

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 2, 2020

Findings Date: December 2, 2020

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: G-11959-20

Facility: The Breast Center of Greensboro Imaging

FID #: 200745

County: Guilford

Applicant(s): Diagnostic Radiology and Imaging, LLC

Project: Develop a mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system

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

Diagnostic Radiology and Imaging, LLC (referred to as “the applicant” or “DRI”) proposes to develop a new mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system and a drivable coach to serve Guilford and Rockingham counties in North Carolina. The applicant currently operates five fixed mammography units at its existing imaging center in Guilford County, The Breast Center of Greensboro Imaging (“The Breast Center” or “Greensboro Imaging”). The mobile diagnostic program will have 13 monthly host sites and five annual event sites. In Section Q, Form F.1a, the applicant indicates the cost to acquire the proposed mammography equipment and installation is \$1,127,190. Following acquisition of the proposed mammography 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

The applicant does not propose to offer a new institutional health service for which there are any applicable policies in the 2020 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system and a drivable coach to serve Guilford and Rockingham counties.

Designation as a Diagnostic Center

DRI currently provides mammography, MRI, ultrasound, and bone density services at The Breast Center of Greensboro Imaging. The applicant plans to acquire a mobile mammography unit to serve its proposed host sites. In Section Q, Form F.1a, the applicant indicates the cost to acquire the proposed mammography equipment and installation is \$1,127,190. Following acquisition of the proposed mammography equipment, the combined costs of all the medical

diagnostic equipment in the mobile diagnostic program 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 CON.

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 21, the applicant identifies the primary service area as Guilford and Rockingham counties. Facilities may also serve residents of counties not included in their service area.

On page 19, the applicant states that it does not provide mobile mammography services in any of its facilities in North Carolina, therefore, there is no historical patient origin data to report. The applicant provides the historical patient origin for fixed mammography services at Greensboro Imaging, as illustrated on the table below.

County	The Breast Center of Greensboro Imaging Historical Project Origin 1/1/2019-12/31/2019 (CY 2019)	
	# of Patients	% of Total
Guilford	29,752	76.85%
Rockingham	3,026	7.82%
Randolph	2,307	5.96%
Alamance	966	2.50%
Forsyth	940	2.43%
Other Counties*	1,119	2.89%
Other States	606	1.57%
Total	38,716	100.00%

Source: Section C.2, page 20.

*Includes all other North Carolina counties, each of which represent <1% of total patient origin.

Totals may not foot due to rounding.

The following table illustrates projected patient origin for the proposed mobile mammography services for the first three full fiscal years of operation.

Projected Patient Origin						
County	1st FFY CY 2022		2nd FFY CY 2023		3rd FFY CY 2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Guilford	3,184	74.0%	3,438	74.0%	3,697	74.0%
Rockingham	1,076	25.0%	1,161	25.0%	1,249	25.0%
Other NC counties*	43	1.0%	46	1.0%	50	1.0%
Total	4,303	100.0%	4,645	100.0%	4,996	100.0%

Source: Section C, page 21

*Includes Randolph, Davidson, and Alamance counties, each of which represents <1% of patient origin.

In Section C, page 22, the applicant provides the assumptions and methodology used to project its patient origin. On page 22, the applicant states:

“The proposed mobile service is targeted to make access to screening mammography more convenient and readily available to local women, particularly the medically underserved...DRI projects the mobile mammography patient origin based on the location of the prospective host sites...The projected payor mix is consistent with the historical mammography patient origin at DRI’s Breast Center...”

The applicant’s assumptions are reasonable and adequately supported because it is based on the historical mammography patient origin at Greensboro Imaging and the assumption that the vast majority of women screened will be residents of the local area.

Analysis of Need

In Section C, pages 22-43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- Greensboro Imaging experienced a 4.99% Compound Annual Growth Rate (CAGR) between CY2016-CY2019 of mammograms performed, demonstrating high utilization of its five existing fixed mammography units (page 23).
- Based on data from North Carolina Office of State Budget Management (NCOSBM), Guilford County, the proposed service area, is projected to grow by 32,611 additional residents from 2020 to 2025, a CAGR of 1.17%, which is slightly higher than the projected statewide population CAGR of 1.11% (page 24).
- Based on data from the North Carolina Cancer Registry, high mortality and incidences of breast cancer rates in North Carolina, particularly among women ages 45-84, demonstrate the need for screening mammography services (pages 24-29).
- Increased focus and support by the medical community for preventive screening for breast cancer (pages 29-34).
- Underuse of mammography services by several medically underserved demographic groups, including uninsured women, racial and ethnic minority women and women with lower income (see pages 34-42).
- The convenient location of the proposed host sites will improve continuity of care for patients, by addressing the issue of lack of access to transportation by older women due

to physical barriers or access to a personal vehicle; which can impact access to healthcare services (pages 42-43).

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

- The applicant provides population projections for the service area to support the projected need for mammography services.
- The applicant provides data regarding the mortality rate and the incidences of breast cancer in Guilford and Rockingham counties and the increased focus on preventive screening and early diagnosis.
- The applicant provides reasonable and adequately supported information to support its assertion that the lack access to screening mammography for older women and the medically underserved in the proposed service area support the need for additional diagnostic services.

Projected Utilization

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

Projected Utilization			
Mobile Mammography	1st FFY CY 2022	2nd FFY CY 2023	3rd FFY CY 2024
# of Units	1	1	1
#of Procedures	4,303	4,645	4,996

In Section Q, pages 108-114, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Service Area Population

The applicant projects utilization based on the service area projected population growth and the growth of the targeted female population. Referencing data from NCOSBM, the applicant demonstrates the projected population growth in the proposed service area. The applicant determined that the primary demographic group in need of screening mammography services is women age 45-84, based on recommendations by the American College of Obstetricians and Gynecologists, American Cancer Society (ACS) and American College of Radiology (ACR) recommendations.

Guilford and Rockingham Counties Projected Population							
	2020	2021	2022	2023	2024	2025	CAGR
Guilford	545,348	551,354	557,647	564,197	570,977	577,959	1.17%
Rockingham	91,830	91,849	91,857	91,860	91,863	91,864	0.01%
North Carolina	10,630,690	10,753,496	10,873,632	10,992,997	11,112,320	11,233,133	1.11%

Source: Section Q, page 108, 2019 NCOSBM

Guilford and Rockingham Counties Projected Female Population Age 45-84							
	2020	2021	2022	2023	2024	2025	CAGR
Guilford	114,532	116,032	117,514	119,068	120,658	122,338	1.33%
Rockingham	22,406	22,430	22,442	22,428	22,403	22,442	0.03%

Source: Section Q, pages 109-110, 2019 NCOSBM

Step 2: Projected Need for Female Breast Screening Mammography in the Service Area

The applicant projects the need for female breast screening mammograms based on NCOSBM projected female population growth in the service area, and the recommendation for yearly mammograms among women age 45-84. The applicant projects a need for 144,780 mammograms in 2025 in Guilford and Rockingham counties, as illustrated in the table below.

Guilford and Rockingham Counties Projected Demand for Female Breast Screening Mammograms						
	2020	2021	2022	2023	2024	2025
Guilford	114,532	116,032	117,514	119,068	120,658	122,338
Rockingham	22,406	22,430	22,442	22,428	22,403	22,442
Total	136,938	138,462	139,956	141,496	143,061	144,780

Source: Section Q, page 110

Step 3: DRI Mammography Market Share Calculation

In Section Q, page 111, the applicant states that in 2019, The Breast Center performed mammograms for 29,752 Guilford County residents, and 3,026 for Rockingham county residents. The applicant states that 68% of the mammograms performed were screened mammograms. Therefore, The Breast Center had a 17.9% share of the potential screened mammogram market for Guilford County and a 9.2% for Rockingham County. The following chart illustrates the market share calculations of mammograms performed at The Breast Center of Greensboro Imaging.

Guilford		
A	Total DRI Guilford Mammograms	29,752
B	Screening %	68%
C	Total Guilford Screening Mammograms*	20,231
D	Guilford Population Women aged 45-84	113,038
E	Potential Screening mammograms**	113,038
F	The Breast Center Market Share***	17.9%
Rockingham		
A	Total DRI Rockingham Mammograms	3,026
B	Screening %	68%
C	Total Guilford Screening Mammograms*	2,058
D	Guilford Population Women aged 45-84	22,390
E	Potential Screening mammograms**	22,390
F	The Breast Center Market Share***	9.2%

Source: Section Q, page 112

*A x B = C, **D x 1 = E, ***C / E = F

Step 4: Projected Mobile Mammography System Utilization

The applicant projects the potential mobile mammography market share to be 4.5% for Guilford County, and 2.0% for Rockingham County. The applicant states that this projection is comparable to Greensboro Imaging’s 2019 market share of 17.9% divided by the total amount of the existing fixed mammography units (17.9% / 5 = 3.58% for Guilford; 9.2% / 5 = 1.84% for Rockingham). The applicant states that its projected market share is reasonable because of its unique marketplace as the only mobile mammography service provider focused on bringing services closest to where women work and live in Guilford and Rockingham counties. The applicant also applies a ramp up assumption for the initial four months of service in 2021, and for each of the initial three full project years.

The Breast Center of Greensboro Imaging Projected Utilization Mobile Mammography Service				
	2021	2022	2023	2024
Guilford				
Projected Screening Mammograms	116,032	117,514	119,068	120,658
DRI Market Share/1 Unit	4.5%	4.5%	4.5%	4.5%
Potential Mobile Utilization	5,221	5,288	5,358	5,430
Ramp up %		75%	75%	75%
Projected Mobile Utilization	770	3,966	4,286	4,615
Rockingham				
Projected Screening Mammograms	22,430	22,442	22,428	22,403
DRI Market Share/1 Unit	2.0%	2.0%	2.0%	2.0%
Potential Mobile Utilization	449	449	449	448
Ramp up %		75%	80%	85%
Projected Mobile Utilization	193	337	359	381
Total Projected Mobile Utilization	963	4,303	4,645	4,996

Section C, page 113

Step 5: Projected Mobile Mammography System Utilization by Host Site Location

The applicant projects 13 monthly host sites and five annual event host sites for the proposed mobile mammography services. The applicant assumes that the procedure capacity for the

mobile mammography unit will be a monthly capacity of 458 procedures based on the following formula:

11 hours a day x 30 minute procedure x 5 days a week x 50 weeks in a year = 5,500. 5,500 / 12 = 458 monthly capacity

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

- Projected utilization is based on projected population growth data from NCOSBM and historical utilization of its existing mammography services in Guilford and Rockingham counties.
- Projected utilization is based on projected population growth of women age 45-84 in the service area, a group for whom annual mammography screenings are recommended.
- The applicant projects utilization and reasonable market shares based on the existing mammography services in the identified service area.
- The applicant provides reasonable and adequately supported information to justify the need for mobile mammography service.

Access to Medically Underserved Groups

In Section C, page 50, the applicant states:

“DRI has historically provided care and services to medically underserved populations...As a certified provider under Title XVII (Medicare), DRI offers imaging services to the elderly. Also, DRI provides services to low-income persons as a certified provider under Title XIX (Medicaid).

...

Further, DRI does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factor that would classify a patient underserved.

...

DRI has provided free or low-cost mammograms and education to hundreds of women in the community. Since 2015 DRI has provided hundreds of mammograms to local medically underserved women via the BCCCP.”

In supplemental information, 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	46.0%
Racial and ethnic minorities	49.9%
Women	99.48%
Persons with Disabilities	7.5%
The elderly	38.7%
Medicare beneficiaries	20.0%
Medicaid recipients	16.0%

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:

- As a certified provider of Medicare and Medicaid, the applicant provides services to low-income persons and the elderly.
- The applicant incorporates non-discrimination, patient discount and charity care policies, therefore, providing services to patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age and ability to pay.
- The applicant partnered with grant programs to provide services to underserved and uninsured patients.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

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

- The applicant adequately identifies the population to be served for all the reasons described above.
- The applicant adequately explains why the population to be served needs the services proposed in this application for all the reasons described above.
- Projected utilization is reasonable and adequately supported for all the reasons described above.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions 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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to develop a mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system and a drivable coach to serve Guilford and Rockingham counties.

In Section E, pages 59-62, 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 this was not an effective alternative due to the lack of access to the existing mammography services by women in the community, particular the medically at risk population.

Develop an Additional Fixed Mammography Unit-The applicant states that this was a less effective alternative since it does not address the regional travel barriers which impact medical underserved women who cannot travel to central Greensboro.

Locate the Proposed Mobile Mammography System at Other Host Sites-The applicant states that this alternative was considered, however, the identified host sites were determined to be more efficient. The applicant states that as mobile mammography service grows and matures, extending serves to other host sites locations in the Greater Piedmont Triad will be considered.

Acquire a 2D Digital Mammography System Instead of a 3D System-The applicant states that this alternative was not considered due to the advantages of a 3D system in comparison to a 2D system. The applicant states that the benefits of a 3D system include a higher percentage of cancer detection, clearer imaging, fewer callbacks and unnecessary additional imaging, and optimal imaging for breast density.

On pages 61-62, the applicant states that its proposal is the most effective alternative for the following reasons:

- The proposed project will address the issue of lack of access to travel to the existing outpatient imaging facility for women in the local community.

- The mobile mammography service will redirect some mammography patients to the mobile services alleviating the high volume experienced at Greensboro Imaging.
- The proposed project will provide patients with convenient, high-quality and cost-effective diagnostic imaging.

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 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

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. Diagnostic Radiology and Imaging, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new mobile diagnostic program by acquiring a tomosynthesis or a 3D mammography system.**
- 3. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. The certificate holder shall not change or add host sites unless it first obtains a determination from the Healthcare Planning and Certificate of Need Section authorizing the change in host sites.**
- 5. The acquisition of the tomosynthesis or the 3D mammography system shall constitute development of a mobile diagnostic program and shall not result in the creation of a diagnostic center located at any of the host sites.**
- 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 develop a mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system and a drivable coach to serve Guilford and Rockingham counties.

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.

Capital Costs	
Medical Equipment	\$1,054,690
Furniture	\$5,000
Consultant Fees	\$46,000
Financing Costs	\$1,500
Other (delivery, IT, project contingency)	\$20,000
Total	\$1,127,190

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

In Section F, pages 65-66, the applicant projects that start-up costs will be \$15,000 and initial operating expenses will be \$60,000 for a total working capital of \$75,000. In Section Q, the applicant provides the assumptions and methodology used to project the capital and working capital needs of the project.

Availability of Funds

In Section F, page 64, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	DRI	Total
Loans	\$1,054,690	\$1,054,690
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (line of credit)	\$72,500	\$72,500
Total Financing	\$1,127,190	\$ 1,127,190

* OE = Owner's Equity

In Section F, page 66, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$0
(c)	Lines of credit	\$75,000
(d)	Bonds	\$0
(e)	Total *	\$75,000

Exhibit F.2 contains a copy of letter dated August 10, 2020 and August 31, 2020 from First Citizens Bank, confirming that a loan will be made available to DRI to cover the capital costs of the proposed project (including the loan amortization schedule) and confirming a line of credit in the amount of \$169,000 for the application, consulting fees and working capital needs of the proposed project. Exhibit F.2 also contains a letter from the Director of Finance of DRI, expressing its intentions to fund \$160,000 of a \$2 million line of credit from First Citizens Bank towards the capital and working capital needs of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.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.

	1 st FFY CY 2022	2 nd FFY CY 2023	3 rd FFY CY 2024
Total Procedures	4,303	4,645	4,996
Total Gross Revenues (Charges)	\$2,067,875	\$2,277,162	\$2,498,072
Total Net Revenue	\$1,066,005	\$1,173,895	\$1,287,775
Average Net Revenue per Procedure	\$247.73	\$252.72	\$257.76
Total Operating Expenses (Costs)	\$1,020,866	\$1,132,915	\$1,222,569
Average Operating Expense per Procedure	\$237.24	\$243.89	\$244.70
Net Income	\$45,140 [45,139]	\$40,980	\$65,206

Note: Project Analyst's calculation in brackets

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 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 mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system and a drivable coach to serve Guilford and Rockingham counties.

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 21, the applicant identifies the primary service area as Guilford and Rockingham counties. Facilities may also serve residents of counties not included in their service area.

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mammography services in Guilford County. The applicant states:

“To the knowledge of DRI, Guilford County residents have minimal access to mobile mammography services. Specifically, DRI is aware that Novant Health operates a mobile mammography system within Guilford County for one day every other month. DRI is not aware of any mobile mammography service in Rockingham County.”

The following table identifies the fixed mammography units operating in a hospital in the proposed service area based the 2020 License Renewal Applications submitted to the Agency and available during this review. There is a total of five mammography units utilized at four hospitals.

Location	Units	Inpatient Procedures	Outpatient Procedures
Guilford			
High Point Regional Health	1	2	2,908
Moses Cone Hospital*	0	0	0
Wesley Long Hospital*	0	0	0
Women’s Hospital*	0	0	0
MedCenter High Point*	1	0	2,561
Rockingham			
UNC Rockingham Hospital**	2	0	4,809
Annie Penn Hospital	1	2	7,446
Total	5	4	17,724

Source: Section G, page 71, 2020 Hospital License Renewal Applications

*Operates on the Cone Health License

**Includes mammography equipment located at UNC Rockingham Wright Imaging Center, but operating under the hospital license

In Section G, page 72, the applicant identifies the following fixed mammography systems operated at freestanding imaging centers in Guilford County. On page 71, the applicant states that DRI is not aware of any freestanding mammography units located in Rockingham County.

Facility	City
Central Carolina OB/GYN	Greensboro
Cone health MedCenter High Point Imaging	High Point
Green Valley OB/GYN	Greensboro
Greensboro OB/GYN Associates	Greensboro
High Point Regional Health	High Point
Physicians for Women of Greensboro	Greensboro
Piedmont Comprehensive Women’s Center	High Point
Premier Imaging	High Point
Solis Women’s Health Radiology Associates of NC, PC	Greensboro
The Breast Center of Greensboro Imaging	Greensboro
Wendover OB/GYN and Fertility, Inc	Greensboro

In Section G, pages 72-73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved mammography services in Guilford and Rockingham counties. The applicant states:

“DRI’s proposal will not result in unnecessary duplication of existing or approved health service capabilities. This proposal is different because the mobile mammography service is designed to address barriers associated with lack of transportation or other socio-economic challenges to accessing the existing fixed mammography services operating in Guilford and Rockingham counties. The mobile mammography services proposed in this application are needed to ensure that residents of Guilford and Rockingham counties have adequate access to this vital diagnostic screening tool.”

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 mobile mammography services is needed in addition to the existing or approved mammography services.

Conclusion

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 application is conforming to this criterion based on 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, 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		
		1st FFY CY 2022	2 nd FFY CY 2023	3 rd FFY CY 2024
Administrator	0.00	0.15	0.15	0.20
Driver/Security	0.00	1.00	1.00	1.00
Other (Mammography Tech)	0.00	1.50	1.75	2.00
Other (Scheduled/Business Office Specialist)	0.00	0.20	0.20	0.20
TOTAL	0.00	2.80	3.10	3.40

The assumptions and methodology used to project staffing are provided in Section H, page 74. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 75-77, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit H.3, 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 78, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Image Interpretation
- Coach Driver
- Vehicle Maintenance
- Medical Equipment Maintenance
- Medical Physics
- Medical Direction
- Business Office/Registration
- Medical Record/Information Technology
- Administration, Human Resources/Payroll and Staff Education
- Materials Management
- Quality Assurance/Performance Improvement
- Radiation Safety
- Lined Service
- Pharmaceuticals

On pages 78-79, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, pages 79-80, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

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

NA

(11) The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.
Repealed effective July 1, 1987.

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

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 88, the applicant states that DRI has offered mammography services in Guilford County for many years. However, DRI does not currently provide mobile Mammography services.

In Section L, page 90, the applicant provides the historical payor mix during CY 2019 for fixed mammography services at Greensboro Imaging, as shown in the table below.

The Breast Center at Greensboro Imaging Historical Payor Mix, CY 2019	
Payor Category	Fixed Mammography Services as Percent of Total
Self-Pay	0.53%
Charity Care	**
Medicare*	36.87%
Medicaid*	2.42%
Insurance*	58.30%
Workers Compensation	0.00%
TRICARE	0.40%
Other (community discount programs)	1.48%
Total	100.00%

*Including any managed care plans

**Included in self-pay.

In Section L, page 89, the applicant compares the demographics of mammography patients at Greensboro Imaging to the demographics of Guilford County during CY 2019.

The Breast Center of Greensboro Imaging	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	99.48%	52.70%
Male	0.52%	47.30%
Unknown	0.00%	0.00%
64 and Younger	61.30%	84.50%
65 and Older	38.70%	15.50%
American Indian	**	0.80%
Asian	**	5.30%
Black or African- American	**	35.40%
Native Hawaiian or Pacific Islander	**	0.10%
White or Caucasian	**	50.00%
Other Race	**	8.40%
Declined / Unavailable	**	0.00%

*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>.

**Not available; DRI does not track patient racial/ethnic origin.

Sources: DRI, and United States Census Bureau QuickFacts for Guilford County, July 1, 2019 estimate.

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 90-91, the applicant states:

“DRI has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and handicapped persons. However, for information purposes, DRI does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.”

In Section L, page 91, 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 92, 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.

Projected Payor Mix 3rd FFY, CY 2024	
Payor Category	Fixed Mammography Services as Percent of Total
Self-Pay	30.0%
Charity Care	**
Medicare*	20.0%
Medicaid*	16.0%
Insurance*	30.0%
Workers Compensation	0.0%
TRICARE	0.0%
Other (community discount programs)	4.0%
Total	100.0 %

*Including any managed care plans

**Included in self-pay.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 30% of total services will be provided to self-pay patients, 20% to Medicare patients and 16% to Medicaid patients.

On pages 92-93, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on the historical outpatient visits for the four hospital-based locations for mammography services in Guilford and Rockingham counties: Cone Health's MedCenter High Point, High Point Regional Health, Annie Penn Hospital, and UNC Rockingham.
- The applicant considers the percentage of county residents who do not have health insurance.
- The applicant projects payor mix based on its assumption that the proposed project will improve access to mammography services for women underserved.

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 95, 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

In Section M, page 96, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a mobile diagnostic program by acquiring one tomosynthesis or 3D mammography system and a drivable coach to serve Guilford and Rockingham counties.

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 21, the applicant identifies the primary service area as Guilford and Rockingham counties. Facilities may also serve residents of counties not included in their service area.

In Section G, page 71, the applicant states:

“To the knowledge of DRI, Guilford County residents have minimal access to mobile mammography services. Specifically, DRI is aware that Novant Health operates a mobile mammography system within Guilford County for one day every other month. DRI is not aware of any mobile mammography service in Rockingham County.”

The following table identifies the fixed mammography units operating in a hospital in the proposed service area based the 2020 License Renewal Applications submitted to the Agency and available during this review. There is a total of five mammography units utilized at four hospitals.

Location	Units	Inpatient Procedures	Outpatient Procedures
Guilford			
High Point Regional Health	1	2	2,908
Moses Cone Hospital*	0	0	0
Wesley Long Hospital*	0	0	0
Women’s Hospital*	0	0	0
MedCenter High Point*	1	0	2,561
Rockingham			
UNC Rockingham Hospital**	2	0	4,809
Annie Penn Hospital	1	2	7,446
Total	5	4	17,724

Source: Section G, page 71, 2020 Hospital License Renewal Applications

*Operates on the Cone Health License

**Includes mammography equipment located at UNC Rockingham Wright Imaging Center, but operating under the hospital license

In Section G, page 72, the applicant identifies the following fixed mammography systems operated at freestanding imaging centers in Guilford County. On page 71, the applicant states that DRI is not aware of any freestanding mammography units located in Rockingham County.

Facility	City
Central Carolina OB/GYN	Greensboro
Cone health MedCenter High Point Imaging	High Point
Green Valley OB/GYN	Greensboro
Greensboro OB/GYN Associates	Greensboro
High Point Regional Health	High Point
Physicians for Women of Greensboro	Greensboro
Piedmont Comprehensive Women's Center	High Point
Premier Imaging	High Point
Solis Women's Health Radiology Associates of NC, PC	Greensboro
The Breast Center of Greensboro Imaging	Greensboro
Wendover OB/GYN and Fertility, Inc	Greensboro

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 97, the applicant states:

“With this proposed project, DRI is offering mobile mammography services at various geographic locations in the Greater Piedmont Triad in order to improve patient access to quality, cost-effective breast cancer screening. As an existing, experienced diagnostic imaging provider, but a new provider of mobile mammography services, DRI will have a positive effect on competition. The proposed project will promote cost-effective, high quality screening mammography services that will be more accessible by local residents...”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 97-98, the applicant states:

“The proposed mammography system is modern technology and offers ease of operation, excellent imaging quality, patient comfort, and energy efficiency capabilities. The ease of use will enable a higher volume of mammograms per day, thus containing the cost per procedure. Because the proposed equipment is mobile and will be hosted by existing host site facilities, operational infrastructure costs are practically zero, and the DRI corporate support structure already exists.”

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

Regarding the impact of the proposal on quality, in Section N, page 99, the applicant states:

“DRI will maintain the highest standard and quality of care, consistent with the standards that it has sustained throughout its many years of providing diagnostic imaging services in Guilford County.

...

DRI will utilize its existing quality-related policies and procedures, which serve well in operating its existing mammography services. These quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize medical diagnostic services.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 99-100, the applicant states:

“The proposes project will enable improved access to screening mammography services for medical underserved groups. DRI has identified three groups of medically underserved women to target with its proposed mobile mammography service: working women, women who may be uninsured or underinsured, and women in more distant and rural areas.

...

DRI has historically provided care and services to medically underserved populations. DRI does not discriminate based on income, race, ethnicity, creed, color, age, religion, nation origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factors that would classify a patient as underserved.”

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

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because it adequately demonstrates the following:

- the need the population to be served has for the proposal, the proposal would not result in an unnecessary duplication of existing and approved health services, and the reasonableness of projected revenues and operating costs which collectively results in a cost-effective proposal.
- the quality of the care to be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 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 which was 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 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 the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three imaging centers and two facilities licensed under Moses H. Cone Memorial Hospital located in North Carolina.

In Section O, page 104, the applicant states that, DRI imaging centers and the Cone Health facilities in North Carolina have provided quality care and operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding the submittal of the application. According to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred at MedCenter High Point and Annie Penn Hospital. However, both facilities are currently back in compliance. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all five 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 mobile mammography service which will be a diagnostic center. There are no administrative rules that are applicable to proposals for a mobile mammography service or a diagnostic center.