

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 26, 2020

Findings Date: March 26, 2020

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11800-19

Facility: Raleigh Radiology Fuquay-Varina

FID #: 190504

County: Wake

Applicant: Raleigh Radiology, LLC

Project: Develop a new diagnostic center by adding one new CT scanner to existing 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner services in Fuquay-Varina

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

Raleigh Radiology, LLC (hereinafter referred to as Raleigh Radiology or “the applicant”) proposes to develop a new diagnostic center, Raleigh Radiology Fuquay-Varina, by adding a computed tomography (CT) scanner to an existing physician office that currently provides 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner services in Fuquay-Varina. With the proposed addition of the CT scanner, 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 and Policies

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. Also, there are no policies in the 2019 SMFP that are applicable to this review. 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- (2) Repealed effective July 1, 1987.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, Raleigh Radiology Fuquay-Varina, by adding a CT scanner to an existing physician office that currently provides 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner services, and is located at 601 Attain Street, Suite 100, in Fuquay-Varina.

Designation as a Diagnostic Center

In Section C.1, page 26, the applicant describes the proposed project as follows:

“Raleigh Radiology, LLC proposes to add a new computed tomography (‘CT’) scanner to its existing physician office in Fuquay-Varina NC. The capital cost associated with the proposed acquisition of a CT scanner will result in equipment utilized by the facility, which costs \$10,000 or more, to exceed \$500,000. ... Raleigh Radiology, LLC submitted capital costs of existing equipment and received Agency concurrence that the expenditure was non-reviewable in December 2016 (Exhibit C.1). The approved value of equipment located in the building, including the allocated cost of the buildout was \$454,102. ... The proposed capital cost for the CT scanner and related installation based on the quotes in Exhibit F.1, pages 2-26, will cause the facility to reach the statutory threshold for definition of a diagnostic center (GS 131E-176(7a).”

In Section Q, Form F1.a, the applicant indicates the cost to acquire and install the proposed CT scanner is projected to be \$607,672. Thus, 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, the applicant identifies the service area as comprised of census tract areas in Wake and Harnett counties. Facilities may also serve residents of counties not included in their service area.

In Section C.3, page 32, the applicant provides a table showing projected patient origin during the first three full fiscal years (CY2021-CY2023) following project completion, which is shown below.

Raleigh Radiology Fuquay-Varina Projected Patient Origin						
	FY 1 – CY2021		FY 2 – CY2022		FY 3 – CY2023	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	1,690	73.5%	2,213	73.5%	2,505	73.6%
Harnett	495	21.5%	646	21.5%	728	21.4%
Out-of-Area	115	5.0%	150	5.0%	170	5.0%
	2,299	100.0%	3,009	100.0%	3,403	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 32

However, in Section Q, page 115 of the application, the applicant projects that 7 percent of patients will originate from “out-of-area,” and not 5 percent as shown in the table above. In its response to comments, the applicant states that the table in Section C.3, page 32, is incorrect, and that 7 percent is the correct out-of-area migration being projected going forward. The use of 7 percent for out-of-area patient origin does change the total number of patients and percent for Wake and Harnett counties. However, that change is immaterial to the outcome of the projections.

In Section C.3, page 33, and Section Q of the application, 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 35-38).
- The lack of CT scanner providers locally and the increasing traffic congestion in the proposed service area which is increasing travel times to Raleigh, necessitating the development of services more locally (pages 38-39).
- The income, health, social and educational status of the proposed service area support the need for additional diagnostic services in a lower cost, freestanding setting (pages 39-41).
- Support by the physician community and their expressed intention to refer patients to the proposed CT scanner (page 41).

- The proposed CT scanner’s imaging capabilities (page 42).

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 Fuquay-Varina CT Scanner Projected Utilization				
Component	Partial CY2020*	FY 1 CY2021	FY 2 CY2022	FY 3 CY 2023
CT Scans	323	2,299	3,009	3,404
HECT Units	514	3,662	4,793	5,421

*The applicant projects the CT scanner will become operational in October 2020.

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 census tract areas in Wake and Harnett counties in proximity to the facility as the service area. See pages 110-112 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, adjusted for inpatient and emergency department CT scanner use (123.63 CT scans per 1,000 population), which it calculated based on FY2018 utilization data from DHSR. See page 113 of the application. A commenter stated that the applicant’s use rate was unreasonable and projected a use rate of 136.17 CT scans per 1,000 population, for all settings, in the applicant’s proposed service area. The applicant responded that it’s projected use rate (123.62 CT scans per 1,000 population) is reasonable and conservative because it is lower than the rate calculated by the commenter.

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 2.5 percent market share in the first partial year, 18 percent in the first full year, 23 percent in the second full year, and

25 percent in the third full year. See page 114 of the application. With regard to its market share projections, on page 114 of the application, the applicant states,

“The applicant assumed low utilization of Raleigh Radiology Fuquay-Varina in the initial year; and, as the community and referring providers become more aware of the diagnostic center’s lower charge schedule and high-quality service, the market share will increase. Referring physicians and residents in the service area will also develop a better understanding of appropriate use of the proposed facility by the third year. ... A 25 percent market share is reasonable. It represents only one in four CT scans in the market. It is conservative because there are only two other CT imaging providers in the same area.”

Step 4: Project CT Scanner Volumes with In-Migration - Based on the applicant’s experience operating the imaging center at the Fuquay-Varina location, it projected an additional seven percent of CT scanner patients would originate from outside the service area. See page 115 of the application.

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

- Projected utilization is based on population data and historical state data regarding CT scanner use rates.
- The applicant projects reasonable market shares and market share growth rates based on the number of existing CT scanner providers in the identified service area and increasing awareness of the services by the providers and patients in the community over the time period. Also, in Exhibit I.2, the applicant provides copies of letters from physicians expressing their support for the project and their intention to refer patients to the proposed CT scanner, including the number of patients projected to be referred.
- The applicant provides reasonable and adequately supported information to justify the need for the CT scanner.

Access

In Section C.11, pages 47-50, 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 and CT scanner during the third year of operation (CY2023) following completion of the project, as shown in the following table.

Payment Source	Entire Facility	Percent of Total CT Procedures
Self Pay	2.2%	2.1%
Charity Care	0.5%	0.5%
Medicare	24.6%	36.6%
Medicaid	1.3%	3.0%
Insurance	60.6%	48.7%
Other*	10.8%	9.0%
Total**	100.0%	100.0%

Source: Table on page 93 of the application.

*The applicant states 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
- Written comments
- Responses to comments

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.

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, Raleigh Radiology Fuquay-Varina, by adding a CT scanner to an existing physician office that currently provides 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner services.

In Section E, pages 60-62, 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 service area for additional, competitively-priced, outpatient CT scanner services, and, therefore, 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 Fuquay-Varina location is centrally located and has good road access.

Acquire an Additional CT Scanner: The applicant states it considered the alternative of developing the diagnostic center with more than one CT scanner, but determined that one CT would adequately meet the needs of the proposed service area.

On page 62, the applicant states that its proposal is the most effective alternative because it provides enhanced access to outpatient CT scanner services at competitive prices.

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
- Written comments
- Responses to comments

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.**
 - 2. Raleigh Radiology, LLC shall develop a diagnostic center in Fuquay-Varian 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, Raleigh Radiology Fuquay-Varina, by adding a CT scanner to an existing physician office that currently provides 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner services.

Capital and Working Capital Costs

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

Renovation Costs	\$52,558
Medical Equipment Costs	\$405,948
Non-Medical Equipment	\$5,000
Miscellaneous Costs/Contingency	\$144,166
Total	\$607,672

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

In Section F.3, pages 66-67, the applicant projects there will be no start-up costs or initial operating expenses associated with the proposed project because the facility is an existing and operational imaging center.

Availability of Funds

In Section F.2, page 65, 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	\$607,672	\$607,672
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Tenant Allowance)	\$0	\$0
Total Financing	\$607,672	\$607,672

* OE = Owner's Equity

Exhibit F.2 contains a letter dated September 25, 2019 from a Vice President for BB&T Company documenting their intention to provide a loan to Raleigh Radiology, LLC to finance the capital costs 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 Fuquay-Varina Revenue and Expenses			
	FY 1 (CY2021)	FY 2 (CY2022)	FY 3 (CY2023)
Total Gross Revenues (Charges)	\$7,151,155	\$8,853,452	\$9,428,927
Total Net Revenue	\$2,350,540	\$2,749,494	\$2,819,570
Total Operating Expenses (Costs)	\$1,854,442	\$2,198,599	\$2,319,320
Net Income / (Loss)	\$496,098	\$550,896	\$500,250

In its response to comments, the applicant states that salary and benefits expenses were inadvertently understated by \$9,558 in Year 1, \$12,678 in Year 2 and \$13,435 in Year 3.

However, as indicated in the table above, the error would not have a material impact on the projected financial feasibility of the proposed project.

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
- Written comments
- Responses to comments

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, Raleigh Radiology Fuquay-Varina, by adding a CT scanner to an existing physician office that currently provides 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner 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 census tract areas in Wake and Harnett counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 71, the applicant identifies two providers of CT scanner 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 CT scanners.

In Section G.3, page 72, 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. The proposed service will offer freestanding pricing at Raleigh Radiology, LLC’s recognized lower charge structure. The existing diagnostic center will continue to offer users low-price contract rates available at other Raleigh Radiology practice sites.”

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
- Written comments
- Responses to comments

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 Fuquay-Varina Projected Staffing			
Position	FY1 (CY2021)	FY2 (CY2022)	FY3 (CY2023)
Radiology Technologists	3.0	3.0	3.5
Business Office	1.0	1.5	2.0
Total	4.0	4.5	5.5

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 74-75, 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 78, the applicant identifies the physician that will provide radiologist coverage for the proposed diagnostic center.

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
- Written comments
- Responses to comments

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 76-77, and Exhibit I.1, the applicant adequately explains how each ancillary and support service will be made available. In Section I.2, page 78, 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 82, the applicant states the project involves renovating 436 square feet of leased space in the existing physician office. Line drawings are provided in Exhibit K.1.

In Section K.3, page 84, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, pages 84-85, 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 85, 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

This is not an existing facility. However, for information purposes, in Section L, page 91, the applicant provides the historical payor mix for the period from January to August 2019 for the existing physician office, as shown in the table below.

Payment Source	Existing Physician Office
Self Pay	2.2%
Charity Care	0.5%
Medicare	24.6%
Medicaid	1.3%
Insurance	60.6%
Other*	10.8%
Total**	100.0%

Source: Table on page 91 of the application.

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

**Totals may not foot due to rounding.

In Section L, page 90, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility during the Last Full FY2019	Percentage of the Population of the Service Area
Female	73.3%	50.8%
Male	26.7%	49.2%
Unknown	NA	NA
64 and Younger	67.2%	86.7%
65 and Older	32.8%	13.3%
American Indian	NA	0.8%
Asian	NA	1.3%
Black or African-American	NA	13.0%
Native Hawaiian or Pacific Islander	NA	0.1%
White or Caucasian	NA	77.0%
Other Race	NA	24.2%
Declined / Unavailable	NA	NA

Conclusion

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.2, page 91, the applicant states that the facility is under no obligation under any applicable federal regulations.

In Section L.2, page 92, 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.3, page 93, 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	Entire Facility	Percent of Total CT Procedures
Self Pay	2.2%	2.1%
Charity Care	0.5%	0.5%
Medicare	24.6%	36.6%
Medicaid	1.3%	3.0%
Insurance	60.6%	48.7%
Other*	10.8%	9.0%
Total**	100.0%	100.0%

Source: Table on page 93 of the application.

*The applicant states 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 2.1 percent of total CT scanner services will be provided to self-pay patients, 36.6 percent to Medicare patients, and 3.0 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.

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 94, 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 96, 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, Raleigh Radiology Fuquay-Varina, by adding a CT scanner to an existing physician office that currently provides 3D mammography, bone density, x-ray, ultrasound and mobile MRI scanner 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 census tract areas in Wake and Harnett counties. Facilities may also serve residents of counties not included in their service area.

In Section N.1, page 97, 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 two diagnostic centers in the proposed service area. ... As a freestanding competitor, Raleigh Radiology will provide reason keep prices at the 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.”

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
- Written comments
- Responses to comments

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.

In Form A, the applicant identifies two diagnostic centers that are owned, operated, or managed by the applicant or a related entity, including Raleigh Radiology Blue Ridge and Raleigh Radiology Cary. On page 100, the applicant states, "*Raleigh Radiology, LLC's proposed CT scanner 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 two 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.

C

The applicant proposes to develop a new diagnostic center by acquiring a CT scanner. There are no administrative rules that are applicable to proposals to develop new diagnostic centers. However, the Criteria and Standard for Computed Tomography Equipment, NCAC 14C .2300, are applicable.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

NCAC 14C .2303 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

- (1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;
- C- The applicant projects to perform 5,264 HECT units in the third year of operation of the proposed equipment. In Section Q, and Exhibit C.12, the applicant provides the assumptions and methodology used to project HECT units. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference
- (2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and

- NA- The applicant states that neither the applicant nor any related entity owns a controlling interest in any fixed or mobile CT scanner in the proposed CT service area.

- (3) each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.

- NA- The applicant states that neither the applicant nor any related entity owns a controlling interest in any existing or approved fixed or mobile CT scanner in the proposed CT service area.