REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: April 29, 2021
Findings Date: April 29, 2021

Project Analyst: Tanya M. Saporito
Assistant Chief: Lisa Pittman

Project ID #: J-11988-20
Facility: Raleigh Radiology Midtown Diagnostic Center
FID #: 222879
County: Wake
Applicant(s): QC Radiology, LLC
Project: Develop a new diagnostic center to include CT, mammography, bone density, X-ray, ultrasound, C-Arm and interventional radiology 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.

NA

QC Radiology, LLC (hereinafter referred to as QC or "the applicant") proposes to develop a new diagnostic center, Raleigh Radiology Midtown Diagnostic Center (RRM), in leased space in an existing medical office building (MOB) located at 5111 Falls of Neuse Road in Raleigh. The applicant states that members of QC are also members of Raleigh Radiology, LLC (RR), a physician group that provides management services throughout Wake County to five other existing or approved diagnostic imaging centers.

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 computed tomography (CT) scanner, mammography, X-ray, bone densitometry, ultrasound, C-Arm and interventional radiology 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 2020 SMFP
- acquire any medical equipment for which there is a need determination in the 2020 SMFP
- offer a new institutional health service for which there are any policies in the 2020 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 proposes to develop a new diagnostic center by acquiring and installing a CT scanner, mammography, X-ray, bone densitometry, ultrasound, C-Arm and interventional radiology equipment in leased space in Raleigh that will be renovated to accommodate the diagnostic center.

In Section B, page 15, the applicant states that Raleigh Radiology Associates, Inc. (RRA) is a physician group practice and a related entity to RR, both of which have provided radiology services in Wake County for over 46 years. Physicians from RRA formed the management company, RR to oversee its diagnostic centers.

In Section C.1, page 24 the applicant states RRM will organize as a physician office, with a full-time physician from RRA during all hours of operation. The applicant states this is a different arrangement from an independent Diagnostic and Treatment Center, which offers imaging services and has a radiologist off site to read and interpret images. The applicant proposes to renovate 15,000 square feet of existing space in a medical office building, and proposes the following equipment:

- Interventional radiology (IR) equipment – one C-arm and one single-plane digital lab
- Computed tomography (CT)
- Mammography – two digital mammography units with Tomosynthesis capability
- Ultrasound – two units
- X-ray – one general unit
- Bone densitometry (DEXA) – one unit
- iSTAT lab testing –a portable unit used for testing blood samples to determine patient capacity to tolerate contrast agents. It is used for CT and IR.

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 2020 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, pages 34-35, the applicant states there are two service areas for the proposed project, depending on the diagnostic services, as shown in the following tables:

Projected Patient Origin, General Diagnostic Imaging (CT, X-ray, Ultrasound, DEXA, Mammography

County	1st Full FY (CY 2022)		2nd Full FY (CY 2023)		3rd Full FY (CY 2024)	
	# Pts.	% of Total	# Pts.	% of Total	# Pts.	% of Total
Wake County*	13,582	98.4%	16,237	98.4%	18,956	98.4%
Other	228	1.7%	272	1.7%	318	1.7%
Total	**13,810**	**100.0%**	**16,509**	**100.0%**	**19,274**	**100.0%**

*The applicant provides a list of census tracts within Wake County which comprise projected patient origin for general diagnostics.
"Other" includes other areas in Wake County, other NC counties and other states, primarily South Carolina and Virginia.

Projected Patient Origin, Interventional Radiology

COUNTY	1ST FULL FY (CY 2022)		2ND FULL FY (CY 2023)		3RD FULL FY (CY 2024)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Wake County	1,132	70.0%	1,298	70.0%	1,470	70.0%
Johnston County	113	7.01%	130	7.01%	147	7.01%
Harnett County	97	6.0%	111	6.0%	126	6.0%
Other*	275	17.0%	315	17.0%	357	17.0%
Total	**1,617**	**100.0%**	**1,854**	**100.0%**	**2,100**	**100.0%**

*"Other" includes other NC counties and other states, primarily South Carolina and Virginia.

Projected Patient Origin – Entire Facility

COUNTY	1ST FULL FY (CY 2022)		2ND FULL FY (CY 2023)		3RD FULL FY (CY 2024)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Wake County	14,714	95.4%	17,535	95.5%	20,426	95.6%
Other*	713	4.6%	829	4.5%	948	4.5%
Total	**15,427**	**100.0%**	**18,364**	**100.0%**	**21,374**	**100.0%**

*"Other" includes Johnston and Harnett counties, other NC counties and other states, primarily South Carolina and Virginia.

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

In Section C.3, the applicant refers to Section Q for the assumptions and methodology used to project the number of patients by county, stating that the applicant expects future patient origin for general diagnostics to follow a pattern similar to RRA history.

The applicant's assumptions are reasonable and adequately supported based on the following:

- projected patient origin is based on the historical patient origin for RRA physicians at other diagnostic centers in Wake County
- projected growth is based on the projected Wake County population growth.

Analysis of Need

In Section C, pages 37-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Population growth and aging in the service area – the applicant examined population growth projections in Wake County and the other counties in the service area. The applicant determined that 8.2% of the total projected population growth is expected to be in the RRM general diagnostic service area. In addition, the applicant determined that the 18-65 population group in Wake County is expected to increase at a higher rate than the population as a whole, and the over 65 age group will increase at a greater rate than all groups. The applicant states the population groups 18-65 and over 65 are the groups most likely to utilize imaging and diagnostic imaging services. (pages 40-42)

- Social determinants of health – the applicant examined social determinants such as income and education that tend to affect patients' ability to support a healthy lifestyle. Additionally, the price of many imaging services can be a deterrent to many patients in need of imaging services. The applicant further determined that Wake, Johnston and Harnett counties each have high percentages of people who are obese, who smoke, who suffer from vascular disease, kidney disease, and who are underinsured or uninsured; and for whom access to healthcare is challenging. The applicant also examined specific imaging modalities and their impact on the social determinants of health in the service area, to determine that the populations in the service area need the imaging modalities proposed in this application. Specifically, the applicant states Wake County is a health care destination for many patients in surrounding counties, in part because of the specialized care that is not available in the more rural or surrounding counties. (pages 42-50)

- US Preventive Task Force recommendations for diagnostic screenings – the applicant states the US Preventive Task Force (USPTF) recommends biennial mammography screening for women ages 50-74 who are asymptomatic. The applicant states that by the third project year following completion of the proposed diagnostic imaging facility, Wake County will have 332,222 females in that age group. Women who are at higher risk and men will also require breast mammography screening. The proposed mammography equipment will meet that demand. (pages 50-52)

- Other diagnostic imaging screening – the applicant states that the USPTF publishes recommendations for diagnostic screening for other diseases as well, including but not limited to ultrasound for abdominal aortic aneurysm, DEXA screening for osteoporosis in women, and annual CT scans for lung cancer in adults who have been heavy smokers. (page 52)

- General access for diagnostic imaging services – the applicant states that underinsured, uninsured and persons with special needs are more likely to encounter challenges regarding access to imaging services. Additionally, the average consumer is responsible for an increasing portion of outpatient medical costs because deductibles and coinsurance rates are increasing. The applicant states it has historically provided access to diagnostic imaging services at lower patient cost than other imaging providers in the area (pages 52-53)

- Physician referrals – the applicant provides letters from area physicians in Exhibit I.2 which indicate an interest in the imaging center and an intent to refer patients. The following table from application page 53 summarizes the number of referrals as indicated by the physician letters:

MODALITY	PROJECTED # PTS. REFERRED	PROJECTED # SCANS/PROCEDURES
CT	6,840	4,520
IR	3,240	3,024
Ultrasound	8,988	5,289
Mammography	8,676	5,732
DEXA	5,184	1,114
X-ray	9,360	6,932

Source: application page 53, Section Q, pages 130-158.

The information is reasonable and adequately supported based on the following:

- The applicant provides population and health data to support the projected use of the proposed diagnostic equipment.

- The applicant provides reasonable and adequately supported information to support its assertion that the proposed diagnostic equipment is needed to meet the growing population and the growing segment of residents age 18-64 and over 65 in the service area.

- The applicant provides reasonable and adequately supported information to support its assertion that the proposed diagnostic equipment is needed to meet the need for service area residents whose medical needs can be met by the proposed imaging equipment.

- The applicant provides reasonable and adequately supported information to show that the proposed diagnostic equipment is needed for the medically underserved residents in the service area.

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 2022-CY 2024, as summarized in the following table:

RRM Projected Utilization by Modality

MODALITY	1ST FULL FY (CY 2022)	2ND FULL FY (CY 2023)	3RD FULL FY (CY 2024)
CT Scanner			
# Units	1	1	1
# of Scans	2,206	3,349	4,520
X-ray			
# Units	1	1	1
# Procedures	4,060	5,479	6,932
Mammography			
# Units	2	2	2
# Procedures	9,497	9,696	9,901
Ultrasound			
# Units	2	2	2
# Procedures	3,098	4,181	5,298
IR			
# Units	1	1	1
# Procedures	1,164	1,335	1,512
DEXA			
# Units	1	1	1
# Procedures	1,026	1,069	1,114
iSTAT			
# Units	1	1	1
# Procedures	88	134	181
C-arm			
# Units	1	1	1
# Procedures	1,164	1,335	1,512

Source: Form C, Section Q

In Section Q, pages 130-158, the applicant provides the assumptions and methodology used to project utilization. The applicant provides two methodologies, one of which projects utilization for general imaging (CT, X-ray, ultrasound, bone density and mammography); and the second of which projects utilization for IR, the C-arm and digital radiography unit (iSTAT). Both methodologies are summarized below:

General Radiology

Step 1: Identify the population to be served by general radiology services – the applicant utilized Claritas mapping and demographic software for the areas in Wake County proposed to be served by the diagnostic center and calculated a compound annul growth rate (CAGR) for years 2021-2026. The applicant determined that the overall population in the Wake County proposed service area will grow by a CAGR of 1.22% from 2021 to 2026. The applicant assumes that the census tracts that comprise the proposed Wake County service area for general diagnostic imaging have roadways that are accessible to the proposed site, are within 20 minutes travel time to the proposed site and coincide with ZIP codes in which RRA has historically served patients.

Step 2: Project CT scanner need for RRM service area – Relying on data from 2020 Hospital License Renewal Applications (LRAs) submitted to the North Carolina Division of Health Service Regulation and population data from the North Carolina Office of State Budget and Management (NCOSBM), the applicant calculated a CT use rate for acute care hospitals in the state. The applicant determined that the statewide hospital CT use rate for FY 2019 was 208.92 CT scans per 1,000 population. In order to calculate a use rate for outpatient CT scans, the applicant adjusted the hospital use rate by 65%, for an outpatient CT use rate of 135.8 per 1,000 [208.92 x 0.65 = 135.8]. The applicant states this use rate is conservative, given that it excludes information from physician offices, adjusts hospital use rates to exclude emergency and inpatient scans and is supported by additional data provided by the applicant in Exhibit C.10 that shows CT use is increasing. See the following table, prepared by the Project Analyst, that illustrates the applicant's projections:

WAKE COUNTY RRM SERVICE AREA PROJECTED CT SCAN NEED

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Population*	146,187	147,965	149,767
Use Rate	135.8	135.8	135.8
# CT Scans	19,852	20,094	20,338

*From Exhibit C.10 and Section Q, page 132 of the application

The applicant assumes that beginning in 2022, utilization will no longer be affected by COVID-19 anomalies.

Step 3: Project CT scanner market share for RRM service area – the applicant states it does not anticipate that the entire RRM service area need calculated in Step 2 will be served by RRM. The applicant projected a 10% market share in Year one, a 15% market share in year 2, and a 20% market share in year 3, as illustrated in the following table:

RRM SERVICE AREA PROJECTED CT SCAN MARKET SHARE

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
# CT Scans from Step 2	19,852	20,094	20,338
Market Share RRM	10%	15%	20%
# CT Scans	1,985	3,014	4,068

The applicant states on page 135 that a 20% market share in the third project year is reasonable because it represents one in five scans, letters of support in Exhibit I.2 indicate an intent to refer a total of more than the projected number of CT scans based on market share and RRM will be one of only two freestanding outpatient diagnostic centers in the proposed service area.

Step 4: Project CT scanner utilization adding in-migration – relying on internal data from area physician practices served by RRA physicians, the applicant states that between 2018 and 2020, an average of 22.6% of patients who received a CT scan from a Raleigh Radiology location came from outside Wake County. The applicant projects that in-migration from outside of Wake County for patients being served by RRM will be 10% through all three project years, as shown in the following table:

RRM PROJECTED IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Market Share # CT Scans	1,985	3,014	4,068
Projected In-Migration	10%	10%	10%
# CT Scans	2,206	3,349	4,520

The applicant states 10% in-migration is reasonable because it represents less than the number of patients historically served by RRA physicians, the use rates are conservative, letters of support indicate an intent to refer more patients than are projected to be served, and the proposed location close to I-440 will provide easy access for out-of-county patients.

Step 5: Project X-ray need for RRM service area – As with CT scan projections, the applicant compiled X-ray use rate data from hospital LRAs and calculated an X-ray use rate for FY 2019 of 256.35 scans per 1,000 population. The applicant reduced that by 65% to eliminate emergency and inpatient X-ray scans and calculated an outpatient use rate of 166.63 scans per 1,000 population [256.35 x 0.65 = 166.63]. Based on the population projections for the three project years, the applicant projected the following number of X-rays needed by the service area population:

WAKE COUNTY RRM SERVICE AREA PROJECTED X-RAY NEED

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Population*	146,187	147,965	149,767
Use Rate	166.63	166.63	166.63
# X-rays Needed	24,359	24,665	24,955

*From Exhibit C.10 and Section Q, page 137 of the application. Numbers may not sum due to rounding by Project Analyst.

Step 6: Project X-ray market share – the applicant states it does not anticipate that the entire RRM service area need calculated in Step 5 will be served by RRM. The applicant projected a 15% market share in Year one, a 20% market share in year 2, and a 25% market share in year 3, as illustrated in the following table:

RRM SERVICE AREA PROJECTED X-RAY MARKET SHARE

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
# X-rays Needed	24,359	24,665	24,955
Market Share	15%	20%	25%
Market Share X-rays	3,654	4,931	6,239

As with the CT scan market share projections, the applicant states the 25% market share in the third project year is reasonable because it represents one in four X-rays, letters of support in Exhibit I.2 indicate an intent to refer a total of more than the projected number of X-rays based on market share and RRM will be one of only two freestanding outpatient diagnostic centers in the proposed service area.

Step 7: Project X-ray utilization adding in-migration – relying on internal data from area physician practices served by RRA physicians, the applicant states that between 2018 and 2020, an average of 16.2% of patients who received an X-ray from a Raleigh Radiology location came from outside Wake County. The applicant projects that in-migration from outside of Wake County for patients being served by RRM will be 10% through all three project years, as shown in the following table:

RRM X-RAY UTILIZATION WITH IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Market Share X-rays	3,654	4,931	6,239
In-Migration	10%	10%	10%
Market Share X-rays	4,060	5,479	6,932

Numbers may not sum due to rounding.

The applicant states 10% in-migration is reasonable because it represents less than the number of patients historically served by RRA physicians, the use rates are conservative, letters of support indicate an intent to refer more patients than are projected to be served, and the proposed location close to I-440 will provide easy access for out-of-county patients.

Step 8: Project ultrasound need for RRM service area – the applicant examined ultrasound utilization data from the National Ambulatory Medical Care Survey to calculate a use rate of 101.72 per 1,000 population, which represents outpatient ultrasound use across the US. The applicant increased that use rate by 20% to project ultrasound need within the RRM service area. The applicant states the use of that data and the increase by 20% are both reasonable because it excludes hospital volume and recent research indicates increasing ultrasound utilization, particularly in outpatient settings. See the following table that illustrates projected service area ultrasounds based on the use rate:

WAKE COUNTY RRM SERVICE AREA PROJECTED ULTRASOUND NEED

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Population	146,187	147,965	149,767
Use Rate	127.14	127.14	127.14
# Ultrasounds Needed	18,586	18,813	19,042

Numbers may not sum due to rounding.

Step 9: Project ultrasound market share – the applicant states it does not anticipate that the entire RRM service area need calculated in Step 8 will be served by RRM. The applicant projected a 15% market share in Year one, a 20% market share in year 2, and a 25% market share in year 3, as illustrated in the following table:

RRM SERVICE AREA PROJECTED ULTRASOUND MARKET SHARE

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
# Ultrasounds Needed	18,586	18,813	19,042
Market Share	15%	20%	25%
Market Share Ultrasounds	2,788	3,763	4,761

The applicant states the 25% market share in the third project year is reasonable because it represents one in four ultrasounds, letters of support in Exhibit I.2 indicate an intent to refer a total of more than the projected number of ultrasounds based on market share and RRM will be one of only two freestanding outpatient diagnostic centers in the proposes service area.

Step 10: Project ultrasound utilization adding in-migration – relying on internal data from area physician practices served by RRA physicians, the applicant states that between 2018 and 2020, an average of 15.9% of patients who received an ultrasound at a Raleigh Radiology location came from outside Wake County. The applicant projects that in-migration from outside of Wake County for patients being served by RRM will be 10% through all three project years, as shown in the following table:

RRM ULTRASOUND UTILIZATION WITH IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Market Share Ultrasounds	2,788	3,763	4,761
In-Migration	10%	10%	10%
Market Share X-rays	3,098	4,181	5,289

Numbers may not sum due to rounding.

The applicant states 10% in-migration is reasonable because it represents less than the number of patients historically served by RRA physicians, the use rates are conservative, letters of support indicate an intent to refer more patients than are projected to be served, and the proposed location close to I-440 will provide easy access for out-of-county patients.

Step 11: Identify population to be served by bone densitometry equipment – the applicant utilized Claritas mapping and demographic software for the areas in Wake County proposed to be served by the diagnostic center and calculated a compound annual growth rate (CAGR) for years 2021-2026. The applicant states the methodology for bone density equipment differs from other imaging services, because the target population for this type of imaging is women age 65 and older. The applicant determined that the 65 and older female population in the Wake County proposed service area will grow by a CAGR of 4.19% from 2021 to 2026.

Step 12: Project bone density need for RRM service area – Relying on data from 2020 Hospital License Renewal Applications (LRAs) submitted to the North Carolina Division of Health Service Regulation and population data from the North Carolina Office of State Budget and Management (NCOSBM), the applicant calculated a bone density use rate of 82.84 bone density scans per 1,000 population. The applicant also calculated a national bone density scan use rate of 166.67, based on the 2018 USPSTF physician office data for the US. The applicant

elected to use the national use rate of 166.67 scans per 1,000 population, because that use rate is based on patients who received scans only in an outpatient setting such as RRM.

The following table prepared by the Project Analyst illustrates the applicant's projections:

WAKE COUNTY RRM SERVICE AREA PROJECTED BONE DENSITOMETRY NEED

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Population*	13,852	14,429	15,033
Use Rate	166.67	166.67	166.67
# Bone Density Scans	2,309	2,405	2,505

*From Exhibit C.3 and Section Q, page 143 of the application
Numbers may not sum due to rounding.

Step 13: Project bone density market share – the applicant states it does not anticipate that the entire RRM service area need calculated in Step 12 will be served by RRM. The applicant projected a 40% market share in each of the three project years, as illustrated in the following table:

RRM SERVICE AREA PROJECTED BONE DENSITY MARKET SHARE

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
# Bone Density Scans Needed	2,309	2,405	2,505
Market Share	40%	40%	40%
Market Share Bone Density Scans	923	962	1,002

The applicant states the 40% market share is reasonable because it is based on a small geographic area, the methodology appropriately uses the population of females age 65 and older and letters of support in Exhibit I.2 indicate an intent to refer a total of more than the projected number of bone density scans based on market share. Additionally, RRM will be one of only two freestanding outpatient diagnostic centers in the proposed service area. The applicant states the methodology absorbs the small number of male patients who will receive bone density scans.

Step 14: Project bone density utilization adding in-migration – relying on internal data from area physician practices served by RRA physicians, the applicant states that between 2018 and 2020, an average of 13.8% of patients who received bone density scans at a Raleigh Radiology location came from outside Wake County and from outside North Carolina. The applicant projects that in-migration from outside of Wake County for patients being served by RRM will be 10% through all three project years, as shown in the following table:

RRM BONE DENSITY UTILIZATION WITH IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Market Share Bone Density Scans	923	962	1,002
In-Migration	10%	10%	10%
Market Share X-rays	1,026	1,069	1,114

Numbers may not sum due to rounding.

The applicant states 10% in-migration is reasonable because it represents less than the number of patients historically served by RRA physicians, the use rates are conservative, letters of support indicate an intent to refer more patients than are projected to be served, and the proposed location close to I-440 will provide easy access for out-of-county patients.

Step 15: Identify population to be served by mammography equipment – the applicant utilized Claritas mapping and demographic software for the areas in Wake County proposed to be served by the diagnostic center and calculated a compound annual growth rate (CAGR) for years 2021-2026. The applicant states the methodology for mammography equipment differs from other imaging services, because the target population for this type of imaging is women age 40 and older. The applicant determined that the 40 and older female population in the Wake County proposed service area will grow by a CAGR of 2.11% from 2021 to 2026.

Step 16: Project mammography need for RRM service area – Relying on data from 2020 Hospital License Renewal Applications (LRAs) submitted to the North Carolina Division of Health Service Regulation and population data from the North Carolina Office of State Budget and Management (NCOSBM), the applicant calculated an outpatient mammography use rate of 289.40 mammograms per 1,000 population. The applicant also calculated a national mammography use rate of 653.3 mammograms per 1,000 population, based on the 2018 USPSTF physician office data for women age 40 and above in the US. The applicant elected to use the national use rate of 653.3 mammogams per 1,000 population, reduced by 25%, or 489.98. The applicant states this use rate is reasonable because it is based on outpatient data. The following table prepared by the Project Analyst illustrates the applicant's projections:

WAKE COUNTY RRM SERVICE AREA PROJECTED MAMMOGRAPHY NEED

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Population*	40,334	41,180	42,048
Use Rate	489.98	489.98	489.998
# Mammograms Needed	19,763	20,177	20,603

*From Exhibit C.10 and Section Q, page 150 of the application
Numbers may not sum due to rounding.

Step 17: Project mammography market share – the applicant states it does not anticipate that the entire RRM service area need calculated in Step 16 will be served by RRM. The applicant projected a 25% market share in each of the three project years, as illustrated in the following table:

RRM SERVICE AREA PROJECTED MAMMOGRAPHY MARKET SHARE

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
# Mammograms Needed	19,763	20,177	20,603
Market Share	25%	25%	25%
Market Share Mammograms	4,941	5,044	5,151

The applicant states the 25% market share is reasonable because it is based on a small geographic area, the methodology appropriately uses the population of females age 40 and

older, letters of support in Exhibit I.2 indicate an intent to refer a total of more than the projected number of ultrasounds based on market share, the projected market share represents fewer mammograms than were actually provided by RRA physicians at the RR Cedarhurst location in 2019 and RRM will be one of only two freestanding outpatient diagnostic centers in the proposes service area.

Step 18: Project mammography utilization adding in-migration – relying on internal data from area physician practices served by RRA physicians, the applicant states that between 2018 and 2020, an average of 13.7% of patients who received bone density scans at a Raleigh Radiology location came from outside Wake County. The applicant projects that in-migration from outside of Wake County for patients being served by RRM will be 10% through all three project years, as shown in the following table:

RRM MAMMOGRAPHY UTILIZATION WITH IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Market Share Mammograms	4,941	5,044	5,151
In-Migration	10%	10%	10%
Market Share Mammograms	5,490	5,605	5,723

Numbers may not sum due to rounding.

The applicant states 10% in-migration is reasonable because it represents less than the number of patients historically served by RRA physicians, the use rates are conservative, letters of support indicate an intent to refer more patients than are projected to be served, and the proposed location close to I-440 will provide easy access for out-of-county patients.

The applicant states the projected mammography utilization estimates "2D mammograms" and does not include "3D mammograms" or tomosynthesis. Therefore, the applicant separately projected tomosynthesis utilization at RRM by projecting that 73% of all mammograms will involve the extra step required for a tomosynthesis scan. This percentage estimate is based on the experience of the RRA physicians at other outpatient imaging locations in Wake County. See the following table that summarizes this utilization, from page 153 of the application:

RRM TOMOSYNTHESIS UTILIZATION WITH IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Total 2D Mammograms	5,490	5,605	5,723
Tomosynthesis Percentage	73%	73%	73%
Market Share Mammograms	4,007	4,092	4,178

Numbers may not sum due to rounding.

Interventional Radiology

Step 1: Identify the population to be served by interventional radiology (IR) – the applicant uses a different service area for IR than for general radiology, stating that Wake, Johnston and Harnett counties represent the primary service area. Using data from NCOSBM, the applicant

determined that the population of those three counties is projected to increase by a CAGR of 1.92% from 2021-2026. The applicant states IR procedures use a C-arm and a digital radiography unit. The applicant states there are few freestanding facilities in the service area that provide IR services, and only two offer services similar to those proposed in this application. Only the applicant proposes to offer orthopedic and spine IR procedures.

Step 2: Project IR need for RRM service area – Relying on data from 2020 Hospital License Renewal Applications (LRAs) submitted to the North Carolina Division of Health Service Regulation and population data from the North Carolina Office of State Budget and Management (NCOSBM), the applicant calculated an outpatient IR use rate of 15.91 procedures per 1,000 population. The following table prepared by the Project Analyst illustrates the applicant's projections:

WAKE COUNTY RRM SERVICE AREA PROJECTED IR NEED

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Population*	1,518,357	1,547,981	1,577,695
Use Rate	15.91	15.91	15.95
# Mammograms Needed	24,155	24,627	25,099

*From Exhibit C.10 and Section Q, page 155 of the application
Numbers may not sum due to rounding.

Step 3: Project IR market share – the applicant states it does not anticipate that the entire RRM service area need calculated in Step 2 will be served by RRM. The applicant projected a 10% market share for IR procedures in the third project year, as illustrated in the following table:

RRM SERVICE AREA PROJECTED IR MARKET SHARE

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
# IR Procedures Needed	24,155	24,627	25,099
Market Share	8%	9%	10%
Market Share IR Procedures	1,932	2,216	2,510

The applicant states the 10% market share in the third project year is reasonable because it represents one in ten IR procedures projected in a three-county area and letters of support in Exhibit I.2 indicate an intent to refer a total of more than the projected number of IR procedures than the projections estimate.

Step 4: Project IR utilization adding in-migration – relying on internal data from area physician practices served by RRA physicians, the applicant states that between 2018 and 2020, an average of 13.7% of patients who received bone density scans at a Raleigh Radiology location came from outside Wake County and from out of state. The applicant states it considered patient origin information from the Wake Spine and Specialty Surgical Center (WCSSSC), which projects a 26.6% in-migration for its IR services. The applicant elected to utilize a 17% in-migration, because it is conservative when compared to the WSSSC projections and it accounts for growth from Wake County referring physicians. Therefore,

the applicant projects in-migration from outside of Wake County for patients being served by RRM will be 17% through all three project years, as shown in the following table:

RRM IR UTILIZATION WITH IN-MIGRATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Market Share IR Procedures	1,932	2,216	2,510
In-Migration	17%	17%	17%
Total IR Procedures	2,328	2,670	3,024

Numbers may not sum due to rounding.

The applicant states 17% in-migration is reasonable because it is comparable to the 16.5% of patients from outside Wake County historically served by RRA physicians, the use rates are conservative, letters of support indicate an intent to refer more patients than are projected to be served, and the proposed location close to I-440 will provide easy access for out-of-county patients.

The applicant separated the total projected IR utilization in the table above into procedures that require use of the C-Arm and the digital radiography unit, assuming an even distribution of each. The applicant projects that 50% of all IR will be digital radiography and 50% will be procedures involving the C-arm, as shown in following table from page 158 of the application:

RRM DIGITAL RADIOGRAPHY AND C-ARM UTILIZATION

	1ST PROJECT YEAR (CY 2022)	2ND PROJECT YEAR (CY 2023)	3RD PROJECT YEAR (CY 2024)
Total IR Procedures	2,328	2,670	3,024
% Digital Radiography	50%	50%	50%
Total Digital Radiography Procedures	**1,164**	**1,335**	**1,512**
% C-Arm	50%	50%	50%
Total C-Arm Procedures	**1,164**	**1,335**	**1,512**

Numbers may not sum due to rounding

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

- Projected utilization is based on RRA physicians' historical experience on similar diagnostic modalities in the service area.
- Projected population increases in the service area are expected to support an increase in the utilization of diagnostic services.
- Decreases in utilization from anomalous 2020 data due to COVID-19 are expected to normalize in 2022.
- 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.11, page 60, the applicant provides the estimated percentage for each medically underserved group to be served at RRM in CY 2024, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	4.2%
Racial and ethnic minorities	34.2%
Women	51.4%
Persons with Disabilities	8.5%
The elderly	24.6%
Medicare beneficiaries	24.6%
Medicaid recipients	1.9%

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 61-64 of the application
- RRA physicians and diagnostic imaging locations have historically provided care and services to medically underserved populations
- The applicant states on pages 61-63 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 by acquiring and installing CT, X-ray and C-arm services, mammography, ultrasound, bone densitometry and interventional radiology equipment in renovated leased space in Raleigh.

In Section E, pages 74-76, 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 effectively serve the volume of patients and the older patient population group projected to use the facility would not be well-served by this option, because Raleigh Radiology Cedarhurst has relocated and there is no outpatient imaging center close enough to the proposed service area to serve patients in need of imaging services. Therefore, the applicant determined that this is not an effective alternative.

- Offer different imaging modalities – the applicant states offering fewer imaging modalities than it proposes would not serve its patients. In addition, the applicant states office-based labs (OBL) are emerging as an outpatient location in which many different interventional radiology services are offered with conscious sedation, thereby providing many patients with outpatient, low-cost options for interventional radiology procedures that will allow them to return home shortly after the procedure. Many of the referring physicians, including neurologists, prefer to refer their patients to OBLs. Thus, offering fewer or different imaging modalities was not an effective alternative for the applicant.

- Different location – the applicant states that other locations did not offer the criteria it had for timely availability of diagnostic and interventional radiology services, affordability, proximity to the former Cedarhurst location and compatibility with other medical practices. Other locations were not an effective alternative.

On page 74, the applicant states that its proposal is the most effective alternative because it addresses the shortfalls of the alternative options considered by the applicant and is best positioned to serve patients needing radiology services in the proposed service area.

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 radiology 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. **QC Radiology, 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 Midtown Diagnostic Center, by acquiring Computed Tomography (CT), X-ray, Mammography, Ultrasound and Bone Densitometry equipment, and a C-Arm and Interventional Radiology Unit.**

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. **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 Midtown Diagnostic Center shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

    a. **Payor mix for the services authorized in this certificate of need.**
    b. **Utilization of the services authorized in this certificate of need.**
    c. **Revenues and operating costs for the services authorized in this certificate of need.**
    d. **Average gross revenue per unit of service.**
    e. **Average net revenue per unit of service.**
    f. **Average operating cost per unit of service.**

5. **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 by acquiring and installing CT, X-ray and C-arm services, mammography, ultrasound, bone densitometry and interventional radiology equipment in renovated leased space in Raleigh.

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 table below.

Site Costs	NA
Construction Costs	$900,000
Miscellaneous Costs	$3,713,426
Total	**$4,613,426**

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 certified cost estimate from a licensed architect that includes cost for design and upfit of 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 and supplemental information provided at the Agency's request, the applicant projects that start-up costs will be $250,809 and initial operating expenses will be $579,712 for a total working capital of $830,521. In Section Q and in supplemental information provided at the Agency's request, 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 and supplemental information provided at the Agency's request, the applicant details projected start-up expenses based on one month of start-up.
- In Section Q and supplemental information provided at the Agency's request, the applicant details projected initial operating expenses based on a five-month initial operating period, defined as the number of months between offering of services and the time when cash in-flow exceeds cash out-flow.
- In Section Q and supplemental information provided at the Agency's request, the applicant details projected working capital expenses based on its experience.

Availability of Funds

In supplemental information provided at the Agency's request, 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	$4,613,426	$4,613,426
Accumulated reserves or OE *	$	$
Bonds	$	$
Other (Specify)	$	$
Total Financing	**$4,613,426**	**$4,613,426**

* OE = Owner's Equity

In Section F, page 81 and supplemental information provided at the Agency's request, 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	$830,521
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	$0
Lines of credit	$
Bonds	$
Total	**$830,521**

Exhibit F.2 contains a copy of a November 9, 2020 letter from BB&T (now Truist Commercial Banking) expressing its willingness to provide financing for up to $6.3 million for the projected capital cost and working capital needs of the project. Exhibit F.2 also contains a November 15, 2021 letter signed by the Chief Operating Officer of QC Radiology, LLC 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 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 for each modality proposed to be located in the diagnostic center. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below:

	1ST FULL FISCAL YEAR	2ND FULL FISCAL YEAR	3RD FULL FISCAL YEAR
Total Procedures/Tests	22,303	26,578	30,961
Total Gross Revenues (Charges)	$10,792,800	$13,040,680	$15,348,551
Total Net Revenue	$4,563,054	$5,378,739	$6,205,810
Average Net Revenue per Procedure/Test	$204.59	$202.38	$200.44
Total Operating Expenses (Costs)	$4,486,415	$5,120,994	$5,502,101
Average Operating Expense per Procedure/Test	$201.16	$192.68	$177.71
Net Income	$76,639	$257,745	$703,709

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

Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

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 by acquiring and installing CT, X-ray and C-arm services, mammography, ultrasound, bone densitometry and interventional radiology equipment in renovated leased space in Raleigh.

N.C.G.S. §131E-176(24a) states, "*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*" The 2020 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 34-36, the applicant states the patient origin for the diagnostic center is primarily Wake County and other areas. The applicant states on page 34 that the patient origin from "other areas" will vary and includes the remainder of the North Carolina counties, as well as Virginia and South Carolina. Facilities may also serve residents not included in their service area.

The applicant states it is unaware of any publicly available data to show inventory and utilization of existing diagnostic centers; however, in Section G.1, pages 85-88, the applicant identifies 23 hospital based and freestanding 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 for the Wake County area.

In Section G, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in the proposed service area. On page 89 the applicant states:

> *"This proposal will not result in unnecessary duplication of existing diagnostic imaging services in the service area. The proposed center responds to several needs:*
>
> 1. *Access to commonly used imaging services that RRA has been providing in the Midtown area;*
> 2. *Expanded scope of office-based IR in Wake County; and,*
> 3. *Freestanding outpatient imaging pricing at Raleigh Radiology rates.*
>
> *As part of the RRA practice, the proposed location will offer patients and payors the low-price contract rates available at other Raleigh Radiology practice sites."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed diagnostic center is needed in addition to the existing or approved diagnostic centers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 by acquiring and installing CT, X-ray and C-arm services, mammography, ultrasound, bone densitometry and interventional radiology equipment in renovated leased space in Raleigh.

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

Raleigh Radiology Midtown Projected Staffing

POSITION	YEAR 1	YEAR 2	YEAR 3
Registered Nurse	1.0	1.0	1.0
Clerical	3.0	3.0	3.0
Radiology Technicians	9.0	9.0	9.5
Total	**13.0**	**13.0**	**13.5**

Source: Form H in Section Q of the application. Numbers may not sum due to rounding by Project Analyst.

The assumptions and methodology used to project staffing are provided in Section Q and clarifying information provided at the Agency's request. 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Ancillary and Support Services

In Section I, the applicant identifies the necessary ancillary and support services for the proposed services. On page 97, 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, the applicant describes its efforts to develop 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.

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.

(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

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

(11) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new diagnostic center by acquiring and installing CT, X-ray and C-arm services, mammography, ultrasound, bone densitometry and interventional radiology equipment in renovated leased space in Raleigh.

In Section K, the applicant states that the project involves renovating 15,000 square feet of existing space in a medical office building that will be leased to the applicant. Line drawings are provided in Exhibit K.2.

On page 103 and in Exhibit K.2, the applicant provides information about the current owner, 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.

On page 103, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant will lease space in a medical office building, thereby reducing delay and many costs associated with site development.
- The office building will have other tenants besides the applicant, thereby sharing expenses related to utilities, waste treatment and water.
- 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 104, 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 104, 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;

NA

The applicant proposes to develop a new diagnostic facility. Therefore, Criterion (13a) is not applicable to this review.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

The applicant proposes to develop a new diagnostic facility. Therefore, Criterion (13b) is not applicable to this review.

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

C

In Section L.3, page 110, 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 2024) following completion of the project, as shown in the following table.

PAYMENT SOURCE	PERCENT OF TOTAL PROCEDURES	CT	MAMMO	X-RAY	US	DEXA	TOMO	IR
Self Pay	2.2%	2.0%	2.0%	5.0%	3.0%	1.0%	1.0%	2.0%
Charity Care	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
Medicare*	25.8%	25.5%	23.5%	23.0%	18.0%	51.5%	25.0%	29.5%
Medicaid*	1.9%	2.0%	1.0%	3.0%	3.0%	1.0%	0.0%	2.0%
Insurance*	67.4%	68.0%	71.0%	67.0%	74.0%	45.0%	72.5%	63.0%
Other**	2.2%	2.0%	2.0%	1.5%	1.5%	1.0%	1.0%	3.0%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

*The applicant states these include managed care plans
**"Other" includes Champus, MedSolutions, TRICARE and Workers Compensation.
Totals may not foot due to rounding.
IR includes angiography, C-Arm and iSTAT

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.2% of total services will be provided to self-pay patients, 25.8% to Medicare patients, and 1.9% to Medicaid patients.

In Section Q and in clarifying information provided at the Agency's request, the applicant provides the assumptions and methodology used to project payor mix during

the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience operating other similar facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Clarifying information requested by the Agency

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

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

C

In Section L.5, page 111, 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
- Clarifying information requested by the Agency

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

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

C

In Section M, page 113, 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.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new diagnostic center by acquiring and installing CT, X-ray and C-Arm services, mammography, ultrasound, bone densitometry and interventional radiology equipment in renovated leased space in Raleigh.

N.C.G.S. §131E-176(24a) states: "*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*" The 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, page 34 the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C, pages 34-36, the applicant states the patient origin for the diagnostic center is primarily Wake County and other areas. The applicant states on page 34 that the patient origin from "other areas" will vary and includes the remainder of the North Carolina counties as well as Virginia and South Carolina. Facilities may also serve residents not included in their service area.

The applicant states it is unaware of any publicly available data to show inventory and utilization of existing diagnostic centers; however, in Section G.1, pages 85-88, the applicant identifies 23 hospital based and freestanding 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 for the Wake County area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 114, the applicant states:

> *"The proposed diagnostic center will be the only one of two freestanding outpatient diagnostic imaging centers in the service area.*
>
> *As a new competitor in the service area, QCR will provide market competition where* [Hospital outpatient department] *charges dominate. The competitive option for consumers and others for whom price is a concern should work to contain prices for outpatients at the local hospital.*
>
> *…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, eight hours a day and plans to expand nine hours daily in its third year to respond to community demand.*
>
> *…*
>
> *The multi-specialty office-based IR will be one of the first office-based settings to offer more complex IR services like kyphoplasty.*[1] *"*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 115, 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….*
>
> *As noted elsewhere in the application, the proposed lower fee structure will advance cost effective care throughout the community."*

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 115, the applicant states:

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[1] Kyphoplasty is surgical procedure designed to stop pain caused by a spinal fracture, to stabilize the bone, and to restore some or all of the lost vertebral body height due to a compression fracture. *See* https://www.spine-health.com/treatment/back-surgery/description-kyphoplasty-surgery

"The proposed center will pursue American College of Radiology accreditation for all available imaging modalities.

…

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, pages115-116, the applicant states:

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

…

The proposed diagnostic center will have a generous mix of patients who are beneficiaries of government supported Medicare, Medicaid, programs [sic]. *The 'Other' payor category includes Veterans Administration Community Care and Mission Act beneficiaries."*

See also Section 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 and & the applicant's record of providing quality care in the past (if applicable).

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
- 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 the reasons stated above.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A 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 four diagnostic centers located in North Carolina and currently operating.

In Section O, page 118, the applicant states:

> *"RRLLC practices register with the Center for Medicare and Medicaid Service. All Raleigh Radiology physicians are in good standing with CMS and with the North Carolina Medical Board.*
>
> *RRLLC suspended mammography services at Raleigh Radiology Blueridge 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 the cases were acceptable to the ACR. Neither ACR nor FDA indicated that RLLC overlooked visible cancer or disease on any image. RRLLC notified patients by letter. A Corrective Action Plan was completed, and ACR reinstated 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.

In Section O, page 119, the applicant states that none of the facilities identified in Form A have had any incidents resulting in a finding of Immediate Jeopardy for the 18 months preceding submission of the application.

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.

C

The applicant proposes to develop a new diagnostic center, and to install a CT scanner and other diagnostic imaging equipment.

The Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 are applicable to this review. The application is conforming to all applicable criteria. The specific criteria are discussed below.

10A NCAC 14C .2303 PERFORMANCE STANDARDS

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

(1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;

-C- In Section C.12, page 66, the applicant projects that the proposed CT scanner will perform 7,085 HECT units in the third year of operation (CY 2024). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and

-NA- Neither the applicant nor any related entity owns a controlling interest in any existing fixed or mobile CT scanner located in the service area.

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

-NA- Neither the applicant nor any related entity owns a controlling interest in any existing fixed or mobile CT scanner located in the service area.