

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 23, 2021

Findings Date: October 4, 2021

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: J-12060-21

Facility: Raleigh Radiology Holly Springs

FID #: 210623

County: Wake

Applicant(s): RR WM Imaging Holly Springs, LLC

Project: Develop a new diagnostic center to include mammography, bone density, x-ray and ultrasound services

REVIEW CRITERIA

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

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

C

RR WM Imaging Holly Springs, LLC, hereinafter referred to as RR or “the applicant”, proposes to develop a new diagnostic center, Raleigh Radiology Holly Springs (“RRHS”) in leased space as an element of a physician office in Holly Springs.

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.”

In this application, the applicant proposes to acquire a 3-D tomosynthesis mammography unit, an ultrasound unit, bone densitometry and X-ray equipment, the total cost of which will exceed the statutory threshold of \$500,000. Therefore, the equipment qualifies the facility as a diagnostic center, which is a new institutional health service and requires a Certificate of Need (CON)

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2021 SMFP
- acquire any medical equipment for which there is a need determination in the 2021 SMFP
- offer a new institutional health service for which there are any policies in the 2021 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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, RR, proposes to develop a new diagnostic center, Raleigh Radiology Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building (MOB).

In Section C.1, page 28, the applicant states it will lease space in a medical office building currently being developed by a third party. The applicant states that that RRHS will organize and bill as a physician office, and the physicians from Raleigh Radiology Associates, Inc. (“RRA”) will provide physician coverage as necessary. On pages 29-30, the applicant describes the proposed equipment as follows:

- Mammography and 3-D tomosynthesis equipment – the applicant states the proposed 3-D tomosynthesis technology uses computer reconstruction to allow physicians to see masses and distortions more clearly than conventional 2-D mammography. The 3-D tomosynthesis mammography detects 41% more invasive breast tissues and helps reduce false positives.
- Bone densitometry – the applicant states the bone densitometry (“DEXA”) is an enhanced x-ray used to detect diseases that adversely affect bone density and mineral content.
- Ultrasound – the applicant states ultrasound equipment provides real-time imaging using high-frequency sound waves to create Doppler images in soft tissues. Because there is no radiation used in an ultrasound, this type of imaging is ideal for diagnosing disease or defects of internal organs and tissues without exposing the patient to radiation.
- X-ray – this type of imaging is critical for detecting bone abnormalities and disease, complications of lung disease, and screening for heart, stomach, lung, kidney and abdominal complications or disease.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 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.

The applicant proposes to develop a new diagnostic center and thus has no historical patient origin to report. In Section C, page 33, the applicant provides a table to illustrate census tracts within Wake, Chatham and Lee counties from which RRHS patients will come, as shown in the following table:

Projected Patient Origin, Raleigh Radiology Holly Springs

Census Tract	1 ST FULL FY (CY 2023)		2 ND FULL FY (CY 2024)		3 RD FULL FY (CY 2025)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
37037-020702	149	2.8%	189	2.8%	240	2.8%
37105-030701	184	3.5%	234	3.4%	297	3.4%
37183-053005	186	3.5%	235	3.5%	298	3.4%
37183-053006	134	2.5%	171	2.5%	218	2.5%
37183-053201	496	9.3%	634	9.4%	811	9.4%
37183-053202	184	3.5%	235	3.5%	300	3.5%
37183-053203	340	6.4%	434	6.4%	554	6.4%
37183-053204	213	4.0%	272	4.0%	348	4.0%
37183-053205	167	3.1%	214	3.2%	273	3.2%
37183-053206	212	4.0%	272	4.0%	348	4.0%
37183-053207	447	8.4%	571	8.4%	729	8.4%
37183-053405	204	3.8%	260	3.8%	332	3.8%
37183-053412	282	5.3%	361	5.3%	461	5.3%
37183-053413	272	5.1%	347	5.1%	443	5.1%
37183-053414	391	7.4%	499	7.4%	638	7.4%
37183-053415	152	2.9%	195	2.9%	249	2.9%
37183-053416	243	4.6%	310	4.6%	396	4.6%
37183-053417	177	3.3%	225	3.3%	287	3.3%
37183-053418	253	4.8%	323	4.8%	413	4.8%
37183-053419	121	2.3%	154	2.3%	196	2.3%
37183-053420	269	5.1%	344	5.1%	440	5.1%
37183-053421	232	4.4%	297	4.5%	380	4.4%
Total	5,307	100.0%	6,777	100.0%	8,652	100.0%

In Section C.3, the applicant refers to Exhibit C.3 for the assumptions and methodology used to project the number of patients by census tract, stating that the applicant expects future patient origin for the facility to follow referral patterns similar to those at existing RRA sites.

The applicant’s assumptions are reasonable and adequately supported because they are based on the historical patient origin for other diagnostic centers operated by RRA physicians in the area.

Analysis of Need

In Section C, pages 35-44, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Population growth in Wake County and Raleigh metro area – the applicant states Wake County is one of the fastest growing counties in the state, and the Raleigh metro area one of the fastest growing in the country. As a result, smaller towns outside of Raleigh, like Holly Springs, are expanding and incorporating services like health care into the community plans. The applicant examined its own

historical data and determined that in 2020 alone, RR locations captured approximately 35% of the available imaging procedures from patients in the Holly Springs area, as shown in the following table, from page 35:

Estimated Imaging Procedures in Holly Springs Market Captured by RR

MODALITY	ESTIMATED PROCEDURES AVAILABLE	RR ACTUAL PROCEDURES	RR % OF HOLLY SPRINGS MARKET
X-ray	24,507	5,369	22%
Ultrasound	18,701	6,239	33%
Mammography	16,214	9,070	56%
DEXA	4,451	1,393	31%
Total	68,873	22,071	35%

The applicant identified census tracts within a 20 minute drive time from the proposed location in Holly Springs and found that the ZIP codes within those census tracts are part of an area already served by RRA physicians, which includes portions of Lee and Chatham counties as well as Wake County. The applicant states that in 2020, RRA physicians provided approximately 22,071 imaging reports for patients who reside in the ZIP codes that overlap those census tracts.

The applicant explains that RR maintains a centralized scheduling system within which patients can select time slots that are convenient. In doing so, there is some migration among the various RR sites. However, the applicant projects no in-migration from patients who reside outside the defined service area. (pages 35-38).

- Population growth and aging in the Holly Springs service area – Using Claritas population data, the applicant determined that in 2021, the RRHS service area will have approximately 13% of the total Wake County population. Additionally, using Claritas data and data from the North Carolina State Office of Budget and Management (NC OSBM), the applicant determined that between 2021 and 2026, Wake County will increase by approximately 108,857 people, 11.4% of which will be in the RRHS service area, as shown in the following table: (page 38)

AREA	YEAR			NET CHANGE	
	2010	2021	2026	2010-2021	2021-2026
RRHS Service Area	109,332	149,761	162,186	52,854	12,425
Wake County	906,882	1,130,815	1,239,815	223,933	108,857

Source: application page 38

The applicant cites research to show that utilization of imaging services is typically high in the population group age 18-64, and even higher in the over 65 age group. Data from Claritas and NC OSBM shows that those age groups are projected to increase at a higher rate than younger age groups in the RRHS service area, as shown in the following table from page 39:

HOLLY SPRINGS SERVICE AREA	AGE GROUPS			
	<18	18-44	45-64	>65
2021	39,516	49,943	43,163	17,139
2026	40,553	52,781	46,171	22,681
Growth	1,037	2,838	3,008	5,542

- Health Status – the applicant states data from the North Carolina State Center for Health Statistics and the North Carolina Institute of Medicine indicate that diagnostic imaging services will be in high demand in Wake County, as shown below:

- 11.8% of the adult population age 18-64 has no health insurance
- 171 per 100,000 residents in 2012-2016 were diagnosed with breast cancer
- 12% of adults currently smoke
- 11.4% of the population is age 65 or older
- Citing data from County Health Trends, the applicant states female breast cancer incidence in Wake County was higher in 2012-2016 than in 2002-2006.

In addition, the applicant states health metrics from the other counties within the service area, Lee and Chatham counties, also indicate a need for increased access to diagnostic imaging services, as shown in the following table from page 40:

METRIC	CHATHAM	LEE
Age adjusted female breast cancer incidence/100K population, 2012-2016	182.3	146.3
% of adults 18-64 without health insurance	15.9%	20.1%
% adults who are current smokers	14.0%	17.0%

- Cancer screening recommendations – the applicant states the American Cancer Society publishes screening recommendations for various types of cancer, as does the US Preventive Services Task Force (“USPSTF”). The USPSTF also publishes screening recommendations for other types of diseases involving diagnostic equipment such as ultrasound and DEXA. These agencies also provide reports that underscore the need for increased access to lower-cost diagnostic screening imaging, which the applicant proposes to provide. (pages 41-42)
- Access for diagnostic imaging services – the applicant states persons who are uninsured, underinsured or who have special needs are more likely to face challenges accessing diagnostic imaging services, ranging from payment arrangements to special accommodations to services. The applicant states the proposed diagnostic center will address these issues by providing low-cost and easy access to diagnostic imaging services in the proposed service area. (pages 42-43)
- Traffic congestion in Wake County – using data from the NC Department of Transportation, the applicant researched traffic patterns along major routes in the Holly Springs area of Wake County and determined that drive times from Holly Springs to the Raleigh area during peak congestion can be up to 30 minutes. The

applicant proposes to locate the diagnostic center along Highway 55, which is a major artery through the area. The applicant proposes to offer lower-cost diagnostic imaging services than are currently offered. (pages 43-44)

Relying on RRLLC’s experience in operating other diagnostic centers in North Carolina, the applicant assumed the center will operate nine hours per day five days per week, 52 weeks per year, with the exception of 8 holidays. The applicant used that data to illustrate the maximum annual capacity of the proposed equipment in the third project year, CY 2025. See the following table, from application page 44:

MODALITY	PROC./HR.	HRS./DAY	FULL DAYS/PY 3	# UNITS	MAX. CAPACITY	PY 3 VOLUME	DIFFERENCE	FTE PY 3	MAX FTE CAPACITY	DIFFERENCE
	a	b	c	d	e	f	g	h	i	j
X-ray	4.0	9.0	252	1.0	7,711	3,990	3,722	0.55	4,241	252
Ultrasound	2.0	9.0	252	1.0	3,856	3,044	811	1.10	4,241	1,197
DEXA	2.0	9.0	252	1.0	3,856	880	2,976	0.30	1,157	277
Mammo	4.0	9.0	252	1.0	7,711	5,380	2,331	1.05	8,097	2,716
Total								3.00		

Notes:

- a: applicant experience
- b: Planned hours of operation per day at RRHS
- c: RRHS will operate 5 full days / week, 52 weeks per year, with 8 holidays $[(5 \times 52) - 8 = 252]$
- d: number of units per modality
- e: $a \times b \times c \times d \times 85\%$ efficiency factor
- f: PY 3 (Cy 2025) projected utilization by modality
- g: $e - f = g$
- h: number of FTEs allocated to each modality in PY 3 (CY 2025) based on experience of applicant
- i: $a \times b \times c \times d \times 85\%$ efficiency factor
- j: $i - f = j$

Projected Utilization

In Section Q Form C, the applicant projects utilization for the proposed diagnostic equipment for first three full fiscal year of operation, CY 2023-CY 2025, as summarized in the following table

RRHS Projected Utilization by Modality

MODALITY	Interim Year (7/22-12/22)	1 ST FULL FY (CY 2022)	2 ND FULL FY (CY 2023)	3 RD FULL FY (CY 2024)
X-ray				
# Units	1	1	1	1
# Procedures	1,268	2,576	3,141	3,990
Mammography				
# Units	1	1	1	1
# Procedures	1,508	3,085	4,208	5,380
# Tomosynthesis Procedures	1,101	2,252	3,072	3,928
Ultrasound				
# Units	1	1	1	1
# Procedures	967	1,966	2,397	3,044
DEXA				
# Units	1	1	1	1
# Procedures	249	526	666	880

Source: Form C, Section Q

In Section Q, pages 115-128, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

Step 1: Identify the population to be served by x-ray and ultrasound – the applicant examined ZIP codes in areas currently served by Raleigh Radiology Cary and Fuquay-Varina offices. The applicant further refined those ZIP codes into census tracts that exist along major roads in the Holly Springs area. Using Claritas software, the applicant analyzed population projections within those census tracts for 2021 and 2026 and calculated a compound annual growth rate (CAGR) with which it then interpolated data for 2022-2025 for each of the identified census tracts in the proposed service area. The overall CAGR for all the census tracts was calculated to be 1.61%.

Step 2: Project x-ray need – the applicant calculated an outpatient x-ray use rate of 256.35 x-rays per 1,000 population based on data from the 2020 Hospital License Renewal Applications (LRAs) submitted to the Division of Health Service Regulation Healthcare Planning Section. The applicant reduced that use rate to 65%, or 166.63 x-rays per 1,000 population [$256.35 \times 0.65 = 166.63$] to reflect those patients who received x-rays as hospital outpatients. See the following table that illustrates the projected number of x-rays need in the RRHS service area during 2022-2025, using the outpatient x-ray use rate of 166.63 scans per 1,000 population:

X-ray Need for RRHS Service Area, 2022-2025

	2022	2023	2024	2025
Population All Census Tracts	152,166	154,610	157,094	159,619
Use Rate	166.63	166.63	166.63	166.63
Total X-rays Needed	25,355	25,762	26,176	26,597

Source: application Section Q page 118

Step 3: Project x-ray market share and volumes for RRHS service area – the applicant states it does not anticipate that all the RRHS service area x-rays that will be needed will be performed at the proposed facility. The applicant projects the facility to be operational in July 2022, and its project years (PY) are calendar years (CY). Thus, the applicant projects a 5% market share in the first partial year of operation, and then 10%, 12% and 15%, respectively, in each of the first three PYs, as shown in the following table:

RRHS Projected X-ray Market Share, 2022-2025

	2022	2023	2024	2025
# X-rays Needed in RRHS Service Area	25,355	25,762	26,176	26,597
RRHS Projected Market Share	5%	10%	12%	15%
RRHS X-rays Needed after Market Share	1,268	2,576	3,141	3,990

Source: application Section Q page 119

In Exhibit I.2, the applicant provides letters of support from providers who indicate an intent to refer patients to the proposed facility. Those referral estimates, based on the providers’ past referral patterns, indicate an intent to refer 4,260 x-rays, which exceeds the PY 3 projections.

Step 4: Project ultrasound need for RRHS service area – the applicant utilized several databases and studies to determine use rates for ultrasound. The applicant also calculated a use rate from the 2016 National Ambulatory Medical Care Survey (NAMCS) that, among other things, measured visits for diagnostic imaging services such as ultrasound. The applicant found a wide range of use rates in its research, stating that the fluctuation is a result of many factors, including but not limited to CMS and insurer encouragement to shift outpatient procedures to non-hospital settings for lower rates. The applicant states it utilized the 2016 NAMCS use rate and increased it by 20% between 2016 and 2022. The adjusted use rate is 127.14 scans per 1,000 population. The applicant states utilizing that use rate is reasonable because it relies only on the NAMCS data and excludes hospital volumes. See the following table that illustrates the projected number of ultrasounds based on the census tract populations from Step 1 and the use rates from the NAMCS data adjusted upward by 20%:

Ultrasound Need for RRHS Service Area, 2022-2025

	2022	2023	2024	2025
Population All Census Tracts	152,166	154,610	157,094	159,619
Use Rate	127.14	127.14	127.14	127.14
Total Ultrasounds Needed	19,347	19,658	19,974	20,295

Source: application Section Q page 120
 Numbers may not sum due to rounding

Step 5: Project ultrasound market share and volumes for RRHS service area – the applicant states it does not anticipate that all the RRHS service area ultrasounds that will be needed will be performed at the proposed facility. The applicant projects the facility to be operational in July 2022, and its project years (PY) are calendar years (CY). Thus, the

applicant projects a 5% market share in the first partial year of operation, and then 10%, 12% and 15%, respectively, in each of the first three PYs, as shown in the following table:

RRHS Projected Ultrasound Market Share, 2022-2025

	2022	2023	2024	2025
# Ultrasounds Needed in RRHS Service Area	19,347	19,658	19,974	20,295
RRHS Projected Market Share	5%	10%	12%	15%
RRHS Ultrasounds Needed after Market Share	967	1,966	2,397	3,044

Source: application Section Q page 121

In Exhibit I.2, the applicant provides letters of support from providers who indicate an intent to refer patients to the proposed facility. Those referral estimates, based on the providers' past referral patterns, indicate an intent to refer 3,456 ultrasounds, which exceeds the PY 3 projections.

Step 6: Identify population to be served by bone density equipment – the applicant states the methodology for projecting bone density utilization differs because that imaging service targets older females. Therefore, the applicant utilized the same ZIP code and census tract analysis as in Step 1. The applicant utilized data and recommendations from the USPSTF and CMS, which recommend scanning every 24 months for women age 65 and older whose physician determines she is estrogen deficient and at risk for osteoporosis based on medical history. The applicant thus determined the number of women age 65 and over in the census tracts determined to comprise the RRHS service area.

Step 7: Project bone density scan need for RRHS service area – the applicant calculated a bone density scan use rate of 500 scans per 1,000 female population age 65 and over, based on 2018 USPSTF physician office data. See the following table:

Bone Density Need for RRHS Service Area Female Age 65 and Over, 2022-2025

	2022	2023	2024	2025
Population All Census Tracts Females 65+	9,960	10,516	11,104	11,727
Use Rate RRHS	500	500	500	500
Total Bone Density Scans Needed	4,980	5,258	5,552	5,864

Source: application Section Q page 123

Numbers may not sum due to rounding

Step 8: Project bone density market share and volume for RRHS service area – the applicant states it does not anticipate that all the RRHS service area bone density scans that will be needed will be performed at the proposed facility. The applicant projects the facility to be operational in July 2022, and its project years (PY) are calendar years (CY). Thus, the applicant projects a 5% market share in the first partial year of operation, and then 10%, 12% and 15%, respectively, in each of the first three PYs, as shown in the following table:

RRHS Projected Bone Density Market Share, 2022-2025

	2022	2023	2024	2025
Total Bone Density Scans Needed	4,980	5,258	5,552	5,864
RRHS Projected Market Share	5%	10%	12%	15%
RRHS Bone Scans Needed after Market Share	249	526	666	880

Source: application Section Q page 124

In Exhibit I.2, the applicant provides letters of support from providers who indicate an intent to refer patients to the proposed facility. Those referral estimates, based on the providers’ past referral patterns, indicate an intent to refer 1,836 bone density scans, which exceeds the PY 3 projections.

Step 9: Identify population to be served by mammography equipment – the applicant states the methodology for projecting mammography utilization differs because that imaging service targets females age 40 and over. Therefore, the applicant utilized the same ZIP code and census tract analysis as in Step 1. The applicant utilized data and recommendations from the American College of Radiation, Society of Breast Imaging and American Society of Breast Surgeons, which recommend regular breast screening beginning at age 40 for women. The applicant thus determined the number of women age 40 and over in the census tracts determined to comprise the RRHS service area.

Step 10: Project mammogram need for RRHS service area – the applicant first calculated an outpatient mammography use rate based on 2019 data from research it conducted. The applicant determined the national mammography use rate is 667.7 mammograms per 1,000 female population age 40 and over. See the following table:

Mammogram Need for RRHS Service Area, 2022-2025

	2022	2023	2024	2025
Population All Census Tracts Female Age 40+	37,648	38,508	39,389	40,291
Use Rate	667.7	667.7	667.7	667.7
Total Mammograms Needed	25,137	25,711	26,300	26,902

Source: application Section Q page 126

Step 11: Project mammography market share and volume for RRHS service area – the applicant states it does not anticipate that all the RRHS service area bone density scans that will be needed will be performed at the proposed facility. The applicant projects the facility to be operational in July 2022, and its project years (PY) are calendar years (CY). Thus, the applicant projects a 6% market share in the first partial year of operation, and then 12%, 16% and 20%, respectively, in each of the first three PYs, as shown in the following table:

RRHS Projected Mammography Market Share, 2022-2025

	2022	2023	2024	2025
Total Mammograms Needed	25,137	25,711	26,300	26,902
RRHS Projected Market Share	6%	12%	16%	20%
RRHS Mammograms Needed after Market Share	1,508	3,085	4,208	5,380

Source: application Section Q page 127

In Exhibit I.2, the applicant provides letters of support from providers who indicate an intent to refer patients to the proposed facility. Those referral estimates, based on the providers’ past referral patterns, indicate an intent to refer 3,756 mammograms, which exceeds the PY 1 projections.

Step 11: Project tomosynthesis utilization for RRHS – the applicant estimated, based on Raleigh Radiology internal data, that approximately 73% of women who receive regular 2-D mammograms will be referred for 3-D mammograms, or tomosynthesis procedures. See the following table:

RRHS Projected Tomosynthesis Utilization, 2022-2025

	2022	2023	2024	2025
Total RRHS Mammograms	1,508	3,085	4,208	5,380
Tomosynthesis Factor	73%	73%	73%	73%
Total Tomosynthesis Mammograms	1,101	2,252	3,072	3,928

Source: application Section Q page 128

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based on RRA physicians’ historical experience on similar diagnostic modalities and national and local data.
- Projected population increases in the service area are expected to support an increase in the utilization of diagnostic services.
- Specific imaging modalities are adjusted according to age and gender-appropriate recommendations.
- Letters of support in Exhibit I.2 project more referrals than patients projected to be served on each of the proposed imaging modalities

Access to Medically Underserved Groups

In Section C.6, page 52, the applicant provides the estimated percentage for each medically underserved group to be served at RRHS in CY 2025, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	3.5%
Racial and ethnic minorities	21.7%
Women	51.1%
Persons with Disabilities	4.1%
The elderly	13.4%
Medicare beneficiaries	23.3%
Medicaid recipients	1.5%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant states its commitment to providing care for each group listed in the table above on pages 50-52 of the application
- RRA physicians and diagnostic imaging locations have historically provided care and services to medically underserved populations
- The applicant states on pages 50-52 that RRM will not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay, or any other factor that would classify a patient as underserved

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or 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 Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

In Section E, pages 62-63, 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 address the growing need for diagnostic imaging services or improved access to reasonably priced diagnostic imaging services in the proposed service area. Therefore, the applicant determined that this is not an effective alternative.
- Develop the project in a different area – the applicant considered developing a diagnostic imaging facility in a different location in the geographic area to be served but determined that the proposed Holly Springs location provides access via major road ways. In addition, the selected parcel already meets zoning requirements, utilities are available and parking will be sufficient. Thus, the applicant states the proposed location is best suited to serve the patients projected to be served.
- Acquire different quantities of diagnostic equipment – the applicant considered acquiring different quantities of medical diagnostic equipment but determined that one of each proposed unit of equipment would provide competition and respond to the qualitative and quantitative needs of the patients proposed to be served. The applicant states it may add to the imaging capability over time.

On page 63, the applicant states that its proposal is the most effective alternative because the site location, mix of proposed services, and timing of the proposed diagnostic center would most effectively enable the applicant to meet the diagnostic imaging needs of the patients proposed to be served.

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

- The applicant demonstrates that it will provide state-of-the-art diagnostic imaging services for the patients it proposes to serve in an affordable, easily-accessible location.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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. RR WM Imaging Holly Springs, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a diagnostic center, Raleigh Radiology Holly Springs, by acquiring no more than one unit each of mammography, bone densitometry, x-ray and ultrasound equipment.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on November 1, 2021. The second progress report shall be due on March 1, 2022 and so forth.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. 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 Holly Springs 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.**

6. The certificate holder 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 Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

Capital and Working Capital Costs

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

Site Costs	NA
Construction Costs	\$403,000
Miscellaneous Costs	\$1,208,146
Total	\$1,611,147

In Section Q and Exhibit F.1, the applicant provided the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provided a cost estimate from a licensed general contractor that includes construction costs for the space to be leased for the proposed diagnostic center
- The applicant provided equipment cost quotes for each piece of proposed medical equipment

In Section F, the applicant projects that start-up costs will be \$77,854 and initial operating expenses will be \$233,236 for a total working capital of \$311,090. In Section Q the applicant provided the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant or its related entities has experience in developing diagnostic centers and operating the type of diagnostic and interventional radiology equipment proposed in this application.

- In Section Q the applicant details projected start-up expenses based on one month of start-up.
- In Section Q the applicant details projected working capital expenses based on its experience developing and operating other diagnostic imaging centers.

Availability of Funds

In Section F, page 64 the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	QC RADIOLOGY, LLC	TOTAL
Loans	\$1,611,147	\$1,611,147
Accumulated reserves or OE *	\$	\$
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$1,611,147	\$1,611,147

* OE = Owner's Equity

In Section F, page 67 the applicant states that the working capital needs of the project will be funded as shown in the table below:

SOURCES OF FINANCING FOR WORKING CAPITAL	AMOUNT
Loans	\$311,090
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$
Lines of credit	\$
Bonds	\$
Total	\$311,090

Exhibit F.2 contains a copy of an April 8, 2021 letter from BB&T (now Truist Commercial Banking) expressing its willingness to provide financing for up to \$2.3 million for the projected capital cost and working capital needs of the project. Exhibit F.2 also contains an April 12, 2021 letter signed by the Chief Operating Officer of Raleigh Radiology committing the funds to the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides evidence of funding in an amount that exceeds the combined capital and working capital needs of the project.
- The applicant demonstrates its commitment to applying those funds to the 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.2b, the applicant projects that revenues will exceed operating expenses in second and third full fiscal years following completion of the project, as shown in the table below:

Raleigh Radiology Holly Springs Entire Facility			
	1ST FULL FISCAL YEAR	2ND FULL FISCAL YEAR	3RD FULL FISCAL YEAR
Total Procedures/Tests	10,405	13,484	17,222
Total Gross Revenues (Charges)	\$2,961,234	\$3,890,054	\$4,968,262
Total Net Revenue	\$1,306,524	\$1,717,365	\$2,182,402
Average Net Revenue per Procedure/Test	\$125.57	\$127.36	\$126.72
Total Operating Expenses (Costs)	\$1,409,481	\$1,606,926	\$1,791,433
Average Operating Expense per Procedure/Test	\$135.46	\$119.17	\$104.02
Net Income (loss)	(\$102,957)	\$110,439	\$390,969

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the applicant's historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Written remarks submitted in lieu of a public hearing

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 for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

- (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 Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2021 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.

The applicant states it is unaware of any publicly available data to show inventory and utilization of existing diagnostic centers located in the proposed service area. In Section G.1, page 73, the applicant identifies four providers of the types of diagnostic imaging services proposed in this application that are currently located in the proposed service area based on internet searches and hospital license renewal applications from DHSR. See the following table from page 73:

PROVIDER	X-RAY	ULTRASOUND	MAMMOGRAPHY	DEXA
Duke Imaging Holly Springs			X	
UNC Rex Holly Springs Hospital*	X	X	X	X
WakeMed Apex Healthplex	X	X		X
Duke Primary Care Apex	X			
Wake Radiology Holly Springs	X	X	X	X

Source: Application page 73

*UNC Rex Holly Springs Hospital is projected to be operational Fall 2021

In Section G, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic imaging services in the service area. On page 75, the applicant states:

“The proposed center responds to the need for freestanding, value-based imaging services in the Holly Springs service area.

Price is an important criterion for patients. Because of its affiliation with RRLLC and RRA, RRWMIHS will offer patients and payors the low-price contract rates available at other Raleigh Radiology practice sites. The expected charge structure will be lower than hospitals, substantially lower than academic medical centers, and lower than other competing freestanding imaging centers in the service area.

...

The applicants are committed to serve the growing and underserved areas of Wake County. As Section C of this application demonstrates, population growth in the service area, combined with health status and increasing demand for outpatient

healthcare services, will sustain the need for the proposed additional capacity. Growth in the size and age of the service area population ... will only increase need for diagnostic imaging in this part of the county.

As Wake County's population grows, traffic congestion becomes a larger barrier to health care access. This proposed diagnostic center ... will provide an important quality alternative to coping with traffic, associated delays, and related stress in the service area."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved diagnostic imaging 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
- Supplemental information requested by the Agency
- Written comments
- Remarks made in lieu of a public hearing
- Responses to comments

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

The applicant proposes to develop a new diagnostic center, Raleigh Radiology Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

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

Raleigh Radiology Holly Springs Projected Staffing

POSITION	Interim Period*	YEAR 1	YEAR 2	YEAR 3
Radiology Technologist	1.5	3.0	3.0	3.0
Clerical	1.0	1.0	1.0	1.0
Total	2.5	4.0	4.0	4.0

Source: Form H in Section Q

*The applicant states RRHS is not existing and thus has no historical staffing data. Services are projected to be offered July 2022, and the project year is a calendar year. The interim period is July 1, 2022 to December 31 2022.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3. In Section H, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in the Section H.

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 all the reasons described 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

The applicant proposes to develop a new diagnostic center, Raleigh Radiology Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

Ancillary and Support Services

In Section I, page 80 the applicant identifies the necessary ancillary and support services for the proposed services. On page 81, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in

Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 82, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following

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.

- (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.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

The applicant proposes to develop a new diagnostic center, Raleigh Radiology Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

In Section K, the applicant states that the project involves upfitting 6,200 square feet of existing space in a medical office building that will be leased to the applicant. Line drawings are provided in Exhibit K.1.

On page 86 and in Exhibits K.2 and K.4, the applicant provides information about the owner/developer, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. The site appears to be suitable for the proposed diagnostic center based on the applicant's representations and supporting documentation.

- The applicant will lease space in an existing medical office building which will be upfitted to accommodate the proposed diagnostic center; therefore, many costs associated with site development will be eliminated or reduced.
- The diagnostic center space will be associated with a radiology physician practice, thus assuring physician coverage in the office.
- The prototype design of the shell space is simple, thus reducing the cost of the building envelope.

On page 86, 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 based on the applicant's statements regarding provision of diagnostic imaging services to a large charity care, Medicare and Medicaid patient base and the offering of imaging services in a low-cost outpatient setting.

On page 87, 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 for all the reasons described above.

- (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 persons with disabilities, 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

The proposed diagnostic center is not yet operational and thus has no historical payor source data for this particular location. However, the applicant or a related entity operates diagnostic centers in other areas in North Carolina. In supplemental information requested by the Agency, the applicant provides the historical payor mix during CY 2020 for the all RR diagnostic imaging services, as shown in the table below:

PAYOR CATEGORY	SERVICES AS % OF TOTAL
Self-Pay	5.32%
Charity Care	0.12%
Medicare	25.15%
Medicaid	1.95%
Insurance	61.02%
Workers Compensation	0.01%
TRICARE	1.52%
Other (specify)	0.15%
Total	100.00%

In supplemental information requested by the Agency, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA*
Female	Not Available	51.40%
Male	Not Available	48.60%
Unknown	Not Available	--
64 and Younger	70.60%	88.00%
65 and Older	29.40%	12.00%
American Indian	Not Available	0.80%
Asian	Not Available	7.70%
Black or African-American	Not Available	21.00%
Native Hawaiian or Pacific Islander	Not Available	0.10%
White or Caucasian	Not Available	67.90%
Other Race	Not Available	2.50%
Declined / Unavailable	Not Available	--

*In supplemental information requested by the Agency, the applicant states RR does not collect patient data regarding gender or race. Additionally, the applicant states over 82% of RR patients are from Wake County; therefore, demographic data provided in the table above reflects Wake County demographic data.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency.

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 ... persons [with disabilities] 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 supplemental information requested by the Agency, the applicant states it is under no obligation to provide uncompensated care, community service or access by minorities or persons with disabilities.

In supplemental information requested by the Agency, the applicant states that during the 18 months immediately preceding the application deadline, 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

- (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 95, the applicant projects the following payor mix for each proposed imaging modality and the entire proposed diagnostic center during the third year of operation (CY 2025) following completion of the project, as shown in the following table:

Raleigh Radiology Holly Springs Projected Payor Mix, CY 2025

PAYOR SOURCE	% OF TOTAL
Self-Pay	2.3%
Charity Care	0.5%
Medicare*	23.3%
Medicaid*	1.5%
Insurance*	70.8%
Other^	1.7%
Total	100.0%

*Includes any managed care plans

^Includes Champus, TRICARE, MedSolutions, Workers Comp

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.3% of total services will be provided to self-pay patients, 23.3% to Medicare patients, and 1.5% 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 experience operating other similar diagnostic imaging centers in North Carolina.

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 C.6, pages 50-51 and Section L.5, page 97, 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

The applicant proposes to develop a new diagnostic center, Raleigh Radiology Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

In Section M, page 98, 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 M.2. The applicant adequately demonstrates that 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 application is conforming to this criterion for all the reasons described above.

- (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 Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 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.

The applicant states it is unaware of any publicly available data to show inventory and utilization of existing diagnostic centers located in the proposed service area. In Section G.1, page 73, the applicant identifies four providers of the types of diagnostic imaging services proposed in this application that are currently located in the proposed service area based on internet searches and hospital license renewal applications from DHSR. See the following table from page 73:

PROVIDER	X-RAY	ULTRASOUND	MAMMOGRAPHY	DEXA
Duke Imaging Holly Springs			X	
UNC Rex Holly Springs Hospital*	X	X	X	X
WakeMed Apex Healthplex	X	X		X
Duke Primary Care Apex	X			
Wake Radiology Holly Springs	X	X	X	X

Source: Application page 73

*UNC Rex Holly Springs Hospital is projected to be operational Fall 2021

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 99, the applicant states:

“The proposed diagnostic center will be one of only three freestanding outpatient diagnostic imaging centers in the service area. ...

As a new diagnostic center in the service area, RRWMIHS will offer market competition where [hospital outpatient department] charges dominate. The competitive option for consumers should work to contain prices for outpatients at the local hospital.

Competition will work both ways. Because it is a new market entrant, the proposed diagnostic center must outperform others to attract and retain patients.

The center will be open five days a week, nine hours a day. Its design will meet current OSHA and ADA standards, encouraging others to respond. It will also use technology, contracts, and bi-lingual hiring practices to respond to the community's diversity and thereby enhance competition."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 99-100, the applicant states:

"The design and staffing structure of the facility support a low-charge, low-reimbursement structure. Initial staffing will involve cross-trained individuals. Thus, one tech can support multiple modalities while volume is low.

The center will contain administrative costs by sharing overhead with RRLLC. This will give the center direct and immediate access to staff skilled in policies and procedures, billing, third-party contract negotiations, human resources, and facility management."

See also Sections C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 100, the applicant states:

"The proposed center will pursue American College of Radiology accreditation for all available imaging modalities. This third party, peer reviewed oversight will provide transparency to the proposed project's technical quality.

All technical staff and physicians who read/interpret the studies will be required to maintain appropriate and current licensure and continuing education.

The applicants will acquire all equipment from quality vendors held accountable for meeting current Food and Drug Administration and NC Radiation Safety certification at the time of sale and the facility will have a maintenance program that supports sustained adherence to these standards."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 100, the applicant states:

“... The facility will accept referred patients without regard to source of payment and has plans to provide charity for medical necessity.”

See also Sections L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described 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 O Facilities, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five diagnostic centers located in North Carolina.

In Section O, page 103, the applicant states:

“RRLLC maintains American College of Radiology accreditation for covered modalities at all of its facilities.

RRLLC adheres to Food and Drug Administration ('FDA') guidelines for mammography imaging. Only radiologists with appropriate certification will interpret the mammography images at RRHS.

RRLLC practices register with the Centers for Medicare and Medicaid Service. All Raleigh Radiology physicians are, and will continue to be, in good standing with CMS and with the North Carolina Medical Board.

RRLLC suspended mammography services at Raleigh Radiology Blue Ridge in November 2019 following a review by FDA and ACR. The ACR limited its inquiry to a small number of mammography cases, and only as to the technical quality of the mammography images generated. The majority of cases were acceptable to the ACR. Neither ACR nor FDA indicated that RRLLC overlooked visible cancer or disease on any image. RRLLC notified patients by letter. RRLLC completed a Corrective Action Plan, and ACR reinstated full mammography accreditation on April 7, 2020.

All facilities operated and/or managed by RRLLC have full accreditation with ACR at the time of this submission."

In Exhibit O.3, the applicant provides a copy of the email confirming ACR accreditation as of April 7, 2020.

After reviewing and considering information provided by the applicant and considering the quality of care provided at all four diagnostic centers, 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.

G.S. 131E-183 (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, Raleigh Radiology Holly Springs to include mammography, bone density, x-ray and ultrasound imaging services in leased space in a medical office building.

The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017. The project does not involve any other regulated medical diagnostic equipment for which there are

applicable Criteria and Standards. Therefore, there are no performance standards applicable to this review