

**Comments in Opposition to Sentara Advanced Imaging Solutions, LLC
Project #R-012271-22
On behalf of Chesapeake Diagnostic Imaging Centers, LLC**

INTRODUCTION AND BACKGROUND

The 2022 State Medical Facilities Plan (“2022 SMFP”) included a need determination for one fixed MRI unit in the four-county MRI service area including Pasquotank, Camden, Currituck, and Perquimans Counties (“MRI Service Area”). In response to this need determination, two applications were filed for fixed MRI services including:

- Chesapeake Diagnostic Imaging Centers, LLC (“CDIC”) d/b/a Chesapeake Regional Imaging Center (“CRIC”) proposes a new freestanding imaging center in Elizabeth City, Pasquotank County. Project #R-012266-22.
- Sentara Advanced Imaging Solutions, LLC (“SAIS”) proposes a new freestanding imaging center in Moyock, Currituck County. SAIS also proposes to eliminate the mobile MRI unit that it owns which has historically served the MRI Service Area. Project #R-012271-22.

SAIS’s non-conformity with multiple statutory Project Review Criteria and MRI Performance Standards renders its application non-approvable. Moreover, even if the SAIS application was approvable, which it is not, CRIC’s application is far superior comparatively and should be approved.

Sentara’s History of Need and Competition Suppression in the Four-County MRI Service Area

As part of this review, it is essential to understand the history of MRI services in the four-county MRI Service Area. As detailed in the CRIC application, Sentara’s years-long efforts to suppress competition are summarized:

- SAIS affiliate Sentara Albemarle Medical Center (“SAMC” or “Sentara”)¹ is the only provider of MRI services to the MRI Service Area and has been for more than a decade.
- SAMC and its predecessor (owner/parent company) have engaged in a long-term, deliberate effort to suppress competition and prevent the entrance of a new MRI provider in the service area. See CRIC CON application page 58.
 - First, SAMC obtained approval for a mobile MRI to serve the area through the **2006 SMFP** need determination, but it did not implement this project until **2016**. This approved but not operational mobile unit suppressed the MRI need for **10 years**. See CRIC CON application page 58.
 - Every year that a need determination appeared in a proposed SMFP since at least 2007, SAMC filed petitions to remove the need determination for an additional fixed MRI unit in the four-county service area, including, most recently in 2018, 2019, 2020, 2021, and even 2022 SMFPs. See SAIS application, page 50. **To be clear, SAMC filed a petition to eliminate the need for a fixed MRI from the 2022 SMFP for which it is now applying.** See CRIC CON application page 5.

¹ For ease of reference, these comments may refer to SAMC and SAIS as, more broadly, Sentara.

- SAMC claimed repeatedly that overall MRI volume and volume growth of MRI scans did not warrant a determination of need. Now SAIS claims significant growth in demand to support its application.
- SAMC has exclusively provided MRI services *only in Pasquotank County* and only as a hospital-based provider despite its ability to use its mobile MRI affiliate to expand access and provide services in a more cost-effective, freestanding setting if it so chose.

SAIS's Application is Non-Conforming with Multiple Review Criteria and Standards

- SAIS is Non-conforming with Criterion (1) – Discussed in detail at Pages 4-6.
 - The project fails to provide access to the SMFP defined MRI Service Area, leaving Perquimans County *completely out* of its projected utilization volumes.
 - The project fails to provide an increase in MRI capacity to the service area. The relinquishment of the mobile MRI unit, which SAIS admits is essentially fixed, upon implementation of the proposed fixed unit results in no additional MRI capacity within the service area beyond what is available today.
 - The project fails to promote equitable access and maximize health value for resources expended. SAIS locates the project in an area with the highest level of access and affluence in the four-county service area. SAIS volume projections verify that it does not intend to serve historically underserved populations.
 - Sentara admittedly proposes to spend almost \$2.7 million to replicate a project it can complete today with its mobile unit, and in fact plans to, at a fraction of the cost.

- SAIS is Non-Conforming with Criterion (3) - Discussed in detail at Pages 6-21.
 - The proposed project does not adequately identify the population to be served. The project omits Perquimans County—one county of the four-county MRI Service Area—completely and fails to provide any reasonable explanation.
 - Perquimans County residents apparently will not have access to the lower cost, freestanding MRI that SAIS proposes.
 - The proposed project includes counties located as far away from the service area as Mecklenburg County in an “Other Counties” capture category, but it does not intend to serve the entire service area. The proposed population to be served is illogical and flawed.
 - SAIS does not demonstrate it will meet the needs of the service area population. There is absolutely a need for additional MRI capacity in the service area, and there has been for years, but this project does not propose to provide it because SAIS proposes to eliminate its mobile service.
 - The proposed project is designed to suppress need for MRI services in the service area. Sentara has a long history of utilizing its existing MRI resources and approvals, as well as the SMFP petition process, to eliminate quantifiable need for MRI services in the SMFP. SAIS's proposed project is yet another tactic to keep a competitor from bringing MRI services to the service area.
 - The utilization projections are flawed and unreasonable. SAIS's utilization projections are based on circuitous calculations and arbitrary assumptions, including capture rates, by county.
 - The proposed project fails to enhance access for all residents of the service area, especially those in groups that are historically medically underserved such as Perquimans County.

- SAIS is Non-Conforming with Criterion (3a) – Discussed in detailed at Pages 21-22.
 - The proposed project fails to demonstrate how the relinquishment of the mobile MRI unit will meet the needs of the service area. This tactic results in no increased MRI capacity for the four-county service area as a result.
- SAIS is Non-Conforming with Criterion (4) – Discussed in detail at Page 22.
 - SAIS’s proposed project is admittedly a more costly and less effective alternative. The CON project duplicates SAIS’s more cost-effective plans to deploy its mobile MRI to Moyock.
- SAIS is Non-Conforming with Criterion (5) – Discussed in detail at Pages 22-24.
 - As noted in Criterion (3), SAIS’s utilization projections are unreliable and unreasonable.
 - The proposed project fails to fully document that it has included all appropriate project costs.
 - SAIS claims it will not bill professional fees; however, charges and reimbursement appear to be global rates that would include professional fees.
 - SAIS fails to include sufficient lease expenses and offsetting professional fee expenses for its apparent global charges.
- SAIS is Non-Conforming with Criterion (6) – Discussed in detail at Page 24.
 - The proposed project is duplicative and is not cost-effective. SAIS proposes to complete the same project twice when it could be implemented at the same site with its existing mobile MRI unit for minimal cost. SAIS only applied to effectively replace the mobile MRI unit with a fixed unit to block competition in the service area and to tie up need for an additional MRI unit for years to come.
- SAIS is Non-Conforming with Criterion (7) – Discussed in detail at Page 24.
 - As SAIS’s application projects full-time service, it would be anticipated that a full-time Registration Rep would be needed by the third year of operation. Therefore, staffing appears to be understated.
- SAIS is Non-Conforming with Criterion (8) – Discussed in detail at Page 25.
 - SAIS fails to document that it has the commitment of a radiology group to provide reading for the MRI, as well as a physician to serve as Medical Director. Contrast cannot be used without an onsite physician, which also has not been documented.
- SAIS is Non-Conforming with Criterion (12) – Discussed in detail at Pages 25-26.
 - The proposed project fails to demonstrate that it has a viable site. Several sections of the provided lease agreement preclude Sentara and SAIS from leasing (or subletting) the proposed site.

- SAIS is Non-Conforming with Criterion (13) – Discussed in detail at Pages 14-16 and 26-29.
 - The proposed project is located so as not to be accessible for underserved patients. SAIS does not project to serve Perquimans County, which has a high level of medically underserved residents.
- SAIS is Non-Conforming with Criterion (18a) – Discussed in detail at Page 29.
 - The proposed project does not promote competition in the MRI Service Area. Sentara is the only existing MRI provider in the service area. Residents must currently leave the service area or the state to access another provider of MRI services. Approval of this project would perpetuate Sentara’s current monopoly on MRI diagnostics within the four-county service area.

For these reasons, the project should be found non-conforming with Criteria (1), (3), (3a), (4), (5), (6), (7), (8), (12), (13), and (18a).

Historical MRI Access in the Four-County Service Area

Notably, SAIS could have essentially implemented its proposed project at any time and intends to operationally implement this project prior to CON approval. Page 34 of the SAIS application states:

“Of note, prior to and independent of the proposed project, Sentara will begin providing mobile MRI services on a mobile pad that is currently being developed at the existing MOB in Moyock where the proposed project will be developed.”

Page 23 further expands on SAIS’s intent:

“Pending the approval of this application, Sentara will relinquish the CON for the mobile MRI scanner upon development of the fixed scanner as a condition of obtaining the CON approval to develop the proposed fixed MRI scanner.”

Thus, at any time, SAIS could have identified a location in Moyock, Currituck County, such as a physician practice or other outpatient location, and relocated its existing mobile unit to this location to provide freestanding MRI services. Only now, when faced with a potential competitor in the service area, does SAIS initiate the relocation of its existing mobile MRI unit to Moyock.

Furthermore, SAIS proposes to relinquish the CON for its mobile MRI unit that it has been operating in a fixed capacity simply to obtain CON approval and block any competitor from entering the market. Essentially, SAIS proposes to replace its mobile MRI (which has historically operated as a fixed unit) with the proposed fixed MRI, resulting in no actual increase in approved MRI capacity in the four-county service area. SAIS/Sentara are utilizing this “shell game” to prevent competition and do not propose to increase access to MRI services.

This disingenuous proposal should not be approved.

Criterion (1): SAIS’s Application is Inconsistent with the 2022 SMFP and Policy GEN-3

SAIS’s application is inconsistent with both the 2022 SMFP and Policy GEN-3. SAIS’s proposal fails to increase access to MRI services in the SMFP-defined MRI Service Area of Pasquotank, Camden, Currituck,

and Perquimans Counties. Perquimans County is omitted entirely from the utilization projections, yet SAIS's application curiously anticipates serving patients from many counties outside the service area, as far away as Mecklenburg County. ***In fact, some of the counties listed in SAIS's application require patients to drive through Perquimans County to reach the proposed MRI.***

Additionally, SAIS's long-term plan for implementing this proposed project results in no additional MRI capacity in the four-county service area. The application proposes implementing a project that it can (and, according to its application, now will) implement immediately through the relocation of its existing mobile MRI unit that is currently used on a full-time basis at Sentara Albemarle Medical Center ("SAMC") to the proposed project site in Moyock, Currituck County. However, SAIS states that it will take its mobile unit out of service completely when the proposed project is implemented. As a result, SAIS proposes a project that results in no additional immediate or long-term capacity increase for the MRI Service Area.

In addition to inconsistency with the 2022 SMFP, SAIS's proposal is inconsistent with numerous aspects of Policy GEN-3, including but not limited to:

- *Promoting equitable access and maximizing healthcare value for resources expended*
 - SAIS locates its proposed freestanding MRI facility in the service area's most affluent county (Currituck), yet farthest away for the most populous part of the service area (Elizabeth City and Pasquotank County) and with the population having the most limited financial resources (Perquimans County).
 - SAIS's proposed project wastes healthcare dollars and resources. The application states that SAIS can and will establish the same project in the exact Currituck County location through moving its existing mobile MRI unit, which only requires the construction of a mobile pad. Nevertheless, SAIS proposes to replicate that project with this proposed project in an adjacent medical office building ("MOB") utilizing basically the same fixed MRI technology currently offered at SAMC. The proposed project brings nothing new to the service area that the applicant cannot provide today without CON approval. This project proposes to spend approximately \$2.7 million to duplicate technology and services that Sentara already does or will offer at a fraction of the cost. Upon implementation, there will be no additional MRI capacity in the service area beyond the capacity that is available today.
- *Providing access to services for patients with limited financial resources and demonstrating the availability of capacity to provide these services*
 - As discussed in detail regarding Criterion (3), Perquimans County has the most financially vulnerable population of the four service area counties. It is also located farthest from SAIS's proposed project site. SAIS projects that ***no patients at all*** for the freestanding MRI center will originate from Perquimans County. Consistent with SAIS's proposed location in Moyock, the patient projections by county have the highest percentages of patients originating from the two most affluent counties in the service area (Currituck and Camden Counties).
- *Documenting how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan*
 - As discussed in detail in Criterion (3), SAIS utilizes a cumbersome and murky process to project volumes for the proposed project. This results in volumes that are not reliable.

- The proposed project fails to add any new MRI capacity to the service area, as required by the SMFP. Moreover, the elimination of SAIS’s mobile unit upon implementation of the proposed project creates net neutral MRI capacity for the service area.
 - The proposed project is simply a “shell game”—based on unreliable volumes—devised to push out the timeline for generating additional need for fixed MRI (in a future SMFP) while keeping competitors out of the service area.
- *Addressing the needs of all residents in the proposed service area*
 - The proposed project does not meet the needs of all residents in the service area. As noted previously, the proposed project omits Perquimans County completely and fails to target the most vulnerable service area communities. Instead, SAIS proposes a site that is only convenient to a portion of the SMFP identified service area.
 - Interestingly, the proposed project neglects to include or discuss the Southeastern Virginia/Hampton Roads population that is geographically more proximate to the proposed site compared to the service area population, including the rural, underserved county it will entirely fail to serve.

Each of these will be addressed in more detail below and in detailed responses to inconsistency with Criteria (3), (3a), (4), (5), (6), (7), (8), (13), and (18a).

Criterion (3): SAIS’s Proposed Project Does Not Meet the Need for or Enhance Accessibility to Fixed MRI Services

The SAIS application fails to meet the need for fixed MRI services as required by Criterion (3) for numerous reasons. Among these, SAIS does not adequately identify and explain a rational basis for the population it intends to serve. Additionally, SAIS does not demonstrate that its proposed project meets the need for an additional fixed MRI unit as intended and calculated within the 2022 SMFP. It appears that the intention of this proposed project focuses more on suppressing future MRI need rather than addressing the current need. SAIS’s utilization projections are flawed and unreasonable while the project generally fails to enhance accessibility, both overall and to vulnerable and underserved populations within the MRI Service Area.

SAIS Has Not Adequately Identified the Population to Be Served

SAIS fails to provide a meaningful analysis of its patient population and patient origin projections, resulting in illogical projected patient origin(s). On page 39 of the application, SAIS lists its patient projections by county. Application Item 3a (p. 39) provides no explanation or analysis related to geographic origin. Instead, SAIS provides a convoluted methodology for converting projected weighted scans in total to scan by county and then to patient projections by county. This is only a speculative basis for the allocation of patient origin by county.

SAIS projects its patients to originate from Currituck, Pasquotank, Camden, and Other Counties. See **Figure 1** on the next page. This presentation of patient origin is illogical for several reasons. First, the table and all patient projections omit Perquimans County from the proposed patient base. Perquimans County is not even included in the list of “Other” counties, which make up approximately 10 percent of the patient total.

Figure 1

b. **Service Component(s)** – Complete the following table for each service component included in this proposal for the facility or campus identified in Section A, Question 4.

MRI	SAIS-Moyock*					
	1 st Full FY		2 nd Full FY		3 rd Full FY	
	01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Currituck	437	29.7%	595	30.7%	648	31.8%
Pasquotank	444	30.2%	583	30.1%	613	30.0%
Camden	428	29.1%	561	29.0%	589	28.8%
Other^	163	11.1%	198	10.2%	191	9.3%
Total	1,471	100.0%	1,937	100.0%	2,041	100.0%

* This should match the name provided in Section A, Question 4.
 ** Home health agencies should report the number of unduplicated clients.
 ^Based on the historical patient origin at SAMC, other may include Alamance, Beaufort, Bertie, Cabarrus, Carteret, Chowan, Craven, Dare, Gates, Guilford, Halifax, Hertford, Hyde, Martin, Mecklenburg, Pitt, Tyrrell, Vance, Wake, Washington, Wilson and other counties in NC, as well as other states.

Source: Application for Project #R-012271-22, p.39

Perquimans County’s absence from the list is questionable in several respects. First and foremost, if the impetus for the proposed project is to enhance capacity and access for the service area, the proposed MRI should be located so that it will serve all parts of the four-county service area. An entire county within the MRI Service Area should not be completely omitted from being served. Second, the footnote to the “Other” category states that it is “based on the historical patient origin at SAMC” and “may include Alamance, Beaufort, Bertie, Cabarrus, Carteret, Chowan, Craven, Dare, Gates, Guilford, Halifax, Hertford, Hyde, Martin, Mecklenburg, Pitt, Tyrrell, Vance, Wake, Washington, Wilson, and other counties in NC, as well as other states.” Note the absence of Perquimans County entirely, which is intentional, as SAIS projects zero patients to shift from SAMC to SAIS. See Form C Assumptions and Methodology page 7.

According to the Form C Assumptions and Methodology page 6, in CY 2021, Perquimans County patients accounted for 13.4 percent of all outpatient MRI services at SAMC, making it the second largest county of origin for outpatient MRI behind Pasquotank County. Yet, none of these patients are expected to shift to SAIS. That also means that all Perquimans patients are expected to continue utilizing more expensive hospital-based MRI services at the SAMC. This exacerbates health disparities, as residents of this lower-income county will not have access to the more cost-effective freestanding MRI services compared to comparatively wealthy Moyock, Currituck County.

Finally, it is geographically illogical for many of the counties in the “Other” area to be included since travel patterns from these counties, including Chowan, Tyrrell, Washington, and Martin, would require traveling through Perquimans and Pasquotank Counties to reach the distant MRI location in Moyock. This group of “Other” counties represents 9 to 11 percent of projected patients for the project, and most of these counties are less proximal to Moyock than Perquimans County. ***If Perquimans County patients are not anticipated to travel to the new site, it is illogical that these other patients will travel to SAIS-Moyock for care. As a result, patient projections could be overstated by more than 10 percent.*** It is simply unclear where these patients will come from.

While the SAIS location in Moyock is perfectly positioned on the border to serve Virginia patients, there is no mention of this other than the reference to “other states” in the patient origin table. In fact, the site is more likely to serve Virginia patients than many service area and other North Carolina patients. SAIS may not have mentioned Virginia because it has applied for another MRI imaging location 10 miles away from the proposed Moyock location in the southern part of the City of Chesapeake, Virginia.

SAIS Has Not Demonstrated that the Identified Population Has a Need for the Services Proposed

There is no disputing that a need exists for an additional fixed MRI unit to serve Pasquotank, Camden, Currituck, and Perquimans Counties. However, SAIS’s proposed project does not meet this need. As previously discussed, the proposed project will not serve the entire service area—leaving Perquimans County out entirely. As discussed in detail to follow, Perquimans County is composed of the highest minority population and is the most financially underserved of the four service area counties.

Furthermore, the proposed project does not add MRI capacity to the service area beyond what currently exists. SAIS currently operates a mobile MRI unit on a full-time basis at SAMC. As shown in Figure 15 in the CRIC application (p. 58), almost 3,000 scans were performed on the SAIS mobile MRI unit in 2021, 63 percent more than the fixed unit at SAMC. Figure 15 from the SAIS CON application is replicated below. The mobile MRI unit is and has been operating as a full-time unit.

Figure 15
Sentara Albemarle Medical Center MRI Trends

Mobile MRI					
	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
IP With Contrast or Sedation	-	12	12	14	81
IP Without Contrast or Sedation	1	9	38	19	314
Total Inpatient	1	21	50	33	395
OP With Contrast or Sedation	24	200	216	253	699
OP Without Contrast or Sedation	94	568	790	881	1,898
Total Outpatient	118	768	1,006	1,134	2,597
Total	119	789	1,056	1,167	2,992
Fixed MRI					
	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
IP With Contrast or Sedation	123	186	150	140	79
IP Without Contrast or Sedation	244	401	462	437	215
Total Inpatient	367	587	612	577	294
OP With Contrast or Sedation	736	846	841	759	444
OP Without Contrast or Sedation	2,399	2,299	2,236	2,298	1,096
Total Outpatient	3,135	3,145	3,077	3,057	1,540
Total	3,502	3,732	3,689	3,634	1,834

Source: SMFP 2019-Draft SMFP 2023

Source: Application for Project #R-012266-22., p.58

According to Section D of SAIS’s application, “upon completion of the project, Sentara will terminate its mobile diagnostic program, including the mobile MRI scanner. However, rather than one fixed MRI scanner and one mobile MRI scanner, Sentara will own and operate two fixed MRI scanners in the service area – one at SAMC, and one at the freestanding diagnostic center.” In other words, there are two MRI units in full-time operation in the service area today, and there will be two MRI units in full-time operation upon implementation of this proposed project. Indeed, the utilization of the proposed MRI unit in Moyock in PY 3 of 2,684 weighted scans (SAIS application, p. 64) is less than the 2,992 total scans performed on the mobile MRI in FY 2021. **SAIS’s proposed project adds no capacity to the service area and fails to**

serve a significant portion of the SMFP-identified service area. Moreover, as noted under Criterion (3a) below, SAIS fails to provide a Form D and does not provide any interim utilization for the mobile unit in its current location or the planned new mobile site in Moyock.

SAIS Plans and Projections are Designed to Suppress Need

The unstated impetus for SAIS’s proposed project is to continue its longstanding suppression of need for an additional MRI services provider in the four-county service area. SAIS states on page 34 of its application that it can bring the same services it proposes to offer in the same location by simply relocating its existing mobile MRI to Moyock. SAIS also states its intent to do this in the interim period until the proposed project is fully implemented. SAIS provides no compelling reason it should spend approximately \$2.7 million to renovate and establish a fixed MRI service in the same location.

Figure 2 shows the SMFP need trajectory utilizing the SAIS Form C Assumptions (p. 3). Without an additional MRI unit approved, SAIS’s projected utilization and proposed plan to eliminate the mobile unit at Moyock generates a need for an additional fixed unit through 2028.

**Figure 2
Need Trajectory Without Placeholder for 2022 SMFP Need Determination**

	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028
Total Weighted Scans*	7,610	7,964	8,334	8,723	9,128	9,552	9,998
SAMC Existing Fixed Units	1	1	1	1.92	2	2	2
SAIS Mobile Equivalent Scanners**	0.6	1	1	0.08	0	0	0
Total Fixed Equivalent Scanners	1.6	2	2	2.00	2	2	2
Average Scans per Scanner	4,756	3,982	4,167	4,362	4,564	4,776	4,999
SMFP Need Threshold	3,775	3,775	3,775	4,118	4,118	4,118	4,118
SMFP Need Determination	YES	YES	YES	YES	YES	YES	YES

*Source: Form C Assumptions p.3.

**SAIS mobile assumed to be used full time as stated in the application. Although the timing of such plans are not provided and no Form D.2 is provided to identify the utilization of the mobile in the interim period.

However, the approval of a fixed unit for Sentara shown as the 2022 SMFP Need “placeholder” would tie up the need for another fixed unit in the service area for at least another three years until the new unit was implemented and operational in CY 2025 and a new 2026 SMFP was developed. See **Figure 3. Should SAIS receive the CON and remove its mobile MRI from service, the need for a fixed MRI unit identified by the 2022 SMFP will not be identified again as a need until approximately the 2026 SMFP. It would likely be 2028 or later before the same fixed MRI (which was identified as a need in 2022 and in draft SMFPs for years before that) would be approved and fully implemented. Thus, Sentara would again utilize approved but undeveloped services to manipulate and suppress need through the SMFP planning process.**

**Figure 3
Need Trajectory with Project**

	CY 2022	CY 2023	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028
Total Weighted Scans*	7,610	7,964	8,334	8,723	9,128	9,552	9,998
2022 SMFP Need - Place Holder	1	1	1				
SAMC Existing Fixed Units	1	1	1	1.92	2	2	2
SAIS Mobile Equivalent Scanners**	0.6	1	1	0.08	0	0	0
Total Fixed Equivalent Scanners	3	3	3	2	2	2	2
Average Scans per Scanner	2,927	2,655	2,778	4,362	4,564	4,776	4,999
SMFP Need Threshold	3,775	3,775	3,775	4,118	4,118	4,118	4,118
SMFP Need Determination	NO	NO	NO	YES	YES	YES	YES

*Source: Form C Assumptions p.3.

**SAIS mobile assumed to be used full time as stated in the application. Although the timing of such plans are not provided and no Form D.2 is provided to identify the utilization of the mobile in the interim period.

The Applicant’s Utilization Projections Are Flawed and Unreasonable

As discussed below, the utilization projections provided by SAIS are flawed and unsupported. SAIS utilizes a methodology that is cumbersome and confusing—based on illogical assumptions regarding patient origin—and lacking in supporting data.

SAMC’s/SAIS’s Historical and Projected Utilization Trend is Questionable

As the first step in its projections, SAIS presents the historical and projected utilization for the combined SAMC/SAIS operations based on calendar year (“CY”) data that cannot be confirmed by its license renewal application (“LRA”) submissions. The CY data presents an unsupported trend starting with Q3 2021 and the first two quarters of 2022, which have been annualized for the CON application. It is important to keep in mind that for many years, SAMC claimed the need determination in the SMFP should be removed because MRI volume in the area was not growing. This claim continued through SAMC’s 2022 SMFP petition that included monthly data through Q2 2021 in support of this claim. See **Attachment A** for copies of SAMC’s 2021 SMFP and 2022 SMFP petitions that provided monthly data in support of its claims.

Monthly scan utilization from SAMC’s petitions, FY data from the 2021 LRA, and annualized 2022 data for January to June 2022 from SAIS’s CON application allow for a quarterly trend to be calculated as shown in **Figure 4** on the next page. This trend suggests, after years of claims of no growth, Q4 2021 and Q1-Q2 2022 have shown significant spikes in utilization that miraculously align for preparation of the SAIS CON application. By process of elimination of known and unknown data points, Q3 2021 can be determined from the 2022 LRA. This figure of 1,366 scans represents a 7 percent increase from Q2 2021. Based on CY 2021 included in the SAIS CON application, Q4 2021 can be calculated as 1,552 scans, a 14 percent increase from Q3 2021. From CY 2022 annualized in the SAIS CON application, Q1 and Q2 2022 can be estimated to average 1,606 scans per quarter—another 3 percent increase in just two quarters. *SAIS conveniently claims a 21 percent increase in scan volume between CY 2021 and CY 2022 despite historical claims of little to no growth in the market. Such dramatic increases in utilization without support are specious at best.*

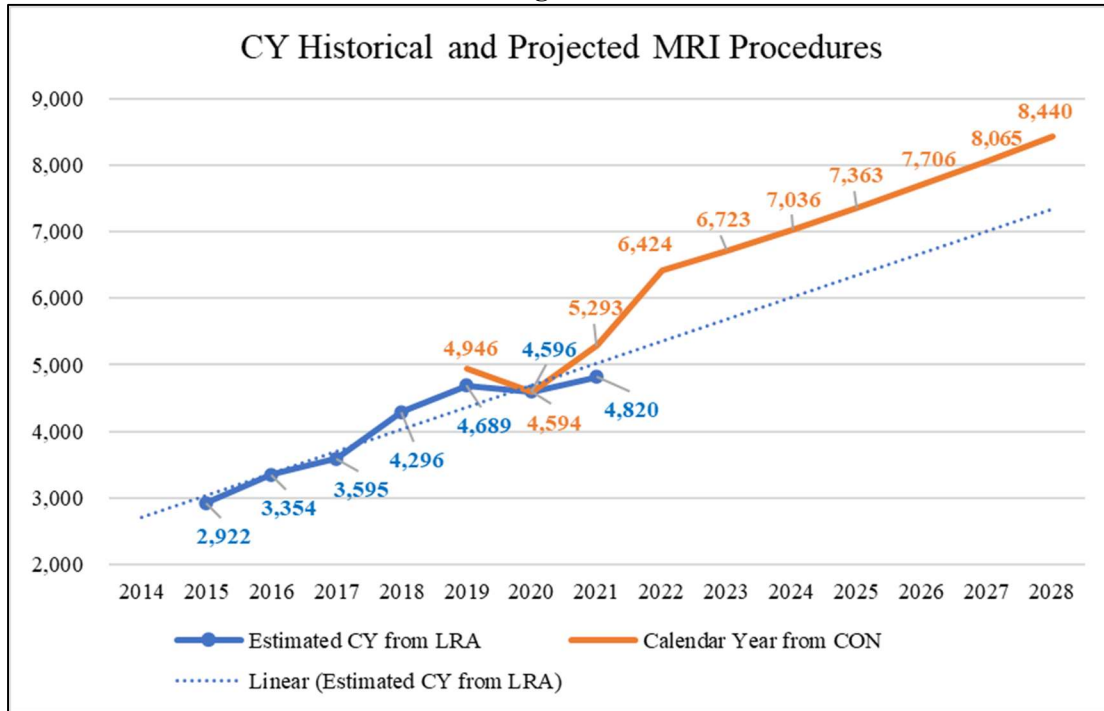
Figure 4
Comparison of Monthly, Fiscal Year, and Calendar Year MRI Trends
(Fixed and Mobile Combined)

Source For Quarterly Data:	Quarter:	Monthly Data	FY from Monthly Data	FY from LRA	CY from Monthly Data	CON Data
July 2020 Petition	Q4 2019	1,278				
July 2021 Petition	Q1 2020	1,243	4,789	4,801	4,596	4,594
	Q2 2020	932				
	Q3 2020	1,336				
	Q4 2020	1,085				
	Q1 2021	1,098				
	Q2 2021	1,277				
FY 2021 LRA less 3 Qs above	Q3 2021	1,366				5,293
CY 2020 from CON less 3Qs above	Q4 2021	1,552				
CON based on 2 Quarters annualized	Q 1 2022	1,606				6,424
	Q2 2022	1,606				
	Q3 2022	1,606				
	Q4 2022	1,606				

Sources: SAMC 2021 SMFP Petition and 2022 SMFP Petition
 SAMC LRAs, and SAIS CON Form C Assumptions and Methodology page 1.

From the questionable utilization increases claimed for Q4 2021 and year to date 2022, SAIS uses a 4.7 percent CAGR to project forward from annualized 2022. **Figure 5** demonstrates how SAIS projected baseline utilization from the Form C Assumptions and Methodology page 2, which varies from the historical trend experienced by SAMC. Again, in contrast to claims in SAMC’s petitions, the projected utilization far exceeds the trend based on verifiable historical data.

Figure 5



Source: SAMC LRA, Petitions, and CON utilization projection assumptions.

The Projected Patient Origin is Erroneous and Illogical

Patient origin is traditionally the basis and starting point for utilization projections. After projecting overall SAMC volume without regard to county of origin, SAIS then spreads the total projected volume by county and finally shifts volume to SAIS. The projected patient origin, both before the shift and after the shift, for the proposed project is illogical and erroneous.

First, the assumptions of change in patient origin on Form C Assumptions and Methodology pages 5 and 6 lead to an illogical baseline projection of outpatient scans by county, as shown in **Figure 6**. The resultant patient origin reflects CAGR growth rates by county that are completely inconsistent with population growth trends. For example, Pasquotank County resident weighted MRI scans are projected to grow by 5.1 percent CAGR while the population is only growing at 0.3 percent CAGR. Perquimans County resident weighted MRI scans are projected to grow by 4.5 percent CAGR while the population declines. This flawed baseline projection underlies SAIS projected volume.

Figure 6
Outpatient Weighted Scans

	CY 2026	CY 2027	CY 2028	CAGR %	Population CAGR%
Pasquotank	3,650	3,835	4,029	5.1%	0.3%
Perquimans	907	948	990	4.5%	-0.4%
Camden	781	820	860	4.9%	0.7%
Currituck	798	869	948	9.0%	3.7%
Other	671	652	627	-3.3%	
Total	6,807	7,124	7,454	4.6%	

Next, the shift of patients from SAMC to SAIS completely ignores Perquimans County, and it includes patients from numerous counties that must travel through Perquimans to reach the proposed facility in Moyock. In considering the reasonableness of these assumptions, the following should be considered:

- For the MRI Service Area patient volume, SAIS assumes that 30 percent of its total patients would originate from Pasquotank County, where there is an existing MRI scanner, and travel to Moyock for care. (SAIS CON p. 39.)
- SAIS projects 9 to 11 percent of patients to come from “Other” counties outside of the MRI Service Area and are assumed to drive from all over eastern North Carolina to the proposed new location on the Virginia boarder.
- “Other” includes patients from Chowan County who would have to drive through Perquimans County and through Pasquotank County to the distant facility in Moyock. This demonstrates why it is unreasonable to exclude patients from Perquimans County.
- “Other” also includes patients from Bertie County, who, due to the Albemarle Sound and Chowan River, would also travel through Chowan County, Perquimans County, Pasquotank County, and Camden County to reach the proposed MRI in Moyock.
- “Other” patients in Tyrell, Washington, and Martin Counties would also travel around the Albemarle Sound and through Chowan County, Perquimans County, Pasquotank County, and Camden County to reach the proposed MRI in Moyock.

These examples demonstrate that it is unreasonable to include these counties, as well as other states, in the “Other” patient origin category and exclude Perquimans County entirely.

Necessary Information is Omitted from the Project Assumptions

SAIS fails to provide form C2.a, which would provide the historical and interim utilization of the mobile MRI it owns. There is no information about the projected utilization of the mobile unit despite the fact that SAIS intends in the interim period to place and utilize its mobile unit at effectively the same site as its proposed fixed MRI site. This interim utilization is directly related to the future utilization of the fixed MRI unit. As SAIS correctly determined, the upcoming relocation of the mobile MRI unit to Moyock and the commitment to relinquish the mobile MRI unit upon implementation of the proposed fixed unit are direct components of this project (See SAIS application, Section D, pp. 69-72). As such, Form C2.a is a necessary data source to quantitatively evaluate the reasonableness of the utilization projections for the fixed unit. See additional discussion under Criterion (3a).

The Methodology Utilized by SAIS is Flawed, Cumbersome, and Unreasonable

SAIS utilizes a detailed methodology that analyzes population growth and Sentara’s historical utilization by service area county, then applies a CAGR based on population growth and historical MRI growth to determine future patient origin percentages for outpatient MRI services. See Form C Assumptions and Methodology pages 5-6. While SAIS utilizes historical data to determine a basis for its growth assumptions, it makes unreasonable assumptions concerning projected patient origin percentages by service area county/ “Other.” This percentage is then utilized to determine the potential outpatient MRI scans by county at SAIS-Moyock.

These intensive and detailed calculations are disregarded in the next steps of the process when the arbitrary projected capture percentages of SAIS-Moyock patients are applied to the projected MRI scans. SAIS provides little explanation for the capture rates on the Form C Assumptions and Methodology page 7 and provides no explanation for the 0 percent capture rate used for Perquimans County. More importantly the capture rates are illogical with respect to geography. Why would 20 percent of patients leave Pasquotank County, where SAMC operates an MRI, to travel farther to Moyock? Why would 40 percent of patients who mostly live west of the service area, drive farther through Perquimans and/or Pasquotank to obtain MRI services in Moyock? Consequently, the volumes have little to no meaning or reliability.

	<i>Capture</i>	<i>CY25*</i>	<i>CY26 (PY1)</i>	<i>CY27 (PY2)</i>	<i>CY28 (PY3)</i>
Pasquotank	20%	695	730	767	806
Perquimans	0%	0	0	0	0
Camden	90%	670	703	738	774
Currituck	90%	659	718	782	853
Other	40%	274	268	261	251
Total Weighted MRI Scans		2,298	2,419	2,548	2,684

*Adjusted to account for a project start date of February 1, 2025, or 11 months of CY 2025.

Source: Application for Project #R-012271-22, Form C Assumptions and Methodology, p.7

It is also unclear how the utilization for the CY 2025 time period has been adjusted for an 11-month period. If the MRI scans for this period of 2,298 are reflective of 11 months, then they can be annualized for the full CY 2025 as follows: $2,298 \div 11 \times 12 = 2,506$. This would mean that the full year volume for CY 2025 of 2,506 exceeds the CY 2026 projection of 2,419 and is almost as high as the CY 2027 projection. It does not appear that SAIS took into consideration only 11 months of operation in CY 2025.

SAMC/SAIS Simply Will Not Meet the Need

Regardless of the flawed projection methodology, there is little question that the proposed project will meet threshold utilization requirements. As stated by the applicant (Form C Assumptions and Methodology, p. 2), Sentara's current MRI volumes meet the Year 3 threshold requirements and its historical trends indicate future growth. With no additional MRI capacity being added to the service area because of this proposed project, the unit will not be underutilized.

Conversely, the proposed project does not meet the need because it does not add capacity to the service area. Quantitative need for an additional unit in the service area will be generated in a later SMFP, practically 5 years from now, following the implementation of SAIS's proposed project. Another provider would likely not be operational for 8 more year. SAIS uses a complex methodology to divert attention from the fact that it is not adding capacity to the service area. Instead, patients are shuffled around to obscure the in-migration of patients from southeastern Virginia while suppressing the SMFP need for MRI and keeping competition at bay.

SAIS Fails to Disclose Other Projects that Will Impact Utilization Projections

Developed concurrently with the SAIS-Moyock application, SAIS also filed a Virginia certificate of public need application (COPN Request No. VA-8670) on October 3, 2022, for a mobile MRI site in the City of Chesapeake, Virginia. This proposed mobile site will be located only 10 miles or a 15-minute drive from the proposed Moyock site. COPN Request No. VA-8670 certainly overlaps the service area of the proposed SAIS-Moyock project, yet SAIS does not account for how that will impact utilization projections.

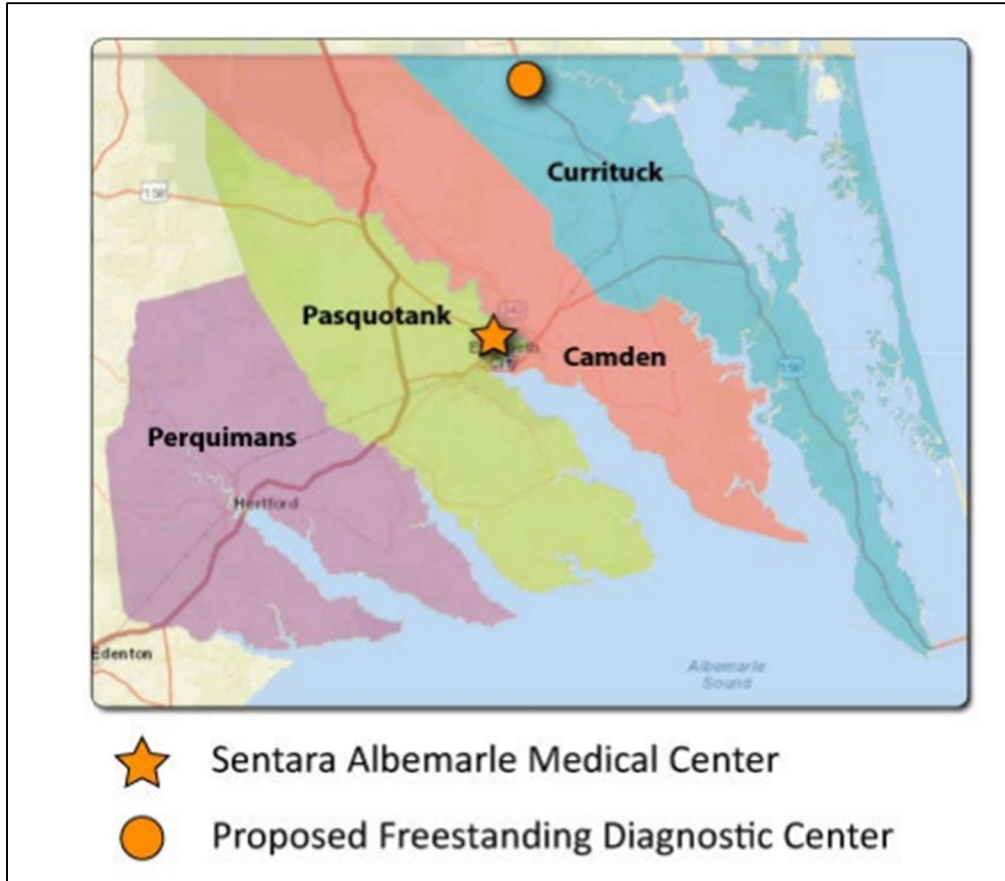
Conclusion to the Applicant's Utilization Projections Are Flawed and Unreasonable

For the reasons outlined above, the utilization projections provided by SAIS are not reliable. Projected volumes are likely overstated and the patient origin for the project is unsupported and illogical. Failure to include projected patient volume for Perquimans County shows the project will not meet the identified service area need. Despite SAIS's plan to discontinue use of its mobile unit, integral utilization data and projections related to the mobile MRI unit are omitted from the application. With this plan, SAIS will limit competition and hold the total MRI units in the county to two fixed units when they admit there are already essentially 2 fixed units. Moreover, a cumbersome and murky methodology for projecting MRI utilization at SAIS-Moyock results in projections that cannot be relied upon for assessing financial feasibility and meeting the need of the service area. Finally, SAIS fails to disclose the intent or impact of operating another mobile MRI unit just 10 miles from the proposed project.

SAIS Does Not Demonstrate Access to All Residents of the Area, Particularly Low-Income Persons, Racial and Ethnic Minorities, Women, and the Elderly

SAIS's application claims to enhance access for vulnerable and underserved populations, particularly low-income persons, and racial and ethnic minorities, but its proposed project does the opposite. SAIS neither proposes to locate its MRI to increase access for low-income or minority portions of the service area, nor does it propose to offer breast MRI to enhance access to care for women.

SAIS has chosen Moyock, Currituck County for its proposed project. Located at the northernmost part of the four-county service area on the Virginia border, the Moyock site does not provide geographic accessibility to patients residing in Pasquotank and Perquimans Counties. See SAIS service area map replicated below. In actuality, this site provides enhanced accessibility only to Currituck and Camden Counties, as well as the Hampton Roads area of Virginia.



Source: Application for Project #R-012271-22, p.33

The SMFP indicates the service area that a proposed project is intended to serve. In this case, it is the four-county area that includes Pasquotank, Camden, Currituck, and Perquimans Counties. Pasquotank, the most densely populated of the four counties, will not be well-served by the proposed facility. SAIS only projects to capture 20 percent of its appropriate Pasquotank County MRI patients to serve at the proposed facility. This is significant since Pasquotank County patients composed 52.6 percent of the SAMC fixed scanner patients in CY 2021 (SAIS application, Form C Assumptions and Methodology p. 6).

As noted previously, SAIS does not intend to serve Perquimans County patients at all. The county is absent from the projected patient origin on page 39 of the application. As one of the four counties in the SMFP MRI Service Area, Perquimans County should figure prominently. Nonetheless, Perquimans County is not even included in the footnote for the “Other” 21 North Carolina counties, *as well as other states*, for projections. Still, SAIS utilizes and analyzes Perquimans County throughout its methodology, then applies a zero percent capture rate for this county without an explanation.

Perquimans County has the highest percentage of elderly, women, and households with incomes below \$35,000. See **Figure 7**. However, SAIS does not anticipate serving this patient population at all. Instead, SAIS projects a 90 percent capture rate for Camden and Currituck Counties, which are home to the fewest minority, elderly, and low-income individuals and households of the four-county service area.

**Figure 7
Demographic Analysis**

	Perquimans County	Pasquotank County	Camden County	Currituck County	North Carolina
% 65 +	28.46%	18.45%	18.17%	17.78%	17.75%
% of Women	52.09%	51.30%	50.09%	50.23%	51.33%
% of Racial Minority	26.39%	43.42%	18.43%	11.07%	34.37%
% Hispanic/Latino	3.04%	6.42%	3.37%	4.89%	10.35%
% Below 35K Income	33.52%	31.59%	23.21%	18.82%	
% Uninsured*	9.0%	11.8%	7.2%	12.3%	10.7%

Source: Spotlight and US Census Bureau Quickfacts

Note: *US Census Data used 2020: CAS 5-Year Estimates Subject Tables

The SAIS application shows that it will not be accessible for the 65 and older population. The table on SAIS application page 44 (replicated below) shows that Perquimans County has by far the largest percentage of elderly population in the MRI Service Area. The percent of 65 and older population in Perquimans County is significantly higher than the average for the state and the service area. Yet, SAIS does not project to serve any patients from Perquimans County.

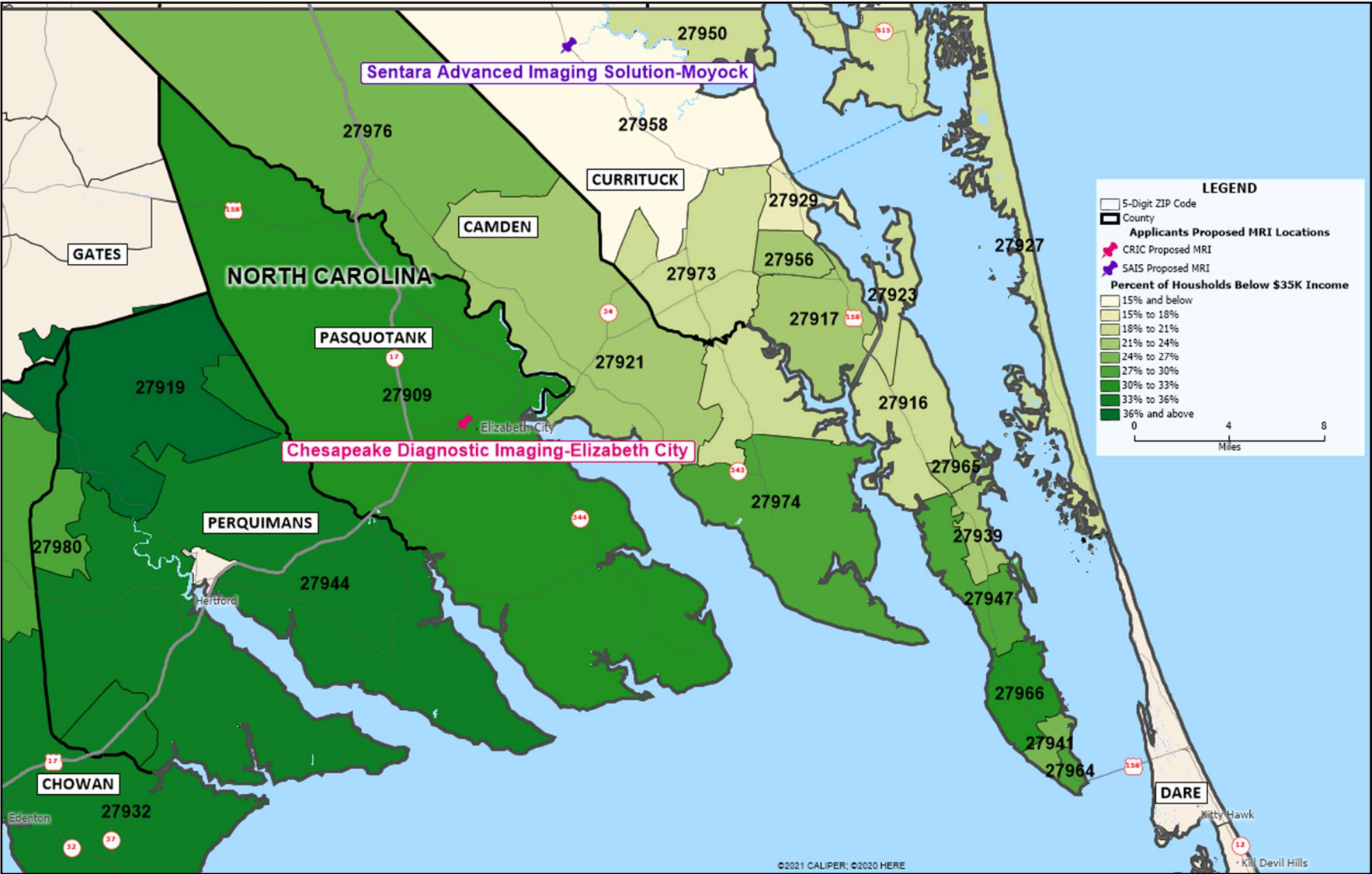
Service Area Age 65 and Older Population Growth				
County	2022		2028	
	Total 65 and Over	Percent 65 and Over	Total 65 and Over	Percent 65 and Over
Camden County	1,950	18.5%	2,384	21.8%
Currituck County	5,348	17.7%	7,370	20.3%
Pasquotank County	6,931	17.0%	7,966	19.2%
Perquimans County	3,626	28.4%	3,733	29.9%
Service Area Total	17,855	18.9%	21,453	21.2%
Statewide Total	1,860,777	17.5%	2,195,286	19.4%

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

Source: Application for Project #R-012271-22, p.44

SAIS has positioned its proposed site to be in the most economically advantaged portion of the service area. The heat map below in **Figure 8** uses Claritas Spotlight household income data to show the percentage of 2022 household incomes below \$35,000 that are located in each ZIP code in the service area. The heat map shows that the SAIS proposed site ZIP code (27958) has the lowest percentage of households, 13.75 percent, with income below \$35,000 in the entire four-county service area. ***In other words, SAIS proposed site is in the most affluent ZIP code in the four-county service area.*** The ZIP codes immediately surrounding Moyock also have relatively low percentages of household incomes below \$35,000 (light greens).

Figure 8
Household Income Percent Below 35K Heat Map



Source: Maptitude and Spotlight

SAIS’s proposed site is the furthest from the ZIP codes with higher percentages of low-income families (dark greens) in Pasquotank and Perquimans Counties. Of the four counties in the service area for this proposed project, Currituck is the most economically advantaged county in the area and is the most remote from the counties with the highest percentages of minority, women, elderly, and low-income residents.

SAIS projects lower percentages of Medicare, Medicaid, and Self-Pay/Charity Care patients than Sentara/SAMC has historically served on an outpatient basis. This is unsurprising given the location of SAIS-Moyock. **Figure 9** below compares SAMC’s FY 2022 outpatient services payor mix to the projected payor mix during the third full fiscal year of the proposed project (SAIS’s application, p. 86). ***SAIS-Moyock projects to provide far less care to self-pay, Medicare, and Medicaid patients and far more care to those with commercial insurance than it has historically provided to outpatients at SAMC.***

**Figure 9
Sentara Payor Mix Comparison**

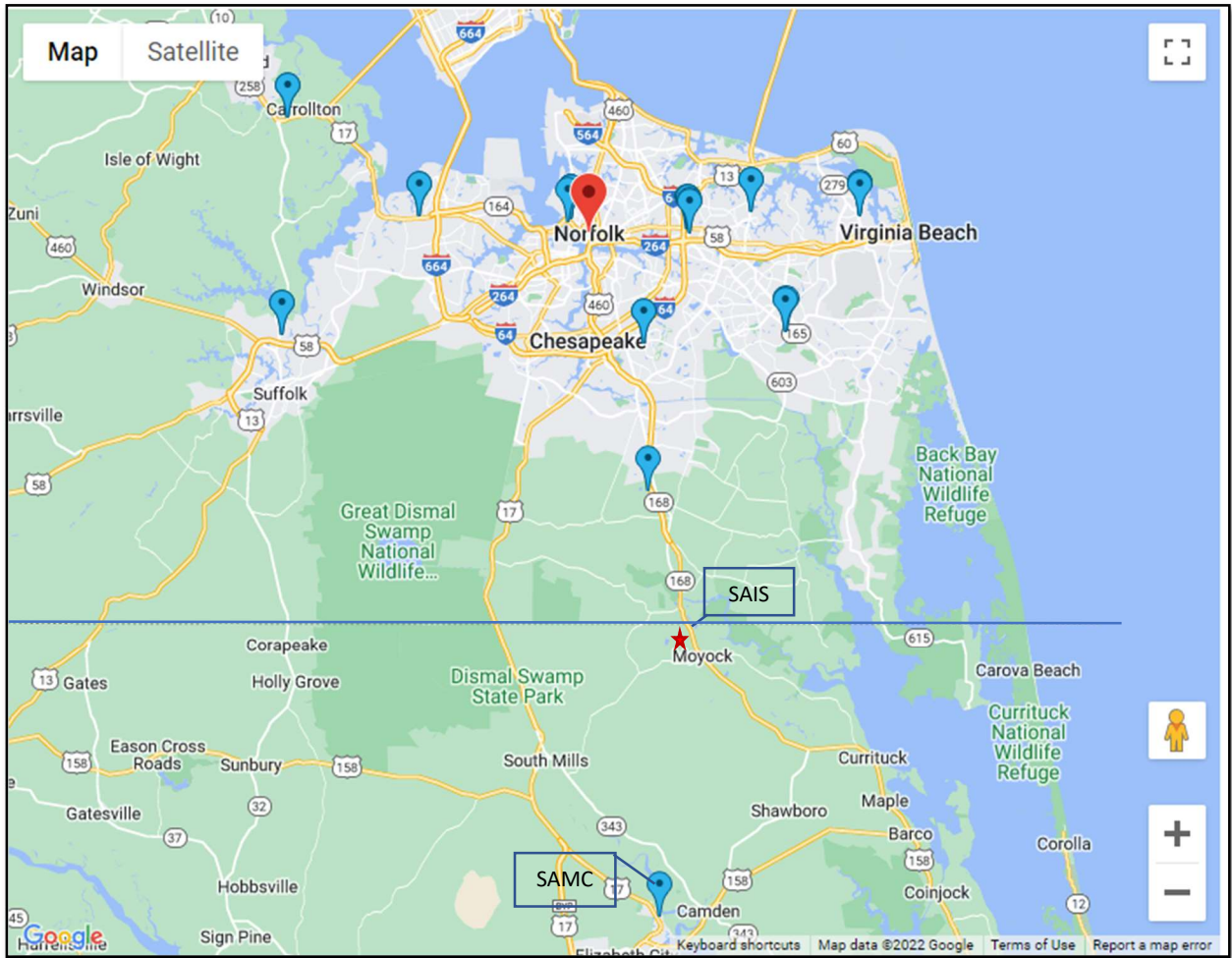
Payor Source	Outpatient Visit Payor Mix	Projected Payor Mix
Self Pay	4.5%	3.7%
Charity Care	0.0%	
Medicare*	47.1%	38.0%
Medicaid*	12.3%	8.8%
Insurance*	30.6%	43.8%
Other (specify)	5.5%	5.7%
TOTAL	100.0%	100.0%

Source: 2022 LRA and Section L of Application

** includes any managed care plans*

SAIS proposes to locate its facility in a part of the service area that has significant access to healthcare in North Carolina and Southeastern Virginia. As previously mentioned, SAIS’s application does not disclose its current mobile MRI efforts only 10 miles away in the City of Chesapeake, Virginia (COPN Request No. VA-8670). This lack of disclosure raises questions about the conceivability of the proposed Moyock site. As **Figure 10** on the following page demonstrates, SAIS-Moyock will be more accessible to ***parts of Virginia*** than it will be to portions of the North Carolina MRI Service Area. For example, the SAIS-Moyock location is 24.6 miles from Elizabeth City, North Carolina, the largest city in the service area, but only 10.6 miles from southern Chesapeake, Virginia.

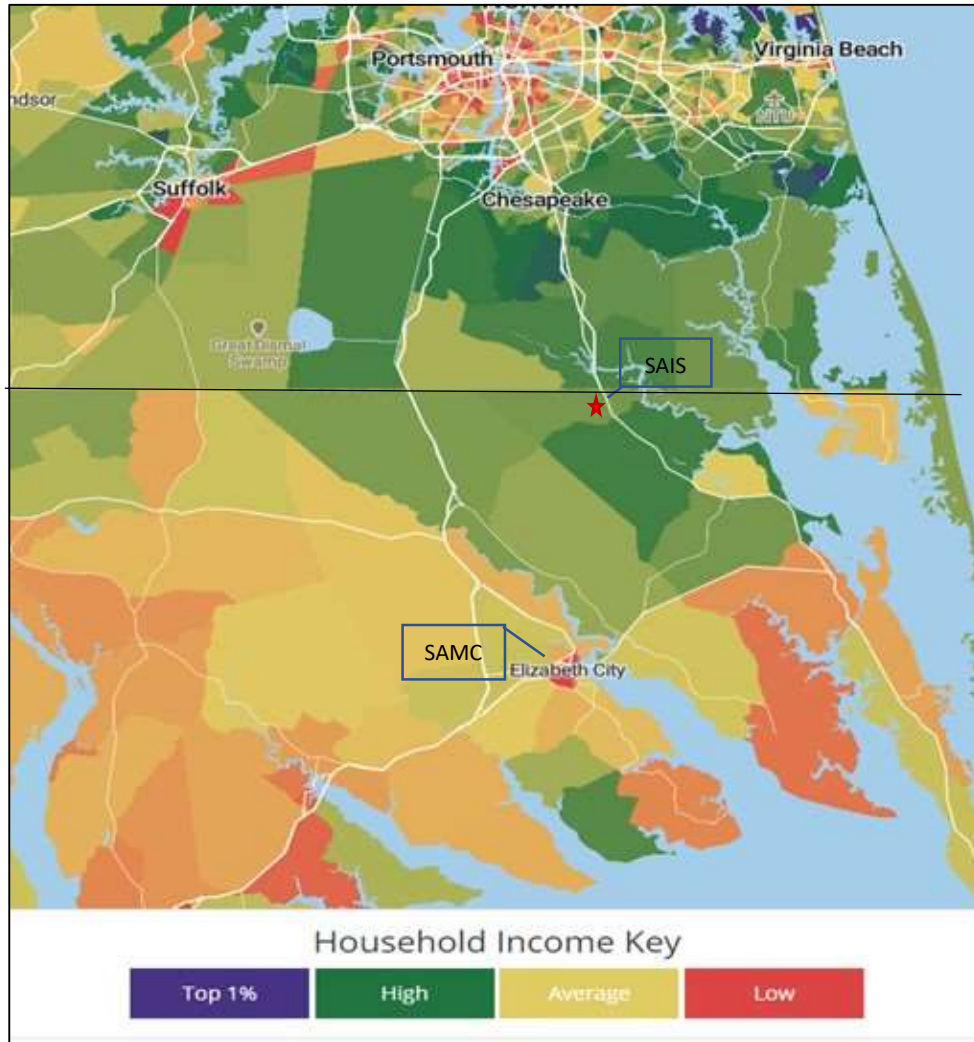
Figure 10
Existing Sentara Imaging Facilities



Source : <https://www.sentara.com/hospitalslocations.aspx?filters=ImagingCenter>

Like northern Currituck County, southern Chesapeake is also much more affluent than Elizabeth City and Perquimans/Pasquotank Counties as shown in **Figure 11** below. Clearly SAIS has not adjusted its payor mix to account for the affluence of the communities in which it will be located, calling its payor mix projections further into question.

Figure 11
Household Income in Communities Surrounding Moyock



Source: Bestneighborhood.org

SAIS Fails to Meet the Criteria and Standards for MRI Services 10A NCAC 14C.2703

SAIS’s own projections make it clear that there is a need for two fixed MRI units and a mobile unit in the MRI Service Area. However, SAIS’s application simply swaps a mobile for a fixed MRI and provides no additional capacity for the service area.

SAIS projects sufficient weighted MRI scan volume to operate two fixed units and a full-time mobile unit in the service area. As shown in **Figure 12**, based on the 2022 SMFP and the MRI Performance Standards under 10A NCAC.2703(b)(7)(C) and (8), the combined utilization threshold for two fixed units and one mobile unit in the service area would require a weighted scan volume of 9,094. SAIS projects the combined utilization of the two fixed units in the third year of operation to be 9,998 adjusted MRI scans (see SAIS’s CON application p. 65). This is sufficient volume to support two fixed units and SAIS’s full-time mobile unit.

Figure 12
Sentara Projected Volume and MRI Performance Standard

Unit or Location	Threshold Adjusted MRI Procedures
Sentara Albemarle Medical Center <i>(SMFP 2 fixed MRIs in the service area)</i>	2,883
SAIS-Moyock Proposed <i>(SMFP 2 fixed MRIs in the service area)</i>	2,883
SAIS Mobile <i>(SMFP mobile threshold)</i>	3,328
<i>Total Threshold Volume</i>	<i>9,094</i>
Total Sentara/SAIS CY 2028 Weighted Procedure Volume	9,998

Contrary to SAIS’s projected scan volume, the application commits to eliminating the mobile unit that could serve to expand access in the service area, leaving the MRI Service Area’s need unmet. This demonstrates that SAIS does not plan to expand access but is motivated to block competing providers from the service area. This protectionism harms the MRI Service Area and broadly reduces MRI capacity. If SAIS did not relinquish the mobile CON, it could be used to expand access to other areas within the service area or even adjacent areas. Notably, the SAIS mobile unit was used to serve Sentara Kitty Hawk Advance Imaging Center in Dare County as recently as the 2020 SMFP. However, Sentara/SAIS eliminated this service and reduced access to care. ***Given that the North Carolina State Health Coordinating Council voted in September 2022 to add need determinations for three mobile MRI units in the state in response to petitions, there is broad need for additional mobile MRI capacity in the state. Despite this need, SAIS plans to relinquish its mobile MRI CON if this proposed project is approved and becomes operational.***

Criterion (3a): SAIS Fails to Document How the Reduction of MRI Services will Adequately Meet the Needs of the Population Presently Served

SAIS correctly identifies that Criterion (3a) applies to the proposed project, but it does not reasonably document that the needs of service area residents will be met by the elimination of MRI services. It fails to address or justify that the SMFP calculates a need for an additional fixed MRI unit based upon the existence and utilization of Sentara’s fixed and mobile MRIs. As previously noted, the elimination of the mobile MRI unit effectively results in a replacement project rather than an addition of MRI capacity.

SAIS fails to provide Form D.2 for the mobile MRI service that will be eliminated through the proposed project. SAIS claims this form is not applicable. This claim is patently wrong, and there is no basis for the claim. SAIS, the applicant, is eliminating a mobile MRI unit that it states will be operating in essentially the same location as the proposed fixed unit in the interim period until the fixed unit is fully implemented. The historical and interim utilization of the mobile MRI unit is necessary to evaluate the implications of eliminating this service. This alone should result in a finding of non-conformance with Criterion 3a.

Moreover, SAIS’s own projections show there is a need for the existing fixed unit, an additional fixed unit, and the mobile unit as discussed in detail under Criterion (3). SAIS has not demonstrated that the population currently served by the mobile MRI will be adequately served when it is gone. SAIS’s projections show there is need for two fixed MRI units in addition to the existing mobile unit to meet the service area need. By simply swapping the proposed fixed CON for the existing mobile unit CON, SAIS is not meeting the need

identified in the SMFP and will leave service area residents underserved. Moreover, SAIS own utilization projections demonstrate that it will not be able to adequately serve its projected patients without the mobile unit it plans to eliminate as shown in **Figure 12** above.

Criterion (4): SAIS's Proposed Project is Not the Least Costly or Most Effective Alternative

SAIS's proposed project does not represent the least costly or the most effective alternative. The least costly, most effective, and most timely alternative is exactly what SAIS planned to do prior to this application by locating its mobile MRI on a full-time basis at the site in Moyock. Because this can be achieved and is already planned, it is highly questionable why SAIS would need or want to spend more than two million dollars to effectively accomplish the same result through this proposed project.

SAIS's proposed project does not represent the most effective alternative. Whether SAIS is relocating its mobile MRI unit or purchasing a fixed unit and relinquishing its mobile MRI unit, its proposed project only plans to redistribute Sentara's/SAIS's existing patient base to two locations. The proposed project does not intend to serve any additional patients. SAIS's utilization methodology is based entirely on its existing patient base, and it does not consider patients who are traveling outside the service area for MRI diagnostic services. A more effective alternative would add MRI capacity to the service area as intended by the 2022 SMFP. SAIS's proposed project will result in net neutral capacity that will not address the need for a fixed MRI scanner.

Criterion (5): SAIS Fails to Demonstrate that the Project is Financially Feasible

SAIS's proposed project costs are clearly and significantly understated in terms of capital costs, leasing rates, and professional fees. Additionally, SAIS significantly overstates reimbursement rates.

There are numerous flaws throughout the application that impact the financial feasibility of the proposed project. These include flawed utilization projections, incomplete project costs, inaccurate lease rates, among other technical issues.

As discussed in detail under Criterion (3), the utilization projections for SAIS and its parent company, Sentara, are flawed and based on erroneous assumptions. SAIS fails to provide interim projections essential to better understand ramp up assumptions and capture rates for its mobile MRI unit. Consequently, SAIS's utilization projections are at best unreliable and at worst significantly flawed. Utilization is fundamental to financial feasibility, and SAIS's unreliable projections directly undermine the financial feasibility of the proposed project.

Furthermore, SAIS does not include sufficient project costs to implement the proposed project based on Form F.1a. The total estimate for Medical Equipment included in Form F.1a, Capital Costs is \$1,401,515, which is the exact estimate of the MRI unit itself. The estimated capital cost includes no budget or estimate for other minor medical equipment, furnishings, fixtures, or equipment related to upfit the space. Finally, consultant fees are not included in Form F.1a even though a consultant is listed in the application for the proposed project. Thus, SAIS proposed project costs are clearly understated.

SAIS's application also underestimates lease costs for the medical office building in Form F.3b. Sentara intends to transfer or assign an existing lease from Sentara Medical Group to SAIS. Sentara Medical Group's existing lease was executed in 2013, and it appears to still be in place today. Section 4.b of the Lease included in SAIS's application Exhibit K.4-2 provides for an annual increase in the base rent. The Summary of the Lease Provisions identifies base rent to be \$60,000 and the base rent adjustment percentage to be 2.5 percent with the lease beginning in 2013. Utilizing this information, the lease costs through the

planning horizon are projected on the following page. The escalated annual lease cost of the building for the first three full years of operation should be \$82,711, \$84,778, and \$86,898, respectively. However, SAIS’s projections in Form F.3b show rental expense to be far less than this. Because the applicant erroneously utilizes the base \$60,000 from 2013 for its first partial year of operation in 2025, its lease expenses are underestimated by more than \$20,000 per year and become more understated each year. Thus, SAIS’s lease expenses are clearly understated. See **Figure 13** for more detail.

**Figure 13
Discrepancy in Rent Expense**

	2013	2014	2015	2016	2025	2026	2027	2028
Base Rent	\$ 60,000	\$ 61,500	\$ 63,038	\$ 64,613	\$ 80,693	\$ 82,711	\$ 84,778	\$ 86,898
Annual Percentage Adjustment	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
Rent Expense Listed in Form F.3b					\$ 55,000	\$ 61,500	\$ 63,038	\$ 64,613

Source: Application for Project #R-012271-22, Lease Exhibit and Form F.3b

On page 84 of SAIS’s application, it states that professional fees are excluded from the project and will be billed separately by the physician. Form F.3b also does not show any professional fees. As SAIS will not be utilizing global billing, its charges and net revenue should only represent the facility component of the patient encounter. It appears that SAIS has significantly overstated its reimbursement, perhaps basing net reimbursement on hospital rates, and reflecting global billing including physician fees. Based on MRI cost and payment data for Medicare from www.medicare.gov, SAIS is far overstating its reimbursement. **Figure 14** provides average Medicare fees and payments for the most common MRI procedures from the www.medicare.gov website. The average Medicare payment for just the facility fee is estimated to be \$109.40.

**Figure 14
FY 2022 Medicare Average Fees and Payments for Common MRI Procedures**

CPT	Description	FY 2021 Procedures	Freestanding/Ambulatory Setting				% Facility Fee	Medicare Facility Payment
			Average Doctor Fee	Average Facility Fee	Total Fee	Medicare Pays		
70551	MRI brain w/ contrast	520	\$ 72	\$ 119	\$ 191	\$ 152	62.3%	\$ 94.70
70533	MRI brain w/ and w/o contrast	515	\$ 111	\$ 190	\$ 301	\$ 241	63.1%	\$ 152.13
72141	MRI cervical spine w/o contrast	402	\$ 72	\$ 119	\$ 191	\$ 153	62.3%	\$ 95.32
72148	MRI lumbar spine w/o contrast	762	\$ 72	\$ 119	\$ 191	\$ 153	62.3%	\$ 95.32
73221	MRI upper joint w/o contrast	335	\$ 66	\$ 119	\$ 185	\$ 148	64.3%	\$ 95.20
73721	MRI lower joint w/o contrast	539	\$ 66	\$ 119	\$ 185	\$ 148	64.3%	\$ 95.20
74183	MRI abdomen w/ and w/o contrast		\$ 106	\$ 190	\$ 296	\$ 237	64.2%	\$ 152.13
772195	MRI pelvis w/o contrast		\$ 71	\$ 119	\$ 190	\$ 152	62.6%	\$ 95.20
	Average:		\$ 80	\$ 137	\$ 216	\$ 173	63.2%	\$ 109.40

Sources: SAMC 2022 LRA, <https://www.medicare.gov/procedure-price-lookup/cost/70553/>

This average payment when inflated three percent annually to the SAIS projection period results in an average reimbursement ranging from \$113 to \$123 per scan. This is less than half of the average reimbursement per scan projected by SAIS in Form F.2b as shown in **Figure 15**. When SAIS net revenue is corrected for a reasonable reimbursement rate based on www.medicare.gov, the net revenue for SAIS will be nearly \$600,000 lower than projected in Form F.2b.² **Given that SAIS is only projecting a net income of \$81,064 in the third year, this mistake completely eliminates the possibility that SAIS’s proposed project will be financially feasible.**

² It is noted that Medicare only represents one payor; however, many insurance companies base their payment rates on Medicare. With some payors reimbursing more than Medicare and some less, the Medicare average is a reasonable estimate for the purposes of determining the reasonability of SAIS’s reimbursement.

Figure 15
SAIS Corrected Net Revenue and Shortfall

	FY 2022	CY2025	CY2026	CY2027	CY2028
Projected Average Medicare Facility Fee Payment	\$ 109.40	\$ 119.54	\$ 123.13	\$ 126.82	\$ 130.63

SAIS Projected Revenue:

	CY2025	CY2026	CY2027	CY2028
Procedures (Form C.3)	711	1,635	2,153	2,268
Net Revenue (Form F2.b)	\$ 255,594	\$ 606,244	\$ 822,264	\$ 892,169
Average Reimbursement per Procedure	\$ 359.49	\$ 370.79	\$ 381.92	\$ 393.37

SAIS Corrected Revenue without Physician Fee:

	CY2025	CY2026	CY2027	CY2028
Procedures (Form C.3)	711	1,635	2,153	2,268
Average Reimbursement per Procedure from	\$ 119.54	\$ 123.13	\$ 126.82	\$ 130.63
Net Revenue (Corrected)	\$ 84,996	\$ 201,319	\$ 273,053	\$ 296,267
Shortfall from Form F.2b	\$ (170,598)	\$ (404,925)	\$ (549,211)	\$ (595,902)

For the reasons discussed above, SAIS’s project is not financially feasible and should be found non-conforming with Criterion (5).

Criterion (6): The SAIS Proposal Represents an Unnecessary Duplication of Services

SAIS intends to implement the same project twice with this application. SAIS’s application states that it will relocate its existing mobile MRI unit to the proposed project site in Moyock for use as a freestanding MRI scanner until the renovation of a MOB for a new, fixed unit is approved and fully implemented. SAIS further states it has the capability of implementing the project without CON review and with minimal costs related to constructing a mobile pad and moving the mobile MRI unit to Moyock. In this application, SAIS opts to relocate the mobile MRI to Moyock *and* to apply for a CON to replicate that project with a fixed unit housed in a MOB at the same location. In other words, SAIS is planning to spend more than \$2 million to do the same project twice—one that it claims can and is already being done without regulatory approval. Therefore, SAIS should be found non-conforming with Criterion (6).

Although SAIS fails to provide any interim utilization projections for volume the mobile unit will do in Moyock, it is clear that the applicant will swap out the mobile unit for the fixed unit then take the mobile out of service. This action will leave an underserved population that, according to SAIS and SMFP projections, has sufficient need for two fixed MRI units *and* a mobile unit.

As a result, SAIS should be found non-conforming with Criterion (6).

Criterion (7): The Staffing Projected by SAIS is Inadequate

SAIS only accounts for 0.5 FTE for administrative functions, a Registration Rep related to the proposed facility for each of the first three years of operation. Since the proposed facility projects full-time service, it should be anticipated that a full-time Registration Rep would be needed in all three years operation. Therefore, staffing appears to be inadequate.

Criterion (8): SAIS Does Not Show Adequate Support for the Project and Coordination with the Healthcare Delivery System

Necessary Ancillary and Support Services

While SAIS provides a generic letter indicating that ancillary and support services will be provided, SAIS fails to document the availability of a radiology group that will read the images for the proposed fixed MRI and the willingness of any radiologist to serve as a medical director for the proposed site. Equally critical is the need for an onsite physician as required to provide contrast, which is also undocumented. Without these critical functions, SAIS has not documented several of the fundamental required support services.

Coordination with the Existing Health Care System

SAIS's application documents little support or coordination for the proposed project outside of its parent organization, Sentara, and includes no support from patients, businesses, or elected officials.

SAIS provides 32 letters of support with its application for the proposed project, yet all are form letters and nearly all are signed by Sentara-affiliated providers. More surprising is that SAIS does not show ***any support*** from patients, businesses, or elected officials in service area or Moyock, Currituck County, specifically. ***To emphasize the latter point, it should be noted that the Currituck County Board of Commissioners did not support the project.*** As a result, SAIS fails to show consistency with Criterion (8).

Criterion (12): SAIS Does Not Demonstrate That the Proposed MOB and Related Renovations Represent the Best Alternative

SAIS provides a letter of intent ("LOI") from Sentara Medical Group ("SMG") stating that it intends to lease its existing space to SAIS for the proposed project. However, SMG does not own or control this space; it leases it from CPM Commercial, LLC ("CPM"). The existing lease that SMG intends to assign to SAIS is included in the application as Exhibit K-4.2 and contains several clauses that appear to prohibit multiple aspects of this transaction, including subletting and the proposed renovations without express consent from CPM. SAIS has provided no evidence of CPM's consent to assign or sublease the space, and there is no indication that the renovations required to accommodate the proposed MRI have been approved by the landlord.

An excerpt from the lease provided in the application, Lease Section I.20, Assignment and Subletting (p. 11), is shown below. Based on this language, SMG shall not lease or sublet without the written consent of the landlord unless it is to an entity that controls, is controlled, or is under common control with the Tenant. While SMG and SAIS both appear to be Sentara affiliates, there is no documentation that these two entities meet this definition. SMG does not appear to be related to this project in any way other than through this lease.

20. Assignment and Subletting.

(a) **Consent Required.** Tenant shall not assign this Lease or sublet the Premises or any part thereof (collectively such events are referred to as "Transfers") without obtaining the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. In the event of any Transfer permitted under the terms of this Section, Tenant shall remain fully and primarily liable for all of the obligations of Tenant under this Lease. Consent by Landlord to any one Transfer shall not be deemed to waive the requirement that Landlord's consent be obtained for future Transfers.

(b) **Landlord Consent Not Required.** Notwithstanding any other provision of this Lease to the contrary, Tenant may assign this Lease or sublet the Premises without Landlord's consent to any entity that controls, is controlled by or is under common control with Tenant, or to any entity resulting from a merger, acquisition, consolidation, reorganization or name change of or with Tenant, or in connection with the sale of all or substantially all of the assets of Tenant.

Source: Application for Project #R-012271-22, Exhibit K-4.2

Additionally, SAIS proposes to make almost \$950,000 in structural changes and renovations to the proposed space to accommodate the MRI unit. Lease Section I.10(a), "Alterations," (below) prohibits tenants from making alterations, additions, or improvements of a structural nature without the landlord's consent. The shielding component of the proposed renovation is likely to be structural in nature. Even if this is not the case, the lease requires the landlord's approval of interior, non-structural alterations with a total out-of-pocket cost exceeding \$50,000.

10. Alterations.

(a) Tenant shall not make any alterations, additions or improvements (collectively, "Alterations") of a structural nature in or to the Premises or any Alterations to the exterior of the Premises, without Landlord's prior written consent which shall not be unreasonably withheld or delayed. Interior, non-structural Alterations with a total out-of-pocket cost to Tenant of Fifty Thousand Dollars (\$50,000.00) or less shall not require Landlord's consent. Tenant shall not make interior, non-structural Alterations with a total out-of-pocket cost exceeding Fifty Thousand Dollars (\$50,000.00) without first obtaining Landlord's prior written consent, which shall not be unreasonably withheld or delayed.

Source: Application for Project #R-012271-22, Exhibit K-4.2, p5

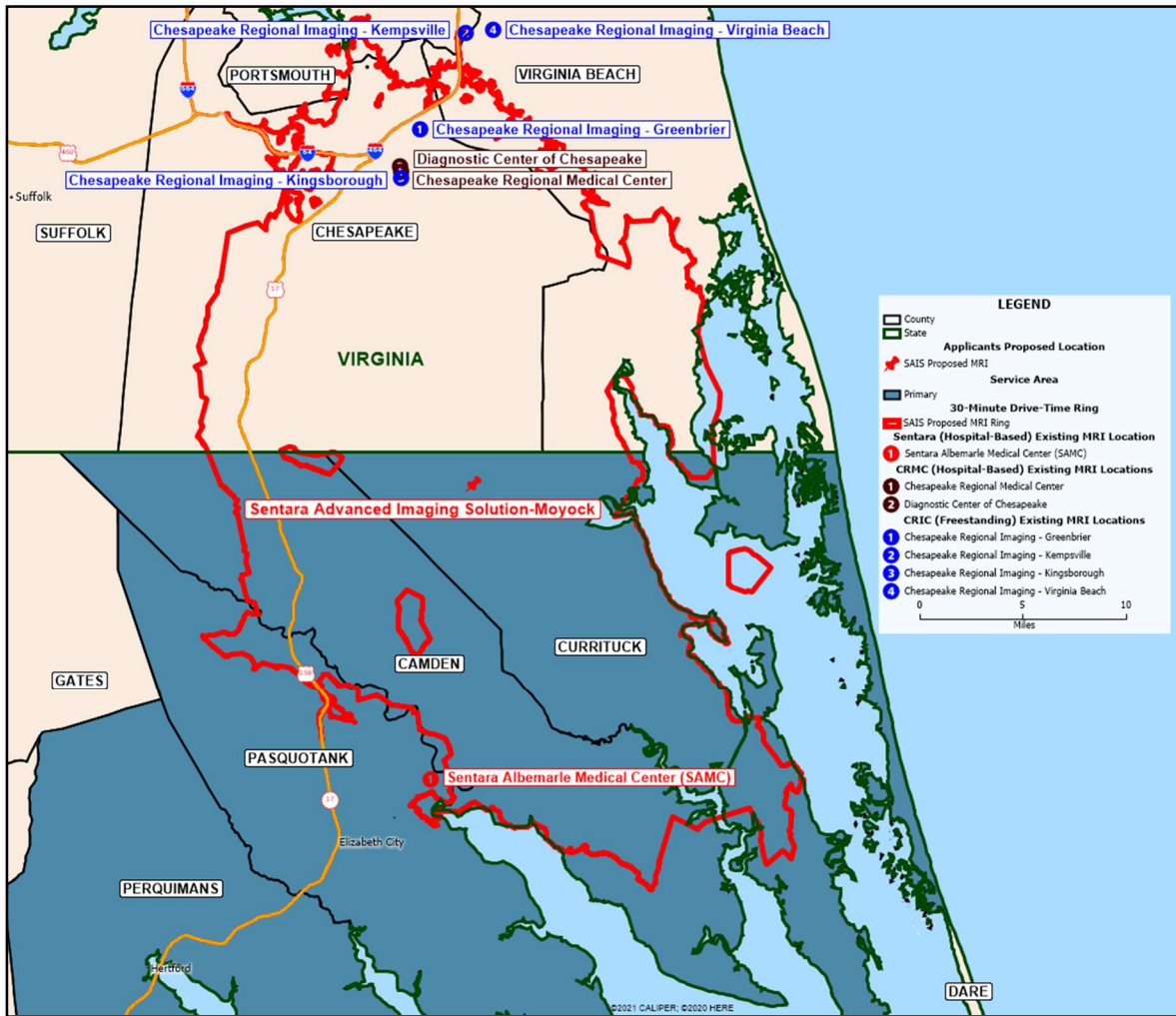
There is no evidence or documentation from CPM, the landlord, that either the sublease agreement or the proposed renovations have been approved. As a result, SAIS should be found non-conforming with Criterion (12).

Criterion (13): SAIS's Project Will Not Serve Medically Underserved Patients

Of the numerous issues presented heretofore regarding the SAIS application, enhanced access for medically underserved communities is perhaps the most significant flaw. SAIS's proposed project completely fails to increase access to MRI services for the four-county service area, and it ignores the two counties with the highest percentage of historically underserved populations.

Figure 16 shows a 30-minute drive-time map for the proposed project. The residents within the service area living within a 30-minute drive-time for the proposed facility primarily originate from Currituck and Camden Counties. The ring captures a small area of northern Pasquotank County, but it largely leaves out Pasquotank, particularly Elizabeth City, and Perquimans Counties. The proposed location is easily accessible to Hampton Roads, Virginia, but the proposed site in Moyock excludes the two most densely populated counties in the four-county service area.

Figure 16
30-Minute Drivetime Around SAIS

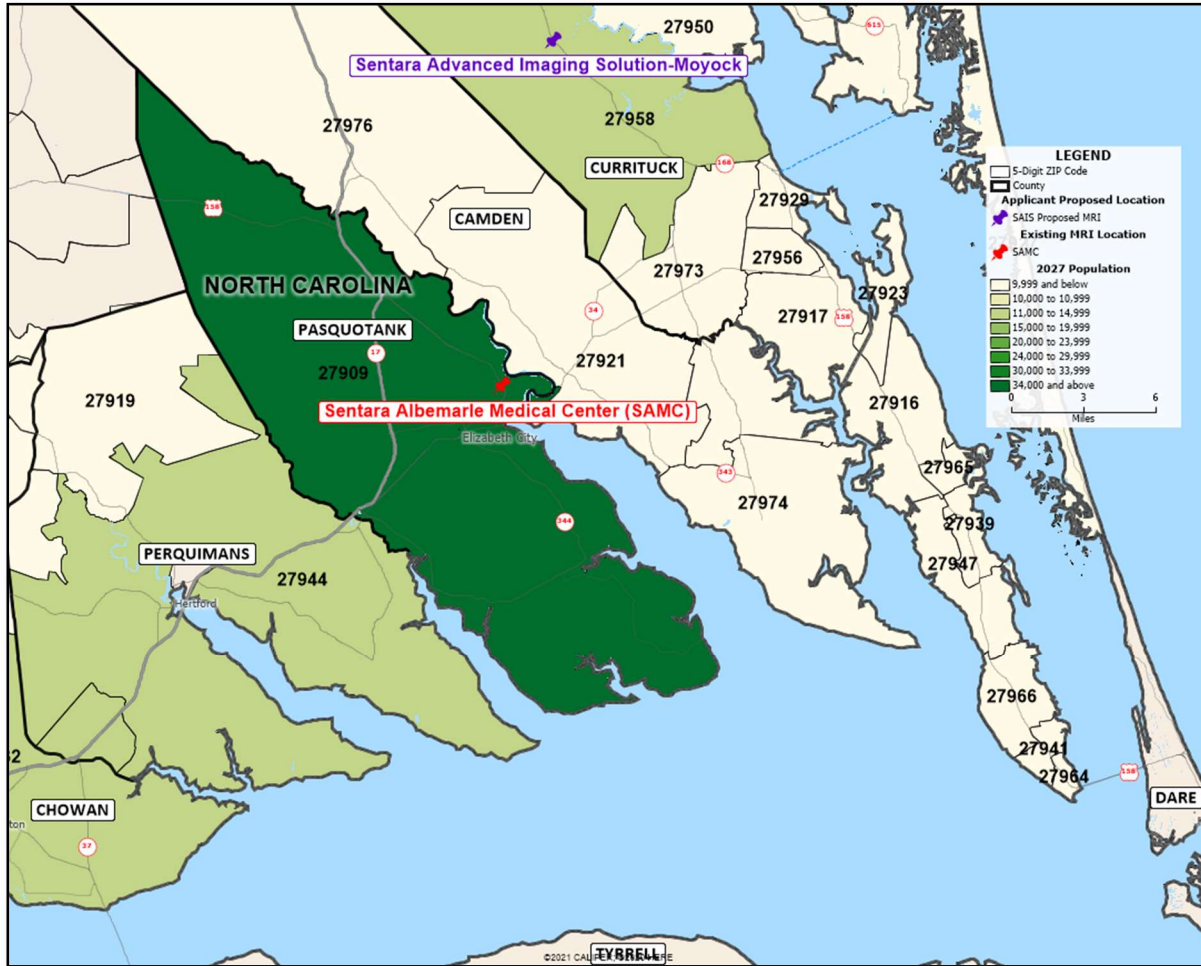


Source: Maptitude

As discussed in detail related to Criteria (1) and (3), Perquimans and Pasquotank Counties have the highest percentages of residents from groups that are historically medically underserved. These groups include women, minorities, those with low-income, and the elderly. There is no question that Perquimans and Pasquotank patients will not be served by the proposed project. *SAIS-Moyock projects to serve zero patients originating from Perquimans County and only projects to capture 20 percent of SAMC/Sentara outpatients originating from Pasquotank County.* This proposed project is focused on serving the more affluent populations of Camden and Currituck Counties.

As importantly, SAIS-Moyock is not situated to enhance access to the overall service area. Shown in **Figure 17** below is a map of the 2027 (Project Year 2) population composition for ZIP codes in the four-county service area. The largest population bases are in Pasquotank ZIP codes while the smallest population bases are located in Camden and Currituck Counties. Even with the growth expected in the Moyock/Currituck County ZIP code, as well as other parts of Currituck and Camden Counties, it is far less densely populated than Pasquotank County. *Most significantly, only the less densely populated areas of Camden and Currituck Counties are located within a 30-minute drive time of the proposed project site.*

Figure 17
2027 Service Area Population Heat Map



Source: Maptitude

Finally, upon implementation of SAIS-Moyock, there is no increased accessibility to MRI services at all. There may be an MRI unit located closer to one segment of the service area population, but there is no increased MRI capacity in the whole service area. There are two MRI units currently operating full-time in the service area, and there will be two MRI units operating full-time in the service area upon implementation of this proposed project. The only difference is that SAIS will replace a full-time mobile MRI unit with a full-time fixed unit.

The proposed project does not increase accessibility to medically underserved communities; it moves MRI capacity farther away. SAIS’s failure to increase MRI capacity through its proposed project further

emphasizes its disconnection to the community and the service area's needs that flows through the project review criteria. Thus, SAIS should be found non-conforming with Criterion (13).

Criterion (18a): SAIS's Proposed Project Will Not Positively Impact Competition in the Service Area

Sentara is the only provider of acute care services in the four-county service area, and it is the only existing provider of MRI services. Residents of Pasquotank, Camden, Currituck, and Perquimans Counties have no choice in MRI provider within the service area. Likewise, Sentara has no competition in the service area for most healthcare services including MRI. As of the time of filing, Sentara chooses to operate its fixed and mobile MRI units as hospital-based units in terms of location, as well as billing. While the fixed unit is located within the hospital and is owned by SAMC, the mobile MRI unit is owned by SAIS and could have been operating as a freestanding unit in various locations throughout the service area. *Sentara elected to utilize the mobile unit from the hospital location and to bill its use as a hospital-based service until now.*

The need generated for a fixed MRI unit in the 2022 SMFP has forced Sentara's hand. It is clear from its proposal that SAIS-Moyock is the latest attempt to suppress the need for fixed MRI services in the community for several more years and to keep competition out of the service area. The proposed project will detrimentally and fundamentally impact competition in the service area. As such, SAIS should be found non-conforming with Criterion (18a).

Comparative Review of Pasquotank/Camden/Currituck/Perquimans County Service Area Fixed MRI CON Applications

According to G.S. 131E-183(a)(1) and the 2022 State Medical Facilities Plan (“SMFP”), no more than one fixed MRI scanner may be approved for Pasquotank/Camden/Currituck/Perquimans County service area in this review. Because the application in the review collectively proposed to develop two fixed MRI scanners, one in Pasquotank County and the other in Currituck County, all applicants cannot be approved for the total number of proposed fixed MRI scanners. The following comparative analysis of the proposal is to explain why **Chesapeake Diagnostic Imaging Centers, LLC (“CDIC”) d/b/a Chesapeake Regional Imaging Center (“CRIC”)** is the best applicant and should be approved.

Both applicants are seeking to develop a new freestanding diagnostic center with one fixed MRI scanner. SAIS proposed a new freestanding diagnostic center with one fixed closed-bore MRI in Currituck County, with quality and capabilities equivalent to Sentara's existing hospital-based fixed MRI scanner and projected 2,684 weighted scans in its third full year of operation (CY 2028). CRIC proposed to add a new freestanding diagnostic center with one fixed, wide-bore MRI in Pasquotank County, with expanded diagnostic imaging services, including breast coil capabilities, and projects 3,540 weighted scans in its third full year of operation (FY 2027).

Furthermore, the analysis of comparative factors and the conclusions reached by CRIC concerning specific factors are determined partly by whether the CON applications included data that can be compared between applicants.

Conformity with Statutory and Regulatory Review Criteria

Table 17E-3 on page 364 of the 2022 SMFP identifies a need for one Fixed MRI scanner in the Pasquotank/Camden/Currituck/Perquimans County service area. Table 17E-1, page 356, shows that SAIS affiliate Sentara Albemarle Medical Center (“SAMC” or “Sentara”) is the only provider in the Pasquotank/Camden/Currituck/Perquimans County service area with one fixed MRI scanner and one mobile MRI scanner, which was equivalent to 1.31 fixed MRI scanners. SAMC/SAIS admits the mobile unit is essentially a full-time fixed unit.

Only **CRIC’s** application conforms to all applicable statutory and regulatory review criteria. **SAIS’s** application does not conform to numerous statutory and regulatory review criteria as outlined above.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the most effective alternative regarding this comparative factor.

CRIC proposed implementing a FUJIFILM Echelon Oval 1.5T MRI scanner, a unique **oval** design MRI scanner that provides the high image quality of a 1.5T MRI with an open feel to accommodate larger and claustrophobic patients. It has the **widest bore** in the industry (**74cm** oval bore), accommodating bariatric patients and improving comfort for claustrophobic patients. **CRIC’s** selected MRI scanner also can **lower the table to 20”** to accommodate pediatric (small), non-mobile, infirm, and elderly patients. It is important to note that elderly patients have higher utilization of MRI services than any other group. The FUJIFILM Echelon Oval 1.5T MRI is appropriate for all image types, including **breast coil** for breast MRI scans, which are not currently being offered in the service area.

SAIS proposed implementing a Siemens Magnetom Sola 1.5T MRI scanner that utilizes whole-body superconductive Zero Helium Boil-Off 1.5T magnetic resonance system. **SAIS’s** selected MRI scanner has

a bore of **70 cm** that they claim will reduce patient anxiety and claustrophobia. **SAIS** chose the Siemens Magnetom Sola 1.5T MRI to provide quality diagnostic imaging services in a freestanding environment **equal** to that of the existing hospital-based fixed MRI scanner.

Both **CRIC** and **SAIS** proposed MRIs in a freestanding environment that can deliver high-quality diagnostic images and accommodate claustrophobic patients. However, **SAIS** plans to operate the same technology *already available* in the four-county service area, with the only difference being the freestanding care environment. Additionally, it is unclear if **SAIS** is billing globally or is only billing technical fees as discussed in Criterion (5). It is indeterminable that **SAIS** will be a cost-effective alternative, as the total charges and reimbursement for its MRI services including professional fees cannot be calculated. In contrast, **CRIC** is expanding the scope of services by offering breast coil services and a wider bore. In addition, its proposed charges and expenses reflect global billing. Therefore, regarding the scope of services, **CRIC** is the most effective alternative.

Geographic Accessibility (in the Service Area)

The 2022 SMFP identifies a need for one fixed MRI in the Pasquotank/Camden/Currituck/Perquimans County service area. **Figure 18** below identifies the locations of the existing and proposed fixed MRI scanners in the service area. The existing provider, SAMC, and **CRIC’s** proposed MRI are located in Pasquotank County while **SAIS’s** proposed MRI is located in Currituck County.

Figure 18

Facility	# of Fixed MRI Scanners	Hospital-Based or Freestanding	Locations
Existing MRI Scanners			
SAMC - Elizabeth City*	1	Hospital-Based	Pasquotank County (27909)
Proposed MRI Scanners			
CRIC - Elizabeth City	1	Freestanding	Pasquotank County (27909)
SAIS - Moyock	1	Freestanding	Currituck County (27985)

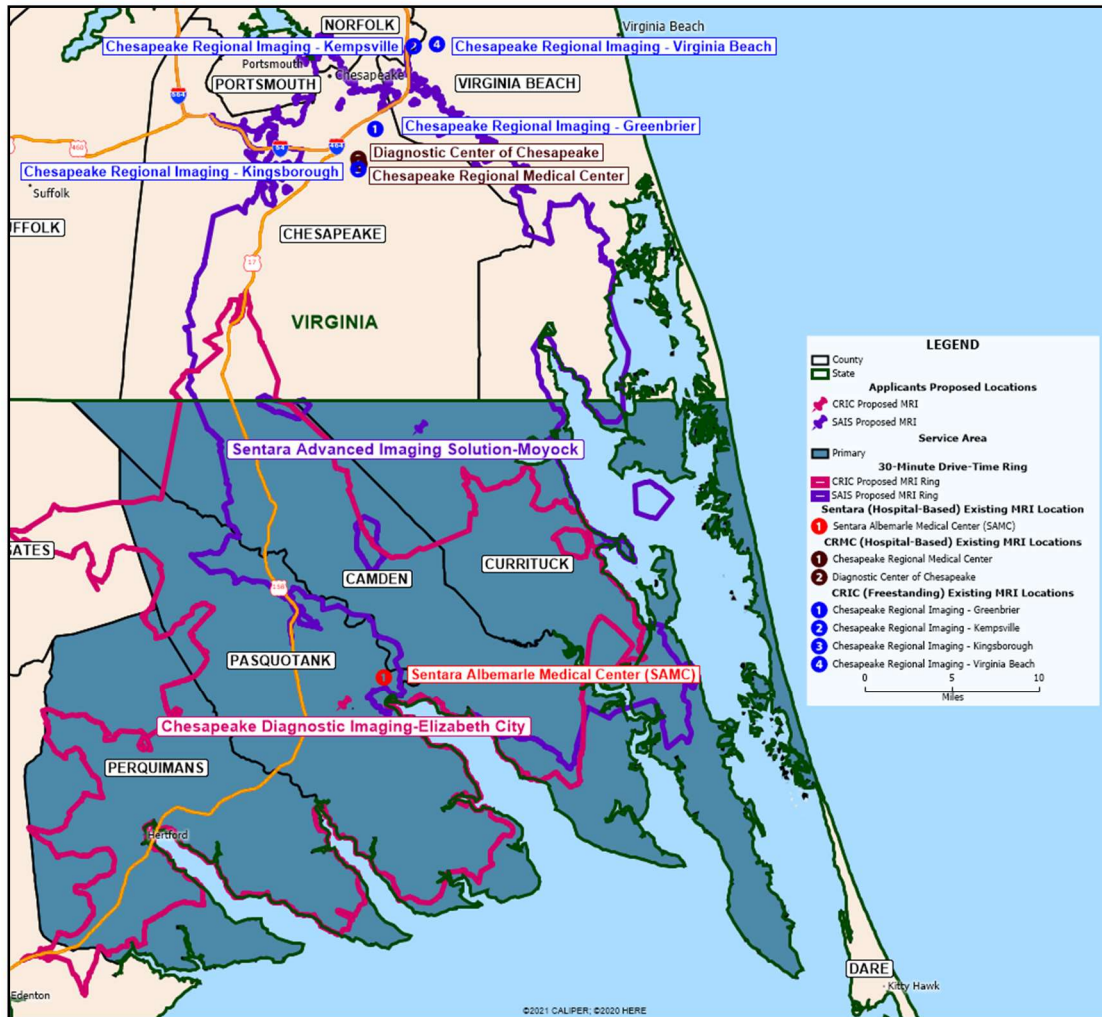
* also has a mobile MRI

Concerning geographic accessibility, both applicants have proposed to build freestanding fixed MRI scanners. If approved, either applicant will bring more affordable MRI services to the four-county service area. However, in terms of MRI services, both applicants already serve residents in the four-county service area. **SAIS** is proposing to build its diagnostic imaging center in Currituck County near the border of Virginia, which is 16 miles (about 20 minutes) away from Chesapeake Regional Imaging – Kingsborough, which is already offering MRI services in a freestanding environment. Therefore, **SAIS’s** project would duplicate services. **CRIC** is proposing to build its diagnostic imaging center in Pasquotank County, located 3.6 miles (more than 7 minutes) away from SAMC’s existing fixed MRI and **SAIS’s** mobile MRI based at SAMC. Sentara’s existing MRIs are hospital-based whereas **CRIC’s** proposed fixed MRI is freestanding. Thus, **CRIC** expands financial and geographic access to patients by offering a less costly alternative in a location that is accessible to the entire four-county service area.

Figure 19 below shows the 30-minute drive-time ring (“DTR”) around each applicant’s proposed location. **CRIC’s** 30-minute DTR (in **Pink**) covers most of the counties in the four-county MRI Service Area, which needs a fixed MRI. Within **CRIC’s** 30-minute DTR (in **Pink**), the only existing MRIs are **SAIS’s** mobile MRI based at SAMC and SAMC’s fixed MRI scanner (**Red label**). In contrast, **SAIS’s** 30-minute DTR (in **Purple**) mainly covers Currituck and Camden Counties and a small area of Pasquotank County. **SAIS’s** DTR covers a significant portion of the City of Chesapeake, Virginia, but fails to expand access in more

than half of the SMFP service area counties for this project. Furthermore, SAIS's 30-minute DTR (in Purple) includes two existing freestanding MRIs (Blue labels) operated by CRIC. It should also be noted that there are numerous other Sentara-affiliated MRI scanners located in Virginia within the SAIS 30-minute DTR as previously shown in Figure 10. Thus, the geographic location of CRIC is more effective in meeting the demands of the four-county service area.

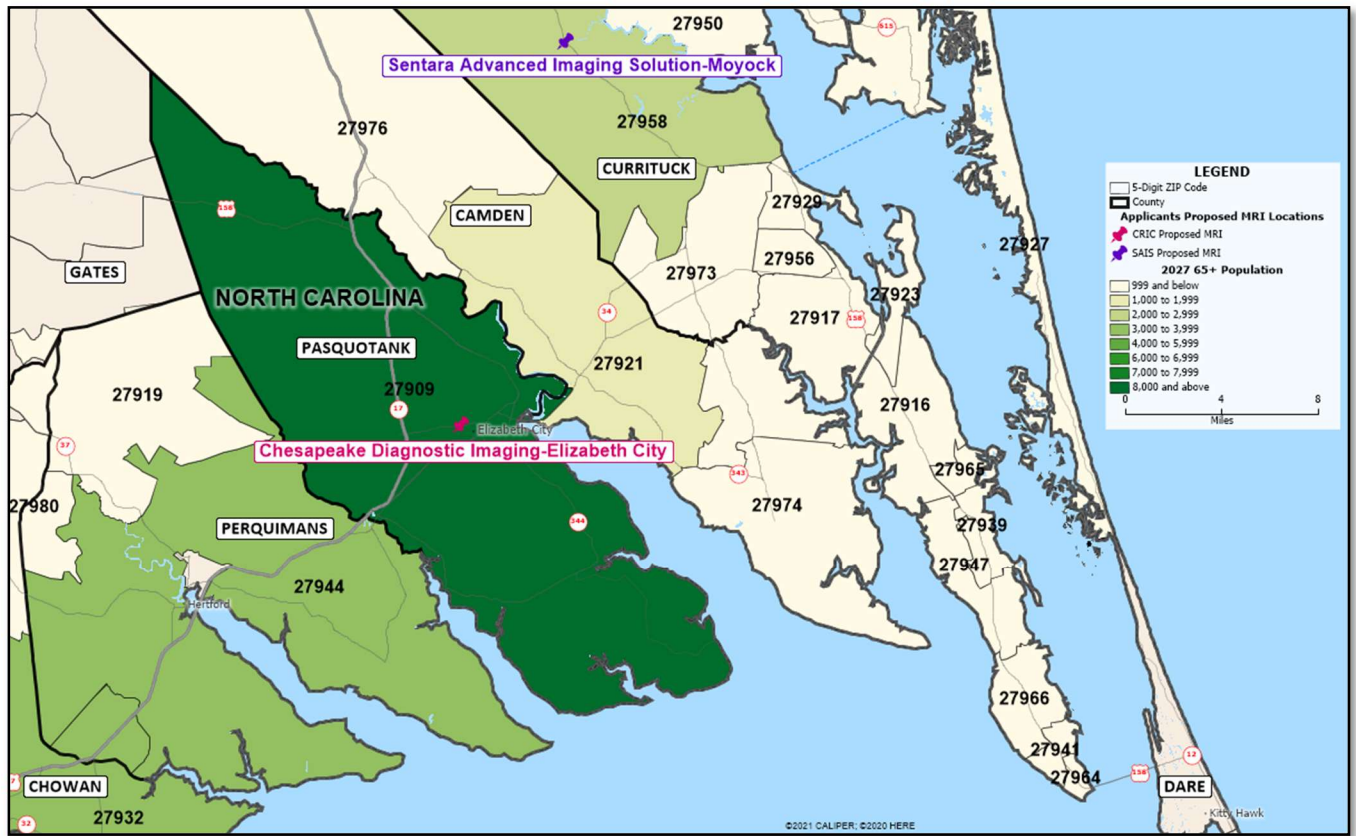
Figure 19
30-Minute Drive-Time Ring Map



Source: Maptitude

It is well known that the 65 and older population utilizes healthcare services, including MRI services, at a statistically higher rate than any other age group. Increasing life expectancy coupled with age-related comorbidities has resulted in the continued growth in demand for healthcare services. Figure 20 shows the population density in the four-county service area for the elderly population. Clearly Pasquotank and Perquimans Counties are the most densely populated counties of elderly residents based on data from Claritas Spotlight by ZIP code even when growth through 2027 is considered. CRIC will be in close proximity to the largest base of elderly residents while SAIS is farther from this population. It should also be noted that SAIS does not project to serve Perquimans County, which has the second largest density of 65 and older population.

Figure 20
Service Area 2027 65+ Population Density Map



Source: Maptitude and Spotlight

Figure 21 on the next page shows a drive time analysis to demonstrate travel distance in minutes and miles from the top two major cities or towns in each county to the proposed locations of each applicant. The drive time analysis shows that of the two applicants, **CRIC** is most accessible to the residents of five of the eight major cities or towns (Camden County – Camden; Pasquotank County – Elizabeth City; Pasquotank County – Nixonton Township; Perquimans County – Hertford; and Perquimans County – Albemarle Plantation) in the service area. In comparison, **SAIS** is the most accessible for three of the eight major cities or towns.

Regarding geographic accessibility, **CRIC** is the most effective applicant as it is the most accessible to the majority of residents, including elderly residents, within the four-county MRI Service Area.

**Figure 21
Drive Time Analysis**

County - Major City or Town	Minutes	
	Chesapeake Regional Imaging Center - Elizabeth City	Sentara Advanced Imaging Solution - Moyock
Camden County - Camden (27921)	9-14	20-26
Camden County - South Mills (27976)	16-20	16
Currituck County - Moyock (27958)	30-40	1
Currituck County - Grandy (27939)	40-50	30-45
Pasquotank County - Elizabeth City (27909)	5-6	28-40
Pasquotank County - Nixonton Township	14-18	40
Perquimans County - Hertford (27944)	18-26	40-50
Perquimans County - Albemarle Plantation	26-35	50-60
County - Major City or Town	Miles	
	Chesapeake Regional Imaging Center - Elizabeth City	Sentara Advanced Imaging Solution - Moyock
Camden County - Camden (27921)	6.2	18.3
Camden County - South Mills (27976)	14.4	12.0
Currituck County - Moyock (27958)	25.0	0.3
Currituck County - Grandy (27939)	31.7	29.8
Pasquotank County - Elizabeth City (27909)	1.5	25.0
Pasquotank County - Nixonton Township	9.0	33.6
Perquimans County - Hertford (27944)	17.2	39.3
Perquimans County - Albemarle Plantation	23.8	45.9

Source: Google Maps, 2022

Note: Depart Time at 8:00am

Service to the Planning Area Counties (Access by Service Area Residents)

The service area for this review of a fixed MRI scanner is Pasquotank/Camden/Currituck/Perquimans County. Facilities may also serve residents of counties not included in the service area. Generally, the application projected to be the most accessible to Pasquotank/Camden/Currituck/Perquimans County residents is the most effective alternative with regard to this comparative factor. **Figure 22** on the next page shows the projected patient origin by county for the two applicants.

Figure 22
Projected Planning Area Patient Origin - Year 3

County	CRIC		SAIS	
	Count	Percentage	Count	Percentage
Perquimans County	152	5.2%	0	0.0%
Pasquotank County	597	20.5%	613	30.0%
Camden County	325	11.2%	589	28.9%
Currituck County	1,108	38.1%	648	31.7%
Total Planning Area	2,182	75.0%	1,850	90.6%
Total Project Patients	2,910	100.0%	2,041	100.0%
Rank	More Effective		Less Effective	

Source: Section C Projected Patient Origin of the respective applications

Simply comparing the percentage from each county can in fact penalize the applicant serving more patients from the service area. **Figure 22** shows that **CRIC** is projected to serve the most patients in the planning service area counties, including the most patients from Currituck County. Most importantly, **SAIS** fails to project any patients from Perquimans County, which is a part of the planning area that determined the need for the fixed MRI scanner. Perquimans County is even excluded from **SAIS's** list of "Other" counties. See further discussion under Criterion (3).

Therefore, regarding this comparative factor, **CRIC** is the most effective alternative in serving the planning area.

Competition (Patient Access to a New Provider)

Sentara currently operates one fixed MRI scanner in the service area. Sentara's affiliate, SAIS, operates one mobile MRI scanner in Pasquotank County at SAMC. Both are hospital-based scanners and represent the only MRI services currently offered in the service area. The four-county service area for this project is unique given its largely rural composition; its roadways and waterways create distinctive and unusual healthcare travel patterns. Currently, Sentara/SAIS is the *only* choice of provider of MRI services within this unique service area. Patients seeking lower-cost MRI services within the Chesapeake Regional Healthcare (or any other system) must leave the area and the state for care. If **SAIS's** proposed MRI is approved, Sentara/SAIS will continue to be the sole provider of MRI services to the four-county service area. Conversely, if **CRIC's** application is approved, it will result in an alternative provider and choice for service area residents. Only **CRIC** projects to allow more North Carolinians to stay in state to receive cost effective MRI services, thereby increasing access to care for these patients.

Therefore, regarding competition, **CRIC** is the most effective alternative.

Projected Utilization

Figure 23 below shows each applicant's projected MRI weighted procedures in the third full year of operation. Generally, the applicant with the higher projected MRI weighted procedures is the more effective alternative regarding this comparative analysis factor.

Figure 23
Fixed MRI Scanners Projected Utilization Comparison - Year 3

Facility	# of Fixed MRI Scanners (or Fixed Equiv.)	Total Weighted MRI Procedures Performed Year 3	Rank
CRIC	1	3,540	More Effective
SAIS	1	2,684	Less Effective

Source: Section Q Form C.2b of the respective applications

As shown in **Figure 23**, **CRIC**'s projected weighted MRI procedures are higher than **SAIS**. Therefore, regarding projected utilization, **CRIC** is the most effective alternative.

Projected Financial Access (Access by Underserved Groups)

“Underserved groups” is defined in G. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, the applications in this review are compared with respect to three underserved groups: charity care patients (i.e., medically indigent, or low-income persons), Medicare patients, and Medicaid patients. Access by each group is treated as a separate factor. As noted previously, there are numerous questions regarding **SAIS** payor mix and its inconsistency with the demographic factors present in the areas they will serve in Moyock.

Projected Charity Care

Figure 24 shows projected charity care during the third full year following the completion of the project for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative regarding this comparative factor.

Figure 24
Projected Charity Care – Projected Year 3

Applicant	Gross Revenue	Charity Care	Charity Care as a % of Gross Revenue	Rank
CRIC	\$5,265,314	\$131,633	2.5%	Less Effective
SAIS	\$3,714,001	\$132,531	3.6%	More Effective

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

Based on each facility's pro forma financial statements presentation, **CRIC**'s percent of charity care to gross patient revenue is estimated to be 2.5 percent. **SAIS**'s projected charity care is 3.6 percent, meaning they are expected to provide more charity care than **CRIC** based on charges. On the simple basis of percent charity care, **SAIS** is more effective. However, as discussed in Criterion (5), it is unclear if **SAIS** revenue projections are based on accurate charge and reimbursement rates without professional fees, thus, the comparison of payor mix based on charges is questionable. When it comes to the number of charity patients and low-income patients, (reference Section L 4.a & b) **CRIC** is projected to serve 242 patients. In contrast **SAIS**'s number of patients in Section L is 64. Moreover, **SAIS**'s projected payor mix is unsupported and inconsistent with the communities it will serve as discussed previously.

Therefore, regarding this comparative factor, the charity care commitment of each applicant is deemed inconclusive.

Projected Medicare

Figure 25 shows projected Medicare revenue during the third full year following project completion from each facility. Generally, the applicant projecting the highest Medicare revenue is the more effective alternative regarding the comparative factor to the extent the Medicare revenue represents the number of Medicare patients served. As discussed in Criterion (5), it is unclear if **SAIS** revenue projections are based

on accurate charge and reimbursement rates without professional fees, thus, the comparison of payor mix based on charges is questionable.

**Figure 25
Projected Medicare – Projected Year 3**

Applicant	Gross Revenue	Medicare	Medicare as a % of Gross Revenue	Rank
CRIC	\$5,265,314	\$1,842,860	35.0%	Less Effective
SAIS	\$3,714,001	\$1,410,926	38.0%	More Effective

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

Based on each facility's pro forma financial statements presentation, **CRIC's** percent of Medicare to gross patient revenue is estimated to be 35.0 percent. **SAIS** projected Medicare to gross patient revenue is 38.0 percent, meaning they are expected to serve proportionally more Medicare patients than **CRIC**. As noted above, **SAIS's** payor mix projections appear to be questionable in relation to the demographics of its service area.

Therefore, regarding Medicare, **SAIS** is the most effective applicant based on charges; however, its charges are questionable and it is non-conforming with criteria related to financial feasibility and payor.

Projected Medicaid

Figure 26 shows projected Medicaid revenue during the third full year following project completion from each facility. Generally, the applicant projecting the highest Medicaid revenue is the more effective alternative regarding the comparative factor to the extent the Medicaid revenue represents the number of Medicaid patients served. As discussed in Criterion (5), it is unclear if **SAIS** revenue projections are based on accurate charge and reimbursement rates without professional fees, thus, the comparison of payor mix based on charges is questionable.

**Figure 26
Projected Medicaid– Projected Year 3**

Applicant	Gross Revenue	Medicaid	Medicaid as a % of Gross Revenue	Rank
CRIC	\$5,265,314	\$263,266	5.0%	Less Effective
SAIS	\$3,714,001	\$325,769	8.8%	More Effective

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

Based on each facility's pro forma financial statements presentation, **CRIC's** percent of Medicaid to gross patient revenue is estimated to be 5.0 percent. **SAIS** projected Medicaid to gross patient revenue is 8.8 percent, meaning they are expected to serve proportionally more Medicaid patients than **CRIC**. As discussed in Criterion (5), it is unclear if **SAIS** revenue projections are based on accurate charge and reimbursement rates without professional fees, thus, the comparison of payor mix based on charges is questionable. As noted above, **SAIS's** payor mix projections appear to be questionable in relation to the demographics of its service area.

Based on the numbers available regarding Medicaid, **SAIS** is the most effective applicant; however, its charges are questionable and it is non-conforming with criteria related to financial feasibility and payor.

Projected Average Revenue per MRI Procedure

Gross Revenue

Figure 27 shows the projected average gross revenue per MRI procedure in the third full year following project completion for each facility. Generally, the application projecting the lowest average gross revenue per patient is the more effective alternative regarding this comparative factor to the extent that the average reflects a lower cost to the patient or third-party payor. However, SAIS does not appear to factor professional fees into their projections. Therefore, for the two applicants projected gross revenue per MRI procedure to be comparable, professional fees must be removed from CRIC's gross revenue to attempt to accurately compare gross revenue per scan.

Figure 27
Projected Gross Revenue per MRI Procedure – Year 3

Applicant	Gross Revenue	MRI Procedures*	Gross Revenue per MRI Procedure	Rank
CRIC	\$5,265,314	3,540	\$1,487	NA
CRIC w/o Prof Fees**	\$4,001,639	3,540	\$1,130	More Effective
SAIS	\$3,714,001	2,684	\$1,384	Less Effective

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

*weighted

**Gross charge for professional fee based on ratio of net to gross total revenue x professional fee expense.

As such, Figure 27 shows CRIC's gross revenue per MRI procedure including and excluding professional fees. Excluding professional fees from CRIC's gross revenue to effectively compare the two applicants, CRIC projects to earn a gross revenue of \$1,130 per MRI procedure. In contrast, SAIS projects to earn a gross revenue of \$1,384 per MRI procedure. As discussed in Criterion (5), SAIS has questionable charge and reimbursement rates without professional fees, thus, the comparison of payor mix based on charges is inappropriate. SAIS projects to charge a gross revenue of \$1,384 per MRI procedure, which is higher than CRIC's charges adjusted without professional fees. Therefore, regarding this comparative factor, CRIC is the most effective alternative.

Net Revenue

Figure 28 shows the projected average net revenue per MRI procedure in the third full year following project completion for each facility. Generally, the application projecting the lowest average net revenue per patient is the more effective alternative regarding this comparative factor to the extent that the average reflects a lower cost to the patient or third-party payor. However, SAIS does not include professional fees in its projection. Therefore, for the two applicants projected net revenue per MRI procedure to be comparable, professional fees must be removed from CRIC's net revenue.

Figure 28
Projected Net Revenue per MRI Procedure – Year 3

Applicant	Net Revenue	MRI Procedures*	Average Net Revenue per MRI Procedure	Rank
CRIC	\$1,310,505	3,540	\$370	NA
CRIC w/o Prof Fees	\$995,984	3,540	\$281	More Effective
SAIS	\$892,168	2,684	\$332	Less Effective

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

*weighted

** CRIC professional fee expense subtracted.

As such, **Figure 28** shows **CRIC**'s net revenue per MRI procedure, including and excluding professional fees. Excluding professional fees from **CRIC**'s net revenue indicates an average net revenue of \$281 per MRI procedure. In contrast, **SAIS** financial projections result in a net revenue of \$332 per MRI procedure, which is more than that of **CRIC** adjusted for technical fees only. Therefore, regarding this comparative factor, **CRIC** is the most effective alternative.

Projected Average Expenses per MRI Procedure

Total Expense

Figure 29 shows the projected average total expense per MRI procedure in the third full year following project completion for each facility. Generally, the application projecting the lowest average total expense per procedure is the more effective alternative regarding this comparative factor to the extent it reflects a more cost-effective service that could also result in lower costs to the patient or third-party payor. However, as mentioned earlier, **SAIS** does not factor in professional fees in its projected expenses. Therefore, for the two applicants' projected average expense per MRI procedure to be comparable, professional fees must be removed from **CRIC**'s total expense. As shown below, **CRIC** is the most effective alternative with lower expense per procedure when professional fees are subtracted. Alternatively, professional fees would need to be added to **SAIS** expenses presuming they are billing globally.

Figure 29
Projected Average Total Expense per MRI Procedure – Year 3

Applicant	Total Expense	MRI Procedures*	Average Expense per MRI Procedure	Rank
CRIC	\$1,227,391	3,540	\$347	NA
CRIC w/o Prof Fees**	\$912,870	3,540	\$258	More Effective
SAIS	\$811,103	2,684	\$302	Less Effective

Source: Section Q Form C.2b and Form F.3b of the respective applications

*weighted

** CRIC professional fee expense subtracted.

Operating Expense

Figure 30 on the next page shows the projected average operating expense per MRI procedure in the third full year following project completion for each facility. Generally, the application projecting the lowest average operating expense per scan is the more effective alternative concerning this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor. Again, because **SAIS** does not include professional fees in its projection, professional fees must be removed from **CRIC**'s operating expense for the applicants projected operating expense per MRI procedure to be comparable. As shown in **Figure 30**, **CRIC** and **SAIS** operating expenses per MRI procedure are \$198 and \$196, respectively. Therefore, regarding this comparative factor, it is deemed inconclusive as the average expenses are within \$5 of each other. As noted above, **SAIS** has understated multiple additional categories of expenses including lease expense and staffing expense further rendering this comparison inconclusive.

Figure 30
Projected Average Operating Expense per MRI Procedure – Year 3

Applicant	Operating Expense	MRI Procedures*	Average Expense per MRI Procedure	Rank
CRIC	\$1,014,448	3,540	\$287	NA
CRIC w/o Prof Fees**	\$699,927	3,540	\$198	Inconclusive
SAIS	\$525,888	2,684	\$196	Inconclusive

Source: Section Q Form C.2b and Form F.3b of the respective applications

*weighted

** CRIC professional fee expense subtracted.

Project Timing

Figure 31 shows the date when the fixed MRI will come online (when MRI will be available for use) as reported in the application. Generally, the applicant that can have the fixed MRI available the earliest is the most effective alternative regarding this comparative factor.

Figure 31
Fixed MRI Online and Available

Applicant	Opening Date	Rank
CRIC	4/1/2024	More Effective
SAIS	2/1/2025	Less Effective

Source: Section Q Form C.2b of the respective applications

As shown in the table, **CRIC** will be the first to bring its fixed MRI online. Upon approval of **CRIC's** application, it projects to bring the MRI online on April 1, 2024, which is 10-months earlier than **SAIS's** projection date of February 1, 2025. Therefore, regarding timing, **CRIC** will have a fixed MRI online more efficiently, making it the most effective applicant.

Community Support

Figure 32 shows the number of letters of support received for each applicant. Generally, the applicant who receives the most letters of support and the best quality letters of support is the most effective alternative regarding this comparative factor.

Figure 32

	Form Letters	Unique Letters	Total LOS	Rank
CRIC	31	7	38	More Effective
SAIS	32	0	32	Less Effective

CRIC and **SAIS** each included 32 letters of support in the initial application submissions. **CRIC** received at least an additional 6 letters of support since its application submission, as reflected in **Figure 32**. All of **SAIS's** letters of support were form letters and nearly all are from affiliates of Sentara. In contrast, **CRIC's** letters of support consisted of a combination of form letters and unique letters. **CRIC** included letters of support from the Chairmen for Camden, Currituck, and Perquimans County Boards of Commissioners, respectively. It should also be noted that the Currituck County Board of Commissioners provided a letter of support for **CRIC's** project even though it is located in Pasquotank County. **CRIC** also received 7 unique letters, including one from the Chamber Director for the Perquimans County Chamber of Commerce (a county **SAIS** does not project to serve), the President & CEO of the Elizabeth City Chamber of Commerce

(the home city of SAMC), patients, and other community organizations. Therefore, regarding project community support, **CRIC** is the most effective alternative.

Conclusion

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during the review would result in a fixed MRI scanner in excess of the need determination in the Pasquotank/Camden/Currituck/Perquimans County service area. Only **CRIC**'s project can be approved because it is the only applicant that conforms to all project review criteria and applicant performance standards. However, if both applicants were approvable, **CRIC**'s project is also the most effective alternative to meet the need based on the summary below. As such, **CRIC**'s project should be approved.

Summary of Comparative Factors

Comparative Factor	CRIC	SAIS
Conformity with Statutory and Regulatory Review Criteria	Yes	No
Scope of Services	More Effective	Less Effective
Geographic Accessibility (in the Service Area)	More Effective	Less Effective
Service Planning Area Counties (Access by Service Area Residents)	More Effective	Less Effective
Competition (Patient Access to a New Provider)	More Effective	Less Effective
Projected Utilization	More Effective	Less Effective
Access by Charity Care Patients	Inconclusive	Inconclusive
Access by Medicare Patients	Less Effective	More Effective
Access by Medicaid Patients	Less Effective	More Effective
Projected Average Gross Revenue per MRI Procedure	More Effective	Less Effective
Projected Average Net Revenue per MRI Procedure	More Effective	Less Effective
Projected Total Expenses per MRI Procedure	More Effective	Less Effective
Projected Average Operating Expense per MRI Procedure	Inconclusive	Inconclusive
Project Timing	More Effective	Less Effective
Community Support	More Effective	Less Effective
Total	More Effective	Less Effective

Attachment A
SAMC Petitions

PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION

Petition to Remove the Fixed MRI Need Determination in the Pasquotank/Camden/Currituck/Perquimans Service Area in the *2021 State Medical Facilities Plan*

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

Sentara Albemarle Medical Center (SAMC) respectfully petitions the State Health Coordinating Council (SHCC) to remove the need determination for one fixed MRI scanner in the Pasquotank/Camden/Currituck/Perquimans service area in the *2021 State Medical Facilities Plan (SMFP)*. Table 17E-3 in the *Proposed 2021 SMFP* shows a need for an additional fixed MRI scanner for that service area; SAMC requests that the need determination be removed so that there will be no need for a fixed MRI scanner in that service area in the *2021 SMFP*.

REASON FOR THE REQUESTED ADJUSTMENT

While the standard methodology has generated a need for a second fixed MRI scanner for four years, and though there has been some growth in MRI volume in the service area, SAMC continues to believe that prudent health planning would delay the allocation of another fixed MRI scanner in the service area for another year. The reasons to remove the need determination from the *2021 SMFP* are similar to those in previous years but remain nonetheless pertinent, as discussed in this petition.

For more than a decade, SAMC has been the sole provider of MRI services in the four-county service area. While the hospital's mobile MRI scanner served two sites in Currituck County in the mid-2000s, the volume at these sites was low and SAMC is currently the only site of MRI service in the service area. As the only MRI provider in the four-county area, SAMC believes that despite the proposed need determination, there is no need for an additional fixed MRI scanner in the service area at this time, for the following reasons.

1. Low volume growth trends

Over the past seven years, MRI volume in the service area has changed only modestly. As shown in the table below, the utilization of SAMC's fixed MRI scanner has fluctuated slightly, but the overall trend has been only a modest increase in volume.

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SMFP Year	Fixed MRI Volume (weighted scans)
2014	3,790
2015	3,720
2016	3,603
2017	3,304
2018	3,776
2019	3,992
2020	4,380
Proposed 2021	4,330
CAGR*	1.92%

*Compound Annual Growth Rate.

As shown, volume for the most recent year actually declined slightly from the previous year. In addition to the scans provided by the fixed MRI, most of the growth in volume in the service area has been accommodated by SAMC's mobile MRI scanner. However, in Fiscal Year (FY) 2019, that scanner performed only a total of 1,167 weighted scans. As discussed in further detail below, SAMC's mobile MRI scanner has additional capacity to accommodate future growth.

SAMC does not believe any compelling reasons exist at present that would change the historical growth rates in the service area, at least not significantly enough to fully utilize the existing fixed scanner and require a second fixed scanner (see discussion under #3 below). In particular, the service area experiences outmigration for tertiary and other services not available in the service area, and many of those patients have MRI scans performed as part of those services in other parts of North Carolina and other states. As long as this outmigration persists, it is unlikely that MRI volume generated by these patients will be performed in the service area. As such, SAMC does not believe that another fixed MRI scanner is needed in the service area at this time.

2. Low population with minimal growth

The four counties in the service area are small, rural, and are projected to experience relatively low population growth. As shown below, the projected compound annual growth rate (CAGR) over the next five years for the combined service area population is less than one percent.

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County	2020 Population	2025 Population	CAGR
Camden	10,717	11,079	0.67%
Currituck	27,952	30,085	1.48%
Pasquotank	39,685	39,602	- 0.04%
Perquimans	13,637	19,737	0.15%
Total	91,991	94,503	0.54%

Source: North Carolina Office of State Budget and Management (NC OSBM), November 2019 projections, accessed July 2020.

Of note, Pasquotank County is projected to have a slight decrease in population over the next five years. Although Currituck County has a higher growth rate than the other counties in the service area, its population is still relatively low, and could likely not support a fixed MRI scanner. To that point, Table 17E-1 in the *Proposed 2021 SMFP* shows that no county with a population lower than Currituck’s has a fixed MRI scanner, except those with a hospital, which Currituck County does not have. Further, none of the MRI sites in counties of a similar or smaller size, whether fixed or mobile, have the volume required to demonstrate need for a second fixed MRI scanner in a Certificate of Need review, which is 3,775 weighted scans. Thus, SAMC does not believe that the current and projected population growth in the service area warrants a second fixed MRI scanner at this time.

3. Sufficient MRI capacity

According to the *SMFP*, the annual maximum capacity of a fixed MRI scanner is 6,864 scans per year. With a total of 4,330 scans performed in FY 2019, the existing fixed MRI scanner at SAMC is capable of performing an additional 2,534 scans before reaching capacity. While SAMC agrees with the standard methodology, which allows for planning well in advance of reaching maximum capacity, given the historical volume and population trends, SAMC believes that the existing fixed scanner has sufficient capacity to meet any normal growth for the foreseeable future.

Moreover, as discussed above, SAMC owns an existing mobile MRI scanner, which is able to provide additional capacity at SAMC if needed. In FY 2019, the mobile MRI scanner performed 1,167 weighted scans. Clearly, the mobile scanner has sufficient capacity to provide additional service to the Pasquotank/Camden/Currituck/Perquimans service area, if needed. To that point, the increase in SAMC’s mobile MRI volume drove the overall growth in MRI volume in the service area from FY 2018 to 2019, as shown below.

SAMC Fixed and Mobile MRI Scanner Volume

	FY 2018	FY 2019	Difference
Fixed MRI Scans	3,732	3,689	-43
Mobile MRI Scans	789	1,056	267
Total	4,521	4,745	224

Source: 2020 and 2021 *SMFPs*.

Although a mobile scanner may have lower practical capacity, due to time needed to relocate the unit, the nature of mobile service and other factors, SAMC believes its mobile unit can provide capacity needed for growth in the immediate future. Further, an existing mobile MRI scanner, particularly one with available capacity, may be a more prudent option for a rural multi-county area than a second fixed MRI scanner, which would not likely be well utilized.

4. Difficulty meeting CON rules

Another reason for removing the need determination is the likelihood that a CON applicant, including SAMC, would have difficulty meeting the prospective performance standards in the CON rules for fixed MRI scanners. The CON rules, which were written to mirror the *SMFP* methodology, require an applicant in a service area with one existing fixed MRI scanner to project that the proposed MRI scanner will achieve a minimum of 3,775 weighted scans by the third project year. If the applicant has an existing fixed MRI scanner, it has to reasonably project that each scanner will achieve 3,775 weighted scans. Since SAMC performed 4,330 weighted scans in FY 2019, it would need to project its volume to grow by nearly 43 percent by the third project year in order to meet this standard.

If the need remains in the *2021 SMFP*, and if SAMC applies for the additional fixed MRI scanner, assuming the additional scanner is made operational by October 2022 (the start of FY 2023), the third project year would be FY 2025. Thus, SAMC would need to project 7,550 ($3,775 \times 2 = 7,550$) weighted scans by FY 2025. To grow from 4,330 weighted scans in 2019 to 7,550 in 2025 requires a 9.7 percent compound annual growth rate. As shown above, the service area has not experienced that level of historical growth either in population or MRI scans. While a few urban and suburban areas with high growth and immigration may be able to rationalize a 9.7 percent annual growth rate, SAMC is doubtful that the Healthcare Planning and Certificate of Need Section would find such a rate reasonable in a CON review in its service area, without substantial documentation of the expected change from the historical trend.

Not only would SAMC have difficulty meeting the performance standards for its fixed MRI, but it would also have difficulty meeting the historical volume requirements for its mobile MRI scanner. The CON rules require an applicant to demonstrate that each of its existing mobile MRI scanners in a service area performed a total of 3,328 weighted MRI scans in the most recent 12-month period. Since SAMC's mobile MRI scanner performed 1,167 weighted scans in FY 2019, it is unlikely that the mobile scanner would grow by an additional 2,161 scans prior to filing the CON application. More importantly, SAMC's mobile MRI scanner does have available capacity to serve residents of the service area, which obviates the need for another fixed scanner at this time.

5. SAMC was previously approved for a second fixed scanner that was never developed.

As many members of the SHCC may be aware, the current methodology for fixed MRI scanners was developed for the *2005 SMFP*. During the early to mid-2000s, MRI volume was rapidly increasing, as clinical applications for the technology increased and costs for the equipment decreased. During this time of growth and subsequent to the *2006 SMFP*, SAMC was approved to develop a second fixed MRI scanner. As shown below, MRI volume was

increasing during this time, and if the trend had continued, a second scanner would have been needed.

	<i>Service Area MRI Volume (weighted scans)</i>
2005	4,490
2006	4,793
2007	4,877
CAGR	4.2%

Source: 2007-2009 SMFPs.

Before the project was developed, however, the economic downturn occurred, with the greatest impact in rural areas like northeastern North Carolina. As unemployment grew, healthcare volume declined, including for technology like MRI. Although the economy improved from the height of the recession, other factors, such as the push by insurers for pre-authorization and the implementation of health reform, continued to suppress growth in volume for services like MRI, as shown below.

	<i>Service Area MRI Volume (weighted scans)</i>
2008	4,277
2009	4,253
2010	3,834
CAGR	-5.3%

Source: 2010 - 2012 SMFPs.

As a result, SAMC (at the time not part of Sentara Healthcare) decided not to develop the second fixed MRI scanner and relinquished its Certificate of Need. With 4,330 scans performed in FY 2019, SAMC’s MRI volume is 13 percent lower than the highest volume year, 2007, when the sole fixed MRI scanner at SAMC performed 4,877 scans¹. SAMC does not currently expect MRI volume in the service area to exceed this historical level in the near future; thus, the existing fixed MRI at SAMC is sufficient to meet the current and expected future need in the service area.

6. Impacts of novel coronavirus

Furthermore, public health concerns, such as the novel coronavirus (COVID-19) pandemic, create a wide variety of challenges that may make it difficult for some healthcare providers to sustain normal levels of operation. In consideration of the challenges faced during a crisis like COVID-19 and the expected fluctuations in patient volume related to the public health concern, SAMC believes that it currently has the capacity necessary to provide care to the

¹ Although the 2009 SMFP shows an inventory of two fixed MRI scanners at Albemarle Hospital, the second MRI scanner shown was a placeholder for the approved but inchoate fixed MRI scanner, which was never developed.

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entirety of the service area, including situations that necessitate the utilization of its existing fixed and mobile MRI scanners for COVID-19 related cases. As shown below, in the months prior to the onset of the COVID-19 pandemic, SAMC’s total MRI volume fluctuated around 400 scans per month; however, SAMC’s total MRI volume decreased precipitously from March to April—one month after the beginning of the COVID-19 pandemic. This steep decline coincides with the enactment of public health mandates directing healthcare providers to temporarily suspend elective services/procedures, as well as with stay-at-home ordinances that may have dissuaded individuals from seeking care to limit exposure to the virus.

<i>Year</i>	<i>Month</i>	<i>Mobile MRI Volume</i>	<i>Fixed MRI Volume</i>	<i>Total MRI Volume</i>	<i>Percent Change</i>
2019	October	124	341	465	-
	November	92	316	408	-12.3%
	December	89	316	405	-0.7%
2020	January	102	338	440	8.6%
	February	85	315	400	-9.1%
	March	93	297	390	-2.5%
	April	38	173	211	-45.9%
	May	58	244	302	43.1%
	June	97	287	384	27.2%

Source: SAMC internal data.

However, as shown above, beginning in May 2020, total MRI volume began to increase, returning to near pre-pandemic volume by June 2020. Moreover, as discussed above, the four counties in the multi-county service area have relatively smaller populations, most of which are dispersed throughout rural coastal areas. As a result, the residents of the service area make up less than one percent of the state’s population ($91,991/10,630,691 = 0.0087$ or 0.87 percent) and only 0.41 percent of all the state’s confirmed COVID-19 cases as of July 20, 2020² ($409/99,975 = 0.0041$ or 0.41 percent), as shown below.

² N.C. DHHS and local health departments began reporting confirmed COVID-19 cases on March 14, 2020.

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County	2020 Population	Confirmed COVID-19 Cases (as of July 20, 2020)	COVID-19 Cases per 10,000 Population*	Percent of State's COVID-19 Cases
Camden	10,717	46	43	0.05%
Currituck	27,952	51	18	0.05%
Pasquotank	39,685	267	67	0.27%
Perquimans	13,637	45	33	0.04%
Total SA	91,991	409	44	0.41%
Total State	10,630,691	99,975	94	100.00%

Source: NC OSBM, Nov. 2019 projections, accessed July 2020; N.C. DHHS, local health departments via WRAL, accessed July 2020 at <https://www.wral.com/coronavirus/north-carolina-coronavirus-cases-maps-graphs-live-updates/19010016/>.

*COVID-19 Cases per 10,000 Population = (Confirmed COVID-19 Cases) / (2020 Population/10,000)

As shown above, the Pasquotank/Camden/Currituck/Perquimans service area has done relatively well thus far in controlling the spread of COVID-19, with only 409 confirmed cases. In addition, the multi-county service area has an infection rate of 44 confirmed cases per 10,000 population, which is less than half of the state average of 94 confirmed cases per 10,000 population. As such, SAMC believes that it has sufficient capacity to continue to provide MRI services to its patient population, in part due to the ongoing public health crisis.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

If the petition is not approved, the need determination will remain in the final 2021 SMFP. It is possible that another entity will apply for the MRI scanner and project sufficient volume to be approved. However, the CON process does not require such an applicant to demonstrate volume for all the MRI scanners in the service area; thus, the second scanner could project volume on its scanner that would effectively leave the scanner at SAMC with little to no volume and still be approved. Given the trends documented above, SAMC believes that it is not reasonable to assume that a total of 7,550 MRI scans will be performed in the service area in the near future. As such, the SHCC should consider that two fixed MRI scanners in the service area would not both be well-utilized, and the second MRI scanner would be unnecessary duplication.

ALTERNATIVES CONSIDERED

SAMC considered not filing a petition and potentially applying for the need determination in the 2021 SMFP. However, given the cost of submitting an application, the cost of developing a second fixed MRI scanner, and the available capacity of SAMC's fixed and mobile MRI scanners to serve the area, SAMC determined that the best alternative was to ask the SHCC to remove the need determination.

UNNECESSARY DUPLICATION

As discussed above, SAMC believes that the need determination could lead to unnecessary duplication, given the available capacity of fixed and mobile MRI scanners to serve the area. Thus, the approval of the petition will obviate the potential for unnecessary duplication.

BASIC PRINCIPLES

Safety and Quality

The existing MRI service at SAMC provides care in a safe and high-quality manner and can continue to do so while meeting the expected future volume demand of the patients it serves. As part of Sentara Healthcare, SAMC has a mission to improve health every day. This mandate is pursued through a disciplined strategy to achieve Top 10 percent performance in key measures through shared best practices, transformation of primary care through clinical integration and strategic growth that adds value to the communities it serves. This mission will ensure that patients have access to MRI services in the service area, without needing a second fixed MRI scanner at this time.

Access

Sufficient MRI capacity exists in the service area to meet the need of the population for some time, even in the event of a public health crisis such as COVID-19. SAMC, a not-for-profit hospital with a mission to serve the community, provides care to all in medical need of services, including the medically underserved, without regard to age, race, gender, disability, payor status, or ability to pay. Compared to a second fixed MRI scanner, SAMC's mobile MRI scanner can more effectively provide access at multiple sites across the multi-county service area and beyond. Given these factors, SAMC does not believe that approval of the petition will prevent anyone in the service area from accessing MRI services as needed.

Value

The removal of the need determination for the service area will enhance value by preventing the potential development of an unneeded second MRI scanner. The existing fixed and mobile MRI scanners in the service area can accommodate any reasonable and anticipated growth in volume, which will increase their utilization, helping to maximize the value of the existing capacity in the service area.

CONCLUSION

SAMC supports the standard MRI methodology in the *SMFP*, which takes a tiered approach to determining need in order to ensure access to the service in areas with different levels of existing capacity. If growth in MRI scans continues, there may be a true need for another fixed MRI in future years. However, given the unique factors in the Pasquotank/Camden/Currituck/Perquimans service area, such as low volume growth trends, low population growth, sufficient fixed and mobile MRI capacity, and the difficulty an applicant would have in meeting

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the CON rules given these factors, SAMC believes that the citizens of North Carolina, particularly those in northeastern North Carolina, would best be served by removing the need determination from the *2021 SMFP*.

**PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION
DUE TO THE IMPACT OF COVID-19**

**Petition to Remove the Fixed MRI Need Determination in the
Pasquotank/Camden/Currituck/Perquimans Service Area in the
*Proposed 2022 State Medical Facilities Plan***

1. PETITIONER

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President
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2. STATEMENT OF THE REQUESTED ADJUSTMENT

Sentara Albemarle Medical Center (SAMC) proposes that the need determination for one fixed MRI scanner in Chapter 17 of the *Proposed 2022 State Medical Facilities Plan (SMFP)* be removed for the Pasquotank/Camden/Currituck/Perquimans service area due to impact of the COVID-19 pandemic.

3. REASON FOR THE REQUESTED ADJUSTMENT

While the standard methodology has generated a need for a second fixed MRI scanner for five years, and though there has been some growth in MRI volume in the service area, SAMC continues to believe that prudent health planning would delay the allocation of another fixed MRI scanner in the service area for another year, particularly as SAMC and the rest of the nation continues to monitor and manage the impacts of the COVID-19 pandemic. In addition to the COVID-19 pandemic's impact on MRI utilization, the reasons to remove the need determination from the *Proposed 2022 SMFP* are similar to those in previous years but remain nonetheless pertinent.¹

For more than a decade, SAMC has been the sole provider of MRI services in the four-county service area with one fixed and one mobile MRI scanner. While the hospital's mobile MRI scanner served two sites in Currituck County in the mid-2000s, the volume at these sites was low and SAMC is currently the only site of MRI service in the service area. As the only MRI provider in the four-county area, SAMC believes that despite the proposed need determination, there is no need for an additional fixed MRI scanner in the service area at this time.

Specifically, the COVID-19 pandemic has created a wide variety of challenges that make it difficult for some healthcare providers to sustain normal levels of operation. In consideration of the

¹ Please see <https://info.ncdhhs.gov/dhsr/mfp/pets/index.html> for previously approved petitions submitted by SAMC to remove need determinations for additional fixed MRI scanners in the *SMFP* for the Pasquotank/Camden/Currituck/Perquimans service area from 2017 to 2020.

challenges faced during a crisis like COVID-19 and the expected fluctuations in patient volume related to the public health concern, SAMC believes that it currently has the capacity necessary to provide care to the entirety of the service area, including situations that necessitate the utilization of its existing fixed and mobile MRI scanners for COVID-19 related cases. As shown below, in the months prior to the onset of the COVID-19 pandemic, SAMC’s total MRI volume fluctuated around 400 scans per month; however, SAMC’s total MRI volume decreased precipitously from March to April 2020—one month after the beginning of the COVID-19 pandemic. This steep decline coincides with the enactment of public health mandates directing healthcare providers to temporarily suspend elective services/procedures, as well as with stay-at-home ordinances that may have dissuaded individuals from seeking care to limit exposure to the virus.

SAMC Fixed and Mobile MRI Scanner Utilization*

<i>Year</i>	<i>Month</i>	<i>Inpatient MRI Volume</i>	<i>Outpatient MRI Volume</i>	<i>Total MRI Volume</i>	<i>Total MRI Volume Percent Change</i>
2020	January	47	395	442	
	February	57	351	408	-7.7%
	March	46	347	393	-3.7%
	April	47	169	216	-45.0%
	May	57	251	308	42.6%
	June	35	373	408	32.5%
	July	70	373	443	8.6%
	August	67	387	454	2.5%
	September	51	388	439	-3.3%
	October	52	332	384	-12.5%
	November	47	296	343	-10.7%
	December	33	325	358	4.4%
2021	January	66	281	347	-3.1%
	February	72	292	364	4.9%
	March	69	318	387	6.3%
	April	45	329	374	-3.4%
	May	53	342	395	5.6%
	June	65	443	508	28.6%

Source: SAMC internal data. Please see Attachment A.

*Non-weighted scans.

As shown above, beginning in May 2020, total MRI volume began to increase, returning to near pre-pandemic volume by June 2020. However, starting in October 2020, total MRI volume decreased and did not fully recover until June 2021. Nonetheless, through June 2021, total MRI volume never reached pre-pandemic levels. Of note, from mid-September 2020 to mid-April 2021, SAMC’s MRI services were supported by its mobile scanner only as its fixed MRI scanner was replaced. The new technology associated with the replacement fixed MRI scanner allows for

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faster patient throughput and provides patients with enhanced scanning capabilities, which further increases SAMC's ability to support patient demand. SAMC believes that the fluctuations in total MRI volume that have trended downward is indicative of the general public's response to an evolving global pandemic that dictates the manner in which individuals make decisions about their daily lives, particularly when it comes to the need to access an elective healthcare service like an MRI scan. Although the table above shows that MRI volumes hit their zenith in June 2021, SAMC expects total MRI volume to continue to fluctuate downward as new variants of COVID-19 arise such as the delta variant.

Even in the event of a public health crisis such as COVID-19, sufficient MRI capacity exists in the service area to meet the need of the population for some time. SAMC, a not-for-profit hospital with a mission to serve the community, provides care to all in medical need of services, including the medically underserved, without regard to age, race, gender, disability, payor status, or ability to pay. Compared to a second fixed MRI scanner, SAMC's mobile MRI scanner can more effectively provide access at multiple sites across the multi-county service area and beyond. According to the *Proposed 2022 SMFP*, in Federal Fiscal Year 2020, SAMC's mobile scanner performed only 1,287 weighted scans. Further, the removal of the need determination for the service area will enhance value by preventing the potential development of an unneeded second MRI scanner. The existing fixed and mobile MRI scanners in the service area can accommodate any reasonable and anticipated growth in volume, which will increase their utilization, helping to maximize the value of the existing capacity in the service area.

In consideration of these factors, SAMC believes that removing the need determination for one fixed MRI scanner in Chapter 17 of the *Proposed 2022 SMFP* be removed for the Pasquotank/Camden/Currituck/Perquimans service area due to the COVID-19 pandemic

4. ALTERNATIVES CONSIDERED

SAMC considered not filing a petition and potentially applying for the need determination in the *Proposed 2022 SMFP*. However, given the ongoing COVID-19 pandemic, the cost of submitting an application, the cost of developing a second fixed MRI scanner, and the available capacity of SAMC's fixed and mobile MRI scanners to serve the area, SAMC determined that the best alternative was to ask the State Health Coordinating Council to remove the need determination.

5. PLEASE SEE ATTACHMENT A

ATTACHMENT A

Sentara Albermarle Medical Center Fixed and Mobile MRI Scanner Utilization*

<i>Year</i>	<i>Month</i>	<i>Inpatient MRI Volume</i>	<i>Outpatient MRI Volume</i>	<i>Total MRI Volume</i>	<i>Total MRI Volume Percent Change</i>	
2020	January	47	395	442		
	February	57	351	408	-7.7%	
	March	46	347	393	-3.7%	
	April	47	169	216	-45.0%	
	May	57	251	308	42.6%	
	June	35	373	408	32.5%	
	July	70	373	443	8.6%	
	August	67	387	454	2.5%	
	September	51	388	439	-3.3%	
	October	52	332	384	-12.5%	
	November	47	296	343	-10.7%	
	December	33	325	358	4.4%	
	Total		609	3,987	4,596	
2021	January	66	281	347	-3.1%	
	February	72	292	364	4.9%	
	March	69	318	387	6.3%	
	April	45	329	374	-3.4%	
	May	53	342	395	5.6%	
	June	65	443	508	28.6%	
	Total		370	2,005	2,375	

Source: Sentara Albermarle Medical Center internal data.

*Non-weighted scans.