

Comments on the Competing Application for an Additional MRI Scanner in the Pasquotank/Camden/Currituck/Perquimans Service Area

October 31, 2022

Comments on the Competing Application for an Additional Fixed MRI Scanner in the Pasquotank/Camden/Currituck/Perquimans Service Area

submitted by

Sentara Advanced Imaging Solutions, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Sentara Advanced Imaging Solutions, LLC (SAIS) hereby submits the following comments related to the competing application submitted by Chesapeake Diagnostic Imaging Centers, LLC (CDIC) (Project ID # R-12266-22) to develop an additional fixed MRI scanner at Chesapeake Regional Imaging Centers-Elizabeth City (CRIC-Elizabeth City) to meet the need identified in the 2022 State Medical Facilities Plan (2022 SMFP) for the Pasquotank/Camden/Currituck/Perguimans service area. SAIS's comments on the competing application include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards¹." See N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, SAIS has organized its discussion by issue, noting some of the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria creating the non-conformity on the application.

GENERAL COMMENTS

As noted in SAIS's application, this MRI review is rather unique in that it involves a multicounty service area, while most MRI service areas are for single counties. As explained in further detail below, if the multicounty service area in this review were a single county, it would be the largest county by land area in the state. As such, it is truly remarkable that the competing applicant, out of hundreds of square miles, dozens of towns and four distinct counties <u>chose a location less than one-half mile from the approved site of the only existing fixed MRI scanner in the entire service area</u>. Given the relatively rarity of a multicounty MRI review, particularly one in which a county is proposed to have its first access to a fixed MRI scanner—ever—SAIS believes that the Agency should consider comparative factors that have been used by the Agency in similar reviews in the past, and SAIS has included those factors in the comparative analysis that follow the specific comments on the CDIC application.

Even standing alone, the CDIC application fails to demonstrate the need for a fixed MRI scanner in Pasquotank County, and instead supports the location in Currituck County, as SAIS proposes. The following issues demonstrate that CDIC is non-conforming with multiple statutory and regulatory review criteria and should not be approved:

- Failure to demonstrate that it is the most effective or least costly alternative;
- Failure to demonstrate the availability of funds for the capital and operating needs for the proposed project;
- Failure to demonstrate that its utilization projections are based on reasonable and adequately supported assumptions;
- Failure to demonstrate that it promotes access and maximizes healthcare value;
- Failure to demonstrate that it would not result in unnecessary duplication of services;

¹ SAIS is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the application filed on September 15, 2022 by SAIS (Project ID # R-12271-22).

- Failure to demonstrate that it has proposed a reasonable project development schedule; and,
- Failure to demonstrate that it has provided all the required information to be approved.

Each of these issues is discussed in turn below.

APPLICATION SPECIFIC COMMENTS

1. <u>The CDIC application fails to demonstrate that it has proposed the least costly or most effective alternative.</u>

On pages 93 and 94 of its application, CDIC discusses three alternatives it considered regarding the development of a fixed MRI:

- Maintain the status quo;
- New construction; and,
- Alternative locations in Elizabeth City.

While CDIC addresses the three alternatives above, CDIC does not address an additional alternative relevant to this review, which is the alternative of developing the proposed MRI scanner in Currituck County.

As described in Section C.1 of the CDIC application, it is applying to develop a freestanding diagnostic imaging center with MRI capability in Elizabeth City, Pasquotank County. According to Section A.4 of the application, CDIC is proposing to develop the new freestanding diagnostic imaging center at 1825 West City Drive Elizabeth City, NC. Of note, in 2020, Sentara Albemarle Medical Center (SAMC) applied to relocate its hospital (and fixed MRI scanner) from its existing site to the intersection of Halstead Boulevard Extension and Thunder Road (Project ID # R-12007-20) and, according to Google Maps, the proposed site for CDIC is approximately 2,000 feet from SAMC's new site in Pasquotank County. The only existing fixed MRI scanner in the four-county service area is located at SAMC; thus, CDIC's proposal would result in two fixed MRI scanners in Pasquotank County and zero in the three other counties that comprise the multicounty service area.

CDIC's proposal to develop the fixed MRI scanner in Pasquotank County near the new site of SAMC is not the most effective alternative, particularly because the only fixed MRI scanner in the fourcounty service area is located in Pasquotank County and because the copious amounts of information in the CDIC application support the need in Currituck County. For example, in Section C.3b of the application, <u>CDIC projects to serve more Currituck County patients than any other county</u>. In fact, as demonstrated in its response to Section C.3b, CDIC projects that over one-third (38.1 percent) of its total MRI patients in project year 3 (State Fiscal Year 2027) will originate from Currituck County. This observation is not unexpected as the Currituck County population is projected to grow significantly as discussed on page 48 of the CDIC application, *"Currituck County is growing exponentially faster than the other counties in the service area, with an annual rate of 3.1 percent, which far outpaces the total service area and the state as a whole. While all age cohorts in the total MRI service area are projected to grow at an annual rate (3.2 percent) that far outpaces all other age groups...Currituck County's elderly population is growing at a significant annual rate of 5.6 percent." Based on the statistics and the acknowledgement of* the elderly's utilization of healthcare services cited in its application, to best meet the growing population needs of the service area, CDIC could have proposed developing the MRI in Currituck County, and, in fact, CDIC's application demonstrates that a location in Currituck County would be a more effective alternative, despite the application's silence on the consideration of this alternative.

Furthermore on page 29 of its application, CDIC discusses that the top issue identified by respondents to a community health needs assessment originated from Camden and Currituck counties as the CDIC application states, "[T]he *number one issue identified by respondents to a CHNA survey was access to care. Interestingly, the largest proportion of these respondents (41%) that identified access to care as the top unmet healthcare need were from Currituck or Camden Counties—even with CRH playing a vital safety-net role in the care of these residents."* The CDIC application also discusses the fact that there are three Medically Underserved Areas in the service area, including Camden, Currituck, and Perquimans counties (and not Pasquotank County). As stated on page 51 of the application, "Camden, Currituck, and Perquimans Counties, each of which do not have an MRI unit, are all federally designated MUAs. The increased access and choice resulting from the proposed project will directly address rural and underserved populations in this MRI service area." These discussion support the need for MRI capacity in Currituck County, which, as noted above, was an alternative not even considered by CDIC.

In addition to the growing population in the service area noted above, the CDIC application also discusses the fact that there is an increase in development activity in Currituck County. Pages 52 and 53 of the application states, "Currituck County is driving the growing and aging population in the service area. According to the Currituck 2040 Vision Plan, the mainland of Currituck County is experiencing a conversion from rural farmland to exurban, suburban, and residential communities...There are also a few major economic development projects occurring in Currituck County. One project is the Mid-Currituck Bridge (aka Mid-County Bridge), which will be a sevenmile, two lane toll bridge that will connect Aydlett to Corolla, creating a second crossing of the Currituck Sound to help alleviate congestion and improve flow of evacuation traffic in the event of hurricane or severe storm." On page 54, the application goes on to discuss the develop of Currituck Station, which is "a long-term economic development (over a 20 to 25-year period) mixed-use plan that blends residential, commercial, cultural, institutional, and entertainment uses. Currituck Station, containing more than 3,000 acres adjacent to the border of Virginia, is located on the western side of the county (168 Caratoke Highway in Moyock). One of the main goals of the Currituck Station project is to create jobs. In 2021, Tractor Supply Company broke ground for a store in Currituck Station and is now open for business. The Coastal Virginia Offshore Wind ("CVOW") Project drives economic development via job creation and billions of dollars in project investment; the wind industry invests heavily in local communities, providing significant revenue in the form of property, state, and local taxes. CVOW will be anchored in the Hampton Roads region and will deliver clean, renewable energy to the grid and plans to be fully constructed by 2026. Once CVOW is entirely built, it can power up to 660,000 homes and create 1,100 jobs.

To reiterate, all of these discussions are in the CDIC application, yet it fails to even consider locating the proposed MRI scanner in Currituck County. Based on CDIC's own analysis in its application, it fails to demonstrate that it proposed the least costly or most effective alternative in accordance with Criterion 4. As such, the CDIC application is non-conforming with Criterion 4, and by extension Criteria 1, 3, 6 and 18a.

2. CDIC's initial operating expenses are understated, and it has failed to demonstrate the availability of funds for the capital and operating needs for the proposed project.

CDIC calculates its initial operating expenses (IOE) of \$24,100 on page 97 of the application and states its assumption that the initial operating expenses will maximize after the initial 12-month period. CDIC does not provide detailed calculations to show how the \$24,100 was determined; however, it is clear from the financial information provided in the application that this IOE is understated.

According to Form F.2b, CDIC expects to operate at a net loss of \$104,315 for partial year 2024. If depreciation expense (a non-cash item) is removed, the loss will be \$51,080. At a minimum, CDIC's IOE will be greater after three months (\$51,080) than the 12-month value provided (\$24,100). However, this value assumes that it will receive payments immediately which is inconsistent with Section P.

Per Section P milestone 15, CDIC will not have Medicare or Medicaid certification or facility accreditation until July 1, 2024, three months after it begins operations. It is likely that its reimbursement will be minimal during this period while it awaits certification and accreditation. CDIC did not factor this delay in reimbursement in its initial operating expenses. According to Form F.2b, the expected cash expenses during this period are \$254,617 (total expenses less depreciation for partial year 2024), which represents just three months. On page 98, CDIC states that it expects expenses to exceed projected revenues for the first 12 months of operations; as such the actual initial operating expenses will be higher. Regardless of the actual amount, it is clear that CDIC's initial operating expenses are significantly understated.

Thus, CDIC fails to reasonably demonstrate the availability of funds or the capital and operating needs for the proposed project, as well as the financial feasibility of the project, and its application is non-conforming with Criterion 5.

3. CDIC fails to demonstrate that its utilization projections are based on reasonable and adequately supported assumptions.

The utilization projections and assumptions in Form C include multiple inconsistencies as well as several unreasonable and unsupported assumptions, as detailed below.

The number of patients cited in Step 1 is inconsistent with the number of patients cited in Step 2. As shown in the table on page 147 of the CDIC application and excerpted below, the total number of patients for 2018 through 2021 is 9,468 (2,097 + 2,451 + 2,353 + 2,567 = 9,468).

Historical Service Area Outpatient MRI Procedures at Chesapeake Facilities					
					2018-21
County	2018	2019	2020	2021	CAGR%
CAMDEN	249	330	322	413	18.4%
CURRITUCK	1,106	1,304	1,231	1,228	3.5%
PASQUOTANK	577	624	617	731	8.2%
PERQUIMANS	165	193	183	195	5.7%
Grand Total	2,097	2,451	2,353	2,567	7.0%

STEP 1:	
Historical Service Area Outpatient MRI Procedures at Chesapeake Facilitie	es

Source: Chesapeake Health System internal data.

The table provided on page 148 of the application and excerpted below, however, shows a total of 9,575 patients for the same time period.

	0-17	18-24	25-44	45-64	65+	Total
Camden County	13	29	318	595	359	1,314
Currituck County	48	119	1,095	2,331	1,476	5,069
Pasquotank County	23	45	663	1,175	739	2,645
Perquimans County	5	13	102	329	304	753
Total Service Area	89	206	2,178	4,430	2,878	9,575

Patients by Age Group (2018-2021)

However, this number is also incorrect, and yet a third total of 9,781 for the service area is calculated by adding the individual totals for each age group (89 + 206 + 2,178 + 4,430 + 2,878 = 9,781). The differences in totals for the service area bring into question the accuracy and reliability of the data provided; therefore, the utilization projections are based on unreasonable and inadequately supported assumptions.

In Step 5 of its methodology, the application projects shifts to the proposed MRI "based on drive times and proximity to the proposed MRI versus other Chesapeake affiliated locations." The shifts are assumed to be 75 percent for Camden and Currituck counties and 80 percent for Pasquotank and Perquimans counties, without a reasonable justification for these percentages. These shifts are in fact unreasonable, particularly given the application fails to provide the location of the "other Chesapeake affiliated locations" from which patients are expected to shift. One such location is located south of Chesapeake, Virginia, approximately 16 miles and 19 minutes from Moyock in Currituck County², and as shown on page 65 of the CDIC application, accounted for the highest number of scans originating from the service area. In contrast, the proposed CDIC location in Elizabeth City is 25 miles and 32 minutes from Moyock. The application fails to explain why such a high percentage of its patients would shift to a facility that is farther away from the CDIC-affiliated facilities they currently utilize.

Additionally, on page 149, the sentence fragment, "*This percent is expected to ramp up as the new location becomes established and referral patterns develop recognizing*" ends prematurely, without providing the conclusion on which the assumptions and any utilization projections are based; as such, the partial statement does not support the projections.

In Steps 7 and 8, the CDIC application projects inmigration from outside the four-county service area. The application fails to demonstrate that the projected shifts are reasonable, however. For example, patients leaving these counties to access MRI services at CDIC-affiliated facilities in Virginia are not doing so because of the lack of a closer MRI scanner. For example, the hospital in Dare County, owned in part by Chesapeake Regional Health, has a fixed MRI scanner, as do the hospitals in Chowan and Hertford counties, which are owned by the other owner of the Dare County hospital. The results of these unreasonable assumptions are shown by the projected patient origin on page 43, which projects that, in Year 3, over 500 patients will originate from Dare County, which is more than two of the four counties of the primary service area, and nearly as many patients as the applicant projects to originate from Pasquotank County, where the proposed

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https://chesapeakeregional.com/locations/imaging-center-kingsborough; Distance measured using Google Maps.

scanner will be located. According to patient origin reports from the Healthcare Planning and Certificate of Need Section, in 2021, Dare County accounted for 2,063 MRI scans, of which 1,601 were performed in Dare County, and the remaining 462 were performed in the rest of the state³. Incredibly, CDIC projects that <u>more Dare County patients will receive MRI scans at the proposed site in Pasquotank County than had MRI scans in the rest of the state in 2021</u>. The projections for other counties are similarly unreasonable, such as Gates County, which accounted for only 260 MRI scans—statewide—in 2021, yet CDIC projects that over 100 Gates County patients will receive an MRI scan at its facility by Year 3.

The combination of the various "growth" and "shift" assumptions in the methodology, particularly for adjacent patient inmigration (Steps 7 and 8) results in an unreasonably high and unsupported growth in utilization projections for CDIC's proposed MRI. Although the application fails to show the individual growth rates resulting from the shifts, the table below provides this calculation.

	FY2025	FY2026	FY2027	2025-2027 CAGR
Inmigration Scans	457	667	728	26.21%
Service Area Scans	1,828	2,002	2,182	9.25%
Total Scans	2,285	2,669	2,910	12.85%

As shown above, the application projects an incredible CAGR of more than 26 percent for inmigration scans, and nearly 13 percent CAGR for total scans, which is clearly unreasonable and unsupported.

While this incredible growth rate is obfuscated in the multiple steps of the methodology, as noted above, the impact of the applicant's assumptions of both market volume growth and market share growth result in unreasonable utilization projections.

In Steps 9, 10 and 11 of the methodology found on page 151 of its application, CDIC provides historical and projected scans by type, labeling them as "With/With & Without" and "Without" without an explanation as to what each group includes. The definition of "adjusted MRI procedure" in the MRI rules refer to the methodology in the SMFP. The relevant portion of the MRI methodology in the 2022 SMFP, found on page 342, has the following weighting for outpatient scans:

Procedure Type	Base Weight	Inpatient Weight	Contrast Weight	Procedure Time in Minutes
Outpatient - No Contrast/Sedation	1.0	0.0	0.0	30
Outpatient - with Contrast/Sedation	1.0	0.0	0.4	42

As shown, the table does not speak to weighting for "With/With & Without" as a subset of MRI scans. Thus, the basis for CDIC's projections are unclear at a minimum, but appear to overweight the scans in favor of more with contrast. As shown in the historical data provided in the SAIS application (page 1 of the Form C Assumptions and Methodology), in annualized 2022, SAMC

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https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/30-PatientOrigin MRI-2022.pdf

provided 1,934 outpatient scans with contrast, or 34 percent of the total of 5,646 outpatient scans and projects only 46 percent of scans to involve contrast at SAIS. According to the 2022 SMFP, the hospital in Dare County performed a similar ratio, 38 percent outpatient contrast scans, based on 745 scans out of 1,964 total outpatient scans. CDIC, however, projects that more than one-half— 54 percent—of its outpatient MRI scans should be counted as "with contrast" scans. Given the lack of explanation provided in the application and the unreasonably high rates of contrast scans projected, CDIC has failed to demonstrate that its projected utilization, based on the unexplained weighting, is reasonable.

CDIC's methodology includes yet another numerical inconsistency. The final table in the second Step 10 shows 3,540 total weighted scans in FY 2027; however, the concluding narrative below states "CRIC projects 3,447 weighted scans in FY 2027."

Lastly, CDIC uses inconsistent data in its utilization projections. Specifically, CDIC's methodology includes historical outpatient MRI procedures performed at affiliated facilities in two different steps, Step 1 and Step 9, citing internal data sources. However, the volumes are dramatically different. In Step 1, historical volumes ranged from 2,097 in 2018 to 2,567 in 2021. In Step 9, historical scans for the same time period ranged from 584 in 2018 to 645 in 2021. The data in Step 1 is used to project future utilization from service area counties, while data from Step 9 is used to project weighted MRI scans. The inconsistent data calls into question the validity of both sets of data used to project volume, particularly given the other issues with the projections noted above.

Based on these issues, the application fails to reasonably identify the patient population, has failed to demonstrate the need for the project, and has failed to demonstrate that the utilization projections are adequately supported and based on reasonable assumptions. As such, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18(a), as well as the performance standards at 10A NCAC 14C .2103, and the CDIC application should be denied.

4. <u>CDIC fails to demonstrate that it promotes access and maximizes healthcare value.</u>

In Section N of its application, CDIC argues that the project will lower cost for MRI services by offering these services in a freestanding setting without consideration for the services already provided in the same location, less than 2,000 feet away from the new location of SAMC. As CDIC acknowledges on page 132 of its application, three of the counties in the four-county service area are designated as medically underserved areas. As such, SAMC operates as a safety net provider, delivering health care services to patients regardless of their ability to pay. Safety net providers serve a disproportionate share of uninsured and low-income patients. Maximizing healthcare value for resources expended would logically entail the development of services in a location of the four-county service area that would more effectively allocate resources and enable greater geographic access. Currently, three of the four counties in the service area do not have a fixed MRI scanner. As illustrated in the map below, based on data provided on page 43 of SAIS' application, Currituck County has the greatest projected population growth rate of the area and lacks access to fixed MRI services.



Source: Esri

As noted above, CDIC projects that the majority of its MRI patients will originate in Currituck County, and that a greater number of patients will come from Dare County than from two of the four counties in the *SMFP* service area. Currently, patients living in Camden, Currituck and Perquimans County must all leave their county to access fixed MRI services. The approval of CDIC's proposal will not change that. In fact, as noted above, CDIC projects that patients from Currituck County, particularly the northern portion, will travel farther for care than they currently do. This will increase the burden on patients, including more time off from work, fuel and other costs associated with traveling to access healthcare services.

Based on these issues, CDIC failed to demonstrate that it conforms with the Basic Principles in the *2022 SMFP*, and therefore, it is non-conforming with Criterion 1.

5. <u>The approval of CDIC's MRI application would result in unnecessary duplication of services.</u>

As noted previously, CDIC proposes to develop a freestanding MRI at 1825 W. City Drive, Elizabeth City, NC in Pasquotank County, <u>less than 2,000 feet from the approved location of the fixed MRI scanner located at Sentara Albemarle Medical Center</u> (at the intersection of Halstead Boulevard Extension and Thunder Road, also in Elizabeth City). Since the need methodology in the SMFP only determines that another MRI scanner is needed within the four-county service area,

applicants must demonstrate the need of the patients they propose to serve and that the proposed project would not result in unnecessary duplication of existing resources. Therefore, an applicant must demonstrate that the particular patient population it proposes to serve needs the MRI scanner and that it is needed in the location as proposed.

As shown in the map below, not only does CDIC's proposed location unnecessarily duplicate MRI services it also fails to consider the population trends of the service area—trends that were noted in its application.



Source: Esri.

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Even if CDIC could be found conforming with the need determination in the *SMFP* and with Criterion 1 (which, as noted above, SAIS does not believe it should), the applicant still fails to demonstrate that the patients it proposes to serve, <u>nearly 80 percent of which are from outside</u> <u>Pasquotank County</u>, need an MRI scanner located in Pasquotank County. Moreover, the proposed project would clearly result in unnecessary duplication, because of its proximity to the only other fixed MRI scanner in the service area at SAMC. Combined, the four counties in the service area comprise 976 square miles⁴, according to publicly available data. If they were a single county, they would be the largest county in the state by land area. Given the size of this area, the proposed

https://www.indexmundi.com/facts/united-states/quick-facts/north-carolina/land-area#table

location so close to the only other fixed scanner in the service area would unnecessarily duplicate what is already approved for that location, while ignoring hundreds of miles—and hundreds of patients—who would be better served at a location in a different service area county.

CDIC also states on pages 106 to 107 of the application that its proposal will increase access to a wide bore for claustrophobic and obese patients and provide breast MRI scans, the latter of which it states are not available in the service area. The implication of both of these statements, that CDIC would be the first to offer these, is simply incorrect, based on the capabilities of the existing scanner at SAMC. Although it is not required by the application form, Sentara would certainly be willing to provide the Agency detailed information regarding its historical MRI scans by type and MRI scanner capabilities upon request to demonstrate that CDIC's statements are simply false.

In consideration of the factors discussed above, it is clear that the approval of CDIC would result in an unnecessary duplication of existing and approved services in in the Currituck, Camden, Pasquotank, and Perquimans service area and that its application is non-conforming with Criteria 1, 3, 4 and 6 and the performance standards at 10A NCAC 14C .2103. Therefore, the Agency should deny this application.

6. <u>CDIC fails to demonstrate that its project schedule is reasonable.</u>

As described on page 40 of its application, CDIC proposes to "*renovate existing space and install a FUJIFILM Echelon Oval 1.5T MRI.*" On page 143, CDIC indicates that the construction contract would be executed on August 1, 2023 and that construction would be completed February 15, 2023, which is five and a half months <u>prior</u> to the construction contract being executed.

Milesto	one	Date (dd (man)
1	Financia - Obtained	
1	Financing Obtained	5/1/2023
2	Drawings Completed	7/1/2023
3	Land Acquired	N/A
4	Construction / Renovation Contract(s) Executed	<mark>8/1/2023</mark>
5	25% of Construction / Renovation Completed (25% of the cost is in place)	10/1/2023
6	50% of Construction / Renovation Completed	11/1/2023
7	75% of Construction / Renovation Completed	12/1/2023
8	Construction / Renovation Completed	2/15/2023
9	Equipment Ordered	5/1/2023
10	Equipment Installed	2/1/2024
11	Equipment Operational	3/1/2024
12	Building / Space Occupied	3/15/2024
13	Licensure Obtained	3/15/2024
14	Services Offered *	4/1/2024
15	Medicare and / or Medicaid Certification Obtained	7/1/2024
16	Facility or Service Accredited	7/1/2024
17	First Annual Report Due * ^	10/1/2025

Clearly, the proposed construction schedule is unreasonable, and as such, **the applicant fails to demonstrate its conformity with Criterion 12.**

 The CDIC application cannot be approved as submitted, as it is incomplete and fails to include all information necessary for the Agency to conduct the review pursuant to N.C. Gen. Stat. § 131E-182(b).

CDIC fails to provide all requested information required in response to the CON application form as it fails to identify all related entities in response to Form O Facilities and the performance standards.

As defined in 10A NCAC 14C .0202(10) as well as the definition portion of the CON application form (page 14), when used in the application form, "related entity means a person that:

- (d) Shares the same parent corporation or holding company with the applicant;
- (e) Is a subsidiary of the same parent corporation or holding company as the applicant; or,
- (f) <u>Participates with the applicant in a joint venture that provides the same type of health services</u> proposed in the application."

[emphasis added]

Section 0.1 of the CON application form requires an applicant to "[i]*dentify all existing and approved facilities providing the same service components included in this proposal <u>that are owned, operated or managed by the applicant or a related entity</u> in North Carolina by completing <u>Form O Facilities</u>, which is found in Section Q." [<u>emphasis added</u>]. However, while CDIC identifies Chesapeake Diagnostic Imaging Center in response to <u>Form O Facilities</u> (see page 158 of CDIC's application), it fails to identify all the CRH entities which offer MRI services. In Section A.1 the application states that CGH Holding Company is the parent company of CDIC and Exhibit A-6.1 provides the Chesapeake Regional Healthcare (CRH) Table of Organization which shows CRH as the ultimate parent company of CGH Holding Company. On page 28 of its application and in Exhibit A-6.1, the application states that CRH owns a 40 percent share of The Outer Banks Hospital, which according to the 2022 SMFP operates one fixed MRI in Dare County. As such, the CDIC application fails to identify all related entities in response to <u>Form O Facilities</u>. As CDIC's response to Form O Facilities is incomplete, likewise, its responses to Section O.4 and O.5 are incomplete. Further, all of CDIC's related entities should be considered in the Agency's quality review under Criterion 20, not just the partial list included in CDIC's application.*

CDIC has failed to demonstrate that the project is consistent with the review criteria implemented under N.C. Gen. Stat. § 131E-183 and that the project is needed, and the CDIC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2100 et seq. The CDIC application should not be approved.

COMPARATIVE ANALYSIS FOR FIXED MRI SCANNER

As noted above, SAIS believes that the CDIC application is non-conforming with multiple statutory and regulatory review criteria and should not be approved. Further, SAIS believes it has presented the most compelling application to develop the additional fixed MRI scanner at Sentara Advanced Imaging Solutions-Moyock (SAIS) in Currituck County. The SAIS (Project ID # R-12271-22) and the CDIC (Project ID # R-12266-22) applications both propose to develop an additional fixed MRI scanner in response to the 2022 SMFP need determination for the Pasquotank/Camden/Currituck/Perquimans service area. Given that both applicants propose to meet the need for the additional fixed MRI scanner in the multicounty service area, only one can be approved. To determine the comparative factors that are applicable in this review, SAIS examined recent Agency findings for competitive fixed MRI scanner reviews. In addition, this MRI review is rather unique in that it involves a multicounty service area, while most MRI service areas are for single counties. In the early 2000s, many MRI service areas included multiple counties, and the comparative factors used in those reviews reflected the need to analyze the most effective application when applicants proposed sites in different service area counties⁵. In particular, the comparative analysis included an examination of the population in each service area county and the ratio of existing MRI scanners to population to determine the most effective location for the proposed MRI scanner, as well as the percentage of each county's population that left the county for MRI services. Multicounty reviews also often included a use rate analysis, with the most effective location determined to be the proposal to locate the new scanner in the county with the lowest use rate, thereby improving access to MRI services in counties with lower use rates. While these reviews occurred several years ago, given subsequent changes in the MRI methodology, there have been only a few multicounty MRI reviews since that time; moreover, those reviews, including the 2021 MRI review for the Buncombe/Graham/Madison/Yancy service area did not involve applicants proposing to locate the MRI scanner in different counties, hence no such analysis was necessary, and the Agency Findings from the reviews in the 2000s are more helpful in providing an example of this analysis. Based on that examination and the facts and circumstances of the competing applications in this review, SAIS believes the following comparative factors will be helpful to the Agency in its review:

- Conformity with Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility
- Fixed MRI Scanners per 100,000 Population
- MRI Use Rates by County
- County Out-Migration for MRI Scanner Services
- Competition (Patient Access to a New Provider)
- Access by Service Area Residents
- Access by Underserved Groups
 - Projected Charity Care
 - As a Percent of Gross Revenue
 - As a Percent of Net Revenue
 - Per Weighted MRI Scan
 - Projected Medicare

⁵ For reference, please see the Agency Findings for the following reviews: 2002 Service Area 19 (Harnett, Johnston, Wake) and 2003 Service Area 15 (Davidson, Guilford, Randolph), both of which were reviewed by then-Project Analyst and current Team Leader, Mike McKillip.

- Projected Medicaid
- Projected Average Gross Revenue per Weighted MRI Scan
- Projected Average Net Revenue per Weighted MRI Scan
- Projected Average Operating Expense per Weighted MRI Scan

SAIS believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

The CDIC application is non-conforming with multiple statutory and regulatory review criteria. In contrast, the SAIS application is conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with statutory and regulatory review criteria, the SAIS is the more effective alternative.

Scope of Services

The following table compares the scope of services proposed to be offered. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

Applicant	Type of MRI Scanner	Hospital Based or Freestanding
SAIS	1.5T	Freestanding
CDIC	1.5T	Freestanding

Source: Section C.1 of the respective applications.

SAIS and CDIC both propose to develop a 1.5T MRI scanner in a freestanding outpatient setting. Thus, with regard to scope of services, the SAIS and the CRIC applications are equally effective alternatives. Of note, while CDIC makes a point of the capacity to perform MRIs on children, SAIS believes that CDIC did not demonstrate that it could safely and effectively perform MRIs on children in its proposed freestanding outpatient setting, particularly since pediatric MRIs often require sedation and monitoring for potential adverse reactions to contrast. Pediatric MRI scans are often associated with the need for specialized pediatric care, which is available at Children's Hospital of the King's Daughters in Norfolk, the closest children's hospital to the service area.

Historical Utilization

Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that the provider with higher historical utilization rates has a greater need for the proposed fixed MRI scanner in order to serve its projected patients. Neither CDIC nor any of its related entities own, manage, or operate MRI services in the service area; however, SAIS and Sentara Albemarle Medical Center (SAMC) are wholly owned by Sentara Healthcare and SAMC currently provides fixed MRI services in the service area and is the only MRI service provider in the Pasquotank/Camden/Currituck/Perquimans service area. Thus, with regard to historical utilization, the SAIS application is the more effective alternative.

Geographic Accessibility

As shown in Chapter 17-E of the 2022 SMFP, there are only nine multicounty MRI service areas in the state, and only three with as many as four counties. The 2022 SMFP identifies the need for one fixed MRI scanner in the multicounty service area. The following table illustrates where in the service area each applicant proposes to develop its proposal.

Applicant	County	Address	
SAIS	Currituck	446 Caratoke Highway Moyock, NC 27958	
CDIC	Pasquotank	1825 West City Drive Elizabeth City, NC 27909	

Source: Section A.4 of the respective applications.

As shown above, SAIS proposes to develop the fixed MRI scanner in Currituck County while CDIC proposes to develop the fixed MRI scanner in Pasquotank County. As stated above, currently, SAMC is the only provider of fixed MRI services in the service area, and it operates in Pasquotank County. Thus, since one of the applicants proposes to develop the MRI scanner in a county that already has access to fixed MRI services and one applicant proposes to develop the MRI scanner in a county without access to fixed MRI services, geographic accessibility is a particularly important comparative factor in this review. Of note, as noted above, in 2020, SAMC applied to relocate its hospital (and fixed MRI scanner) from its existing site to the intersection of Halstead Boulevard Extension and Thunder Road (Project ID # R-12007-20) and, according to Google Maps, the proposed site for CDIC is approximately 2,000 feet from SAMC's approved site in Pasquotank County. As such, the proposed project from CDIC will be located within close proximity of the only existing fixed MRI scanner in the service area and will therefore not improve geographic access to fixed MRI services. Further, SAIS's application will result in the first and only fixed MRI service in Currituck County, a county which is driving the growth in the service area and from which many patients currently leave each year to access MRI services, as noted in CDIC's application. Therefore, with regard to geographic accessibility, the SAIS application proposes to enhance the greatest geographical coverage with the fixed MRI scanner resource allotted in the need determination and represents the more effective alternative.

Fixed MRI Scanners per 100,000 Population

Location	2022 Population	Percent of Total	Fixed MRI Scanners	Fixed MRI Scanners per 100,000 Population
Camden	10,554	11.2%	0	0.0
Currituck	30,291	32.1%	0	0.0
Pasquotank	40,882	43.3%	1	2.45
Perquimans	12,758	13.5%	0	0.0
Total MRI Service Area	94,485	100.0%	1	1.06
North Carolina	10,631,667		256	2.41

The following table shows the number of existing and approved fixed MRI scanners per 100,000 population for the service area and for North Carolina.

Source: NC OSBM Population Estimates, Table 17E-1 of the 2022 SMFP

As indicated in the table above, the statewide average was 2.4 fixed MRI scanners per 100,000 population in the *2022 SMFP*, the Pasquotank County figure is 2.45 fixed MRI scanners per 100,000 population, which is slightly higher than the statewide average, while the figure for Camden, Currituck and Perquimans counties are zero because there are no fixed MRI scanners in those counties. Therefore, Pasquotank already has comparable access to the state as a whole, and Currituck County, with the highest population of the counties without a fixed MRI scanner, would benefit the most from the addition of a fixed MRI scanner. Therefore, the application submitted by SAIS is the most effective alternative with regard to this comparative factor.

MRI Use Rates by County

Accessibility to MRI services may also be assessed by a comparison of MRI utilization rates. Counties with higher MRI use rates (i.e., number of county residents who received MRI services per 1,000 population) may reflect higher access to MRI services, and counties with lower MRI use rates may reflect less access to MRI services. The following table shows the total number of residents who received MRI procedures during 2021 by county, and the MRI use rate per 1,000 population.

County of Origin	MRI Patients	2021 Population	MRI Use Rate per 1,000 Population
Camden	462	10,469	44.1
Currituck	700	29,305	23.9
Pasquotank	2,464	40,743	60.5
Perquimans	933	12,966	72.6
North Carolina	961,745	10,535,205	91.3

Source: 2022 Patient Origin Report for MRI Services, <u>https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/30-PatientOrigin MRI-2022.pdf</u>

As shown in the table above, while each of the service area counties has a lower MRI use rate than the state as a whole, Currituck County has, by far, the lowest MRI use rate and would therefore benefit the most from access to a fixed MRI scanner in the county. Therefore, the application submitted by SAIS is the most effective alternative with regard to this comparative factor.

County Out-Migration for MRI Scanner Services

The following tables illustrate where the residents of the service area went for MRI procedures during 2021, as reported on the 2022 Patient Origin Report for MRI Services referenced above.

Camden County				
County	# of Residents	% of Total		
Pasquotank	423	91.56%		
Durham	10	2.16%		
Pitt	8	1.73%		
Dare	7	1.52%		
Wake	5	1.08%		

Chowan	4	0.87%
Hertford	2	0.43%
Orange	2	0.43%
Nash	1	0.22%
Total	462	100.00%

Perquimans County

County	# of Residents	% of Total
Pasquotank	574	61.52%
Chowan	228	32.57%
Pitt	82	11.71%
Durham	17	2.43%
Orange	12	1.71%
Hertford	7	1.00%
Wake	6	0.86%
Dare	4	0.57%
Craven	1	0.14%
Wilson	1	0.14%
Jackson	1	0.14%
Total	933	100.00%

Currituck County

County	# of Residents	% of Total
Pasquotank	407	58.14%
Dare	228	32.57%
Pitt	22	3.14%
Durham	16	2.29%
Wake	14	2.00%
Orange	5	0.71%
Chowan	4	0.57%
Moore	2	0.29%
Watauga	1	0.14%
Hertford	1	0.14%
Total	700	100.00%

Pasquotank County

County	# of Residents	% of Total
Pasquotank	2282	92.61%
Pitt	45	1.83%
Chowan	41	1.66%

Durham	32	1.30%
Dare	14	0.57%
Wake	13	0.53%
Hertford	11	0.45%
Orange	10	0.41%
Nash	3	0.12%
Wilson	3	0.12%
Craven	2	0.08%
New Hanover	2	0.08%
Carteret	1	0.04%
Caldwell	1	0.04%
Cabarrus	1	0.04%
Beaufort	1	0.04%
Johnston	1	0.04%
Mecklenburg	1	0.04%
Total	2,464	100.00%

The following table compares the number of residents of each county in the service area who had an MRI procedure and went to a facility outside of their county of residence.

County	Total Number of Patients Receiving an MRI Procedure	Number of Residents who had an MRI Procedure and Went to a Facility in Another County	Percentage of Total Number of Residents Who Went to Another County for MRI Services
Camden	462	462	100.00%
Currituck	700	700	100.00%
Pasquotank	2,464	182	7.39%
Perquimans	933	933	100.00%

Source: 2021 data from 2022 Patient Origin Reports

As shown in the table above, 2,464 Pasquotank County residents received an MRI procedure during FY 2021, of which only 182 or 7.39 percent went to a facility outside of Pasquotank County. In comparison, 700 Currituck County residents received an MRI procedure during 2021, of which 700 or 100 percent went to a facility outside of Currituck County.

Therefore, based on the percentage of patients traveling out-of-county for MRI services, the most effective location for improving geographic access to MRI services among the counties proposed in the competing applications is Currituck County. Therefore, the application submitted by SAIS is the most effective alternative with regard to this comparative factor.

Competition (Patient Access to a New Provider)

In some reviews, the Agency considers the introduction of a new provider in the service area to be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients. However, the Department of Health and Human Services has recognized the need to ensure access to healthcare in as equitable a manner as possible. As noted on page 2 of the 2022 SMFP, "[t]he State Health Coordinating Council (SHCC) assigns the highest priority to a methodology that favors providers delivering services to a patient population representative of all payer types in need of those services in the service area." SAIS's proposed project seeks to address this principle and will improve access to fixed MRI services in the service area by developing the first freestanding fixed MRI scanner at the proposed diagnostic center in Currituck County, which will serve as a convenient and cost-effective alternative for patients and will also serve to provide capacity relief for the existing fixed MRI scanner at SAMC. The development of freestanding MRI capacity in the region will expand access to the excellent care for which Sentara Healthcare is known in a lower cost freestanding environment. SAIS's project will also allow the existing hospital-based MRI scanner at SAMC to retain sufficient capacity to accommodate growth in inpatient MRI scans and those outpatient MRI scans that must be performed in a hospital setting, including MRI scans performed on emergency department and observation patients. In this way, the proposed project will ensure continued access to essential MRI services for patients across northeastern North Carolina.

The language on page 3 of the 2022 SMFP also supports the approval of the SAIS project in stating that,

"The SHCC recognizes that some essential, but unprofitable, medical services may require support by revenues gained from profitable services or other sources. The SHCC also recognizes a trend to the delivery of some services in more accessible, less complex, and less costly settings. Whenever verifiable data for outcome, satisfaction, safety, and costs for the delivery of such services to representative patient populations justify, the SHCC will balance the advantages of such ambulatory facilities with the needs for financial support of medically necessary but unprofitable care."

SAIS believes that its proposal is indicative of the balance referred to in the quote above; that is, Sentara Healthcare must rely on revenues from profitable services, such as MRI services, to support essential, but unprofitable medical services, like emergency services and many inpatient services, the latter of which Sentara Healthcare is the only provider of in the service area. The language of the SHCC policy continues by saying,

"The <u>needs of rural and small communities</u> that are distant from comprehensive urban medical facilities <u>merit special consideration</u>. In rural and small communities, selective competition that disproportionately captures profitable services may threaten the viability of sole providers of comprehensive care and emergency services. For this reason, methodologies that balance value, quality, and access in urban and rural areas may differ quantitatively. The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible, under prevailing quality and value standards." (emphasis added)

SAIS supports the wisdom of a policy that promotes special consideration for rural communities, such as those it serves in northeastern North Carolina. SAIS believes that the proposed project is a unique and appropriate way to address each of these sometimes-conflicting issues, by developing a healthcare service like MRI in a new county and in a lower cost setting, but as part of the existing safety net provider that serves rural and small communities by using those revenues to support unprofitable services needed by

the community. Thus, given the discussion above, SAIS believes that this comparative factor is not useful in this review, and in fact, as discussed in Section N of its application, in this instance, Sentara does not believe that selective competition for MRI services in the area from another provider would have a favorable impact on cost-effectiveness, quality and access by the medically underserved. If the Agency does utilize this factor in its comparative analysis, given the facts discussed above, SAIS is the more effective alternative.

Access by Service Area Residents

On page 341, the 2022 SMFP defines a fixed MRI scanner as "an MRI scanner that is not a mobile MRI scanner." and defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1." Based on that definition, for purpose of this review, the service area comprises four counties including Pasquotank, Camden, Currituck, and Perquimans. The following table provides the total number of service area residents and the percentage of service area residents to be served by SAIS and CDIC.

Applicant	Service Area Residents Served	Projected Total Patients	Service Area Residents Served as a % of Total Patients
SAIS	1,850	2,041	90.6%
CDIC	2,182	2,910	75.0%

Access by Service Area Residents – Project Year 3

Source: Section C.3(b) of the respective applications.

As shown above, CDIC proposes to serve more service area residents compared to SAIS; however, SAIS proposes to serve a higher percentage of service area residents. Moreover, the patient volume projected by CDIC is not based on reasonable and adequately supported assumptions. Thus, with regard to this comparative factor, the SAIS application is a more effective alternative.

Access by Underserved Groups

The following table shows projected fixed MRI scan percentages provided to Self-Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in Section L.3(a) of each application.

Applicant	Self-Pay/ Indigent/Charity as % of Total	Medicare % of Total	Medicaid % of Total	Total Underserved Groups
SAIS	3.7%	38.0%	8.8%	50.5%
CDIC	3.6%	35.3%	5.8%	44.7%

Self-Pay/Indigent/Charity, Medicare, and Medicaid MRI Scans – Project Year 3

Source: Section L.3(a) of the respective applications.

As shown above, SAIS projects to serve the highest percentage of Self-Pay/Indigent/Charity patients compared to CDIC. Moreover, SAIS projects to serve the highest percentage of Medicare and Medicaid patients and projects to serve the highest total percentage of underserved groups compared to CDIC. Thus, with regard to access to underserved groups, the SAIS application is the more effective alternative.

The following tables show charity care as a percent of gross and net revenue in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form F.2).

Applicant	Charity Care	Gross Revenue	Charity Care % of Gross Revenue
SAIS	\$132,531	\$3,714,002	3.6%
CDIC	\$131,633	\$5,265,314	2.5%

Source: Form F.2 of the respective applications.

*Weighted MRI Scans are used as the MRI performance rules exclusively analyze weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

Applicant	Charity Care	Net Revenue	Charity Care % of Net Revenue
SAIS	\$132,531	\$892,169	14.9%
CDIC	\$131,633	\$1,310,505	10.0%

Source: Form F.2 of the respective applications.

*Weighted MRI Scans are used as the MRI performance rules exclusively analyze weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

As shown above, the SAIS application projects to provide the highest charity care percentages of gross and net revenue compared to CDIC. Thus, with regard to this comparative factor, the SAIS application is the more effective alternative.

The following table provides the average charity care amount provided per weighted MRI scan based on the information provided in each applicant's pro forma financial statements (Form C and Form F.2)

Applicant	Charity Care	Weighted MRI Scans	Charity Care per Weighted MRI Scan
SAIS	\$132,531	2,684	\$49
CDIC	\$131,633	3,540	\$37

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

*Weighted MRI Scans are used as the MRI performance rules exclusively analyze weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

As shown above, the SAIS application projects to provide the highest amount of charity care per weighted MRI scan and is the more effective alternative.

Projected Average Gross and Net Revenue per Weighted MRI Scan

The following table shows the projected gross revenue per weighted MRI scanner in the third year of operation based on the information provided in each applicant's pro forma financial statements (Forms C and F.2).

Applicant	Weighted MRI Scans*	Gross Revenue	Average Gross Revenue per Weighted MRI Scan
SAIS	2,684	\$3,714,002	\$1,384
CDIC	3,540	\$5,265,314	\$1,487

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

*Weighted MRI Scans are used as the MRI performance rules exclusively analyze weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

As shown above, SAIS projects the lowest gross revenue per weighted MRI scan in the third operating year and is the more effective alternative.

The following table shows the projected net revenue per weighted MRI scan in the third year of operation based on the information provided in each applicant's pro forma financial statements (Forms C and F.2).

Applicant	Weighted MRI Scans*	Net Revenue	Average Gross Revenue per Weighted MRI Scan
SAIS	2,684	\$892,169	\$332
CDIC	3,540	\$1,310,505	\$370

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

*Weighted MRI Scans are used as the MRI performance rules exclusively analyze weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

As shown above, SAIS projects the lowest net revenue per weighted MRI scan in the third operating year and is the more effective.

Projected Average Operating Expense per Weighted MRI Scan

The following table shows the projected average operating expense per weighted MRI scan in the third year of operation for each of the applicants, based on the information provided in applicants' pro forma financial statements (Forms C and F.3).

Applicant	Weighted MRI Scan	Operating Expenses	Average Op Expense per Weighted MRI Scan
SAIS	2,684	\$811,105	\$302
CDIC	3,540	\$1,227,391	\$347

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

*Weighted MRI Scans are used as the MRI performance rules exclusively analyze weighted scans. Weighted scans account for differences in MRI scans which can result in a particular MRI scan taking more time and resources than a different MRI scan, such as one requiring the use of contrast.

As shown above, SAIS projects the lowest operating expense per weighted MRI scan in the third operating year and is the more effective alternative.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for the fixed MRI scanner.

Comparative Factor	SAIS	CDIC
Conformity with Review Criteria	Yes	No
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	More Effective	Less Effective
Geographic Accessibility	More Effective	Less Effective
Fixed MRI Scanners Per 100,000 Population	More Effective	Less Effective
MRI Use Rates by County	More Effective	Less Effective
County Out-Migration for MRI Scanner Services	More Effective	Less Effective
Competition (Access to a New Provider) (If used by the Agency)	More Effective	Less Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Underserved Groups	More Effective	Less Effective
Projected Charity Care as a Percent of Gross Revenue	More Effective	Less Effective
Projected Charity Care as a Percent of Net Revenue	More Effective	Less Effective
Projected Charity Care per Weighted MRI Scan	More Effective	Less Effective
Projected Average Gross Revenue per Weighted MRI Scan	More Effective	Less Effective
Projected Average Net Revenue per Weighted MRI Scan	More Effective	Less Effective
Projected Average Operating Expense per Weighted MRI Scan	More Effective	Less Effective

To summarize the comparative review for the fixed MRI scanner, SAIS believes that its application is clearly the more effective alternative for the additional fixed MRI scanner in the multicounty service area. SAIS's application is also fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the SAIS's proposal should be approved.