

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 26, 2021

Findings Date: April 26, 2021

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: F-11990-20

Facility: Novant Health Presbyterian Breast Center

FID #: 200894

County: Mecklenburg

Applicant(s): Presbyterian Breast Center, LLC

Novant Health, Inc.

Project: Relocate diagnostic center to new site within the county, replace some existing equipment, and add additional mammography equipment and an ultrasound unit

REVIEW CRITERIA

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

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

C

Presbyterian Breast Center, LLC and Novant Health, Inc. (referred to as “the applicant”) propose to relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit. The existing diagnostic center currently provides mammography, ultrasound, DEXA, and stereotactic breast biopsy services at its existing diagnostic center. In Section Q, Form F.1a, the applicant indicates the cost to acquire the proposed mammography equipment, ultrasound unit and installation is \$12,198,260. Following acquisition of the proposed equipment, the combined costs of all the medical diagnostic equipment will exceed the statutory threshold of \$500,000. Therefore, the proposed project qualifies as a diagnostic center, which is a new institutional health service, and which requires a Certificate of Need (CON).

N.C. Gen. Stat. 131E-176(7a) states:

““Diagnostic center” means a freestanding facility, program, or provider, including but not limited to, physicians’ offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.”

Need Determination

The applicant does not propose to develop any beds or services nor acquire any medical equipment for which there is a need determination in the 2020 SMFP.

Policies

There is one policy in the 2020 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4, on page 31 of the 2020 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in

paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, page 14, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant states that Novant Health is sustainably managing energy and water consumption by participating in activities such as assigning oversight to a Corporate Energy Manager, benchmarking portfolio efficiency by performing utility assessments and progressively converting to more efficient equipment, environmentally preferable products and practices.

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 based on the following:

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates the project’s plan to assure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 based on the following:
 - Novant Health has an existing Sustainable Energy Management Plan (SEMP) and provides supporting documentation in K.4.
 - The applicant states that Novant Health will work with the Agency to develop a plan that conforms to, or exceeds, energy efficiency and water conservation standards.

(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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional

mammography units and one ultrasound unit. The services to be relocated include mammography, ultrasound, DEXA, and stereotactic breast biopsy.

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 26, the applicant identifies the primary service area as Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

Presbyterian Breast Center Historical Patient Origin, 01/01/2019-12/31/2019 (CY2019)										
County	Bone Density (DEXA)		Mammography		Stereotactic		Ultrasound		Total	
	Patients	% of Total	Patients	% of Total	Patients	% of Total	Patients	% of Total	Patients	% of Total
Mecklenburg	1,510	88.1%	9,690	79.7%	98	73.7%	3,280	77.9%	14,578	80.0%
Gaston	99	5.8%	751	6.2%	6	4.5%	214	5.1%	1,070	5.9%
York	22	1.3%	388	3.2%	6	4.5%	163	3.9%	579	3.2%
Union	21	1.2%	352	2.9%	9	6.8%	159	3.8%	541	3.0%
Cabarrus	18	1.1%	344	2.8%	6	4.5%	147	3.5%	515	2.8%
Lincoln	12	0.7%	126	1.0%	2	1.5%	48	1.1%	188	1.0%
Iredell	4	0.2%	57	0.5%	2	1.5%	54	1.3%	117	0.6%
Stanly	5	0.3%	65	0.5%	1	0.8%	12	0.3%	83	0.5%
Other*	23	1.3%	379	3.1%	3	2.3%	133	3.2%	538	3.0%
Total	1,714	100.0%	12,152	100.0%	133	100.0%	4,210	100.0%	18,209	100.0%

Source: Section C, page 21

*Includes less than one percent patient origin remaining in North Carolina counties and other states.

Presbyterian Breast Center Projected Patient Origin for Mammography						
County	1 st Full FY CY2024		2 nd Full FY CY2025		3 rd Full FY CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Mecklenburg	10,535	79.7%	10,874	79.7%	11,223	79.7%
Gaston	817	6.2%	843	6.2%	870	6.2%
York	422	3.2%	435	3.2%	449	3.2%
Union	383	2.9%	395	2.9%	408	2.9%
Cabarrus	374	2.8%	386	2.8%	398	2.8%
Lincoln	137	1.0%	141	1.0%	146	1.0%
Iredell	62	0.5%	64	0.5%	66	0.5%
Stanly	71	0.5%	73	0.5%	75	0.5%
Other*	412	3.1%	425	3.1%	439	3.1%
Total	13,212	100.0%	13,637	100.0%	14,074	100.0%

Source: Section C, page 23

*Includes less than one percent patient origin remaining in North Carolina counties and other states.

Presbyterian Breast Center Projected Patient Origin for Ultrasound						
County	1 st Full FY CY2024		2 nd Full FY CY2025		3 rd Full FY CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Mecklenburg	4,179	77.9%	4,450	77.9%	4,657	77.9%
Gaston	273	5.1%	290	5.1%	304	5.1%
York	208	3.9%	221	3.9%	231	3.9%
Union	203	3.8%	216	3.8%	226	3.8%
Cabarrus	187	3.5%	199	3.5%	209	3.5%
Lincoln	61	1.1%	65	1.1%	68	1.1%
Iredell	69	1.3%	73	1.3%	77	1.3%
Stanly	15	0.3%	16	0.3%	17	0.3%
Other*	169	3.2%	180	3.2%	189	3.2%
Total	5,363	100.0%	5,711	100.0%	5,977	100.0%

Source: Section C, page 23

*Includes less than one percent patient origin remaining in North Carolina counties and other states.

Presbyterian Breast Center Projected Patient Origin for DEXA						
County	1 st Full FY CY2024		2 nd Full FY CY2025		3 rd Full FY CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Mecklenburg	1,656	88.1%	1,708	88.1%	1,762	88.1%
Gaston	109	5.8%	112	5.8%	115	5.8%
York	24	1.3%	25	1.3%	26	1.3%
Union	23	1.2%	24	1.2%	24	1.2%
Cabarrus	20	1.1%	20	1.1%	21	1.1%
Lincoln	13	0.7%	14	0.7%	14	0.7%
Iredell	4	0.2%	5	0.2%	5	0.2%
Stanly	5	0.3%	6	0.3%	6	0.3%
Other*	25	1.3%	26	1.3%	27	1.3%
Total	1,880	100.0%	1,939	100.0%	2,000	100.0%

Source: Section C, page 24

*Includes less than one percent patient origin remaining in North Carolina counties and other states.

Presbyterian Breast Center Projected Patient Origin for Stereotactic Breast Biopsy						
County	1 st Full FY CY2024		2 nd Full FY CY2025		3 rd Full FY CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Mecklenburg	151	73.7%	156	73.7%	161	73.7%
Gaston	9	4.5%	10	4.5%	10	4.5%
York	9	4.5%	10	4.5%	10	4.5%
Union	14	6.8%	14	6.8%	15	6.8%
Cabarrus	9	4.5%	10	4.5%	10	4.5%
Lincoln	3	1.5%	3	1.5%	3	1.5%
Iredell	3	1.5%	3	1.5%	3	1.5%
Stanly	2	0.8%	2	0.8%	2	0.8%
Other*	5	2.3%	5	2.3%	5	2.3%
Total	205	100.0%	211	100.0%	218	100.0%

Source: Section C, page 24

*Includes less than one percent patient origin remaining in North Carolina counties and other states.

In Section C, page 25-26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on Presbyterian Breast Center’s historical patient origin for diagnostic services and its expectation that projections will be consistent with the facility’s historical experience.
- The applicant projected patient origin by modality based on the CY2019 ratio of diagnostic procedures to patients.

Analysis of Need

In Section C, pages 26-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

Presbyterian Breast Center Service Area (pages 26-27)

The 2020 SMFP does not define the service area for diagnostic centers. The applicant defines the service area as Mecklenburg County based on the Presbyterian Breast Center’s experience providing diagnostic services in the local marketplace and its efforts to remain consistent with the historical and projected patient utilization. The applicant proposes to relocate the facility less than a half mile from the current location. The applicant states that the proposed project will not impact patient access to services.

Utilization of Presbyterian Breast Center Services (pages 27-33)

The applicant states that Presbyterian Breast Center has experienced an increase in demand for women’s diagnostic services. Presbyterian Breast Center is a major referral center for Novant Health providers and community physicians because the facility is the only Novant Health comprehensive breast center in Central Charlotte. On pages 27-33, the applicant describes the

utilization of each modality experienced at Presbyterian Breast Center, including the effects on utilization from COVID-19.

Mammography

The applicant states that the facility is at capacity for screening mammograms with only one screening mammogram unit. As a result, the facility is experiencing a screening wait of eight business days during non-peak months. The proposed project includes the acquisition of two additional 3D mammography machines. The applicant states that the facility experienced a Compound Annual Growth Rate (CAGR) of 3.2 percent during CY2016-CY2019 for screening mammogram procedures as illustrated in the table below.

Presbyterian Breast Center Screening Mammogram Procedures						
	CY2016	CY2017	CY2018	CY2019	3-Year CAGR	CY2020*
Screening Mammogram	7,594	7,877	7,974	8,349	3.2%	6,671

Source: Section C, page 28

*Annualized based on January-September data.

The applicant states that Presbyterian Breast Center also experienced a growth in diagnostic mammogram procedures which further demonstrates the need for the proposed project to ensure continued access to high quality diagnostic services. See table below.

Presbyterian Breast Center Diagnostic Mammogram Procedures						
	CY2016	CY2017	CY2018	CY2019	3-Year CAGR	CY2020*
Diagnostic Mammogram	6,630	6,427	6,582	6,792	0.8%	5,847

Source: Section C, page 29

*Annualized based on January-September data.

Breast Ultrasound

The applicant states that breast ultrasound procedures are conducted, if necessary, after a mammogram procedure. In addition to mammograms, Presbyterian Breast Center has experienced steady and robust growth in breast ultrasound procedures. The applicant states that the facility experienced a CAGR of 4.9 percent during CY2016-CY2019 for breast ultrasound procedures as illustrated in the table below.

Presbyterian Breast Center Breast Ultrasound Procedures						
	CY2016	CY2017	CY2018	CY2019	3-Year CAGR	CY2020*
Breast Ultrasound	3,965	3,884	4,068	4,582	4.9%	3,919

Source: Section C, page 29

*Annualized based on January-September data.

Breast Biopsies

The applicant states that breast biopsies are additional diagnostic procedures that determine if a patient might have breast cancer. The applicant states that as the demand for screening and diagnostic mammograms continues to increase, the demand for breast biopsies procedures will similarly increase. The following table summarizes recent annual biopsy utilization at Presbyterian Breast Center.

Presbyterian Breast Center Breast Biopsy Procedures					
	CY2016	CY2017	CY2018	CY2019	CY2020*
Mammography Biopsy	219	162	84	103	84
Breast Biopsy	609	432	414	309	277
Stereotactic Breast Biopsy	264	206	182	148	136

Source: Section C, page 30

*Annualized based on January-September data.

Bone Densitometry (DEXA)

The applicant states that Presbyterian Breast Center also experienced a growth in bone density procedures, however the proposed project will not increase the number DEXA units. The applicant states that the proposed project involves replacing an aged unit, which further demonstrates the need for the proposed project to ensure continued timely access to high quality diagnostic services. See table below.

Presbyterian Breast Center Bone Densitometry (DEXA) Procedures						
	CY2016	CY2017	CY2018	CY2019	3-Year CAGR	CY2020*
DEXA Procedures	1,538	1,736	1,625	1,765	4.7%	1,192

Source: Section C, page 31

*Annualized based on January-September data.

Automated Breast Ultrasound System (ABUS)

The applicant states that Presbyterian Breast Center intends to acquire a new Automated Breast Ultrasound System (ABUS), which is used as a supplemental screening modality in addition to a screening mammogram procedure. The ABUS is designed specifically for dense breast imaging since mammograms can be harder to read in women with dense breasts. The applicant states that the facility does not currently offer ABUS, however patients have requested the procedure or sought this service from other providers in the service area. The applicant states that obtaining an ABUS machine will enhance the continuum of diagnostic services at Presbyterian Breast Center.

COVID-19

The applicant states that the Presbyterian Breast Center was one of six centers in the Novant Health system that remained open for limited hours for diagnostic exams during COVID-19. Although the facility incorporated the adjustments associated with COVID-19 and temporarily affected its diagnostic utilization, the applicant does not anticipate that the COVID-19 pandemic will have a negative long-term impact on the need for diagnostic services at the facility or in Mecklenburg County. The applicant states that the recommendations for breast

health screening have not changed, the incidence of breast cancer has not change and anticipates that future demand for diagnostic services will continue to be consistent with pre-pandemic levels.

Need to Enhance Access to Presbyterian Breast Center Services (pages 33-34)

The applicant states that there are various deficiencies associated with the existing facility:

- The current space is dated and has a sub-optimal design for modern breast center workflow.
- The waiting area is undersized with poor lighting.
- There are no ADA-accessible bathrooms.
- The center hallways are narrow and difficult to move patients through.
- Dressing rooms are too small for bariatric patients who must be taken elsewhere to change.
- There is not enough space to expand the facility to accommodate growing patient volumes.
- Parking is at a considerable distance to the entrance of the facility.

As part of the proposed project, Presbyterian Breast Center is relocating to a new location that will be state-of-the-art and designed to provide a focused, less clinical approach to breast health. The applicant states that the new facility will be designed to optimize patient comfort and access.

Service Area Demographics (pages 35-36)

The applicant uses data from the North Carolina Office of State Budget Management (NCOSBM) to demonstrate the growing and aging population in the service area which warrants the need for the proposed project.

The applicant states that the female population in the service area is projected to grow by a CAGR of 1.8 percent, as illustrated in the table below.

Female Population Projected Growth Mecklenburg County								
	2020	2021	2022	2023	2024	2025	2026	CAGR
Mecklenburg	577,691	589,889	601,077	611,456	621,363	631,713	642,399	1.8%

Source: Section C, page 35; NCOSBM

The applicant states that the American Cancer Society recommends that women aged 45+ should begin annual mammography screenings. Women comprise of 51 percent of the 2020 population in Mecklenburg County. The CAGRs for age cohorts 40+ are projected at rates comparable to or higher compared to the overall female population growth rate in Mecklenburg County. The applicant projects that the growth in female population age 40+ will drive additional demand for women’s diagnostic services. The following table summarizes projected population growth by age cohort.

Female Population Projected Growth by Age Cohort Mecklenburg County			
	2020	2026	CAGR
0-14	108,447	113,773	0.8%
15-24	67,009	73,932	1.7%
25-39	134,951	140,959	0.7%
40-44	43,916	51,004	2.5%
45-54	79,068	87,951	1.8%
55-64	66,841	74,651	1.9%
65-74	46,351	56,706	3.4%
75+	31,108	43,423	5.7%
All Ages	577,691	642,399	1.8%

Source: Section C, page 35; NCOSBM

The applicant states that African American women are at the highest risk of serious health impact from breast cancer. Based on data from NCOSBM, 35 percent of the female population in Mecklenburg County is African American. The CAGRs for age cohorts 40+, including African American women, are projected at rates comparable to or higher compared to the overall female population growth rate in Mecklenburg County. The applicant projects that the growth in the African American female population 40+ will drive additional demand for women’s diagnostic services. The following table summarizes projected population growth of African American women by age cohort.

African American Female Population Projected Growth by Age Cohort Mecklenburg County			
	2020	2026	CAGR
35-44	32,080	34,741	1.3%
45-54	30,183	34,106	2.1%
55-59	12,737	15,256	3.1%
60-64	10,646	13,146	3.6%
65+	22,384	31,176	5.7%
All Ages	204,044	232,592	2.2%

Source: Section C, page 36; NCOSBM

Breast Cancer Incidence (pages 36-38)

The applicant states that access to breast imaging services is critical to early detection and diagnosis of breast cancer. The applicant bases its conclusion on the following factors related to breast cancer incidence:

- According to the Centers for Disease Control, breast cancer is the second most common cancer among women in the United States.
- African American women die from breast cancer at a higher rate than other women and often have aggressive forms of breast cancer.
- Each year over 6,000 North Carolina women will be diagnosed with breast cancer and over 1,000 will die from the disease.

- Women in North Carolina have a one-in-eight lifetime risk of developing breast cancer. According to the NC Central Cancer Registry, the breast cancer incidence rate in Mecklenburg from 2014-2018 was higher than the statewide breast cancer incidence rate.

Breast Cancer Screening Rate (pages 38-39)

The applicant states that according to the American Cancer Society, when breast cancer is detected earlier, and is in the localized stage, the 5-year relative survival rate is 99 percent. Breast cancer screening can reduce death rates from female breast cancer by detecting it earlier, in more treatable stages. The applicant states that its proposed project is consistent with the positive trend of increasing breast cancer screening and decreasing service area female breast cancer deaths.

Support for the Project (page 39)

The applicant states that Presbyterian Breast Cancer has received letters of support from numerous physicians in specialties that routinely refer women for imaging studies. The letters indicate their support and intent to continue to refer patients for diagnosis services. The applicant provides supporting documentation in Exhibit I.3.

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

- The applicant demonstrates the growth in utilization of its existing services at Presbyterian Breast Center.
- The applicant uses clearly cited and reasonable historical and demographic data to identify the population to be served, its projected growth and the need to expand its diagnostic services.
- The applicant provides data regarding the incidences of breast cancer in Mecklenburg County and North Carolina and the need for preventive screening and early diagnosis.

Projected Utilization

In Section C, page 88, the applicant provides historical and projected utilization, as illustrated in the following table.

Presbyterian Breast Center Projected Utilization			
	1st FFY CY 2022	2nd FFY CY 2025	3rd FFY CY 2026
Mammography			
# of Units	6	6	6
# of Procedures	16,574	17,107	17,655
Ultrasound			
# of Units	4	4	4
# of Procedures	6,231	6,635	6,944
DEXA			
# of Units	1	1	1
# of Procedures	1,936	1,997	2,059
Stereotactic Breast Biopsy			
# of Units	1	1	1
# of Procedures	228	235	243

In Section Q, pages 89-101, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant begins its projected utilization for interim and the first three years of the proposed project with the historical utilization of services at Presbyterian Breast Center. The applicant states that although the facility's annualized procedures were lower in 2020 attributed to COVID-19, it projects that demand for breast diagnostic services will continue consistent with pre-pandemic levels. The applicant states that screening recommendations for breast cancer or incidence of breast cancer has not changed as a result of COVID-19.

With the exception of ABUS ultrasound procedures, the following table illustrates the facility's historical utilization of each modality.

Presbyterian Breast Center Historical Screening Mammography Procedures						
	CY2016	CY2017	CY2018	CY2019	3-Year CAGR	CY2020* Annualized
Screening Mammography	7,594	7,877	7,974	8,349	3.2%	6,671
Diagnostic Mammography	6,630	6,427	6,582	6,792	0.8%	5,847
Mammography Biopsy	219	162	84	103		84
Breast Ultrasound	3,965	3,884	4,068	4,582	4.9%	3,919
Breast Ultrasound Biopsy	609	432	414	309		277
Stereotactic Breast Biopsy	264	209	182	148		136
DEXA	1,538	1,736	1,625	1,765	4.7%	1,192

Source: Section Q, pages 89-100

*Annualized based on January-September data

Mammography Procedures

Screening Mammography

The applicant begins its projections for the interim years of the project (CY2022-CY2023) using half of the 3-year CAGR (3.2% / 2 = 1.6%). It is projected that during CY2021 screening mammography procedures will resume at approximately 95 percent of its CY2019 procedure volume. To project CY2022 procedures, the applicant applied the 3-year CAGR to CY2019 volume. The applicant projects that in the first year of the project, screening mammography procedures will increase by 5 percent. This is based on the initial relief of capacity constraints and backlog of patients. The second and third year of the project will subsequently increase based on the 3-year CAGR.

Presbyterian Breast Center Projected Screening Mammography Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
Screening Mammography	7,932	8,483	8,619	9,050	9,341	9,640

Source: Section Q, pages 90-91

Totals may not foot due to rounding.

Diagnostic Mammography

The facility experienced a 3-year CAGR of 0.8 percent from CY2016 to CY2019. To project diagnostic mammography procedures, the applicant applies the CY2019 ratio of diagnostic mammography procedures to screening mammography procedures [CY2019 6792 diagnostic mammography / 8,349 screening mammography procedures = .8135]. To project CY2022 procedures, the applicant applied the 3-year CAGR to CY2019 volume

Presbyterian Breast Center Projected Diagnostic Mammography Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
Diagnostic Mammography	6,452	6,901	7,012	7,362	7,599	7,843

Source: Section Q, page 92
 Totals may not foot due to rounding.

Mammography Biopsy

The applicant states that the number of mammography biopsy procedures has varied in the past because the type of biopsy procedure is predicated on what’s appropriate for the patient. To project mammography biopsy procedures, the applicant applies the CY2016-CY2019 weighted average ratio of mammography biopsy procedures to screening mammography procedures to projected mammography screening volume.

	CY2016-CY2019 Weighted Average
Screening Mammography	31,794
Mammography Biopsy	568
% of Screening Mammography that result in Mammography Biopsy	1.8%

Source: Section Q, page 93

Presbyterian Breast Center Projected Mammography Biopsy Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
Mammography Biopsy	142	152	154	162	167	172

Source: Section Q, page 93
 Assumption: 1.8% x projected annual mammography screening procedures
 Totals may not foot due to rounding

Ultrasound Procedures

Breast Ultrasound

The applicant states that Presbyterian Breast Center experienced robust growth for breast ultrasound procedures. A breast ultrasound is often performed as a follow-up test after an abnormal finding on a mammogram.

To project breast ultrasound procedures, the applicant applies the 3-year CAGR of 4.9 percent. To project CY2022 procedures, the applicant applied the 3-year CAGR to CY2019 volume. The applicant projects that during CY2021 breast ultrasound procedures will resume at approximately 95 percent of its CY2019 procedure volume.

Presbyterian Breast Center Projected Breast Ultrasound Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
Breast Ultrasound	4,353	4,808	5,046	5,295	5,557	5,831

Source: Section Q, page 95
 Totals may not foot due to rounding.

Breast Ultrasound Biopsy

As in breast ultrasound procedures, the applicant states that the number of breast ultrasound biopsy procedures has varied in the past because the type of breast ultrasound biopsy procedure is predicated on what's appropriate for the patient. To project breast ultrasound biopsy procedures, the applicant applies the CY2016-CY2019 weighted average ratio of breast ultrasound biopsy procedures to screening mammography procedures.

	CY2016-CY2019 Weighted Average
Screening Mammography	31,794
Breast Ultrasound Biopsy	1,764
% of Screening Mammography that result in Breast Ultrasound Biopsy	5.5%

Source: Section Q, page 97

Presbyterian Breast Center Projected Breast Ultrasound Biopsy Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
Breast Ultrasound Biopsy	440	471	478	502	518	535

Source: Section Q, page 97
 Assumption: 5.5% x projected annual mammography screening procedures
 Totals may not foot due to rounding.

ABUS Ultrasound Procedures

The applicant states that the proposed ABUS machine will expand the scope of diagnostic ultrasound procedures at the facility. ABUS is as a supplemental screening modality and designed specifically for dense breast imaging.

The applicant begins its projections by consulting with its clinical leadership to confirm the prevalence of breast density among the facility's patient base. Based on the assumption that 40 percent of screening patients have dense breasts, the applicant conservatively estimates 12 percent will receive an ABUS procedure. The applicant projects that 15 percent of its screening mammography patients with dense breasts will receive an ABUS procedure during the second and third projects years. The applicant's estimates are based on the facility's operational experience.

Presbyterian Breast Center Projected ABUS Ultrasound Procedures					
			CY2024	CY2025	CY2026
A		Screening Mammography Procedures	9,050	9,341	9,640
B	A x 40%	Screening Mammography patients w/Dense Breasts (40%)	3,620	3,736	3,856
C		% of Projected patients to Receive ABUS Procedure	12%	15%	15%
D	B x C	ABUS Procedures	434	560	578

Source: Section C, page 98
 Totals may not foot due to rounding

Stereotactic Breast Biopsy

As in other biopsy procedures, the applicant states that the number of stereotactic breast biopsy procedures has varied in the past because the type of stereotactic breast biopsy procedure is predicated on what’s appropriate for the patient. To project stereotactic breast biopsy procedures, the applicant applies the CY2016-CY2019 weighted average ratio of stereotactic breast biopsy procedures to screening mammography procedures.

	CY2016-CY2019 Weighted Average
Screening Mammography	31,794
Stereotactic Breast Biopsy	800
% of Screening Mammography that result in Stereotactic Breast Biopsy	2.5%

Source: Section Q, page 99

Presbyterian Breast Center Projected Breast Ultrasound Biopsy Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
Stereotactic Breast Biopsy	200	213	217	228	235	243

Source: Section Q, page 95
 Assumption: 2.5% x projected annual mammography screening procedures
 Note: The title of the chart on page 95 states “breast Ultrasound Biopsy” however the project analyst assumes that the applicant meant “Stereotactic Breast Biopsy” based on the chart in Section Q, page 101.
 Totals may not foot due to rounding.

Bone Density (DEXA)

The applicant states that Presbyterian Breast Center experienced robust growth for DEXA procedures. The facility experienced a 3-year CAGR of 4.7 percent from CY2016 to CY2019. To project DEXA procedures, the applicant conservatively applies two-thirds of the 3-year CAGR (4.7% x 2/3 = 3.1%). The applicant states that given the capacity limitations with only one DEXA machine, it assumes a slightly more conservative projected model for DEXA compare to modalities with multiple pieces of equipment. To project CY2022 procedures, the applicant applied the 3-year CAGR to CY2019 volume. The applicant projects that during

CY2021, DEXA procedures will resume at approximately 95 percent of its CY2019 procedure volume.

Presbyterian Breast Center DEXA Procedures						
	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026
DEXA	1,677	1,820	1,877	1,936	1,997	2,059

Source: Section Q, page 100
 Totals may not foot due to rounding.

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

- Projected utilization is based on the historical utilization of its existing diagnostic services at Presbyterian Breast Center.
- Projected utilization is based on the assumption that incidences of breast cancer and recommendations for services will not change and will continue to be consistent with pre-pandemic levels.
- The applicant provides reasonable and adequately supported information to justify the need for diagnostic services.

Access to Medically Underserved Groups

In Section C, page 44, the applicant states:

“Existing Novant Health affiliates and Presbyterian Breast Center will continue to 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)

...

Novant Health adheres to a series of Charity Care and related policies that create the framework for access to services by patients with limited financial means...”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	1.4%
Racial and ethnic minorities	34.4%
Women	99.0%
Persons with Disabilities*	5.4%
The elderly	26.5%
Medicare beneficiaries	24.2%
Medicaid recipients	2.6%

*The applicant states that the estimated percentage will mirror the population percentages for this population. The percentage can be found online using the united states Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

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 and its affiliates have a long history of providing services consistent with civil rights and discrimination laws.
- The applicant incorporates charity care policies, therefore, providing services to patients with limited means.
- Presbyterian Breast Center currently provides services to the identified medically 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.

C

The applicant proposes to relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit. The services to be relocated include mammography, ultrasound, DEXA, and stereotactic breast biopsy.

In Section D, page 50, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 50, the applicant states:

“The needs of the patients currently utilizing Presbyterian Breast Center will continue to be met following completion of the project. The new location is less than ½ mile from the current location; thus, patient access will not be impacted as a result of the proposed project. In fact, the proposed project will significantly enhance patient

access via development of a new facility designed to reduce anxiety and optimize patient accessibility and comfort.”

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

- The relocation of the facility will not impact accessibility for the existing patients since the facility will be located less than mile from the original location.
- The existing patients will continue to access to the facility therefore there is no reduction or elimination of services.

In Section D, page 49, the applicant states that the entire facility and all existing services will be relocated to a new location a half a mile away.

The population presently utilizing the services will continue to have access since the facility will be located less than mile from the original location. Therefore, no services will be reduced as part of the project.

Access to Medically Underserved Groups

In Section D, page 52, the applicant states:

“The proposed project will have no negative effect on each group...the new location is approximately ½ mile from the current location; thus, patient access will not be impacted as a result of the proposed project.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use the diagnostic center will be adequately met following completion of the project for the following reasons:

- The relocation of the facility will not impact accessibility for the existing patients from the identified groups since the facility will be located less than mile from the original location.
- there is no reduction or elimination of services for existing patients from the identified groups.

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 needs of the population currently using the services to be relocated will be adequately met following project completion for all the reasons described above.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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.

C

The applicant proposes to relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

In Section E, page 53, 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 that maintaining the status quo is not an effective alternative because it would fail to provide enhanced and convenient access to the existing patients. The applicant states that the existing facility is not ADA compliant. It is dated and undersized to accommodate the growing demand for diagnostic services and does not have sufficient space available to expand.

Relocate Presbyterian Breast Center to Another Location in the Service Area-The applicant states that this was not an effective alternative because Presbyterian Breast Center has a long history of providing diagnostic services and its patients are familiar with the location. The applicant states that locating the facility to another location in Mecklenburg County could disrupt referral patterns or unnecessarily hinder geographic access for a large portion of patients. The applicant states that this alternative is also not cost-effective because of higher capital costs associated with land acquisition. Novant Health owns the land at the proposed location.

On page 53, the applicant states that its proposal is the most effective alternative because it would relieve capacity constraints and enhance patient access for the facility's well-utilized diagnostic services. In addition, the proposed project will maintain geographic continuity of geographic access while significantly enhancing patient experience in a modern facility.

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

- The proposed project will address the growing need for diagnostic services and continue to provide access to its existing patients.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Presbyterian Breast Center, LLC and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate Presbyterian Breast Center, an existing diagnostic center, to a new site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.**
- 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 fourth month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on August 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 Section Q of the application and that would otherwise require a certificate of need.**

5. **The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
 6. **No later than three months after the last day of each of the first three full fiscal 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.**
 7. **The certificate holder 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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 102, the applicant projects the total capital cost of the project, as shown in the table below.

Presbyterian Breast Center Capital Costs	
Site Preparation	\$1,208,707
Construction/Renovation Contract(s)	\$5,055,802
Landscaping	\$68,000
Architect/Engineering	\$268,366
Medical Equipment	\$1,971,379
Non-Medical Equipment	\$163,715
Furniture	\$529,189
Consultant Fees (CON Consultant)	\$42,500
Interest during Construction	\$283,490
Information Technology	\$727,529
Low Voltage (nurse call, overhead paging, CATV)	\$85,000
Security/Fire Alarm	\$48,316
Special Inspections	\$40,000
Escalation	\$626,970
Project Contingency	\$1,079,279
Total	\$12,198,260

In Section Q, page 106, 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 incorporated construction and landscaping estimates to determine capital costs.
- The applicant based medical and non-medical equipment on architectural floor plans and room designation.
- Financing not included since capital costs will be funding through cash reserves.

In Section F, Page 57, the applicant states that there will be no start-up or initial operating expenses because the facility is an existing diagnostic center and the proposed relocation project will not require working capital needs.

Availability of Funds

In Section F, page 55, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing			
Type	Presbyterian Breast Center, LLC	Novant Health, Inc.	Total
Loans	\$ 0	\$0	\$0
Accumulated reserves or OE *	\$0	\$12,198,260	\$12,198,260
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing	\$0	\$12,198,260	\$12,198,260

* OE = Owner's Equity

Exhibit F-2 contains a letter from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc., parent entity of Presbyterian Breast Center, LLC, authorizing the use of accumulated reserves for the capital needs of the project. The letter states that the Consolidated Balance Sheets from Novant Health, Inc. for year ending 2019 shows that Novant Health, Inc. had over \$400 million in cash and cash equivalents and over \$800 million in assets to fund the capital cost of the proposed project. The applicant adequately demonstrates the availability of sufficient funds for the capital costs of the project based on the amount of accumulative reserve available to the applicant.

Financial Feasibility

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

NH Presbyterian Breast Center	1st FFY CY2024	2nd FFY CY2025	3rd FFY CY2026
Total Procedures	24,969	25,974	26,901
Total Gross Revenues (Charges)	\$10,475,459	\$11,158,292	\$11,856,263
Total Net Revenue	\$5,866,861	\$6,249,287	\$6,640,191
Average Net Revenue per Procedure	\$234.96	\$240.59	\$246.83
Total Operating Expenses (Costs)	\$6,142,645	\$6,368,152	\$6,583,906
Average Operating Expense per Procedure	\$246.01	\$245.17	\$244.74
Net Income	(\$275,784)	(\$118,865)	\$56,285

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 106-107. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant projects gross patient revenue based the 2019 actual gross charges by payor for Presbyterian Breast Center and projected diagnostic procedures for each modality and a price increase of three percent annually.
- Deductions from gross patient revenue are based on Presbyterian Breast Center's actual experience during CY2019.
- 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 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 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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

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 26, the applicant identifies the primary service area as Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 62, the applicant identifies the following outpatient breast imaging providers in the service area based on publicly available information. The applicant states that not all are diagnostic centers or offer a full range of women’s imaging services.

Facility	City
Novant Health Breast Center Ballantyne	Charlotte
Novant Health Breast Center Charlotte*	Charlotte
Novant Health Breast Center Huntersville	Huntersville
Novant Health Breast Center Matthews	Matthews
Novant Health Breast Imaging Center Mint Hill	Charlotte
Novant Health Imaging University City	Charlotte
Novant Health Imaging Museum	Charlotte
Novant Health Imaging SouthPark Breast Center	Charlotte
Novant Health Imaging Steele Creek	Charlotte
Randolph Road Breast Center	Charlotte
Morehead Breast Center	Charlotte
Medical Center Plaza Breast Center	Charlotte
SouthPark Breast Center	Charlotte
University Breast Center	Charlotte
Pineville Breast Center	Charlotte
Matthews Breast Center	Matthews
Ballantyne Breast Center	Charlotte
Prosperity Crossing Breast Center	Charlotte
Steele Creek Breast Center	Charlotte
Blakeney Breast Center	Charlotte
Huntersville Breast Center	Huntersville

*Presbyterian Breast Center, LLC d/b/a Novant Health Breast Center Charlotte is the facility associated with the proposed project.

In Section G, page 63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic services in Mecklenburg County. The applicant states:

“The proposed project is needed to expand and enhance access to Presbyterian Breast Center’s well-utilized diagnostic services. No other provider can meet the identified need. While other imaging services are available in the area, Presbyterian Breast Center enjoys a long history of nearly three decades providing breast imaging services in Mecklenburg County. The proposed project will not result in development of new services, rather it will enhance and expand the existing high quality diagnostic 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 based on the following:

- The proposed project will meet the need of the existing and well-utilized diagnostic center.
- The proposal would not result in an increase in diagnostic services but enhance the existing services.
- The applicant adequately demonstrates that the proposed diagnostic services is needed in addition to the existing or approved diagnostic 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 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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

In Section Q, page 105, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(As of 12/31/2019)	3 rd Full Fiscal Year CY2026
Clerical Staff	2.17	2.42
Radiologists Technologists	10.89	18.89
Administrator	1.14	1.14
Business Office	0.17	0.33
TOTAL	14.36	22.78

The assumptions and methodology used to project staffing are provided in Section Q, page 108. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3. In Section H, pages 64-65, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects staff based on the estimated full-time staffing equivalents necessary to provide services and the expected volumes with minimum staffing requirements.
- The applicant recruits staff through their established regional and corporate human resources department.

- Presbyterian Breast Center maintains an annual allocation to cover staff training needs and license and certification maintenance.

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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

Ancillary and Support Services

In Section I, page 66, the applicant identifies the necessary ancillary and support services for the proposed services. On page 66, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits C.1-1, H.3 and I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on Presbyterian Breast Center's long history of providing diagnostic imaging services and its existing ancillary and support services.

Coordination

In Section I, page 66, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.3. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the facility's extensive referral relationships and its other established relationships with local healthcare and social service providers.

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:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - 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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

In Section K, page 70, the applicant states that the project involves constructing 13,500 square feet of new space. Line drawings are provided in Exhibit K.1.

On pages 71-72, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed diagnostic center based on the applicant's representations and supporting documentation.

On page 70, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following.

- The applicant's efforts to contain costs include developing a layout that will maximize space efficiency.
- The applicant states that estimated costs provided by the design architect and general contractor were based on their experience and current market costs for materials and labor.

On pages 70-71, 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 their experience in developing similar facilities and their consideration into the design, up-fit scope, type of modalities offered, equipment selection, location and staffing model to ensure financial viability.

On page 71, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 74, the applicant provides the historical payor mix during CY2019 for the proposed services, as shown in the table below.

NH Presbyterian Breast Center Historical Payor Mix, CY 2019					
Payor Category	Entire Facility as Percent of Total	Mammography	Ultrasound	Stereotactic	Bone Density
Self-Pay	3.5%	2.6%	6.6%	9.7%	0.8%
Charity Care	1.4%	1.1%	2.3%	4.8%	0.5%
Medicare*	24.2%	25.5%	10.0%	0.7%	60.6%
Medicaid*	2.6%	2.5%	3.8%	0.0%	1.5%
Insurance*	67.2%	67.4%	75.8%	81.0%	36.4%
Workers Compensation	0.0%	0.0%	0.0%	0.0%	0.0%
TRICARE	1.0%	0.9%	1.4%	3.7%	0.2%
Other (other Govt)	0.0%	0.0%	0.0%	0.0%	0.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Section L, page 74

*Including any managed care plans.

In Section L, page 73, the applicant provides the following comparison.

NH Presbyterian Breast Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY (CY 2019)	Percentage of the Population of the Service Area*
Female	99.0%	51.1%
Male	1.0%	48.9%
Unknown		
64 and Younger	73.5%	88.0%
65 and Older	26.5%	12.0%
American Indian	0.3%	1.0%
Asian	2.2%	5.7%
Black or African-American	34.4%	33.7%
Native Hawaiian or Pacific Islander		
White or Caucasian	53.2%	56.8%
Other Race	5.9%	2.8%
Declined / Unavailable	4.0%	

*The percentage can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 74, the applicant states:

“Presbyterian Breast Center is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, Presbyterian Breast Center provides and will continue to provide services to all persons in need of medical care, regardless of race, religion, national origin, sex, age, disability, or source of payment.”

In Section L, page 75, 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.

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 76, 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.

NH Presbyterian Breast Center Projected Payor Mix, CY 2026					
Payor Category	Entire Facility as Percent of Total	Mammography	Ultrasound	Stereotactic	Bone Density
Self-Pay	3.5%	2.6%	6.6%	9.7%	0.8%
Charity Care	1.4%	1.1%	2.3%	4.8%	0.5%
Medicare*	24.2%	25.5%	10.0%	0.7%	60.6%
Medicaid*	2.6%	2.5%	3.8%	0.0%	1.5%
Insurance*	67.2%	67.4%	75.8%	81.0%	36.4%
Workers Compensation	0.0%	0.0%	0.0%	0.0%	0.0%
TRICARE	1.0%	0.9%	1.4%	3.7%	0.2%
Other (specify)	0.0%	0.0%	0.0%	0.0%	0.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Section L, page 76

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.5% of total services will be provided to self-pay patients, 1.4% to charity care patients, 24.2% to Medicare patients and 2.6% to Medicaid patients.

On page 76, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on Presbyterian Breast Center's historical payor mix for diagnostic services.
- The applicant does not expect the proposed project will have an impact on the facility's payor mix.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one

mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

In Section M, page 79, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the applicant's established training program with Rowan Community College for clinical and non-clinical education.

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 relocate Presbyterian Breast Center, an existing diagnostic center, to new a site within Mecklenburg County, replace some existing equipment (one mammography unit, two ultrasounds and one bone density unit), and add two additional mammography units and one ultrasound unit.

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 26, the applicant identifies the primary service area as Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 62, the applicant identifies the following outpatient breast imaging providers in the service area. The applicant states that not all are diagnostic centers or offer a full range of women’s imaging services.

Facility	City
Novant Health Breast Center Ballantyne	Charlotte
Novant Health Breast Center Charlotte*	Charlotte
Novant Health Breast Center Huntersville	Huntersville
Novant Health Breast Center Matthews	Matthews
Novant Health Breast Imaging Center Mint Hill	Charlotte
Novant Health Imaging University City	Charlotte
Novant Health Imaging Museum	Charlotte
Novant Health Imaging SouthPark Breast Center	Charlotte
Novant Health Imaging Steele Creek	Charlotte
Randolph Road Breast Center	Charlotte
Morehead Breast Center	Charlotte
Medical Center Plaza Breast Center	Charlotte
SouthPark Breast Center	Charlotte
University Breast Center	Charlotte
Pineville Breast Center	Charlotte
Matthews Breast Center	Matthews
Ballantyne Breast Center	Charlotte
Prosperity Crossing Breast Center	Charlotte
Steele Creek Breast Center	Charlotte
Blakeney Breast Center	Charlotte
Huntersville Breast Center	Huntersville

*Presbyterian Breast Center, LLC d/b/a Novant Health Breast Center Charlotte is the facility associated with the proposed project.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, 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 80, the applicant states:

“Presbyterian Breast Center will continue to offer women’s imaging services at a reasonable and competitive rate.”

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

Regarding the impact of the proposal on quality, in Section N, page 80, the applicant states:

“The existing facility contains space which are not ADA compliant or operationally efficient. Also, the spaces are aesthetically outdated compared to patient expectations. The project will improve accessibility via development of a modern facility designed to optimize patient comfort and experience.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 80, the applicant states:

“...Novant Health facilities adhere to Novant Health Charity Care Policies which have been deemed one of the more generous and comprehensive policies in North Carolina. Presbyterian Breast Center will continue to comply with the Novant Health set of Charity Care and related policies which are designed to eliminate barriers to care regardless of ability to pay.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 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 based on all the reasons described above.

- (19) Repealed effective July 1, 1987.

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

C

On Form A in Section Q, the applicant identifies all diagnostic centers in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 23 diagnostic centers located in North Carolina.

In Section O, pages 82 and 84, the applicant states:

“At Novant Health, safety and quality care are embedded into every service line, alongside a commitment to identify opportunities for improvement, set goals to accomplish change, and work together in an inclusive manner to make a measurable difference...Novant Health applies evidence-based practice methods to prevent medical errors by building accountability for finding and fixing system problems.

...

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

On pages 82-83, the applicant describes its existing programs and methods used to ensure and maintain quality care:

- Contracting with technicians and biomedical engineers to ensure that preventive maintenance recommended by the manufacturer is performed on diagnostic imaging equipment
- Meeting with referring physicians to obtain feedback on image quality, report quality, convenience of scheduling and accessibility, and patient experience
- Novant Health’s organization-wide patient safety program, “First Do No Harm” which involves patient safety processes to identify and prevent negative patient outcomes based on high-risk or high-volume issues
- Novant Health’s Infection Prevention Plan, which involves efforts to reduce the risk of transmission of infection for patients, employees, and others in the healthcare setting

After reviewing and considering information provided by the applicant regarding the quality of care provided at all 23 diagnostic centers, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of

health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to relocate an existing diagnostic center, replace one mammography unit, two ultrasounds and one bone density unit, and add two additional mammography units and one ultrasound unit. There are no administrative rules that are applicable to proposals for ultrasound, bone density, and mammography services or a diagnostic center.