

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 14, 2021

Findings Date: September 14, 2021

Project Analyst: Julie M. Faenza

Co-Signer: Gloria C. Hale

Project ID #: F-12085-21

Facility: Charlotte Radiology Union West Breast Center

FID #: 210480

County: Union

Applicant: Charlotte Radiology, P.A.

Project: Develop a new diagnostic center with 2 mammography units and 2 ultrasound units

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

Charlotte Radiology, P.A. (hereinafter referred to as Charlotte Radiology or “the applicant”) proposes to develop a new diagnostic center, Charlotte Radiology Union West Breast Center (CR-Union West), in a medical office building (MOB) currently under development on the campus of Atrium Health Union West (AH-Union West). The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

The applicant does not propose to:

- Acquire any medical equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP).
- Offer a new institutional health service for which there are any applicable 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- (2) Repealed effective July 1, 1987.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 proposes to develop a new diagnostic center on the campus of AH-Union West.

Patient Origin

N.C.G.S. §131E-176(24a) defines “service area” as “... *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 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 30-31, and Section G, page 73, the applicant defines the service area as ZIP codes 28079, 28104, 28110, and 28173. Facilities may also serve residents of counties, in in this case ZIP codes, not included in their service area.

CR-Union West is not an existing facility. The following tables illustrate projected patient origin during the first three full fiscal years following project completion.

CR-Union West Projected Patient Origin – FYs 1-3 (CYs 2023-2025) - Mammography						
ZIP Code	FY 1 – CY 2023		FY 2 – CY 2024		FY 3 – CY 2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
28173 (Waxhaw)	4,603	34.5%	4,698	34.5%	4,796	34.5%
28110 (Monroe)	3,301	24.8%	3,370	24.8%	3,440	24.8%
28079 (Indian Trail)	2,728	20.5%	2,785	20.5%	2,843	20.5%
28104 (Matthews)	2,704	20.3%	2,760	20.3%	2,818	20.3%
Total	13,335	100.0%	13,613	100.0%	13,897	100.0%

Source: Section C, page 31

CR-Union West Projected Patient Origin – FYs 1-3 (CYs 2023-2025) - Ultrasound						
ZIP Code	FY 1 – CY 2023		FY 2 – CY 2024		FY 3 – CY 2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
28173 (Waxhaw)	462	32.3%	471	32.3%	481	32.3%
28110 (Monroe)	382	26.8%	390	26.8%	398	26.8%
28079 (Indian Trail)	313	21.9%	320	21.9%	326	21.9%
28104 (Matthews)	271	19.0%	277	19.0%	282	19.0%
Total	1,428	100.0%	1,458	100.0%	1,488	100.0%

Source: Section C, page 31

CR-Union West Projected Patient Origin – FYs 1-3 (CYs 2023-2025) – Entire Facility						
ZIP Code	FY 1 – CY 2023		FY 2 – CY 2024		FY 3 – CY 2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
28173 (Waxhaw)	5,084	34.4%	5,190	34.4%	5,298	34.4%
28110 (Monroe)	3,658	24.8%	3,735	24.8%	3,812	24.8%
28079 (Indian Trail)	3,026	20.5%	3,089	20.5%	3,153	20.5%
28104 (Matthews)	2,995	20.3%	3,058	20.3%	3,121	20.3%
Total	14,763	100.0%	15,071	100.0%	15,384	100.0%

Source: Section C, page 32

In the table showing projected patient origin for ultrasound patients, the total for FY 3 (CY 2025) is off by one – the total should be 1,487. This does not affect the outcome of the review in any way and for consistency with the application the Project Analyst will continue using the 1,488 patients in the Findings.

In Section C, pages 30-31, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projected patient origin based on the population it analyzed to project utilization.
- While the facility itself has no historical patient origin, the projected patient origin is based on historical utilization of the same services the applicant proposes to provide at other locations owned by the applicant.

Analysis of Need

In Section C, pages 33-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The development of the AH-Union West campus makes it important to develop CR-Union West in order to provide comprehensive outpatient healthcare services to western Union County.
- Charlotte Radiology is the exclusive provider of breast radiology services for Atrium Health facilities and the Levine Cancer Institute. The closest Charlotte Radiology location

to AH-Union West with mammography and diagnostic services is 15 miles and 22-34 minutes away.

Additionally, there is a need for two units of both mammography and ultrasound equipment, because patients needing breast surgery undergo imaging at CR-Union West immediately prior to surgery and any subsequent imaging of biopsies or tissue would then be performed on the same piece of imaging equipment at CR-Union West. If CR-Union West had only one unit of mammography and ultrasound equipment, it would disrupt treatment and diagnostic imaging for other patients.

- According to the North Carolina Office of State Budget and Management (NC OSBM), the Union County population is projected to grow at a Compound Annual Growth Rate (CAGR) of 1.9 percent between 2021 and 2025 and Union County is one of the top five counties for projected numerical population growth. Further, most breast cancer patients are women over 45, and the population of women as a percentage of total population in Union County is projected to increase. Additionally, the population of women age 45 and older is projected to grow at a CAGR of 2.4 percent between 2021 and 2025 in Union County, which is higher than the projected population growth rate.

The applicant also states that the population growth in Union County is oriented more toward the western side of the county, and according to ESRI population residing in the four ZIP codes the applicant proposes as its service area have a combined projected CAGR of 2.1 percent between 2020 and 2025.

- The applicant states that, according to the North Carolina State Center for Health Statistics, North Carolina had a higher age-adjusted incidence rate of breast cancer than the United States as a whole between 2013 and 2017. The applicant further states that according to the North Carolina Central Cancer Registry, between 2015 and 2019 Union County had a higher incidence of breast cancer than any other type of cancer and had the third-highest incidence rate of breast cancer among all 100 North Carolina counties.

The applicant states the North Carolina female breast cancer mortality rates have been decreasing due to improved treatment and advances in detection. The applicant states early detection using mammography is critical to increasing survival rates of breast cancer patients.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reasonable support for the stated need to develop the diagnostic center in the proposed location.
- The applicant provides reliable data from publicly available sources to support its statements of need for the proposed project.

Projected Utilization

On Form C.2a in Section Q, the applicant provides projected utilization, as illustrated in the following table.

CR-Union West Projected Utilization – FYs 1-3 (CYs 2023-2025)			
Component	FY 1 (CY 2023)	FY 2 (CY 2024)	FY 3 (CY 2025)
Mammography – Units	2	2	2
Mammography – Procedures	13,335	13,613	13,897
Ultrasound – Units	2	2	2
Ultrasound – Procedures	1,428	1,458	1,488
Total Procedures	14,763	15,071	15,384

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the annual maximum capacity per unit for each type of medical diagnostic equipment proposed in this application, as well as the assumptions and methodology used to project the annual maximum capacities, as shown in the table below.

Annual Maximum Capacity for Each Type of Medical Diagnostic Equipment Proposed					
Equipment Type	# Units	Tests/Hour	Hours/Day	Days/Year	Maximum Annual Capacity*
Mammography Unit	2	4.0	8	250	8,000
Ultrasound Unit	2	2.0	8	250	4,000

Source: Form C Utilization – Assumptions and Methodology subsection of Section Q

*Maximum Annual Capacity = (Units X Tests X Hours X Days)

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

The applicant uses “normalized” CY 2020 data in its projections. The applicant describes how it calculated “normalized” CY 2020 data for March – May 2020, the months most heavily impacted by COVID-19, by substituting historical utilization from March – May 2019 instead of annualizing data from months in CY 2020 where COVID-19 did not impact utilization as much as others.

Mammography Units

- The applicant analyzed historical mammography utilization by residents of its defined service area at its other Charlotte Radiology locations. The applicant states mammography utilization by residents of its defined service area increased by 10.8 percent annually between CY 2017 and CY 2020 normalized.
- The applicant states it projects growth in mammogram utilization between CY 2021 and CY 2025 at an annual growth rate of 2.1 percent, which is ESRI’s CY 2020 through CY 2025 annual projected population growth rate for Union County.

- The applicant projects 75 percent of the historical patients from the service area will shift to CR-Union West, based on convenience, location, and services that can be provided on the same campus.
- The assumptions and methodology for mammography utilization are shown in the table below.

CR-Union West Mammography Projected Utilization						
	CY 2020*	CY 2021	CY 2022	FY 1 CY 2023	FY 2 CY 2024	FY 3 CY 2025
Service Area Procedures	16,714	17,062	17,418	17,780	18,151	18,529
Assumed Shift	--	0%	38%**	75%	75%	75%
CR-Union West Procedures	--	0	6,532	13,335	13,613	13,897

*CY 2020 Normalized

**Based on a projected opening date of July 1, 2022

- The applicant projects to perform 13,897 mammograms at CR-Union West in CY 2025. Based on the calculated maximum capacity of the mammography units, the applicant projects the mammography units will be utilized at 86.9 percent of capacity in CY 2025.

Ultrasound Units

- The applicant analyzed historical ultrasound utilization by residents of its defined service area at its other Charlotte Radiology locations. The applicant states ultrasound utilization by residents of its defined service area increased by 2.9 percent annually between CY 2017 and CY 2020 normalized.
- The applicant states it projects growth in ultrasound utilization between CY 2021 and CY 2025 at an annual growth rate of 2.1 percent, which is ESRI’s CY 2020 through CY 2025 annual projected population growth rate for Union County.
- The applicant projects 75 percent of the historical patients from the service area will shift to CR-Union West, based on convenience, location, and services that can be provided on the same campus.
- The assumptions and methodology for ultrasound utilization are shown in the table below.

CR-Union West Ultrasound Projected Utilization						
	CY 2020*	CY 2021	CY 2022	FY 1 CY 2023	FY 2 CY 2024	FY 3 CY 2025
Service Area Procedures	1,790	1,827	1,865	1,904	1,943	1,984
Assumed Shift	--	0%	38%**	75%	75%	75%
CR-Union West Procedures	--	0	699	1,428	1,458	1,488

*CY 2020 Normalized

**Based on a projected opening date of July 1, 2022

- The applicant projects to perform 1,488 ultrasounds at CR-Union West in CY 2025. Based on the calculated maximum capacity of the ultrasound units, the applicant projects the ultrasound units will be utilized at 18.6 percent of capacity in CY 2025.
- The applicant states that, despite the low capacity of the ultrasound units, it is critical that there be two available ultrasound units due to the need to simultaneously accommodate both surgical procedures and outpatient diagnostic procedures.

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

- The applicant projected utilization based on historical utilization by residents of the service area at its other existing facilities.
- The applicant uses a projected annual growth rate of 2.1 percent for both mammography and ultrasound procedures, equivalent to the projected annual growth rate for the population of Union County, which is more conservative than the historical increases in utilization of mammography and ultrasound units.
- There are no performance standards applicable for any of the pieces of existing or proposed diagnostic imaging equipment at CR-Union West.
- The applicant provides reasonable and adequately supported information to demonstrate the need for two ultrasound units based on the need to provide care to different types of patients versus maximizing utilization of the proposed ultrasound units.

Access to Medically Underserved Groups

In Section C, page 48, the applicant states:

“Charlotte Radiology is committed to providing services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Imaging services at Union West Breast Center will be available to and accessible by any patient who has a clinical need for such services supported by the orders of a patient’s physician or surgeon.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

CR-Union West – FY 3 (CY 2025)	
Medically Underserved Groups	% of Total Patients
Low income persons	--
Racial and ethnic minorities	--
Women	99.8%
Persons with disabilities	--
Persons 65 and older	29.4%
Medicare beneficiaries	25.0%
Medicaid recipients	1.4%

Source: Section C, page 49

In Section C, page 49, the applicant states that the above table:

“...[is] based on CY 2020 Charlotte Radiology percentages for the patient population. Charlotte Radiology does not maintain data that includes the number of low income persons, racial and ethnic minorities, or [disabled] persons it serves. As such, Charlotte Radiology does not have a reasonable basis to estimate the percentage of low income, racial and ethnic minorities, and [disabled] persons to be served by the project; however, neither low income, racial and ethnic minorities, nor [disabled] persons are denied access to the services.”

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 provides a statement documenting its willingness to serve all residents of the service area without regard to any factor that might classify someone as part of an underserved group.
- The applicant projects to serve underserved groups and explains why it does not have data for certain categories of underserved groups.

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 on the campus of AH-Union West.

In Section E, pages 59-60, 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 prevent patients from having local access to diagnostic services and would mean breast surgery services could not be provided at AH-Union West; therefore, this is not an effective alternative.

Develop the Diagnostic Center with Fewer Units: The applicant states developing the diagnostic center with fewer units of equipment would disrupt patient care in the office when the equipment is needed for surgical patients; therefore, this is not an effective alternative.

Develop the Diagnostic Center in a Different Location: The applicant states developing the diagnostic center at a different location would impede the ability to provide breast surgery services at AH-Union West; therefore, this is not an effective alternative.

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

- The applicant provides reasonable 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

- 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. Therefore, the application is approved subject to the following conditions:

- 1. Charlotte Radiology, P.A. (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 in a medical office building on the campus of Atrium Health Union West with no more than two ultrasound units and no more than two mammography units.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on February 1, 2022. The second progress report shall be due on May 1, 2022 and so forth.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Sections F and Q of the application or that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new diagnostic center on the campus of AH-Union West.

Capital and Working Capital Costs

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

Construction/Renovation	\$600,600
Consultant/A&E Fees	\$111,250
Medical Equipment	\$833,487
Non-Medical Equipment/Furniture	\$95,356
Other*	\$140,250
Total	\$1,780,943

*"Other" includes IS, security, and internal allocation

On Form F.1a Assumptions immediately following Form F.1a in Section Q, the applicant provides 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 relies on the experience of the project architect and states the project architect has experience with similar projects.
- The applicant relies on vendor quotes for equipment costs.
- The applicant provides the assumptions for the various other costs.

In Section F, pages 64-65, the applicant projects that start-up costs will be \$364,059 and initial operating expenses will be \$1,165,796 during an initial operating period of four months for a total working capital of \$1,529,855. On page 65, the applicant provides 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 identifies the expenses and time period involved in projecting start-up costs.

- The applicant identifies the expenses and time period involved in projecting initial operating costs.

Availability of Funds

In Section F, pages 62-63 and 66-67, the applicant states both the capital and working capital costs of the project will be funded via accumulated reserves of US Radiology Specialists, Charlotte Radiology’s management company. Exhibit F.2 contains a letter dated June 8, 2021 from a Vice President of Bank of America, NA, stating that US Radiology Specialists is a client of Bank of America and has a combined balance of greater than \$10 million in cash deposits. Exhibit F.2 also contains a letter dated June 15, 2021 from the Vice President of Operations of Charlotte Radiology, committing to use the funding provided by US Radiology Specialists to fund the capital and working capital costs of the proposed 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 documentation showing US Radiology Specialists has sufficient cash available to fund the proposed capital and working capital costs.
- The applicant provides a letter committing to use the funding provided by US Radiology Specialists toward the proposed capital and working capital costs.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2b in Section Q, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years of the project, as shown in the table below.

CR-Union West Revenue and Expenses – FYs 1-3 (CYs 2023-2025)			
	FY 1 (CY 2023)	FY 2 (CY 2024)	FY 3 (CY 2025)
Total Procedures	14,763	15,071	15,384
Total Gross Revenues (Charges)	\$13,760,398	\$14,468,370	\$15,212,768
Total Net Revenue	\$4,955,816	\$5,210,793	\$5,478,888
Average Net Revenue per Procedure	\$336	\$346	\$356
Total Operating Expenses (Costs)	\$3,840,770	\$4,032,143	\$4,291,924
Average Operating Expense per Procedure	\$260	\$268	\$279
Net Profit / (Loss)	\$1,115,046	\$1,178,650	\$1,186,964

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides the details of what items are included in each category and what the projections are based upon (experience, inflation, etc.).
- 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

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 on the campus of AH-Union West.

N.C.G.S. §131E-176(24a) defines “service area” as “... *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 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 30-31, and Section G, page 73, the applicant defines the service area as ZIP codes 28079, 28104, 28110, and 28173. Facilities may also serve residents of counties, in in this case ZIP codes, not included in their service area.

In Section G, page 73, the applicant states there are no hospitals in its defined service area and the applicant is unaware of any data source which provides the inventory of existing and

approved non-hospital facilities which provide mammography and breast ultrasound services in its defined service area.

In Section G, page 73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in ZIP codes 28079, 28104, 28110, and 28173. The applicant states:

“...Charlotte Radiology is not aware of any other providers in the proposed service area that provide the same services proposed in this application. Further, the need for the proposed project is based on the need for local access to comprehensive breast care services for the residents of western Union County and to support the surgeons who will practice at Atrium Health Union West. ..., currently the closest comprehensive breast care services are located at Charlotte Radiology’s Pineville Breast Center. As the exclusive provider of breast services for Atrium Health and LCI facilities, the proposed project is essential to support the surgical and oncology services to be provided at Atrium Health Union West, a role that no other provider can fulfill, while also providing local access to Charlotte Radiology’s comprehensive screening and diagnostic breast services. Given that there are currently no other providers of comprehensive breast services in the service area, the proposed project will not result in an unnecessary duplication of services.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant adequately demonstrates there are no existing hospitals that need a related diagnostic center on its campus in its defined service area.
- The applicant adequately demonstrates that the proposed diagnostic center is needed in addition to any existing or approved diagnostic centers.

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.

- (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 on the campus of AH-Union West.

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

CR-Union West Projected Staffing – # of FTEs			
Position	FY 1 – CY 2023	FY 2 – CY 2024	FY 3 – CY 2025
Front Desk	2.0	2.0	2.5
Diagnostic Tech	3.0	3.0	3.5
Tech Assistant	1.0	1.0	1.0
Total	6.0	6.0	7.0

The assumptions and methodology used to project staffing are provided on Form H and immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted on Form F.3b. In Section H, pages 75-76, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs used at other Charlotte Radiology facilities which will be used at CR-Union West.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant has experience in recruiting new employees and providing training and has systems in place it can use at CR-Union West.
- The applicant includes appropriate salary projections in Form F.3b for the employees it proposes to hire.

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.

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

C

The applicant proposes to develop a new diagnostic center on the campus of AH-Union West.

Ancillary and Support Services

In Section I, page 78, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 78-80, the applicant explains how each ancillary and support service 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 based on the following:

- The applicant has experience in providing the necessary ancillary and support services.
- The applicant provides documentation of the availability of the necessary ancillary and support services.

Coordination

In Section I, page 80, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits C.6-3 and I.2. While this will be a new diagnostic center, the applicant is an existing entity and has established relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an established entity which has existing relationships with other local health care and social service providers.
- The applicant is proposing to develop the project specifically to coordinate with other health care system 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 all the reasons described 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. Therefore, Criterion (9) is not applicable to this review.

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

NA

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

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

C

The applicant proposes to develop a new diagnostic center on the campus of AH-Union West.

In Section K, page 83, the applicant states that the project involves upfitting (renovating) 3,170 square feet of space in a medical office building currently under development on the campus of AH-Union West. Line drawings are provided in Exhibit C.1-1.

On page 85, the applicant identifies the proposed site and states that the project does not involve the acquisition of land. Exhibit C.1-2 contains a letter of intent from Atrium Health (the owner of the campus and medical office building) to lease space in the medical office building to CR-Union West. The site appears to be suitable for the proposed diagnostic center based on the applicant's representations and supporting documentation.

On pages 83-84, 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 proposed project will be developed in a medical office building rather than in an entirely new building on a new site.
- Utilization of shared spaces like elevators and bathrooms will promote cost effectiveness.

On page 84, 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 following:

- The proposed project is being developed in a medical office building in leased space rather than in new construction.
- The location provides convenience to patients and reduces patient costs for traveling between different sites.

On page 84, 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

CR-Union West is not an existing 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

CR-Union West is not an existing 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, pages 90-91, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

CR-Union West Payor Mix – FY 3 (CY 2025)			
Payor Source	% Patients – Total	% Patients – Mammography	% Patients - Ultrasound
Self-Pay	0.8%	0.7%	2.1%
Medicare*	25.0%	25.9%	17.5%
Medicaid*	1.4%	1.3%	2.5%
Insurance*	72.7%	72.1%	77.9%
Other**	0.1%	0.1%	0.0%
Total	100.0%	100.0%	100.0%

Note: The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.

*Including any managed care plans

**"Other" includes Worker's Compensation and TRICARE

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.8 percent of total services will be provided to self-pay patients, 25 percent to Medicare patients, and 1.4 percent to Medicaid patients.

In Section L, page 90, 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 based on the following:

- Projected payor mix is based on the historical experience of patients projected to use the same services at CR-Union West and from the same service area.
- The applicant provides reasonable and adequately supported information to explain why there are no projected changes to the payor mix in future years.

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 the reasons stated above.

- (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, 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 based on the reasons stated above.

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

C

The applicant proposes to develop a new diagnostic center on the campus of AH-Union West.

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 in Exhibits M.1-1 and M.1-2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant has a history of providing access for health professional training programs for training purposes at its other existing facilities.
- The applicant has numerous existing arrangements with health professional training programs and provides documentation of those existing arrangements.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to develop a new diagnostic center on the campus of AH-Union West.

N.C.G.S. §131E-176(24a) defines “service area” as “... *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 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 30-31, and Section G, page 73, the applicant defines the service area as ZIP codes 28079, 28104, 28110, and 28173. Facilities may also serve residents of counties, in this case ZIP codes, not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 96, the applicant states:

“Charlotte Radiology believes the proposed project will have a positive effect on competition in the proposed services [sic] area. As the exclusive provider of breast services for Atrium Health and LCI facilities, the proposed project is essential to support the surgical and oncology services to be provided at Atrium Health Union West, a role that no other provider can fulfill, while also providing local access to Charlotte Radiology’s comprehensive screening and diagnostic breast services. By developing the project as proposed, Charlotte Radiology will bring comprehensive breast services directly to the residents of western Union County for the first time.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 96, the applicant states:

“..., by developing Union West Breast Center in the MOB currently under development on Atrium Health Union West’s campus, Charlotte Radiology is able to avoid the costs associated with constructing a new building from the ground up. The costs associated with the development of the proposed project are limited to the cost of the diagnostic imaging equipment and the necessary upfit of space currently under development within the MOB rather than the higher costs associated with new construction. Moreover, the proposed project will allow patients to benefit from the co-location of Charlotte Radiology’s world-class breast services alongside the surgical services and oncology services offered at Atrium Health Union West and LCI-Union West, providing convenient access to a full continuum of breast services and minimizing the costs of travelling to multiple sites for their care.”

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

Regarding the impact of the proposal on quality, in Section N, pages 96-97, the applicant states:

“Each of Charlotte Radiology’s breast centers is accredited by ACR, certified by the FDA, recognized as a Breast Imaging Center of Excellence, and comprised of physicians that are board-certified and subspecialized in mammography/breast imaging, having completed fellowships post-residency. ... Charlotte Radiology will utilize quality control and improvement policies at Union West Breast Center to ensure the provision of the highest quality care for patients, as it does at each of its existing facilities.”

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, pages 97-98, the applicant states:

“..., Charlotte Radiology is committed to providing services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. ...

Charlotte Radiology historically has provided substantial care and services to all persons, including the medically underserved. ... Upon completion of the proposed project, Union West Breast Center will be a participating Medicare and Medicaid provider to serve the elderly and low income residents of Union County.

... Patients in need of services from Charlotte Radiology will not be denied the necessary care based on their ability to pay. Charlotte Radiology is committed to work with all patients that may need financial assistance for services. Charlotte Radiology’s financial assistance program provides reduced cost screening mammograms for those patients that qualify for the program. Based on this commitment, low income and medically underserved persons will continue to have access to all imaging services provided by Charlotte Radiology. ...

As an example of this commitment, Charlotte Radiology, in partnership with LCI, developed Project Pink to provide local uninsured women aged 40 and older with access to essential breast cancer screening services. The Project Pink program provides free screening mammograms, as well as diagnostic breast imaging, related procedures, and diagnostic follow-up care. Through this program, Charlotte Radiology has provided over 1,000 uninsured and underinsured women in the region with vital breast cancer services and have identified more than 60 cases of breast cancer since the program began in 2011. Charlotte Radiology also provides imaging services and support for women who qualify for the North Carolina Breast and Cervical Cancer Control Program public health program.

... Union West Breast Center will be accessible to persons with disabilities as required by the Americans with Disabilities Act.”

See also Sections C and L 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.
- 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 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

The applicant proposes to develop a new diagnostic center on the campus of AH-Union West.

On Form O in Section Q, the applicant identifies all other diagnostic centers in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 10 diagnostic centers and 9 non-diagnostic center breast imaging centers located in North Carolina.

In Section O, page 101, the applicant states:

“Each of the facilities identified in Form O has continually maintained all relevant licensure, certification, and accreditation ..., for the 18 months preceding the submission of this application. No facilities on Form O Facilities have had incidents resulting in an immediate jeopardy during the 18 month look-back period.”

After reviewing and considering information provided by the applicant regarding the quality of care provided at all 10 diagnostic centers and all 9 non-diagnostic center breast imaging 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. There are no administrative rules that are applicable to proposals to develop new diagnostic centers.