

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 25, 2019

Findings Date: November 25, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: G-11754-19

Facility: Triad Breast Imaging Center

FID #: 190382

County: Guilford

Applicant: Triad Breast Imaging Center, LLC

Project: Develop a new diagnostic center including mammography, ultrasound, and dual energy x-ray absorptiometry scan

### 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

Triad Breast Imaging Center, LLC (hereinafter referred to as Triad Breast Imaging Center or “the applicant”) proposes to develop a new diagnostic center, Triad Breast Imaging Center, in an existing medical office building at 3515 W. Market Street in Greensboro. The combined value of the medical diagnostic equipment costing \$10,000 or more and the proposed replacement R&F system and some construction costs 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.

**Need Determination**

The applicant does not propose to develop any beds or services for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP) nor acquire any medical equipment for which there is a need determination in the 2019 SMFP.

**Policies**

The applicant does not propose to offer a new institutional health service for which there are any applicable policies in the 2019 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- (2) Repealed effective July 1, 1987.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, Triad Breast Imaging Center, in an existing medical office building at 3515 W. Market Street in Greensboro. The proposed diagnostic center will include three diagnostic modalities, including mammography, ultrasound and bone density.

**Designation as a Diagnostic Center**

In Section C, page 15, the applicant states the proposed diagnostic center will offer mammography, bone density, and ultrasound services. In Section C, page 15, and Section F.1, page 78, the applicant provides a table showing the new medical diagnostic equipment, with each costing \$10,000 or more, which is summarized below:

<b>Triad Breast Imaging Center: Medical Diagnostic Equipment</b>		
<b>Equipment</b>	<b>Number of Units</b>	<b>Cost</b>
Mammography	1	\$509,548
Ultrasound	1	\$119,732
Bone Density	1	\$39,000
<b>Subtotal</b>		<b>\$668,280</b>
Other Costs*		\$990,932
<b>Totals</b>		<b>\$1,659,212</b>

\*See Form F.1a for all non-medical equipment costs.

As shown in the table above, the combined cost of the medical diagnostic equipment is more than \$500,000 and therefore a certificate of need is required to develop a diagnostic center.

**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 2019 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 22, the applicant defines the service area as Guilford and Rockingham counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

**Mammography: Projected Patient Origin**

County	FY1 10/1/2020 – 9/30/2021		FY2 10/1/2021 – 9/30/2022		FY3 10/1/2022 – 9/30/2023	
	# of patients	% of total	# of patients	% of total	# of patients	% of total
Guilford	3,080	95%	3,318	95%	3,782	95%
Rockingham	162	5%	175	5%	184	5%
Total	3,242	100%	3,493	100%	3,674	100%

Source: Section C.3, page 18

**Ultrasound: Projected Patient Origin**

County	FY1 10/1/2020 – 9/30/2021		FY2 10/1/2021 – 9/30/2022		FY3 10/1/2022 – 9/30/2023	
	# of patients	% of total	# of patients	% of total	# of patients	% of total
Guilford	273	95%	294	95%	309	95%
Rockingham	14	5%	15	5%	16	5%
Total	287	100%	310	100%	326	100%

Source: Section C.3, page 18

**Dexa\*: Projected Patient Origin**

County	FY1 10/1/2020 – 9/30/2021		FY2 10/1/2021 – 9/30/2022		FY3 10/1/2022 – 9/30/2023	
	# of patients	% of total	# of patients	% of total	# of patients	% of total
Guilford	200	95%	216	95%	227	95%
Rockingham	11	5%	11	5%	12	5%
Total	211	100%	227	100%	239	100%

Source: Section C.3, page 18

\*Bone Density

In Section C, page 19, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 19-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 22, the applicant states:

- The population in Guilford and Rockingham counties is both aging and growing, particularly women 65 and older, who frequently use breast imaging and other women’s imaging services (page 25).
- The service area of Guilford and Rockingham counties have high cancer incidence rates including breast cancer rates, the treatment of which is benefitted by early detection and diagnosis (pages 25-26).
- Currently, a large base of Novant Health patients seeking women’s imaging services at Novant Health hospitals and imaging services in Davidson, Forsyth and Rowan counties originate from the service area of Guilford and Rockingham counties (pages 22-24).
- The proposed project will reduce travel time for patients to access women’s imaging services within the Novant Health system (page 24).

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

- Reliable data sources are used to support assertions about population growth and aging in the proposed service area.
- The applicant provides reasonable and adequately supported information to support its assertion that a large number of existing Novant Health patients utilizing women’s imaging services at Novant Health facilities outside the proposed service area originate from Guilford and Rockingham counties.

*Projected Utilization*

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

**Triad Breast Center Imaging: Projected Utilization**

Component	FY1 10/1/2020 – 9/30/2021	FY2 10/1/2021 – 9/30/2022	FY3 10/1/2022 – 9/30/2023
Mammography	3,242	3,493	3,674
Ultrasound	287	310	326
Dexa	211	227	239
Totals	3,740	4,030	4,239

Source: Section Q, pages 75-76.

In Section C, pages 27-30, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step1: Determine Base of Patients

**Outpatient Women’s Imaging Services, by Type, in the Calendar Year 2018 at Identified Novant Health Facilities: Patient Origin- Guilford and Rockingham Counties**

	<b>KMC*</b>	<b>TMC**</b>	<b>WMQ***</b>	<b>RMC Mobile****</b>	<b>Total Service Area Procedures</b>
Mammography Screening	1,935	371	2,091	539	4,936
Mammography Diagnostic	289	52	316	11	668
Ultrasound	243	51	215	5	514
Dexa	301	--	29	4	334
<b>Total</b>	<b>2,768</b>	<b>474</b>	<b>2,651</b>	<b>559</b>	<b>6,452</b>

Source: Internal Novant Health data

\*Novant Health Kernersville Medical Center

\*\*Novant Health Thomasville Medical Center

\*\*\*Novant Health Breast Center-Winston-Salem

\*\*\*\*Rowan Medical Center Mobile Unit

The table above reflects the total number of patients from Guilford and Rockingham counties utilizing certain Novant Health facilities outside of Guilford and Rockingham counties for women’s imaging services for the calendar year 2018. See page 27 of the application.

Step 2: Determine Internal Shift of Patients-

On page 27, for each imaging service the applicant determined that 60% of the existing patients from KMC and TMC in Step 1, would shift to the proposed Triad Breast Imaging Center, and 40% of the existing patients from WMQ and RMC Mobile would shift to the proposed Triad Breast Imaging Center, calculated as follows.

**Mammography Screening**

	<b>CY2018 Actual</b>	<b>% Shift</b>	<b># of Projected Procedures to Shift</b>
KMC	1,935	60%	1,161
TMC	371	60%	223
WMQ	2,091	40%	836
RMC Mobile	539	40%	216
<b>Total Historical Patients</b>	<b>4,936</b>		<b>2,436</b>

Source: Section C, page 28.

**Mammography Diagnostic**

	<b>CY2018 Actual</b>	<b>% Shift</b>	<b># of Projected Procedures to Shift</b>
KMC	289	60%	173
TMC	52	60%	31
WMQ	316	40%	126
RMC Mobile	539	40%	216
<b>Total Historical Patients</b>	<b>1,196</b>		<b>547</b>

Source: Section C, page 28.

**Ultrasound**

	<b>CY2018 Actual</b>	<b>% Shift</b>	<b># of Projected Procedures to Shift</b>
KMC	243	60%	146
TMC	51	60%	31
WMQ	215	40%	86
RMC Mobile	5	40%	2
<b>Total Historical Patients</b>	<b>514</b>		<b>264</b>

Source: Section C, page 28.

**Dexa**

	<b>CY2018 Actual</b>	<b>% Shift</b>	<b># of Projected Procedures to Shift</b>
KMC	301	60%	181
TMC	--	60%	--
WMQ	29	40%	12
RMC Mobile	4	40%	2
<b>Total Historical Patients</b>	<b>334</b>		<b>194</b>

Source: Section C, page 28.

Step 3: Determine Population Growth

	<b>Population Growth</b>
Project Year 1: 10/1/2020 – 9/30/2021	3.53%
Project Year 2: 10/1/2021 – 9/30/2022	2.86%
Project Year 3: 10/1/2022 – 9/30/2023	2.86%

Source: Table on page 29 of the application.

The projected population growth rates for the first three project years are reasonable. The applicant determined population growth rates for the first three project years utilizing data from the North Carolina Office of State Budget and Management (NCOSBM), including the growth rate for women 65 and over, and projected patient origin percentages of 95% from Guilford County and 5% from Rockingham County. On page 25, the applicant states, *“imaging services are provided at the greatest rate to patients age 65 and older.”* The population growth for project year one represents 1.75 years of growth from 2018 until the proposed opening of the facility. Based on projected patient origin the applicant determined a weighted average of 2.86 percent which was applied to the second and third project years. See pages 28-29 of the application.

Step 4: Determine Incremental Growth

The applicant assumes a 5% incremental growth rate in project year one and year two due to the opening of a new Novant Health facility in Greensboro, and a 2.5% incremental growth rate in project year three which mimics the population growth rate. These growth rates are applied to the number of historic procedures expected to shift as determined in Step 2. See page 29 of the application.

**Mammography Screening**

Project Year	Historic # of Procedures Expected to Shift*	% Population Growth	% Incremental Growth	Projected Procedures
FY1	2,436	3.53%	5.0%	2,648
FY2	2,436	2.86%	10.0%	2,853
FY3	2,436	2.86%	12.5%	3,001

\*From Step 2.

Source: Section C, page 29.

**Mammography Diagnostic**

Project Year	Historic # of Procedures Expected to Shift*	% Population Growth	% Incremental Growth	Projected Procedures
FY1	547	3.53%	5.0%	594
FY2	547	2.86%	10.0%	640
FY3	547	2.86%	12.5%	673

\*From Step 2.

Source: Section C, page 29.

**Ultrasound**

Project Year	Historic # of Procedures Expected to Shift*	% Population Growth	% Incremental Growth	Projected Procedures
FY1	264	3.53%	5.0%	287
FY2	264	2.86%	10.0%	310
FY3	264	2.86%	12.5%	326

\*From Step 2.

Source: Section C, page 29.

**Dexa**

Project Year	Historic # of Procedures Expected to Shift*	% Population Growth	% Incremental Growth	Projected Procedures
FY1	194	3.53%	5.0%	211
FY2	194	2.86%	10.0%	227
FY3	194	2.86%	12.5%	239

\*From Step 2.

Source: Section C, page 29.

**Step 5: Calculate Utilization by Procedure: Summary**

	FY1 10/1/2020 – 9/30/2021	FY2 10/1/2021 – 9/30/2022	FY3 10/1/2022 – 9/30/2023
Mammography Screening	2,648	2,853	3,001
Mammography Diagnostic	594	640	673
Total Mammography	3,242	3,493	3,674
Ultrasound	287	310	326
Dexa	211	227	239
<b>Totals</b>	<b>3,740</b>	<b>4,030</b>	<b>4,239</b>

Source: Section C, page 30.

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

- Projected utilization is based on population data from NCOSBM.
- The applicant uses a growth rate for the 65+ group because imaging services are provided at the greatest rate to this population, thereby creating additional demand.
- The applicant utilizes historic patient data from the proposed service area to project utilization.
- The applicant provides reasonable and adequately supported information to justify the need for the equipment.

**Access**

In Section C, page 36, the applicant states that Triad Breast Imaging Center will provide services in a manner that is consistent with:

- Title VI of the Civil Rights Act of 1963 (and any applicable amendments)
- Section 504 of the Rehabilitation Act of 1973 (and any applicable amendments, and
- The Age Discrimination Act of 1975 (and any applicable amendments).

In Section L, page 63, 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.

<b>Payor Source</b>	<b>Entire Facility</b>	<b>Mammogram</b>	<b>Ultrasound</b>	<b>Dexa</b>
Self-Pay/Charity Care	1.0%	1.0%	1.0%	1.0%
Medicare*	24.9%	24.9%	24.9%	24.9%
Medicaid *	2.8%	2.8%	2.8%	2.8%
Insurance*	68.2%	68.2%	68.2%	68.2%
TRICARE	1.7%	1.7%	1.7%	1.7%
Other (Institutional)	1.4%	1.4%	1.4%	1.4%
<b>TOTAL</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 63 of the application.

\*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Response to remarks made at the public hearing



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 projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) 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, eliminate or relocate mammography, ultrasound, and dual energy x-ray absorptiometry scan services; 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 in Greensboro to include mammography, ultrasound and bone density services.

In Section E, page 43, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: The applicant states this option would not meet the Novant Health patient need within the service area for the proposed diagnostic imaging services. Therefore, this is not an effective alternative.
- Add a Mobile Unit in Greensboro: The applicant states that this option would result in capacity restraints based on projected utilization of the proposed services. Therefore, this is not an effective or least costly alternative.

On page 43, the applicant states that its proposal is the most effective alternative because it provides more convenient and enhanced access for the projected patient population to the proposed diagnostic imaging services.

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 review 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
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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. Triad Breast Imaging Center, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Triad Breast Imaging Center, LLC shall develop a new diagnostic center in Greensboro with no more than one 3D mammography unit, one ultrasound unit and one bone densitometer unit.**
- 3. Triad Breast Imaging Center, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Triad Breast Imaging Center, LLC 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. Triad Breast Imaging Center, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance 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 in Greensboro to include mammography, ultrasound and bone density services.

**Capital and Working Capital Costs**

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

Site Costs	\$0
Construction Costs	\$420,310
Miscellaneous Costs	\$1,238,902
<b>Total</b>	<b>\$1,659,212</b>

In Section Q, Form F.1a and Exhibits F-1 (Tab 3) and K-3 (Tab 10), the applicant provides the assumptions used to project the capital cost.

In Section F, page 46, the applicant projects that start-up costs will be \$35,414 and initial operating expenses will be \$84,027 for a total working capital of \$119,441. On pages 45-46, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F, page 44, the applicant states that the capital cost will be funded as shown in the table below.

**Sources of Capital Cost Financing**

Type	Triad Breast Imaging Center, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$1,659,212	\$1,659,212
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$1,659,212</b>	<b>\$1,659,212</b>

\* OE = Owner's Equity

In Section F, page 46, the applicant states that the working capital needs of the project will be funded as shown in the table below.

<b>Sources of Financing for Working Capital</b>		<b>Amount</b>
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$119,441
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	<b>Total *</b>	<b>\$119,441</b>

Exhibit F-2.1, Tab 4, contains a letter dated August 1, 2019 from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc. (Novant) documenting that Novant is the parent entity of Triad Breast Imaging Center, LLC, that Novant is willing to commit accumulated reserves to fund the capital and working capital costs of the project and that Novant has sufficient accumulated reserves which are available to fund the proposed project. Exhibit F-2.2, Tab 4, contains the 2018 and 2017 audited financial statements for Novant which show cash and cash equivalents for 2018 of \$228,653,000.

**Financial Feasibility**

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

	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>	<b>3<sup>rd</sup> Full Fiscal Year</b>
Total Procedures	3,740	4,030	4,239
Total Gross Revenues (Charges)	\$891,286	\$989,208	\$1,071,721
Total Net Revenue	\$464,360	\$515,377	\$558,367
Average Net Revenue per Procedures	\$124	\$128	\$132
Total Operating Expenses (Costs)*	\$302,968	\$313,682	\$323,691
Average Operating Expense per Procedures	\$81	\$78	\$76
Net Income**	\$161,392	\$201,695	\$234,676

Totals might not foot due to rounding.

\*Note: The total operating expenses in Form 2 did not match the total operating expenses in Form 3, which Form 2 identified as the source of total operating expense, therefore the Project Analyst used the total operating expenses from Form 3.

\*\*As calculated by the Project Analyst.

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
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 in Greensboro to include mammography, ultrasound and bone density services.

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 2019 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 22, the applicant defines the service area as Guilford and Rockingham counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 50, the applicant identifies eleven providers of mammography services in the proposed service area based on publicly available data, but states that not all the providers identified are diagnostic imaging centers or offer a full range of women’s imaging services. Furthermore, the applicant states it is “*not aware of a public data source that provides annual utilization for non-hospital facilities that provide the services proposed in this project. While limited data is available for some hospital imaging services, a full range of women’s imaging services are not reported publicly.*”

In Section G, pages 50-51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic imaging services in the proposed service area constituting Guilford and Rockingham counties. The applicant, on page 50, states,

*“The need for the proposed project is based on the need for Novant Health to provide convenient access to diagnostic imaging services for existing Novant Health patients in Guilford and Rockingham County. No other provider can meet the identified need. While other imaging services are available in the area, there is no facility available for patients that prefer to remain in the Novant Health Network. Novant Health’s Guilford and Rockingham County patients are currently traveling significant distances for women’s imaging services.”*

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
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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

In Section Q, Form H, page 81, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

<b>Triad Breast Imaging Center: Projected Staffing</b>			
<b>Position</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
Radiology Technologists	1.5	1.5	1.5
Business Office	1.0	1.0	1.0
<b>Total</b>	<b>2.5</b>	<b>2.5</b>	<b>2.5</b>

**Source:** Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section C, page 31. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.2, which is found in Section Q. In Section H.2 and H.3, pages 52-53, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I, page 56, the applicant identifies the proposed medical director. In Exhibit I-3 (Tab 8), the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed

services. In Exhibit H-3.1 (Tab 5) and Exhibit H-3.2 (Tab 5), the applicant provides supporting documentation.

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 54, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Medical Direction
- Front Desk
- Management of Center
- Equipment Maintenance

On page 54, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.1 (Tab 6) and Exhibit I.1.2 (Tab 6).

In Section I, pages 55-56, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2 (Tab 7), Exhibit C-4 (Tab 2) and Exhibit I-3 (Tab 8).

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
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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.

### C

In Section K.2, page 58, the applicant states that the project involves up fitting 3,821 square feet of leased space in a medical office building. Line drawings are provided in Exhibit K-2 (Tab 9).

On page 58, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-3 (Tab 10).

On page 58, 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.

In Section K.3, page 59, 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.

- (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;

### NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. 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

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. 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, page 63, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Payor Source</b>	<b>Entire Facility</b>	<b>Mammogram</b>	<b>Ultrasound</b>	<b>Dexa</b>
Self-Pay/Charity Care	1.0%	1.0%	1.0%	1.0%
Medicare*	24.9%	24.9%	24.9%	24.9%
Medicaid *	2.8%	2.8%	2.8%	2.8%
Insurance*	68.2%	68.2%	68.2%	68.2%
TRICARE	1.7%	1.7%	1.7%	1.7%
Other (Institutional)	1.4%	1.4%	1.4%	1.4%
<b>TOTAL</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on page 63 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.0% of total services will be provided to self-pay/charity care patients, 24.9% to Medicare patients and 2.8% to Medicaid patients.

On page 63, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the actual payor mix of patients collectively traveling to existing Novant Health imaging services in Forsyth, Rowan, and Davidson counties for the proposed modalities.

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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

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

C

In Section L.5, page 65, 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
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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 67, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2 (Tab 13).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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 in Greensboro to include mammography, ultrasound and bone density services.

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 2019 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 22, the applicant defines the service area as Guilford and Rockingham counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 50, the applicant identifies eleven providers of mammography services in the proposed service area based on publicly available data, but states that not all the providers identified are diagnostic imaging centers or offer a full range of women’s imaging services. Furthermore, the applicant states it is, “*not aware of a public data source that provides annual utilization for non-hospital facilities that provide the services proposed in this project. While limited data is available for some hospital imaging services, a full range of women’s imaging services are not reported publicly.*”

In Section N, page 68, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 68, the applicant states,

*“The proposed project will have a favorable impact on cost-effectiveness, quality of care, and provide access to the medically underserved. There will also be no adverse impact on*

*existing providers in the Greensboro area. The proposed facility is open to the public, with the presumption that a large number of patients will come from Novant Health.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Response to remarks made at the public hearing

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

In Section Q, Form A, the applicant identifies twenty-two diagnostic centers that are owned and operated by Novant Health.

On page 71, the applicant states,

*“During the 18-month look-back period, neither DHSR nor CMS has determined that the listed facilities operated out of compliance with Medicare Conditions of Participation.”*

The Project Analyst notes that this includes no incidents resulting in a finding of immediate jeopardy. After reviewing and considering information provided by the applicant regarding the quality of care provided at the other twenty-two facilities, 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.