

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 25, 2019

Findings Date: October 25, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: J-11746-19

Facility: Raleigh Radiology Clayton

FID #: 070469

County: Johnston

Applicant: Pinnacle Health Services of North Carolina, LLC

Project: Develop a new diagnostic center by replacing an existing digital radiography and fluoroscopy system

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Pinnacle Health Services of North Carolina, LLC (hereinafter referred to as PHSNC or “the applicant”) proposes to develop a new diagnostic center, Raleigh Radiology Clayton (RRC), at 166 Springbrook Avenue, Suite 103, in Clayton. The applicant currently operates an existing freestanding outpatient imaging center at this location. The value of the existing medical diagnostic equipment does not meet the threshold for establishing a diagnostic center. The applicant proposes to replace its existing radiography and fluoroscopy (R&F) system. The combined value of the existing medical diagnostic equipment costing \$10,000 or more and the proposed replacement R&F system, including related construction costs, exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

N.C. Gen. Stat. 131E-176(7a) states:

*“Diagnostic center” means a freestanding facility, program, or provider, including but not limited to, physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”*

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP);
- acquire any medical equipment for which there is a need determination in the 2019 SMFP; or
- offer a new institutional health service for which there are any applicable policies in the 2019 SMFP.

Therefore, Criterion (1) 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 proposes to develop a new diagnostic center by replacing its existing R&F system at RRC. RRC is an existing freestanding outpatient imaging center located in Clayton.

### Designation as a Diagnostic Center

In Section C, page 18, Exhibit 3 and Form F.1a, the applicant states the proposed diagnostic center will include existing diagnostic equipment, each valued at more than \$10,000, totaling \$441,408 plus the new capital costs associated with the R&F replacement equipment totaling \$264,552 for a total of \$664,150, which is summarized below:

<b>Raleigh Radiology Clayton Medical Diagnostic Equipment</b>		
<b>Existing Equipment: Capital Cost</b>	<b># of Units</b>	<b>Cost</b>
Ultrasound System #1	1	\$61,915
Ultrasound Table #1	1	\$8,129
Ultrasound System #2	1	\$70,015
Ultrasound Table #2	1	\$8,124
DBT System -3D Mammography	1	\$212,778
Digital radiography film reader	1	\$15,799
Digital radiography system (being replaced)	1	\$41,810
Bone Densitometer	1	\$22,839
<b>Sub-Total</b>		<b>\$441,408</b>
<b>New Equipment- Capital Costs</b>		
R&F Equipment	1	\$216,169
Construction/Renovation		\$3,383
Consultant Fees		\$40,000
Other(contingency)		\$5,000
<b>Sub-Total</b>		<b>\$264,552</b>
<b>Overall Total</b>		<b>\$664,150*</b>

\*Less the removal of the old R&F system valued at \$41,810

As shown in the table above, the combined cost of the equipment is more than \$500,000 and therefore a certificate of need is required to develop a diagnostic center.

**Patient Origin**

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 29, the applicant defines the service area as Johnston County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

<b>County</b>	<b>Current (CY2018)</b>		<b>Third Full FY of Operation following Project Completion (CY2022)</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Johnston	3,450	62.8%	3,902	62.8%
Wake	1,604	29.2%	1,814	29.2%
Harnett	187	3.4%	211	3.4%
Wayne	66	1.2%	75	1.2%
Other*	187	3.4%	211	3.4%
<b>Total</b>	<b>5,494</b>	<b>100.0%</b>	<b>6,214</b>	<b>100.0%</b>

Source: Section C, pages 22-23.

\*Other includes <1.0% patient origin from the remaining counties in North Carolina and other states.

Totals may not foot due to rounding

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C.4, page 24, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The existing R&F system is well utilized, experienced robust growth in recent years and projects continued increases in utilization (pages 28-29).
- RRC is an existing imaging facility located in Johnston County. The population of Johnston County is projected to grow which presumes continued increases in demand for healthcare services (pages 29-30).
- The existing R&F system has exceeded its useful life and is experiencing frequent and costly unscheduled downtime (pages 26-28).
- RRC provides a continuum of radiographic services and the existing R&F diagnostic equipment is an integral part of those services (page 27).
- The proposed replacement R&F system is cost-effective and will enable RRC to continue to ensure quality of care and meet patient expectations (pages 24-26).
- The proposal to replace the R&F equipment at RRC is supported by physicians who refer to RRC (pages 28-29 and Exhibit 13).

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reasonable and adequately supported information to support its assertion that the existing R&F equipment had exceeded its useful life and needed replacement.
- The applicant provides reasonable and adequately supported information to support its assertion that is well utilized, experienced robust growth in recent years and projects continued increases in utilization.
- Reliable data sources are used to support assertions about population growth in the proposed service area.

### *Projected Utilization*

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables.

**Raleigh Radiology Clayton: Historical R&F Utilization**

Component	CY2015	CY2016	CY2017	CY2018	CY2019*	3-YR CARG*
X-Ray	3,943	4,134	4,896	5,121	5,474	
Fluoroscopy	287	301	357	373	399	
Total R&F Procedures	4,230	4,435	5,253	5,494	5,873	9.1%

\*Compound Annual Growth Rate (CAGR)

\*\*Annualized based on 5 months of data (Jan-May)

Source: Section Q, page 93.

**Raleigh Radiology Clayton: Projected R&F Utilization**

Component	CY2020	CY2021	CY2022
X-Ray	5,579	5,684	5,792
Fluoroscopy	406	414	422
Total R&F Procedures	5,985	6,098	6,214

Totals may not foot due to rounding.

Source: Section Q, page 94.

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

Step #1: Calculated the projected population growth rate for Johnston County

County	2019	2020	2021	2020	2023	4-year CAGR
Johnston	204,784	209,403	213,493	217,351	221,169	1.9%

Source: North Carolina Office of State Budget and Management (NCOSBM)

See Section Q, page 94.

Step #2: Apply the projected population growth rate for Johnston County to RRC's annualized R&F utilization for CY2019

**Raleigh Radiology Clayton: Projected R&F Utilization**

Component	CY2019	CY2020	CY2021	CY2022
X-Ray	5,474	5,579	5,684	5,792
Fluoroscopy	399	406	414	422
Total R&F Procedures	5,873	5,985	6,098	6,214

Totals may not foot due to rounding.

See Section Q, page 94.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on the applicant's historical data and projected service area population growth as evident from the NCOSBM.
- The applicant uses a conservative projected growth rate of 1.9% which is less than the historic growth rate of 9.1%.
- The applicant provides reasonable and adequately supported information to justify the need for the equipment.

**Access**

In Section C, page 37, the applicant states it will provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental condition, age, ability to pay, or any other factor that would classify a patient as underserved. In Section L, page 76, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

**Raleigh Radiology Clayton: Projected Payor Mix CY2022 (OY3)**

Payor Source	X-ray	Fluoroscopy	Ultrasound	Bone Density	Mammography	MRI
Medicaid*	6.8%	4.4%	4.7%	1.3%	1.8%	4.1%
Medicare*	20.3%	10.7%	14.2%	37.6%	16.8%	19.3%
Self-Pay/Charity Care	4.7%	2.5%	6.9%	1.1%	2.5%	1.0%
Insurance*	63.0%	58.2%	70.6%	58.1%	75.0%	59.2%
Workers Compensation	1.1%	16.3%	0.7%	0.0%	0.1%	11.1%
Other (Gov't)	4.0%	8.0%	2.9%	1.9%	3.8%	5.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

\*Including any managed care plans.

Source: Table on page 76 of the application.

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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.

The applicant does not propose to reduce, eliminate or relocate GI endoscopy rooms or services; therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to develop a new diagnostic center by replacing its existing R&F system at RRC.

In Section E, pages 47-48 , the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo: The applicant states this option would not meet the need as the R&F system is no longer supported by the equipment manufacturer, is beyond its useful life, and is experiencing expensive repairs and regular downtime that causes delay in patient care. Therefore, this is not an effective alternative.

Develop the Diagnostic Center in a Different Area: RRC is an existing facility which has operated at the same location in Clayton for 12 years. The current Clayton location is easily accessible to the major transportation arteries of NC 42, U.S. Highway 70, Interstate 40 and Business 70. The current location has been well received by patients. Further, the project is limited to replacement of one of RRC's existing imaging modalities, there is no change proposed for the other existing modalities. The proposed replacement equipment can be accommodated at the existing Clayton location with only a modest flooring replacement. Therefore, this is not an effective or least costly alternative.

Acquire More than One R&F System: The applicant states it considered adding more than one R&F system however, it was determined that one R&F system was sufficient to meet the quantitative and qualitative needs of the patients and referring physicians based on discussions involving administrative and clinical personnel. Therefore, this is not an effective or least costly alternative.

On pages 47-48, the applicant states that its proposal is the most effective alternative because a replacement R&F system at the current, existing location best meets the needs of RRC's referring physicians and patients.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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 develop a new diagnostic center in Clayton by replacing an existing digital radiography and fluoroscopy system. Upon project completion the diagnostic center shall have no more than two ultrasound units, one mammography unit, one bone density unit and one radiography and fluoroscopy unit.**
  - 3. Pinnacle Health Services of North Carolina, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
  - 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Pinnacle Health Services of North Carolina, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. Payor mix for the services authorized in this certificate of need.**
    - b. Utilization of the services authorized in this certificate of need.**
    - c. Revenues and operating costs for the services authorized in this certificate of need.**
    - d. Average gross revenue per unit of service.**
    - e. Average net revenue per unit of service.**
    - f. Average operating cost per unit of service.**
  - 5. Pinnacle Health Services of North Carolina, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

The applicant proposes to develop a new diagnostic center by replacing its existing R&F system at RRC.

**Capital and Working Capital Costs**

In Section Q, Form F.1.a, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$3,383
Miscellaneous Costs (Including Equipment)	\$261,169
<b>Total</b>	<b>\$264,552</b>

In Section F, pages 49-50, Section Q, and Exhibits 7-8, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 51-52, the applicant projects that there will be no working capital costs as this is an existing facility.

**Availability of Funds**

In Section F, page 50, the applicant states that the capital cost will be funded as shown in the table below.

Type	PHSNC	Total
Accumulated reserves or OE *	\$264,552	\$264,552
<b>Total Financing</b>	<b>\$264,552</b>	<b>\$264,552</b>

\* OE = Owner's Equity

Exhibit 9 contains a letter dated July 30, 2019 with an attached bank statement from the Managing Member of Pinnacle Health Services of North Carolina, LLC (PHS) and CEO of Outpatient Imaging Affiliates (OIA) which owns 100% interest in PHS which states that OIA *“can and will commit funds to PHS and PHS will commit funds to cover the capital cost. [of the CON project ... please see the attached OIA bank statement which indicates the availability of these funds for this CON project. This will not impact PHS’s ability to finance any other projects.”* The attached bank statement of OIA from Fifth Third Bank shows that OIA had adequate cash to fund the proposed project.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that

revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
Total Procedures*	21,578	21,885	22,300
Total Gross Revenues (Charges)	\$11,946,950	\$12,173,856	\$12,405,176
Total Net Revenue	\$3,787,327	\$3,859,259	\$3,932,590
Average Net Revenue per Procedure	\$176	\$176	\$176
Total Operating Expenses (Costs)	\$2,616,247	\$2,667,534	\$2,719,865
Average Operating Expense per Procedure	\$121	\$122	\$122
Net Income	\$1,171,080	\$1,191,725	\$1,212,725

\*Procedures include: projected procedures for digital x-ray, digital fluoroscopy, ultrasound, mammography, bone density and MRI equipment. See Section Q, Financial Assumptions, Notes (1).

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 applicant proposes to develop a new diagnostic center by replacing its existing R&F system at RRC.

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services

*from a health service facility.”* The 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 29, the applicant defines the service area as Johnston County. Facilities may also serve residents of counties not included in their service area.

In Section G, pages 57, the applicant states it is unaware of any publicly available data to show inventory and utilization of existing and approved non-hospital-based facilities and equipment providing services like those proposed in this application. On pages 57-58, the applicant identifies Johnston Health, which operates two hospital campuses under one hospital license, as an existing health service facility that operates in the service area with equipment and services like those proposed in this application, including FY2018 total procedures from the 2019 Hospital License Renewal Application (LRA).

In Section G, page 59, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Johnston County. The applicant states:

*“PHSNC’s proposal will not increase the number of R&F units at RRC and will not result in unnecessary duplication of existing or approved health service capabilities in Johnston County. The need for the replacement R&F equipment is internal to RRC and does not involve or impact any other healthcare provider. PHSNC adequately demonstrates the need to replace the identified R&F medical diagnostic equipment at RRC.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase in R&F equipment in Johnston County.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic centers.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(6/01/2019)	2nd Full Fiscal Year (CY2021)
Administrator	0.20	0.20
Business Office Supervisor	0.20	0.20
X-ray/Fluoro/Dexa Tech	1.25	1.25
U/S Tech	2.20	2.20
MRI Tech	2.40	2.40
Sales Liason	0.20	0.20
Registration/Admin Support	1.50	1.50
Mammo Tech	1.75	1.75
Clinical Mgr	0.20	0.20
<b>TOTAL</b>	<b>9.90</b>	<b>9.90</b>

The assumptions and methodology used to project staffing are provided in Section H. page 60. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, page 61 and pages 61-62, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 65, the applicant identifies the current medical director. In Exhibit 5, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

In Section I, page 63, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Information Technology
- Medical Records
- Accounting and Billing
- Patient Scheduling
- Human Resources/Payroll
- Equipment Maintenance
- Quality and Performance Improvement
- Housekeeping/Linens
- Infection Control
- Staff Education

On page 63, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 2.

In Section I, pages 63-64, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 13.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the

North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 75, the applicant provides the historical payor mix during CY2018 for the proposed services, as shown in the table below.

Payor Source	X-ray	Fluoroscopy
Medicaid*	6.8%	4.4%
Medicare*	20.3%	10.7%
Self-Pay/Charity Care	4.7%	2.5%
Insurance*	63.0%	58.2%
Workers Compensation	1.1%	16.3%
Other (Gov't)	4.0%	8.0%
Total	100.0%	100.0%

\*Including any managed care plans.

Source: Table on page 75 of the application.

In Section L, page 74, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY (CY2018)	Percentage of the Population of the Johnston County
Female	75.0%	51.0%
Male	24.9%	49.0%
Unknown	0.1%	0.0%
64 and Younger	74.8%	86.7%
65 and Older	25.2%	13.3%
American Indian	*	0.9%
Asian	*	0.9%
Black or African-American	*	16.8%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	67.2%
Other Race	*	14.0%
Declined / Unavailable	*	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 75, the applicant states that it has no such obligations.

In Section L, page 76, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 76, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

**Raleigh Radiology Clayton: Projected Payor Mix CY2022 (OY3)**

Payor Source	X-ray	Fluoroscopy	Ultrasound	Bone Density	Mammography	MRI
Medicaid*	6.8%	4.4%	4.7%	1.3%	1.8%	4.1%
Medicare*	20.3%	10.7%	14.2%	37.6%	16.8%	19.3%
Self-Pay/Charity Care	4.7%	2.5%	6.9%	1.1%	2.5%	1.0%
Insurance*	63.0%	58.2%	70.6%	58.1%	75.0%	59.2%
Workers Compensation	1.1%	16.3%	0.7%	0.0%	0.1%	11.1%
Other (Gov't)	4.0%	8.0%	2.9%	1.9%	3.8%	5.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

\*Including any managed care plans.

Source: Table on page 76 of the application.

On page 77, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the

project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience at RRC during CY2018.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 78, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 10.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

### C

The applicant proposes to develop a new diagnostic center by replacing its existing R&F system at RRC.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 29, the applicant defines the service area as Johnston County. Facilities may also serve residents of counties not included in their service area.

In Section G, pages 57, the applicant states it is unaware of any publicly available data to show inventory and utilization of existing and approved non-hospital-based facilities and equipment providing services like those proposed in this application. On pages 57-58, the applicant identifies Johnston Health, which operates two hospital campuses under one hospital license, as an existing health service facility that operates in the service area with equipment and services like those proposed in this application, including FY2018 total procedures from the 2019 Hospital License Renewal Application (LRA).

In Section N, page 81, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 81, the applicant states,

*“As a new CON-designated diagnostic center, RRC will continue to have a positive effect on competition in the service area. The proposed equipment replacement will promote cost effective, high quality medical diagnostic imaging services that will continue to be accessible by local residents ... The project will enable PHSNC to better meet the needs of RRC’s*

*existing patient population, and to ensure more timely provision of and convenient access to outpatient medical diagnostic imaging services for all area residents. PHSNC assumes no adverse effect on current diagnostic imaging services in the service area, as RRC has been offering diagnostic imaging services in Clayton since 2007, and RRC physicians have been longtime existing providers of these medical diagnostic services in Johnston County.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form A, the applicant identifies three diagnostic centers that are owned, operated, or managed by the applicant or a related entity, including Raleigh Radiology Cedarhurst, Raleigh Radiology Wake Forest and Wake Forest Baptist Imaging. In Section O, page 90, the applicant states,

*“Neither PHSNC nor its management company OIA has ever had its Medicare or Medicaid provider agreement terminated. All PHSNC and OIA’s operational diagnostic centers have provided quality care and operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding submission of the application.”*

After reviewing and considering information provided by the applicant regarding the quality of care provided at the other three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop a new diagnostic center. There are no administrative rules that are applicable to proposals to develop new diagnostic centers.