

**Comments Submitted by**  
**Novant Health New Hanover Regional Medical Center, LLC**  
**Novant Health, Inc.**

**In Opposition to**

**Project ID # O-12370-23**  
**Wilmington Health, PLLC**

**And**

**Project ID # O-12374-23**  
**EmergeOrtho, P.A.**

**May 31, 2023**

**Comments Submitted by Novant Health New Hanover Regional Medical Center, LLC and Novant Health, Inc.**

Pursuant to N.C. Gen. Stat. § 131E-185, Novant Health New Hanover Regional Medical Center, LLC and Novant Health, Inc. (collectively, “NH New Hanover”) submit the following comments in opposition to the application filed by Wilmington Health, PLLC (“Wilmington Health”) to acquire one fixed MRI scanner and the application filed by EmergeOrtho, P.A. (“EmergeOrtho”) to acquire one fixed MRI scanner.

For the reasons stated in these Comments as well as any other reasons the Agency may discern, the Wilmington Health and EmergeOrtho applications are not approvable due to multiple non-conformities with review criteria and rules. The Wilmington Health and EmergeOrtho applications are also less effective alternatives in the comparative analysis. The NH New Hanover application is fully conforming and is also a more effective alternative. Accordingly, the NH New Hanover application should be approved, and the Wilmington Health and EmergeOrtho applications should be denied.

**Comments in Opposition to  
Project ID # O-12370-23  
Wilmington Health, PLLC**

**Application Specific Comments**

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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.”

Policy GEN-3, *2022 SMFP*, page 30, emphasis added.

Although Wilmington Health’s application conforms to the need determination, it is not consistent with all applicable policies in the SMFP, including Policy GEN-3. Therefore, the application does not conform with Criterion (1).

Wilmington Health’s proposed MRI scanner is limited in two key respects: 1) it will serve mostly patients of its own practice; and 2) it will serve outpatients only. This limitation translates into limited services to medically underserved patients. As the following table highlights, Wilmington Health proposes to serve a mere 67 Medicaid patients or 2.0 percent of Wilmington Health’s MRI patients in Year 3. By contrast, NH New Hanover’s proposal, which will serve both inpatients and outpatients regardless of referral source, projects Year 3 Medicaid patient volume of 1,234 patients or 12.5 percent of MRI patients.

	<b>Project Year 3</b>	
<b>Applicant</b>	<b>Medicaid Patients</b>	<b>% of Medicaid Patients</b>
NH New Hanover	1,234	12.5%
Wilmington Health	67	2.0%

Wilmington Health has not demonstrated equitable access to its fixed MRI service. In addition, for the reasons discussed below with respect to Criterion (3), Wilmington Health has failed to demonstrate the need for its proposal, and those same facts also make the application non-conforming with Criterion (1).

For these reasons, in addition to any other reasons the Agency may discern, Wilmington Health’s application is non-conforming with Criterion (1) and cannot be approved.

- (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.

**Patient Origin**

Wilmington Health fails to provide a reasonable and supported basis for its patient origin projections. In response to Section C.2.a., Wilmington Health provides the patient origin for the contracted scanner that formerly operated for part of 2022 at 8090 Market Street. Wilmington Health does not provide the historical patient origin for the fixed MRI scanner it operates at 1202 Medical Center Drive. As reflected in the following tables, the mobile MRI scanner patient origin is dramatically different from the proposed patient origin for the fixed MRI scanner.

**2022 Mobile MRI Scanner Historical Patient Origin at Proposed Location**

<b>Contracted Mobile MRI</b>	<b>Wilmington Health at Porters Neck – 8090 Market Street *</b>	
	<b>Last Full FY 01/01/2022 to 11/30/2022</b>	
<b>County or other geographic area such as ZIP code</b>	<b>Number of Patients</b>	<b>% of Total</b>
New Hanover	140	34.6%
Pender	138	34.3%
Onslow	80	19.7%
Brunswick	34	8.4%
Other^	12	2.9%
<b>Total</b>	<b>403</b>	<b>100.0%</b>

\* This should match the name provided in Section A, Question 4.

^ Other includes Columbus, Carteret, Wake, and Duplin counties, as well as other states.

Source: Wilmington Health CON Application, Page 36.

**Fixed MRI Scanner Patient Origin at Proposed Location**

MRI Services	Wilmington Health at Porters Neck – 8090 Market Street *					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
New Hanover	972	55.0%	1,377	55.0%	1,833	55.0%
Pender	493	27.9%	699	27.9%	930	27.9%
Onslow	225	12.8%	319	12.8%	425	12.8%
Other^	76	4.3%	108	4.3%	144	4.3%
<b>Total</b>	<b>1,766</b>	<b>100.0%</b>	<b>2,503</b>	<b>100.0%</b>	<b>3,332</b>	<b>100.0%</b>

\* This should match the name provided in Section A, Question 4.

\*\* Home health agencies should report the number of unduplicated clients.

^ Other includes Bladen, Brunswick, Carteret, Columbus, Duplin, Sampson, and Wake counties, as well as other states.

Source: Wilmington Health CON Application, Page 38.

Wilmington Health does not explain why an MRI scanner that operated at the exact location proposed in the application would have such a different patient origin from the proposed patient origin. Notably, in comparison to its mobile MRI scanner patient origin, Wilmington Health projects to serve a much higher percentage of New Hanover County residents at the same location. But with no way to assess the reasonableness of this projection, it appears Wilmington Health artificially increased its number of New Hanover County residents in an attempt to improve its chances in a competitive review, as the Agency’s comparative analysis usually considers the percentage of county residents proposed to be served. The other significant difference is the omission of Brunswick County from the projected patient origin. The Agency should not be misled by Wilmington Health’s failure to provide reasonable and supported projections.

Wilmington Health states that its projected patient origin is based on both the fixed and mobile MRI scanners, but then omits the historical patient origin for the existing fixed MRI scanner.<sup>1</sup> Without the patient origin information for the fixed scanner at Medical Center Drive, the Agency cannot evaluate the reasonableness of Wilmington Health’s statement. The Agency is also unable to evaluate the statement that “[i]t is reasonable to expect that more patients from counties to the north of New Hanover will choose the proposed Porters Neck scanner while more patients from counties to the south of New Hanover will choose the scanner in Wilmington.” Interestingly, when compared to the mobile scanner

<sup>1</sup> Wilmington Health CON Application, page 38.

that used to operate at Porter’s Neck, the projected patient origin shows a significant drop in patients from both Pender County and Onslow County, which are counties to the north of New Hanover. Wilmington Health also states that “the historical patient origin of the contracted mobile MRI is a factor utilized to project patient origin of the proposed fixed MRI, as detailed in Form C Assumptions and Methodology.” However, a thorough review of Form C Assumptions and Methodology results in no further description in the development of projected patient origin. It is therefore impossible for the Agency to assess the reasonableness of the applicant’s patient origin. The application should therefore be disapproved under Criterion (3).

**Demonstration of Need**

Wilmington Health emphasizes growth in Brunswick County, but as previously discussed, Brunswick County is not a named county for the applicant’s projected patient origin.

**Top Five Counties by Percentage Growth 2013-2023**

<i>County</i>	<i>2013</i>	<i>2023</i>	<i>Numerical Growth</i>	<i>Percent Growth</i>
Brunswick	112,685	157,537	44,852	39.8%
Johnston	177,960	242,959	64,999	36.5%
Currituck	24,177	32,208	8,031	33.2%
Cabarrus	188,675	240,512	51,837	27.5%
Pender	54,172	67,729	13,557	25.0%
<b>North Carolina</b>	<b>9,804,787</b>	<b>10,794,463</b>	<b>989,676</b>	<b>10.1%</b>

Source: NC OSBM, Exhibit C.4-1.

Source: Wilmington Health CON Application, Page 42.

In Wilmington Health’s projected patient origin, Brunswick is aggregated with the “Other” counties, which in total accounts for only 4.3% of the projected patient origin.<sup>2</sup> Thus, Brunswick County growth is not material to this project. Further, by omitting Brunswick County as a named county in its patient origin projections, Wilmington Health only draws more attention to the questionable patient origin it has projected. According to Wilmington Health, 8.4% of the patient origin for the contracted mobile MRI scanner originated from Brunswick County. But Brunswick County patient origin has essentially

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<sup>2</sup> Wilmington Health CON Application, page 38.

vanished from the patient origin for its proposed fixed MRI scanner. The applicant does not explain why this occurred.

Contrary to Wilmington Health's suggestion, there is no need for a "*freestanding* fixed MRI service" as distinguished from any other type of fixed MRI service.<sup>3</sup> The need determination is for one fixed MRI scanner in New Hanover County. As long as the scanner is located in New Hanover County, the SMFP is agnostic concerning whether the fixed MRI scanner is located in a freestanding facility or a hospital. Neither the SMFP nor the CON Law expresses a preference for one location over another, and Criterion (3) makes no distinction between freestanding sites and hospital sites. New Hanover County has two freestanding fixed MRI scanners now: one at Wilmington Health's facility on Medical Center Drive, and the other at EmergeOrtho.<sup>4</sup> Thus, competition already exists between the hospital and these freestanding sites. In addition, because the freestanding sites are owned by physician practices, the patients who would use these scanners are mainly patients of the physician practices; these scanners are not community-wide resources available to any patient, as is the case with NH New Hanover. As the NH New Hanover application demonstrates through reasonable and supported projections, developing a fixed MRI scanner inside its hospital on 17<sup>th</sup> Street is the most effective alternative in this review to serve the largest population of patients including inpatients and outpatients, emergent and scheduled patients, as well as low acuity and high acuity patients.

As far as lower costs are concerned, lower out of pocket costs may be relevant when: (1) the patient is a patient of the practice that owns the scanner; and (2) the patient is insured. For patients who are outside of the practice and who are uninsured and unable to pay, the Wilmington Health and Emerge Ortho scanners offer no advantage over the hospital; in fact, they may be even less accessible than the hospital's scanners, as evidenced by the difference in Medicaid service previously discussed.

Regarding Wilmington Health's generic statement that "freestanding facilities are also often more accessible than busy hospital campuses," the Agency is not able to tell whether that is in fact the case when considering NH New Hanover and Wilmington Health specifically.<sup>5</sup> The Agency is also unable to tell whether location is a significant factor in a patient's choice of where to receive an MRI scan.

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<sup>3</sup> Wilmington Health CON Application, page 44.

<sup>4</sup> 2023 State Medical Facilities Plan, page 347.

<sup>5</sup> Wilmington Health CON Application, page 45.



Wilmington Health claims that it will be able to bring its proposed MRI scanner online at almost the same time as the fixed MRI scanner at NH Scotts Hill.<sup>6</sup> Even if this were true, it is irrelevant. The NH Scotts Hill application was approved in 2022 and is not under review now. The Agency has historically not compared applicants’ speed of development. Nor has the Agency historically compared current applications with past applications.

Wilmington Health’s discussion of “need for additional freestanding MRI capacity for patients served at Wilmington Health” demonstrates that this proposal is designed to serve patients served by a particular physician practice, i.e., Wilmington Health. It is not a community-wide asset, which is the case for the MRI scanners at NH New Hanover.<sup>7</sup>

Additionally, Wilmington Health provides a chart<sup>8</sup> showing MRI volumes at Wilmington Health and NH New Hanover, culminating in a CAGR calculation for 2018-2021.

**Wilmington Health and NHRMC Total Adjusted Scans by Provider\***

<i>Provider</i>	<i>FFY18</i>	<i>FFY19</i>	<i>FFY21</i>	<i>18-21 CAGR</i>
Wilmington Health	3,467	4,625	3,759	2.7%
New Hanover Regional Medical Center	25,998	29,122	26,079	0.1%

Source: 2020, 2021, and 2023 SMFPs, Exhibit C.4-2.

\*Includes MRI scans performed on fixed and mobile MRI scanners.

Source: Wilmington Health CON Application, Page 47.

While Wilmington Health reports a higher CAGR than NH New Hanover over the period 2018-2021, NH New Hanover’s adjusted MRI scan volume is many times Wilmington Health’s volume. For example, in FFY 2021, NH New Hanover’s scan volume was almost seven times Wilmington Health’s. Moreover, the CAGR chart is flawed because it omits 2020. Even with COVID in 2020, there is no basis for simply omitting an entire year as though it did not happen.

Additionally, in FFY 2021, the four MRI scanners that provided the 26,079 adjusted MRI scans at NH New Hanover averaged 6,519 adjusted MRI scans each or at 130.6 percent  $[6,519 / 4,992) \times 100]$  of the

<sup>6</sup> Wilmington Health CON Application, pages 46-47.

<sup>7</sup> Wilmington Health CON Application, page 47.

<sup>8</sup> Wilmington Health CON Application, page 47.

adjusted MRI scan threshold of 4,992. Conversely, Wilmington Health operated at a mere 75.3 percent  $[3,759 / 4,992] \times 100$  of the adjusted MRI scan threshold of 4,992.

Wilmington Health also emphasizes its acquisition of Carolina Sports Medicine and “its numerous MRI referrals each year.”<sup>9</sup> No specific information is provided that would allow the Agency to ascertain the number of historical or anticipated referrals from Carolina Sports Medicine.

Wilmington Health describes perceived efficiencies and economies of scale, which may be beneficial to Wilmington Health, but they do not explain why the population proposed to be served needs the services of another fixed MRI scanner from Wilmington Health.<sup>10</sup> The key issue under Criterion (3) is what patients need, not what the applicant believes it needs.

The discussion about out of county utilization of New Hanover County MRI scanners is interesting but ultimately irrelevant under Criterion (3).<sup>11</sup> The need determination exists, regardless of where the patients originate. Further, out of county utilization does not explain why patients need another fixed MRI scanner from Wilmington Health at the location Wilmington Health proposes.

Finally, Wilmington Health’s claim to have referred out 600 MRI scans to other sources does not support Wilmington Health’s argument.<sup>12</sup> First, all providers face competition. Second, there are many reasons why patients are referred elsewhere, and not all of them necessarily lead to the conclusion that the provider who made the referral needs another MRI scanner. As Wilmington Health acknowledges, at least part of Wilmington Health’s alleged capacity issue is related to its existing fixed scanner at Medical Center Drive; that machine needed to be upgraded, which Wilmington Health has now done. This means faster scan times which means more patients can be accommodated.<sup>13</sup> Since the upgrade was completed shortly before this application was filed, there has not been sufficient time to determine the impact of the upgraded scanner on patient throughput. Another factor is the loss of the mobile scanner at its Porters Neck location.<sup>14</sup> The Agency does not manage contractual relationships. Other factors

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<sup>9</sup> Wilmington Health CON Application, page 48 and Form C Utilization, page 4 (referring to “many” Carolina Sports patients who need MRI scans.).

<sup>10</sup> Wilmington Health CON Application, page 48.

<sup>11</sup> Wilmington Health CON Application, pages 49 and 50.

<sup>12</sup> Wilmington Health CON Application, page 50.

<sup>13</sup> Wilmington Health CON Application, page 48.

<sup>14</sup> Wilmington Health CON Application, page 33.

may be proximity to where a patient lives, i.e., an Onslow, Pender, or Brunswick resident may find it more convenient to receive a scan closer to where the patient lives. Other factors may be patient preference for a different provider; cost; or the type of scan required. Without knowing the specific reasons why each of these 600 patients was referred elsewhere (information not provided by Wilmington Health), the Agency is not able to draw any meaningful conclusions from this information.

Wilmington Health has not demonstrated the need for another fixed MRI scanner through reasonable and supported assumptions.

**Utilization**

As shown by Wilmington Health in Section Q, Form C.2b, it is only proposing to “shift MRI scanner volume from its existing fixed MRI scanner to the proposed fixed MRI scanner.” By merely proposing to move volume around, there will be limited benefit to the service area if Wilmington Health is approved for the fixed MRI scanner.

The following tables are the two Form C.2b tables included in Section Q.

<b>Form C.2b Projected Medical Equipment Utilization upon Project Completion ^</b> <b>Wilmington Health at Medical Center Drive</b>	<b>Interim Full FY</b>	<b>1st Full FY</b>	<b>2nd Full FY</b>	<b>3rd Full FY</b>
	F: 01/01/2024	F: 01/01/2025	F: 01/01/2026	F: 01/01/2027
	T: 12/31/2024	T: 12/31/2025	T: 12/31/2026	T: 12/31/2027
<b>MRI Scanner (see Tab C)</b>				
# of Units	1	1	1	1
# of Procedures	5,142	4,121	3,755	3,332
# of Weighted Procedures	5,641	4,538	4,151	3,697

Source: Wilmington Health CON Application, Section Q, Page 3.

Form C.2b Projected Medical Equipment Utilization upon Project Completion <sup>A</sup>  Wilmington Health at Porters Neck	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	F: 09/15/2024	F: 01/01/2025	F: 01/01/2026	F: 01/01/2027
	T: 12/31/2024	T: 12/31/2025	T: 12/31/2026	T: 12/31/2027
MRI Scanner (see Tab C)				
# of Units	1	1	1	1
# of Procedures	404	1,766	2,503	3,332
# of Weighted Procedures	444	1,945	2,767	3,697

Source: Wilmington Health CON Application, Section Q, Page 4.

The following table shows the “shifting” of MRI scans from Medical Center Drive to Porters Neck.

### Wilmington Health MRI “Shifting”

			Year 1	Year 2	Year 3
	2023	2024	2025	2026	2027
Medical Center Drive	5,233	5,142	4,121	3,755	3,332
Annual Decrease in MRI Scans		91	1,021	366	423
Cumulative Decrease in MRI Scans		91	1,112	1,478	1,901
Porters Neck		404	1,766	2,503	3,332
Cumulative MRI Shift from Medical Center Drive		91	1,112	1,478	1,901
New MRI Scans		313	654	1,025	1,431

Source: Wilmington Health CON Application, Section Q, Pages 3-4.

As the table highlights, in Project Year 3, Wilmington Health has effectively “shifted” 57.1 percent  $[(1,901 / 3,332) \times 100]$  of the proposed fixed MRI scanner’s volume from its existing fixed MRI scanner, less than 12 miles away. Wilmington Health only proposes to actually increase new MRI scans by 1,431 MRI scans in Project Year 3. Wilmington Health does not propose to meet an unmet need in New Hanover County.

Wilmington Health has arbitrarily and without any explanation projected that both fixed MRI scanners would provide 3,332 MRI scans, resulting in 3,697 adjusted MRI scans.<sup>15</sup> It is strange indeed that both

<sup>15</sup> Wilmington Health CON Application, Form C Utilization – Assumptions and Methodology, page 6.

scanners are projected to perform exactly the same number of MRI scans in 2027. It appears that Wilmington Health did this in order to meet the Performance Standard of 3,494 adjusted MRI scans per MRI scanner. This arbitrary calculation is unreasonable and unsupported.

Finally, with respect to access by medically underserved patients, please refer to the discussion under Criterion (1) and Criterion (13).

Wilmington Health has not demonstrated the quantitative or qualitative need for an additional fixed MRI scanner. For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health's application is non-conforming with Criterion (3) and cannot be approved.

- (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.

Wilmington Health assumes there is no alternative other than acquiring another fixed scanner. There is no discussion of maintaining the status quo. This is a glaring omission. The least costly or most effective alternative is for Wilmington Health to fully utilize its newly upgraded fixed unit on Medical Center Drive. That upgrade was only completed in March 2023, so Wilmington Health has not had the opportunity to fully benefit from the upgrade in just two months.

Please also refer to the Utilization and Wilmington Health MRI “Shifting” discussion in Criterion (3). The same facts that make the Wilmington Health application non-conforming with Criterion (3) also make it non-conforming with Criterion (4).

For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health’s application is non-conforming with Criterion (4) and cannot be approved.

- (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.

For the stated reasons in Criteria (1), (3), (4), (6), (12), (13), and (18a), as well as the Performance Standards in addition to any other reasons the Agency may discern, Wilmington Health's application is non-conforming with Criterion (5) and cannot be approved.

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

Wilmington Health again suggests that “*freestanding* fixed MRI services” are distinct from other types of MRI services. They are not distinct. Adding more freestanding fixed MRI services does not enhance competition where: 1) multiple options now exist to receive MRI services in New Hanover County, including at freestanding fixed MRI scanner locations; and 2) the freestanding fixed MRI scanner locations will only serve a subset of the service area’s population, i.e., outpatients who are also patients of Wilmington Health. Further, as Wilmington Health acknowledges, its March 2023 upgrade to the Medical Center Drive MRI scanner will help alleviate some of the perceived capacity constraints by providing faster scanning capabilities.

Please also refer to the Utilization and Wilmington Health MRI “Shifting” discussion in Criterion (3).

For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health’s application is non-conforming with Criterion (6) and cannot be approved.



- (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.

Please refer to the Utilization and Wilmington Health MRI “Shifting” discussion in Criterion (3). The same facts that make the Wilmington Health application non-conforming with Criterion (3) also make it non-conforming with Criterion (12).

Please also refer to the discussion in Criterion (4). The same facts that make the Wilmington Health application non-conforming with Criterion (4) also make it non-conforming with Criterion (12).

For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health’s application is non-conforming with Criterion (12) and cannot be approved.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
  - (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
  - (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and
  - (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

Under Criterion (13), Wilmington Health provided incomplete information, just as it did in Criterion (3). The historical payor mix it provides is for the contracted mobile MRI service. Wilmington Health omits entirely the payor mix for its fixed MRI scanner. This error is repeated in the response to Section L.1.b.

**Last Full FY before Submission of Application**  
**01/01/2022 to 11/30/2022**

<b>Wilmington Health at Porters Neck – 8090 Market Street</b>	
<b>Payor Source</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	1.2%
Charity Care <sup>^</sup>	
Medicare *	44.4%
Medicaid *	1.0%
Insurance *	45.4%
Workers Compensation <sup>^^</sup>	
TRICARE <sup>^^</sup>	
Other (Other Payor) <sup>^^</sup>	8.0%
<b>Total</b>	<b>100.0%</b>

\* Including any managed care plans.

<sup>^</sup> Wilmington Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

<sup>^^</sup> Workers Compensation and TRICARE are included in the Other payor category.

Source: Wilmington Health CON Application, Page 98.

Similar to its patient origin, Wilmington Health states it based its projected payor mix on both its fixed MRI scanner and the contracted mobile MRI scanner. But without the payor mix from its existing fixed MRI scanner, there is no way for the Agency to assess the reasonableness of the projection. One thing is clear, though – the projected payor mix is dramatically different from the payor mix of the contracted mobile MRI scanner, even though the proposed location is the same. Notably, the percentage of self-pay patients is half of what it was on the mobile MRI scanner. The applicant should have explained the difference but failed to do so.

Please also refer to the discussion under Criterion (1) regarding access by Medicaid patients.

**Projected Payor Mix during the 3<sup>rd</sup> Full FY  
01/01/2027 to 12/31/2027**

<b>Wilmington Health at Porters Neck – 8090 Market Street</b>	
<b>Payor Source</b>	<b>Percentage of Total Patients Served</b>
Self-Pay	0.6%
Charity Care <sup>^</sup>	
Medicare *	44.5%
Medicaid *	2.0%
Insurance *	48.1%
Workers Compensation <sup>^^</sup>	
TRICARE <sup>^^</sup>	
Other (Other Payor) <sup>^^</sup>	4.8%
<b>Total</b>	<b>100.0%</b>

\* Including any managed care plans.

<sup>^</sup> Wilmington Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

<sup>^^</sup> Workers Compensation and TRICARE are included in the Other payor category.

Source: Wilmington Health CON Application, Page 101.

For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health’s application is non-conforming with Criterion (13) and cannot be approved.

(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.

Please refer to prior discussion under Criteria (1), (3), (4), (5), (6), (12), (13), and the Performance Standards, as well as the Comparative Analysis.

For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health's application is non-conforming with Criterion (18a) and cannot be approved.

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

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (7) project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project:
  - (a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
  - (b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
  - (c) 1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and

Please refer to the Utilization and Wilmington Health MRI “Shifting” discussion in Criterion (3). The same facts that make the Wilmington Health application non-conforming with Criterion (3) also make it non-conforming with the Performance Standards.

For these stated reasons, in addition to any other reasons the Agency may discern, Wilmington Health’s application is non-conforming with the Performance Standards and cannot be approved.

**Comments in Opposition to  
Project ID # O-12374-23  
EmergeOrtho, P.A.**

**Application Specific Comments**

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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.”

Policy GEN-3, *2022 SMFP*, page 30, emphasis added.

Although EmergeOrtho’s application conforms to the need determination, it is not consistent with all applicable policies in the SMFP, including Policy GEN-3. Therefore, the application does not conform with Criterion (1).

EmergeOrtho’s proposed MRI scanner is limited in two key respects: 1) it will serve mostly patients of its own practice; and 2) it will serve outpatients only. This limitation translates into limited services to medically underserved patients. As the following table highlights, EmergeOrtho proposes to serve just 175 Medicaid patients or 3.76 percent of EmergeOrtho’s MRI patients in Year 3. By contrast, NH New Hanover’s proposal, which will serve both inpatients and outpatients regardless of referral source, projects Year 3 Medicaid patient volume of 1,234 patients or 12.5 percent of MRI patients.

<b>Applicant</b>	<b>Project Year 3</b>	
	<b>Medicaid Patients</b>	<b>% of Medicaid Patients</b>
NH New Hanover	1,234	12.5%
EmergeOrtho	175	3.76%

In addition, the EmergeOrtho proposal does not satisfy Policy GEN-3 because it proposes to acquire a lower strength scanner that is limited in its usefulness. See discussion under Criterion (3) for further detail.

EmergeOrtho has not demonstrated equitable access to its fixed MRI service. In addition, for the reasons discussed below with respect to Criterion (3), EmergeOrtho has failed to demonstrate the need for its proposal, and those same facts also make the application non-conforming with Criterion (1).

For these reasons, in addition to any other reasons the Agency may discern, EmergeOrtho’s application is non-conforming with Criterion (1) and cannot be approved.



- (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.

Criterion (3) focuses on the need the population has for the services proposed. EmergeOrtho proposes to operate a 1.2 Tesla MRI scanner but fails to demonstrate why the service area population needs a lower-strength MRI scanner. In a competitive review like this one, the Agency must consider which applicant's proposal will benefit the most people. In an MRI review, the Tesla strength of the scanner and its capabilities are integrally related to patient benefit. While 1.2 Tesla scanners are still in use, the known disadvantages of a 1.2 Tesla MRI Scanner include the following:

1. **Reduced Signal-to-Noise Ratio:** The signal-to-noise ratio (SNR) is an essential factor in MRI, influencing image quality and diagnostic accuracy. A 1.2T MRI scanner has a lower SNR compared to higher field strength scanners.<sup>16</sup> The lower SNR can lead to decreased image quality, particularly in areas where the signal is inherently weak, such as the brainstem or areas distant from the receiver coils. Consequently, the visibility of small lesions or subtle abnormalities may be compromised.
2. **Limited Image Resolution:** One significant disadvantage of a 1.2T MRI scanner is its relatively lower image resolution compared to higher field strength scanners. Higher field strengths, such as 1.5T or 3T, offer improved spatial resolution, allowing for more precise imaging of small anatomical structures or subtle pathological changes.<sup>17 18</sup> In some cases, the lower resolution of a 1.2T scanner may limit its ability to detect or accurately characterize certain conditions.
3. **Limited Spectroscopic Imaging:** Magnetic Resonance Spectroscopy (MRS) is a technique that allows the measurement of metabolite concentrations within specific regions of interest. However, the lower field strength of a 1.2T scanner may limit the sensitivity and accuracy of

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<sup>16</sup> Keil B, Blau JN, Biber S, et al. A 64-channel 3 T array coil for accelerated brain MRI. *Magn Reson Med*. 2013;70(1):248-258.

<sup>17</sup> Smith AM, Webb AG. *Introduction to Magnetic Resonance Imaging: Principles and Techniques*. CRC Press; 2018.

<sup>18</sup> Cho ZH, et al. The future of brain MRI. *Magnetic Resonance Materials in Physics, Biology, and Medicine*. 2015; 28(Suppl 1): S23-S33.

spectroscopic imaging, making it less reliable for certain applications.<sup>19</sup> Higher field strength scanners, such as 3T or 7T, are preferred for MRS studies that require greater spectral resolution and sensitivity.

4. Longer Imaging Times: Due to the lower SNR, 1.2T MRI scanners often require longer imaging times to compensate for the decreased signal strength. Longer scan times can be challenging for patients, particularly those who are uncomfortable or claustrophobic inside the MRI scanner.<sup>20</sup> Additionally, prolonged scanning times increase the likelihood of motion artifacts, which can degrade image quality and hinder accurate diagnosis.
5. Challenging Imaging of Difficult-to-Visualize Structures: Certain anatomical regions, such as the prostate or coronary arteries, can be challenging to visualize even with higher field strength MRI scanners. With a 1.2T scanner, the visualization of these structures becomes even more difficult due to the limitations in spatial resolution and SNR.<sup>21</sup> This drawback may require additional imaging techniques or alternative modalities to obtain adequate diagnostic information. **The lower field strength results in the following MRI scans that should not be performed on the proposed MRI scanner; breast, cardiac, prostate, as well as functional and advanced neuro and spine scans.**
6. Limited Availability of Specialized Coils and Sequences: The availability of specialized coils and sequences is crucial for optimizing image quality and diagnostic capabilities in MRI. However, compared to higher field strength scanners, 1.2T scanners may have limited access to advanced coil configurations and cutting-edge pulse sequences. This can restrict the versatility and application range of the scanner, especially for complex or research-oriented imaging studies.<sup>22</sup>
7. Limited Accessibility: While 1.2T MRI scanners are still used in various medical facilities, they are becoming less common as higher-field scanners become more prevalent. This reduced accessibility may limit the availability of cutting-edge imaging techniques or research opportunities that require higher magnetic field strengths.
8. Potential Need for Repeat Scans: Lower-field MRI scanners may yield images with lower diagnostic confidence, particularly in complex cases or challenging anatomical regions. As a

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<sup>19</sup> Star-Lack JM, Adalsteinsson E, Gold GE, et al. In vivo 3D spectroscopic imaging of the proximal femur with parallel MRI. *Magn Reson Med*. 2000;43(5):771-778.

<sup>20</sup> Grissom WA, Tkach JA. Magnetic resonance imaging physics: a review. *Semin Neurol*. 2008;28(4):436-443.

<sup>21</sup> Sodickson DK, Manning WJ. Simultaneous acquisition of spatial harmonics (SMASH): fast imaging with radiofrequency coil arrays. *Magn Reson Med*. 1997;38(4):591-603.

<sup>22</sup> McRobbie DW, Moore EA, Graves MJ, Prince MR. MRI from Picture to Proton. Cambridge University Press; 2017.

result, there is a possibility of needing additional scans or follow-up imaging, leading to increased patient inconvenience, potential delays in diagnosis, and increased healthcare costs.

9. Limited Access to Advanced Techniques: Some advanced imaging techniques, such as magnetic resonance spectroscopy (MRS) or dynamic contrast-enhanced MRI (DCE-MRI), may require higher field strengths for optimal results. With a 1.2 Tesla scanner, access to these advanced techniques may be limited, restricting the ability to fully characterize certain diseases or conditions.
10. Limited Research Potential: In the field of research and development, higher-field MRI scanners offer greater opportunities for innovation and advancement. The use of a 1.2T scanner may limit the ability to participate in cutting-edge research or clinical trials that require higher magnetic field strengths.
11. Potential Upgrade Costs: If a facility owns a 1.2T MRI scanner and wishes to upgrade to a higher-field system, it may involve significant costs, including the purchase of new equipment, installation, and staff training.

### **Patient Origin Discussion**

Similar to Wilmington Health, EmergeOrtho does not provide the historical patient origin for its fixed scanner on Shipyard Boulevard. EmergeOrtho apparently considered this information in developing its projected patient origin.<sup>23</sup> But since the Agency does not have this information, the Agency cannot determine whether the proposed patient origin is reasonable.

Moreover, EmergeOrtho states that certain patients in certain zip codes will “shift” from the Shipyard Boulevard scanner to the proposed Porter’s Neck scanner.<sup>24</sup> EmergeOrtho does not provide any information about the historical number of these patients from these zip codes who received MRI scans at the Shipyard Boulevard location. Without this historical information, the Agency has no basis for determining whether the shift is reasonable.

Since the applicant did not provide reasonable and supported assumptions for its proposed patient origin, the application should be disapproved under Criterion (3).

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<sup>23</sup> EmergeOrtho CON Application, page 33.

<sup>24</sup> EmergeOrtho CON Application, pages 33 and 130.

## Enhanced Access Discussion

EmergeOrtho complains about the limitations of a leased mobile MRI scanner including the environment and the closed bore.<sup>25</sup> At the same time, EmERGEOrtho highlights that it operates several mobile MRI scanners in response to Section A.6. Additionally, EmERGEOrtho submitted three CON applications to operate additional mobile MRI scanners in North Carolina in 2023. EmERGEOrtho's criticisms about mobile MRI scanners are irrelevant.

In addition, EmERGEOrtho's predominant patient base is patients with orthopedic needs. Thus, the EmERGEOrtho proposal does not enhance access for a variety of patients. It is intended for patients of EmERGEOrtho, and those patients will be mainly orthopedic cases. For example, a woman in need of a breast MRI scan would have no reason to go to EmERGEOrtho. As previously discussed, the 1.2T MRI scanner is inherently limited in the types of scans it performs. In addition to breast scans, the 1.2T MRI scanner is not used for cardiac, prostate, as well as functional and advanced neuro and spine scans.

EmERGEOrtho also discusses "patient demand for value-based MRI services" and provides the BlueCross BlueShield Treatment Cost Estimator. According to EmERGEOrtho, it is the least expensive provider represented on the chart.<sup>26</sup> While the chart states that the data was "referenced March 2023," the time period covered by the data is unknown, so the reader does not know how current this information is. Moreover, this is data from one payor's cost estimator; it is unknown what other payors' treatment cost estimators (if they have them) show. The data provided also does not show what a patient's out of pocket or co-pay might be. For uninsured patients, the data does not show that a self-pay patient might pay, and it does not provide any information about charity care. At Novant Health, a family of four with income up to 300% of the federal poverty level and no insurance receives no bill from Novant Health hospitals or physicians; all that is required is completion of a one-page form.

Allegedly lower prices, especially for scans performed on a refurbished 1.2T machine, are not synonymous with adding value. For the reasons stated above, the images on a 1.2T do not have the quality of a 1.5T or 3T machine and may not be the best option for the patient.

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<sup>25</sup> EmERGEOrtho CON Application, pages 39 and 40.

<sup>26</sup> EmERGEOrtho CON Application, page 41.

Further, as discussed above with respect to Wilmington Health, the Agency should not simply accept, without question, that MRI offered at a freestanding site is better, faster, and cheaper than MRI services performed at a hospital. The issue is a nuanced one, and many variables, not the least of which is the patient’s medical condition that necessitates the MRI, must be considered. Moreover, New Hanover County residents have a range of options currently for MRI scans, including two freestanding sites, so adding another freestanding site by an existing provider will not necessarily promote competition on price or quality. This is especially true here, due to the inherent limitations of a refurbished 1.2T scanner.

EmergeOrtho provides a variety of demographic data.<sup>27</sup> The data are not unique to EmergeOrtho and do not demonstrate why the population proposed to be served needs another MRI from EmergeOrtho at the location EmergeOrtho proposes.

EmergeOrtho discusses “improved geographic access”.<sup>28</sup> But as EmergeOrtho notes, NH New Hanover has been approved to develop an MRI scanner at NH Scotts Hill, which is projected to open in 2024. NH Scotts Hill will be a small hospital designed to promote convenience and accessibility.

The northern part of New Hanover County is obviously growing, but that does not mean there is a need for another MRI scanner in that area right now. Moreover, EmergeOrtho’s MRI volume is entirely outpatient, scheduled MRI scans. Most of EmergeOrtho’s scan volume is orthopedic scans. In most cases, the patient will require only one scan – it is not as though the patient will be making repeated trips over the course of many weeks or months, as would be the case with radiation oncology treatments or chemotherapy appointments. Thus, while traffic can be an issue anytime a patient seeks health care services, the issue also needs to be put in proper context. With scheduled, non-emergent MRI, a patient can seek to schedule their scan at a time that is most suitable for the patient.

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<sup>27</sup> EmergeOrtho CON Application, pages 42 through 46.

<sup>28</sup> EmergeOrtho CON Application, page 47.

**Utilization**

As shown by EmergeOrtho in Section Q, Form C.2b, it is only proposing to “shift” 25.7 percent of MRI scanner volume from its existing fixed MRI scanner to the proposed fixed MRI scanner, which will equal 32.6 percent of the proposed MRI scanner’s volume. There will be limited benefit to the service area if EmergeOrtho is approved for the fixed MRI scanner.

The following tables are included in Form C.2b Assumptions and Methodology in Section Q.

**Total Projected Shipyard Boulevard Fixed MRI Procedures**

<b>Shipyard after shift</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>
Fixed unweighted procedures	5,391	5,519	5,649	5,783	5,919
Shifted to Porters Neck	-	-	1,065	1,288	1,521
Total unweighted	5,391	5,519	4,585	4,495	4,398
Weighted procedures	5,541	5,672	4,712	4,620	4,520
Weighting ratio	1.028	1.028	1.028	1.028	1.028

Totals may not foot due to rounding.

Source: EmergeOrtho CON Application, 133.

**Total Projected EmergeOrtho – Wilmington Porters Neck MRI Procedures**

<b>Porters Neck total after shift</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>
Shifted from Shipyard Blvd.	1,065	1,288	1,521
Market share gain	1,624	2,558	3,144
Total unweighted procedures	2,689	3,846	4,665
Weighted procedures	2,764	3,952	4,794
Weighting ratio	1.028	1.028	1.028

Totals may not foot due to rounding.

Source: EmergeOrtho CON Application, Page 132.

The following table shows the “shifting” of MRI scans from Shipyard Boulevard to Porters Neck.

**EmergeOrtho MRI “Shifting”**

			Year 1	Year 2	Year 3
	2023	2024	2025	2026	2027
Shipyard Blvd	5,391	5,519	5,649	5,783	5,919
Annual Decrease in MRI Scans			1,065	1,288	1,521
Shipyard Blvd After MRI Scan Shift	5,391	5,519	4,585	4,495	4,398
Porters Neck			2,689	3,846	4,665
Accumulative MRI Shift from Medical Center Drive			1,065	1,288	1,521

Source: EmERGEOrtho CON Application, Pages 132-133.

As the table highlights, in Project Year 3, EmERGEOrtho has effectively “shifted” 32.6 percent  $[(1,521 / 4,665) \times 100]$  of the proposed fixed MRI scanner’s volume from its existing fixed MRI scanner. Similar to Wilmington Health, EmERGEOrtho is simply shifting its existing MRI scan volume between two sites located less than 12 miles from each other. EmERGEOrtho does not propose to meet an unmet need in New Hanover County.

EmERGEOrtho discusses the MRI scan shift from Shipyard Boulevard to Porters Neck.<sup>29</sup> EmERGEOrtho concludes that MRI scans will shift from 10 zip codes located north of the Shipyard Boulevard facility at a rate of 55%, 65%, and 75% during Project Years 1-3, respectively. This shift is based on the following:

- Convenient northern New Hanover County outpatient location
- Full-time availability of a Porters Neck fixed MRI scanner
- Reduced travel burden for patients seeking MRI services
- More timely access to fixed MRI services
- Proximity to referring physicians located in Porters Neck and northern New Hanover County

<sup>29</sup> EmERGEOrtho CON Application, pages 131 and 132.

However, EmergeOrtho fails to provide any details to explain or support these five variables on which the MRI scan volume shift is based. EmergeOrtho also does not provide information about the historical number of patients from these ten zip codes who received MRI scans at the Shipyard Boulevard location.

Furthermore, EmergeOrtho arbitrarily and without any explanation projects “organic” market growth of 4.5%, 7.0%, and 8.5% over Project Years 1-3.<sup>30</sup> EmergeOrtho provides no explanation as to the reasonableness of these percentages or even how they were projected other than to state the following:

For the Porters Neck fixed MRI scanner, EmergeOrtho projects organic MRI growth (market share) of 4.50% in CY2025, 7.00% in CY2026, and 8.50% in CY2027.

There is no explanation in the application or exhibits that discusses the “organic” market growth.

For these stated reasons, in addition to any other reasons the Agency may discern, EmergeOrtho’s application is non-conforming with Criterion (3) and cannot be approved.

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<sup>30</sup> EmergeOrtho CON Application, page 130.



- (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.

Recognizing that its choice of a refurbished 1.2T scanner is questionable, EmergeOrtho pivots by criticizing 3T scanners. EmergeOrtho states, “[m]ost implants are safe to go into a 1.2T or 1.5T MR scanner, but not a 3.0T scanner.”<sup>31</sup> This statement is inaccurate. EmergeOrtho inappropriately seeks to artificially limit the patient population that can be scanned on a 3.0T MRI scanner and to question the safety of a 3.0T MRI scanner.

A recent study searched over 402 articles and after eliminating articles over 10 years old, as well as duplicate articles, and articles not related to orthopedic implants or to safety, 15 articles were reviewed. Of those 15 articles, 11 articles discussed implant displacement, 13 articles discussed RF heating, and 4 articles discussed torque.<sup>32</sup>

The results were as follows:

The concerns of MRI in patients with metal implants are centered on theoretic migration and RF heating of implants, causing damage to surrounding tissues. Numerous studies examining the safety of surgical implants have been published over the past 3 decades, concluding that most passive (no power associated with their operation) nonferromagnetic or weakly ferromagnetic implants are safe for patients in any setting requiring an MRI at 1.5 T or less.<sup>31-34</sup> The results of this review are similar. In general, MRI with field strengths up to 7.0 T can safely be used in patients with orthopedic implants, because the risk of implant-based complications is extremely low.

EmergeOrtho has not demonstrated that the acquisition of a lower-strength MRI scanner, specifically a refurbished 1.2T MRI scanner, is the most effective alternative. For this reason, in addition to any other reasons the Agency may discern, EmergeOrtho’s application is non-conforming with Criterion (4) and cannot be approved.

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<sup>31</sup> EmergeOrtho CON Application, page 71.

<sup>32</sup> Attachment A, “MRI Safety with Orthopedic Implants”

- (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.

The Agency needs to consider whether EmergeOrtho has the financial capacity to undertake four separate MRI scanner projects. As the Agency knows, in the May 1, 2023 review cycle<sup>33</sup>, EmergeOrtho proposes to acquire four MRI scanners: the fixed MRI scanner in the New Hanover County review and three mobile MRI scanners in the statewide mobile MRI review. The total capital cost for all four projects is \$6,148,293. This does not include start up and working capital. Of the four projects, the fixed MRI scanner project is the most expensive project, with a projected capital cost of \$2,246,570. Interestingly, EmergeOrtho proposes two different funding sources for the four projects: a loan from Truist Bank for the fixed MRI scanner and loans from First Citizens Bank for the mobile MRI scanners. There is nothing to indicate that Truist Bank knows anything about the loans for the mobile MRI scanners or that First Citizens Bank knows anything about the loan for the fixed MRI scanner. EmergeOrtho has not provided audited financial statements or any documentation from its accounting firm about its financial condition. The Truist Bank letter in Exhibit F.2 states that EmergeOrtho “currently has excess deposits and cash flow which are far in excess of the current project costs.” Truist Bank’s use of the word “currently” is important because the bank makes no representations concerning: (1) whether the current deposits and cash flow are representative of EmergeOrtho’s historical deposits and cash flow; or (2) EmergeOrtho’s future deposits or cash flow position. There is no information in any of the four applications that discuss other financial obligations EmergeOrtho may have, such as equipment loans for other equipment. It would be unusual for a physician organization such as EmergeOrtho not to have other borrowings, and as the physician practice takes out more loans, it may run afoul of covenants in its other loans such as debt to equity ratios or overall limits on borrowing. The Agency simply does not have the information it needs to determine whether EmergeOrtho can undertake all of these projects.

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<sup>33</sup> Attachment B - May 2023 Application Log

For this reason, as well as for the stated reasons in Criteria (1), (3), (4), (6), (12), (13), (18a), and the Performance Standards in addition to any other reasons the Agency may discern, EmergeOrtho's application is non-conforming with Criterion (5) and cannot be approved.

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

Please refer to the Utilization and EmergeOrtho MRI “Shifting” discussion in Criterion (3), as well as the Comparative Analysis.

For these stated reasons, in addition to any other reasons the Agency may discern, EmergeOrtho’s application is non-conforming with Criterion (6) and cannot be approved.

- (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.

Please refer to the Utilization and EmergeOrtho MRI “Shifting” discussion in Criterion (3). The same facts that make the EmergeOrtho application non-conforming with Criterion (3) also make it non-conforming with Criterion (12).

Please also refer to the alternative discussion in Criterion (4). The same facts that make the EmergeOrtho application non-conforming with Criterion (4) also make it non-conforming with Criterion (12).

For these stated reasons, in addition to any other reasons the Agency may discern, EmergeOrtho’s application is non-conforming with Criterion (12) and cannot be approved.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
  - (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
  - (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and
  - (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

Under Criterion (13), EmergeOrtho highlights that it currently serves 0.0% charity care patients, 0.44% self-pay patients, and 3.08% Medicaid patients at its Porters Neck facility. EmergeOrtho highlights that it will “expand” charity care access for patients in need from 0.0% to 0.68% at the Porters Neck facility. While .68 is mathematically greater than zero, it is implausible to suggest that this *de minimus* attempt at offering charity care constitutes an “expansion.”

EmergeOrtho states it based its projected payor mix on both its fixed MRI scanner and its mobile MRI scanner. But without the payor mix from its fixed MRI scanner, there is no way for the Agency to assess the reasonableness of the projection.

<Fixed MRI Scanner>	
Payor Source	Percentage of Total Patients Served
Self-Pay	0.63%
Charity Care	1.50%
Medicare *	36.12%
Medicaid *	3.76%
Insurance *	48.99%
Workers Compensation	2.25%
TRICARE	6.43%
Other (liability, SNF, correctional)	0.30%
<b>Total</b>	<b>100.0%</b>

\* Including any managed care plans.

Totals may not foot due to rounding.

Source: EmERGEOrtho CON Application, Page 105.

EmergeOrtho has no charity care or reduced cost policy.<sup>34</sup> EmERGEOrtho refers to charity care patients on a case-by-case basis.<sup>35</sup> This is quite different from NH New Hanover, which has a variety of policies focused on charity and reduced cost care. One of the most noteworthy features of these policies is that an uninsured person with household income up to 300% of Federal Poverty Level receives no bill from Novant Health facilities or physicians.

Please also refer to the discussion in Criterion (1) regarding access by Medicaid recipients.

For these stated reasons, in addition to any other reasons the Agency may discern, EmERGEOrtho's application is non-conforming with Criterion (13) and cannot be approved.

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<sup>34</sup> EmERGEOrtho CON Application, page 106.

<sup>35</sup> EmERGEOrtho CON Application, page 57.

(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.

Please refer to prior discussion under Criteria (1), (3), (4), (5), (6), (12), (13), and the Performance Standards, as well as the Comparative Analysis.

For these stated reasons, in addition to any other reasons the Agency may discern, EmergeOrtho's application is non-conforming with Criterion (18a) and cannot be approved.



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

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(7) project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project:

- (a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;
- (b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
- (c) 1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and

Please refer to the Utilization and EmergeOrtho MRI “Shifting” discussion in Criterion (3). The same facts that make the EmergeOrtho application non-conforming with Criterion (3) also make it non-conforming with the Performance Standards.

For these stated reasons, in addition to any other reasons the Agency may discern, EmergeOrtho’s application is non-conforming with the Performance Standards and cannot be approved.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2023 SMFP, no more than one MRI scanner may be approved for New Hanover County in this review. Because each application proposes to acquire a fixed MRI scanner in New Hanover County, all applications cannot be approved. For the reasons set forth below, the application submitted by NH New Hanover should be approved and the other applications should be disapproved.

### **Conformity with Statutory and Regulatory Review Criteria**

The applications submitted by Wilmington Health and EmergeOrtho do not conform with all applicable statutory and regulatory review criteria. NH New Hanover conforms with all applicable statutory and regulatory review criteria. NH New Hanover is the most effective alternative.

### **Scope of Services**

The applications submitted by Wilmington Health and EmergeOrtho only propose to provide outpatient MRI services, whereas NH New Hanover proposes to provide a much broader scope of services to include both inpatient and outpatient MRI services, and a variety of medical conditions. NH New Hanover is the most effective alternative.

### **Geographic Location**

All applicants propose to operate the fixed MRI scanner in New Hanover County. Therefore, geographical location is not a significant factor.

### **Competition (Access to a New or Alternate Provider)**

NH New Hanover, Wilmington Health, and EmergeOrtho all provide fixed MRI scanner services in New Hanover County. As discussed above, both Wilmington Health and EmergeOrtho already offer fixed MRI services at freestanding sites in New Hanover County, so their applications to offer “freestanding fixed

MRI services” do not propose anything new or different. Accordingly, this factor does not favor any applicant in this review.

**Historical Utilization**

The following table illustrates utilization of the existing fixed MRI scanners for Wilmington Health, EmergeOrtho, and NH New Hanover provided in the 2023 SMFP representing FY 2021 and the 2024 Proposed SMFP representing FY 2022 reported utilization.

	MRI Scanners		Adjusted MRI Scans		Adjusted MRI Scans per MRI Scanner	
	FY2021	FY2022	FY2021	FY2022	FY2021	FY2022
NH New Hanover	4	4	22,753	22,749	5,688	5,687
Wilmington Health	1	1	3,759	4,548	3,759	4,548
EmergeOrtho	1	1	4,612	4,991	4,612	4,991

Source: 2023 SMFP and Proposed 2024 SMFP, Table 17E-1.

NH New Hanover performed the highest number of adjusted MRI scans per fixed MRI scanner in FY 2021 and FY 2022. Therefore, NH New Hanover is the most effective alternative for this comparative factor.

**Access by Service Area Residents**

The 2023 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 the purpose of this review, New Hanover County is the service area. The following table illustrates access by service area residents during the third full fiscal year following project completion.

Applicant	Total MRI Patients	Total New Hanover MRI Patients	% of Total MRI Patients
NH New Hanover	9,871	4,136	41.9%
Wilmington Health	3,332	1,833	55.0%
EmergeOrtho	4,665	2,139	45.9%

Source: NH New Hanover, Wilmington Health, and EmergeOrtho CON Applications, Section Q, Form C.2b.

Wilmington Health projects to serve the highest percentage of service area residents during the third full fiscal year following project completion. In addition, as discussed above in Criterion (3), neither Wilmington Health nor EmergeOrtho’s patient origin is based on reasonable and supported assumptions. NH New Hanover’s patient origin is based on reasonable and supported assumptions, and NH New Hanover proposes to serve a higher number of New Hanover County residents. Moreover, NH New Hanover proposes to serve both inpatients and outpatients, while Wilmington Health and EmergeOrtho propose to serve only outpatients. Therefore, regarding projected service to residents of the service area, the application submitted by NH New Hanover is a more effective alternative.

**Projected Access by Medicare Patients**

The following table compares a) the number of Medicare patients in Project Year 3; and b) Medicare patients as a percentage of total patients. Generally, the application projecting the highest number or percentage is the most effective alternative regarding these comparative factors. The applications are listed in the table below in decreasing order of effectiveness.

Applicant	Project Year 3	
	Medicare Patients	% of Medicare Patients
NH New Hanover	5,360	54.3%
Wilmington Health	1,483	44.5%
EmergeOrtho	1,988	42.62%

Source: NH New Hanover, Wilmington Health, and EmergeOrtho CON Applications, Table L.3.b.

As shown in the table, in Project Year 3, NH New Hanover projects to serve the highest percentage of Medicare patients and the highest number of Medicare patients. Accordingly, NH New Hanover is a more effective alternative.

**Projected Access by Medicaid Patients**

The following table compares a) the number of Medicaid patients in Project Year 3; and b) Medicaid patients as a percentage of total patients. Generally, the application projecting the highest number or

percentage is the most effective alternative regarding these comparative factors. The applications are listed in the table below in decreasing order of effectiveness.

	<b>Project Year 3</b>	
<b>Applicant</b>	<b>Medicaid Patients</b>	<b>% of Medicaid Patients</b>
NH New Hanover	1,234	12.5%
Wilmington Health	67	2.0%
EmergeOrtho	175	3.76%

Source: NH New Hanover, Wilmington Health, and EmergeOrtho CON Applications, Table L.3.b.

As shown in the table, in Project Year 3, NH New Hanover projects to serve the highest number of Medicaid patients and the highest percentage of Medicaid patients. Accordingly, NH New Hanover is a more effective alternative.

**Projected Charity Care**

**Projected Charity Care as a Percent of Net Revenue**

**Projected Average Net Revenue per Adjusted MRI Scan**

**Projected Average Operating Expense per Adjusted MRI Scan**

EmergeOrtho bills for “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their proformas. NH New Hanover and Wilmington Health do not bill for “professional fees” nor do NH New Hanover and Wilmington Health include an expense line in their proformas for professional fees. These differences in billing impact revenues (both gross and net) and expenses, do not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

## Summary

Comparative Factor	NH New Hanover	Wilmington Health	EmergeOrtho
Conformity with Statutory and Regulatory Review Criteria	<b>Most Effective</b>	Less Effective	Less Effective
Scope of Services	<b>Most Effective</b>	Less Effective	Less Effective
Geographic Location	Inconclusive	Inconclusive	Inconclusive
Competition (Access to a New or Alternate Provider)	Inconclusive	Inconclusive	Inconclusive
Historical Utilization	<b>Most Effective</b>	Less Effective	Less Effective
Access by Service Area Residents	<b>Most Effective</b>	Less Effective	Less Effective
Projected Access by Medicare Patients	<b>Most Effective</b>	Less Effective	Less Effective
Projected Access by Medicaid Patients	<b>Most Effective</b>	Less Effective	Less Effective
Projected Charity Care	Inconclusive	Inconclusive	Inconclusive
Projected Charity Care as a Percent of Net Revenue	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Adjusted MRI Scan	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Adjusted MRI Scan	Inconclusive	Inconclusive	Inconclusive

As shown in the Summary, NH New Hanover is the most effective alternative for the following six factors:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Access by Service Area Residents
- Projected Access by Medicare Patient
- Projected Access by Medicaid Patient

All other factors are inconclusive in determining an effective alternative.

## **CONCLUSION**

For the reasons stated in these comments in addition to any other reasons the Agency may discern, the Wilmington Health application and the EmergeOrtho application should be denied because neither application is conforming with the review criteria, and both are less effective alternatives in the Comparative Analysis when compared to the NH New Hanover application. The NH New Hanover CON application should be approved.

As demonstrated in its application and shown in these comments, the NH New Hanover CON application should be approved for the following reasons:

- The NH New Hanover application fully conforms to all applicable review criteria and is comparatively superior to the Wilmington Health application and the EmergeOrtho application.
- NH New Hanover has a demonstrated need to increase its fixed MRI scanner capacity.
- The NH New Hanover application expands MRI service access in New Hanover County and the broader service area because it will meet the needs of both inpatients and outpatients with a variety of medical conditions and will serve patients regardless of which physician practice referred them.
- Like all Novant Health facilities, NH New Hanover has a generous and easy-to-understand charity care and related policies that ensure care for all.
- NH New Hanover has multiple American College of Radiology MRI accreditations and has received numerous accolades for quality care.

**Attachment A**



# MRI Safety with Orthopedic Implants



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## KEYWORDS

- Magnetic resonance imaging • Radiofrequency-induced heating • Implant migration • Torque
- Safety

## KEY POINTS

- This study reviews the current literature on MRI safety with orthopedic implants.
- MRI is safe in patients with orthopedic implants regarding migration and torque.
- Radiofrequency-induced heating of implants during MRI showed small differences among studies, although not clinically significant.
- Pediatric patients may be at an increased risk for thermal injury if anesthetized and/or unable to report temperature change during MRI.
- A risk-to-benefit ratio should be applied when using MRIs with orthopedic implants in pediatric patients requiring sedation.

## INTRODUCTION

MRI is a valuable diagnostic tool, with utility in pediatric and musculoskeletal imaging due to its lack of ionizing radiation and excellent soft tissue contrast. A continual increase in MRI usage has been demonstrated in the United States, with a 5% rise annually, peaking at 118 examinations per 1000 population (64 in an ambulatory setting and 54 in an inpatient hospital setting).<sup>1</sup> Additionally, the United States has the second-most MRI units per capita, with a 188% increase since 1995, reaching 39 per 1 million population in 2015.<sup>2,3</sup> What makes MRI unique is the method by which the images are obtained. MRI uses a magnet to alter proton rotation, producing signals as the protons return to their baseline rotation at differing rates in various tissues of the body. The magnetic fields used to manipulate the protons during the imaging sequence come in varying strengths for different uses; however, nearly all clinically used scanners in the United States are under 3.0 T,<sup>4</sup> and only one 7.0-T scanner has received approval from the United States Food and

Drug Administration for clinical use.<sup>5</sup> Scanners with strengths over 3.0 T are routinely used in research; however, this article's focus is on recommendations on clinically relevant field strengths.

MRI is considered safer and is generally preferred in the pediatric population compared with CT scans for advanced imaging because it does not use ionizing radiation. MRI is not without risk, however, and the Food and Drug Administration<sup>6</sup> receives reports of approximately 300 adverse events associated with these examinations annually. Second-degree burns are the most commonly reported problems and are often due to the formation of internal currents (via skin-to-skin contact)<sup>7,8</sup> or from external metallic objects contacting the body (electrocardiogram leads,<sup>9</sup> pulse oximeters,<sup>10</sup> microfiber tech clothing,<sup>11</sup> medical patches,<sup>12</sup> and so forth). Projectile events (objects drawn into the magnetic field), crush injury of the digits by the patient table, patient falls, and hearing loss or tinnitus are the next most commonly reported problems with MRI, all unrelated to the presence of an orthopedic

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implant. Additionally, pediatric patients requiring anesthesia to inhibit movement during the long MRI acquisition time are at higher risk of adverse events during the MRI sequence.<sup>13-15</sup> Over the past several decades, the safety, compatibility, and imaging artifact caused by surgical implants have been tested in numerous *in vivo* and *ex vivo* studies. Because MRI units use strong magnets, metal implants pose a particular hazard with their potential for dislodgment, heating of the implant, and possible damage to surrounding tissues. Although newer orthopedic implants seem safe for MRI, concerns remain with the increasing field strength of MRI scanners. Additionally, confusion remains regarding MRI use immediately postoperatively in patients with surgical implants. This study reviews the current literature concerning the safety of MRI in patients with orthopedic implants. Information was sought about displacement, torque, and radiofrequency-induced (RF) heating of orthopedic implants, paying special attention to any articles pertaining to pediatric orthopedics.

## LITERATURE SEARCH

This study did not require institutional review board approval. PubMed was searched using the terms, "MRI and Safety and Orthopedic Implant"; "MRI and Safety and Surgical Implants"; "MRI and Safety and Medical Implants"; "MRI and Orthopedic Hardware and Soft Tissue"; "Magnetic Resonance Imaging and Radiofrequency Heating and Metal Implants"; "MRI and Safety and Pediatric and Orthopedics"; and "MRI and Safety and Spinal Implants." Google Scholar was also searched using these terms to capture relevant articles not listed on PubMed. Only articles published within the past decade were reviewed and only those that discussed MRI safety pertaining to orthopedics were included. In addition, the Web site *mrifafety.com* was reviewed.

## LITERATURE SEARCH RESULTS

The PubMed search produced 402 articles. After narrowing the results to the past 10 years, 219 articles remained. After excluding duplicate articles, articles not pertaining to orthopedic implants, and articles discussing topics other than safety, 15 remained for review.<sup>16-30</sup> Implant displacement was discussed in 11 articles,<sup>16-22,26-28,30</sup> RF heating in 13,<sup>16-21,23-25,27,28,30</sup> and torque in 4.<sup>21,22,26,27</sup> **Table 1** summarizes the results of the 15 studies.

## Implant Displacement

Implant displacement in 1.5-T, 3.0-T, and 7.0-T scanners has been the focus of numerous studies.<sup>16-22,26-28,30</sup> The experimental studies examined the change in the hanging angle of implants in scanners during an imaging sequence compared with prior to imaging (**Fig. 1**). A displacement angle of 45° indicated that the translational force of the magnet was equivalent to the force of gravity, and an angle over 45° indicated a potential for implant displacement with MRI.<sup>21,29</sup> Overall, significant displacement in orthopedic implants was infrequent. Two studies reported deflection angles over 45° using a 7.0-T MRI.<sup>21,22</sup> In Feng and colleagues'<sup>21</sup> study, 2 stainless-steel implants showed deflection of more than 45° at 7.0 T. Dula and colleagues<sup>22</sup> reported a deflection angle of 55° for the Synergy Hip System (Smith and Nephew, Memphis, TN) (metal not reported). The deflection angle for all other implants reported was well below 45°, with most below 10° (see **Table 1**). Except for a known ferromagnetic posterior spinal implant with a deflection angle of 65°,<sup>26</sup> all other implants had no significant displacement in 1.5-T and 3.0-T scanners. All studies but 2<sup>19,28</sup> were performed in *ex vivo* conditions, and the 2 *in vivo* studies failed to demonstrate any clinically or radiographically significant implant migration. Two studies also found no detrimental effects of MRI on magnetic-controlled growing rods.<sup>27,28</sup>

## Torque

Torque describes the rotational displacement and speed at which the implant aligns with the magnetic field. Only 4 studies reported torque values.<sup>21,22,26,27</sup> Feng and colleagues<sup>21</sup> reported 1+ (minimal) torque in 2 titanium implants and 1 titanium alloy implant. Dula and colleagues<sup>22</sup> reported 2+ (moderate) torque in a pyrocarbon knee implant, a Synergy Hip System, and a titanium alloy hip stem with a cobalt-chrome head stem. They also reported 1+ (minimal) torque in a cobalt-chrome staple and an oxidized zirconium knee implant. McComb and colleagues<sup>26</sup> reported 2+ (moderate) torque in 1 highly ferromagnetic posterior spinal implant but deemed the risk to patient safety minimal, given the rigid fixation of the implant.

## Radiofrequency-induced Heating

RF heating of implants during MRI sequencing was discussed in 13 of the 15 articles,<sup>16-21,23-25,27-30</sup> with 8 showing a change

**Table 1**  
Results of reviewed articles

Author	Implant	MRI Field Strength	Deflection Angle	Torque (1–4)	Temperature Change (°C)
Yang et al, <sup>16</sup> 2009	1 Charite (Depuy Spine, Raynham, MA) 1 ProDisc-L (Depuy Synthes, Raynham, MA)	<1.5 T <1.5 T	7.5° 6.0°	NR NR	0.4 0.6
Zou et al, <sup>17</sup> 2015	7 Titanium plates and screws 7 Stainless-steel plates and screws	1.5 T 1.5 T	4.28° 7.74° <sup>a</sup>	NR NR	0.48 0.74 <sup>b</sup>
Kumar et al, <sup>18</sup> 2006	6 Stainless-steel 3 Femoral prostheses 1 Condylar blade plate 1 Femoral nail 1 Ex fix clamp 5 Titanium 1 Femoral prosthesis 1 Shoulder hemiprosthesis 1 Tibial buttress plate 1 Femoral recon nail 1 Tibial nail 1 Cobalt-chrome femoral prosthesis 1 Carbon fiber ex fix rod 2 Stainless-steel hip prostheses 1 Titanium plate	0.25 T and 1.0 T	0° 0° 0° Significant (at 1.0 T) 0° — — — — — 0° 0° 0° NR NR NR NR NR NR NR NR	NR	NR — — — — NR — — — — NR — NR 0.1–0.2 0.1 0
Makhdom et al, <sup>19</sup> 2015	19 Stainless-steel Fassier-Duval rod (Pega Medical, Laval, Canada)	1.5 T	0°	NR	0

(continued on next page)



Table 1  
(continued)

Author	Implant	MRI Field Strength	Deflection Angle	Torque (1-4)	Temperature Change (°C)
Tsukimura et al, <sup>20</sup> 2017	4 Pure titanium rods	3.0 T 7.0 T	1.0°-2.0° at 3.0 T 5.0°-6.2° at 7.0 T	NR	0.2-0.5 at 3T -0.2-0.4 at 7 T
	4 Titanium alloy rods		1.0°-2.3° at 3.0 T 5.7°-7.7° at 7.0 T		-0.3-0.3 at 3 T -0.2-0.2 at 7 T
	4 Cobalt-chrome rods		5.0°-6.0° at 3.0 T 17.8°-21° at 7.0 T		0.1-0.4 at 3 T 0-0.6 at 7T
	1 Titanium alloy/cobalt-chrome screw		3.2° at 3.0 T 10.0° at 7.0 T		0.2 at 3 T -0.3 at 7 T
Feng et al, <sup>21</sup> 2015	1 Titanium alloy cross-link bridge		2.2° at 3.0 T 6.7° at 7.0 T		0 at 3 T -0.2 at 7 T
	10 Stainless-steel	7.0 T	16°-47° (5 implants >44)	0	-0.54-0.41 (2 implants)
	6 Titanium		1°-44° (1 implant 44)	1 (2 implants)	0.21 (1 implant)
	4 Titanium alloy 2 Cobalt-chrome 2 Aluminum oxide 1 Vitallium		0°-7° 1°-2° 0°-17° 18°	— 1 (1 implant) — —	— — — —
Dula et al, <sup>22</sup> 2014	PEEK HTO plate	7.0 T	0°	0	NR
	PEEK distal radius plate		0°	0	
	Pyrocarbon knee implant		0°	2	
	Cobalt-chrome staple		23°	1	
	Oxidized zirconium knee implant		5°	1	
	Synergy Hip System		55°	2	
	Titanium alloy hip stem and cobalt-chrome-molybdenum hip stem		45°	2	
Titanium and silver-plated cannulated screw		8°	0		

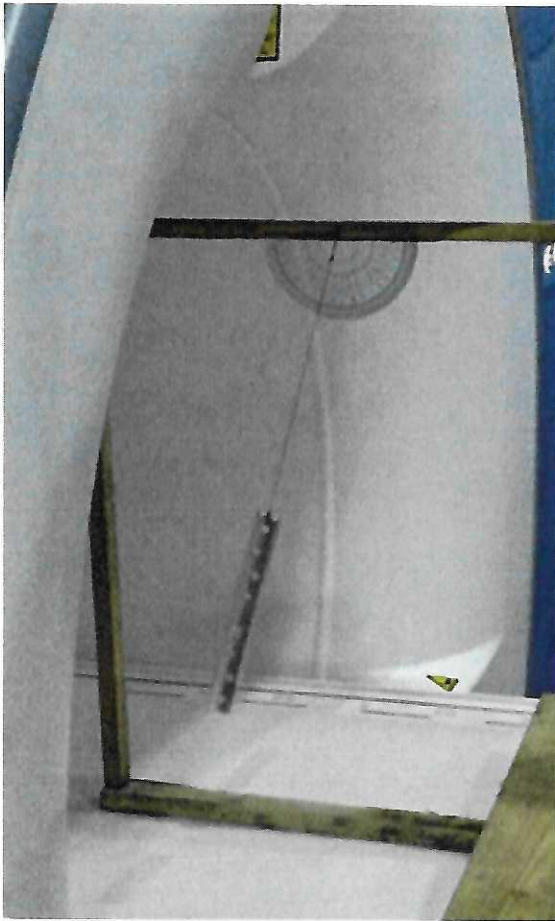
Author(s)	Implant	Field Strength	Angle	Number of Subjects	Findings
Muranaka et al, <sup>23</sup> 2011; Muranaka et al, <sup>24</sup> 2007; Muranaka et al, <sup>25</sup> 2010	Stainless-steel humeral implant	1.5 T	NR	NR	6.4–14.7 (depending on absorption rate, angle, and location)
	1 Cobalt-chrome hip implant				9.0
	1 Titanium alloy hip implant				5.3
McComb et al, <sup>26</sup> 2009	Posterior spinal fixator (Anatomica, Gothenburg, Sweden) with fixation blocks, expansion screws, and spindle bolt Highly ferromagnetic components	1.5 T and 3.0 T	65°	4	NR
Budd et al, <sup>27</sup> 2016	2 Magnetic-controlled growing rods	1.5 T	0°	0	No detectable heating
Schroeder et al, <sup>28</sup> 2018	28 Stainless-steel plates and screws in pediatric patients with DDH	1.5 T	No implant migration or loosening	NR	No thermal effects to soft-tissues noted
Poon et al, <sup>29</sup> 2017	3 Magnetic-controlled growing rods	1.5 T	NR	NR	0.39–1.61
Mansour et al, <sup>30</sup> 2009	4 Steinmann pins (varying sizes) Tractor bow (external for traction) Kirschner wire bow (external for traction)	1.5 T	<10° <45° Highly ferromagnetic removed from study	NR NR —	<3 1.9 —

Abbreviations: DDH, developmental hip dislocation; ex fix, external fixation; HTO, high tibial osteotomy; PEEK, polyetheretherketone; 1 torque, mild or low; 2 torque, moderate; greater than 3 torque, high; NR, not reported.

<sup>a</sup> The difference in value between the titanium implants and stainless-steel implants was significant ( $P < .001$ ).

<sup>b</sup> There was an absence of blood circulation in the cadaver swine leg tested. In humans, this value would be lower.





**Fig. 1.** Demonstration of the experimental setup used to assess hanging angle displacement of implants during an imaging sequence. (From Zou YF, Chu B, Wang CB, et al. Evaluation of MR issues for the latest standard brands of orthopedic metal implants: plates and screws. *Eur J Radiol* 2015;84(3):451; with permission.)

of less than  $1^{\circ}\text{C}$ .<sup>16–21,27,28</sup> Only 5 studies showed more than  $1^{\circ}\text{C}$  change.<sup>23–25,29,30</sup> Muranaka and colleagues<sup>23–25</sup> found increases from  $5.3^{\circ}\text{C}$  to  $14.7^{\circ}\text{C}$  in a stainless-steel humeral implant and cobalt-chrome and titanium hip implants. These experiments were performed in a laboratory setting using a tissue-equivalent, gel-filled polypropylene model. The humeral implant showed a  $12.3^{\circ}\text{C}$  increase at 2-cm depth after a 15-minute 1.5-T MRI sequence.<sup>23</sup> In these studies, implants deeper (6 cm) in the model had less temperature rise ( $<5.0^{\circ}\text{C}$ ), and the edges of the implants demonstrated the most volatile temperature increases ( $14.7^{\circ}\text{C}$ ). The maximum temperature rise was noted when the implant tip was parallel with the static magnetic field, and when the implant was moved away from the center of the irradiation coil (static magnetic field), less temperature rise was noted.

## DISCUSSION

The concerns of MRI in patients with metal implants are centered on theoretic migration and RF heating of implants, causing damage to surrounding tissues. Numerous studies examining the safety of surgical implants have been published over the past 3 decades, concluding that most passive (no power associated with their operation) nonferromagnetic or weakly ferromagnetic implants are safe for patients in any setting requiring an MRI at 1.5 T or less.<sup>31–34</sup> The results of this review are similar. In general, MRI with field strengths up to 7.0 T can safely be used in patients with orthopedic implants, because the risk of implant-based complications is extremely low.

In this review, 3 of the studies cited areas of concern regarding displacement of orthopedic implants during MRI.<sup>21,22,26</sup> In total, 4 implants violated the previously stated goals for deflection angles being below  $45^{\circ}$ . The clinical relevance of orthopedic implant migration during MRI remains in doubt, however, and the results of this review support the assessment that in vivo orthopedic implants are likely unaffected by translational forces (even if they exceed  $45^{\circ}$  under experimental protocols) because they are firmly fixed to bone or are sutured in place, providing sufficient counter-force during imaging.<sup>30</sup> Additionally, in the 2 in vivo studies of this cohort, no clinical or radiographic evidence of implant migration was found after 1.5-T MRI sequencing in osteogenesis imperfecta patients with Fassier-Duval rods<sup>19</sup> or in 28 pediatric patients with developmental hip dysplasia treated with osteotomy and stainless-steel fixation,<sup>28</sup> thus supporting the hypothesis of rigid implant fixation being sufficient to secure the implants in place.

Concerns also exist in the literature regarding RF heating of orthopedic implants. RF heating theoretically occurs due to eddy currents in implants paralleling the static magnetic field of the scanner and causes heating and tissue damage.<sup>17,18,25</sup> Of this cohort, 5 studies reported temperature increases beyond the accepted range of  $1^{\circ}\text{C}$ , and 3 studies reported temperature increases of  $5.3^{\circ}\text{C}$  to  $14.7^{\circ}\text{C}$ .<sup>23–25,29,30</sup> These 3 outliers were ex vivo studies using a tissue-equivalent model with “the same electrical properties of muscle” and failed to document the baseline temperature change of the model during imaging without hardware implanted.<sup>23–25</sup> This lack of a control group calls into question if the temperature increases were due to baseline heating of the model or to RF



heating of the implant. Although the results of these 3 studies are alarming, the insufficiencies in their methods breed skepticism regarding their clinical utility. All other studies of the cohort found the temperature change to be negligible, and both *in vivo* studies had zero patients reporting issues relating to RF heating or subjective burning.<sup>19,28</sup> In short, fears of temperature increases and subsequent tissue damage from RF heating may be unfounded, as suggested by the other studies.<sup>19,28,30</sup>

The effect of magnetic field strength has been studied. Although nearly all clinically used scanners in the United States are 3.0 T or below, 3 studies included in this cohort were performed at 7.0 T,<sup>20–22</sup> a strength often reserved for research purposes. Displacement forces generally increased with increasing magnetic field strength, but most implants remained in their accepted ranges at 7.0 T. RF heating was not associated with field strength, and did not demonstrate increases in temperature with increasing field strength.<sup>20</sup> With recent approval of the first clinical 7.0-T scanner in the United States,<sup>5</sup> little evidence supports limiting clinical use of MRI due to magnetic field strength.

Confusion remains regarding the use of MRI immediately postoperatively, and there is a paucity of recent literature discussing this issue in correlation with orthopedic implants. Shellock<sup>31</sup> stated that patients with passive nonferromagnetic implants can safely undergo MRI at 1.5 T or less immediately postoperatively, but if an implant is weakly magnetic, practitioners should wait 6 weeks to 8 weeks after the procedure. This statement was referring to coils, filters, and stents, however, that could migrate due to their lack of rigid fixation, not orthopedic implants affixed to bone or when displacement is not a problem.<sup>30</sup> Furthermore, other articles have not reported adverse events related to early postoperative MRI (2 hours–1 day) in the presence of implants,<sup>28,32</sup> and early postoperative MRI remains the standard of care after spinal surgery in patients with postoperative neurologic changes.<sup>35–37</sup>

Image artifact in patients with metal implants does not pose a direct hazard to the patient but can lead to misinterpretation of the results. All metals generate image artifact regardless of their ferromagnetic properties and become an issue if the area of interest is near the implant. Although artifact was outside the scope of this study, 7 articles directly discussed artifact distortion with orthopedic implants.<sup>16–19,23,27,28</sup> In 2 *in vivo* studies,<sup>19,28</sup> image distortion was not present, although it was problematic in other studies.<sup>16–18,23,27</sup> Modifications of MR pulse

sequences and optimization of scanning parameters, however, such as field of view, fast spin-echo, and short-tau inversion recovery, can minimize image distortion.<sup>17,18</sup> The ordering practitioner should weigh the benefits of each imaging sequence in relation to the possible image distortion of the implant. Also, the presence of bullets, shrapnel, and other foreign bodies was not examined in this study, but these articles may pose a threat of migration during imaging.<sup>38–40</sup> Clinical judgment and appropriate caution are warranted when foreign bodies are located near vital organs or the spine. As with all metallic implants, the composition of the foreign bodies affects the possible MRI interactions, with steel objects posing the greatest risk.

In the United States, the use of MRI continues to increase, with minimal associated adverse events. MRIs have a positive risk-to-benefit ratio, with 118 annual examinations per 1000 population in the United States<sup>1</sup> and only 300 adverse events.<sup>6</sup> Appropriate caution remains necessary, however, when ordering MRI in children. Pediatric patients are more likely to require sedation to inhibit movement, thus leaving them unable to express any possible issues that might arise during scanning or during recovery.<sup>13–15</sup>

The limitations of this study include that most of articles examined were laboratory-based studies, with only 2 retrospective clinical studies.<sup>19,28</sup> Additionally, only 2 studies<sup>19,28</sup> focused on pediatric patients. Lastly, zero reports of thermal burns via orthopedic implants or instances of implant migration have been published in the past 10 years, so the true risk of MRI is difficult to determine.

In summary, MRI is safe after orthopedic device implantation and can be performed postoperatively with little concern regarding implant migration. There is conflicting information regarding RF heating of implants, and various implant and patient-specific factors are involved with this phenomenon. Although implants pose minimal risk to patients, individual assessment of implant properties and MRI-related interactions is warranted and can be easily investigated. A risk-to-benefit ratio should be applied when deciding to use MRI in pediatric patients. If the information gained from the MRI is more valuable than the potential risk of anesthesia, migration, or heating, which is extremely low, then the study is likely warranted.

## REFERENCES

1. Organization for Economic Cooperation and Development. Magnetic resonance imaging (MRI)



- exams. [Web.]. 2017. Available at: <https://data.oecd.org/healthcare/magnetic-resonance-imaging-mri-exams.htm>. Accessed December 12, 2017.
2. Organization for Economic Cooperation and Development. Magnetic resonance imaging (MRI) units. [Web.]. 2016. Available at: <https://data.oecd.org/healthqt/magnetic-resonance-imaging-mri-units.htm>. Accessed December 12, 2017.
  3. Centers for Disease Control and Prevention. Table 123. Number of magnetic resonance imaging (MRI) units and computed tomography (CT) scanners: Selected countries, selected years 1990–2009. Health, United States, 2011 [Web.]. 2011. Available at: <https://www.cdc.gov/nchs/hsr/contents2011.htm#123>. Accessed December 12, 2017.
  4. Rinck P, editor. Facts and figures. magnetic resonance in medicine. A critical introduction. The basic textbook of the European magnetic resonance forum. 11th edition. 2017. Available at: <http://magnetic-resonance.org/ch/21-01.html?q=facts>. Accessed January 2, 2018.
  5. Caccamo S. FDA clears first 7T magnetic resonance imaging device. [Web.]. 2017. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm580154.htm>. Accessed December 12, 2017.
  6. United States Food and Drug Administration. MRI (Magnetic Resonance Imaging) Benefits and Risks. [Web.]. 2017. Available at: <https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/ucm482765.htm>. Accessed December 12, 2017, 2017.
  7. Eising EG, Hughes J, Nolte F, et al. Burn injury by nuclear magnetic resonance imaging. *Clin Imaging* 2010;34(4):293–7.
  8. Friedstat JS, Moore ME, Goverman J, et al. An unusual burn during routine magnetic resonance imaging. *J Burn Care Res* 2013;34(2):e110–1.
  9. Abdel-Rehim S, Bagirathan S, Al-Benna S, et al. Burns from ECG leads in an MRI scanner: case series and discussion of mechanisms. *Ann Burns Fire Disasters* 2014;27(4):215–8.
  10. Haik J, Daniel S, Tessone A, et al. MRI induced fourth-degree burn in an extremity, leading to amputation. *Burns* 2009;35(2):294–6.
  11. Pietryga JA, Fonder MA, Rogg JM, et al. Invisible metallic microfiber in clothing presents unrecognized MRI risk for cutaneous burn. *AJNR Am J Neuroradiol* 2013;34(5):E47–50.
  12. Kuehn BM. FDA warning: remove drug patches before MRI to prevent burns to skin. *JAMA* 2009;301(13):1328.
  13. Kaila R, Chen X, Kannikeswaran N. Postdischarge adverse events related to sedation for diagnostic imaging in children. *Pediatr Emerg Care* 2012;28(8):796–801.
  14. Tith S, Lalwani K, Fu R. Complications of three deep sedation methods for magnetic resonance imaging. *J Anaesthesiol Clin Pharmacol* 2012;28(2):178–84.
  15. Srinivasan M, Turmelle M, Depalma LM, et al. Procedural sedation for diagnostic imaging in children by pediatric hospitalists using propofol: analysis of the nature, frequency, and predictors of adverse events and interventions. *J Pediatr* 2012;160(5):801–6.e1.
  16. Yang CW, Liu L, Wang J, et al. Magnetic resonance imaging of artificial lumbar disks: safety and metal artifacts. *Chin Med J (Engl)* 2009;122(8):911–6.
  17. Zou YF, Chu B, Wang CB, et al. Evaluation of MR issues for the latest standard brands of orthopedic metal implants: plates and screws. *Eur J Radiol* 2015;84(3):450–7.
  18. Kumar R, Lerski RA, Gandy S, et al. Safety of orthopedic implants in magnetic resonance imaging: an experimental verification. *J Orthop Res* 2006;24(9):1799–802.
  19. Makhdom AM, Kishta W, Saran N, et al. Are Fassier-Duval rods at risk of migration in patients undergoing spine magnetic resonance imaging? *J Pediatr Orthop* 2015;35(3):323–7.
  20. Tsukimura I, Murakami H, Sasaki M, et al. Assessment of magnetic field interactions and radiofrequency-radiation-induced heating of metallic spinal implants in 7 T field. *J Orthop Res* 2017;35(8):1831–7.
  21. Feng DX, McCauley JP, Morgan-Curtis FK, et al. Evaluation of 39 medical implants at 7.0 T. *Br J Radiol* 2015;88(1056):20150633.
  22. Dula AN, Virostko J, Shellock FG. Assessment of MRI issues at 7 T for 28 implants and other objects. *AJR Am J Roentgenol* 2014;202(2):401–5.
  23. Muranaka H, Horiguchi T, Ueda Y, et al. Evaluation of RF heating due to various implants during MR procedures. *Magn Reson Med Sci* 2011;10(1):11–9.
  24. Muranaka H, Horiguchi T, Usui S, et al. Dependence of RF heating on SAR and implant position in a 1.5T MR system. *Magn Reson Med Sci* 2007;6(4):199–209.
  25. Muranaka H, Horiguchi T, Ueda Y, et al. Evaluation of RF heating on hip joint implant in phantom during MRI examinations. *Nihon Hoshasen Gijutsu Gakkai Zasshi* 2010;66(7):725–33.
  26. McComb C, Allan D, Condon B. Evaluation of the translational and rotational forces acting on a highly ferromagnetic orthopedic spinal implant in magnetic resonance imaging. *J Magn Reson Imaging* 2009;29(2):449–53.
  27. Budd HR, Stokes OM, Meakin J, et al. Safety and compatibility of magnetic-controlled growing rods and magnetic resonance imaging. *Eur Spine J* 2016;25(2):578–82.
  28. Schroeder KM, Haurno LS, Browne TS, et al. Evaluation of postoperative MRI in pediatric patients



- after orthopaedic hardware implantation. *Curr Orthop Pract* 2018;29(2):140–3.
29. Poon S, Nixon R, Wendolowski S, et al. A pilot cadaveric study of temperature and adjacent tissue changes after exposure of magnetic-controlled growing rods to MRI. *Eur Spine J* 2017;26(6):1618–23.
  30. Mansour A, Block J, Obremesky W. A cadaveric simulation of distal femoral traction shows safety in magnetic resonance imaging. *J Orthop Trauma* 2009;23(9):658–62.
  31. Shellock FG. Magnetic resonance safety update 2002: implants and devices. *J Magn Reson Imaging* 2002;16(5):485–96.
  32. Shellock FG. MRISafety.com. [Web.]. 2017. Available at: <http://www.mrisafety.com/>. Accessed September 31, 2017.
  33. Shellock FG. Biomedical implants and devices: assessment of magnetic field interactions with a 3.0-Tesla MR system. *J Magn Reson Imag JMRI* 2002;16(6):721–32.
  34. Tsai LL, Grant AK, Morteale KJ, et al. A practical guide to MR imaging safety: what radiologists need to know. *Radiographics* 2015;35(6):1722–37.
  35. Bommireddy R, Kamat A, Smith ET, et al. Magnetic resonance image findings in the early post-operative period after anterior cervical discectomy. *Eur Spine J* 2007;16(1):27–31.
  36. Crocker M, Jones TL, Rich P, et al. The clinical value of early postoperative MRI after lumbar spine surgery. *Br J Neurosurg* 2010;24(1):46–50.
  37. Leonardi MA, Zanetti M, Saupe N, et al. Early post-operative MRI in detecting hematoma and dural compression after lumbar spinal decompression: prospective study of asymptomatic patients in comparison to patients requiring surgical revision. *Eur Spine J* 2010;19(12):2216–22.
  38. Martinez-del-Campo E, Rangel-Castilla L, Soriano-Baron H, et al. Magnetic resonance imaging in lumbar gunshot wounds: an absolute contraindication? *Neurosurg Focus* 2014;37(1):E13.
  39. Eshed I, Kushnir T, Shabshin N, et al. Is magnetic resonance imaging safe for patients with retained metal fragments from combat and terrorist attacks? *Acta Radiol* 2010;51(2):170–4.
  40. Dedini RD, Karacozoff AM, Shellock FG, et al. MRI issues for ballistic objects: information obtained at 1.5-, 3- and 7-Tesla. *Spine J* 2013;13(7):815–22.

**Attachment B**

Certificate of Need  
Application Log for May 1, 2023 Reviews

HSA	County	Project ID	Date Application Received	Proposed Capital Expenditure	Fee Owed	Competitive?	Expedited Review Requested?	Public Hearing Required	Written Comment End Date	FID	Facility	Project Type	Project Description	Review-Analyst	Co-Signer
II	Alamance	G-012365-23	4/17/2023	\$2,053,000	\$8,159	Yes	Not Requested	Yes	5/31/2023	230323	Alliance Healthcare Services Mobile MRI 2023	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
I	Buncombe	B-012363-23	4/17/2023	\$200,357	\$5,000	No	Received	No	5/31/2023	923279	The Laurels of Summit Ridge	COR/Change of Scope	COR for Project ID #B-12182-22 (Relocate no more than 8 NF beds from the Laurels of GreenTree Ridge for a total of no more than 68 NF beds and 23 ACH beds upon completion of this project and Project ID# B-11270-16 (relocate 29 ACH beds))	Terris Riley	Lisa Pittman
I	Buncombe	B-012380-23	4/17/2023	\$29,374,000	\$50,000	No	Not Requested	Yes	5/31/2023	230341	Mission Hospital-Mission FSER West ED	ED	Develop a freestanding ED in west Buncombe County licensed under Mission Hospital	Tanya Saporito	Mike McKillip
III	Cabarrus	F-012367-23	4/17/2023	\$110,113,480	\$50,000	No	Not Requested	Yes	5/31/2023	943049	Atrium Health Cabarrus	Hospital	Develop 65 acute care beds pursuant to the 2023 SMFP need determination	Julie Faenza	Micheala Mitchell
IV	Durham	J-012378-23	4/17/2023	\$2,794,002	\$10,382	Yes	Denied	Yes	5/31/2023	230334	Duke Imaging Mobile MRI	MRI	Acquire one mobile MRI pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
IV	Durham	J-012377-23	4/17/2023	\$5,614,982	\$18,845	No	Not Requested	Yes	5/31/2023	956937	Duke North Pavilion	COR/Change of Scope	COR for Project J-11613-18 (renovate and upfit space in North Pavilion for hospital services)	Terris Riley	Lisa Pittman
IV	Durham	J-012357-23	4/14/2023	\$1,572,837	\$6,719	Yes	Denied	Yes	5/31/2023	230317	EmergoOrtho Mobile MRI Blue Ridge/Foothills Route	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
IV	Durham	J-012358-23	4/14/2023	\$4,255,500	\$5,767	Yes	Denied	Yes	5/31/2023	230319	EmergoOrtho Mobile MRI Triad Route	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
IV	Durham	J-012359-23	4/14/2023	\$1,073,386	\$5,220	Yes	Denied	Yes	5/31/2023	230320	EmergoOrtho Mobile MRI Triangle Route	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
II	Forsyth	G-012362-23	4/17/2023	\$100,000	\$5,000	Yes	Denied	Yes	5/31/2023	230321	Well Care Home Health of Forsyth County	Home Health	Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination	Ena Lightbourne	Gloria Hale
II	Forsyth	G-012364-23	4/17/2023	\$231,975	\$5,000	Yes	Denied	Yes	5/31/2023	230322	Novant Health Home Care-Forsyth	Home Health	Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination	Ena Lightbourne	Gloria Hale
II	Forsyth	G-012369-23	4/17/2023	\$115,464	\$5,000	Yes	Not Requested	Yes	5/31/2023	230327	Aveanna Home Health - Forsyth	Home Health	Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination	Ena Lightbourne	Gloria Hale
II	Forsyth	G-012356-23	4/14/2023	\$65,000	\$5,000	Yes	Denied	Yes	5/31/2023	230318	PHC Home Health-Forsyth	Home Health	Develop a new Medicare-certified home health agency pursuant to the 2023 SMFP need determination	Ena Lightbourne	Gloria Hale
II	Guilford	G-012372-23	4/17/2023	\$2,296,107	\$8,888	Yes	Not Requested	Yes	5/31/2023	230325	Novant Health-Norfolk, LLC (1)	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
II	Guilford	G-012373-23	4/17/2023	\$2,296,107	\$8,888	Yes	Not Requested	Yes	5/31/2023	230326	Novant Health-Norfolk, LLC (2)	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
II	Guilford	G-012352-23	4/5/2023	\$1,420,339	\$6,261	No	Received	No	5/31/2023	230309	CK Vascular Center	ORS	Develop one dedicated vascular access OR for HSA II pursuant to the 2023 SMFP need determination	Cindy Bradford	Lisa Pittman

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III	Mecklenburg	F-012368-23	4/17/2023	\$2,281,309	\$8,844	Yes	Not Requested	Yes	5/31/2023	230328	Carolina Neurosurgery & Spine (1)	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
III	Mecklenburg	F-012381-23	4/17/2023	\$2,281,309	\$8,844	Yes	Not Requested	Yes	5/31/2023	230333	Carolina Neurosurgery & Spine (2)	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
V	Moore	H-012360-23	4/14/2023	\$27,766,529	\$50,000	No	Not Requested	Yes	5/31/2023	220730	Southern Pines Surgery Center	ORS	Develop a new ASF by relocating two existing ORs from Surgery Center of Pinehurst and 4 procedure rooms	Julie Faenza	Micheala Mitchell
V	New Hanover	O-012370-23	4/17/2023	\$3,163,742	\$11,491	Yes	Not Requested	Yes	5/31/2023	230324	Wilmington Health at Porters Neck- 8090 Market Street	MRI	Acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination	Tanya Saporito	Lisa Pittman
V	New Hanover	O-012374-23	4/17/2023	\$2,246,570	\$8,740	Yes	Denied	Yes	5/31/2023	230344	EmergoOrtho- Wilmington Porters Neck	MRI	Acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination	Tanya Saporito	Lisa Pittman
V	New Hanover	O-012361-23	4/14/2023	\$6,855,305	\$22,566	Yes	Not Requested	Yes	5/31/2023	943372	Novant Health New Hanover Regional Medical Center	MRI	Acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination	Tanya Saporito	Lisa Pittman
V	New Hanover	O-012353-23	4/5/2023	\$2,782,656	\$10,348	Yes	Received	Yes	5/31/2023	030359	Delaney Radiologist Group	MRI	Acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination	Tanya Saporito	Lisa Pittman
III	Stanly	F-012366-23	4/17/2023	\$5,379,000	\$18,137	No	Not Requested	Yes	5/31/2023	040560	Atrium Health Imaging Locust	MRI	Acquire one fixed MRI scanner pursuant to the 2023 SMFP need determination	Cindy Bradford	Gloria Hale
IV	Wake	J-012375-23	4/17/2023	\$2,337,215	\$9,012	Yes	Denied	Yes	5/31/2023	230330	PHSNC Mobile MRI Scanner	MRI	Acquire one mobile MRI scanner pursuant to the 2023 SMFP need determination	Greg Yakaboski	Mike McKillip
IV	Wake	J-012371-23	4/17/2023	\$10,575,554	\$33,727	Yes	Not Requested	Yes	5/31/2023	953429	UNC REX Hospital	LINAC	Acquire one linear accelerator pursuant to the 2023 SMFP need determination	Julie Faenza	Micheala Mitchell
IV	Wake	J-012382-23	4/17/2023	\$4,313,930	\$14,942	No	Received	No	5/31/2023	110707	Wake County Health & Rehab Center	NF	COS/COR for Project ID# J-8713-11 (Develop a new 95-bed nursing facility) to relocate 25 NF beds from Enfield Oaks Nursing and Rehabilitation Center (Halifax County) for a total of 120 NF beds upon project completion	Terris Riley	Gloria Hale
IV	Wake	J-012383-23	4/17/2023	\$6,703,093	\$22,109	No	Not Requested	Yes	5/31/2023	101149	Britthaven of Holly Springs	NF	COS/COR for Project ID# J-12123-21 (Cost overrun for Project ID# J-8618-10 (Develop a new 90-bed nursing facility) to relocate 30 NF beds from Enfield Oaks Nursing and Rehabilitation Center (Halifax County) for a total of 120 NF beds upon project completion	Terris Riley	Gloria Hale
IV	Wake	J-012376-23	4/17/2023	\$9,601,883	\$30,806	Yes	Not Requested	Yes	5/31/2023	090441	WakeMed Medical Park Imaging/Lab Services	LINAC	Acquire one linear accelerator pursuant to the 2023 SMFP need determination	Julie Faenza	Micheala Mitchell

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IV	Wake	J-012384-23	4/17/2023	\$34,131,928	\$50,000	No	Not Requested	Yes	5/31/2023	230342	Triangle Health and Rehabilitation Center	NF	Develop a new 120-bed NF by relocating 30 NF beds from Bethany Woods Nursing and Rehabilitation (Stanly County), 5 NF beds from Enfield Oaks Nursing and Rehabilitation Center (Halifax County), 9 NF beds from Harmony Hall Nursing and Rehabilitation Center (Lenoir County), 10 NF beds from Maple Grove Health and Rehabilitation Center (Guilford County), 12 NF beds from Pine Ridge Health and Rehabilitation Center in (Davidson County), 20 NF beds from University Place Nursing and Rehabilitation Center (Mecklenburg County), 20 NF beds from Westwood Hills Nursing and Rehabilitation center (Wilkes County), and 14 NF beds from Willow Creek Nursing and Rehabilitation Center (Wayne County)	Cindy Bradford	Gloria Hale
IV	Wake	J-012379-23	4/17/2023	\$33,518,000	\$50,000	Yes	Not Requested	Yes	5/31/2023	230343	Duke Radiation Oncology Garner	LINAC	Acquire one linear accelerator pursuant to the 2023 SMFP need determination	Julie Faenza	Micheala Mitchell
IV	Wake	J-012354-23	4/12/2023	\$34,454,934	\$50,000	No	Not Requested	Yes	5/31/2023	230316	Liberty Commons Nursing & Rehabilitation Center of Wake County	NF	Develop a new 125-bed NF by relocating 19 NF beds from Liberty Commons of Alamance, 28 NF beds from Cross Creek (Hyde County), 20 NF beds from Oak Forest (Forsyth County), and 58 NF beds from Golden Years (Cumberland County)	Cindy Bradford	Micheala Mitchell
IV	Wake	J-012355-23	4/12/2023	\$32,801,423	\$50,000	No	Not Requested	Yes	5/31/2023	230315	Liberty Commons Rehabilitation and Nursing Care of Raleigh	NF	Develop a new 125-bed NF by relocating 122 NF beds from Liberty Commons of Carteret County (Project ID # P-12179-22 (Develop a new facility by relocating no more than 122 NF beds from Harborview Health Care Center)) and 3 NF beds from Pinehurst Healthcare and Rehabilitation (Moore County)	Cindy Bradford	Micheala Mitchell
		<b>Totals</b>		<b>33</b>	<b>\$381,770,916</b>	<b>\$653,693</b>									