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Re:

Project ID	Freestanding Fixed MRI (Smithfield)
J-12507-24	Johnston Imaging, LLC
J-12504-24	Freestanding Fixed MRI Scanner (Clayton)
	RR WM Imaging Clayton, LLC

Dear Ms. Bradford:

On behalf of RR WM Imaging Clayton, LLC, (“RRWMIC”) applicant for Project ID J-12504-24, thank you for the opportunity to comment on the above referenced applications for one new fixed MRI scanner in Johnston County. We understand that your time is limited, so we focus on key issues in this review.

We believe that the applications submitted confirm and support the proposal from RR WM Imaging, LLC as the most qualified to address the identified need.

We understand that the Agency must consider the extent to which each applicant meets all statutory review criteria in G.S 131E-183. Because Johnston Imaging failed to provide all required information about its financial operations, we believe the Agency should find it non-conforming to Criterion 18a. Because proposed volume shifts will reduce the number of procedures completed on existing fixed MRI units owned by the parent company, this CON application may also be non-conforming to Criterion 1, Policy Gen-3. For details see [Attachment B](#).

We do not believe the Johnston Imaging, LLC proposal is fully conforming. However, we understand that the Agency has discretion regarding comparative factors when the Agency finds that all applicants conform to the statutory review criteria. In the event the Agency does not agree with our analysis, we offer the following observations about the comparative effectiveness of the two applications.

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Equity in access is important. We ask that you particularly weigh each application for the extent to which the proposed project will *improve* access to MRI services for Johnston County residents.

Both applicants or their related party owners have experience with MRI services and CON applications. Both currently provide health services in Johnston County.

With only one new fixed MRI scanner available to Johnston County this year, a competitor should enhance value, access and quality. In this review batch, RRWMIC is the only new competitor in Johnston County. Though, technically, neither applicant currently owns MRI equipment in Johnston County, Johnston Imaging, LLC (“Johnston Imaging”) has only one member, Johnston Health Services Corporation (JHSC). JHSC owns the only two fixed MRI scanners in Johnston County. RR WM Imaging, Clayton, LLC owns none. It provides access to MRI services in Johnston County by means of a service arrangement with Akumin, Inc, a Florida-based company that owns mobile MRI equipment. Neither RRWMIC nor any of its affiliates have ownership rights to that MRI equipment nor can they guarantee continuous presence of the MRI service in Johnston County. In fact, Akumin can provide only 20 hours a week of mobile MRI service in Clayton.

Proposed locations differ. Raleigh Radiology Clayton will be in the center of the largest number of county residents. Johnston Imaging, LLC. proposes to locate in the geographic center of the county –not the population center – and on the same campus with an existing MRI unit.

Johnston County has no freestanding MRI scanners. JHSC scanners are hospital-based. Though both CON applications propose freestanding settings, the proposals differ significantly for the customer. RRWMIC proposes a physician office-based MRI unit in a physician office diagnostic center that also offers complementary imaging services. Patients / customers will receive only one bill for services; the bill will include both the physician fee for interpretations and the technical fee for production of the image(s). In reviewing the applications. Johnston Imaging will bill patients only for the technical fee. Another provider will bill for the physician interpretation. The amount of the physician fee is not included in the Johnston Imaging application. it is important to allow for this distinction when making any comparison of costs and revenues.

Because Johnston Imaging does not include the physician fee element of its MRI service, the Agency should recognize that difference and deduct Physician Professional Fees on Form F.3.b Expenses for RRWMIC from its Total Expenses before comparing unit costs of RRWMIC with those of Johnston Imaging. Similarly, any comparison of Net Revenue should adjust out the Physician fee charge element from RRWMIC Net Revenues. To calculate the adjusted Net Revenue, the Agency can reduce RRWMIC Net Revenue to 80 percent of the Net Revenue line on Form F.2.b.

Another notable difference is in customer access approach. RRWMIC acknowledges Johnston County’s low MRI use rates as a sign of access disparity, and it budgets generously for an outreach program. See Marketing line item on Form F.3.b. By contrast, Johnston Imaging, Inc. presents a passive, slow growth program, assuming gradual word of mouth will result in patients choosing to “shift” from its existing hospital-based MRI units in both Clayton and Smithfield to its freestanding MRI in Smithfield.

Johnston Imaging points out proposed enhancements for whole body imaging-- a sophisticated and expensive scan modality for certain cancer detection. It mentions myeloma. Whole body MRI imaging is not yet approved by all payors. The application provides no information about myeloma in Johnston County and no explanation of charge increases and payment limitations associated with these types of

scans. Moreover, careful examination of the vendor quote for RRWMIC shows the same capability is available on the proposed Raleigh Radiology Clayton equipment, when and if such use is appropriate.

RR WM Imaging proposes a much more accessible schedule. RRWMIC proposes weekend and extended weekday hours. Johnston Imaging proposes only a 40-hour Monday to Friday work week.

Both applicants have imaging services in Johnston County. On measures of Access to Underserved Groups, RRWMIC has a much better history of serving racial and ethnic minorities as noted in responses to Question C.6. Of all patients served at Raleigh Radiology Clayton, 38.4 percent were racial and ethnic minorities, compared to 25.0 percent by Johnston Imaging.

We encourage the Agency to include these noteworthy differences in any comparative evaluation of the two applicants. As demonstrated in the supporting information on **Attachment A**, the proposal from RRWMIC is far superior to the one from Johnston Imaging.

Thank you for the time and attention you and your staff give to reviewing these important and detailed documents. Please do not hesitate to contact me should you have any questions.

Sincerely,

Frank Manole

Franke Manole
Chief Operating Officer
RR WM Imaging, LLC

Attachment(s)

Attachments

Comparative Metrics of Applicants A
Competitive Review of J-12507-24, Johnston Imaging, LLC. B

ATTACHMENT A

Comparison of Johnston MRI 2024 CON Applications

Comparative Factor	Notes	RRWMIC	Johnston Imaging	Notes
Geographic Accessibility	closest to largest number of Johnston County patients in need	More	Less	RRClayton is a town with no MRI and closer to the largest number of county residents.
Competition	access to new or alternate provider	More	Less	RR Clayton is owned by a provider that does not own other MRI units in the county
Access by Medicare Patients	mcare as percent of gross revenue	Less	More	Johnston Imaging proposes higher percent Medicare: 51.4% vs 28.4%
Access by Medicaid Patients	mcaid as percent of gross revenue	Less	More	Johnston Imaging proposes higher percent Medicaid, 15.4% vs 8.0%
Projected avg Net Rev per MRI Procedure	lowest ANR per weighted scan	More	Less	See data. When adjusted for true comparison, RR Clayton is lower
Projected Avg Op Exp per MRI Procedure	Lowest AOE per weighted scan	More	Less	See data. When adjusted for true comparison, RR Clayton is lower
Access by Service Area Residents	Highest Percentage of SA res	More	Less	RR Clayton proposes to reach more Johnston County Residents
Competitive Value	Staffing / hours per week	More	Less	RRClayton is open more hours per week

Average Net Revenue Per Weighted Scan FY 3

Measure	RR WM Imaging	Johnston Imaging
Net Revenue Form F.2b	\$2,042,827	\$1,663,394
Net Revenue less Professional Component	\$1,634,262	\$1,634,262
Weighted Scans	6,250	4,583
Average Net Revenue per Weighted Scan	\$261.48	\$356.59

Average Operating Expense Per Weighted Scan FY 3

Measure	RR WM Imaging	Johnston Imaging
Expense Form F.3b	\$1,750,923	\$1,117,908
Net Expense less Physician Component Form F.3b	\$1,296,961	\$1,117,908
Weighted Scans	6,250	4,583
Average Expense per Weighted Scan	\$207.51	\$243.92

In past reviews, the Agency has described certain comparisons as “inconclusive” when some applicants bill Globally, and others bill Technical only. However, RRWM Imaging suggests that, in this review, although applicants’ billing approaches differ, two metrics can be compared and should be considered: Projected Average Net Revenue Per Weighted MRI Procedure and Projected Average Total Operating Cost per MRI procedure. This argument is supported by a recent ALJ decision: Pinnacle Health Services of North Carolina LLC d/b/a Cardinal Points Imaging of the Carolinas Wake Forest and Outpatient Imaging Affiliates LLC v. NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need Section, Duke University Health System Inc., Respondent-Intervenor. Final Decision, 21 DHR 04543, Office of Administrative Hearings, State of North Carolina, County of Wake, filed July 19, 2022.

The Table below summarizes the differences and how to compare them.

Global versus Technical Billing – MRI

	Global (Professional and Technical)	Technical Only
Billing	The patient receives a single bill that includes both the technical portion – the actual scan – and the professional fees – reading of the scan – from the provider where the scan occurred. Form F.2.b includes both the fee paid to the physician and the fee paid for the image.	Patient receives two bills. One for the technical portion – actual scan – from the location where the service occurred, and a second for professional fees – reading of scan. The professional fee usually comes from a radiologist who may or may not be located where the scan occurred.
Operating	The pro forma Form 3b in the CON application provides a line-item accounting for the expense associated with the physician cost..	The pro forma Form 3b in the CON application does not provide a line-item accounting for the expense associated with the physician service..

Other Measures FY 3

Measure	RR WM Imaging	Johnston Imaging
Total Johnston County Patients Ques C.3	3,864	3,588
Total Hours per week Question C.1 or elsewhere	70 (page 32)	40 (page 99)
Percentage of Racial and Ethnic Minority Patients Served in Existing program	38.4	25.0

**Competitive Review of – Freestanding Fixed MRI Smithfield
Johnston Imaging, LLC / Project ID # J-12507-24**

Overview

There are two competitive applications for the need identified in the 2024 State Medical Facilities Plan for one additional fixed Magnetic Resonance Imaging unit located in Johnston County. The application from Johnston Imaging, LLC does not provide a complete answer to, hence should be found non-conforming to Criterion 18a.

CON Review Criteria

- 18 a. 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 the service for which competition will not have a favorable impact.

Competition

In answer to question A.6, the application states:

“Neither the applicant nor a related entity owns, operates or manages any diagnostic centers in North Carolina. For informational purposes, Johnston Health Services Corporation, the sole member of Johnston Imaging LLC, owns and operates two fixed MRI scanners in Johnston County.”

Criterion 18a requires the applicant to demonstrate the expected effect of the proposed services on competition in the service area. According to the 2024 SMFP, the service area is Johnston County. The only provider of fixed MRI in the service area is the sole member of the applicant, Johnston Health Services Corporation. This applicant is not a new competitor in Johnston County.

Effectively, this applicant proposes to compete with itself in Johnston County. The only service enhancement is the MRI billing structure. The only service included in the diagnostic center is the proposed MRI. Other outpatient imaging services in the Johnston County Medical Mall do and will continue to bill at Hospital Outpatient Department rates.

The application indicates that the facility will be located in Johnston Medical Mall. The website for Johnston Medical Mall indicates that the location offers other ambulatory imaging services in Johnston Medical Mall Suite 1302, a separate suite, which the application notes operate as a hospital-based outpatient department (p34). Those

complementary diagnostic imaging services will bill at much higher rates and patients will get yet more bills for those services¹:

- Ultrasound
- 3D Mammography
- 3D Stereo Tomography Biopsy
- Stereotactic Breast Biopsy
- Bone Density Testing
- Diagnostic X-Rays

If Johnston Imaging does not offer these services in the new freestanding diagnostic center, then, at best, the Agency should ask, whether, absent the possibility of another party competing for this MRI CON, would the parent company, JHSC, have developed this project as a second MRI in the Medical Mall hospital outpatient department and billed MRI, too, at the higher hospital outpatient department rates.

Cost Effectiveness

The application indicates that “The proposed project **will reallocate some MRI utilization** from UNC Health Johnston’s two hospital campuses, postponing the need to expand hospital-based services and facility construction projects. The application provides no information on the financial impact of this reallocation on the operating cost effectiveness of those existing JHSC MRI units. This is important because Form C.2.b on pages 108 and 109 demonstrates that Utilization of UNC Health Johnston Smithfield Campus will drop by 54 percent between FY 26 and FY 29. Unit cost of existing JHSC MRI services will increase.

No. Procedures FY 26	3,992
No. Procedures FY 29	<u>1,809</u>
Difference	2,183
2,183/3992 = 54.7% reduction in procedures	

The application provides no form F.2b or F.3b for the parent company. On that basis, the application could also be considered non-conforming to Criterion 1, because the application does not demonstrate value in its proposed volumes.

Quality

The application refers to Section B.20 which discusses quality of the sole member of Johnston Imaging, JHSC. The only quality enhancement described in B.20 for the Johnston Imaging project is the lower charge associated with the freestanding IDTF billing (p30).

¹ Source: <https://www.johnstonhealth.org/locations/profile/johnston-health-ambulatory-imaging/>

Access

The application proposes an increase in Medicaid percentage of Gross Revenue. However, this increase is not a result of the project, but a byproduct of Medicaid expansion (p95).

Thus, the application does not demonstrate how the project will have a positive effect on enhanced competition in the service area. Hence, it should be found non-conforming to Criterion 18a.

JohnstonMRI2024 RRClayton Comments






J-12504-24

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