REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned NC = Nonconforming

NA = Not Applicable

Decision Date: March 29, 2021 Findings Date: April 6, 2021

Project Analyst: Tanya M. Saporito Co-Signer: Fatimah Wilson

COMPETITIVE REVIEW

Project ID #: G-011981-20 Facility: DRI Summerfield

FID #: 200818 County: Guilford

Applicant(s): Diagnostic Radiology & Imaging, LLC

Project: Develop a new diagnostic center by acquiring no more than one fixed MRI scanner

pursuant to the need determination in the 2020 SMFP

Project ID #: G-011986-20

Facility: Southeastern Orthopaedic Specialists, P.A.

FID #: 200823 County: Guilford

Applicant(s): Southeastern Orthopaedic Specialists, PA

Project: Develop a new diagnostic center by acquiring no more than one fixed MRI Scanner

pursuant to the need determination in the 2020 SMFP

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

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 – Both Applications

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 Guilford County. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of two new fixed MRI scanners. However, pursuant to the need determination, only one additional fixed MRI scanner may be approved in this review.

Policies

One policy in Chapter 4 of the 2020 SMFP is applicable to the applications received in response to the need determination.

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."

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner Diagnostic Radiology & Imaging, LLC, d/b/a Greensboro Imaging (DRI), the applicant, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Guilford County MRI service area.

Policy GEN-3. In Section B.2, pages 15-16, the applicant explains why it believes its application is conforming to Policy GEN-3.

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 does not propose to acquire more fixed MRI scanners than are determined to be needed in the Guilford County MRI service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in Guilford County;
 - The applicant adequately documents how the project will promote equitable access to MRI services in Guilford County; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

Southeastern Orthopaedic Specialists, P.A. (SOS), the applicant, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Guilford County MRI service area.

Policy GEN-3. In Section B.2, pages 24-26, the applicant explains why it believes its application is conforming to Policy GEN-3.

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 does not propose to acquire more fixed MRI scanners than are determined to be needed in the Guilford County MRI service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in Guilford County;
 - The applicant adequately documents how the project will promote equitable access to MRI services in Guilford County; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (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 - Both Applications

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County. The members of DRI are Greensboro Radiology, P.A. and Moses Cone Medical Services, Inc. Moses Cone Medical Services, Inc. is affiliated with The Moses H. Cone Memorial Hospital.

Patient Origin

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 Guilford County. Facilities may also serve residents of counties not included in their service area.

The proposed facility has no historical patient origin to report since it does not exist. In Section C, page 22, the applicant provides its historical patient origin for calendar year (CY) 2019 for its W. Wendover imaging center located in Greensboro in Guilford County, as illustrated in the following table:

COUNTY / ZIP CODE	LAST F 1/1/2019 –	
	# OF PATIENTS	% OF TOTAL
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%
Total	15,816	100.00%

^{*}The applicant state *Other NC Counties* includes all other NC counties, each of which represents less than 1% of total patient origin.

Numbers may not sum due to rounding.

The following table illustrates projected patient origin for the new diagnostic center for the first three full calendar years of operation:

County	1 st FULL FY CY 2022		2 ND Ft CY 2	JLL FY 2023	3 RD FULL FY CY 2024		
	# PTS	% OF TOTAL	# PTS	% OF TOTAL	# PTS	% OF TOTAL	
Guilford	1,613	56.5%	1,999	56.8%	2,407	57.0%	
Rockingham	1,118	39.2%	1,350	38.4%	1,598	37.9%	
Alamance	23	0.8%	34	1.0%	46	1.1%	
Randolph	13	0.5%	20	0.6%	27	0.6%	
Forsyth	7	0.2%	11	0.3%	15	0.3%	
Davidson	3	0.1%	5	0.1%	7	0.2%	
Other NC Counties*	72	2.5%	89	2.5%	106	2.5%	
Virginia	5	0.2%	8	0.2%	11	0.3%	
Other States	1	0.0%	2	0.1%	3	0.1%	
Total	2,857	100.0%	3,518	100.0%	4,219	100.0%	

Source: Section C.3, page 23.

Percentages may not sum due to rounding

In Section C, pages 24-26, the applicant provides the assumptions and methodology used to project patient origin which is based on the applicant's historical W. Wendover imaging center patient origin. The applicant also adjusts patient origin to reflect a projected shift of those patients proposed to transfer to DRI Summerfield because of the proposed facility's proximity to those patients' residence. The applicant assumes the projected MRI patients at the Summerfield location will represent the same ZIP codes in northern Guilford and southern Rockingham counties that are currently served by the W. Wendover location. The applicant's assumptions are reasonable and adequately supported because they are based on actual historical patient origin for the applicant's other Guilford County MRI scanners.

Analysis of Need

In Section C.4, pages 26-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need determination in the 2020 SMFP for one additional fixed MRI scanner in Guilford County The 2020 SMFP has determined there is a need for one additional fixed MRI scanner based on a total of 12 existing fixed MRI scanners and 67,634 adjusted MRI scans. (pages 26-27).
- Historical MRI utilization in Guilford County The applicant states the 12 existing fixed MRI scanners in Guilford County are well utilized and that the use rate in Guilford County from federal fiscal year (FFY) 2013 to FFY 2019 was higher in Guilford County than in the state as a whole (pages 27-29).
- High utilization of DRI's existing fixed MRI scanners in Greensboro The applicant states the W. Wendover Avenue imaging center in Greensboro operates three fixed MRI scanners. The utilization of those three scanners increased by a compound annual growth rate (CAGR) of 7.92% in the three-year period FFY 2016 FFY 2019 and a four-year CAGR of 5.09% during FFY 2015 FFY 2019 for unweighted MRI scans (pages 29-30).
- Growth and aging of Guilford County population The applicant cites data from the North Carolina Office of State Budget and Management (OSBM) to illustrate the over 65 population group in Guilford County is projected to increase by a five-year CAGR of 3.15%, whereas the general population of Guilford County is projected to increase by a five-year CAGR of 1.17% from 2020 to 2025. The applicant states that typically it is the older cohorts that utilize MRI services because the aging process causes significant changes in the neuromuscular and skeletal system (pages 30-32).
- General health status of Guilford County population The applicant states physicians use MRI scans in care management of cancer, vascular disease, renal disease, neuromuscular issues, and other health issues. Data from the North Carolina Center for Health Statistics indicates that Guilford County residents have higher rates of cancer, heart disease, neurological disease and other diseases, which demonstrate a need for increased diagnostic resources (pages 32-33).
- Geographic considerations of a need for a freestanding fixed MRI scanner in the proposed location The applicant states the population in the Summerfield area of Greensboro is growing, and several residential neighborhoods are either being developed or are planned, all within a five-mile radius of the proposed location of DRI Summerfield. The applicant states the closest MRI is the W. Wendover Avenue facility which, depending on traffic conditions, can take 20 minutes one-way for residents close to Summerfield to reach. The proposed location of DRI Summerfield will ease that burden for existing patients and serve residents of Guilford and neighboring Rockingham counties more efficiently than the existing MRI services (pages 33-36).

- Physician support for the proposed MRI The applicant states local radiologists, physicians and community members support the proposed MRI scanner in the Summerfield location (page 37). The applicant provides letters of support from area radiologists, referring physicians and community members in Exhibit I.2, which state that an additional MRI scanner will help to alleviate existing capacity constraints, and that physicians will refer patients for MRI services.
- Need for value-based fixed MRI in Guilford County The applicant states Guilford County currently has 12 fixed MRI scanners, six of which are hospital-based. The applicant states free-standing MRI services are typically provided at a lower cost than hospital-based services, which benefits patients who desire a low-cost option (page 37).

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

- There is a need determination in the 2020 SMFP for one additional fixed MRI scanner in Guilford County.
- The applicant relies on population growth statistics, a ZIP code analysis of its existing W. Wendover patients, and its own historical MRI utilization in its existing imaging facility to support its need for an additional fixed MRI scanner in Greensboro.
- The applicant's existing MRI scanners have been operating in excess of the threshold requirement of 4,805 weighted MRI scans per fixed MRI scanner required by 10A NCAC 14C .2703(b)(3).
- The applicant adequately demonstrates the need for a freestanding fixed MRI scanner in the Summerfield area of Greensboro in addition to the existing free-standing and hospital-based fixed MRI scanners in Greensboro, based on historical and projected utilization.

Projected Utilization

In Section Q, Form C, the applicant provides historical utilization, as illustrated in the following table based on the applicant's internal data:

HISTORICAL W. WENDOVER UTILIZATION

	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020*	3-YEAR CAGR
Total Unweighted Procedures	12,580	13,891	14,375	15,816	8,172	7.93%
Total Weighted Procedures	14,455	15,990	16,625	18,383	9,578	
Weighting Ratio	1.149	1.151	1.157	1.162	1.172	

^{*}For this year to date utilization, the applicant used 8 months of data through August 31, 2020. The applicant states the data is anomalous based on the impact of the COVID-19 pandemic and resulting decreased utilization.

In Section Q, pages 108-118, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

• Projected DRI MRI procedures at W. Wendover – The applicant examined DRI's historical fixed MRI utilization at W. Wendover form 2016-2020. The applicant considers 2020 data anomalous and does not factor 2020 utilization in its projections.

The applicant reports its data in calendar years, which differs from SMFP data reporting (the SMFP uses a federal fiscal year).

For clarity, the following table prepared by the Project Analyst illustrates annualized 2020 data:

PROCEDURES	2020 YEAR TO DATE	DIVIDED BY 8 MONTHS	x 12 Months (2020 Annualized)	
Unweighted Procedures	8,172	1,021.5	12,258	
Weighted Procedures	9,578	1,197.25	14,367	

• MRI Growth Rate at W. Wendover – The applicant calculated a 7.93% compound annual growth rate (CAGR) for the three-year period CY 2016 through CY 2019 at its W. Wendover location. The applicant projected MRI procedures based on 50% of the 7.93% three-year CAGR, or 3.96% [7.93 / 2 = 3.96]. Additionally, the applicant averaged its weighting ratios for CY 2016-CY 2020 at W. Wendover and applied this average (1.158) to project the number of weighted MRI procedures, as seen in the following table from page 109:

PROJECTED W. WENDOVER UTILIZATION

	CY 2020*	CY 2021	CY 2022	CY 2023	CY 2024
Total Unweighted Procedures	12,258	17,095	17,773	18,477	19,210
Total Weighted Procedures	14,367	19,800	20,584	21,401	22,249
Weighting Ratio	1.172	1.158	1.158	1.158	1.158

^{*}annualized

 Guilford County MRI Use Rate – Using population statistics for Guilford County from the NCSOBM and the total number of MRI procedures performed in the county from previous SMFPs, the applicant calculated an annual historical MRI use rate for Guilford County for each year from FY 2015 – 2019, as shown in the following table from page 110:

Guilford County Historical MRI Use Rate, FY 2015-FY2019

YEAR	COUNTY	# PROCEDURES	USE RATE / 1,000
	POPULATION		
FY 2015	516,493	56,242	108.9
FY 2016	523,934	52,279	99.8
FY 2017	528,041	50,146	95.0
FY 2018	534,346	56,842	106.4
FY 2019	539,666	55,693	103.2

Source: application page 110; applicant states data is from NCOSBM and 2015-2021 SMFPs

The applicant averaged the use rates from FY 2015–FY 2019, to arrive at an average Guilford County MRI use rate of 102.6.

• Guilford County total MRI utilization – The applicant states it used NCSOBM Guilford County projected population for years 2020-2024 multiplied by the average Guilford County MRI use rate of 102.6 to project total Guilford County MRI utilization for CYs 2020-2024, as shown in the following table:

	2019	2020	2021	2022	2023	2024
Guilford County MRI Procedures	55,693	55,976	56,593	57,239	57,911	58,607

Source: application page 110

• DRI MRI 2019 Market Share – The applicant calculated a 28.4% market share of total Guilford County MRI procedures on its existing MRI scanners based on FY 2019 data at the W. Wendover imaging center location, as shown in the following table:

DRI Market Share	2019
W. Wendover Unweighted Procedures	15,816
Guilford County Unweighted Procedures	55,693
DRI Market Share %	28.4%

 Projected Guilford County DRI Summerfield MRI Market Share – Based on the historical utilization and growth of the applicant's W. Wendover MRI scanners, the applicant projects market share increases at the Summerfield location of 0.5% in CY 2022, 0.75% in CY 2023 and 1.0% in CY 2024, as shown in the following tables:

DRI Summerfield Projected Market Share of Guilford County MRI Procedures

-						
	2019	2020	2021	2022	2023	2024
Guilford County MRI Procedures	55,693	55,976	56,593	57,239	57,911	58,607
Current Market Share %	0.0%					
Projected Summerfield Market Share %		0.0%	0.0%	0.5%	0.75%	1.0%

DRI Summerfield Projected MRI Procedures Based on Market Share Percentages

			0
PROJECTED DRI SUMMERFIELD	CY 2022	CY 2023	CY 2024
Total Unweighted MRI procedures	286	434	586

• Shift of procedures from W. Wendover Avenue location – The applicant projects that some of the existing patients who live in 11 ZIP codes in the northern portion of Guilford County and portions of Rockingham, Stokes and Caswell counties will shift their care from DRI's W. Wendover location to the proposed Summerfield location because the Summerfield location will be closer to patients' residences, it will offer fixed MRI services in a northern Guilford County outpatient location, referring physicians in the northern part of Guilford County will be closer, travel will be less burdensome and the proximity will allow for more timely access to needed MRI services. The applicant projects that 65% of DRI's existing patients who reside in those 11 ZIP code areas will transfer their MRI services to the Summerfield location in the first project year, 75% in the second project year, and 85% will shift in the third project year. The applicant provides a table on page 114 to illustrate the 11 ZIP codes that represent existing patient residences and the projected number of unweighted MRI procedures that would shift to the proposed Summerfield outpatient location. See the following table from page 114:

Projected Unweighted MRI Procedures to Shift from W. Wendover to Summerfield

ZIP CODE RESIDENCE	2022	2023	2024
27025	121	145	171
27027	56	67	79
27048	84	101	119
27214	275	330	389
27288	191	230	270
27310	127	152	180
27320	453	543	640
27326	39	46	55
27357	148	177	209
27358	332	398	469
27455	744	893	1,052
Total	2,570	3,083	3,633

Source: Application page 114

• Total projected Summerfield MRI procedures after shift – The applicant projects unweighted MRI procedures at the W. Wendover location following the projected shift of patients / procedures to the proposed Summerfield location. The applicant applies a weighting ratio of 1.158 to project the weighted MRI procedures, as shown in the following table:

W. WENDOVER AVE. AFTER SHIFT	CY 2021	CY 2022	CY 2023	CY 20224
Fixed Unweighted Procedures	17,095	17,773	18,477	19,210
Shifted to Summerfield		2,570	3,083	3,633
Total Unweighted Procedures	17,095	15,202	15,394	15,577
Weighted Procedures	19,800	17,608	17,829	18,041
Weighting Ratio	1.158	1.158	1.158	1.158

 Total combined DRI MRI procedures – The applicant combined the total projected MRI procedures at both the W. Wendover Avenue and Summerfield locations to determine the total projected fixed MRI procedures for the applicant in Guilford County, as shown in the following table:

Combined W. Wendover Avenue and Summerfield Weighted Fixed MRI Procedures

	CY 2021	CY 2022	CY 2023	CY 2024
W. Wendover Ave. Procedures	19,800	17,608	17,829	18,041
Summerfield Procedures	-	3,308	4,074	4,887
Total Procedures	19,800	20,916	21,904	22,928
Average Weighted Procedure/Scanner		5,229	5,476	5,732

The projected number of weighted MRI procedures per fixed MRI scanner exceeds the threshold of 4,805 weighted MRI procedures per fixed MRI scanner as required by 10A NCAC 14C .2703(b)(3).

The applicant projected DRI fixed MRI market share for both locations as shown in the following table:

	CY 2019	CY 2020*	CY 2021	CY 2022	CY 2023	CY 2024
W. Wendover Avenue	28.40%	21.90%	30.21%	26.56%	26.58%	26.58%
Summerfield	0.00%	0.00%	0.00%	4.99%	6.07%	7.20%
Total Market Share %	28.40%	21.90%	30.21%	31.55%	32.66%	33.78%

^{*}The applicant states CY 2020 data is anomalous due to the COVID-19 pandemic. Thus, the increase in market share between CY 2020 and CY 2021 appears to be great but is reasonable when considered against the actual CY 2019 market share.

Comments submitted by SOS indicate that DRI's projected market share is unreasonable and unsupported. However, notwithstanding the anomalous decrease in utilization due to COVID-19 and the Governor's stay-at-home mandate through most of 2020, the market share projections submitted by DRI are reasonable and adequately supported as explained in these Agency Findings. In addition, on pages 3-4 of its response to comments, DRI stated that it showed in the application it has "longestablished market share in Guilford County, and that the projected Greensboro Imaging market share in the third project year is not unreasonable as compared to Greensboro Imaging's current market share." On page 4 of its response to comments, DRI states: "... Greensboro Imaging's projected PY3 market share of 33.78% is only 5.38 percentage points higher than its 2019 market share of 28.4%, and on a per scanner basis, is less than Greensboro Imaging's 2019 market share when operating just three fixed MRI scanners." Moreover, the market share projections for the proposed Summerfield location are projected as a part of the overall DRI projected market share, which is reasonable and adequately supported based on its historical market share. It is not unreasonable to project a market share based on documented market share, and then to assign a portion of that projected market share to a proposed location that will be closer to many of its historical patients.

• Cone Health MRI utilization projections – The members of DRI are Greensboro Radiology, P.A. and Moses Cone Medical Services, Inc. Moses Cone Medical Services, Inc. is affiliated with The Moses H. Cone Memorial Hospital, which is part of Cone Health. Cone Health owns and operates four fixed MRI scanners. The applicant also projected MRI utilization at Cone Health because of its affiliation. Using Cone Health historical MRI utilization from 2016-2019, the applicant calculated the three-year CAGR for fixed MRI procedures at Cone Health to be 0.87%. The applicant applied the historical Cone Health fixed MRI CAGR to the 2019 weighted and unweighted procedures to project utilization for the fixed MRIs at Cone Health. In addition, the applicant calculated the average weighted ratio for the Cone Health fixed MRI scanners by averaging the CY 2016 – CY 2020 weighted ratio and held that ratio constant through CY 2024. See the following table, from page 118:

MRI Procedures	2020*	2021	2022	2023	2024
Fixed Unweighted	12,426	14,790	14,919	15,049	15,180
Fixed Weighted	16,485	19,488	19,658	19,829	20,002
Weighting Ratio	1.327	1.318	1.318	1.318	1.318
Average Weighted Procedure/Scanner		4,872	4,915	4,957	5,000

^{*}The data for 2020 is anomalous due to COVID-19; the applicant projected future utilization using 2019 data and the 0.87% CAGR for fixed MRI procedures at Cone Health.

The applicant projects that each of the four fixed MRI scanners at Cone Health will perform in excess of the performance standard of 4,805 weighted MRI procedures per fixed MRI scanner pursuant to 10A NCAC 14C .2703(b)(3).

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

- The applicant's market share projections for the proposed diagnostic center are reasonable and adequately supported based on the applicant's historical market share at its W. Wendover location.
- The applicant utilized data from the 2020 SMFP to support its projected utilization.
- The applicant's utilization projections are supported by the historical utilization of MRI scanners owned by the applicant or a related entity.
- The applicant provided adequate support for the increase in incremental projections.
- The projected utilization of the applicant's existing and proposed MRI scanners meets the Performance Standards in 10A NCAC 14C 2700.

Access to Medically Underserved Groups

In Section C, page 43, the applicant states:

"DRI is fully committed to the health and well-being of all patients. DRI has historically provided care and services to medically underserved populations, including all of the above listed groups. As a certified provider under Title XVIII (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 as underserved."

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. 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 described above.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and install it in renovated space in its existing medical office clinic in Greensboro, Guilford County, thereby creating a diagnostic center. SOS currently leases space in which it

operates an orthopedic clinic providing mobile MRI services, fluoroscopy, X-ray and electromyography (EMG) services.

Patient Origin

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 Guilford County. Facilities may also serve residents of counties not included in their service area.

The proposed facility has no historical patient origin to report since it does not exist. In Section C, page 30, the applicant provides historical patient origin for the leased mobile MRI scanner for the last full FY prior to submitting the application, as illustrated in the following table:

COUNTY / ZIP CODE	LAST FULL FY 10/1/2019 – 9/30/2019		
	# OF PATIENTS	% OF TOTAL	
Guilford	3,479	70.8%	
Alamance	412	8.4%	
Rockingham	384	7.8%	
Randolph	345	7.0%	
Forsyth	125	2.5%	
Davidson	72	1.5%	
Other*	96	2.0%	
Total	4,913	100.00%	

^{*}The applicant state *Other* includes less than 1% from the remaining counties in North Carolina and other states. Percentages may not sum due to rounding.

The following table illustrates projected patient origin for the first three full fiscal years of operation:

County	_	JLL FY -9/30/2023		JLL FY -9/30/2024	3 RD FU 10/1/2024-	
	# PTS	% OF TOTAL	# PTS	% OF TOTAL	# PTS	% OF TOTAL
Guilford	3,813	70.8%	3,859	70.8%	3,904	70.8%
Alamance	452	8.4%	457	8.4%	462	8.4%
Rockingham	421	7.8%	426	7.8%	431	7.8%
Randolph	378	7.0%	383	7.0%	387	7.0%
Forsyth	137	2.5%	139	2.5%	140	2.5%
Davidson	79	1.5%	80	1.5%	81	1.5%
Other*	105	2.0%	106	2.0%	108	2.0%
Total	5,385	100.0%	5,449	100.0%	5,513	100.0%

Source: Section C.3, page 31.

Percentages may not sum due to rounding

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin which is based on the patient origin of existing MRI patients served on the mobile MRI scanner. The applicant's assumptions are reasonable and adequately supported because they are based on actual historical patient origin for the applicant's mobile MRI

services provided at the orthopedic clinic in Greensboro where the proposed fixed MRI will be located.

Analysis of Need

In Section C.4, pages 33-49, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The need determination in the 2020 SMFP for one additional fixed MRI scanner in Guilford County The 2020 SMFP has determined there is a need for one additional fixed MRI scanner, which the applicant reproduces on pages 33-36.
- Historical SOS mobile MRI utilization on an older scanner The applicant states SOS has provided mobile MRI service at its Greensboro location since 1998 through a contract with Alliance, and that in FY 2019, SOS performed the highest number of mobile MRI procedures of "any mobile host site in North Carolina". In addition, the applicant states there was a decrease in utilization in FFY 2020, which is directly attributable to the COVID-19 pandemic and the Governor's Stay at Home Mandate imposed as a result. The applicant states it mobile MRI service has also been adversely impacted by the fact that the scanner leased from Alliance is older and thus experienced repair downtime which resulted in a 45 minute to one-hour scan time for patients. The mobile MRI scanner is located in a trailer in SOS's parking lot which potentially negatively impacts patients, particularly during inclement weather. (pages 36-40).
- Need for access to cost-effective MRI services in Greensboro and access to medically underserved patients The applicant states that, according to the Blue Cross Blue Shield's "Treatment Cost Estimator", SOS is "the community's lowest cost MRI provider" for four common MRI procedures. The applicant cites the former President's Executive Order that directed the Health and Human Services Secretary to increase price transparency and the Clear Pricing Project set forth in the 2020 SMFP to show that there is a continuing need and demand for pricing transparency for patients. Additionally, the down time and inability to set staffing or costs associated with leasing an MRI combine to hinder SOS's dedication to providing low-cost MRI services to the medically underserved populations (pages 40-43).
- SOS service area demographics The applicant cites data from the NCOSBM to illustrate that the general population of Guilford County is projected to increase by a five-year CAGR of 1.2% from 2020 to 2025. The applicant states Guilford County's median age is currently 37.4, and the over 65 age group is projected to increase over the next four years. The applicant states medically underserved and obese patients need access to cost-effective MRI services. Obesity puts a strain on the musculoskeletal system, and studies show that obesity is a concern for orthopedic surgeons. The applicant cites county health data to show that 31% of adults in Guilford County are obese. The applicant states the outdated mobile MRI that has been providing services is a closed bore scanner and the chamber is narrow, thus presenting difficulty for those obese or claustrophobic patients. The proposed MRI scanner will better accommodate obese or claustrophobic patients. Additionally, the applicant states the impact of the

COVID-19 pandemic and resulting economic downturn could increase patient reliance on NC Medicaid recipients, of which SOS serves a large percentage (pages 43-48).

• Physician support for the proposed MRI – The applicant states local radiologists, physicians and community members support the proposed fixed MRI scanner in the Greensboro (page 49). The applicant provides letters of support from area radiologists, referring physicians and community members in Exhibit I.2, which state that the proposed fixed MRI will better accommodate obese and claustrophobic patients and will allow SOS to expand MRI services to Medicare and Medicaid recipients. In addition, the letters indicate that physician referrals will increase.

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

- There is a need in the 2020 SMFP for one additional fixed MRI scanner in Guilford County.
- The applicant uses its historical experience with providing MRI services on a mobile MRI scanner to support its demonstration of need for a fixed MRI scanner in Greensboro.
- The applicant cites NCOSBM data and its experience to illustrate the need for an openbore fixed MRI to better serve Guilford County's obese and medically underserved populations.
- The applicant adequately demonstrates the need for a freestanding fixed MRI scanner at the SOS location in addition to existing hospital-based fixed MRI scanners in Greensboro.

Projected Utilization

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

	PRIOR FULL FY FFY 2019	PRIOR FULL FY FFY 2020	PRIOR FULL FY FFY 2021	1 st FULL FY FFY 2022	2 ND FULL FY FFY 2023	3 RD FULL FY FFY 2024
# Scanners	1 (Mobile)	1 (Mobile)	1 (Mobile)	1 (Fixed)	1 (Fixed)	1 (Fixed)
# Procedures	4,968	4,913	4,913	5,385	5,449	5,513
# Weighted Procedures	5,147	5,105	5,105	5,595	5,662	5,728

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

• SOS historical mobile MRI utilization – the applicant examines the historical utilization of the mobile MRI scanner at its facility from FFY 2017 to FFY 2020 and states the utilization is based on referral patterns of SOS physicians and other area physicians. The applicant states the decreased FFY 2020 utilization is directly attributable to the COVID-19 pandemic and resulting Stay at Home Mandate issued by the Governor of North Carolina pursuant to Executive Order No. 121. The applicant projected future MRI utilization using a 1.2% growth rate, representing the CAGR from FFY 2017 –

- 2019. The applicant states the growth rate is comparable to the projected population growth rate for Guilford County as determined by the NCOSBM.
- Determine the SOS MRI patient "referral leakage" the applicant states that it has had to refer approximately 10% of its patients who could have been served by SOS to other MRI providers because the mobile closed bore MRI was not able to accommodate patients who were either obese or well-built, or who suffered from claustrophobia. See the following table that illustrates the calculation of patient leakage as a result of the limitations of the closed bore mobile MRI scanner:

Unweighted MRI Procedures and Referral Leakage

YEAR	SOS MOBILE MRI	SOS MRI REFERRAL	TOTAL POTENTIAL SOS
	Procedures	LEAKAGE	MRI PROCEDURES
FFY 2017	4,853	539	5,392
FFY 2018	4,943	549	5,492
FFY 2019	4,968	552	5,520
FFY 2020	4,913	546	5,459

The applicant states the referral leakage is estimated as 10% of its total procedures, based on "years of experience providing mobile MRI procedures." The applicant calculates the 10% as follows, using FFY 2019 as an example: 4,968 mobile MRI procedures / .90 = 5,520 FFY 2019 potential SOS MRI procedures. 5,520 potential MRI procedures – 4,968 actual SOS mobile MRI procedures = 552 SOS MRI referrals to other providers. This number is what the applicant states is referral "leakage". The applicant states that developing the proposed fixed MRI scanner will reduce referral leakage, particularly since the proposed fixed MRI scanner is a larger chamber with a short bore, thus accommodating those patients who are obese or claustrophobic.

- Project interim year mobile MRI procedures the applicant states the interim year (FFY 2021) utilization will mirror FFY 2020, despite the slight decrease as a result of the COVID-19 pandemic. The applicant states utilization is continuing to increase.
- Project annual growth rate for first three project years the applicant projects future utilization during the first three project year using the 1.2% CAGR it calculated from FFY 2017 2019. The applicant states this is reasonable, given the projected population growth that matches the CAGR, the historical utilization, qualitative benefits of the proposed project and physician and community support for the project. The following table illustrates projected utilization:

	PY 1	PY 2	PY 3
	FFY 2022	FFY 2023	FFY 2024
Fixed Unweighted MRI Procedures	4,971	5,030	5,089

• Project recapture of referral leakage – the applicant states it projects to recapture the 10% referral leakage it calculated in the previous step who could not be served because of the limits of the outdated mobile MRI scanner. The applicant states the recapture is

reasonable because of the applicant's experience, the prevalence of obesity and claustrophobia in the service area and physician and patient statements that the applicant provides in Exhibit I.2. The applicant states it projects to capture 75% of the leakage it calculated, as shown in the following table:

	PY 1	PY 2	PY 3
	FFY 2022	FFY 2023	FFY 2024
SOS Projected Referral Leakage	552	559	565
SOS Recapture of Leakage (75%)	414	419	424

Determine total SOS fixed MRI unweighted procedures – the applicant added the 75% recaptured MRI procedures to the unweighted MRI procedures based on the 1.2% CAGR, as shown in the following table:

Total Unweighted MRI Procedures

	PY 1	PY 2	PY 3
	FFY 2022	FFY 2023	FFY 2024
Projected MRI Procedures	4,971	5,030	5,089
75% Recapture of Leakage	414	419	424
Total Projected MRI Procedures	5,385	5,449	5,513

 Project weighted MRI procedures – the applicant averaged the weighting ratios from FFY 2017 – 2019, which was 1.039. The applicant applied this ratio to the total unweighted MRI procedures calculated in the step above to project total fixed MRI weighted procedures at the SOS facility, as shown in the following table:

Total Weighted MRI Procedures

	PY 1	PY 2	PY 3
	FFY 2022	FFY 2023	FFY 2024
Projected MRI Procedures	5,385	5,449	5,513
Total Projected MRI Procedures	5,595	5,662	5,728

The applicant projects 5,728 weighted MRI procedures on the proposed fixed MRI scanner in the third year following completion of the project as required by 10A NCAC 14C .2703(b)(3).

The information 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 Guilford County MRI service area and this project will meet that need determination by developing an additional fixed MRI scanner in Guilford County.
- The applicant's utilization projections are supported by the historical utilization of MRI scanners owned by the applicant or a related entity.
- The applicant provided adequate support for the increase in incremental projections.
- The projected utilization of the applicant's existing and proposed MRI scanners meets the Performance Standards in 10A NCAC 14C 2700.

Access to Medically Underserved Groups

In Section C.11, pages 53-54, the applicant states "SOS will meet the needs of all patients in need of care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment." On pages 53 and 54, in separate paragraphs the applicant lists each group identified in the table below, and indicates that the percentage proposed to be served as shown:

MEDICALLY UNDERSERVED GROUPS	INFORMATION FROM APPLICATION PAGES 53-54
Low income persons	"six percent of MRI procedures will be Medicaid patients and two percent of MRI
	procedures will be charity care patients during the third project year."
	"35.4 percent of the Guilford County population are Black or African American.
Racial and ethnic minorities	Approximately 8.4 percent are Hispanic or Latino. SOS estimates the
	percentage of MRI patients by racial and ethnic minorities will be comparable to
	[those percentages]."
Women	52.7%
Persons with Disabilities	"SOS estimates the MRI percentage of handicapped persons will mirror the
	population percentages for this population."
	"15.8 percent of the Guilford County population is age 65+ SOS estimates the
The elderly	percentage of elderly MRI patients will be comparable to the percentage
	referenced above:"
Medicare beneficiaries	30.8%
Medicaid recipients	6.0%

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.

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.

(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 [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

- 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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists / Acquire one fixed MRI scanner - 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.

C – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

- In Section E.2, pages 58-61, 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 maintaining the status quo will not effectively serve the growing demand for MRI services or the growing population in the service area.
 - Contract with a mobile MRI provider the applicant states contracting for mobile MRI service may temporarily serve patients in need of MRI services but will not solve the area's need for the type of MRI proposed to meet the long-term needs of all the area's patients.
 - Develop the service in another Guilford County location the applicant states existing MRI services in Guilford County are largely concentrated in Greensboro and High Point, which are in central and southern Guilford County. The applicant states Summerfield is an area in the northern part of the county that is growing rapidly and currently has no MRI services.
 - Develop a hospital-based MRI scanner the applicant states hospital-based MRI utilization is high in Guilford County; however, an additional freestanding fixed MRI would benefit the Summerfield area and would be easily accessible via several major highway routes.

On pages 60-61, the applicant states that its proposal is the most effective alternative because it will allow DRI to provide convenient, cost-effectively diagnostic imaging services to patients in a convenient location and will reduce the capacity constraints that exist on the applicant's existing MRI scanners elsewhere in Guilford County.

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 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks submitted in lieu of a public hearing
- Responses to comments

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

Project ID# G-11986-20 / **Southeastern Orthopaedic Specialists** / **Acquire one fixed MRI scanner** - In Section E.2, pages 66-69, 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 maintaining the status quo is inconsistent with the need determination in the 2020 SMFP and would not rectify existing patient access issues resulting from the existing mobile MRI.
- Develop the proposed fixed MRI in another location the applicant states developing the proposed fixed MRI scanner in another location would not effectively serve the patients currently being served by the mobile scanner at the existing Church Street location. The applicant states this alternative would also disrupt patient referral patterns and would unnecessarily hinder geographic access for a large patient base at SOS.
- Acquire a fixed MRI from a different vendor the applicant considered purchasing a
 different MRI but determined that the selected MRI will most effectively serve its
 patients in a manner that is consistent with the basic principles of the 2020 SMFP of
 promoting safety and quality in the delivery of health care services while maximizing
 healthcare value for the resources expended.
- Pursue a joint venture the applicant considered a joint venture with Alliance, the
 existing mobile MRI service provider, but determined that this was not the most
 effective alternative to achieve its objectives of meeting the identified need in the 2020
 SMFP, reducing costs to patients for MRI services and expanding access to fixed MRI
 services in Guilford County.

On pages 68-69, the applicant states that its proposal is the most effective alternative because it will allow SOS to continue to provide MRI services as it has for 22 years without reducing access to its patient base.

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 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks submitted in lieu of a public hearing
- Responses to comments

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

(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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

Capital and Working Capital Costs

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

Site Costs	NA
Construction / Renovation Costs	\$340,795
Miscellaneous Costs	\$887,636
Total	\$1,228,401

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 because the applicant provides vendor equipment quotes in Exhibit F-1.

In Section F.3, pages 64-65, the applicant projects that start-up costs will be \$10,000 and initial operating expenses will be \$45,000 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 provides documentation of equipment cost in Exhibit F.1.
- The applicant states start-up costs are based on one week of staffing and supply inventory, and other expenses necessary to prepare the MRI for service.

Availability of Funds

In Section F.2, page 63, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

	<u> </u>	
Түре	DRI	TOTAL
Loans	\$724,833	\$724,833
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Line of credit)	\$503,568	\$503,568
Total Financing	\$1,228,401	\$1,228,401

^{*}OE = Owner's Equity

In Section F.3, page 65, 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	
Loans	\$0	
Cash or Cash Equivalents, Accumulated Reserves or OE	\$0	
Lines of credit	\$55,000	
Bonds	\$0	
Total	\$55,000	

In Section F, page 66, the applicant states the line of credit to fund all capital and working capital needs of the project will come from First Citizens Bank. In Exhibit F.2, the applicant provides an August 31, 2020 letter signed by the Senior Vice President of First Citizens Bank documenting a line of credit in the amount of \$2,000,000.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides adequate documentation of a line of credit in excess of the amount of the proposed project capital cost.
- The applicant provides adequate documentation of a line of credit in excess of the amount of the proposed working capital needs of 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 all three full fiscal years following completion of the project, as shown in the table below.

DRI SUMMERFIELD

	1 ST FFY	2 ND FFY	3 RD FFY
	CY 2022	CY 2023	CY 2024
Total weighted MRI scans	3,308	4,074	4,887
Total Gross Revenues (Charges)	\$4,314,663	\$5,313,273	\$6,372,686
Total Net Revenue	\$1,375,581	\$1,693,965	\$2,031,724
Average Net Revenue per MRI scan	\$415.84	\$415.80	\$415.74
Total Operating Expenses (Costs)	\$1,174,641	\$1,518,446	\$1,709,815
Average Operating Expense per MRI scan	\$355.10	\$372.72	\$349.87
Net Income	\$200,940	\$175,519	\$321,909

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 bases its projections on DRI historical experience.
- 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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

Capital and Working Capital Costs

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

Site Costs	NA
Construction / Renovation Costs	\$348,258
Miscellaneous Costs	\$800,729
Total	\$1,148,987

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 because the applicant provides vendor equipment quotes in Exhibit F-1.

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 because the applicant provides construction/renovation cost estimates and vendor equipment quotes in Exhibit F-1.

In Section F.3, pages 72-73, the applicant projects that start-up costs will be \$20,000. The applicant does not project initial operating expenses, stating that the current MRI service will provide sufficient revenue and cash flow so that additional funding to cover the initial operating expenses will not be necessary. Thus the applicant projects a total working capital of \$20,000. 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 provides documentation of renovation and equipment costs in Exhibit F 1
- The applicant states start-up costs are based on costs to hire and train new staff and other miscellaneous expenses approximately two weeks prior to the proposed MRI scanner's installation.

Availability of Funds

In Section F.2, page 70, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Түре	SOS	TOTAL
Loans	\$1,148,987	\$1,148,987
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Line of credit)	\$0	\$0
Total Financing	\$1,148,987	\$1,148,987

^{*}OE = Owner's Equity

In Section F.3, page 73, 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
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or OE	\$20,000
Lines of credit	\$0
Bonds	\$0
Total	\$20,000

Exhibit F.2 provides an October 5, 2020 letter signed by the Senior Vice President of First Citizens Bank that confirms the applicant's eligibility for financing in the amount of \$1.2 million for the capital cost of the project. In Exhibit F.2, the applicant provides an October 9, 2020 letter signed by the Senior Vice President of BB&T documenting sufficient cash in SOS's bank account to cover the projected start-up expenses for the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides adequate documentation of a line of credit in excess of the amount of the proposed project capital cost.
- The applicant provides adequate documentation of sufficient current funds in its deposit account to fund the working capital needs of 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 all three full fiscal years following completion of the project, as shown in the table below.

SOS

	1 ST FFY	2 ND FFY	3 RD FFY
	CY 2022	CY 2023	CY 2024
Total weighted MRI scans	5,595	5,662	5,728
Total Gross Revenues (Charges)	\$6,957,420	\$7,040,108	\$7,122,796
Total Net Revenue	\$2,270,998	\$2,297,988	\$2,324,979
Average Net Revenue per MRI scan	\$405.898	\$405.86	\$405.89
Total Operating Expenses (Costs)	\$1,382,506	\$1,47,2665	\$1,488,570
Average Operating Expense per MRI scan	\$247.09	\$260.09	\$259.87
Net Income	\$888,492	\$825,323	\$836,409

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:

- Procedure gross charges are based on SOS historical experience with no projected increase through the project years.
- 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.

C – Both Applicants

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 Guilford County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing fixed and mobile MRI scanners in Guilford County, and the inpatient (IP) and outpatient (OP) MRI procedures with and without contrast for each MRI scanner, from pages 427-428 of the 2020 SMFP:

Guilford County Fixed and Mobile MRI Procedures

Type*	Site	Fixed	Fixed	Total	OP No	OP With	IP No	IP With	Adjusted
			Equivalent	Scans	Contrast	Contrast	Contrast	Contrast	Total
Hospital-F	Moses H. Cone Memorial Hospital	3	3.00	10,369	3,369	1,497	3,963	1,540	13,785
Hospital-F	Wesley Long Hospital	1	1.00	3,974	1,137	1,814	616	407	5,272
Hospital-F	High Point Regional Health	2	2.00	6,234	2,591	1,508	1,494	641	7,948
Freestanding-F	Cornerstone Imaging	1	1.00	3,596	925	2,671	0	0	4,664
Freestanding-F	Greensboro Imaging - DRI	1	1.00	4,056	2,511	1,545	0	0	4,674
Freestanding-F	Greensboro Imaging - DRI	1	1.00	4,876	2,934	1,942	0	0	5,653
Freestanding-F	Greensboro Imaging- DRI	1	1.00	5,281	3,207	2,074	0	0	6,111
Freestanding-F	Greensboro Orthopaedics, P.A.	1	1.00	5,881	5,509	372	0	0	6,030
Freestanding-F	Triad Imaging	1	1.00	4,268	3,374	894	0	0	4,626
Mobile	Cone MedCenter High Point – Greensboro	0	0.11	506	342	164	0	0	572
Mobile	Carolina Neuro and Spine Associates – Greensboro	0	0.35	1,702	1,138	564	0	0	1,928
Mobile	Cone Health MedCenter High Point	0	0.01	46	35	11	0	0	50
Mobile	Cone Health MedCenter High Point	0	0.12	570	389	181	0	0	642
Mobile	Cone Health MedCenter High Point	0	0.11	540	537	3	0	0	541
Mobile	SE Orthopaedic Specialists, P.A.	0	1.00	4,943	4,453	490	0	0	5,139
Total		12	13.70	56,842					67,634

^{*}F = Fixed scanner

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Guilford County, including the need identified in the 2020 SMFP. The applicant states:

"As evidenced by the need determination in the 2020 SMFP, the State Health Coordinating Council (SHCC) considers the existing and approved 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 scanners ... and determined a need for one additional fixed MRI scanner in Guilford County.

. . .

DRI will offer increased MRI capacity without a charge increase, and will continue to seve a broad range of outpatients."

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 and mobile MRI scanners in Guilford County.

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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

In Section G, page 71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Guilford County, including the need identified in the 2020 SMFP. The applicant states:

"The robust utilization of mobile MRI procedures at SOS supports the need for SOS to develop a fixed MRI scanner at its N Church Street office in Guilford County. The proposed project effectively expands and enhances cost effective access to fixed MRI services in Guilford County.

The proposed project is needed to expand access to SOS's well-utilized MRI services."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- 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 and mobile MRI scanners in Guilford County.

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.

(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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

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

D	PROJECTED FTE STAFF		
Position	2 ND FULL FISCAL YEAR (CY 2023)		
Administrator	0.10		
MRI Technician	1.75		
MRI Technician Assistant	0.75		
Sales Liaison	0.10		
Receptionist	1.50		
Scheduling/Medical Records	1.00		
TOTAL	5.20		

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 Form F.3, which is in Section Q. In Section H, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant's experience in staffing and operating other diagnostic centers and providing MRI 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 all the reasons described above.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

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

Decimion	PROJECTED FTE STAFF		
Position	2 ND FULL FISCAL YEAR (CY 2023)		
Front Office Coordinator	0.50		
MRI Scheduler/Precertification	3.00		
Patient Coordinator	2.90		
MRI Technologist	2.90		
TOTAL	9.30		

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 Form F.3, which is in Section Q. In Section H, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because it is based on the applicant's experience in staffing and operating other diagnostic centers and providing MRI 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 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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

Ancillary and Support Services

In Section I, page 77 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 77-78, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant lists existing providers of existing ancillary and support services and states the same providers will be available for the proposed MRI services.
- The applicant provides supporting documentation of a radiology agreement in Exhibit
 I.1

Coordination

In Section I, page 78 the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides diagnostic imaging services in Greensboro and Guilford County and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project and the availability of radiologists to interpret the MRI scans in Exhibit I.2.
- The applicant provides letters from community healthcare providers expressing support for the proposed project in Exhibit I.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

Ancillary and Support Services

In Section I, page 81 the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is or will be made available. The applicant provides supporting documentation in Exhibits I.1, C.1-1 and C.1-2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant lists existing providers of existing ancillary and support services and states the same providers will be available for the proposed MRI services.
- The applicant documents the availability of radiology services and equipment maintenance in the referenced exhibits.

Coordination

In Section I, page 82 the applicant states it is an existing orthopedic specialty practice with existing relationships with area healthcare providers. The applicant states the physicians associated with SOS have privileges at Cone Health and other area ambulatory surgical facilities and will continue following the addition of the proposed MRI scanner. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently provides diagnostic imaging services in Greensboro and Guilford County and has established relationships with local healthcare and social services providers, which will be in place in the proposed program as well.
- The applicant demonstrates physician support for the project and the availability of radiologists to interpret the MRI scans in Exhibit I.2.
- The applicant provides letters from community healthcare providers expressing support for the proposed project in Exhibit I.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

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.

- (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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County

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

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

In Section K, page 83 the applicant states that the project involves renovating 1,035 of existing space in the existing Summerfield facility. Line drawings are provided in Exhibit K.1.

On page 83, 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 states the facility renovation will be planned by experienced architect and construction professionals.
- The applicant states renovating the existing facility is cost effective because there are
 no major support walls or building columns that need to be moved or modified, thereby
 saving money on renovation.

On page 84, 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:

- The applicant states it will negotiate the cost of the MRI.
- The applicant states that, as a freestanding MRI, it will offer lower charges for MRI services than hospital-based providers.
- The applicant states the new fixed scanner at the proposed Summerfield location will offer low-cost MRI services to Guilford County and surrounding community residents.

On page 84, 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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

In Section K, page 85 the applicant states that the project involves renovating 2,500 square feet of existing space in the facility it leases for the orthopedic practice on N. Church Street in Greensboro. Line drawings are provided in Exhibit K.2.

On page 85, 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 states the facility renovation will be planned by a professional engineer.
- The applicant states the renovation will comply with all applicable building codes and standards.

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:

• The applicant states it will leverage existing staff and infrastructure to contain costs.

- The applicant states that it is currently the lowest cost MRI provider in the area, and it
 will not increase charges to the public following the addition of the proposed fixed
 MRI.
- The applicant states the cost savings afforded by the proposal will permit the applicant to expand access to MRI services to medically underserved patients.

On page 86, 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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

In Section L, page 89, the applicant states the proposed Summerfield location does not currently offer MRI services and thus has no current payor mix for those services. However, on page 91, the applicant provides the historical payor mix for MRI services at the W. Wendover Avenue location during CY 2019, as shown in the table below:

Payor Category	MRI Services as a % of Total
Self-Pay	2.13%
Charity Care	**
Medicare*	44.98%
Medicaid*	4.97%
Insurance*	46.01%
Workers Compensation	0.74%
TRICARE	0.46%
Other (specify)	0.71%
Total	100.0%

Source: Application page 90

In Section L, page 89, the applicant provides the following comparison:

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	77.62%	52.7%
Male	22.37%	47.3%
Unknown	0.01%	0.0%
64 and Younger	58.23%	84.5%
65 and Older	41.77%	15.5%
American Indian	**	0.8%
Asian	**	5.3%
Black or African-American	**	35.4%
Native Hawaiian or Pacific Islander	**	0.1%
White or Caucasian	**	50.0%
Other Race	**	8.4%
Declined / Unavailable	**	0.0%

^{**}The applicant states on page 89 that it does not track patient racial/ethnic origin

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.

^{*}Includes managed care plans

^{**}Applicant states this is included in self-pay

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

In Section L, page 90, the applicant states the SOS specialty practice is not an existing health service facility and does not currently offer fixed MRI services and thus has no current payor mix for those services. However, the applicant provides the historical payor mix for mobile MRI services during FY 2020, as shown in the table below:

Payor Category	Mobile MRI Services as a % of Total
Self-Pay	2.20%
Charity Care	1.02%
Medicare*	33.25%
Medicaid*	4.86%
Insurance*	54.00%
Workers Compensation	4.68%
TRICARE	0.00%
Other (specify)	0.00%
Total	100.0%

Source: Application page 90 *Includes managed care plans

In Section L, page 89, the applicant provides the following comparison for the mobile MRI services provided at SOS for FY 2020:

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	57.6%	52.7%
Male	42.4%	47.3%
Unknown		
64 and Younger	70.3%	84.5%
65 and Older	29.7%	15.5%
American Indian	0.6%	0.8%
Asian	1.0%	5.3%
Black or African-American	19.4%	35.4%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	60.9%	56.0%
Other Race	2.0%	
Declined / Unavailable	15.9%	

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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 91-92, 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 92, 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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

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

"SOS has no obligations to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons. However, SOS provides and will continue to provide

services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment."

In Section L, page 91, the applicant states that during the last five years no patient civil rights access complaints have been filed against any affiliated entity of SOS.

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 -Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

In Section L, page 93, 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:

DRI Fixed MRI Payor Mix, CY 2024

PAYOR SOURCE	% OF TOTAL
Self-Pay / Charity Care	2.13%
Medicare*	44.98%
Medicaid*	4.97%
Insurance*	46.01%
Workers Compensation	0.74%
TRICARE	0.46%
Other (miscellaneous)	0.71%
Total	100.00%

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.13% of total services will be provided to self-pay and charity care patients, 44.98% to Medicare patients and 4.97% to Medicaid patients.

On page 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 CY 2019 MRI payor mix at Greensboro Imaging.
- The applicant assumes existing referring physicians will continue to refer patients to Greensboro Imaging, which will include the Summerfield location.

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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

In Section L, page 91, 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:

SOS Fixed MRI Payor Mix, CY 2024

PAYOR SOURCE	% OF TOTAL			
Self-Pay	2.25%			
Charity Care	2.00%			
Medicare*	33.25%			
Medicaid*	6.00%			
Insurance*	51.82%			
Workers Compensation	4.68%			
Total	100.00%			

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.25% of total services will be provided to self-pay patients, 2.00% to charity care patients, 33.25% to Medicare patients and 6.00% to Medicaid patients.

On pages 91-96, 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 SOS's FFY 2019 and FFY 2020 mobile MRI payor mix, taking into account the decrease in utilization as a result of the COVID-19 pandemic and its temporary impact on utilization.
- The applicant states the projected payor mix for the first three project years will essentially mirror FFY 2019 and FFY 2020 payor mix.
- The applicant states it is dedicated to providing care to underserved populations, as demonstrated by its self-pay, charity care and Medicaid percentages.

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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

In Section L, page 97, 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 – Both Applicants

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

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. 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:

- The applicant states it will offer the proposed fixed MRI to area schools and clinical training programs.
- The applicant states DRI currently has clinical training programs in place with Randolph Community College at its other facilities
- The applicant states the additional proposed MRI at the Summerfield location will provide additional students clinical training opportunities.

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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

In Section M, page 98, 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.1. 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:

- The applicant states it has extensive existing relationships in place with health professional training programs, including Greensboro Area Health Education Center, Elon University, High Point University, Greensboro College, UNC Greensboro and UNC School of Medicine.
- The applicant states the relationship with the educational training programs will continue.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C – Both Applicants

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 Guilford County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing fixed and mobile MRI scanners in Guilford County, and the inpatient (IP) and outpatient (OP) MRI procedures with and without contrast for each MRI scanner, from pages 427-428 of the 2020 SMFP:

Guilford County Fixed and Mobile MRI Procedures

Type*	Site	Fixed	Fixed	Total	OP No	OP With	IP No	IP With	Adjusted
			Equivalent	Scans	Contrast	Contrast	Contrast	Contrast	Total
Hospital-F	Moses H. Cone Memorial Hospital	3	3.00	10,369	3,369	1,497	3,963	1,540	13,785
Hospital-F	Wesley Long Hospital	1	1.00	3,974	1,137	1,814	616	407	5,272
Hospital-F	High Point Regional Health	2	2.00	6,234	2,591	1,508	1,494	641	7,948
Freestanding-F	Cornerstone Imaging	1	1.00	3,596	925	2,671	0	0	4,664
Freestanding-F	Greensboro Imaging - DRI	1	1.00	4,056	2,511	1,545	0	0	4,674
Freestanding-F	Greensboro Imaging - DRI	1	1.00	4,876	2,934	1,942	0	0	5,653
Freestanding-F	Greensboro Imaging- DRI	1	1.00	5,281	3,207	2,074	0	0	6,111
Freestanding-F	Greensboro Orthopaedics, P.A.	1	1.00	5,881	5,509	372	0	0	6,030
Freestanding-F	Triad Imaging	1	1.00	4,268	3,374	894	0	0	4,626
Mobile	Cone MedCenter High Point –	0	0.11	506	342	164	0	0	572
	Greensboro								
Mobile	Carolina Neuro and Spine	0	0.35	1,702	1,138	564	0	0	1,928
	Associates – Greensboro								
Mobile	Cone Health MedCenter High	0	0.01	46	35	11	0	0	50
	Point								
Mobile	Cone Health MedCenter High	0	0.12	570	389	181	0	0	642
	Point								
Mobile	Cone Health MedCenter High	0	0.11	540	537	3	0	0	541
	Point								
Mobile	SE Orthopaedic Specialists, P.A.	0	1.00	4,943	4,453	490	0	0	5,139
Total		12	13.70	56,842					67,634

^{*}F = Fixed scanner

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

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

"Guilford County has a high level of MRI competition, with existing hospital and freestanding fixed MRI scanners. ... With this proposed project, DRI is offering fixed MRI services at a new location in Guilford County in order to improve patient geographic access to high quality, cost-effective diagnostic imaging services."

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

"DRI will develop the fixed MRI project in the most cost-effective manner. The proposed refurbished MRI scanner represents both economical and modern technology, and offers ease of operation, excellent imaging quality, patient comfort, and energy efficiency capabilities. The ease of use will enable a high volume of MRI scans per day, thus containing the cost per procedure."

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

Regarding the impact of the proposal on quality, in Section N, page 98, the applicant states:

"DRI is an experienced local provider of imaging services, and is dedicated to ensuring quality and patient safety through compliance with all applicable licensure and certification standards established regarding diagnostic imaging. 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."

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

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

"The proposed project will enable improved access to screening mammography services for medically underserved groups. DRI is a participating Medicare and Medicaid provider, serving the elderly and medically indigent populations in Guilford County and surrounding communities. ...

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 Medicare, Medicaid and self-pay/medically indigent patients."

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

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

- 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.
- 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.
- 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

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

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and install it in its existing orthopedic specialty practice in Greensboro, Guilford County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 99, the applicant states:

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality and access to fixed MRI services."

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

"The proposed application is indicative of SOS's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. Over the past 22 years, SOS has paid over \$18 million in mobile MRI lease fees. The proposed project dramatically reduces the cost to provide MRI services at SOS while expanding access to service area residents.

The proposed Siemens Magnetom 1.4T MRI system will provide an economic benefit because patient preparation time will be reduced, comfort will increase, and more scans will be conducted during operating hours."

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

Regarding the impact of the proposal on quality, in Section N, pages 99-100, the applicant states:

"SOS is known for providing high quality services and expects the proposed project to expand MRI access while bolstering its high-quality reputation. To ensure patient safety and the delivery of high quality care, SOS will utilize Quality Improvement, Safety, and Infection Control Policies applicable to MRI 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, page 100 the applicant states:

"The proposed project will improve access to fixed MRI services in the service area. SOS has long-promoted economic access to its services as it historically has provided

services to all persons in need of medical care, regardless of age, race, ethnicity, religion, culture/creed, language, physical or mental disability, socioeconomic status, sex, sexual orientation, or gender identity or expression. SOS will continue to serve this population upon completion of the proposed project."

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

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

- 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.
- 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.
- 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

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

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

C – DRI NA - SOS

Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner DRI proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center to be located at 6191 Lake Brandt Road in Summerfield, Guilford County.

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

total of six diagnostic centers operating a total of 11 MRI scanners located in North Carolina. Diagnostic centers are not required to be licensed in North Carolina.

In Section O, page 100, 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 preceding the submission of this application.

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.

Project ID# G-11986-20 / Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

SOS proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center in space it currently leases as medical office space at 1130 N. Church Street, Suite 100 in Greensboro, Guilford County.

On Form A in Section Q, the applicant states SOS does not currently own or operate any health service facilities in North Carolina; however, it currently provides mobile MRI service at its Greensboro location.

In Section O, page 102, the applicant states:

"SOS is committed to providing quality patient care. SOS's current mobile MRI service operates under the quality-regulated programs and procedures governed by the mobile MRI vendor. Thus, SOS will implement policies and procedures for monitoring and evaluating the effective management, safety, and operation of equipment in the use of the proposed fixed MRI services.

. . .

Additionally, SOS will seek accreditation form the American College of Radiology (ACR). The ACR MRI program evaluates staff qualifications, quality control, MR safety policies and image quality."

In Section O, page 103, the applicant states that during the 18 months preceding application submission there were no incidents resulting in a finding of Immediate Jeopardy at any SOS location. After reviewing and considering information, 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 – Both Applicants

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- Both Applications-** Neither of the applicants 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;

-C- DRI. The MRI service area is Guilford County. In Section C, pages 47-49, the applicant states that it owns or operates three fixed MRI scanners at its W. Wendover Avenue diagnostic center in Greensboro. The applicant states that during the most recent full federal fiscal year (October 2018 – September 2019), DRI performed 17,677 weighted MRI procedures. During the most recent full calendar year (January – December 2019), DRI performed 18,383 weighted scans. During the most recent 12 months prior to submission of the application for which the applicant has representative data (March 2019 – February 2020), DRI performed 18,582 weighted MRI procedures, or an average of 6,194 weighted MRI scans per scanner.

The applicant states that the related entity, Cone Health owns and operates four fixed MRI scanners at The Moses H. Cone Memorial Hospital and Wesley Long Hospital. During the most recent full federal fiscal year (October 2018 – September 2019), Cone Health performed 18,565 weighted MRI procedures. During the most recent full calendar year (January – December 2019), Cone Health performed 19,076 weighted scans. During the most recent 12 months prior to submission of the application for which the applicant has representative data (March 2019 – February 2020), Cone Health performed 19,274 weighted MRI procedures, or an average of 4,819 weighted MRI scans per scanner.

The applicant states that MRI utilization from March 2020 to the present has decreased as a result of the COVID-19 pandemic; however, the decrease is anomalous and directly attributable to the pandemic.

- **-NA- SOS.** The MRI service area is Guilford County. In Section C, page 58, the applicant states that neither SOS nor any related entity owns a controlling interest in a fixed MRI scanner in the Guilford County MRI service area.
 - (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- DRI.** The MRI service area is Guilford County. Neither the applicant nor a related entity owns or operates a mobile MRI scanner in Guilford County.
- **-NA- SOS.** The MRI service area is Guilford County. Neither the applicant nor a related entity owns or operates a mobile MRI scanner in Guilford County.
 - (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;

The 2020 SMFP shows that there are more than four (4) fixed MRI scanners located in the fixed MRI service area of Guilford County. Therefore, each 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 or proposes to locate in Guilford County will be at least 4,805 weighted MRI procedures in the third operating year.

- •C- **DRI.** In Section Q, Form C, the applicant states that it projects to perform 22,928 weighted MRI procedures on its existing and proposed MRI scanners during the third year (CY 2024) of the proposed project for an average of 5,732 weighted MRI scans per scanner [22,928 / 4 = 5,732] which exceeds the required average of 4,805 weighted MRI procedures per scanner in this performance standard. Additionally, the applicant projects that the four fixed MRI scanners at Cone Health, a related entity, will perform 20,002 fixed MRI scanners during the third year of the proposed project, which is 5,000 weighted MRI procedures per fixed MRI scanner [20,002 / 4 = 5000.5]. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.
- **-C- SOS.** In Section Q, Form C, the applicant shows the proposed fixed MRI scanner is expected to perform 5,728 weighted MRI scans in the third year of operation following completion of the proposed project.
 - (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- DRI.** 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 4,805 weighted MRI procedures in the third year following completion of the proposed project. The third OY for this project is CY 2024. In Section C.12, page 50 and in Section Q, the applicant projects that the proposed MRI scanner will perform 4,887 weighted MRI procedures in the third year of operation (CY 2024), which is greater than the 4,805 weighted MRI procedures required by the Rule.
- **-NA- SOS.** The MRI service area is Guilford County. Neither the applicant nor a related entity owns or operates a mobile MRI scanner in Guilford County.
 - (6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.
- **-C- DRI.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q.
- **-C- SOS.** 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- Both Applications** Neither of the applicants proposes 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- Both Applications-** Neither of the applicants proposes 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- Both Applications-** Neither of the applicants proposes the acquisition of a dedicated fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2020 SMFP, no more than one fixed MRI scanner may be approved for the Guilford County MRI service area in this review. Because the two applications in this review collectively propose to develop two additional fixed MRI scanners, both applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- Project ID# G-11981-20 / DRI Summerfield / Acquire no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP
- Project ID# G-11986-20 /**Southeastern Orthopaedic Specialists**, **P.A.** / Acquire no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Scope of Services

APPLICANT	Type of Fixed MRI Scanner	HOSPITAL BASED OR FREESTANDING*
DRI Summerfield	1.5T	Freestanding
SOS	1.5T	Freestanding

^{*}Freestanding means not operating as part of a hospital license

Both applicants propose to acquire and operate a 1.5T fixed MRI scanner in a freestanding outpatient setting, which would imply that both applicants will be capable of providing the same types of MRI services to the same types of patients. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

Historical Utilization

The following table illustrates utilization of the existing fixed MRI scanners provided in the **2020** SMFP representing FY 2018 reported utilization.

Fixed MRI Scanners in Guilford County 2020 SMFP Based on FY2018 Data

FACILITY	# OF FIXED MRI SCANNERS*	TOTAL WEIGHTED PROCEDURES	WEIGHTED MRI PROCEDURES PER SCANNER
Cone Health – Moses H. Cone Memorial Hospital	3	13,785	4,595
Cone Health – Wesley Long Hospital	1	5,272	5,272
High Point Regional Health	2	7,948	3,974
Cornerstone Imaging (Wake Forest Baptist Health)	1	4,664	4,664
Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	1	4,674	4,674
Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	1	5,653	5,653
Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	1	6,111	6,111
Greensboro Orthopaedics, PA (Greensboro Orthopaedics, P.A.)	1	3,300	3,300
Triad Imaging (Novant Health Imaging Triad)	1	4,626	4,626
Totals	12	56,033	42,869

Source: 2020 SMFP, page 427

SOS does not currently provide fixed MRI services at a facility and thus has no historical utilization to report. Thus, the result of this analysis is inconclusive.

Geographic Accessibility (Location within the Service Area)

The 2020 SMFP identifies the need for one fixed MRI scanner in Guilford County. The following table illustrates the current location of the existing fixed MRI scanners in Guilford County (there are no approved but not yet operational fixed MRI scanners in Guilford County):

Fixed MRI Scanners in Guilford County 2020 SMFP Based on FY2018 Data

	# OF FIXED	HOSPITAL BASED	LOCATION
	MRI	OR	
FACILITY	SCANNERS*	FREESTANDING	
Cone Health – Moses H. Cone Memorial Hospital	3	Hospital Based	Greensboro
Cone Health – Wesley Long Hospital	1	Hospital Based	Greensboro
High Point Regional Health	2	Hospital Based	High Point
Cornerstone Imaging (Wake Forest Baptist Health)	1	Freestanding	High Point
Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	3	Freestanding	Greensboro
Greensboro Orthopaedics, PA (Greensboro Orthopaedics, P.A.)	1	Freestanding	Greensboro
Triad Imaging (Novant Health Imaging Triad)	1	Freestanding	Greensboro
Total MRI Scanners Greensboro	9		
Total MRI Scanners High Point	3		

Source: 2020 SMFP, page 427

The following table illustrates the proposed location of each applicant's proposed fixed MRI scanner:

Location of Proposed Fixed MRI Scanners

Location of Proposed Fixed Wiki Scanners						
	# OF FIXED LOCATION					
	MRI					
FACILITY	SCANNERS*					
DRI Summerfield	1	Summerfield				
SOS	1	Greensboro				

Each of the applicants proposes to locate the fixed MRI scanner in Guilford County; **DRI** proposes to locate the fixed MRI scanner in Summerfield, and **SOS** proposes to locate the fixed MRI scanner in Greensboro. According to the North Carolina Office of State Budget and Management, the July 2019 population of Greensboro was 293,726 and the July 2019 population of Summerfield was 11,949. The per capita utilization of Greensboro MRI scanners was one MRI scanner per 32,636 population [293,726 total population / 9 MRI scanners = 32,636.22]. There is currently no fixed MRI located in Summerfield, so there is no per capita utilization of MRI scanners for that town. Since **DRI** proposes to locate the proposed MRI scanner in Summerfield, the application submitted by **DRI** is a more effective alternative, because it proposes to locate the proposed fixed MRI scanner in a town that does not currently have a fixed MRI scanner.

Access by Service Area Residents

The 2020 SMFP defines the service area for fixed MRI scanners as "the same as an Acute Care Bed Service Area as defined in Chapter 5, and shown in Figure 5.1.". The 2020 SMFP defines the service area for acute care beds as "the service area in which the bed is located. The acute care bed service areas are the single and multicounty groupings shown in Figure 5.1." Figure 5.1 shows Guilford County as a single county acute care bed service area. Thus, the service area for this review is Guilford County. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional fixed MRI scanners in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion:

APPLICANT	TOTAL POPULATION TO BE SERVED	TOTAL SERVICE AREA RESIDENTS TO BE SERVED	SERVICE AREA RESIDENTS AS % OF TOTAL
DRI Summerfield	4,219	2,407	57.05%
SOS	5,513	3,904	70.81%

As shown in the table above, **SOS** projects to serve the highest number of service area residents during the third full fiscal year following project completion. Therefore, regarding projected service to residents of the service area, the application submitted by **SOS** is a more effective alternative.

Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

"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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per MRI scanner
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total net revenues
- Charity care, Medicare or Medicaid dollars per MRI scanner

Whether the Agency used all the metrics listed above in this review was determined by whether every application included in this review included data that could be compared for each metric.

Projected Charity Care as a Percent of Gross Revenue

The following table compares projected charity care as a percent of gross revenue in the third full fiscal year following project completion for each facility:

APPLICANT	GROSS REVENUE PROJECT YEAR 3	CHARITY CARE PROJECT YEAR 3	CHARITY CARE AS % OF GROSS REVENUE	Number of Charity Care Procedures as % of Gross Revenue
DRI Summerfield	\$6,372,686	\$79,659	1%	42
SOS	\$7,122,796	\$142,456	2%	110

DRI proposes to provide \$79,659 in charity care in its third year of operation. This is 1.0% of gross revenue and represents 42 procedures. **SOS** proposes to provide \$142,456 in charity care in its third year of operation. This is 2.0% of gross revenue and represents 110 procedures. As a percent of gross revenue, **SOS** projects to provide a higher percentage of charity care in the third project year. Therefore, regarding charity care as a percent of gross revenue, the application submitted by **SOS** is a more effective alternative.

Projected Charity Care as a Percent of Net Revenue

The following table compares projected charity care as a percent of net revenue in the third full fiscal year following project completion for each facility:

APPLICANT	NET REVENUE PROJECT YEAR 3	CHARITY CARE PROJECT YEAR 3	CHARITY CARE AS % OF NET REVENUE	Number of Charity Care Procedures as % of Net Revenue
DRI Summerfield	\$2,031,724	\$79,659	4%	169
SOS	\$2,324,979	\$142,456	6%	331

DRI proposes to provide \$79,659 in charity care in its third year of operation. This is 4.0% of net revenue and represents 169 procedures. **SOS** proposes to provide \$142,456 in charity care in its third year of operation. This is 6.0% of net revenue and represents 331 procedures. As a percent of net revenue, **SOS**

projects to provide a higher percentage of charity care and more procedures in the third project year. Therefore, regarding charity care as a percent of net revenue, the application submitted by **SOS** is a more effective alternative.

Projected Medicare and Medicaid

The following table compares projected charity care in the third full fiscal year following project completion for each facility using the following metrics: Medicare and Medicaid patients as a percent of total patients projected to be served by the proposed MRI scanner.

APPLICANT	GROSS REVENUE (GR) PROJECT YEAR 3	MEDICARE PATIENTS AS % OF GROSS REVENUE	NUMBER OF MEDICARE PROCEDURES REPRESENTING GR	MEDICAID PATIENTS AS % OF GROSS REVENUE	NUMBER OF MEDICAID PROCEDURES REPRESENTING GR
DRI Summerfield	\$6,372,686	44.98%	1,899	4.97%	211
SOS	\$7,122,796	33.25%	1,819	6.00%	331

The Agency used Medicare and Medicaid patients as a percent of total patients projected to be served in the third project year.

DRI proposes to provide 44.98% of gross revenue to Medicare patients, which represents 1,899 procedures. **SOS** proposes to provide 33.25% of gross revenue to Medicare patients, which represents 1,819 procedures. **DRI** proposes to provide 4.97% of gross revenue to Medicaid patients, which represents 211 procedures. **SOS** proposes to provide 6.00% of gross revenue to Medicaid patients, which represents 331 procedures.

As shown in the table above, **DRI** projects to serve a greater percentage of Medicare patients, while **SOS** projects to serve a greater percentage of Medicaid patients in the third full fiscal year following project completion. Regarding projected access for Medicare patients, the application submitted by **DRI** is a more effective alternative. Regarding projected access for Medicaid patients, the application submitted by **SOS** is a more effective alternative.

Competition (Access to a New or Alternate Provider)

The following table illustrates the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer fixed MRI scanners than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

GUILFORD	COLINTY	FIXED I	MRI	SCANNERS
UUILFURD	COUNT	LIVEDI	VIIVI	JUANNERS

LOCATION	# Units	FFY 2019 TOTAL	TOTAL WEIGHTED	
		UNWEIGHTED SCANS	Scans	
Moses Cone Memorial Hospital	3	10,263	13,487	
Wesley Long Hospital	1	3,883	5,078	
High Point Regional Health	2	4,523	5,691	
Cornerstone Imaging	1	4,519	4,926	
EmergeOrtho	1	5,809	5,917	
Greensboro Imaging	3	15,276	17,676	
Triad Imaging	1	4,116	4,394	

Greensboro Imaging, a related entity to **DRI Summerfield**, currently operates three fixed MRI scanners in Greensboro. **SOS** does not currently own or operate a fixed MRI scanner, but provides MRI services to its patients via a leased MRI scanner. Therefore, with regard to the introduction of a new provider of fixed MRI services in the service area, the application submitted by **SOS** is a more effective alternative.

Projected Average Net Revenue per Patient Day, Surgical Case or Procedure

The following table compares projected average net revenue per patient day, surgical case or procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average net revenue per patient day, surgical case or procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

AVERAGE NET REVENUE PER PATIENT WEIGHTED MRI PROCEDURE					
3 RD FULL FY					
APPLICANT	TOTAL # OF WEIGHTED MRI	NET REVENUE	AVERAGE NET REVENUE PER		
	Procedures	INEI KEVENUE	WEIGHTED MRI PROCEDURE		
DRI Summerfield	4,887	\$2,031,724	\$415.74		
SOS	5,728	\$2,324,979	\$405.89		

Source: Applications Forms C Utilization and Form F.2

As shown in the table above, **SOS** projects the lowest average net revenue per weighted MRI procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **SOS** is a more effective alternative.

Projected Average Operating Expense per Patient Day

The following table compares projected average operating expense per patient day, surgical case or procedure in the third full fiscal year following project completion for each facility. Generally, regarding this factor, the application proposing the lowest average operating expense per patient day, surgical case or procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

AVERAGE OPERATING EXPENSE PER PATIENT WEIGHTED MRI PROCEDURE 3 RD FULL FY				
APPLICANT TOTAL # OF WEIGHTED MRI PROCEDURES		OPERATING EXPENSE	AVERAGE OPERATING EXPENSE PER WEIGHTED MRI PROCEDURE	
DRI Summerfield	4,887	\$1,709,818	\$349.87	
SOS	5,728	\$1,488,570	\$259.87	

Source: Applications Forms C Utilization and Form F.2

As shown in the table above, **SOS** projects the lowest average operating expense per patient day, surgical case or procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **SOS** is a more effective alternative.

Summary

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

COMPARATIVE FACTOR	DRI SUMMERFIELD	sos
Conformity with Statutory and Regulatory Review Criteria	X	X
Scope of Services	X	Х
Historical Utilization	Inconclusive	Inconclusive
Geographic Accessibility (Location within the Service Area)	Х	
Access by Service Area Residents		Х
Charity Care as a Percent of Gross Revenue		Х
Charity Care as a Percent of Net Revenue		Х
Access by Medicaid Patients		Х
Access by Medicare Patients	X	
Competition (Access to a New or Alternate Provider)		Х
Projected Average Net Revenue per Patient Day, Surgical Case or Procedure		Х
Projected Average Operating Expense per Patient Day, Surgical Case or Procedure		Х

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of two fixed MRI scanners in Guilford County, but the need determination is for only one fixed MRI scanner. Therefore, only one application for one MRI scanner can be approved.

As shown in the table above, **DRI** was determined to be a more effective alternative for the following two factors:

- Geographic Accessibility
- Access by Medicare patients

As shown in the table above, **SOS** was determined to be a more effective alternative for the following five factors:

- Access by service area residents
- Provision of charity care as a percent of gross revenue
- Provision of charity care as a percent of net revenue
- Access by Medicaid patients
- Competition (access to a new or alternate provider)
- Projected average net revenue per weighted MRI scan
- Projected average operating cost per weighted MRI scan

DECISION

Each application is individually conforming to the need determination in the 2020 SMFP for one additional fixed MRI scanner in Guilford County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved as submitted:

• Project ID# G-11986-20/ Southeastern Orthopaedic Specialists, P.A. / Acquire one fixed MRI scanner

And the following application is denied:

• Project ID# G-11981-20 / DRI Summerfield / Acquire one fixed MRI scanner

Project ID# G-11986-20 is approved subject to the following conditions.

- 1. Southeastern Orthopaedic Specialists, P.A. (herein after "the certificate holder") shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2020 SMFP and develop a new diagnostic center.
- 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. 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 third month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the 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.