

COMPETITIVE COMMENTS ON GUILFORD COUNTY
2020 FIXED MRI SCANNER NEED DETERMINATION
SUBMITTED BY SOUTHEASTERN ORTHOPAEDIC SPECIALISTS, PA
DECEMBER 1, 2020

Southeastern Orthopaedic Specialists, P.A. (“SOS”) proposes to develop a fixed MRI scanner in Guilford County (Project ID No. G-11986-20). SOS plans to renovate space to locate the proposed fixed MRI scanner in its existing physician office building; the SOS physician office building housing the new MRI will then meet the CON Law definition of a diagnostic center.

Diagnostic Radiology & Imaging, LLC (“DRI”) also submitted a CON application in response to the need determination in the 2020 State Medical Facilities Plan (“SMFP”) for one new fixed MRI scanner in Guilford County (Project ID No. G-11981-20). According to exhibits attached to the DRI application, DRI proposes to develop a new diagnostic center in 11,000 square feet of existing vacant space, all of which will be leased by DRI and in which DRI will house the proposed fixed MRI scanner as well as two procedure rooms, a recovery room, a CT scanner, and x-ray equipment.

SOS submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the DRI application, including a comparative analysis and a discussion of the most significant issues regarding the applicant’s conformity with the statutory and regulatory review criteria (“the Criteria”) in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the DRI application may exist. Nothing in these Comments is intended to amend the SOS application, and nothing contained in this document should be considered an amendment to the SOS application as submitted.

COMPARATIVE COMMENTS

The Healthcare Planning and Certificate of Need Section developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of the type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue
- Projected Average Total Operating Cost

Conformity to CON Review Criteria

Two CON applications have been submitted, each seeking a fixed MRI scanner in Guilford County. Based on the 2020 SMFP’s need determination for one additional fixed MRI scanner, only one application can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by SOS demonstrates conformity to all Criteria:

Conformity of Competing Applications

Applicant	Project I.D.	Conforming/ Non-Conforming
Southeastern Orthopaedic Specialists, PA	G-11986-20	Yes
Diagnostic Radiology & Imaging, LLC	G-11981-20	No

The SOS application for a fixed MRI scanner is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed below, the DRI application contains errors and flaws which result in multiple non-conformities with the Criteria. Among other issues, DRI’s projected utilization is not reasonable and adequately supported. Therefore, SOS is the most effective alternative regarding conformity with the Criteria.

Scope of Services

With regard to the scope of services, the applications submitted by SOS and DRI are both in response to the 2020 SMFP need determination for one fixed MRI scanner in Guilford County. SOS and DRI propose to develop dedicated outpatient fixed MRI services. Both applicants propose to acquire and operate a fixed MRI scanner in a freestanding outpatient setting. (Freestanding means not operating under a hospital license.) Neither applicant proposes to offer inpatient services.

However, DRI does not comply with all applicable statutory and regulatory criteria, and therefore DRI is not approvable. Therefore, regarding this comparative factor, the SOS application is more effective than the application submitted by DRI. See Application of the Scope of Services factor in the 2019 Wake MRI Review.

Historical Utilization

The following table illustrates the total MRI scans and the adjusted total of MRI scans performed by SOS (based on mobile MRI access) and by DRI and its affiliates as published in Table 17E-1 of the 2021 SMFP.

**MRI Utilization
 Proposed 2021 SMFP (FY2019 Data)**

Service Site (Provider/Owner)	Equipment Type	Total MRI Scans	Adjusted MRI Scans
SOS (Alliance HealthCare Services)	Mobile	4,968	5,147
Greensboro Imaging (DRI)	Fixed	4,917	5,617
Greensboro Imaging (DRI)	Fixed	5,297	6,143
Greensboro Imaging (DRI)	Fixed	5,062	5,916
Cone Health-Moses H. Cone Memorial Hospital	Fixed	10,263	13,487
Cone Health-Wesley Long Hospital	Fixed	3,883	5,078

Source: 2021 Proposed SMFP, Chapter 17, Table 17E-1 (page 339)

DRI and its affiliates control five of the 13 (38%) fixed MRI scanners in Guilford County. SOS does not own a fixed MRI scanner and, therefore, does not have historical fixed MRI utilization. SOS provides mobile MRI services via a lease agreement with Alliance HealthCare Services (“Alliance”). Table 17E-1 (page 428) of the 2020 SMFP appropriately identifies SOS’s MRI service type as “mobile.” A mobile MRI scanner is not equivalent to a fixed MRI scanner. SOS’s application describes the various access and operational limitations associated with the mobile MRI service. Thus, the result of this comparison 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 identifies the existing and approved fixed MRI scanner locations in Guilford County.

Service Area	Service Type	Service Site (Provider/Owner)	Fixed Magnets	Location
Guilford	Hospital Fixed	Cone Health-Moses H. Cone Memorial Hospital	3	Greensboro
Guilford	Hospital Fixed	Cone Health-Wesley Long Hospital	1	Greensboro
Guilford	Hospital Fixed	High Point Regional Health	2	High Point
Guilford	Freestanding Fixed	Cornerstone Imaging (Wake Forest Baptist Hospital)	1	High Point
Guilford	Freestanding Fixed	EmergeOrtho-Triad Region (EmergeOrtho, P.A)	1	Greensboro
Guilford	Freestanding Fixed	Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	1	Greensboro
Guilford	Freestanding Fixed	Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	1	Greensboro
Guilford	Freestanding Fixed	Greensboro Imaging (Diagnostic Radiology & Imaging, LLC)	1	Greensboro
Guilford	Freestanding Fixed	Triad Imaging (Novant Health Imaging Triad)	1	Greensboro

SOS proposes to develop a fixed MRI scanner in Greensboro. DRI claims it proposes to develop a fixed MRI scanner in “Summerfield,” but DRI lists a proposed site (6199 Lake Brandt Road) with a ZIP code of 27455. The “primary/preferred city” for ZIP code 27455 is Greensboro. The Post Office City for ZIP code 27455 is Greensboro, North Carolina. <https://www.unitedstateszipcodes.org/>. Most of the population of Summerfield (93%) lives in ZIP code 27358, not in ZIP code 27455. ZIP codes 27455 and 27410 are associated with the Primary City of Greensboro. <https://www.unitedstateszipcodes.org/>. In other words, the location proposed by DRI is, at best, within a Greensboro ZIP code that borders the ZIP code associated with 93% of the population of Summerfield.

The following table summarizes Guilford County municipalities and their relative access to fixed MRI services. The following table summarizes Guilford County municipalities and their relative access to fixed MRI services.

Municipality	2018 Population	Total Fixed MRI Scanners	Average Population per Total Fixed Scanner
Greensboro	292,286	9	32,476
High Point	106,564	3	35,521
Summerfield	11,812	0	11,812

Source: North Carolina Office of State Management and Budget. Population estimates from July 1, 2018.

Based on the Guilford County population estimates as of July 1, 2018, 32,476 people are using the freestanding fixed MRI scanners located in Greensboro on a per capita basis. While there are no fixed MRI scanners located in Summerfield, the population is only 11,812. The mere absence of a fixed MRI scanner is not a sufficient basis to determine which competing application is most effective with respect to geographic access. Further, the chart on page 36 of the DRI application does not make a case for locating an MRI in Summerfield. DRI attempted to combine the populations within all the communities listed in the chart from Summerfield to Gibsonville to inflate its analysis. More importantly, the chart is based on a highly flawed premise that all patients from Summerfield to Gibsonville will elect to utilize an MRI located in Summerfield which is, of course, not at all a reasonable assumption. This ignores the obvious fact that patients seek care at various healthcare providers in Guilford County, like SOS. SOS patients come to see their physicians at the SOS practice location and, if their physician believes it necessary, the patients can receive an MRI scan at SOS. Regardless of whether the patient's home is in Greensboro or Summerfield, having the MRI performed at SOS is far more convenient than any other option. Many adult patients likely work in Greensboro such that an MRI scanner located near their offices or workplaces would be much more convenient than an MRI located out in sparsely populated Summerfield. Even patients not working in Greensboro are likely to travel to Greensboro for school, shopping, entertainment, and medical care such that a Greensboro MRI would represent a more convenient option than a scanner out in the thinly populated area of Summerfield.

Based on the previous analysis, which shows the Greensboro population having disproportionately higher average population per fixed MRI scanner compared to the Summerfield population, the proposed SOS fixed MRI scanner location in Greensboro is more effective for improving geographic access to fixed MRI services in Guilford County.

SOS proposes to locate an MRI scanner in Greensboro within ZIP code 27401. Approximately 73.5% of the population living in ZIP code 27401 are black or African American. The median household income for ZIP code 27401 is **\$26,401**. <https://www.unitedstateszipcodes.org/27401/>

DRI proposes to locate an MRI scanner in ZIP code 27455. Approximately 72.7% of the population living in ZIP code 27455 are white. The median income for ZIP code 27455 is **\$60,818**. <https://www.unitedstateszipcodes.org/27455/>.

DRI claims its proposed location is in "Summerfield." As noted above, 93% of the population of Summerfield reside in ZIP code 27358. Approximately 90.4% of the population living in ZIP code 27358 are white. The median household income for ZIP code 27358 is **\$88,382**. <https://www.unitedstateszipcodes.org/27358/>.

Based on the previous comparison of zip code demographics for the proposed locations, SOS's proposal to develop a fixed MRI scanner in Greensboro most effectively increases access for minority populations and low income persons.

In its application, DRI suggests the Summerfield area is an appropriate location for its proposed imaging center. It is worth noting that Cone Health has recently pursued CON approval for Guilford County projects and avoided locations in the Summerfield area. For example, in 2020, Cone Health received a CON for a new ASC known as North Elam ASC (CON Project I.D. #G-011895-20). Cone Health did not propose to develop that ASC in Summerfield. Instead, it proposed to develop the new ASC over eight

miles away from the proposed location of the DRI imaging center. In 2018, Cone received a CON for its MedCenter Drawbridge project with various imaging capabilities, including CT and x-ray (CON Project I.D. # G-011467-18). Cone Health did not select Summerfield as its location. Instead, Cone Health’s analysis led it to propose a site on Drawbridge Parkway approximately six miles away from the proposed DRI imaging center site out in Summerfield.

SOS proposes to locate its proposed new fixed MRI scanner within the familiar medical offices where its patients see their physicians to address orthopaedic issues. The proposed DRI imaging center will be a separate site that patients will have to travel to solely to receive an MRI procedure, far apart from the location of the physicians who manage their care. In other words, patients of physicians whose offices are in Greensboro locations will have to travel once to see their physician and again out to another location in Summerfield for their MRI procedure. DRI suggests “thousands” of MRI patients live out in Summerfield or northern Guilford County. However, DRI does not reveal whether most or nearly all those patients are under the care of physicians whose offices are in Greensboro, not out in Summerfield.

An MRI that is co-located with the patients’ physician office offers far superior patient access to convenient imaging services than a more distant MRI location that is not on-site or co-located with the offices of the physicians managing the care of patients. The proposed DRI imaging center is apparently intended to occupy the entirety of the now-vacant 11,000 square-foot Southern States feed store (putting aside the site-related issues discussed elsewhere in these Comments). In other words, the proposed DRI MRI will not be situated within the offices of any treating physicians, such as the orthopaedic physicians of SOS or any other such group.

For these reasons and the reasons described previously regarding geographic access, the proposed fixed MRI scanner at SOS is the most effective alternative for improving access for Guilford County residents.

Access By Service Area Residents

On page 418, the 2020 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2020 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Therefore, for this review, Guilford County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area. The following table compares access by service area residents during the third full fiscal year following project completion for each applicant.

Access by Service Area Residents, PY3	SOS	DRI Summerfield
Guilford County Residents Served	3,903	2,405
% of Guilford County Patients as a % of Total Patients	71%	57%

Source: Form C and Section C.3 of the respective applications

As shown in the table above, SOS projects to serve both the highest number of Guilford County residents (SOS: 3,903 vs. DRI: 2,405) and the highest percentage of service area residents (SOS: 71% vs. DRI: 57%). Therefore, regarding access by service area residents, SOS is the most effective alternative.

As explained elsewhere in these comments, DRI's patient origin projections do not align with DRI's need methodology to project its utilization. Because DRI relies heavily on a projected "shift" of patients from zip codes which are largely within Rockingham County and projects to serve other areas as well, the DRI projection that it will provide 57% of its projected scans to Guilford County residents in PY 3 is not reasonable and adequately supported.

In the 2018 Buncombe County Operating Room Review, Service to Residents of the Service Area was used as a Comparative Factor in the Agency's Comparative Analysis. In that Review, the Agency concluded that the application projecting to serve the highest percentage of Buncombe-Madison-Yancey multicounty OR planning area residents is the more effective alternative with regard to this comparative factor since the need determination is for two additional ORs to be located in this multi-county service area. The Agency determined that the applicant projecting to serve the highest percentage of Buncombe-Madison-Yancey multicounty OR planning area residents during the third operating year was the most effective alternative. Similarly, in the 2019 Wake County MRI Review, Service to Residents of the Service Area was used as a Comparative Factor in the Agency's Comparative Analysis. In that Review, the Agency concluded that the application projecting to serve the highest percentage of Wake County MRI service area residents is the more effective alternative with regard to this comparative factor since the need determination is for one additional MRI to be located in the MRI service area. The Agency determined that the applicant projecting to serve the highest percentage of Wake County MRI service area residents during the third operating year was the most effective alternative.

As it did in the recent Buncombe OR Review and Wake County MRI Review, the Agency should conclude that the SOS application is a more effective alternative than the DRI application because SOS projects to serve a higher number and percentage of Guilford County residents in the third operating year.

Competition (Access to a New or Alternate Provider)

The Agency evaluates access to a new provider in the context of the service at issue, here, fixed MRI services. DRI and its affiliates control five of the 13, or 38%, of the fixed MRI scanners in Guilford County. SOS does not own a fixed MRI scanner. Table 17E-1 (page 428) of the 2020 SMFP appropriately identifies SOS's MRI service type as "mobile." A mobile MRI scanner is not equivalent to a fixed MRI scanner. SOS will be a new fixed MRI service provider in Guilford County. By contrast, DRI and its affiliates control five of the 13, or 38%, of the fixed MRI scanners in Guilford County. Thus, SOS is the most effective alternative regarding access to a new or alternative provider of fixed MRI services.

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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

As compared to SOS’s application, DRI’s proposal is inferior with respect to medically underserved access. DRI projects comparatively lower charity care and Medicaid access than SOS.

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
- Total charity care, Medicare, or Medicaid dollars
- Charity care, Medicare, or Medicaid dollars as a percentage of total gross or net revenues

Which of the above metrics the Agency uses is determined by whether the applications included in the review provide data that can be compared as presented above and whether such a comparison would be of value in evaluating the alternative factors.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion.

	SOS	DRI Summerfield
Charity Care MRI Procedures	110	N/A
Charity Care MRI Procedures as a % of Total MRI Procedures	2.0%	N/A
Charity Care Deduction From Revenue	\$142,456	\$79,659
Charity Care Deduction From Revenue as a % of Total Gross Revenue	2.0%	1.3%
Charity Care Deduction From Revenue as a % of total Net Revenue	6.1%	3.9%

Source: Form C, Section L, and Form F.2 of the respective applications

DRI co-mingled self-pay and charity care projections in Section L.3; therefore, one cannot determine the number of charity care MRI procedures proposed by the applicant.

SOS provides a higher dollar amount of charity care deduction from gross revenue than DRI. SOS also provides the highest charity care deduction as a percent of gross and net revenue than DRI. Thus, regarding access for charity care patients, SOS is the most effective alternative.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion.

	SOS	DRI Summerfield
Medicare MRI Procedures	1,833	1,898
Medicare MRI Procedures as a % of Total MRI Procedures	33.3%	45.0%
Medicare Gross Revenue	\$2,367,617	\$2,866,434
Medicare Gross Revenue as a Percentage of Total Gross Revenue	33.2%	45.0%

Source: Form C, Section L, and Form F.2 of the respective applications

DRI proposes comparatively higher Medicare access, although the difference in proposed Medicare MRI procedures is only 65 procedures (1,898 – 1,833 = 65). However, DRI does not comply with all applicable statutory and regulatory criteria; therefore, DRI is not approvable. Thus, regarding access by Medicare patients, SOS is the most effective alternative.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants.

Project Year 3	SOS	DRI Summerfield
Medicaid MRI Procedures	331	210
Medicaid MRI Procedures as a % of Total MRI Procedures	6.0%	4.97%
Medicaid Gross Revenue	\$427,368	\$316,722
Medicaid Gross Revenue as a Percentage of Total Gross Revenue	6.0%	5.0%

Source: Form C, Section L, and Form F.2 of the respective applications

SOS projects the highest number of Medicaid procedures, highest Medicaid procedures as a percent of total procedures, highest Medicaid gross revenue, and highest percentage of Medicaid as a percent of

gross revenue. Therefore, SOS is the most effective alternative with respect to access for Medicaid patients.

The Agency has acknowledged Medicaid patients may have difficulty accessing healthcare compared to other payor sources, like Medicare. During her deposition in the 2018 Mecklenburg County Home Health Review, Healthcare Planning and Certificate of Need Section Chief Martha Frisone indicated that “Medicare patients, while they may have trouble getting access, don’t have as much trouble as Medicaid patients.”¹ SOS provided information and data in its CON application (pp.45-46, 48, 91-97, Exhibit C.4-3) which support the reasonableness of its projected Medicaid payor mix.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected average net revenue per procedure in the third year of operation for each applicant, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Project Year 3	SOS	DRI Summerfield
MRI Procedures	5,513	4,219
Net Revenue	\$2,324,979	\$2,031,724
Net Revenue Per MRI Procedure	\$422	\$482

Source: Form C and Form F.2 of the respective applications

As shown in the previous table, SOS projects the lowest net revenue per MRI procedure in the third operating year. Therefore, SOS is the most effective alternative with respect to projected average net revenue.

¹ Deposition of Martha Frisone, 2018 Mecklenburg County Home Health Care Review. Deposition transcript page 151, lines 21-23

Projected Average Total Operating Cost per MRI Procedure

The following table compares the projected average operating expense per MRI procedure for the third year of operation following project completion for each applicant, based on the information provided in the applicants’ pro forma financial statements (Section Q).

Project Year 3	SOS	DRI Summerfield
MRI Procedures (Form C)	5,513	4,219
Operating Expenses (Form F.3)	\$1,488,570	\$1,709,815
Operating Expenses Per MRI Procedure	\$270	\$405

Source: Form C and Form F.3 of the respective applications

As shown in the table, SOS projects the lowest operating expense per MRI procedure in the third operating year. Therefore, SOS is the most effective alternative with respect to projected average total operating cost per MRI procedure.

In addition to providing less access for patients, the DRI Application shows the DRI Summerfield MRI scanner will be more costly to operate as compared to the SOS MRI scanner. DRI expects to deliver 4,219 MRI procedures with operating costs that exceed \$1.70 million in Project Year 3. By contrast, SOS expects to deliver 5,513 patients scans with operating costs of \$1.48 in Project Year 3. In the third project year, SOS will be able to provide patients with **access to nearly 1,300 more scans** than DRI and will do so with lower total operating costs than those projected by DRI.

Overall, DRI’s higher operational costs do not appear to be a function of better or higher staffing levels as compared to SOS. DRI proposes to use an “MRI Tech Asst” although it does not explain anything about this type of position and whether the person functioning in this role is or is not equivalent to an MRI Technologist. In Project Year 3, with 60 hours of service per week, the assumption would be that there would be a need for at least 2 or possibly 2.1 MRI Techs. ($60 \text{ hrs} \times 50 \text{ wks} = 3,000 / 2,080 = 1.44 \times 1.4 = 2.016 \text{ FTEs}$). DRI plans to hire only 1.75 MRI Techs and proposes to hire an additional 1.0 FTE in the position of “MRI Tech Asst.” If the Assistant position is not equivalent to an MRI Tech for accreditation and safety purposes, the staffing at 1.75 FTE will not meet the 2.0 or 2.1 FTE expectation.

DRI will have only 5.45 total FTEs of staff in Year 3 with two positions assigned a small fraction (0.1) of FTE time. SOS will have 9.3 FTEs of staff in Year 3 and still offer overall lower operating costs as compared to DRI. In fact, beginning in the first year of operation, SOS will expend over \$500,000 annually to attract and maintain the staffing levels it proposes to utilize in offering MRI services to area residents. DRI will expend less than \$200,000 its first year and well under \$300,000 for staff in its third year.

One of the largest differentiators when comparing operating costs between SOS and DRI is the amount of professional fees. According to page 7 of the DRI application, the members of DRI are Moses Cone Medical Services, Inc. and Greensboro Radiology, P.A. (“Greensboro Radiology”).

SOS has a long-standing contractual arrangement under which it secures professional services from Greensboro Radiology, the same group which would provide these services for the proposed DRI Imaging Center. SOS projects it will pay Greensboro Radiology, under its existing contract, \$396,936 for professional services associated with 5,513 unweighted MRI scans in Project Year 3. DRI projects it will pay Greensboro Radiology \$681,643 for professional services associated with only 4,219 unweighted MRI scans in Project Year 3.

SOS will pay approximately \$72 in professional fees per scan. DRI will pay its member, Greensboro Radiology (the very same Radiology group) \$162 per scan. Thus, DRI plans to pay its member Greensboro Radiology twice as much on a per scan basis as SOS will pay those very same doctors under its existing contract.

For these and other reasons, DRI's average MRI operating costs and revenues are comparatively higher than SOS's average MRI operating costs and revenues. Therefore, with respect to costs and revenue, SOS is the most effective alternative.

Summary

For each of the comparative factors previously discussed, SOS's application is determined to be the most effective alternative with the following comparative metrics:

- Conformity with Review Criteria
- Geographic Access
- Access by Service Area Residents
- Competition/Access to an Alternate Provider
- Access by Charity Care: Total Dollars
- Access by Charity Care: % of Total Gross Revenue
- Access by Charity Care: % of Total Net Revenue
- Access by Medicaid: Highest Medicaid Procedures
- Access by Medicaid: Highest Medicaid Percentage
- Access by Medicaid: Highest Medicaid Dollars
- Access by Medicaid: Percentage of Gross Revenue
- Projected Average Net Revenue per MRI procedure
- Projected Average Total Operating Cost per MRI Procedure

**COMMENTS SPECIFIC TO DIAGNOSTIC RADIOLOGY & IMAGING, LLC (DRI)
PROJECT ID No. G-11981-20**

Failure to Pay the Full Application Fee

At the outset, the DRI Application cannot be considered in this review cycle because DRI failed to pay the full application fee before the start of the Review Period. The application fee required to accompany a CON application is prescribed by statute:

An application fee is imposed on an applicant for a certificate of need.
... The application fee is five thousand dollars (\$5,000) plus an amount equal to three-tenths of one percent (.3%) of the amount of the capital expenditure proposed in the application that exceeds one million dollars (\$1,000,000). In no event may the fee exceed fifty thousand dollars (\$50,000).²

Because CON application fees are prescribed by statute, neither the CON application form nor any regulation (including 10A N.C.A.C. 14C.0203) may override the mandate of the statute. Here, DRI did not properly calculate the CON application fee due according to the formula set forth in N.C. Gen. Stat. § 131E-182(c). Instead, DRI underpaid by a little more than \$0.20. Nothing in the statute permits an applicant to pay—nor the Agency to accept—an application fee rounded downward, such that less than the full amount due is paid.

DRI's underpayment appears to have resulted from it following the instructions in the Agency's CON application form/fee sheet. However, **the burden rests with DRI to ensure it submits the statutorily required application fee in full, notwithstanding any instructions which may appear in the Agency's application form.** The application form/fee sheet specifically references N.C. Gen. Stat. § 131E-182(c); it would not have been difficult for DRI to have referenced the statute before submitting its application.

DRI may argue that this oversight is immaterial or *de minimis*, or otherwise attempt to downplay its underpayment. However, the General Assembly clearly intended the fee to be paid with precision. The statute sets forth a precise formula by which a CON application fee is to be calculated, down to three-tenths of one percent (three decimal places (.003)). And nothing in the statute permits the Agency to impose its own materiality threshold or implement a *de minimis* exception. Nor may the Agency allow DRI to remedy its underpayment at this juncture, now that the Review is underway.

Failure To Adequately Identify Project Scope

The DRI application, as submitted, cannot be approved, because although DRI proposed a comprehensive “new outpatient imaging facility” with multiple capabilities, it completely failed to address the full range

² N.C. Gen. Stat. § 131E-182(c)

of those proposed capabilities in the context of the various Criteria addressing need, access, and financial feasibility, among others.³

In Section K, when the application form asks for a legible line drawing with “use of each room or space ... labeled,” in response, DRI includes Exhibit K.1, a line drawing by Boulder Associates Architects (Charlotte), labeled “Guilford County Imaging Center,” showing:

- Two Procedure Rooms;
- A Recovery Room
- A CT Scanner;
- X-Ray Equipment; and
- An MRI.

Whether intentionally or not, DRI submitted to the CON Section:

- Drawings by an Architectural firm showing the proposed DRI Diagnostic Center will occupy 11,000 square feet and will house a range of capabilities beyond MRI services, including x-ray and CT services; and
- Drawings by an Engineer showing the 11,000 square foot Southern States building which the proposed DRI Diagnostic Center will occupy; and
- Documentation of an agreement with DPC Commercial Development, LLC to lease 11,000 square feet to DRI.

DRI made obvious in its application, as submitted to the CON Section, that its plans are to develop an 11,000 diagnostic center offering MRI, x-ray, CT, and other services.⁴

It would now be illogical and highly disingenuous for DRI to claim that it agreed to lease 11,000 square feet (only about 1,000 sq. ft. of which is needed for its proposed MRI) but that its true intent is to leave the remainder of the 10,000 square feet empty without outfitting the space with the procedure rooms, recovery room, x-ray equipment and CT scanner, all of which are plainly depicted on the Architect’s drawings included in its CON application.

In response to SOS’s comments, DRI has two choices:

³ DRI application, page 22

⁴ DRI describes how it expects physicians to “continue to refer patients to DRI for imaging services (including MRI).” (DRI application, page 37). DRI projects utilization based in part on a “projected shift” of patients from its West Wendover Avenue location in Greensboro where, under the name Greensboro Imaging, DRI offers various services, including MRI, pain management services and CT scanner services. (DRI application, page 24).

- it can represent to the CON Section that it does not intend to offer x-ray, CT services, and procedure/recovery rooms in the proposed DRI Summerfield diagnostic center; or
- it can admit, as is obvious by its submissions, that it does intend to acquire x-ray and CT equipment and build its diagnostic center to include procedure rooms and a recovery room.

If DRI now claims it does not intend to offer x-ray, CT and other services, its statements should be considered an impermissible amendment to its application, which plainly tipped DRI's hand and revealed the full scope of its project plans. Putting aside the amendment problem, if DRI claims it does not intend to offer x-ray, CT services, and procedure rooms in the proposed DRI Diagnostic Center, any DRI Diagnostic Center approval by the CON Section would need to include a condition to that effect. As is commonly done, the CON Section would impose a condition stating: *"DRI 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."*

Kelli Collins, DRI COO and State Health Coordinating Council member, would have to accept that condition, effectively certifying that her intent is to develop an otherwise empty 11,000 square foot diagnostic center with only an MRI machine and no other equipment such as an x-ray and a CT scanner. In that instance, under the CON Law, without another CON, DRI would be prohibited from acquiring x-ray equipment or CT equipment for the proposed DRI Diagnostic Center for one year after project development. See 131E-176's definition of "new institutional health service" which includes include a "change in a project that was subject to [CON] review and for which a [CON] was issued, if the change is proposed during the development of the project or within one year after the project was completed." N.C. Gen. Stat. § 131E-176.

DRI may say it is willing to accept such a condition and will outfit its proposed DRI diagnostic center solely with an MRI, but nevertheless admit that it aspires to add multiple capabilities such as a CT scanner at an unspecified future point. This is no solution to DRI's problems because, under such a scenario, its CON application as submitted is either being impermissibly amended or is unable to demonstrate conformity with the Criteria.

DRI appears to propose to lease vacant space used as a Southern States feed store. Considering its prior use for a non-health purpose, one can fairly assume the vacant space has no existing capabilities such as areas upfitted for patient registration or patient waiting areas. While DRI accounted for costs associated with upfitting the area which will house the MRI scanner itself, it will have to incur costs to upfit more than just that 1,000 sq. ft. area in the vacant Southern States feed store to be able to offer the proposed MRI service. By contrast, SOS accounted for costs associated with upfitting the area within its medical office building that will house its proposed MRI scanner. But, unlike a vacant feed store, SOS is an already-operational medical office building with existing patient check-in areas, waiting rooms, proper restrooms, and the like. This is not the case with the vacant 11,000 sq. ft. Southern States feed store. Thus, the only logical conclusion is that DRI intends to upfit the entire 11,000 square foot of the now-vacant Southern States feed store and run the entire 11,000 square foot space as its new DRI Summerfield diagnostic center. DRI does not intend to go into the Southern States building and renovate only the back corner with a 1,000 square foot space for the MRI scanner. DRI surely doesn't plan to have patients walk through

an empty feed store back to the corner where its MRI will be located. For these reasons, DRI failed to account for the true renovation costs and the operational costs for an 11,000 square foot diagnostic center.

If DRI acknowledges that it does intend to develop an 11,000 square foot DRI Diagnostic Center including x-ray and CT services as well as multiple procedure rooms and other capabilities, its application must be denied because, as submitted, it completely fails to document the population's need for such services and completely omits any access projections, quality data or financial projections associated with its full project scope. Among other omissions, DRI did not address 10A NCAC 14C .2303.

Equipment such as a CT scanner may be acquired without a CON but if a CT scanner is part of an otherwise reviewable project proposal, the need demonstrations and financial showings associated with the CT scanner must be included in that CON application. Procedure rooms are not independently CON-regulated but if proposed, the applicant is expected to discuss the need for the procedure rooms and otherwise show how its project, including procedure rooms, satisfies the Criteria. For instance, when Novant Health proposed a Freestanding Emergency Department in Mountain Island Lake, it chose to propose a fixed CT scanner as part of its project. Novant Health was required to show the need for the CT and include the CT in its financial projections. In diagnostic center reviews, the CON Section expects the applicants to detail all proposed equipment offerings and address need and financial feasibility for the project as proposed. If approved, applicants are routinely limited to acquiring the equipment identified in their CON applications.

DRI will be unable to add units of equipment to its diagnostic center without the need for a subsequent CON Review. For example, in 2020, Duke University Health System, Inc. (DUHS) was required to file a CON application to propose a change of scope to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment. The DUHS CON application was required to present detailed information to identify its proposed patient origin, demonstrate the need of the population to be served for the equipment it proposed, and otherwise show its conformity with all applicable Criteria.

Similarly, Private Diagnostic Clinic, PLLC (PDC) was required to file a CON application to propose a change of scope to a previously approved project, Project I.D. # J-11616-18 (develop a new diagnostic center) to add three additional units of equipment. Specifically, the PDC application addressed a proposal to acquire and locate new equipment at its diagnostic center, Duke Health Holly Springs (DHHS).

These and other examples show clearly that an applicant cannot simply secure CON approval for a diagnostic center and then subsequently add various pieces of equipment to that center without CON review – instead, DRI will have to participate in an entirely new CON review before it can secure the necessary approvals to develop the new imaging center shown in the Architect's drawings submitted in this batch review. Subsequent application(s) will take time to prepare and will be subject to CON review as a change of scope to a previously approved project. The ability to demonstrate need and otherwise satisfy the necessary showings in subsequent change of scope review(s) is far from a foregone conclusion. Approving DRI in this Review would delay patient access to needed MRI services while DRI pursues change of scope approval(s) that could be denied.

DRI's application as submitted cannot be approved. It is either construed as a proposal to renovate just enough space in the back corner of an empty feed store to install an MRI scanner, in which case it is an illogical proposal that does not demonstrate a feasible plan to offer access, quality and value to the residents of Guilford County and surrounding areas. Or it is acknowledged to incorporate a much larger diagnostic center facility plan with multiple capabilities. In that instance, because the application is silent on need for or financial feasibility of those other project components, it simply cannot be approved as submitted.

Failure to Identify Site for Proposed Project

There are multiple issues with the DRI application as it relates to its proposed site:

- DRI identifies its site as 6191 Lake Brandt Road; however, there does not appear to be any building located at that address;
- DRI possibly mis-stated the address of the site and intends instead for its diagnostic center to occupy the 11,000 square foot Southern States building, 6199 Lake Brandt Road;
- The 2007 Engineer drawings appear to identify Hillside Village LLC (Member/Manager: John Stratton of Greensboro) as the owner of the Southern States building, but this entity does not appear to own any sites in Guilford County;
- Per the Secretary of State, Hillside Village LLC was administratively dissolved;
- DRI identifies William Penn Properties LLC as the owner of the site, but that entity does not own any sites on Lake Brandt Road in Guilford County;
- DRI attempts to document its ability to lease the Southern States building via a letter from DPC Commercial Development;
- DPC Commercial Development is not the owner of the Southern States building.

It is possible the site address identified in the DRI application may be vacant land. If so, the representations in the application are not reasonable and adequately supported. In years past, the CON Section conducted site visits. It is questionable whether a site visit can be safely performed during COVID-19. Absent a site visit, there may be a need to investigate public sources on the site proposed by DRI.

DRI indicates the project does not involve the construction of "new space", but rather the renovation of "existing space." On page 11 of the application, DRI responds to the application question for a "new or replacement facility or campus to be developed on a new site." The Applicant identifies 6191 Lake Brandt Road, Summerfield, NC 27455 as the site address.

On page 83, DRI represents its project as "the planned upfit of vacant shell space." On that same page, the applicant claims the project involving "upfitting existing facility shell space" will be cost effective because "the space has no major support walls or building columns that must be removed or modified." On page 85, the application again identifies the proposed site as "6191 Lake Brandt Road (State Road

2347).” It appears Lake Brandt Road and State Road 2347 are one and the same. On page 88, the applicant states its project “will be developed **in an existing building** that already is served by municipal water and sewer, and with power provided by Duke Energy.”

DRI made numerous representations about an existing building at **6191** Lake Brandt Road. Yet, a search on Google Maps shows Lake Brandt Road as of April 2019, and the street view does not show any building situated on Lake Brandt Road corresponding with an address of **6191** Lake Brandt Road. The Guilford County Property Appraiser’s web site indicates addresses on Lake Brandt Road within the range from 6105 to 6696. However, the site does not identify any property with an address of 6191 Lake Brandt Road in Summerfield nor any property with the address 6191 State Road 2347.

The only capital costs identified relative to the building which will house the proposed DRI fixed MRI are for construction/renovation and architect fees based on the applicant’s assumption it will only be incurring “upfit” costs for improvements to an existing building (page 18). If there is no building at **6191** Lake Brandt Road, the application failed to account for all necessary project costs.

Although DRI repeatedly references **6191** Lake Brandt Road as its proposed site throughout the application and exhibits, DRI’s plan instead appears to be to lease the Southern States building which is **6199** Lake Brandt Road. In Exhibit K. 2, DRI attaches drawings prepared in 2007 by Queen Engineering & Design, P.A. which purport to show that DRI intends to develop its imaging center in the building which, up until July 2020, was operated as the Southern States garden/feed/agricultural store. “Southern States agricultural cooperative at 6199 Lake Brandt Road is closing. July 17 [2020] is the last day for the store. A spokesperson for the company said the location is “not generating the profit necessary to sustain the business and that location.” “As a retailer it’s always hard to close stores — it’s the last thing you want to do,” Steve Patterson, senior vice-president for marketing, said in a statement. The store employs three full-time people and 13 part-time workers. They will be given the opportunity to apply for positions at other locations.” https://greensboro.com/blogs/retail_therapy/agricultural-coop-in-summerfield-is-closing/article_576286fd-b941-54e5-9e98-e4f43bb4db8e.html

Although it appears the address for the Southern States location is **6199** Lake Brandt Road, not **6191** Lake Brandt Road, the Engineer’s drawing is clearly labeled “Southern States” and shows the Southern States building as well as its outdoor display and garden center spaces.

Nonconformity Due To Site Issues

The DRI application fails to show conformity with multiple Criteria because it does not adequately demonstrate site availability. In fact, the DRI application leaves the reader guessing as to which of the multiple entities might own the site DRI proposes to use. Without valid documentation of a site, the DRI projections for operations (revenue) and cost (expenses) are not adequately supported and thus, not reasonable.

The Engineer plans appear to show Hillsdale Village, LLC as the owner of the Southern States building. Yet, per the Guilford County Property Appraiser’s site, Hillsdale Village, LLC does not own the proposed site or any property on Lake Brandt Road. In fact, the Secretary of State’s office lists Hillside Village, LLC as administratively dissolved. On page 12 of its application, DRI identifies “William Penn Properties LLC”

as the owner of the building. A search on the Guilford County Property Appraiser's site shows William Penn Properties LLC owns only two properties in Guilford County, one at 1007 NC Highway 150W and one at 1603 Battleground Avenue.

At page 86 of the application, the first part of question K.4.(b) asks the application to "Identify the legal entity that currently holds fee simple title to the proposed site (this is usually available on the county's website)." In response to K.4(b), DRI does not identify the legal entity that holds fee simple title to the proposed site. Based on the Guilford County Property Appraiser's website, the owner is not William Penn Properties. The second part of question K.4.(b) states that if the applicant is not the current owner in fee simple, the applicant is to provide documentation that the site is available for acquisition by purchase, lease, donation or other comparable arrangement. In response, DRI directs the Analyst to Exhibit K.4 for "documentation regarding the availability to lease the site." In Exhibit K.4, DRI does not provide a letter from William Penn Properties, the legal entity identified on page 12 as the "owner of the building." Instead, the applicant provides a letter from the Manager of "DPC Commercial Development" with no indication of the company's address or other information.

A search on the Guilford County Property Appraiser's website indicates there are no properties in Guilford County owned by DPC Commercial Development nor by any entity with a name beginning with "DPC." DPC Commercial Development, LLC is a North Carolina limited liability company with a principal office in Winston-Salem per the NC Secretary of State's website but, based on publicly available data, it is **not** the legal entity that holds title to the proposed site (nor to any site within Guilford County). Inasmuch as publicly available data confirms DPC does **not** own 6191 or 6199 Lake Brandt Road, DPC cannot furnish the necessary documentation of a site available for lease. DPC does not identify itself as a realtor, nor does it indicate it is authorized to act for or on behalf of the property owner (whoever that might be).

DRI may suggest William Penn Properties owns the land and DPC Commercial Development owns the building. However, there are multiple problems with this scenario. First, the applicant stated William Penn Properties was "the owner of the building" and it cannot amend its application at this point in the Review. Second, William Penn Properties is not, according to public sources, the owner of the land. Next, if DPC Commercial Development is the owner of the building but not the land, DRI failed to identify this in response to any applicable question and failed to provide an address for DPC Commercial Development. Again, DRI cannot amend its application at this time.

The "documentation" at Exhibit K.4 is problematic because it is a letter from an entity that does not own the site, thus, it is unable to document its availability. Moreover, the letter states DPC Commercial Development anticipates a "commencement date [presumably for the lease] of November 1, 2020." Obviously, that date is a date in the past and not the date upon which DRI proposes to take occupancy of the premises. Per the DRI Project Timetable, DRI proposes to occupy the building as of December 1, 2021, nearly eleven months after DPC Commercial Development's understanding of the lease commencement date. With such a wide gap between the plans of DRI and the understanding of DPC, the letter does not provide reasonable documentation that DPC agrees to make this site available to DRI (putting aside for a moment that DPC does not own or control the site).

DRI may claim site is not important because an applicant can change its site. While the Agency permits site changes, the identification of an available site is part of a CON application. Here, the applicant

identifies no alternate site. Without the ability to lease space in an existing building, one of the fundamental premises of the DRI proposal is undermined. Much of the DRI application speaks about the need to locate in Summerfield and the cost-efficiencies of renovating existing space. The DRI need methodology is premised on a “shift” of MRI cases based on the proposed location of the DRI center in Summerfield. Without documentation from a true owner or owner’s representative, there is nothing to show DRI can develop this diagnostic center in this part of the County or at the cost it projects. Consequently, the DRI application fails to conform to Criteria 1, 4, 5, 12, and 18a.

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

POLICY GEN-3: BASIC PRINCIPLES 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.”

DRI fails to conform with Criterion 1 and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding Criteria 3, 4, 5, 6, 7, 8, 18a, and 20. Therefore, the application is nonconforming to this criterion and cannot be approved.

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

Population to be Served by the Proposed DRI Project

DRI’s patient origin projections are not reasonable and adequately supported because, as explained below, those projections do not align with the assumptions in DRI’s need methodology.

On page 23, DRI states that 56.5% of its patients will originate from Guilford County and 39.2% of patients will originate from Rockingham County during Project Year 1. Approximately 90% of DRI's MRI procedures are forecasted to come from a shift of patients from various zip codes, with the remainder identified as "market share gain." The patients expected to shift to the proposed DRI Summerfield MRI scanner are identified by zip code on page 114 of the application. If the numbers were reasonable and supported, one would expect the patient origin projections to align with the zip code assumptions used to project utilization. However, of the zip codes listed, only three are Guilford County zip codes and the rest are Rockingham County zip codes. The procedures shifting from Guilford County are only about 44.6% of the total shifted cases (Project Year 1: Guilford County zip codes 27214, 27310, 27455: $275 + 127 + 744 = 1,146$ of 2,570 procedures shifting = 44.6%). Based on the zip code projections identified on page 114, 55.4% of the shifted cases are patients residing in Rockingham County zip codes.

Even if 100% of the 286 "market share gain" in Year One were Guilford County residents, DRI would serve $1,146 + 286 = 1,432$ which is only about 50% of the total of 2,857 MRI procedures in Project Year 1. It is unlikely that the market share gain would be entirely from Guilford County. Thus, the analysis by DRI makes it nearly impossible to accept as reasonable and supported DRI's page 23 projection that 56.5% of its Year One patients will be from Guilford County.

The same is true in Years 2 and 3. Of the procedures shifting from W. Wendover Avenue to Summerfield, only about 44.6% are coming from Guilford County zip codes [(Project Year 2: Guilford County zip codes 27214, 27310, 27455: $330 + 152 + 893 = 1,375$ of 3,083 procedures shifting = 44.6%); (Project Year 3: Guilford County zip codes 27214, 27310, 27455: $389 + 180 + 1,052 = 1,621$ of 3,633 procedures shifting = 44.6%)]. Yet on page 23 of its application, DRI projected 56.8% and 57% of its total patients would come from Guilford County in years 2 and 3.

In Year 3, if 1,621 patients shift from Guilford County and even if 100% of the "market share gain" patients are Guilford County patients, it is impossible for DRI to provide 57% of its scans to Guilford County residents ($1,621 + 586 = 2,207$ of 4,219 = 52.3%). Again, it is unreasonable to assume all the market share gain will come from service to Guilford County residents because DRI projects approximately 5% of patients will originate from areas beyond Guilford and Rockingham counties during Project Year 3. Even using such an assumption, DRI cannot correlate its need methodology assumptions with its patient origin projections.

On page 23, DRI projected approximately 5% of its MRI procedures will be provided to patients that reside neither in Guilford nor in Rockingham Counties during Project Year 3. It is impossible to mathematically "fit" all the patients that would come from Rockingham County per the DRI zip code analysis, together with the DRI-projected patients from other Counties/out of state, and still achieve the Guilford County patient origin projected on page 23. If DRI serves the projected volume of patients from Rockingham County and elsewhere based on the Form C assumptions and methodology for projecting DRI MRI utilization, it will be serving a much lower percentage of Guilford County residents than it represents on page 23.

The above analysis should support a finding that DRI has failed to demonstrate conformity with the prong of Criterion 3 that requires identification of the population to be served. It is not possible to reconcile the DRI need methodology with the DRI patient origin projections. The DRI Application, as submitted, does not identify the population to be served using reasonable and adequately supported assumptions because

of the inconsistencies between its patient origin percentages and the assumptions used to support its utilization projections.

Assumptions & Methodology for Projecting DRI MRI Procedures

DRI does not adequately demonstrate that projected utilization is reasonable and adequately supported. The DRI utilization methodology and assumptions are quite erratic and internally inconsistent. According to DRI, there is data to support MRI procedure growth of anywhere from 0.87% to 7.93%, depending on what numbers and time periods are selected for comparison. DRI uses calendar year data instead of SMFP data despite very little variance between the two; DRI uses one time period to identify a nearly eight percent compound annual growth rate in DRI MRI procedures (7.93%); then DRI uses a different time period to show a 5.39% Guilford County growth rate; then DRI relies on a growth rate of 3.96% to project gains and assigns a portion of those gains to its proposed Summerfield MRI. Then DRI shifts MRI procedures from DRI at W. Wendover Avenue to DRI at Summerfield because an unspecified number of DRI patients would be closer or more conveniently served at Summerfield. To achieve the forecasted utilization, far more patients would have to come to the proposed MRI at Summerfield from outside Guilford County than projected in the patient origin projections.

After asserting that DRI has experienced nearly eight percent growth and Guilford County has experienced over five percent growth and after basing its market share gains on nearly four percent growth, DRI reports that growth in MRI volumes on the four MRI scanners at Cone Health has been under one percent. In projecting a “shift” to its proposed Summerfield MRI, DRI appears to employ the assumption that patients will choose to utilize an MRI scanner closer to their residences. Yet, when projecting utilization for the Cone Health MRI scanners at Cone Memorial Hospital and Wesley Long, DRI does not appear to incorporate any assumption that a percentage of Rockingham County patients will no longer access the MRI scanners at the Cone locations after an ostensibly lower cost and more convenient location exists at Summerfield. DRI was certainly aware that even a small decline in Cone volumes could be material in this Review; thus, it purposely excluded any shift of volumes from Cone facilities despite the benefits it could afford for MRI patients.

Step 2 of DRI’s methodology includes assumptions about DRI Summerfield’s projected MRI market share based on the projected number of MRI procedures in Guilford County. DRI projects Guilford County MRI procedures based on its calculated average Guilford County MRI use rate for the last five years (102.6).⁵ It is critical to note the Guilford County MRI use rate reflects the number of MRI procedures performed in Guilford County regardless of the patients’ county of origin. Indeed, DRI acknowledges the Guilford County MRI use rate is higher compared to the statewide MRI use rate because it is fueled by patient migration from other NC counties. On page 28 of its application DRI states, “As shown on the DHSR MRI Services Patient Origin report (by county of service location) in Exhibit C.4, thousands of residents of other North Carolina counties travel to Guilford County to receive MR imaging.”

While SOS does not dispute the fact that many patients of other counties travel to Guilford County to receive healthcare, including MRI services, DRI’s use of a Guilford County MRI procedure rate calculated

⁵ DRI application, page 110

from MRI procedures by county of service location results in a use rate that is representative of a much broader population than DRI projects to serve. This is an important distinction because DRI projects 95.7 percent of its MRI patient origin will be comprised of Guilford and Rockingham County patients.⁶ The DHSR MRI Services Patient Origin Report: Patients County of Residence provides relevant data regarding the use of MRI services by Guilford and Rockingham County residents. The following table calculates the Guilford and Rockingham County MRI use rates based on MRI procedures performed on residents of the respective counties.

County	Year	County Population	MRI Scans Performed on County Residents	County MRI Procedure Rate
Guilford	2019	539,666	34,175	63.33
Rockingham	2019	91,788	7,067	76.99

Source: 2020 DHSR MRI Services Patient Origin Report: Patients County of Residence (2019 Data)

As shown in the previous table, the MRI procedure rates for Guilford and Rockingham County residents, respectively, are much lower than the DRI calculated use rate of 102.6. Therefore, DRI's calculated use rate results in grossly overstated MRI procedure projections for the population it projects to serve. The use rate relied on by DRI is not consistent with the applicant's projected patient origin. Consequently, DRI failed to present reasonable and supported utilization projections and failed to adequately identify the population to be served by the proposed fixed MRI scanner in Summerfield.

DRI's reliance on an overstated use rate in its methodology calls into question its conformity with the required Performance Standard, 10A N.C.A.C. 14C.2703. The minimum total number of weighted MRI procedures DRI must project to perform in the third year of operation on the proposed Summerfield fixed MRI scanner is 4,805 weighted MRI procedures. DRI projects its proposed Summerfield fixed MRI scanner will perform 4,887 weighted MRI procedures during the third year of the proposed project. That is only 82 weighted MRI scans [or 59 outpatient scans with contrast [59 x 1.4 = 82.6 weighted MRI scans] more than the minimum necessary to comply with this rule. Said differently, if the applicant's proposed fixed MRI scanner performed, in total, just 59 less outpatient scans with contrast, the applicant would not conform to this Rule.

In DRI's third project year, it projects a total of 58,607 Guilford County MRI procedures.⁷ This projection is derived by applying a 102.6 use rate to a Guilford County population figure of 571,218. If DRI had used the Rockingham County use rate of 76.99 (instead of the inflated 102.6 use rate relied on by DRI), the total of Guilford County MRI procedures would be only 43,978, not 58,607. Assuming the Summerfield MRI captures 1% of those procedures in 2024 (DRI App., p. 111), in this step of its methodology, it would project 439 scans, instead of 586 scans, a difference of 147 scans. If DRI's proposed fixed MRI scanner

⁶ DRI application, page 23

⁷ DRI application, page 111

performs, in total, 147 fewer scans, it fails to demonstrate conformity with the Performance Standard, a fatal flaw.

As noted above, DRI projects its proposed Summerfield MRI will capture a percentage each year of the overstated MRI scans projected for Guilford County. These new market share increases for the Summerfield MRI are not reasonable or adequately supported. To achieve DRI’s projected market share increases, the proposed Summerfield MRI would have to capture a significant and rapidly increasing percentage of the overall growth in Guilford MRI procedure volume each year. For example, DRI projects Guilford County MRI procedures will grow from 56,593 in 2021 to 57,239 in 2022, an increase of 646 MRI procedures performed in the County. Of those, DRI expects its Summerfield MRI will capture 286 scans, or approximately **44.3%** of the total MRI growth in Guilford County. The growth in overall Guilford County MRI procedures, as projected by DRI between 2022 and 2023 is 672 scans. Of those, DRI expects its Summerfield MRI will capture 434 MRI procedures, which equates with approximately **64.6%** of the total MRI growth in Guilford County. Between 2023 and 2024, DRI expects overall growth of 696 scans and projects its proposed Summerfield MRI will capture 586 or approximately **84.2%** of the total MRI growth in Guilford County. Please see the following table.

	2021	2022	2023	2024
Guilford County MRI Procedures	56,593	57,239	57,911	58,607
DRI Projection of Organic MRI Procedure Growth		646	672	696
DRI Summerfield Market Share Projections		286	434	586
DRI Summerfield % of Organic MRI Procedure Growth		44.3%	64.6%	84.2%

DRI’s projections fail to consider the numerous MRI scanners in operation in Guilford County, all of which will be vying for a percentage of the overall growth in MRI procedure volume each year. If the proposed DRI Summerfield MRI were to achieve these aggressive totals, it would relegate all existing MRI providers to dividing up a fraction of the minimal remaining growth in MRI procedures.

To project more volume for its proposed Summerfield MRI, Step 3 of DRI’s methodology presents a zip code map and suggests it will shift certain percentages of the overall DRI MRI procedure volume from each zip code to its proposed Summerfield MRI. The DRI zip code projections in the table on page 114 are completely unsupported by any data or even a data source. The MRI procedures by zip code presumably come from some internal DRI data as the patient origin data is reported to the State by County, not by zip code. Nowhere in the DRI application is the zip code data source footnoted and no tables or charts are provided regarding the actual historical number of DRI MRI procedures performed on patients from each zip code.

DRI states “some DRI MRI patients will shift.” DRI states it anticipates a “shift in this utilization pattern of DRI MRI patients.” From this narrative, one might speculate that the shift is exclusively to be from DRI but, again, this is less than clear. At no point does DRI identify, by number, the historical DRI patients served from each of the eleven zip codes used in its methodology.

When DRI assumes a 65% shift in Year One, it is entirely uncertain whether that is reflective of precisely 65% shifting from each individual zip code or whether a higher percentage are expected to come from some zip codes with a lower percentage coming from other zip codes. Looking at the map on page 113, the Project Analyst may validly question whether it would be reasonable to shift 65% from each of the eleven zip codes in the first year, but the Analyst has no way to know whether that was DRI's assumption or whether DRI was assuming more of a shift from closer zip codes and less of a shift from more distant zip codes.

The only "data" that can be found on this topic is a color-coded map labeled "CY2019 DRI MRI Patient Origin by Zip Code." The map does not provide data points but only shading to show ranges such as 200 to 1,000 by zip code. Again, this presentation makes it impossible for the Analyst to conclude that DRI's projections are reasonable and adequately supported. For example, DRI projects its proposed Summerfield MRI will attract 453 patients from zip code 27320 in its first year. The shading on the CY2019 map seems to show this large zip code in the medium color-tone which correlates with historical service of 200 to 1,000 scans in CY 2019. At the risk of stating the obvious, whether the projection to "shift" 453 patients in the initial year is or is not reasonable will depend in large part on how many patients from that zip code DRI historically served – obviously, if the number is closer to 200 than to 1,000, it would be much more difficult to conclude that the projection by DRI is within the range of reasonable.

Based on the maps as presented, it appears that the residences of any number of patients residing in zip code 27455 would likely be as close to Wendover Avenue as to the proposed Summerfield MRI. Yet, DRI projects to shift 744 of these patients to DRI Summerfield in the first year. Again, the shading on the CY2019 map only informs the reader that DRI historically served between 1,001 and 1,624 patients from that zip code. Obviously, if the total from that zip code were closer to 1,001 than to 1,624, it may appear highly unreasonable to project that 744 patients from that zip code would shift to a new location.

The notion of dramatic patient shifts within Guilford and Rockingham Counties is questionable considering many adult patients likely work in Greensboro such that an MRI scanner located near their offices or workplaces would be much more convenient than an MRI located out in sparsely populated Summerfield. Even patients not working in Greensboro are likely to commonly travel to Greensboro for school, shopping, entertainment and medical care such that a Greensboro MRI would represent a more convenient option than a scanner out in the thinly populated area of Summerfield. DRI provides no information on the extent to which area residents regularly use Greensboro resources. Its "shift" projections are not based on reasonable and adequately supported assumptions.

For these reasons, the DRI failed to furnish sufficient information in its application, as submitted, to allow the Project Analyst to conclude that its projections are reasonable and adequately supported.

Access

DRI states on page 19 of its application "that by the third project year the MRI scanner will be available for at least 60 hours per week." However, this is inconsistent with 10A NCAC 14C .2701(2) which states, "Annual capacity of a fixed MRI scanner is 6,864 weighted MRI procedures, which assumes two weighted MRI procedures are performed per hour and the scanner is operated 66 hours per week, 52 weeks per

year (emphasis added).” On page 46 of its application, DRI indicates it acknowledges the applicable definition. Thus, it is curious why DRI proposes to offer fixed MRI services with limited hours per week that fall below the regulatory expectations for fixed MRI services. SOS will operate its proposed scanner 82 hours per week. Therefore, the SOS proposal is far superior to the DRI proposal in terms of patient access.

DRI touts itself as a value-based provider and emphasizes the need to improve accessibility to value-based care.⁸ Using Blue Cross Blue Shield’s Treatment Cost Estimator, SOS compared the average treatment cost of MRI procedures at SOS to the average cost of MRI procedures at other area providers.

Blue Cross Blue Shield Treatment Cost Estimator: MRI Procedures

Provider	MRI Spine	MRI Spine w/o Contrast	MRI Lower Limb	MRI Upper Limb
Southeastern Orthopaedic Specialists, P.A.	\$737	\$737	\$718	\$712
Novant Health Imaging Triad	\$817	\$817	\$933	Cost Not Provided
EmergeOrtho	\$827	\$826	\$807	\$807
Diagnostic Rad & Imaging	\$981	\$855	\$958	\$989
Carolina Neurosurgery & Spine Assoc	\$1,040	\$927	Cost Not Provided	Cost Not Provided
Cornerstone	\$1,048	\$1,049	\$1,165	\$1,410
Wake Forest Baptist Imaging	\$1,195	\$845	\$959	Cost Not Provided
Guilford Neuro Assoc.	\$1,269	\$1,062	Cost Not Provided	Cost Not Provided
High Point Regional Hospital	\$3,023	\$2,618	\$1,596	Cost Not Provided
Cone Health	\$3,756	Cost Not Provided	Cost Not Provided	Cost Not Provided

Source: Blue Cross Blue Shield Treatment Cost Estimator

Based on data from Blue Cross Blue Shield’s Treatment Cost Estimator, SOS is the community’s lowest cost MRI provider for these common MRI procedures. By eliminating mobile MRI service and installing a fixed MRI scanner, SOS will be positioned to improve on its demonstrated commitment to patient access to cost-effective MRI services. DRI is a higher cost MRI provider compared to SOS, Novant Health Imaging Triad, and EmergeOrtho. Therefore, to the extent DRI asserts Guilford County needs access to value-based care, SOS is the most effective alternative in this competitive batch review.

⁸ DRI application, page 38

The DRI application states “the Summerfield location is near a growing medical community that offers primary and specialty care clinics.”⁹ Apart from this statement, the DRI application provides zero information or documentation to support this statement.

Criterion 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.”

DRI is nonconforming with at least the following statutory review criteria: Criteria 1, 3, 5, 6, 7, 8, 18a, and 20. See these Criteria for discussion. Therefore, DRI failed to adequately demonstrate that its proposal is an effective alternative for development of a fixed MRI scanner in Guilford County. Consequently, the DRI application is nonconforming to Criterion 4.

In its discussion of alternative methods, DRI acknowledges a mobile MRI scanner is not the most effective method of meeting the need Guilford County residents have for MRI services.¹⁰ DRI cites many of the limitations and deficiencies SOS currently faces with its mobile MRI service:

- *[P]atients with additional medical equipment, like pain pumps or simulators, are not able to utilize mobile MRI units due to space constraints.*
- *Claustrophobic and obese patients are also limited in their ability to utilize mobile MRI units.*
- *In addition, a mobile scanner necessitates patients having to move outside the building (when inclement weather could present challenges), tends to have more equipment downtime, and is relatively inefficient operationally compared to having a permanent fixed MRI scanner.*
- *In addition, mobile MRI scanner rentals are relatively expensive, which does not secure long-term access. Therefore, this is a more costly and less effective option.*

SOS agrees with these observations by DRI, all supportive of the approval of the SOS application. DRI’s statements inherently validate SOS’s need to replace its leased mobile MRI service with the proposed fixed MRI service.

⁹ DRI application page 32

¹⁰ DRI application, page 59

Criterion 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.”*

Availability of Funds

DRI’s application fails to demonstrate conformity with Criterion 5 because DRI failed to demonstrate the availability of all funds necessary for its project as proposed.

DRI indicates it will “fund the project capital costs and working capital requirements via financing from First Citizens Bank, including an equipment loan and an existing bank line of credit.”¹¹ According to the tables on pages 63 and 65 of the DRI Application, the total amount necessary to cover the capital costs and working capital requirements for DRI’s proposed project is \$1,283,401 (\$1,228,401 in capital costs and \$55,000 in working capital). DRI intends to cover \$558,568 of this amount with a line of credit with First Citizens Bank (\$503,568 toward capital costs and \$55,000 for necessary working capital demands). DRI acknowledges as much in the letter contained in Exhibit F.2 from Greensboro Imaging’s Director of Finance, which states “DRI will fund an estimated \$560,000 of capital and working capital costs through a \$2 million line of credit with First Citizens Bank.” As a percentage, DRI intends to rely on its line of credit for 43.5% of the total cost for implementing its project ($\$558,568 / \$1,283,401 = 43.5\%$). The other 56.5% of the necessary financing for capital costs will come from the conventional/equipment loan ($\$724,833 / \$1,283,401 = 56.5\%$).

DRI identifies two funding sources: 1) a “line of credit” ostensibly intended to cover 43.5% of the total cost of its project (\$503,568 of the capital costs and all \$55,000 of the working capital, for a total of \$558,568) and 2) a loan, intended to cover the remaining 56.5% of its project cost (\$724,833). As explained below, DRI’s reliance on the line of credit is misplaced because the documentation submitted in the DRI Application shows the line of credit is only available to cover certain categories of costs; moreover, nothing is provided to show the line of credit will be available when needed; and DRI does not state whether the funds available through the line of credit are or will be committed elsewhere. With that, there is no properly documented funding source for a significant portion of the funds needed by DRI for its project. Accordingly, DRI fails to demonstrate conformity with Criterion 5.

1. The bank letter DRI supplies specifies that the line of credit can be used for “application, consulting fees, and working capital requirements,” NOT capital costs.

In Exhibit F.2, DRI provides a letter from First Citizens Bank which indicates that DRI “ha[s] a significant line of credit in the amount of \$2,000,000.00 that [it] can use to cover the anticipated \$560,000.00 needed for [its] application, consulting fees, and working capital requirements associated with this Certificate of Need.” First Citizens Bank states DRI can use the line of credit for only three named categories of costs: application, consulting fees, and working capital requirements. It does not state that DRI can use its line of credit in its discretion for any type of capital expenditure.

¹¹ DRI application, page 62

It is entirely possible that DRI is only allowed to use its line of credit for day-to-day operating expenses. A line of credit is commonly understood to be a mechanism used by companies to access funds for working capital needs. Generally speaking, businesses do not use lines of credit to finance one-time asset purchases. For an asset purchase, lenders generally require extra documentation and security in the collateral. Thus, it is logical for First Citizens Bank to have taken care to note and recite in its letter the categories of costs that it understood DRI could use its line of credit to pay. In fact, DRI obviously determined that it did need to secure a separate conventional/equipment loan from First Citizens Bank to finance the purchase of the MRI rather than drawing on its \$2 million line of credit. If DRI could have used its line of credit for any purpose and its line of credit was sufficient to cover all its projected costs, there would be no explanation for the separate capital cost loan described in the DRI application. Rather, it is clear there is some restriction on the funds available through the line of credit, as First Citizens Bank excluded capital costs from the permissible uses mentioned in the letter it supplied to DRI. Alternatively, DRI could have attached information on its line of credit as an exhibit to its Application to show the terms and restrictions (as well as the applicable interest rate as discussed below). For whatever reason, DRI did not do so. The CON Section cannot assume that the documentation would show that DRI can use its line of credit for capital expenses when the only documentation provided to the CON Section by DRI is a bank letter that does not so state.

On its face, the letter from First Citizens Bank fails to authorize DRI to use any portion of the line of credit for **capital costs**. Rather, First Citizens' letter states DRI can use the line of credit specifically for the **application, consulting fees, and working capital**.

The rule of law in North Carolina is that it is permissible for an entity other than an applicant to provide funding to the CON applicant, but the entity providing the funding must commit the funds to the applicant, who must in turn commit those funds to the project:

[I]n cases where the project is to be funded other than by the applicants, the application must contain evidence of a commitment to provide the funds by the funding entity. We hold that without such a commitment, an applicant cannot adequately demonstrate availability of funds¹²

Because First Citizens Bank specifies that the line of credit can be used only for specific purposes, it does not suffice as the required commitment to provide funds for one of DRI's intended purposes for the line of credit: capital costs.

In *Retirement Villages*, one of the CON applicants, Beaver Properties—like DRI in this case—proposed to finance the capital costs for its project from two different funding sources. In Beaver Properties' CON application, Beaver Properties attempted to document the availability of funds for its project in part by including a letter from one of its funding sources, indicating it “would loan Beaver Properties any funds necessary for working capital during the first three years of operation.” But in assessing Beaver Property's conformity with Criterion 5, the Court of Appeals reasoned as follows:

¹² *Retirement Villages, Inc. v. N.C. Dep't of Hum. Res.*, 124 N.C. App. 495, 499, 477 S.E.2d 697, 699 (1996)

Although this letter may arguably show commitment to provide working capital during the first three years of operation, it does not commit [the funding entity] to expend any money for the capital expenses necessary to implement the project. Therefore, we hold that the Agency erred in finding that Beaver Properties satisfied criterion 5.¹³

Applying the Court’s holding from *Retirement Villages* to the facts in the DRI application, although the First Citizen’s letter may show funds for “working capital” needs, it does not show a commitment of money for “capital expenses.” First Citizens has not committed to allowing DRI to access the \$2 million line of credit to pay for capital costs. Because First Citizens Bank specified that DRI could use its \$2 million line of credit for “application, consulting fees, and working capital requirements,” and not capital costs, DRI failed to demonstrate the availability of funds for the full capital needs of the project.

Form F.1a Capital Cost shows the various categories of capital costs for which DRI must show available funds. The First Citizens Bank letter in Exhibit F.2 addresses the availability of the line of credit funds for the application and the consulting fee (identified on Form F.1a as \$48,000). The letter also speaks to line of credit funds being available for working capital requirements, which are identified in the DRI application as \$55,000. Separately, DRI documents a loan for \$724,833 for the MRI. With that, DRI has not identified a funding source for the following capital cost needs of its project:

Capital Cost	Amount Unaccounted For
Construction/Renovation Contracts	\$340,765
Architect/Engineering Fees	\$48,912
Furniture	\$5,000
Financing Costs	\$2,500
Interest during Construction	\$4,423
Other (IT, contingency)	\$53,968
TOTAL	\$455,568

Source: Form F.1a Capital Cost, DRI Application

Criterion 5 requires documentation of availability of funds for all financial needs identified in a CON application, and DRI has not shown a funding source for all financial needs of its project. Consequently, DRI’s Application is nonconforming with Criterion 5.

¹³ *Id.*, 124 N.C. App. at 500, 477 S.E.2d at 700 (emphasis supplied).

2. DRI fails to document that approximately \$560,000 of the line of credit it seeks to use to implement its project is reasonably likely to be available when needed.

DRI is also nonconforming with Criterion 5 for another reason. Even if the reader presumes that DRI is not restricted from using the \$2 million line of credit for capital costs (which it is, see Item #1 above), DRI has failed to document that the nearly \$560,000 it intends to draw from the line of credit is reasonably likely to be available when needed and not otherwise committed elsewhere.

In *Johnston Health Care Ctr., L.L.C. v. N.C. Dep't of Human Res.*, 36 N.C. App. 307, 319, 524 S.E.2d 352, 360 (2000), the North Carolina Court of Appeals upheld the Agency's determination that Johnston Center failed to establish the availability and commitment of funds required under Criterion 5 when the applicant relied on a line of credit that would expire before the commencement of the proposed project. The Court held that this fact constituted substantial record evidence supporting the Agency's finding that Johnston Center's application failed to conform to Criterion 5.

Likewise, DRI fails to establish the availability and commitment of funds because nothing is provided to show that the line of credit will be in place when needed. A line of credit gives a borrower access to a certain sum on certain terms for a specified period. The letter from First Citizens Bank omits critical information including not only the interest rate and the expected repayment date but the date on which the line of credit expires. Nothing exists in the application as submitted to show that First Citizens knew DRI's proposed project timetable or when DRI expected to need access to the funds through the line of credit. DRI could have requested a new letter or attached documentation to its Application but did not do so.

Here, DRI has provided even less information about its line of credit than Johnston Health did in the above-referenced case. In Exhibit F.2, DRI provides a letter from First Citizens Bank indicating DRI "has [its] primary banking relationship with First Citizens Bank" and has "a significant line of credit in the amount of \$2,000,000.00 that [it] can use to cover the anticipated \$560,000.00 . . ." But nowhere in the letter or elsewhere in the DRI Application does DRI describe the extent to which it has utilized the line of credit, either at the time of application submission or historically. The reader is not told how long the line of credit has existed, whether the line of credit has been increased or reduced recently, or most importantly, the expiration date for the line of credit. Indeed, it is not possible for the reader to determine whether the line of credit will even be available to DRI if it were granted CON approval, as there is no indication of when the line of credit expires.

DRI is relying on its future ability to access more than a quarter of its available line of credit at a date in the future. Specifically, DRI will need to access \$558,568 of its \$2 million line of credit—or 27.9% of the total line—to finance this project. It appears DRI uses its \$2 million line of credit with First Citizens Bank to finance its day-to-day operations. It is possible, if not likely, that DRI requires a large percentage of its line of credit to finance other commitments; otherwise, it would not have sought credit in such an amount from First Citizens Bank. And, the line of credit is evidently not available or sufficient for DRI to cover both the capital costs for its proposed project and its other financial obligations, as DRI determined it needed to borrow nearly three-quarters of a million dollars from First Citizens Bank by way of a conventional/equipment loan to finance the MRI acquisition. In other words, DRI decided it could not cover all the capital costs for its proposed project with the \$2 million line of credit alone, despite the

projected capital costs being about \$1.2 million, some \$800,000 less than DRI could access via the line of credit.

The reader is left guessing as to how much of the \$2 million DRI is currently utilizing, what percentage of the \$2 million it has accessed at any given point in time, and what other specific financial commitments DRI addresses with its line of credit. Indeed, DRI intends to use the same line of credit to fund its Alamance County MRI CON project. In November 2020, DRI filed an application seeking CON approval for a \$1.89 million Burlington diagnostic center/MRI project (Project I.D. No. G-011999-20, DRI Burlington). That project was not mentioned in DRI's Guilford County application, nor did DRI provide anything to explain whether or to what extent it would be relying on funds from its line of credit for its Burlington project. Notably, one month after indicating it would use \$560,000 from its line of credit for its Guilford project, DRI indicated it would use another \$541,000 from that same line of credit for its Burlington project.

DRI describes the funds from the line of credit as "currently available" but DRI does not state that the funds are likely to be available "when needed" per its project timetable. With the subsequent filing of the Burlington application, it is obvious DRI will need to access more than half of the funds available through its line of credit to fund both the Guilford and Burlington projects. While it is theoretically possible that the line of credit will still be available to DRI when needed and will not be otherwise committed, there is absolutely nothing to document either of these possibilities. Just a month after stating in its Guilford application that it has a "significant" line of credit of \$2 million dollars, DRI promised to use over \$500,000 from that very same line of credit for a CON project in another County. In fact, neither the DRI letter nor the First Citizens Bank letter included in the DRI Guilford County application documents that the line of credit will be open for any particular time period. Neither one of the letters speaks to whether the line of credit dollars are or will be committed to other DRI financial needs between now and when the funds are needed. DRI's letter states its "intention to use the funds for the proposed CON project," but such is not the same as stating the funds will be available when needed and the funds are not and will not be committed to other DRI financial needs. By its November filing, DRI has shown its willingness to promise use of funds from its line of credit for other endeavors. With that, there is truly no assurance that funds in a sufficient amount will be available for the development of DRI's proposed diagnostic center and MRI in Guilford County.

As discussed elsewhere in this document, DRI's application reveals that it plans to lease 11,000 square feet of space (which will require renovation) and it plans to operate a diagnostic center housing procedure rooms, a recovery room, a CT scanner and x-ray equipment, in addition to the proposed MRI. Although the MRI service cannot be feasibly offered in an empty feed store without renovations to more than just the immediate area occupied by the MRI suite, DRI provides no accounting for the associated costs nor does it document the availability of funds for all of these necessary expenditures. Assuming the MRI area will itself require hundreds of thousands of dollars in renovation, the magnitude of the cost of renovating the entire 11,000 square foot building is likely to be quite significant, perhaps extending into the millions of dollars. Unless DRI intends to disclaim the Architect and Engineer drawings in its application (which would constitute an amendment), DRI has failed to document sufficient funds for its full project plans.

In short, DRI has failed to supply sufficient information in its application as submitted to indicate that nearly \$560,000 of its existing line of credit will be available for this project, or that the line of credit will

not expire before commencement of the project. As such, DRI has failed to adequately demonstrate the availability of funds for the capital and operating needs of its proposed project. DRI's Application is, therefore, nonconforming with Criterion 5. See *Johnston Health*, 36 N.C. App. at 319, 524 S.E.2d at 360.

3. DRI did not account for repayment of working capital nor for the interest expense associated with the amounts borrowed using its line of credit.

As stated previously, DRI has failed to demonstrate the availability of funds for the full capital needs of the project because (1) First Citizens Bank restricts the use of the funds only for the "application, consulting fees, and working capital requirements," and (2) DRI has otherwise failed to demonstrate that the approximately \$560,000 from the line of credit it seeks to use to implement its project is reasonably likely to be available when needed and not otherwise committed. Apart from those issues, DRI is nonconforming to Criterion 5 for yet another reason: It fails to account for repayment of \$55,000 in working capital funds and fails to account for interest expense for the full amount of the funds borrowed using its line of credit.

Curiously, while DRI references an equipment loan from First Citizens Bank in response to Question F.2(b) (Loans) in the application form, it does not reference its \$2 million bank line of credit in its response. Instead, DRI identifies the line of credit under Question F.2(c) (Accumulated Reserves or Owner's Equity). Apparently, DRI considers the line of credit to more closely resemble owner's equity/accumulated reserves than a conventional loan. But regardless of whether DRI classifies its line of credit as accumulated reserves/owner's equity or a conventional loan, DRI must repay all the funds it draws from its line of credit and First Citizens Bank will most assuredly require the payment of interest expense when DRI borrows over a half-million dollars using its line of credit. DRI has omitted the terms for repayment of working capital and completely overlooked the interest expense it must pay when it accesses \$560,000 through its credit line (assuming it could do so).

Unlike the \$724,833 conventional/equipment loan DRI anticipates using to finance the purchase of the MRI itself, DRI does not include an amortization schedule to illustrate how or when it will pay off the nearly \$560,000 in capital/working capital costs for which it will use its line of credit to pay. The reader is left guessing as to the repayment terms on the line of credit: What is the interest rate? At what intervals must DRI make repayment? It is impossible to determine without more information, which DRI cannot provide now because such would constitute an impermissible amendment.

In Form F.3 Operating Costs, DRI accounts for the interest expense associated with the \$724,833 loan. The interest expense is identified in an amortization schedule supplied in Exhibit F.2. DRI also accounts for depreciation of the equipment financed by this loan. But there is no line item for interest expense associated with the \$560,000 to be taken from the line of credit. Nor is there any clear indication (or any assumption) on Form F.1a Capital Cost, to show where DRI has accounted for repayment of the working capital proceeds from its line of credit. DRI provides no amortization schedule to show the interest expense associated with the borrowing through its credit line. A line item on Form F.1a labeled "Interest during Construction" is unexplained and nominal in amount. This line item would not appear to correlate with interest associated with the \$55,000 in working capital, most of which would be borrowed after the project is operational, not during construction. Without more, **DRI has not accounted for the repayment**

of working capital sums nor for the interest expense associated with the repayment of 43.5% of the funds necessary for it to undertake this project. With such a drastic omission, DRI's Application is nonconforming with Criterion 5.

Capital & Operating Needs

DRI's application fails to demonstrate conformity with Criterion 5 because DRI fails to show its projected costs are reasonable and adequately supported. The assumptions used by DRI in preparation of the pro forma financial statements are not reasonable and adequately supported because, as discussed elsewhere in these comments, its projected utilization is questionable.

Site Costs

DRI Exhibit K.3 includes what it is labeled "Upfit Cost Estimate." The Estimate states it is a budget for construction costs at "6191 Lake Brandt Road." Curiously, the Estimate identifies the owner as "Greensboro Imaging." According to the Guilford County Property Appraiser's website, no parcels in the County are owned by Greensboro Imaging or Greensboro Radiology (nor by any of the other entities mentioned in the DRI application; see discussion re: site).

Also, Exhibit K.3 is titled "Opinion of Cost" but there is no indication whatsoever of whose "opinion" is shown on the Exhibit. In other words, there is nothing in the Exhibit to explain whether a credentialed professional prepared the Cost Estimate. Exhibit K.3 is not a certified cost estimate nor is it even representing it was prepared by an architect, contractor, developer, engineer or other such professional.

DRI states its project "will be" planned by experienced architect and construction professionals. However, the applicant does not indicate professionals have had any involvement with the Exhibit K.3 cost estimate.

The application includes a "schematic floor plan" for its "Guilford County Imaging Center" of which the proposed new MRI scanner will be a part. Based on the drawing in the application, the planned Imaging Center will include, among other components:

- Two Procedure Rooms;
- A Recovery Room
- A CT Scanner;
- X-Ray Equipment; and
- An MRI.

The schematics appear to have been prepared by Boulder Associates Architects (Charlotte). Nothing else, including the Cost Estimate, gives any indication it was signed off on by Boulder or any other group. On the Cost Estimate, there is a reference to a "Landmark Budget 10/6/20." Nothing in the application explains who Landmark is, nor is there any description or specifics of any budget prepared by Landmark. That said, Landmark Builders recently completed a large renovation project on the ground floor of Moses Cone Hospital. Assuming the reference on the Cost Estimate is to the same Landmark entity and that

entity prepared a project Budget, it is curious it was omitted from the application. Even without a CON regulation requiring a certified cost estimate, there is still a requirement imposed by Criterion 5 that financial feasibility be premised on reasonable cost projections. A letter from an appropriate professional addressing cost is one way to show that a cost projection is reasonable and adequately supported. Here, DRI did not include such in its application or exhibits and, as such, it failed to demonstrate conformity with the applicable Criteria.

The most obvious reason why a full Budget or certified Cost Estimate is not included is because DRI proposes an 11,000 square foot total facility renovation with multiple health care capabilities and had it included a full scale Budget and Estimate, its plans would have been made all the more clear.

Exhibit K.4 is problematic in yet another respect. The letter states “lease details are discussed further pursuant to a separate Letter of Intent to be executed by both parties.” The problems are many: First, DPC is not a valid party to such a Letter of Intent because nothing documents it owns or controls the site, nor that it is authorized to act as a representative or agent of some other unnamed owner entity. Second, the lease details are important to the cost assumptions in the financial pro formas but appear to be omitted from the application. Third, the “Letter of Intent” which purportedly defines key cost terms is not provided in the DRI application. And finally, the “Letter of Intent” is described as a document “to be executed” meaning that, as of the date of the application, there was no sign-off or agreement to the key lease details. One cannot fairly provide a reasonable and supported projection of lease cost when the Landlord and Tenant have not reached agreement on the lease terms.

Operating Costs

Although its overall operating costs are higher, DRI does not appear to include a reasonable and adequately supported cost projection for its lease expense. DRI does not adequately explain the basis for its lease expense assumption.

SOS allocates almost \$81,000 in Year 3 for lease expense as compared to DRI which allocates approximately \$18,000 in Year 3. This wide gulf in the applicants’ rental expense projections immediately creates a question of the reasonableness of the lease expense assumption relied upon by DRI as both MRI scanners will be housed in Guilford County locations – one would not expect cost per square foot to vary so considerably within the borders of the same North Carolina County.

For its project, DRI only allocates approximately \$6,000 in utilities each year or about \$500 per month. DRI footnotes the expense as about \$6 per sq. ft. By contrast, SOS assumes about \$22,000 in utilities cost in each project year. Inasmuch as DRI will own and operate the entire 11,000 square foot diagnostic imaging center for which it seeks CON approval in this Review, it is unreasonable for DRI to assign just a fraction of overall costs to its proposed project by referencing the area of the building housing the MRI machine. Yet, the DRI lease and utilities cost projections (as well as other projections) appear to be based solely on the approximate 1,000 square feet in space DRI associates with its MRI. As discussed elsewhere, this assumption is highly unreasonable because it is non-sensical to presume DRI will incur no costs to upfit and operate the entryways, restrooms, patient registration and patient waiting spaces in the now-vacant Southern States feed store it envisions occupying to offer MRI services. SOS, on the other hand,

allocates cost using an estimate of fully 2,500 square feet of functional, existing office space and still manages to achieve a lower overall operating cost projection as compared to DRI.

Yet another questionable cost projection in the DRI Application is for “Property and Other Taxes (except income).” SOS projects slightly over \$9,000 each year while DRI includes less than \$600 each year. Not unlike the lease and utility projections, the costs projected by DRI look to be more analogous to costs associated with residential properties in Guilford County. While cost projections may differ if accounted for in different ways and any individual item of disparity may not be material standing alone, numerous cost projections in the DRI Application appear unreasonable and poorly explained.

For these reasons, the DRI application fails to provide reasonable and adequately supported assumptions for its financial and operational projections and, as a result, fails to demonstrate conformity with Criterion 5.

Criterion 6 *“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”*

DRI failed to adequately demonstrate the need for the proposed services (See Criterion 3). Therefore, DRI failed to adequately demonstrate that its proposal will not result in an unnecessary duplication of existing or approved MRI services and is nonconforming to this criterion.

Criterion 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.”*

DRI failed to address the necessary staffing expense associated with the services of a physicist. A qualified medical physicist/MR scientist is critical to safe operation and ACR accreditation. This omission has multiple consequences to DRI’s application. Specifically,

- DRI does not conform to Criterion 7 because it does not show evidence of adequate health manpower for the provision of the proposed services.
- DRI does not conform to Criterion 8 because it does not adequately demonstrate that it will provide or make arrangements for the necessary ancillary and support services, and that the proposed services will be coordinated with the existing health care system.
- DRI does not conform to Criterion 5 because its operating costs and resulting revenues are not based on adequate projections of MRI expenses.

Criterion 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.”*

DRI does not adequately demonstrate that it will provide or make arrangements for the necessary ancillary and support services, and that the proposed services will be coordinated with the existing health care system. As described previously, DRI failed to address the necessary staffing expense associated with the services of a physicist. A qualified medical physicist/MR scientist is critical to safe operation and ACR accreditation. Therefore, the application is not conforming to Criterion 8.

Criterion 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.”*

DRI does not adequately demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. As described previously, the DRI application does not adequately demonstrate site availability. See previous comments regarding “Failure to Identify Site for Proposed Project.” As explained throughout these comments, DRI does not present a reasonable alternative for offering MRI services because it does not explain or account for the 10,000 square feet in space which will require construction/renovation to allow DRI to offer the proposed MRI services in the back corner of the now-vacant Southern States feed store. DRI presents nothing on the costs and charges associated with the x-ray and CT services which are labeled on its Architect’s floor plan submitted in its application. Because only the immediate MRI area is addressed, the overall construction plans are not included and thus are not available for examination to allow the Analyst to determine whether the plans are reasonable, inclusive of energy saving features, etc.

Criterion 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.”*

Based on the facts which result in DRI being non-conforming with Criteria 1, 3, 5, 6, 7, and 8, DRI should also be found non-conforming with Criterion 18a.

Criterion 20 *“An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.”*

The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation recently proposed to develop a new off-site hospital-based outpatient campus for maternal-fetal medicine and outpatient rehabilitation (CON Project I.D. # G-11859-20/Cone Health Women’s Outpatient Center). In the Agency Findings dated April 24, 2020, the CON Section found that, according to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of the April 2020 decision, incidents related to quality of care occurred in all three of Cone’s facilities. These incidents were not revealed nor discussed in Section 0, Criterion (20), of the DRI application. Instead, the DRI application represents that Cone Health’s facilities operated in compliance with Medicare Conditions of Participation during the 18 months immediately preceding the submission of the DRI application.

The Cone Health Women’s Outpatient Center application provided sufficient information in its application as submitted to describe the quality-related incidents at Cone Health’s facilities such that the Agency could determine conformity to Criterion 20; however, DRI failed to provide any information regarding the previous Cone Health facility incidents or any subsequent incidents to demonstrate conformity to criterion 20.