

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 26, 2021

Findings Date: March 26, 2021

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: G-11999-20

Facility: DRI Burlington

FID #: 200895

County: Alamance

Applicant(s): Diagnostic Radiology and Imaging, LLC

Project: Develop a diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP

### 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

Diagnostic Radiology and Imaging, LLC (referred to as “the applicant” or “DRI”) proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

#### **Need Determination**

The 2020 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional magnetic resonance imaging (MRI) scanners in North Carolina by service area. Application of the need methodology in the 2020 SMFP identified a need for one additional fixed MRI scanner in Alamance County service area. Therefore, the applicant’s proposal is consistent with the need determination in the 2020 SMFP.

#### **Policies**

There is one policy in the 2020 SMFP applicable to this review: *Policy GEN-3: Basic Principles.*

*Policy GEN-3* on pages 30-31 of the 2020 SMFP states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B, page 16; Section N, pages 102-103; Section O, pages 105-107, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B, pages 16-17; Section C.11, pages 46-47; Section L, pages 93-98; Sections N, pages 103-104, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section F, pages 64-70; Section K, page 86; Section N.2, pages 100-102; Section Q; and referenced exhibits. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

#### **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 does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
  - The applicant will ensure quality and patient safety through compliance with all applicable local, state and federal standards regarding MRI imaging.
  - DRI has a history of providing services to medically underserved groups.
  - The applicant's proposal will improve access to lower cost, freestanding MRI services to residents of Alamance County.

(2) Repealed effective July 1, 1987.

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

## C

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

### **Patient Origin**

In Section C, page 24, the applicant states that DRI Burlington is not an existing facility, therefore, there is no historical data to report. In Section C, pages 25-26, the applicant provides the historical patient origin for fixed MRI services at the W. Wendover Avenue Imaging Center in Guilford County and the projected patient origin for the proposed fixed MRI scanner to be located at DRI Burlington in Alamance County, as show in the tables below.

<b>Greensboro Imaging W. Wendover Avenue Imaging Center Historical Patient Origin</b>		
<b>County</b>	<b>Last Full FY 01/01/2019-12/31/2019 (CY 2019)</b>	
	<b>Patients</b>	<b>% of Total</b>
Guilford	11,009	69.61%
Rockingham	1,516	9.59%
Randolph	1,245	7.87%
Alamance	725	4.58%
Forsyth	393	2.48%
Davidson	188	1.19%
Other NC Counties*	384	2.43%
Virginia	288	1.82%
Other States	68	0.43%
<b>Total</b>	<b>15,816</b>	<b>100.00%</b>

\*Includes all other NC counties, each of which represent <1% of the total patient origin.  
 Totals may not foot due to rounding

<b>DRI Burlington Projected Patient Origin</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY 01/01/2022-12/31/2022 (CY 2022)</b>		<b>2<sup>nd</sup> Full FY 01/01/2023-12/31/2023 (CY 2023)</b>		<b>3<sup>rd</sup> Full FY 01/01/2024-12/31/2024 (CY 2024)</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Alamance	2,409	82.2%	2,785	81.6%	3,174	81.1%
Guilford	383	13.1%	459	13.5%	541	13.8%
Caswell	76	2.6%	91	2.7%	107	2.7%
Randolph	41	1.4%	50	1.5%	59	1.5%
Orange	19	0.6%	22	0.7%	26	0.7%
Rockingham	2	0.1%	2	0.1%	3	0.1%
Person	1	0.0%	1	0.0%	1	0.0%
Chatham	1	0.0%	1	0.0%	1	0.0%
<b>Total</b>	<b>2,932</b>	<b>100.0%</b>	<b>3,412</b> <b>[3,411]</b>	<b>100.0%</b>	<b>3,912</b>	<b>100.0%</b>

Project Analyst's calculation in brackets.

In Section C, pages 27-28, the applicant provides the assumptions and methodology used to project its patient origin. On page 27, the applicant states:

*“DRI projects the DRI Burlington patient origin based on the projected market share among Alamance County residents needing an MRI procedure, and on the projected shift of some W. Wendover Avenue MRI patients to DRI Burlington...”*

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The projected market share of Alamance County residents needing MRI procedures.

- Some MRI patients will shift from W. Wendover Avenue (Guilford County) to the new DRI Burlington facility.
- The applicant projects the patient origin at the proposed DRI Burlington based on the combination of the projected Alamance County MRI patient market share and the projected patient origin in the 16 targeted zip codes.

**Analysis of Need**

In Section C, pages 29-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which is summarized below.

**The 2020 SMFP Need Determination for One Additional Fixed MRI Scanner in Alamance County (pages 29-30)**

The applicant demonstrates need based on the 2020 SMFP methodology determining the need for one additional MRI scanner in Alamance County, which included the Alamance County adjusted threshold of 4,118 procedures per fixed equivalent scanner. The applicant states that Alamance County exceeded the threshold in FFY2018. See table below.

<b>Alamance County FFY 2018 MRI Scanner Utilization</b>					
	Total MRI Scans	Adjusted/Weighted Total	Service Area Average Procedures	70% Threshold	MRI Need
Alamance County	9,070	10,536	4,164	4,118	1

**Historical Alamance County MRI Procedures (pages 30-32)**

The applicant states that the MRI capacity in Alamance County currently consists of two hospital-based fixed scanners and a couple of mobile MRI sites. The applicant states that Alamance County’s weighted MRI (fixed and mobile) utilization demonstrated a Compound Annual Growth Rate (CAGR) of 7.58% from FFY2015 to FFY2019, as shown in the table below.

<b>Alamance County Weighted MRI utilization Fixed and Mobile MRI Scanners, FFY2015-FFY2019</b>					
FFY2015	FFY2016	FFY2017	FFY2018	FFY2019	4-Year CAGR
8,234	8,755	8,989	10,536	11,030	7.58%

Source: 2017 to Proposed 2021 SMFPs

According to population data from the North Carolina Office of State Budget Management (NCOSBM) and MRI volume data from 2015-proposed 2021 SMFPs, North Carolina has experienced a steady increase in unweighted MRI procedures from FFY2013 to FFY2019. However, Alamance County experienced an increase in unweighted MRI procedures at a lower rate during the same period of time. The applicant states that this is due to the thousands of Alamance County residents traveling to other counties to obtain MRI services, which confirms

the appropriateness of the need determination in the 2020 SMFP for one additional fixed MRI scanner in Alamance County.

Need for a Value-Based Fixed MRI Scanner Capacity in Alamance County (pages 32-34)

Alamance County currently has two hospital-based fixed MRI scanners. The applicant states that the proposed project will offer patients MRI services on a freestanding fixed MRI scanner, which are generally offered at a lower cost in comparison to a hospital-based MRI scanner. The applicant states that patients will benefit directly because of the focus on lower costs and they will also benefit indirectly through lower costs to the payors, which will result in lower costs to the healthcare system.

Alamance County Demographics and Geography (pages 35-39)

The applicant states that the proposed project is supported by the continuing population growth in Alamance County. According to data from NCOSBM, the population in Alamance County is projected to grow at a 5-year CAGR of 1.1% between 2020-2025, as illustrated in the table below.

<b>Alamance County Projected Population, 2020-2025</b>							
<b>Area</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>5- Year CAGR</b>
Alamance	174,055	176,838	178,595	180,353	182,108	183,868	1.10%
North Carolina	10,630,691	10,753,496	10,273,632	10,992,997	11,112,320	11,233,133	1.11%

Source: Section C, page 35, NCOSBM, Vintage 2019

The applicant states that according to data from NCOSBM, by 2025, 19.5% of the Alamance County population will be over 65, up from 17.8% in 2020. The aging population is expected to grow at a five-year CAGR of 2.92%, which is higher than the average growth rate for the total county population.

<b>Alamance County Projected Population Age 65+, 2020-2025</b>					
<b>Age Cohort</b>	<b>2020</b>		<b>2025</b>		<b>5-Year CAGR</b>
65+	31,037	17.8%	35,843	19.5%	2.92%
Total Population	174,055		183,868		1.1%

Source: Section C, page 36, NCOSBM, Vintage 2019

The applicant states that typically older residents utilize healthcare services at a higher rate. The growth and aging of the Alamance County population will continue to increase the demand for healthcare services, including MRI services, which further demonstrates the need for the proposed fixed MRI scanner.

The applicant states that the proposed MRI scanner will provide local and more convenient geographic access for Alamance County residents to obtaining freestanding, full-time “value-based” fixed MRI services. The proposed MRI scanner will be located in Burlington, which is the largest city in Alamance County. Burlington is close to Elon, the third largest town in Alamance County, and close to other municipalities.

High Utilization of DRI’s Existing Fixed MRI Scanners and Service to Alamance County Residents (pages 39-41)

Greensboro Imaging currently operates three fixed MRI scanners at the W. Wendover Avenue Imaging Center Guilford County. The applicant states that DRI has served hundreds of Alamance County residents over the years. The applicant states that Greensboro Imaging is distinguished from its competitors based on its sub-specialty/fellowship trained physicians in breast imaging, neuroradiology, pediatric radiology, full body imaging, vascular and interventional radiology, and musculoskeletal radiology, which ensures true sub-specialty interpreted studies. The applicant states that the comprehensive team of sub-specialists at DRI renders it the most ideal outpatient diagnostic imaging provider to facilitate patient care as patients shift from hospital-based setting to a freestanding facility.

Physician Support (page 41)

The applicant states that DRI is a long-established local healthcare provider and has long-standing working relationships with the referring physician community in Alamance and surrounding counties. In addition, The Greensboro Radiology radiologists who diagnose patients at DRI’s imaging centers have practiced locally for many years. The applicant states that it anticipates that its large network of referring physicians and other community providers of many specialties, will continue to refer patient to DRI for MRI services.

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

- There is a need for one fixed MRI scanner in Alamance County, as stated in the 2020 SMFP.
- The applicant relies on population and demographic growth trends to support the need.
- The applicant demonstrates high utilization of existing fixed MRI scanners serving Alamance residents to support the need.

Projected Utilization

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

<b>Projected Utilization of Proposed Fixed MRI Scanner</b>			
	<b>1<sup>st</sup> FY CY 2022</b>	<b>2<sup>nd</sup> FY CY 2023</b>	<b>3<sup>rd</sup> FY CY 2024</b>
# of Units	1	1	1
# of Procedures	2,932	3,412	3,912
# of Weighted Procedures	3,395	3,952	4,531

In Section Q, pages 111-117, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: DRI Burlington MRI Market Share*

The applicant begins with its projections of the demand for MRI procedures by Alamance County residents for CY2021 through CY2024 by multiplying the annual projected Alamance County population by the average Alamance County resident MRI use rate of 70.9% for the past four years, illustrated below.

<b>Alamance County Residents Projected MRI Procedures, CY2021-CY2024</b>				
<b>MRI Procedures on Alamance County Residents</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
	12,543	12,668	12,793	12,917

The applicant states that the MRI use rate of 70.9% is reasonable and conservative since it is less than the actual FY2019 Alamance County Resident MRI use rate of 71.7%. The following table illustrates the historical MRI utilization rate for Alamance County.

<b>Alamance County Residents Historical MRI Utilization Rate, FFY2016-FFY2019</b>			
<b>Year</b>	<b>County Population</b>	<b>Number of Procedures</b>	<b>Use rate/1000</b>
FY2016	159,836	11,179	69.9
FY2017	163,045	12,138	74.4
FY2018	166,638	11,264	67.6
FY2019	170,483	12,231	71.7

Source: Section Q, page 112; NCOSBM Vintage 2019; MRI volume data from DHSR MRI Patient Origin Reports  
 Totals may not foot due to rounding.

The applicant projects that the proposed fixed MRI scanner will obtain market share among Alamance County residents needing MRI scans during the initial three project years based on DRI's offering access to a 3T scanner, its convenient location, DRI's reputation for high quality services, and patient preference for a freestanding fixed MRI scanner as opposed to a hospital-based fixed MRI scanner. The following table provides DRI Burlington MRI percentage market share projections for Alamance County residents.

<b>Alamance County Projected DRI Market Share Percentage</b>				
	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
<b>Alamance County Residents Procedures</b>	12,543	12,668	12,793	12,917
DRI Burlington new market share %	0.0%	15.0%	17.0%	19.0%

Source: Section Q, page 112

The applicant projects the market share of MRI unweighted procedures at DRI Burlington by multiplying the market share percentage by the total projected Alamance County resident procedures, as illustrated in the table below.

<b>Projected DRI Burlington Market Share MRI Procedures</b>			
	<b>2022</b>	<b>2023</b>	<b>2024</b>
Projected DRI Burlington			
Total Unweighted Procedures	1,900	2,175	2,454

*Step 2: Shift of Procedures from W. Wendover Ave to DRI Burlington*

The applicant projects that some MRI patients will shift their services from DRI’s W. Wendover Avenue facility to the proposed DRI Burlington. The applicant states that the reason for the shift of patients is based on factors such as the offering of a fixed 3T MRI scanner, its convenient outpatient location, and the proximity to referring physicians located in Burlington and Alamance County. The applicant targets 16 zip codes based on the facility’s location. The applicant conservatively assumes a 65% patient shift for Project Year 1, 75% shift for Project Year 2, and 85% for Project Year 3. The following table demonstrates the projected shift of unweighted MRI procedures from W. Wendover Avenue’s fixed MRI scanners to DRI Burlington’s fixed MRI scanner for the targeted zip codes during the initial three project years.

<b>Projected DRI Unweighted MRI Procedures Shifting from W. Wendover Ave. to Burlington</b>			
	<b>2022</b>	<b>2023</b>	<b>2024</b>
Shift to DRI Burlington			
27212, 27215, 27217, 27244, 27249	534	641	755
27253, 27258, 27291, 27298, 27302	275	330	388
27311, 27314, 27315, 27349, 27377, 27379	223	268	316
<b>Total Shifted Procedures</b>	<b>1,031</b>	<b>1,237</b>	<b>1,458</b>

Source: Section Q, page 115  
 Totals may not foot due to rounding.

*Step 3: Total Project Burlington MRI procedures*

To calculate total MRI procedures at DRI Burlington for the first three project years, the applicant combined the projected market share of MRI procedures and the projected shift of W. Wendover Avenue procedures. To calculate the projected weighted MRI procedures, the applicant used the five-year (CY2016-CY2020) average weighted DRI MRI procedure ratio of 1.158% and multiplied it by the projected annual unweighted DRI Burlington MRI procedures. The following table illustrates the applicant’s calculations.

<b>Total Projected DRI Burlington MRI Procedures</b>			
<b>DRI Burlington total after shift</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
Shifted from W. Wendover Ave.	1,031	1,237	1,458
Market share gain	1,900	2,175	2,454
Total unweighted	2,932	3,412	3,912
Weighted procedures	3,395	3,952	4,531
Weighting ratio	1.158	1.158	1.158

Source: Section Q, page 116  
 Totals may not foot due to rounding

*Step 4: Total Projected W. Wendover Avenue MRI procedures after Shift*

To calculate the total projected MRI procedures at W. Wendover Avenue through CY 2024, the applicant subtracted the MRI procedures that will shift from W. Wendover Avenue to DRI Burlington. To calculate the projected weighted MRI procedures, the applicant uses the five-year (CY2016-CY2020) average weighted DRI MRI procedure ratio of 1.158% and multiplied it by the projected annual unweighted W. Wendover Avenue MRI procedures. The following table illustrates the applicant’s calculations.

<b>Total Projected W. Wendover Ave. Fixed MRI Procedures</b>				
<b>W. Wendover Ave. after shift</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
Fixed Unweighted procedures	17,095	17,773	18,477	19,210
Shifted to Burlington		1,031	1,237	1,458
Shifted to Summerfield		2,570	3,083	3,633
Total unweighted	17,095	14,171	14,157	14,119
Weighted procedures	19,800	16,413	16,396	16,353
Weighting ratio	1.158	1.158	1.158	1.158

Source: Section Q, page 116  
 Note: W. Wendover Ave. facility has three MRI scanners.  
 Totals may not foot due to rounding

*Step 5: Total Combined DRI MRI Procedures on Guilford County Fixed MRI Scanners*

The applicant states that for information purposes, it combined the projected total MRI procedures on the W. Wendover Avenue and DRI’s Summerfield fixed MRI scanners. The projected average weighted procedures per scanner exceeds the Guilford County performance standard for MRI scanners, as illustrated in the table below.

<b>Total Projected DRI Fixed MRI Procedures Combined W. Wendover Ave. &amp; Summerfield (Guilford County)</b>				
<b>Combined DRI Fixed in Guilford</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>
Weighted W. Wendover Ave. procedures	19,800	16,413	16,396	16,353
Weighted Summerfield procedures		3,308	4,074	4,887
Total weighted procedures	19,800	19,721	20,471	21,239
Average weighted procedures/scanner		4,930	5,118	5,310

Source: Section Q, page 117

Note: W. Wendover Ave. facility has three MRI scanners, Summerfield has one approved MRI scanner.  
Totals may not foot due to rounding

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

- There is a need determination in the 2020 SMFP for a fixed MRI scanner in the Alamance County MRI service area and this project will meet that need determination by developing a fixed MRI scanner in Alamance County.
- The applicant’s utilization projections are supported by the historical utilization of MRI scanners owned by the applicant.
- The applicant provides adequate support for the projected shift of MRI patients to the proposes DRI Burlington.
- The applicant provides adequate support for the projected population growth in Alamance County.
- The application meets the Performance Standards in 10A NCAC 14C 2700.

**Access to Medically Underserved Groups**

In Section C, pages 46-47, the applicant states:

*“DRI has historically provided care and services to medically underserved population...DRI offers imaging services to the elderly. Also, DRI provided 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 as underserved.”*

In supplemental information provided to the Agency, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low income persons	14.6%
Racial and ethnic minorities	26.4%
Women	52.5%
Persons with Disabilities	8.9%
The elderly	17.1%
Medicare beneficiaries	39.2%
Medicaid recipients	3.27%

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:

- DRI has a history of providing services to medically underserved populations at their established facilities.
- 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.

### **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 all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

In Section E, pages 60-63, 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 Status Quo**-The applicant states that this alternative was not the most effective since the 2020 SMFP identifies a need for one additional fixed MRI scanner in Alamance County and the county does not currently host a freestanding fixed MRI scanner.

**Contract a Mobile MRI Scanner**-The applicant states that this alternative would only serve as a short term solution. In addition, a mobile MRI scanner has limited accessibility and does not address the issue of patients with medical equipment or space constraints for obese patients.

**Develop the Proposed Diagnostic Center in Another Alamance County Location**-The target site for the proposed fixed MRI scanner is Burlington. The applicant states that Burlington is the most populous city in Alamance County and does not have a freestanding fixed MRI scanner. The applicant states that DRI patients, and residents from throughout Alamance County will benefit from the easy geographic access to the facility.

**Obtain a 1.5T Scanner**-The applicant states that obtaining the 3T fixed scanner is more advantageous than obtaining 1.5T because it provides more scanning options, higher resolution, and has a lower risk of distorted images.

On page 63, the applicant states that its proposal is the most effective alternative because DRI Burlington will offer high quality and cost-effective freestanding MRI imaging services in a convenient and easily accessible location.

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 proposal will provide accessible, high-quality and cost-effective imaging services.
- 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. Diagnostic Radiology & Imaging, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop a diagnostic center by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.**
- 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 August 1, 2021. The second progress report shall be due on December 1, 2021 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. 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.**

**6. 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 new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

**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.

<b>Diagnostic Radiology &amp; Imaging, LLC Capital Costs</b>	
Construction/Renovation Contract(s)	\$340,765
Architecture/Engineering Fees	\$48,912
Medical Equipment (includes sales tax and freight)	\$1,409,100
Furniture	\$5,000
Consultant Fees (CON-related)	\$50,000
Financing Costs	\$2,500
Interest during Construction	\$4,246
Other (IT, contingency)	\$34,484
<b>Total</b>	<b>\$1,895,007</b>

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the applicant's experience and estimated vendor quotes.

In Section F, pages 66-67, the applicant projects that start-up costs will be \$11,000 and initial operating expenses will be \$44,000 for a total working capital of \$55,000. In Section Q, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant's working capital assumptions includes expenses such as wages/salaries, benefits, medical supplies, and facility leasing.

- For initial operating expenses, the applicant assumes 15 percent of first year revenues collected during initial three months.

### **Availability of Funds**

In Section F, page 65, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Type</b>	<b>DRI</b>	<b>Total</b>
Loans	\$1,409,100	\$1,409,100
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (line of credit)	\$485,907	\$485,907
<b>Total Financing</b>	<b>\$ 1,895,007</b>	<b>\$ 1,895,007</b>

\*OE = Owner's Equity

In Section F, page 67, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

<b>Sources of Financing for Working Capital</b>	<b>Amount</b>
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$0
Lines of credit	\$55,000
Bonds	\$0
<b>Total *</b>	<b>\$55,000</b>

Exhibit F-2 contains a letter from the Director of Finance for Diagnostic Radiology and Imaging, Inc., stating that capital and working capital will be funded through a commercial loan from First Citizens Bank. Exhibit F-2 also contains a letter from the Senior Vice President of First Citizens Bank stating that a line credit in the amount of \$2,000,000 will be available to the applicant to fund the 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 full fiscal years following completion of the project, as shown in the table below.

	<b>1<sup>st</sup> FFY CY 2022</b>	<b>2<sup>nd</sup> FFY CY 2023</b>	<b>3<sup>rd</sup> FFY CY 2024</b>
Total Procedures	3,395	3,952	4,531
Total Gross Revenues (Charges)	\$4,427,945	\$5,153,573	\$5,908,879
Total Net Revenue	\$1,513,792	\$1,761,864	\$2,020,082
Average Net Revenue per Procedure	\$445.80	\$445.81	\$445.83
Total Operating Expenses (Costs)	\$1,378,313	\$1,714,207	\$1,860,483
Average Operating Expense per Procedure	\$405.98	\$433.75	\$410.61
Net Income	\$135,479	\$47,657	\$159,600

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

- The applicant’s detailed financial assumptions which include projected estimates on payor mix percentages, direct and indirect expenses, depreciation and inflation
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

According to Table 17E-1, page 421 of the 2020 SMFP, there are two fixed MRI scanners located in Alamance County, as illustrated in the table below.

Location	Fixed MRI Scanners Units	Total MRI Scans	Total Weighted MRI Scans
Alamance Regional Medical Center	2	6,929	8,182

In Section G, pages 73-74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Alamance County. On page 73, the applicant states:

*“As evidenced by the need determination in the 2020 SMFP, the State Health Coordinating Council (SHCC) considers the existing fixed MRI scanners inadequate to meet the need in the MRI service area. The SMFP methodology takes into consideration all MRI utilization performed on the existing MRI scanner, and determined a need for one additional fixed MRI scanner in Alamance County. The proposed project will not result in unnecessary duplication as the need was generated by a Cone Health facility, Alamance Regional Medical Center.”*

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:

- There is a need determination in the 2020 SMFP for the proposed fixed MRI scanner.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners.
- The applicant adequately demonstrates that the proposed fixed MRI scanner will provide accessible, high-quality and cost-effective imaging services to Alamance residents.

### **Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

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

Position	Projected FTE Staff
	2nd Full Fiscal Year CY 2023
Administrator	0.1
MRI Tech	1.75
MRI Tech Assistant	0.75
Sales Liaison	0.15
Receptionist	1.5
Scheduling/Medical Records	1.0
<b>TOTAL</b>	<b>5.25</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3. 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.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the applicant's experience in recruiting qualified staff and its existing training programs to ensure competency of staff members.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

#### **Ancillary and Support Services**

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 79-80, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1 and I.3. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Images will be read by radiologists through service agreements.
- DRI staff will provide services such as medical records/Information Technology, administration, material management, quality assurance, and linen services.
- The facility will obtain all pharmacy items from Cone Health Pharmacy Services.

#### **Coordination**

In Section I, pages 80-81, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant's experience as a long-established local healthcare provider
- The applicant's long-standing relationships with the referring physician community in Guilford and surrounding counties, including Alamance.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

C

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

In Section K, page 85, the applicant states that the project involves renovating 1,035 square feet of existing space. Line drawings are provided in Exhibit K.1.

On page 86, 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 proposal will be directed by an experienced architect and construction professionals.
- In Exhibit K.3, the applicant provides a construction cost estimate.
- The proposed project involves renovating an existing space as opposed to constructing a new space.

On page 86, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- As a freestanding MRI provider, DRI will offer MRI charges that are lower compared to hospital-based MRI services.
- The project will offer Alamance County residents a convenient local location for obtaining fixed MRI services.

On pages 86-87, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 93, the applicant provides the historical payor mix during CY 2019 for the MRI services at Greensboro Imaging (which serves Alamance County residents) in neighboring Guilford County, as shown in the table below. On page 92, the applicant states that the existing MRI scanner in Guilford County also serves residents of Alamance County. The applicant does not currently offer MRI services within Alamance County.

<b>Greensboro Imaging Historical Payor Mix CY 2019</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay**	2.13%
Medicare*	44.98%
Medicaid*	4.97%
Insurance*	46.01%
Workers Compensation	0.74%
TRICARE	0.46%
Other (Miscellaneous)	0.71%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans.

\*\*including charity care

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... 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 93, the applicant states:

*“DRI has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and handicapped persons.”*

In Section L, page 94, 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 95, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>DRI Burlington Projected Payor Mix CY 2024</b>	
<b>Payor Category</b>	<b>MRI Services as Percent of Total</b>
Self-Pay**	1.97%
Medicare*	39.20%
Medicaid*	3.27%
Insurance*	53.14%
Workers Compensation	1.51%
TRICARE	0.60%
Other (Miscellaneous)	0.31%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans.

\*\*including charity care

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.97% of total services will be provided to self-pay and charity-care patients, 39.20% to Medicare patients and 3.27% to Medicaid patients.

On pages 95-96, 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 based its projected payor mix on the CY 2019 MRI payor mix for Alamance County residents who obtained an MRI scan at Greensboro Imaging and applied the projected market share earned by DRI Burlington of Alamance residents needing MRI scans.
- The applicant based its projected payor mix on the CY 2019 MRI payor mix at the W. Wendover Ave. facility and applied the MRI procedures projected to shift from W. Wendover Ave. to DRI Burlington.

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 98, 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 develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

In Section M, page 99, 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. The applicant adequately demonstrates that health

professional training programs in the area will have access to the facility for training purposes based on the following:

- DRI will offer its additional fixed MRI scanner to area schools and clinical training programs to provide students clinical training rotation.
- The applicant provides letters to and from Alamance Community College indicating a mutual willingness to establish a clinical training relationship.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## C

The applicant proposes to develop a new diagnostic center (DRI Burlington) in Alamance County by acquiring no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP.

On page 418, the 2020 SMFP defines the service area for a fixed MRI scanner as *the same as an Acute Care Bed service area*. Thus, the service area for this facility consists of Alamance County. Facilities may also serve residents of counties not included in their service area.

According to the 2020 SMFP, there are two fixed MRI scanners located in Alamance County, as illustrated in the table below.

<b>Location</b>	<b>Fixed MRI Scanners Units</b>	<b>Total MRI Scans</b>	<b>Total Weighted MRI Scans</b>
Alamance Regional Medical Center	2	6,929	8,182

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 100, the applicant states:

*“Obtaining the proposed fixed MRI scanner will enable DRI to compete in Alamance County, by offering patient convenience, cost-effective access to the County’s first freestanding MRI service with lower out-of-pocket costs, and access to advanced diagnostic imaging capabilities for patients with special needs.*

...

*As an existing, experienced local diagnostic imaging provider, DRI will have a positive effect on competition in Alamance County.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 101, the applicant states:

*“The capital cost of 3T magnets has decreased significantly over the past 10 years, such that the cost approximates that of a new 1.5T scanner. Insurance companies pay the same amount for an MRI, regardless of whether the exam is performed on a low-field or high-field magnet. DRI provides the highest quality of service from both a clinical and an operational perspective and therefore feels that for this project a 3T scanner is a cost-effective option for providing freestanding MRI services.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 102-103, the applicant states:

*Patient safety and quality will be incorporated into all aspects of the project, including equipment selection, facility design, credentialing, staff education, patient selection and scheduling, and continuous quality measures and patient satisfaction surveys.*

...

*DRI will utilize its existing quality-related policies and procedures, which serve well in operating its existing MRI services.”*

See also Sections B, 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 103-104, the applicant states:

*“DRI has historically provided care and services to medically underserved populations. DRI is committed to caring for the local community, one patient at a time, and will continue to serve the medically indigent with charitable care.*

...

*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 as underserved.”*

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

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

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

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 six diagnostic centers located in North Carolina.

Section O, page 108, the applicant states:

*“DRI has never had its Medicare or Medicaid provider agreement terminated. Each of the DRI imaging centers identified in Form A Facilities has provided quality care and operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding submission of this application. Diagnostic centers are not licensed facilities; therefore, there are no Division of Health Service Regulation license requirements.”*

After reviewing and considering information provided by the applicant regarding the quality of care provided at all six 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.

## C

The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

### **SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER**

#### **10A NCAC 14C .2703 PERFORMANCE STANDARDS**

- (a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*
- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in*

*the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*

- (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
- (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule*

-NA- The applicant does not propose to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

(b) *An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*

- (1) *demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

-NA- The MRI service area is Alamance County. The applicant states that there are no existing fixed MRI scanners in which the applicant or a related entity owns a controlling interest in and located in the proposes MRI service area. Therefore, this rule is not applicable to this review.

- (2) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

-NA- The MRI service area is Alamance County. The applicant states that neither the applicant or a related entity owns a controlling interest in an existing mobile MRI scanner in the Alamance County. Therefore, this rule is not applicable to this review.

- (3) *demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

- (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-C- The 2020 SMFP shows that there are two fixed MRI scanners located in the MRI service area of Alamance County. Therefore, the applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Alamance County will be at least 4,118 weighted MRI procedures in the third year of operation following completion of the proposed project (CY2024). In Section Q, page 116, the applicant projects the proposed fixed MRI at DRI Burlington will perform 4,531 weighted MRI procedures in the third year following completion of the proposed project (CY2024).

In Section Q, page 119, the applicant projects that Alamance Regional Medical Center will perform 8,934 weighted MRI procedures in the third year of operation on the only two fixed MRI scanners located in the proposed service area. Assumptions and Methodology are provided in Section Q, pages 118-119. The applicant states that it projects to perform 13,465 [8,934 + 4,531] weighted MRI procedures on its existing and proposed MRI scanners in the third year of the proposed project for an average of 4,488 weighted MRI scans per scanner [13,465 / 3 = 4,488] which exceeds the required average of 4,118 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

- (4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*
  - (A) *1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
  - (B) *3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
  - (C) *4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
  - (D) *4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
  - (E) *4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-C- The proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or related entity. Therefore, pursuant to the rule, the applicant must demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform 4,118 weighted MRI procedures in the third year following completion of the proposed project. In Section Q, page 116, the applicant projects

the proposed fixed MRI at DRI Burlington will perform 4,531 weighted MRI procedures in the third year following completion of the proposed project (CY2024), which exceeds the required average of 4,118 weighted MRI procedures per scanner in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference

(5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

-NA- The applicant states that neither the applicant or a related entity owns a controlling interest in an existing, approved or proposed mobile MRI scanner in Alamance County.

(6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-C- The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.

(c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- The applicant does not propose the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.

(d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*

(2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- The applicant does not propose the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.

- (e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*
- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
  - (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
- NA- The applicant does not propose the acquisition of a dedicated fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.