he will continue to be the medical director. Also included in Exhibit 11 is a copy of Dr. Brown's licensee information from the North Carolina Medical Board which states that he is board certified in diagnostic radiology.

(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, page 43, the applicant states that a program of continuing education is available for technologists and medical staff and will continue to be available. In Section VII.4, page 96 and in Exhibit 8 the applicant documents and details programs of continuing education for technologists and medical staff.