

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 1, 2020

Findings Date: September 1, 2020

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: F-11904-20

Facility: Women's Institute NorthEast Diagnostic Center

FID #: 200464

County: Cabarrus

Applicant: The Charlotte-Mecklenburg Hospital Authority

Project: Develop a new diagnostic center in an existing MOB by adding ultrasound equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

The Charlotte-Mecklenburg Hospital Authority (hereinafter referred to as CMHA or "Atrium" or "the applicant") proposes to develop a new diagnostic center, Women's Institute NorthEast Diagnostic Center (WINE-DC), located in a medical office building on the campus of Atrium Health Cabarrus (AH Cabarrus) in Cabarrus County. The applicant proposes to add one "new" maternal fetal medicine ultrasound (MFM-U) machine in addition to four existing MFM-U machines. 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 2020 State Medical Facilities Plan (SMFP)
- Offer a new institutional health service for which there are any applicable 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- (2) Repealed effective July 1, 1987.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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new diagnostic center by adding a “new” maternal fetal medicine ultrasound (MFM-U) machine to four existing MFM-U machines located at Women's Institute NorthEast (WINE) on the campus of AH Cabarrus in Cabarrus County.

Designation as a Diagnostic Center

In Section C, pages 25-26, the applicant states the diagnostic center will be developed in the existing WINE clinic, located on the second floor of a medical office building on the campus of AH Cabarrus. The applicant does not propose to include any other areas of the medical office building as part of the proposed diagnostic center. The applicant proposes to acquire an MFM-U machine to replace an existing MFM-U machine, which is currently not in operation. If the proposed project is approved, the applicant proposes to operate the existing but not operational MFM-U machine as a “new” MFM-U machine until the replacement MFM-U machine can be acquired. In Section C, page 25, the applicant states:

“Atrium Health recently became aware that the total cost of all the medical diagnostic equipment which costs \$10,000 or more at Women's Institute NorthEast exceeded \$500,000, thus requiring diagnostic center designation. Upon realizing this, Women's Institute NorthEast took its fifth MFM ultrasound unit out of service until a Certificate of Need for designation as a diagnostic center could be obtained. As such, today the clinic currently is operating only four MFM ultrasound units, and the total value of the medical diagnostic equipment being used to provide health services in the clinic at the time of submission of this application is less than the \$500,000 diagnostic center threshold. Upon approval of the project proposed in this application and corresponding designation as a diagnostic center, [the Women's Institute NorthEast clinic] will operate as a diagnostic center and Atrium Health will bring the proposed “new” equipment – the fifth MFM ultrasound unit...back into operation.”

On page 26, the applicant states it includes the cost of acquiring the replacement MFM-U machine and any costs that would be incurred if the “new” MFM-U machine was being installed for the first time. On page 25, the applicant states there will be no renovation or upfit of space needed to bring the “new” MFM-U machine or the replacement MFM-U machine into operation.

On page 26, the applicant states the equipment will be used in an office-based clinic in support of physician services and will not be operated as an independent diagnostic testing facility.

Patient Origin

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 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 27, the applicant states its service area is Cabarrus, Iredell, Mecklenburg, Rowan, and Stanly counties. Facilities may also serve residents of counties not included in their service area.

WINE-DC is not an existing facility; however, in Section C, page 27, the applicant provided historical patient origin for the WINE clinic during CY 2019. The following table illustrates historical patient origin for the WINE clinic and projected patient origin for WINE-DC during the first three full fiscal years following project completion.

WINE Historical and WINE-DC Projected Patient Origin								
County	CY 2019		FY 1 – CY 2022		FY 2 – CY 2023		FY 3 – CY 2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Cabarrus	3,536	45.3%	3,726	45.3%	3,791	45.3%	3,857	45.3%
Mecklenburg	1,683	21.5%	1,773	21.5%	1,804	21.5%	1,836	21.5%
Rowan	998	12.8%	1,051	12.8%	1,070	12.8%	1,089	12.8%
Stanly	584	7.5%	615	7.5%	626	7.5%	637	7.5%
Iredell	249	3.2%	262	3.2%	267	3.2%	272	3.2%
Other*	763	9.8%	804	9.8%	818	9.8%	832	9.8%
Total	7,813	100.0%	8,232	100.0%	8,376	100.0%	8,523	100.0%

Source: Section C, pages 27-28

*Other includes Alexander, Anson, Buncombe, Burke, Caldwell, Catawba, Cleveland, Davidson, Davie, Durham, Forsyth, Gaston, Guilford, Harnett, Lincoln, McDowell, Montgomery, Moore, Randolph, Richmond, Robeson, Rutherford, Union, and Wilkes counties, as well as other states.

In Section C, page 29, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because its projected patient origin is based on its historical patient origin.

Analysis of Need

In Section C, pages 30-33, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- WINE is a maternal fetal medicine (MFM) clinic located on the campus of AH Cabarrus. The clinic, which provides reproduction and infertility services for its patients, serves high-risk patients, which necessitates ultrasound imaging during almost every patient visit. The ability to perform ultrasound imaging during each patient visit, and having the capacity to do so, is a critical part of managing the health and improving outcomes for these high-risk patients, especially since there can be rapid changes in fetal development.
- By ensuring physicians at the clinic have the necessary MFM ultrasound capacity to monitor and provide care for their patients, WINE-DC allows patients to receive ultrasound imaging at the same location they see their providers and much more quickly than if they had to be referred to an outside clinic with different scheduling.
- Having the necessary MFM ultrasound capacity for physicians to provide care avoids referring patients needing these services to a different location with potentially higher charges. Additionally, as a physician-based practice, WINE-DC will provide patients with an opportunity to lower their out-of-pocket medical costs.
- The “new” MFM-U machine was acquired in 2008 and has reached the end of its useful life – the vendor for the equipment will not service the unit any longer because it does not produce or have the necessary components. The applicant states that, despite needing to replace the “new” MFM-U machine, bringing the “new” MFM-U machine into operation once the CON is approved is preferable to not having the additional MFM-U machine and capacity.
- When the hospital campus now known as AH Cabarrus opened in 1937, it had 46 acute care beds and 10 bassinets; today, it has 457 acute care beds, focuses on research and education, and has an extensive network of inpatient and outpatient providers for its patients. WINE-DC will allow the existing clinic to continue to serve its high-risk patients in a convenient setting close to a hospital.
- According to the North Carolina Office of State Budget and Management (NC OSBM), the Cabarrus County population is projected to grow at a Compound Annual Growth Rate (CAGR) of 1.9 percent between 2019 and 2024, and projects Cabarrus County will have one of the highest numerical growth rates in the state. The Cabarrus County childbearing population will increase by 9.1 percent between 2019 and 2024, while that same population for all of North Carolina will increase by 5.7 percent between 2019 and 2024. The applicant states the increase in the childbearing population of Cabarrus County is significant because it is the patient population it projects to serve at WINE-DC.

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

- The applicant provides reasonable and adequately supported information to support its assertion that the physicians at WINE-DC will need five MFM-U machines to serve patients.
- The applicant adequately demonstrates the need to replace the “new” MFM-U machine.
- Reliable data sources are used to support assertions about population growth.

Projected Utilization

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

WINE-DC Projected Utilization			
	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
# of Units	5	5	5
# of Ultrasounds	8,232	8,376	8,523

In Section C, page 35, and in the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the annual maximum capacity for the five MFM-U machines it proposes for WINE-DC, as shown in the table below.

WINE-DC – Annual Maximum Capacity for MFM-U Machines					
Equipment Type	# Units	Procedures/Hour	Hours/Day	Days/Year	Maximum Annual Capacity*
MFM-U Machine	5	1.33**	7	250	11,667

Source: Section C, page 35; Form C Utilization – Assumptions and Methodology subsection of Section Q

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

**The applicant states a MFM ultrasound is typically longer than a general ultrasound procedure for an OB/GYN visit due to the complexity of monitoring high-risk pregnancies.

In Section C, pages 35-36, and in the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project maximum capacity. The applicant states its historic experience is that one MFM ultrasound takes approximately 45 minutes (or 1.33 procedures per hour), and it assumes all five MFM-U machines will be fully staffed every day WINE-DC will be open to serve patients.

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 number of MFM ultrasounds performed at WINE increased at a CAGR of 16 percent between 2017 and 2019.
- Prior to the COVID-29 pandemic, historical growth in utilization was high. While utilization may diminish in the short term due to the COVID-19 pandemic, it is impossible to determine the extent of any impact from the COVID-19 pandemic at this point.

- The applicant projects growth in the number of MFM ultrasounds at a 1.8 percent annual growth rate, which the applicant states is equivalent to the projected CAGR for the child-bearing population of Cabarrus County between 2019 and 2024.

The applicant’s projected utilization is summarized in the table below.

WINE-DC Projected Utilization – Project Years 1-3 (CYs 2022-2024)						
	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
# of Ultrasounds	7,813	7,950	8,090	8,232	8,376	8,523
Annual Growth Rate		1.8%	1.8%	1.8%	1.8%	1.8%
Number of MFM-U Machines		5	5	5	5	5
Utilization Rate		68.1%	69.3%	70.6%	71.8%	73.1%

* Based on the applicant’s calculated maximum utilization of 11,667 MFM ultrasounds on five MFM-U machines per year.

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

- Projected utilization is based in part on historical data.
- The applicant uses reliable sources for publicly available data it uses in its projected utilization.
- The applicant uses conservative projected growth rates.
- The applicant adequately demonstrates it has considered and accounted for any potential impact to projected utilization from the COVID-19 pandemic.

Access

In Section C, page 41, the applicant states:

“CMHA d/b/a Atrium Health provides services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. Atrium Health’s system-wide policies and procedures with regard to access to care will apply to the proposed diagnostic center. As noted in Atrium Health’s Non-Discrimination Policy Statement, ‘[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of [Atrium Health] on the basis of race, color, religion, national origin, sex, age, disability or source of payment.’ Atrium Health will continue to serve this population as dictated by the mission of Atrium Health, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved.”

In Section C, page 42, the applicant provides the estimated percentage for each medically underserved group during the third full fiscal year of operation following project completion, as shown in the following table.

WINE-DC Medically Underserved Groups – FY 3 (CY 2024)	
Medically Underserved Groups	Percent of Total Patients
Low Income Persons	--
Racial and Ethnic Minorities	28.4%
Women	100.0%
Persons with Disabilities	--
Persons Age 65 or Older	0.0%
Medicare Beneficiaries	0.4%
Medicaid Recipients	38.9%

In Section C, page 42, the applicant states:

“Atrium Health does not maintain data that includes the number of low income persons or [disabled] persons it serves. As such, Atrium Health does not have a reasonable basis to estimate the percentage of low income and [disabled] patients to be served by the project; however..., neither low income nor [disabled] persons are denied access to the proposed 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.

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 following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose 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 adding a “new” MFM-U machine to four existing MFM-U machines located at WINE on the campus of AH Cabarrus in Cabarrus County.

In Section E, page 51, 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 the clinic from being able to treat all of its patients, based on its historical and projected utilization. The applicant states maintaining the status quo would force physicians to refer patients elsewhere or increase wait times and would result in unnecessary delays in care; therefore, this is not an effective alternative.

Develop the Diagnostic Center with More MFM-U Machines: The applicant states developing the diagnostic center with more MFM-U machines is not warranted by patient demand at this time; therefore, this is not an effective alternative.

On page 51, the applicant states its proposal is the most effective alternative because it provides timely and convenient care to patients without adding more equipment than warranted by patient demand.

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

- The application is conforming to all statutory and regulatory criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

- 1. The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**
 - 2. The Charlotte-Mecklenburg Hospital Authority shall develop a new diagnostic center by acquiring a maternal fetal medicine ultrasound machine to replace an existing but not operational maternal fetal medicine ultrasound machine, in addition to four existing maternal fetal medicine ultrasound machines at Women's Institute NorthEast, located in a medical office building on the campus of Atrium Health Cabarrus.**
 - 3. The Charlotte-Mecklenburg Hospital Authority, as part of this project, shall not acquire 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.**
 - 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, The Charlotte-Mecklenburg Hospital Authority 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 Charlotte-Mecklenburg Hospital Authority 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 adding a “new” MFM-U machine to four existing MFM-U machines located at WINE on the campus of AH Cabarrus in Cabarrus County.

Capital and Working Capital Costs

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

Construction Costs	\$11,902
Medical Equipment Costs	\$123,715
Consultant/A&E Fees	\$69,000
Furniture/Miscellaneous Costs	\$5,710
Total	\$210,327

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 55, the applicant states the project does not involve any working capital costs.

Availability of Funds

In Section F, pages 53-54, the applicant states the capital cost of the project will be funded via accumulated reserves of CMHA/Atrium Health. Exhibit F.2-1 contains a letter from the Executive Vice President and Chief Financial Officer of Atrium Health authorizing use of existing accumulated cash reserves to develop the proposed project

Exhibit F.2-2 contains financial statements for CMHA/Atrium Health for the year ending December 31, 2019. As of December 31, 2019, CMHA/Atrium Health had adequate cash and cash equivalents to fund the proposed project.

Financial Feasibility

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

WINE-DC Revenue and Expenses – FYs 1-3 (CYs 2022-2024)			
	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Total Ultrasounds	8,232	8,376	8,523
Total Gross Revenues (Charges)	\$3,935,233	\$4,124,453	\$4,322,772
Total Net Revenue	\$1,639,364	\$1,718,191	\$1,800,808
Average Net Revenue per Ultrasound	\$199	\$205	\$211
Total Operating Expenses (Costs)	\$1,483,291	\$1,539,461	\$1,597,906
Average Operating Expense per Ultrasound	\$180	\$184	\$187
Net Income / (Loss)	\$156,073	\$178,730	\$202,902

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new diagnostic center by adding a “new” MFM-U machine to four existing MFM-U machines located at WINE on the campus of AH Cabarrus in Cabarrus County.

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 27, the applicant states its service area is Cabarrus, Iredell, Mecklenburg, Rowan, and Stanly counties. Facilities may also serve residents of counties not included in their service area.

In Section G, page 60, the applicant lists all hospital facilities offering ultrasound services in its defined service area, and states it is unaware of any publicly available data to show inventory and utilization of existing and approved non-hospital-based facilities and equipment providing services like those proposed in this application. In Exhibit G.2, the applicant provides copies of pages from 2020 License Renewal Applications (LRAs) for facilities in Cabarrus, Iredell, Mecklenburg, Rowan, and Stanly counties with equipment and services like those proposed in this application. On page 61, the applicant lists all the existing and approved diagnostic centers owned or operated by CMHA or an affiliated entity.

In Section G, page 61, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Cabarrus, Iredell, Mecklenburg, Rowan, and Stanly counties. The applicant states:

“The need for the proposed project is based on the need for Atrium Health to continue to provide convenient access to diagnostic services to support the MFM clinic, Women’s Institute NorthEast, The proposed diagnostic center will serve to optimize Atrium Health’s ability to continue to provide patient centered care in a cost-effective manner No other provider can meet the identified need for patients to have an ultrasound in conjunction with their visit to the MFM clinic. Further, though other imaging and diagnostic services may be available in the service area, they are not reasonably available to the patients of the MFM clinic physicians ...”

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
- 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.

- (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

On Form H in Section Q, the applicant provides projected staffing for the proposed services. The applicant projects to employ five FTE (full-time equivalent) radiology technologists to operate the MFM-U machines during each of the first three operating years following project completion.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 63-64, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs and provides supporting documentation in Exhibit H.3. In Exhibit I.2, the applicant provides letters of support from local physicians.

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

In Section I, page 65, the applicant states the following ancillary and support services are necessary for the proposed diagnostic center:

- Housekeeping
- Security
- Maintenance
- Registration
- Administration
- Other Ancillary and Support Services

On page 65, the applicant adequately explains how each ancillary and support service will be made available.

In Section I, pages 65-66, the applicant describes its existing 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.

- (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.

NA

The applicant does not propose to construct any new space or to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 76, the applicant provides the historical payor mix for CY 2019 patients utilizing the MFM-U machines at WINE, as shown in the table below.

Historical Payor Mix – WINE – CY 2019	
Entire Facility	
Payor Source	% of Services
Self-Pay	6.3%
Medicare*	0.4%
Medicaid*	38.9%
Insurance*	53.4%
Other**	1.0%
Total	100.0%

Source: Atrium Health internal data

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 other government payor sources and Worker's Compensation.

In Section L, pages 74-75, the applicant provides the following comparison.

WINE	% of Patients Served during CY 2019	Percent of Population by County				
		Cabarrus	Iredell	Mecklenburg	Rowan	Stanly
Female	100.0%	51.3%	50.8%	51.9%	50.6%	50.1%
Male	0.0%	48.7%	49.2%	48.1%	49.4%	49.9%
Unknown	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
64 and Younger	100.0%	86.8%	83.1%	88.8%	82.4%	81.1%
65 and Older	0.0%	13.2%	15.9%	11.2%	17.6%	18.9%
American Indian	0.3%	0.7%	0.6%	0.8%	0.6%	0.5%
Asian	4.3%	4.4%	2.7%	6.4%	1.3%	2.2%
Black or African-American	23.4%	19.0%	12.3%	32.9%	16.8%	11.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%	0.1%	0.1%	0.1%	0.3%
White or Caucasian	66.3%	73.4%	82.4%	57.5%	79.5%	84.1%
Other Race	0.4%	2.4%	2.0%	2.4%	1.7%	1.5%
Declined / Unavailable	5.3%	0.0%	0.0%	0.0%	0.0%	0.0%

Sources: Atrium Health Internal Data, US Census Bureau QuickFacts

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 76, the applicant states that it has no such obligations.

In Section L, page 76, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.

- (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, page 77, 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.

WINE-DC Payor Mix – FY 3 (CY 2024)	
Payor Source	Percent of Services
Self-Pay	6.3%
Medicare*	0.4%
Medicaid*	38.9%
Insurance*	53.4%
Other**	1.0%
Total	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 other government payor sources and Worker's Compensation.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 6.3 percent of total services will be provided to self-pay patients, 0.4 percent to Medicare patients, and 38.9 percent to Medicaid patients.

In Section L, page 77, 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 for the following reasons:

- Projected payor mix is based on CMHA's historical experience in providing the proposed services.
- The applicant provides reasonable and adequately supported information to explain why there are no changes to the projected 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.

- (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 78, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new diagnostic center by adding a “new” MFM-U machine to four existing MFM-U machines located at WINE on the campus of AH Cabarrus in Cabarrus County.

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 27, the applicant states its service area is Cabarrus, Iredell, Mecklenburg, Rowan, and Stanly counties. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 82, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to diagnostic services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 82, the applicant states:

“The proposed project will enable Atrium Health to continue to provide its patients with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment and efficient utilization of existing resources.”

Regarding the impact of the proposal on quality, in Section N, page 82, the applicant states:

“Atrium Health believes that the proposed project will promote safety and quality in the delivery of healthcare services. Atrium Health is known for providing high quality services and expects the proposed project to bolster this reputation.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 84, the applicant states:

“The proposed project will improve access to diagnostic services in the service area. Atrium Health has long-promoted economic access to its services as it has historically provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay...

Further, as a physician-based service, the proposed diagnostic center will provide services at a low out-of-pocket cost to most patients. Since physician-based services are categorized in a lower tier, patients benefit from low out-of-pocket expenses. As

such, the proposed project will allow Atrium Health to continue to provide access to diagnostic services, including to medically underserved groups.”

Considering all the information in the application, 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 (see Sections C, F, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N of the application and any exhibits)

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

On Form A 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 11 existing and approved diagnostic centers located in North Carolina.

In Section O, page 88, the applicant states:

“Each of the facilities identified...has continually maintained all relevant and applicable licensure, certification, and accreditation for the 18 months preceding the submission of this application.”

After reviewing and considering information provided by the applicant regarding the quality of care provided at all 11 existing and approved 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.
- (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.