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-12062-21
Facility: Raleigh Radiology Chapel Hill
FID #: 210264
County: Orange
Applicant(s): RR WM Imaging Chapel Hill, 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 Chapel Hill, LLC, hereinafter referred to as RR or "the applicant", proposes to develop a new diagnostic center, Raleigh Radiology Chapel Hill ("RRCH") in leased space as an element of a physician office in Chapel Hill.

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 freestanding diagnostic center, Raleigh Radiology Chapel Hill (RRCH), in a medical office building (MOB) currently under development by a third party developer who will lease space to RRCH. Development of the MOB is exempt from CON review pursuant to N. C. Gen. Stat. §131E-184(a)(9). The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

In Section C.1, page 28, the applicant states 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. The applicant states that its experience shows that approximately 73% of mammography patients will receive a tomosynthesis exam.

- 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 and includes Orange County and other North Carolina counties. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to develop a new diagnostic center and thus has no historical patient origin to report. In Section C, page 32, and Exhibit C.3 the applicant provides a table, reproduced below, to illustrate projected patient origin for the proposed facility for the first three fiscal years (FY), which are calendar years (CY) 2023-2025:

Projected Patient Origin, Raleigh Radiology Chapel Hill

County	1ST FULL FY (CY 2023)		2ND FULL FY (CY 2024)		3RD FULL FY (CY 2025)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Orange	5,023	95%	6,126	95%	7,785	95%
Other*	264	5%	322	5%	410	5%
Total	**5,287**	**100.0%**	**6,449**	**100.0%**	**8,194**	**100.0%**

*the applicant states "other" includes all other North Carolina counties and other states

In Section C.3, the applicant refers to Exhibit C.3 for the assumptions and methodology used to project patient origin for the facility. Additional assumptions and methodology regarding patient origin are provided in Section Q, pages 112-128 and in supplemental information requested by the Agency.

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 34-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Population growth in Orange County – the applicant states population is a major determinant of imaging need, and the population of Orange County is projected to increase by a compound annual growth rate (CAGR) of 1.05% between 2021 and 2026, according to population data collected by the applicant. (page 35)

- Age and trends in imaging – the applicant states age is another determinant of imaging need, citing research it conducted that showed imaging services utilization increased in persons age 18-64 and was highest in persons age 65 and above. The applicant examined population growth projections for Orange County from the North Carolina State Office of Budget and Management (NC OSBM) between 2021 and 2026. The applicant found that population growth projections for persons age 65 and above in Orange County are higher than other age groups, as shown in the following table:

Population by Age Group in Orange County, 2021 and 2026

ORANGE COUNTY	AGE GROUPS			
	<18	18-44	45-64	65+
2021	28,102	62,709	36,547	22,917
2026	27,593	65,275	37,301	28,147
Growth in numbers	-509	2,566	754	5,230
% Change	-1.8%	4.1%	2.1%	22.8%

Source: application page 36.
"% Change" calculated by Project Analyst

Citing data from Claritas, the applicant also states that Chapel Hill, the largest city in Orange County and the location of the proposed facility, is growing. The applicant states that there are currently more than 100,000 residents within a five-mile radius of the proposed site in Chapel Hill, and describes the proposed development planned for the area. (pages 35-36)

- Health Status of Orange County residents – the applicant states that data from the North Carolina State Center for Health Statistics (NCSCHS) and the North Carolina

Institute of Medicine (NCIM) predict that county health providers in the state will see high demand for diagnostic services. The applicant cites a report, *"County Trends in Key Health Indicators"*, from the NCSCHS that shows the following Orange County statistics:

- 12.2% of the people in Orange County age 18-64 are uninsured.
- In 2012-2016, breast cancer rates in the county were 181 per 100,000 female population.
- 14% of adults in the county currently smoke.
- 15.3% of the Orange County population are age 65 and over.

- Recommendation for diagnostic imaging screening:
  - Breast cancer – the applicant states that the American Cancer Society (ACS) and US Preventive Services Task Force (USPSTF) recommends regular breast cancer screening for women beginning at age 45-50, continuing through age 74. The screening recommendations increase for women who are more at risk. The applicant states that by project year three, Orange County will have 26,178 females in the age groups recommended for preventive screening. (page 37)
  - Other diagnostic screening – citing data from USPSTF, the applicant provides information regarding ultrasound and DEXA screening for women age 65 and over for osteoporosis and other health issues. The applicant states the preventive screening recommendations are independent of clinical recommendations by individual physicians. (page 38)
  - COVID-19 and cancer screening – the applicant states the ACS reports that up to 85% of patients have missed cancer screening tests because of the COVID-19 pandemic, the stay-at-home order and the fact that many people lost employer-sponsored healthcare coverage during 2020. In addition, the applicant cites data from the American Society for Radiation Oncology (ASTRO) that there is a high number of new patients receiving radiation oncology treatments with more advanced cancers because so many patients did not receive screening during the pandemic. (page 38)

- Access for diagnostic imaging services – the applicant states those patients who are underinsured, uninsured or have special needs are more likely to face challenges when seeking health care. The applicant proposes to offer quality diagnostic imaging services to those groups. Furthermore, RRLLC has historically provided lower-cost diagnostic imaging services to patients served by its other diagnostic imaging facilities, and the applicant proposes the same low-cost services in the Chapel Hill facility. (page 39)

Relying on RRLLC's experience in operating other diagnostic centers in North Carolina, the applicant assumes 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 40:

Maximum Annual Capacity of RRCH Imaging Equipment, PY 3 (CY 2025)

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	4,122	3,589	0.70	5,398	1,276
Ultrasound	2.0	9.0	252	1.0	3,856	3,145	710	0.90	3,470	325
Bone Density	3.0	9.0	252	1.0	5,783	1,189	4,594	0.30	1,735	546
Mammo	4.0	9.0	252	1.0	7,711	4,133	3,578	1.10	8,482	4,349
Total								**3.00**		

"Notes:

- *a: applicant experience*
- *b: Planned hours of operation per day at RRCH*
- *c: RRCH will operate 5full days / week, 52 weeks per year, with 8 holidays [(5 x 52) – 8 = 252)]*
- *d: number of units per modality*
- *e: a*b*c*d*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*b*c*d*85% efficiency factor*
- *j: I – f = j"*

The applicant notes on page 40 that the projected utilization of the diagnostic imaging equipment is less than the calculated capacity.

Projected Utilization

In Section Q Form C.2a, 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

RRCH Projected Utilization by Modality

Modality	Interim Year (7/22-12/22)	1st Full FY (CY 2022)	2nd Full FY (CY 2023)	3rd Full FY (CY 2024)
X-ray				
# Units	1	1	1	1
# Procedures	1,332	2,691	3,263	4,122
Mammography				
# Units	1	1	1	1
# Procedures	1,299	2,649	3,242	4,133
# Tomosynthesis Procedures	948	1,934	2,367	3,017
Ultrasound				
# Units	1	1	1	1
# Procedures	1,016	2,053	2,490	3,145
DEXA				
# Units	1	1	1	1
# Procedures	350	730	913	1,189

Source: Form C, Section Q

In Section Q, pages 111-128, the applicant provides the assumptions and methodology used to project utilization of the diagnostic imaging equipment. On page 111, the applicant states the need methodology is population-based and uses both state and national outpatient hospital utilization rates, as well as population data from Claritas and the North Carolina State Office of Budget and Management (NCOSBM). The applicant states it uses specific demographic profiles as appropriate for the equipment, such as female population over age 65 for bone density need. The specific methodology, presented as a series of steps, appears on pages 112-128 and is summarized below:

Step 1: Identify the population to be served by x-ray and ultrasound – the applicant uses all of Orange County as its service area and used Claritas software to determine population density within Orange County. Using that same software, the applicant analyzed population projections in Orange County and calculated a compound annual growth rate (CAGR) for 2022-2025 based on population data for 2021 and 2026, which the applicant interpolated. The overall CAGR for the service area for 2021-2016 was calculated to be 1.05%. The following table, from page 113, shows the Orange County projected population and the CAGR:

RRCH Service Area Population for X-ray and Ultrasound, 2021-2026

COUNTY	2021	2022	2023	2024	2025	2026	CAGR
Orange	150,275	151,845	153,434	155,042	156,669	158,316	1.05%

Step 2: Project x-ray need – the applicant calculated a hospital outpatient x-ray use rate of 256.35 x-ray scans 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 x 0.65 = 166.63] to reflect those patients who received x-rays as hospital outpatients. Using that use rate, the applicant projected the number of x-rays that would be needed in the service area during 2022-2025, as shown in the following table:

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

	2022	2023	2024	2025
Population	151,845	153,434	155,042	156,669
Use Rate	166.63	166.63	166.63	166.63
Total X-rays Needed	25,301	25,566	25,834	26,105

Source: application Section Q pages 113-114
Numbers may not sum due to rounding

On page 114, the applicant states the use rates are conservative because they do not account for population aging and instead remain constant through all project years.

Step 3: Project x-ray market share and volumes for RRCH service area – the applicant states it does not expect that all the 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 projected the interim year utilization as 50% of the first PY. The applicant's methodology therefore 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 from page 115:

RRCH Projected X-ray Market Share, 2022-2025

	2022	2023	2024	2025
# X-rays Needed in RRCH Service Area	25,301	25,566	25,834	26,105
RRCH Projected Market Share	5%	10%	12%	15%
RRCH X-rays after Market Share	1,265	2,557	3,100	3,916

Source: application Section Q page 115

In Exhibit I.2, the applicant provides letters of support from providers who indicate an intent to refer patients to the proposed facility for x-ray services.

Step 4: Project x-ray utilization with in-migration – the applicant states it does not project that all of the x-rays performed at the proposed facility will be on patients from the service area. The applicant examined RRA physician experience at other practices in Wake County served by RRA physicians between 2017 and 2020. The applicant found that 19.2% of the patients who received an x-ray were from outside Wake County. To be conservative with its projections for RRCH, the applicant projects that 5% of the x-rays to be performed at RRCH will be on patients from outside the service area, held constant through all three project years. See the following table from Section Q, page 116:

RRCH X-ray In-Migration, 2022-2025

	2022	2023	2024	2025
RRCH X-rays after Market Share	1,265	2,557	3,100	3,916
RRCH In-Migration	5%	5%	5%	5%
Total X-rays*	1,332	2,691	3,263	4,112

*Calculated by dividing total x-rays after market share by one minus in-migration rate.
Source: application Section Q page 115

Step 5: Project ultrasound need for RRCH service area – the applicant utilized several databases and studies to determine ultrasound use rates, including a report from the 2016 National Ambulatory Medical Care Survey (NAMCS). 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. Based on its research, the applicant calculated a use rate of 101.72 ultrasounds per 1,000 population. The applicant states it utilized the 2016 NAMCS use rate and increased it by 25% 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 population projections for the service area from Step 1 and the use rates from the NAMCS data adjusted upward by 20%:

Ultrasound Need for RRCH Service Area, 2022-2025

	2022	2023	2024	2025
Orange County Population	151,845	153,434	155,042	156,669
Use Rate	127.14	127.14	127.14	127.14
Total Ultrasounds Needed	19,306	19,508	19,713	19,920

Source: application Section Q page 117
Numbers may not sum due to rounding

Step 6: Project ultrasound market share and volumes for RRCH service area – the applicant states it does not expect that all the RRHS service area ultrasounds that are projected in Step 5 to 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). 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:

RRCH Projected Ultrasound Market Share, 2022-2025

	2022	2023	2024	2025
# Ultrasounds Needed in RRCH Service Area	19,306	19,508	19,713	19,920
RRCH Projected Market Share	5%	10%	12%	15%
RRCH Ultrasounds Needed after Market Share	965	1,951	2,366	2,988

Source: application Section Q page 118
Numbers may not sum due to rounding

Step 7: Project ultrasound with in-migration – the applicant states that, based on internal data from RR, between 2017-2020 an average of 17.1% of RR patients were from outside of Wake County (current location of all RR facilities). In Exhibit C.3, the applicant provides data showing the calculations for the out of area population projections. Based on that data, the applicant projects that 5% of RRCH ultrasound patients will come from outside Orange County. The applicant states 5% represents a conservative estimate, based on the historical patterns of RR, which is a similar regional referral center for diagnostic imaging. The applicant also states the proposed location, close to Interstate 40 and NC 86 will provide easy access for those out-of-county patients. The following table, from page 119, shows the projected ultrasound utilization after the 5% in-migration:

RRCH Ultrasound Utilization with In-Migration, 2022-2025

	2022	2023	2024	2025
RRCH Ultrasounds Needed after Market Share	965	1,951	2,366	2,988
In-migration Percentage	5%	5%	5%	5%
RRCH Ultrasounds with In-Migration	1,016	2,053	2,490	3,145

Source: application Section Q page 119
Numbers may not sum due to rounding

Step 8: Identify population to be served by bone density equipment – the applicant states the methodology for projecting bone density utilization differs from the other general imaging modalities because bone densitometry, or DEXA imaging targets the 65 and over female population. The applicant utilized data and recommendations from the USPSTF

and CMS, which recommend scanning every 24 months for women whose physician determines she is estrogen deficient and at risk for osteoporosis based on medical history, or for all women age 65 and older. Using Claritas and Environics Analytics data, the applicant thus examined the population of women age 65 and over in the service area and calculated a CAGR of 4.24% from 2021-2026, as shown in the following table:

RRCH Service Area Female Population Age 65 and Over, 2021-2026

COUNTY	2021	2022	2023	2024	2025	2026	CAGR
Orange	12,765	13,302	13,864	14,451	15,066	15,709	4.24%

Source: application Section Q page 120

Step 9: Project bone density scan need for RRCH 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 Medicare coverage criteria for that population cohort. The applicant states on page 121 that the Medicare coverage standard is one scan every 24 months for women who are estrogen deficient. See the following table, which illustrates application of the use rate to the projected population of women age 65 and over in the RRCH service area:

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

	2022	2023	2024	2025
Population Women 65+	13,302	13,864	14,451	15,066
Use Rate RRCH	500	500	500	500
Total Bone Density Scans Needed	6,651	6,932	7,226	7,533

Source: application Section Q page 121
Numbers may not sum due to rounding

Step 10: Project bone density market share and volume for RRCH service area – the applicant states it does not anticipate that all the RRCH service area bone density scans projected to 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. The applicant states the percentages are based on a geography with a growing population, letters of referrals provided in Exhibit I.2, and the experience of RR in other diagnostic centers. The following table illustrates the projections:

RRCH Projected Bone Density Market Share, 2022-2025

	2022	2023	2024	2025
Total Bone Density Scans Needed	6,651	6,932	7,226	7,533
RRCH Projected Market Share	5%	10%	12%	15%
RRCH Total Bone Scans Needed	333	693	867	1,130

Source: application Section Q page 122

Step 11: Project bone density utilization with added in-migration – the applicant does not assume all bone density scans to be performed at the proposed facility will be performed on residents of the service area. The applicant states that, based on internal data from RR, between 2017-2020 an average of 15.5% of RR patients who received a bone density scan were from outside of Wake County (current location of all RR facilities). In Exhibit C.3,

the applicant provides data showing the calculations for the out of area population projections. Based on that data, the applicant projects that 5% of RRCH bone density patients will come from outside the service area. The applicant states 5% represents a conservative estimate based on the historical patterns of RR and the proposed location of the facility in a market where people from outside the service area travel for work and/or school. The following table, from page 123, shows the projected bone density utilization after the 5% in-migration:

RRCH Bone Density Utilization with In-Migration, 2022-2025

	2022	2023	2024	2025
Bone Density Scans Needed after Market Share	333	693	867	1,130
In-migration Percentage	5%	5%	5%	5%
Total Bone Density Scans	350	730	913	1,189

Source: application Section Q page 123
Numbers may not sum due to rounding

Step 12: Identify population to be served by mammography equipment – the applicant states the methodology for projecting mammography utilization differs from that of general diagnostic imaging services because mammography targets females age 40 and over. Therefore, the applicant relied on Claritas and Environics Analytics for 2021 and 2026 and interpolated the interim years to determine the age 40 and over female population in the service area. The applicant utilized data and recommendations from the American Cancer Society Breast Cancer Screening Guidelines, which recommends annual breast screening beginning at age 40 for women. The applicant thus determined the number of women age 40 and over in the service area and calculated a CAGR for that population from 2021-2026, as shown in the following table:

RRCH Service Area Female Population Age 40 and Over, 2021-2026

COUNTY	2021	2022	2023	2024	2025	2026	CAGR
Orange	36,242	36,956	37,688	38,438	39,207	39,995	1.99%

Source: application Section Q page 124

Step 13: Project mammogram need for RRCH service area – the applicant first calculated an outpatient mammography use rate for women age 40 and over based on 2019 population data from the U.S. Census Bureau and physician office data from a CDC report entitled *Health United States, 2019*, as documented on application page 125. The applicant determined the national mammography use rate is 667.7 mammograms per 1,000 female population age 40 and over. The applicant elected to use this use rate in its projections because the use rate from the CDC report is based on women who received mammograms on an outpatient basis rather than in a hospital. See the following table, from page 125:

Mammogram Need for RRCH Service Area, 2022-2025

	2022	2023	2024	2025
Population All Census Tracts Female Age 40+	36,956	37,688	38,438	39,207
Use Rate	667.7	667.7	667.7	667.7
Total Mammograms Needed	24,676	25,164	25,665	26,178

Source: application Section Q page 125
Numbers may not sum due to rounding

Step 14: Project mammography market share and volume for RRCH service area – the applicant states it does not anticipate that all the RRCH service mammography procedures 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:

RRCH Projected Mammography Market Share, 2022-2025

	2022	2023	2024	2025
Total Mammograms Needed	24,676	25,164	25,665	26,178
RRCH Projected Market Share	5%	10%	12%	15%
RRCH Mammograms Needed after Market Share	1,234	2,516	3,080	3,927

Source: application Section Q page 126

Step 15: Project mammography utilization with added in-migration – the applicant does not assume all mammograms to be performed at the proposed facility will be performed on residents of the service area. The applicant states that, based on internal data from RR, between 2017-2020 an average of 17% of RR patients who received a bone density scan were from outside of Wake County (current location of all RR facilities). In Exhibit C.3, the applicant provides data showing the calculations for the out of area population projections. Based on that data, the applicant projects that 5% of RRCH mammography patients will come from outside the service area. The applicant states 5% represents a conservative estimate based on the historical patterns of RR and the proposed location of the facility in a market where people from outside the service area travel for work and/or school. The following table, from page 127, shows the projected bone density utilization after the 5% in-migration:

RRCH Mammography Utilization with In-Migration, 2022-2025

	2022	2023	2024	2025
Mammograms Needed after Market Share	1,234	2,516	3,080	3,927
In-migration Percentage	5%	5%	5%	5%
Total Mammograms*	1,299	2,649	3,242	4,134

Source: application Section Q page 127
Numbers may not sum due to rounding
On page 127, the applicant's table, third row ("Total Mammograms")* repeats the number of *"Mammograms Needed After Market Share"* from the first table row. The Project Analyst determined this to be a typographical or cut-and-paste error and thus immaterial to the substantive information in the application, since the total number of mammograms the applicant used in Form C.2a, Utilization, reflects the numbers in the third row of the table above as calculated by the Project Analyst.

Step 16: Project tomosynthesis utilization for RRCH – 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. The following table, from page 128, summarizes this projection:

RRCH Projected Tomosynthesis Utilization, 2022-2025

	2022	2023	2024	2025
Total 2D Mammograms	1,299	2,649	3,242	4,134
Tomosynthesis Factor	73%	73%	73%	73%
Total Tomosynthesis Mammograms*	948	1,933	2,367	3,018

Source: application Section Q page 128

On page 127, the applicant's table, third row ("Total Tomosynthesis Mammograms")* repeats the number of *"Total 2C Mammograms"* from the first table row. The Project Analyst determined this to be a typographical or cut-and-paste error and thus immaterial to the substantive information in the application, since the total number of mammograms the applicant used in Form C.2a, Utilization, reflects the numbers in the third row of the table above as calculated by the Project Analyst.

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 48, the applicant provides the estimated percentage for each medically underserved group to be served at RRCH in CY 2025, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	5.0%
Racial and ethnic minorities	28.3%
Women	52.3%
Persons with Disabilities	5.8%
The elderly	16.7%
Medicare beneficiaries	23.5%
Medicaid recipients	2.9%

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 46-48 of the application.
- RRA physicians have historically provided care and services to medically underserved populations at other diagnostic imaging locations with which they are affiliated.

- The applicant states on pages 46-48 that RRCH 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

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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

In Section E, pages 58-59, 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 Orange County but states the proposed Chapel Hill site is located near major transportation arteries and bus lines in the area. Additionally, the proposed site meets local zoning requirements, is on a bus route and already has sufficient parking. 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, offer imaging services at an affordable price, respond to the qualitative and quantitative needs of the patients proposed to be served and improve access to imaging services in the area. The applicant states it may add to the imaging capability over time.

On page 59, 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 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 Chapel Hill, 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 Chapel Hill, by acquiring one unit each of mammography, bone densitometry, x-ray and ultrasound equipment.**

3. **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.**

4. **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.**

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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 129 and in supplemental information requested by the Agency, the applicant projects the total capital cost of the project as shown in the following table:

Site Costs	NA
Construction Costs	$273,180
Miscellaneous Costs	$1,095,935
Total	**$1,369,115**

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.3, page 62, the applicant projects that start-up costs will be $77,121 and initial operating expenses will be $180,922 for a total working capital of $258,044. 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 for each project year.

Availability of Funds

In Section F.2, page 60, the applicant states that the capital cost will be funded as shown in the table below:

RRCH Sources of Capital Cost Financing

TYPE	Raleigh Radiology WakeMed Imaging Chapel Hill, LLC	TOTAL
Loans	$2,300,000	$2,300,000
Accumulated reserves or OE *	$	$
Bonds	$	$
Other (Specify)	$	$
Total Financing	**$2,300,000**	**$2,300,000**

* OE = Owner's Equity

In Section F, page 63 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	$258,044
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	$
Lines of credit	$
Bonds	$
Total	**$254,044**

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, which is sufficient to cover both of those costs. 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 Chapel Hill Entire Facility

	1ST FULL FISCAL YEAR	2ND FULL FISCAL YEAR	3RD FULL FISCAL YEAR
Total Procedures/Tests	10,057	12,275	15,606
Total Gross Revenues (Charges)	$2,767,432	$3,378,659	$4,297,241
Total Net Revenue	$1,199,626	$1,457,328	$1,844,287
Average Net Revenue per Procedure/Test	$119.28	$118.72	$118.18
Total Operating Expenses (Costs)	$1,258,628	$1,397,122	$1,552,855
Average Operating Expense per Procedure/Test	$125.15	$113.82	$99.50
Net Income (loss)	($59,002)	$60,026	$291,432

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.

The applicant proposes to develop a new freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

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. In Section C, pages 34-35, the applicant states the service area is Orange County and includes other North Carolina counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 69, 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. On page 69, 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 69:

PROVIDER	X-RAY	ULTRASOUND	MAMMO	DEXA
UNC Hospital	X	X	X	X
Wake Radiology Chapel Hill	X	X	X	X
UNC Eastowne	X	X		X
UNC Hospital Imaging Center	X	X	X	X
UNC Hospital – Hillsborough Campus	X	X	X	X

Source: Application page 69

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. The applicant states:

> *"The proposed center responds to the need for freestanding, value-based imaging services in Orange County.*
>
> *Price is an important criterion for patients. Because of its affiliation with RRLLC and RRA, RRWMICH 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 Orange County….*
>
> …

The applicants are committed to serve the growing and underserved areas of Orange County. ... 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 the county 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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

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 Chapel Hill Projected Staffing

POSITION	Interim Period*	YEAR 1	YEAR 2	YEAR 3
Radiology Technologist	2.0	3.0	3.0	3.0
Clerical	1.0	1.0	1.0	1.0
Total	**3.0**	**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, page 74, 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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

Ancillary and Support Services

In Section I, page 76, the applicant identifies the necessary ancillary and support services for the proposed services. On page 77, 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 78, the applicant describes its proposed relationships with other local health care and social service providers and provides supporting documentation of those relationships 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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

In Section K, page 81 the applicant states that the project involves renovating 3,321 square feet of space in a medical office building that will be developed by a third party and leased to the applicant. The applicant provides an April 1, 2021 letter from the third party developer detailing the terms of the lease to RRCH. The applicant provides line drawings in Exhibit K.2.
On pages 84-85, the applicant provides information regarding the zoning and water and sewer availability for the proposed site. The letter in Exhibit K.4 confirms the availability of these services at the facility.

On pages 82-83, the applicant provides the following information:

- 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 83, 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.

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 91, the applicant projects the following payor mix for the proposed diagnostic center during the third year of operation (CY 2025) following completion of the project, as shown in the following table:

Raleigh Radiology Chapel Hill Projected Payor Mix, CY 2025

PAYOR SOURCE	% OF TOTAL
Self-Pay	2.4%
Charity Care	0.5%
Medicare*	23.5%
Medicaid*	2.9%
Insurance*	69.1%
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 2.4% of total services will be provided to self-pay patients, 23.5% to Medicare patients, and 2.9% 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 46-48 and Section L.5, page 93, 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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

In Section M, page 94, 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 from Wake Technical Community College and Johnston Community College 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 freestanding diagnostic center in a MOB currently under development by a third party developer who will lease space to RRCH. The applicant proposes to acquire one unit each of mammography, ultrasound, bone density and X-ray, and states it will provide general diagnostic imaging services with a particular focus on women's breast health.

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. In Section C, pages 34-35, the applicant states the service area is Orange County and includes other North Carolina counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 69, 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. On page 69, 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 69:

PROVIDER	X-RAY	ULTRASOUND	MAMMO	DEXA
UNC Hospital	X	X	X	X
Wake Radiology Chapel Hill	X	X	X	X
UNC Eastowne	X	X		X
UNC Hospital Imaging Center	X	X	X	X
UNC Hospital – Hillsborough Campus	X	X	X	X

Source: Application page 69

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 95, the applicant states:

> *"The proposed diagnostic center will be the only one of four freestanding outpatient diagnostic imaging centers in Orange County. …*
>
> *As a new diagnostic center in the service area,* [RRWMICH] *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 95-96, 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 96, 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.

…

The center will function on a component of a physician office that has a National Provider Identification Number with CMS for payment providing yet more third-party oversight."

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 96, 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 A 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 99, 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. RRLLC completed a Corrective Action Plan, and ACR reinstated full mammography accreditation on April 7, 2020."*

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 Chapel Hill 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