

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 13, 2019

Findings Date: September 13, 2019

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: J-11728-19

Facility: Raleigh Radiology Knightdale

FID #: 190281

County: Wake

Applicant: Raleigh Radiology, LLC

Project: Develop a new diagnostic center with CT scanner, x-ray, mammography, bone density, and ultrasound in Knightdale

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.

C

Raleigh Radiology, LLC (hereinafter referred to as Raleigh Radiology or “the applicant”) proposes to develop a new diagnostic center, Raleigh Radiology Knightdale, in a medical office building being developed at 1101 Great Falls Court in Knightdale. The combined value of the medical diagnostic equipment costing \$10,000 or more 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.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) is applicable to this review. *Policy GEN-4* states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.11, pages 27-28, the applicant provides a written statement describing its plan to work with a design team and facility management group to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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 because the applicant adequately demonstrates that the application is consistent with Policy GEN-4.

- (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, Raleigh Radiology Knightdale, in a medical office building being developed at 1101 Great Falls Court in Knightdale. The proposed diagnostic center will include five diagnostic modalities, including CT scanner, x-ray, mammography, bone density, and ultrasound. In Section A.6, page 13, the applicant states that the developer of the building is Great Falls Owners, LLC. The Agency, in a letter dated June 25, 2019, determined that development of the medical office building, to the extent the development was not part of projects requiring a certificate of need, was exempt from review.

Designation as a Diagnostic Center

In Section C, page 29, the applicant states the proposed diagnostic center will include CT scanner, x-ray, mammography, bone density, and ultrasound. In Section F.1, page 73, the applicant provides a table showing the new medical diagnostic equipment costing \$10,000 or more, which is summarized below:

Raleigh Radiology Knightdale Medical Diagnostic Equipment		
Equipment	Number of Units	Cost
Ultrasound	1	\$145,753
Mammography	1	\$416,522
X-Ray	1	\$174,447
CT Scanner	1	\$655,711
Bone Density	1	\$80,040
Subtotal		\$1,472,475
Taxes		\$36,000
Shipping/Installation		\$3,000
Totals		\$1,511,475

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. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin during the first three full fiscal years (CY2021-CY2023) following project completion.

Raleigh Radiology Knightdale Projected Patient Origin							
Zip Code		FY 1 – CY2021		FY 2 – CY2022		FY 3 – CY2023	
		# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
27545	Knightdale	1,840	14.6%	2,044	14.6%	2,745	14.6%
27591	Wendell	1,360	10.8%	1,506	10.8%	2,018	10.8%
27597	Zebulon	1,522	12.1%	1,683	12.1%	2,252	12.1%
27604	Raleigh	2,974	23.6%	3,291	23.6%	4,403	23.6%
27610	Raleigh	4,696	37.1%	5,204	37.1%	6,975	37.1%
	Out of Area*	248	2.0%	275	2.0%	368	2.0%
		12,639	100.0%	14,003	100.0%	18,761	100.0%

*The applicant states, “Out of area includes patients from other North Carolina counties, and from other states, primarily Virginia, South Carolina.”

Source: Section C.3, page 36

In Section Q, 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, pages 39-48, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The projected growth and aging of the proposed service area population (pages 40-43).
- The increasing traffic congestion in the proposed service area which is increasing travel times to Raleigh, necessitating the development of services more locally (page 43).
- The income, health, social and educational status of the proposed service area support the need for additional diagnostic services (pages 44-47).

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 income, health, social and educational status of the proposed service area support the need for additional diagnostic services.

- Reliable data sources are used to support assertions about population growth and aging in the proposed service area.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as summarized in the following table.

Raleigh Radiology Knightdale Projected Utilization (Procedures by Type)				
Component	Partial 10/1- 12/31/20	FY 1 CY2021	FY 2 CY2022	FY 3 CY 2023
CT Scanner	379	2,309	2,735	3,968
X-ray	983	5,992	6,085	7,209
Mammography	584	3,602	4,320	6,347
Ultrasound	307	1,870	2,215	3,214
Bone Density	43	272	333	499

In Section C, pages 49-51, the applicant provides the annual maximum capacity per unit for each type of medical diagnostic equipment proposed in this application, as well as the assumptions and methodology used to project the annual maximum capacities. The annual maximum capacity for each type of medical diagnostic equipment proposed in this application is shown in the table below.

Raleigh Radiology Knightdale Projected Annual Capacity by Modality* (Procedures by Type)			
Component	Year 1	Year 2	Year 3
Mammography	8,064	10,080	15,322
Ultrasound	3,629	3,024	5,242
Bone Density	605	605	605
X-ray	6,451	6,451	8,064
CT Scanner	2,419	2,822	4,032

*The applicant's projections are based on projected operating hours, time required per procedure, and projected staffing in each of the first three operating years. See application pages 49-51.

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

Step 1: Identify the Geographic Area and Population to be Served - The applicant states it identified the service area population for the proposed diagnostic center based on demographic and mapping software (Claritas). Based on that analysis, the applicant identified five Zip Code areas in the proximity of the proposed facility as the service area. See pages 122-124 of the application.

Step 2: Project CT Scanner Need for the Identified Service Area Population - The applicant states it projected the need for CT scanner services based on the projected service area population and the CT scanner use rate for the state (125.6 CT scans per 1,000 population) which it calculated based on FY2017 utilization data from DHSR. See page 125 of the application.

Step 3: Project CT Scanner Market Share and Volumes - The applicant states it projected its CT scanner volumes based on the assumption that it would achieve one percent market share in the first partial year, 9 percent in the first full year, 10 percent in the second full year, and 14 percent in the third full year. See page 126 of the application.

Step 4: Project CT Scanner Volumes with In-Migration - Based on the applicant's experience operating diagnostic centers at other locations, it projected an additional two percent of CT scanner patients would originate from outside Wake County. See page 127 of the application.

Step 5: Project X-ray Need for the Identified Service Area Population - The applicant states it projected the need for x-ray services based on the projected service area population and the x-ray use rate for the state (325.98 x-ray procedures per 1,000 population) which it calculated based on FY2017 utilization data from DHSR. See page 128 of the application.

Step 6: Project X-ray Market Share and Volumes - The applicant states it projected its X-ray volumes based on the assumption that it would achieve one percent market share in the first partial year, 9 percent in the first full year, 10 percent in the second full year, and 14 percent in the third full year. See page 129 of the application.

Step 7: Project X-ray Volumes with In-Migration - Based on the applicant's experience operating diagnostic centers at other locations, it projected an additional two percent of X-ray patients would originate from outside Wake County. See page 130 of the application.

Step 8: Project Ultrasound Need for the Identified Service Area Population - The applicant states it projected the need for ultrasound services based on the projected service area population and the national ultrasound use rate (101.72 ultrasound procedures per 1,000 population) which it calculated based on data from the 2016 National Ambulatory Medical Care Survey and 2016 U.S. Census data. See page 131 of the application.

Step 9: Project Ultrasound Market Share and Volumes - The applicant states it projected its ultrasound volumes based on the assumption that it would achieve one percent market share in the first partial year, 9 percent in the first full year, 10 percent in the second full year, and 14 percent in the third full year. See page 132 of the application.

Step 10: Project Ultrasound Volumes with In-Migration - Based on the applicant's experience operating diagnostic centers at other locations, it projected an additional two percent of ultrasound patients would originate from outside Wake County. See page 133 of the application.

Step 11: Identify the Population to be Served by Bone Density Equipment - The applicant states it identified the service area population for the proposed bone density equipment

specifically for female patients over the age of 65 years based on demographic and mapping software (Claritas). Based on that analysis, the applicant identified the projected population of women 65 years old and older in the five Zip Code areas in the proximity of the proposed facility. See page 134 of the application.

Step 12: Project Bone Density Scans Needed for the Identified Service Area Population - The applicant states it projected the need for bone density services based on the projected service area population of women age 65 and older and the national bone density scan use rate (211.68 bone density scans per 1,000 population) which it calculated based on data from the 2016 National Ambulatory Medical Care Survey and 2016 U.S. Census data. See page 135 of the application.

Step 13: Project Bone Density Market Share and Volumes - The applicant states it projected its bone density volumes based on the assumption that it would achieve one percent market share in the first partial year, 9 percent in the first full year, 10 percent in the second full year, and 14 percent in the third full year. See page 136 of the application.

Step 14: Project Bone Density Volumes with In-Migration - Based on the applicant's experience operating diagnostic centers at other locations, it projected an additional two percent of bone density patients would originate from outside Wake County. See page 137 of the application.

Step 15: Identify the Population to be Served by Mammography Equipment - The applicant states it identified the service area population for the proposed mammography equipment specifically for female patients over the age of 40 years based on demographic and mapping software (Claritas). Based on that analysis, the applicant identified the projected population of women 40 years old and older in the five Zip Code areas in the proximity of the proposed facility. See page 138 of the application.

Step 16: Project Mammography Needed for the Identified Service Area Population - The applicant states it projected the need for mammography services based on the projected service area population of women age 40 and older and the national mammography use rate (489.98 bone density scans per 1,000 population) which it calculated based on data from the 2017 Health United States (Table 70) and U.S. Census data. See page 139 of the application.

Step 17: Project Mammography Market Share and Volumes - The applicant states it projected its mammography volumes based on the assumption that it would achieve one percent market share in the first partial year, 9 percent in the first full year, 10 percent in the second full year, and 14 percent in the third full year. See page 140 of the application.

Step 18: Project Mammography Volumes with In-Migration - Based on the applicant's experience operating diagnostic centers at other locations, it projected an additional two percent of mammography patients would originate from outside Wake County. See page 141 of the application.

Step 19: Project Tomosynthesis and Mammography Utilization - Based on the applicant's experience operating mammography services at other locations, it projected the volume of tomosynthesis (3-D) mammography procedures. See page 142 of the application.

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

- Projected utilization is based on population data and historical state and national data regarding use rates by modality.
- The applicant projects reasonable market shares and market share growth rates.
- The applicant provides reasonable and adequately supported information to justify the need for the equipment.

Access

In Section C.11, pages 56-59, 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. In Section L.3, page 103, the applicant projects the following payor mix for the proposed diagnostic center during the third year of operation (CY2023) following completion of the project, as shown in the following table.

Payment Source	Percent of Total Procedures
Self Pay	2.8%
Charity Care	0.5%
Medicare	33.1%
Medicaid	2.0%
Insurance	53.5%
Other*	8.1%
Total**	100.0%

Source: Table on page 103 of the application.

*The "Other" category includes Champus, MedSolutions, TRICARE, Workers Compensation and VA.

**Totals may not foot due to rounding.

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 (payer 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.

NA

The applicant does not propose the reduction or elimination of a service. 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 in Knightdale to include CT scanner, x-ray, mammography, bone density, and ultrasound services.

In Section E, pages 69-71, 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 within the proposed services for additional diagnostic imaging services. Therefore, this is not an effective alternative.

Develop the Diagnostic Center in a Different Area: The applicant states it considered the alternative of developing the diagnostic center in another location, but determined that the proposed Knightdale location is ideally suited to the project based on the population of the community and easy accessibility of the site to major transportation arteries.

Acquire Different Medical Diagnostic Equipment: The applicant states it considered the alternative of developing the diagnostic center with different medical diagnostic equipment, but determined that the proposed mix of equipment would be better suited to the particular needs of the proposed service area, in view of the services currently available in the community.

On page 71, the applicant states that its proposal is the most effective alternative because it provides enhanced and more convenient access to patients, and includes the proper mix of diagnostic services.

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 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. Raleigh Radiology, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Raleigh Radiology, LLC shall materially comply with the last made representation.**
- 2. Raleigh Radiology, LLC shall develop a diagnostic center in Knightdale with no more than one CT scanner, one ultrasound unit, one x-ray unit, one bone density unit, and one mammography unit.**
- 3. Raleigh Radiology, 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, Raleigh Radiology, 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. Raleigh Radiology, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 in Knightdale to include CT scanner, x-ray, mammography, bone density, and ultrasound services.

Capital and Working Capital Costs

In Section Q, and in supplemental information, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$195,000
Medical Equipment Costs	\$1,511,475
Non-Medical Equipment	\$15,000
Miscellaneous Costs/Contingency	\$332,862
Total	\$2,054,336

In Section Q, Form F.1(a), the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 76-77, the applicant projects that start-up costs will be \$127,664 and initial operating expenses will be \$277,897 for a total working capital cost of \$405,560. In Section Q, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 74, and in supplemental information, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Raleigh Radiology, LLC	Total
Loans	\$2,054,336	\$2,054,336
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Tenant Allowance)	\$0	\$0
Total Financing	\$2,054,336	\$2,054,336

* OE = Owner's Equity

Exhibit F.2 contains a letter dated June 14, 2019 from a Vice President for Wells Fargo Bank documenting their intention to provide a loan to Raleigh Radiology, LLC to finance the capital costs of the proposed project. Exhibit F.2 also contains a letter dated June 14, 2019 from a Vice President for Wells Fargo Bank documenting that Raleigh Radiology, LLC has sufficient funds to fund the working capital needs of 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.3, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years of the project, as shown in the table below.

Raleigh Radiology Knightdale Revenue and Expenses			
	FY 1 (CY2021)	FY 2 (CY2022)	FY 3 (CY2023)
Total Gross Revenues (Charges)	\$4,337,730	\$5,112,770	\$7,363,509
Total Net Revenue	\$1,894,018	\$2,169,500	\$3,037,500
Total Operating Expenses (Costs)	\$1,520,044	\$1,807,581	\$2,230,600
Net Income / (Loss)	\$373,974	\$361,919	\$806,900

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 and 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

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information provided by the applicant

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 and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 in Knightdale to include CT scanner, x-ray, mammography, bone density, and ultrasound services.

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, the applicant identifies the service area as comprised of five Zip Code areas in eastern Wake County. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 82, the applicant identifies four providers of diagnostic imaging services in the proposed service area based on internet searches for the Wake County area, but states it is unaware of any publicly available data to show inventory and utilization of existing diagnostic centers.

In Section G.3, page 83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in the proposed service area. The applicant states:

“The proposal will not result in unnecessary duplication of existing diagnostic imaging services in the service area. As illustrated in response to question G.1, no other diagnostic center in the area reports CT, ultrasound or bone density scanning. Only one provider reports freestanding 3-D mammography. ... As part of the Raleigh Radiology practice, the proposed center will offer users the low-price contract rates available at other Raleigh Radiology practice sites. ... WakeMed Raleigh Campus has four of the same proposed imaging modalities, but bills all services at the higher hospital outpatient department rates. Moreover, WakeMed Raleigh is at the far western tip of the proposed service area and not as convenient to most residents of the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because 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.

C

In Section Q, Form H, the applicant provides projected staffing for the proposed services as illustrated in the following table.

Raleigh Radiology Knightdale Projected Staffing			
Position	Year 1	Year 2	Year 3
Radiology Technologists	3.0	3.0	4.5
Business Office	1.0	1.5	2.0
Total	4.0	4.5	6.5

Source: Form H in Section Q of the application.

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, pages 86-87, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I.3, page 91, the applicant identifies the proposed medical director.

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.

C

In Section I, page 88, the applicant states that the following ancillary and support services are necessary for the proposed diagnostic center:

- Administration
- Finance and billing
- Medical records
- Housekeeping
- Scheduling
- Radiology
- Physics

In Section I.1, pages 88-89, and Exhibit I.1, the applicant adequately explains how each ancillary and support service will be made available. In Section I.2, page 90, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant provides supporting documentation in Exhibit I.2.

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.

C

In Section K.2, page 94, the applicant states the project involves upfitting 6,000 square feet of leased space in a medical office building being developed by Great Falls Owner, LLC. Line drawings are provided in Exhibit K.1.

In Section K.3, page 95, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, page 96, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, page 96, and Section B.11, pages 27-28, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

(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;

NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

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

C

In Section L.3, page 103, the applicant projects the following payor mix for the proposed diagnostic center during the third year of operation (CY2023) following completion of the project, as shown in the following table.

Payment Source	Percent of Total Procedures
Self Pay	2.8%
Charity Care	0.5%
Medicare	33.1%
Medicaid	2.0%
Insurance	53.5%
Other*	8.1%
Total**	100.0%

Source: Table on page 103 of the application.

*The "Other" category includes Champus, MedSolutions, TRICARE, Workers Compensation and VA.

**Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.8 percent of total services will be provided to self-pay patients, 33.1 percent to Medicare patients, and 2.0 percent to Medicaid patients.

In Section Q, 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 operating other similar facilities.

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.

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

C

In Section L.5, page 104, 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 106, and Exhibit M.2, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

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 in Knightdale to include CT scanner, x-ray, mammography, bone density, and ultrasound services.

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, the applicant identifies the service area as comprised of five Zip Code areas in eastern Wake County. Facilities may also serve residents of counties not included in their service area.

In Section N.1, page 107, 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. The applicant states,

“The proposed diagnostic center will be one of only a few freestanding diagnostic centers in the proposed service area. As illustrated in Table G.1, there are only two imaging centers in the service area. ... As a new freestanding competitor, Raleigh Radiology will provide market competition to keep prices at the only other freestanding competitors low. The competitive option for consumers and others for whom price is a concern should also work to contain prices for outpatients at the local hospital. ... Competition will work both ways. As a new market entrant, the proposed diagnostic center must outperform other to attract and retain patients.”

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 Sections C, D, and 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 Form A, the applicant identifies three diagnostic centers that are owned, operated, or managed by the applicant or a related entity, including Raleigh Radiology Blue Ridge, Raleigh

Radiology Cary, and Raleigh Radiology Brier Creek. On page 110, the applicant states, “As a part of Raleigh Radiology, LLC, the diagnostic center will be subject to an established and continually improving quality management program.” 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.