#### **REQUIRED STATE AGENCY FINDINGS**

#### FINDINGS

C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date:	
Findings Date:	

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February 27, 2023 March 6, 2023

Project Analyst:	Tanya M. Saporito
Co-Signer:	Michael J. McKillip

**COMPETITIVE REVIEW** 

	COMI ETTITVE REVIEW
Project ID #:	R-12266-22
Facility:	Chesapeake Regional Imaging Centers-Elizabeth City
FID #:	220668
County:	Pasquotank
Applicant(s):	Chesapeake Diagnostic Imaging Centers, LLC
Project:	Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination
Project ID #:	R-12271-22
Facility:	Sentara Advanced Imaging Solutions-Moyock
FID #:	220669
County:	Currituck
Applicant(s):	Sentara Advanced Imaging Solutions, LLC
Project:	Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

#### **REVIEW CRITERIA**

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

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

#### **C-Both Applications**

#### Need Determination

The 2022 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2022 SMFP identified a need for one fixed MRI scanner in the Pasquotank/Camden/Currituck/Perquimans multi-county service area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one fixed MRI scanner, for a total of two MRI scanners. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

### **Policies**

One policy in Chapter 4 of the 2022 SMFP is applicable to the applications received in response to the need determination: *Policy GEN-3: Basic Principles* in the 2022 SMFP is applicable to both applications.

#### **Policy GEN-3**

Policy GEN-3 on page 30 of the 2022 SMFP states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

Chesapeake Diagnostic Imaging Centers, LLC, hereinafter referred to as "the applicant", or CDIC, is a subsidiary of Chesapeake Regional Hospital Authority, also known as Chesapeake Regional Healthcare (CRH), a licensed acute care hospital in Chesapeake, Virginia. CDIC also provides diagnostic imaging services in two locations in Virginia: Chesapeake and in Norfolk. In this application, the applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Chesapeake Regional Imaging Centers-

Elizabeth City (CRIC-Elizabeth City), a new freestanding imaging center to be located in Elizabeth City, in Pasquotank County.

*Need Determination.* The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the multi-county MRI service area of Camden, Currituck, Pasquotank and Perquimans counties.

*Policy GEN-3*. In Section B, pages 26-32, the applicant explains why it believes its application is conforming to Policy GEN-3.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/Acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP

Sentara Advanced Imaging Solutions, LLC hereinafter referred to as "the applicant", or SAIS, is a subsidiary of Sentra, which currently owns one fixed MRI scanner and one mobile MRI scanner in the multi-county service area of Camden, Currituck, Pasquotank and Perquimans counties. Sentara is also the parent company to Sentara Albemarle Medical Center ("SAMC"), a licensed acute care hospital with 182 acute care beds in Elizabeth City, in Pasquotank County. SAIS owns the mobile MRI scanner and SAMC owns the fixed MRI scanner, which is located at the hospital in Elizabeth City. On pages 23 of the application, the applicant states it will terminate its mobile MRI program if approved for the fixed MRI scanner proposed in this application and will own and operate two fixed MRI scanners, one at SAMC and one a SAIS-Moyock.

*Need Determination.* The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the multi-county MRI service area of Camden, Currituck, Pasquotank and Perquimans counties.

*Policy GEN-3*. In Section B, pages 27-30, the applicant explains why it believes its application is conforming to Policy GEN-3.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
  - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

### С

### Both Applications

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

Chesapeake Diagnostic Imaging Centers, LLC, hereinafter referred to as "the applicant", or CDIC, proposes to acquire one fixed MRI scanner pursuant to the need determination in the

2022 SMFP, to be located at Chesapeake Regional Imaging Centers-Elizabeth City (CRIC-Elizabeth City), a freestanding imaging center to be located in Elizabeth City, in Pasquotank County.

### Patient Origin

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area includes Pasquotank, Camden, Currituck and Perquimans counties. Facilities may also serve residents of counties not included in their service area.

The applicant provides projected patient origin for the first three fiscal years of operation for the proposed fixed MRI at CRIC-Elizabeth City on pages 43-44 as shown in the following table:

COUNTY	1 <sup>ST</sup> FULL FY	(FY 2025)	2 <sup>ND</sup> FULL FY (FY 2026)		3 <sup>RD</sup> FULL FY	(FY 2027)	
	<b># Р</b> тѕ.	% OF TOTAL	<b># Р</b> тѕ.	% OF TOTAL	<b># Р</b> тѕ.	% OF TOTAL	
Currituck	898	39.3%	1,000	37.5%	1,108	38.1%	
Pasquotank	519	22.7%	558	20.9%	597	20.5%	
Camden	277	12.1%	301	11.3%	325	11.2%	
Perquimans	134	5.9%	143	5.4%	152	5.2%	
In-migration Countie	In-migration Counties						
Dare	322	14.1%	470	17.6%	512	17.6%	
Gates	64	2.8%	94	3.5%	103	3.5%	
Hertford	29	1.3%	42	1.6%	46	1.6%	
Chowan	23	1.0%	34	1.3%	37	1.3%	
Bertie	10	0.4%	15	0.6%	16	0.6%	
Washington	4	0.2%	6	0.2%	7	0.2%	
Tyrrell	4	0.2%	6	0.2%	7	0.2%	
Total	2,285	100.0%	2,669	100.0%	2,910	100.0%	

CRIC-Elizabeth City Projected Patient Origin – MRI Services

Percentages may not sum due to rounding.

As the table above shows, the applicant projects that approximately 80% of the projected total patients who will use the proposed fixed MRI scanner at CRIC-Elizabeth City will originate from four counties that comprise the multi-county fixed MRI service area (Currituck, Pasquotank, Camden and Perquimans).

In Section Q, page 147, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on historical patient origin data for MRI patients in the service area from CRIC's affiliates.

### Analysis of Need

In Section C.4, pages 45-75, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Historical and projected growth and aging of the service area population, particularly those persons age 65 and older.
- The high incidence of chronic illnesses, including cancer, diabetes and heart disease in the service area.
- Demographic and socio-economic composition of the service area and the designation of Camden, Currituck and Perquimans counties as "Medically Underserved Areas" (MUA) by the federal Health Resources & Services Administration.
- Limited access to outpatient MRI services in the service area, particularly in the MUA counties and rural areas of those counties.
- An increase in economic, commercial and residential development in the service area and a high concentration of assisted living, nursing and rehabilitation facilities.
- High utilization of existing MRI services and resulting capacity issues in the service area.
- Documented outmigration of service area patients to Virginia for outpatient MRI services. The patients who choose to travel for lower-cost outpatient MRI scans are often elderly and the travel times can be cumbersome, since much of the counties in the service area are largely rural.
- The need in the service area for outpatient, lower-cost MRI services for the service area residents.
- The need in the service area for a wide-bore MRI scanner that can effectively treat claustrophobic and obese patients, and the need for enhanced breast imaging capacity.
- Documented community and physician support for the proposed project.

The information is reasonable and adequately supported for the following reasons:

- The 2022 SMFP identifies the need for one additional fixed MRI scanner in the multicounty service area of Currituck, Camden, Pasquotank and Perquimans counties.
- The applicant provides information and data to support their assertions regarding service area population growth and aging, as well as the need for lower-cost MRI services in an outpatient setting.
- The applicant provides information and data to support their assertions regarding MRI utilization in the service area and the current outmigration of service area residents to Virginia for MRI services.

#### Projected Utilization

In Section Q, page 146, the applicant provides projected utilization, as illustrated in the following table:

#### 2022 Pasquotank & Currituck MRI Project ID #'s: R-12266-22, R-12271-22 Page 7

	Partial FY 4/1/24-6/30/24	1 <sup>st</sup> FULL FY FY 2025	2 <sup>№</sup> FULL FY FY 2026	3 <sup>№</sup> FULL FY FY 2027
Number of Units	1	1	1	1
# Procedures (unweighted)	493	2,285	2,669	2,910
# Weighted Procedures	599	2,779	3,247	3,540

In Section Q, pages 147-151, the applicant provides the assumptions and methodology used to project utilization for the proposed MRI, as summarized below:

**Step 1:** The applicant examined Chesapeake Health internal data to determine historical outpatient MRI utilization in the service area. The applicant determined that outpatient MRI utilization increased by a compound annual growth rate (CAGR) of 7.0% in all counties from FY 2018-FY 2021, with the highest growth rate occurring in Camden county (18.4%) and the next highest growth rate occurring in Pasquotank County (8.2%), as shown in the table on page 147.

**Step 2:** The applicant obtained population growth data from the North Carolina State Office of Budget and Management (NCOSBM) to calculate the CAGR of the service area population by age and county. The applicant determine that the overall service area population is projected to increase by a CAGR of 1.2% from 2022-2027, with the highest growth projected to be among those persons age 65 and over. The applicant also calculated the percentage of the service area population by age and then determined the percentage of MRI scans by age group to calculate a *"weighted population"* CAGR as a measure of the impact of aging on future MRI demand. See the tables that illustrate these calculations on page 148.

**Step 3:** The applicant applied the *"weighted population CAGR"* from Step 2 to the historical MRI scans by county from Step 1 to project the number of MRI procedures in each of the service area counties CRIC through calendar year (CY) 2027, as shown in the table on page 149.

**Step 4:** The applicant converted the CY projections of MRI procedures to be performed to align with its project years, which are fiscal years (July 1 - June 30). The applicant thus determined a CRIC system total MRI procedure volume, as shown in the table on page 149.

**Step 5:** The applicant calculated a percentage of patients projected to seek MRI services at the proposed location based on drive times. The applicant projects that the number of patients who will seek MRI services at the proposed location will ramp up as referral patterns will result in an increase in the number of MRI procedures being performed at CRIC-Elizabeth City.

**Step 6:** The applicant applied the number of patients projected to seek MRI services at CRIC in Step 5 to the projected system volume from Step 4 to determine the total number of MRI scans to be performed on service area patients at CRIC-Elizabeth City, as shown in the table on page 150.

Step 7: The applicant analyzed internal data to determine the number of CRH patients from counties contiguous to and near the four-county service area who travel to Virginia for

outpatient MRI scans. The applicant states many of these patients reside closer to the proposed CIRC-Elizabeth City location than to the CRH locations in Virginia. The applicant determined that approximately 40% of those patients in counties outside the four-county service area but within the other counties projected to be served by CRIC-Elizabeth City leave the area for outpatient MRI scans. Thus, the applicant projects that these patients will prefer to travel to CRIC-Elizabeth

**Step 8:** The applicant projected total in-migration from those counties outside the service area identified in Step 7 and projected a gradual ramp up from 15% in the partial first year to 25% in the third project year, as shown in the table on page 150.

**Step 9:** The applicant examined historical MRI scans by type (with and without contrast) for MRI scans provided by CRIC affiliates in Virginia for CRIC-Elizabeth City's proposed service area residents. The applicant determined an average percent by type of MRI scan for those residents.

**Step 10:** The applicant applied the average percent by type of MRI scan from Step 9 to the projected number of scans from Step 8 to determine the number of MRI scans by type for all projected patients from the four-county service area and the contiguous and near counties projected to be served by the applicant. See the table that illustrates those projections on page 151 of the application.

**Step 11:** The applicant summarized the projections calculated in Steps 1-10 as shown in the following table from page 151:

SCAN TYPE	Partial FY 4/1/24-6/30/24	1 <sup>st</sup> Full FY FY 2025	2 <sup>№</sup> FULL FY FY 2026	3 <sup>RD</sup> FULL FY FY 2027
Without Contrast	226	1,049	1,225	1,336
With& Without Contrast	373	1,730	2,022	2,204
Total Adjusted Scans*	599	2,779	3,247	3,540

CRIC-Elizabeth City Projected MRI Scans

Projected utilization is reasonable and adequately supported based on the following:

- There is a need determination in the 2022 SMFP for a fixed MRI scanner in the multicounty MRI service area that includes Camden, Currituck, Pasquotank and Perquimans counties and this proposed project will meet that need.
- The applicant's projections of MRI scans to be performed are supported by the historical CRH and CRIC volumes, including those service area residents who travel to Virginia and other locations for outpatient MRI scans.
- The applicant adequately demonstrates that its proposed fixed MRI scanner is reasonably expected to perform more than 2,643 adjusted MRI procedures in the third year of operation following the completion of the proposed project, as required by 10A NCAC 14C .2703(b)(9)(D).

### Access to Medically Underserved Groups

In Section C, page 81, the applicant states:

"The impetus for this project centers around the promotion of equitable access to MRI. ... There are currently no freestanding MRI options in the service area. The need for equitable access to MRI is best demonstrated by the 2,500 plus outpatients who travelled from the identified four-county service area to the Applicant's Virginia-based affiliated providers to receive MRI services last year.

...

The increased access and choice resulting from the proposed project will directly address rural and underserved populations in this MRI service area...."

On page 82, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

CDIC-Liizabeth City Estimated Percentages				
ESTIMATED PERCENTAGE				
OF PATIENTS IN 3 <sup>RD</sup> FULL FY				
9.4%				
17.6%				
56.8%				
35.7%				
35.3%				
5.8%				

\*The applicant states on page 82 that low income persons category includes self-pay, charity care and Medicaid. ^The applicant states it is not able to track this data.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has historically provided access to services to underserved groups in Virginia, including North Carolina residents who travel to its outpatient imaging centers.
- The applicant states that all patients will continue to receive equitable access to MRI services with the approval of the proposed fixed MRI.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

- Comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County. The applicant states on page 33 that the proposed MRI scanner will be developed in renovated space in an existing medical office building in Moyock.

### Patient Origin

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area includes Pasquotank, Camden, Currituck and Perquimans counties. Facilities may also serve residents of counties not included in their service area.

In Section C, page 39, the applicant states the proposed outpatient imaging center does not currently exist and thus has no historical patient origin. On page 39, the applicant provides projected patient origin for the first three project years, CYs 2026-2028 for the proposed fixed MRI services at SAIS-Moyock, as summarized below:

COUNTY	1 <sup>st</sup> FULL FY CY 2026		_	FULL FY 2027		ULL FY 2028
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	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%

\*The applicant state "Other" includes other North Carolina counties listed by the applicant on page 39, as well as other states.

As the table above shows, the applicant projects that approximately 89% of the projected total patients who will utilize the proposed fixed MRI scanner at SAIS-Moyock will originate from four counties that comprise the multi-county fixed MRI service area (Currituck, Pasquotank, Camden and Perquimans).

In Section C, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on SAMC's historical patient origin data for MRI services.

### Analysis of Need

In Section C, pages 41-53, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Historical and projected population growth and aging in the multi-county service area, particularly in the 65 + age group.
- Need in the multi-county service area for additional fixed MRI capacity based on a comparison of population numbers per fixed MRI scanner.
- Limited access in the area to MRI services because of the largely rural composition of the four counties that comprise the multi-county fixed MRI service area.
- Unique geographical characteristics of the four-county service area that inhibits some residents from seeking MRI services, who would have increased access with the proposed location of the MRI scanner in Elizabeth City.
- The need for additional MRI capacity in the service area as published in the 2022 SMFP.
- The need for lower-cost, outpatient MRI services in the multi-county fixed MRI service area.

### Projected Utilization

In Section Q, Form C.2b, the applicant provides projected utilization for the interim period and the first three project years, CYs 2026-2028, as illustrated in the following table:

	Partial FY 2/1/2025- 12/31/2025	1 <sup>s™</sup> FULL FY CY 2026	2 <sup>№</sup> FULL FY CY 2027	3 <sup>RD</sup> FULL FY CY 2028
Number of Units	1	1	1	1
# Procedures (unweighted)	711	1,635	2,153	2,268
# Weighted Procedures	635	1,935	2,548	2,684

In Section Q, *"Form C Utilization – Assumptions and Methodology"*, pages 1-8 the applicant provides the assumptions and methodology used to project utilization for the proposed MRI, as summarized below:

- The applicant examined Sentara system historical MRI utilization from CY 2019-CY 2022 (annualized), for its existing fixed and mobile MRI scanners. The applicant states total MRI utilization increased by a CAGR of 9.3% during that time, despite the impact of the COVID-19 pandemic.
- Relying on the historical utilization rates, the applicant applied a growth rate of 4.7%, approximately one-half of the historical growth rate, to project total MRI utilization of

its existing and proposed MRI scanners. See the table on page 3 that illustrates projected utilization of 9,998 total MRI scans.

- The applicant identified determined that, based on historical utilization, 86.9% of scans historically performed with contrast and 90.5% of scans historically performed without contrast could appropriately be performed at the proposed outpatient facility. See the table on page 4 of the *"Form C Utilization Assumptions and Methodology"* that illustrates the total projected scans appropriate for SAIS-Moyock.
- The applicant then examined the historical patient origin for its outpatient MRI services that could have been appropriately served at a freestanding facility and calculated the percentage of those patients from the four service area counties and other counties.
- The applicant analyzed how patient origin may be impacted by the proposed location of MRI services in Currituck County rather than in Pasquotank County, where SAMC's current MRI services are located. Utilizing population growth projections from the NCSOBM, the applicant multiplied the 4.7% growth rate by the projected population growth distribution in the multi-county service area from 2022-2028, and determined an annual rate of change, or incremental increase in patient origin during that same time, as illustrated in the following table from *"Form C Utilization Assumptions and Methodology"* page 5:

COUNTY	2022	2028	NUMERICAL	GROWTH	2022-2028	% PROJECTED	
	POPULATION	POPULATION	GROWTH	DISTRIBUTION	CAGR	CHANGE	
Pasquotank	40,882	41,468	586	8.6%	4.7%	0.4%	
Perquimans	12,758	12,501	-257	-3.8%	4.7%	-0.2%	
Camden	10,554	10,955	401	5.9%	4.7%	0.3%	
Currituck	30,291	36,378	6,087	89.3%	4.7%	4.2%	
Total	94,485	101,302	6,817	100.0%			

**Projected Annual Patient Origin Change** 

- The applicant applied the incremental percentage change in patient origin calculated above to the historical patient origin for the fixed MRI scanner to project the number of outpatient MRI scans by county.
- The applicant projected a percentage of total MRI scans that would be appropriate for SAIS-Moyock and determined a ratio of outpatient MRI scans with and without contrast, based on historical experience. Using that ratio, the applicant projected total weighted and unweighted MRI scans for both SAMC and SAIS-Moyock, as shown in the following table from page 8:

	2/1/25-	PY 1	PY 2	PY 3
	12/31/25	(CY 2026)	(CY 2027)	(CY 2028)
SAIS-Moyock Weighted MRI Scans	842	1,935	2,548	2,684
SAMC Weighted MRI Scans	7,880	7,193	7,005	7,314
Total Weighted MRI Scans	8,722	9,128	9,553	9,998
Total Fixed MRI Scanners	2	2	2	2
Total Avg. Weighted Scans/Scanner	4,361	4,564	4,777	4,999

#### Projected Sentara MRI Utilization by Facility

The applicant states on page 8 of the *"Form C Assumptions and Methodology"* that the project is projected to become operational on February 1, 2025; the first full operating year is CY 2026.

Projected utilization is reasonable and adequately supported based on the following:

- There is a need determination in the 2022 SMFP for a fixed MRI scanner in the multicounty MRI service area that includes Camden, Currituck, Pasquotank and Perquimans counties and this proposed project will meet that need.
- The applicant's projections of MRI scans to be performed are supported by historical SAMC volumes on its existing fixed MRI scanner.
- The applicant adequately demonstrates that its proposed fixed MRI scanner is reasonably expected to perform more than 2,643 adjusted MRI procedures in the third year of operation following the completion of the proposed project, as required by 10A NCAC 14C .2703(b)(9)(D).

#### Access to Medically Underserved Groups

In Section C, page 60, the applicant states:

"Sentara provides care to persons in need of medical services, including the medically underserved, without regard to age, race, gender, disability, payor status, or ability to pay."

On page 61, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR
Low income persons	
Racial and ethnic minorities	27.2%
Women	59.0%
Persons with disabilities	
Persons 65 and older	36.9%
Medicare beneficiaries	38.0%
Medicaid beneficiaries	8.8%

The applicant states on page 61 that Sentara does not maintain data that includes the number of low income or disabled persons it serves.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant has historically provided access to MRI services to underserved groups and states it will continue to do so.
- The applicant states estimated percentages are based on the historical experience of patients served at SAMC.
- The applicant states that all patients will continue to receive equitable access to low-cost MRI services with the approval of the proposed fixed MRI.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA CRIC-Elizabeth City C SAIS-Moyock

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

# R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

In Section C, page 34, the applicant states that, if approved for the fixed MRI proposed in this application, it will terminate its existing mobile MRI service. The applicant states SAIS currently owns the mobile MRI scanner and projects to serve the same population with the fixed MRI scanner as it did with its mobile MRI scanner. The applicant states that no existing mobile sites will lose service as a result of terminating the mobile service; therefore, no patients currently served or projected to be served will lose access to MRI services following project completion. In Section C, page 51, the applicant states:

"...the new technology associated with the propose fixed MRI scanner allows for faster patient throughput and provides patients with enhanced scanning capabilities compared to the existing mobile MRI scanner, thus further increasing Sentara's ability to support patient demand."

The information is reasonable and adequately supported based on the following:

- The applicant projects to serve the same population with the proposed fixed MRI scanner as is currently served by the mobile MRI scanner.
- The applicant states it is currently providing mobile MRI services and is developing a mobile MRI pad at the proposed location for the fixed MRI scanner, SAIS-Moyock, allowing for a smooth transition for its patients from mobile to fixed MRI services.

In Section Q, Form C.2.b, the applicant provides projected utilization and in Section Q, "*Form C Utilization – Assumptions and Methodology*", the applicant provides the assumptions and methodology to support its projections.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

### CA Both Applications

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP.

In Section E, pages 93-94, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo The applicant states maintaining the status quo ignores the need for additional MRI service in the service area. Thus, maintaining the status quo is not an option.
- New Construction Facility The applicant states it considered new construction to house the proposed fixed MRI scanner but rejected this idea because it would be more costly and less effective for its patients than renovating existing space as proposed. Thus, this alternative is not an effective alternative.
- Alternative Location in Elizabeth City The applicant considered several other locations for the proposed MRI scanner but determined that those locations are not near major thoroughfares and thus would create additional access issues for its patients. The applicant states the chosen location is not only close to major thoroughfares, but is also proximal to its parent company, Chesapeake Regional Healthcare (CRH). Thus, locating the proposed MRI close to CRH ensures efficient patient access and ease of throughput.

The applicant adequately demonstrates that the alternative proposed in this application is its most effective alternative to meet the need based on the following:

- The applicant states the proposed fixed MRI scanner be located close to main thoroughfares in the area and close to multiple existing healthcare providers, ensuring access to MRI services for its patients.
- The applicant states the proposed fixed MRI scanner will provide economies of scale because of the proposed location and the healthcare network within which it will operate.
- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.

### **Conclusion**

#### 2022 Pasquotank & Currituck MRI Project ID #'s: R-12266-22, R-12271-22 Page 17

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

In Section E, pages 75-76, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo The applicant states maintaining the status quo would ignore the need in the service area for additional MRI services. Patients would still lack access to low cost outpatient MRI services, resulting in lengthy wait times for scans and increased cost of hospital-based MRI services. Therefore, the applicant states that the status quo is not a reasonable alternative.
- Develop the project as proposed at a different location The applicant states the proposed location is an existing MOB that will be renovated to accommodate the proposed MRI scanner, thereby saving costs associated with new construction. Additionally, the proposed location in Moyock is in a county that currently has no fixed MRI scanner and is the fastest growing county in the multi-county service area. Thus, the applicant states that a different location will not be as cost effective and is not a reasonable alternative.

On page 76, the applicant states that its proposal is the most effective alternative because the proposed fixed MRI scanner at the proposed location will provide patients in the region with a cost effective alternative for outpatient MRI services.

The applicant adequately demonstrates that the alternative proposed in this application is its most effective alternative to meet the need based on the following:

• The applicant states that the proposal meets the need of patients in the service area by providing enhanced imaging in a cost-effective manner.

- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons *s*tated above.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

#### C Both Applications

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP.

### **Capital and Working Capital Costs**

In Section Q Form F.1a Capital Cost, page 152, the applicant projects the total capital cost of the project as shown in the table below:

CDIC-Elizabeth City Capital Cost		
Site Costs	\$35,000	
Renovation Costs	\$1,696,221	
Miscellaneous Costs	\$1,469,531	
Less TI*	-\$149,800	
Total	\$3,050,952	

\*On page 152, the applicant states it adjusted the total capital cost based on a tenant upfit allowance that will be credited, since the project involves renovating leased space.

In Section Q Form F.1a, page 152, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Renovation cost is based on an estimate from a licensed architect.
- Medical equipment cost is based on vendor quotations.
- The applicant provides as copy of the building lease which includes allowances for building upgrades by the tenant.

In Section F, page 96, the applicant projects that start-up costs will be \$89,767 and initial operating expenses will be \$24,100 for a total working capital of \$113,867. On pages 97-98, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Start-up costs are based on staff recruitment estimates for time and advertising expense from CRH's human resources (HR) department experience.
- Marketing expenses, supplies and minor equipment cost estimates are based on CDIC and its affiliates' historical experience with freestanding imaging centers.
- Initial operating costs are based on the applicant's projected project completion based on its historical experience, accounting for the time it will take for volume to shift and positive cash flow is realized.

### Availability of Funds

In Section F, page 95, the applicant states that the capital cost will be funded as shown in the table below:

Түре	CDIC-ELIZABETH CITY
Loans	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$3,050,952
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$3,050,952

\* OE = Owner's Equity

In Section F, page 98, the applicant states that the working capital cost will be funded as shown in the table below:

#### 2022 Pasquotank & Currituck MRI Project ID #'s: R-12266-22, R-12271-22 Page 20

Түре	CDIC-ELIZABETH CITY	
Loans	\$0	
Cash and Cash Equivalents, Accumulated reserves or OE *	\$113,867	
Bonds	\$0	
Other (Specify)	\$0	
Total Financing	\$113,867	

#### Sources of Working Capital Cost Financing

\* OE = Owner's Equity

In Exhibit F-2.1, the applicant provides a letter dated September 12, 2022 signed by the Chief Financial Officer of Chesapeake Regional Healthcare confirming CRC's willingness to provide funding for the proposed capital and working capital needs of the project and the availability of those funds. Exhibit F-2.2 contains the audited financial statements for Chesapeake Hospital Authority, the parent company to CDIC that documents the availability of sufficient funds for the project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years (FY), of operation (July 1-June 30) following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the last two full fiscal years following completion of the project, as shown in the table below:

	<b>1<sup>st</sup> FULL FISCAL</b>	2 <sup>ND</sup> FULL FISCAL	<b>3<sup>RD</sup> FULL FISCAL</b>
	YEAR	YEAR	YEAR
Total Procedures (unweighted)	2,285	2,669	2,910
Total Gross Revenues (Charges)	\$3,897,754	\$4,688,717	\$5,265,314
Total Net Revenue	\$972,208	\$1,174,435	\$1,310,505
Average Net Revenue per Procedure	\$425	\$440	\$450
Total Operating Expenses (Costs)	\$981,362	\$1,168,060	\$1,227,391
Average Operating Expense per Procedure	\$429	\$438	\$422
Net Income	(\$9,154)	\$6,375	\$83,114

Chesapeake Diagnostic Imaging Center-Elizabethtown

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 154. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient Services gross revenue is based on 2021 CRH freestanding imaging centers historical experience.
- Charity care revenue is projected at 2.5% of gross revenue annually based on CRH historical experience.
- Bad debt is reflected as 1.5% annually as a revenue offset based on CRH historical experience.
- Net revenue per MRI is inflated 3% annually based on CRH MRI experience.
- Contractual adjustments are estimated at 71% annually based on CRH experience.

• Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and • adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the • proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

### R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

In Section O. Form, F. la Capital Cost, the applicant projects the total capital cost of the project. as

SAIS-Moyock Capital Cost		
Construction/Renovation Costs	\$986,069	
Miscellaneous Costs	\$1,690,436	
Total	\$2,676,505	

i beetion Q, i ofin, i . Ta Capital Cost, the applicant projects the total capital cost of the pr	Juli
s shown in the table below.	

In Section Q Form F.1a Assumptions, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- MOB renovation cost is based on an estimate from a licensed architect.
- Medical equipment cost is based on vendor quotations.
- Capital cost estimates are based on Sentara's experience with similar projects. •

In Section F, page 79, the applicant projects that start-up costs will be \$111,342 and initial operating expenses will be \$276,041 for a total working capital of \$387,383. On page 80, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Start-up costs are based on three months projections for supplies, utilities, salaries and other expenses excluding depreciation.
- Initial operating costs are based on a 13 month period and include all non-depreciation expenses, which the applicant calculates as the difference between operating costs and revenues during the initial operating period for the facility.

#### **Availability of Funds**

In Section F, page 77, the applicant states that the capital cost will be funded as shown in the table below:

Түре	SAIS-MOYOCK
Loans	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$2,676,505
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$2,676,505

#### **Sources of Capital Cost Financing**

\* OE = Owner's Equity

In Section F, page 80, the applicant states that the working capital cost will be funded as shown in the table below:

Түре	<b>SAIS-Μ</b> ΟΥΟCΚ	
Loans	\$0	
Cash and Cash Equivalents, Accumulated reserves or OE *	\$387,383	
Bonds	\$0	
Other (Specify)	\$0	
Total Financing	\$387,383	

#### Sources of Working Capital Cost Financing

\* OE = Owner's Equity

In Exhibit F-2.2, the applicant provides a letter dated September 15, 2022 signed by the Executive Vice President and Chief Operating Officer of Sentara Healthcare confirming Sentara's willingness to provide funding for the proposed capital and working capital needs of the project and the availability of those funds. Exhibit F-2.2 contains the audited financial statements for Sentara Healthcare and subsidiaries that documents the availability of sufficient funds for the project.

### **Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation, which the applicant states are calendar years, following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the last two full fiscal years following completion of the project, as shown in the table below:

SAIS-Moyock			
	1 <sup>st</sup> FULL FISCAL	2 <sup>ND</sup> FULL FISCAL	<b>3<sup>RD</sup> FULL FISCAL</b>
	YEAR	YEAR	YEAR
Total Procedures (unweighted)	1,635	2,153	2,268
Total Gross Revenues (Charges)	\$2,523,727	\$3,422,922	\$3,714,002
Total Net Revenue	\$606,244	\$822,264	\$892,169
Average Net Revenue per Procedure	\$371	\$382	\$393
Total Operating Expenses (Costs)	\$760,399	\$792,143	\$811,105
Average Operating Expense per Procedure	\$465	\$368	\$358
Net Income	(\$154,155)	\$30,121	\$81,064

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, *"Form F.2 Assumptions"*. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient Services gross revenue is based on projected payor mix and average charge for each project year, using historical data from Sentara.
- Projected average charges are based on expected freestanding reimbursement and inflated 3.0% annually.
- Contractual adjustments and charity care are based on the applicant's experience and the difference between gross and net revenue by payor.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

#### C Both Applications

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area includes Pasquotank, Camden, Currituck and Perquimans counties. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Pasquotank, Camden, Currituck and Perquimans counties service area, summarized from Table 17E-1, page 356 of the 2022 SMFP:

Fixed Wiki Scamers in Pasquotank, Camden, Curntuck and Perquimans Counties				
PROVIDER	# OF FIXED	SERVICE TYPE	TOTAL MRI	Adjusted
	SCANNERS		SCANS	TOTAL
Sentara Albemarle Medical Center	1	Hospital Fixed	3,634	4,224

#### Fixed MRI Scanners in Pasquotank, Camden, Currituck and Perquimans Counties

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner in Pasquotank County pursuant to the need determination in the 2022 SMFP.

In Section G, pages 106-107, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Pasquotank, Camden, Currituck, Perquimans multi-county service area. On page 106, the applicant states:

"Sentara, the only provider in the service area, offers hospital-based MRI services from both a fixed unit inside the hospital and a mobile unit located immediately outside the hospital. In contrast, CRIC-Elizabeth City proposes to establish a freestanding MRI center that will not be licensed under a hospital and will utilize billing practices associated with freestanding imaging centers. This will result in convenience, ease of access, and lower costs than what is currently available in the service area.

The proposed MRI unit itself also represents new technology for the service area. CRIC-Elizabeth City is proposing to implement a FUJIFILM echelon Oval 1.5T MRI.

... The proposed MRI was chosen to increase access to MRI services for patients in the service are who are obese and claustrophobic and will enhance the access to MRI services for these patients.

Furthermore, CRIC-Elizabeth City has included the cost of a breast coil in this project for the provision of breast MRI scans. To the best of CRH's knowledge, breast MRI scans are not available in the service area and patients in need of this care must travel to Virginia or distant parts of North Carolina for these important services."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2022 SMFP for the proposed fixed MRI scanner in the Pasquotank, Camden, Currituck, Perquimans multi-county service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments received at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

# R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

In Section G, page 87, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Pasquotank, Camden, Currituck, Perquimans multi-county service area. The applicant states:

"The proposed project represents the development of the first ever freestanding fixed MRI scanner by a trusted and experienced provider dedicated to serving patients in the service area.... The proposed freestanding diagnostic center will enable Sentara to serve a greater number of patients, particularly those appropriate for outpatient MRI services, while also enhancing access for higher-acuity patients in need of hospital-based MRI services at SAMC."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2022 SMFP for the proposed fixed MRI scanner in the Pasquotank, Camden, Currituck, Perquimans multi-county service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments received at the public hearing
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

#### C Both Applications

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI service for the interim and first three full fiscal years (FY), as summarized below:

#### 2022 Pasquotank & Currituck MRI Project ID #'s: R-12266-22, R-12271-22 Page 27

Ροςιτιον	Partial Year 4/1/24-6/30/24	1st Full FY 7/1/24- 6/30/25	2ND FULL FY 7/1/25-6/30/26	3rd Full FY 7/1/26- 6/30/27
Radiology Technologists	0.3	1.3	1.3	1.3
Information Technology	0.3	0.5	0.5	0.5
Business Office	0.8	3.0	3.4	3.5
Total	1.4	4.8	5.2	5.3

#### **CRIC-Elizabeth City Staffing**

The assumptions and methodology used to project staffing are provided on Form H Staffing, Section Q, page 157. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 108-110, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates its methods to recruit staff, which includes recruitment through CDIC's existing relationships with area health professional training programs.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification based on CDIC's and CRH's experience.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

# R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI service for the interim and first three full fiscal years (FY), as summarized below:

#### 2022 Pasquotank & Currituck MRI Project ID #'s: R-12266-22, R-12271-22 Page 28

Ροςιτιον	Partial Year 2/225-12/2025	1 <sup>st</sup> FULL FY CY 2026	2 <sup>№</sup> FULL FY CY 2027	3 <sup>₽D</sup> FULL FY CY 2028
Licensed Practical Nurse	0.9	1.0	1.0	1.0
Radiology Technician	1.0	1.1	1.1	1.1
Business Office	0.5	0.5	0.5	0.5
Total	2.4	2.6	2.6	2.6

#### SAIS-Moyock Staffing

The assumptions and methodology used to project staffing are provided in Section Q, "Form H Assumptions". Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 89-90, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates its methods to recruit staff, which includes recruitment through various social media platforms and existing relationships with area college and high school programs.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification based on Sentara's experience.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

#### C Both Applications

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP.

### Ancillary and Support Services

In Section I, page 111, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 112-114, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides a letter signed by the Chief Administrative Officer for CRH that documents support for the necessary ancillary and support services.
- The applicant documents that its parent company, CRH, has experience in providing the ancillary and support services necessary for the project.

### **Coordination**

In Section H, pages 115-117, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in referenced Exhibits. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is part of the CRH health system and has established relationships with other local healthcare and social service providers.
- CRH has established relationships with area physician practices and rural health clinics, in which CRIC-Elizabeth City will participate.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

### Ancillary and Support Services

In Section I, page 91, the applicant identifies the necessary ancillary and support services for the proposed MRI services. On pages 91-92, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides a letter signed by the Executive Vice President and Chief Operating Officer that documents support for the necessary ancillary and support services.
- The applicant documents that it has experience in providing the ancillary and support services necessary for the project.

### **Coordination**

In Section I, page 92, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is a subsidiary of Sentara Healthcare which currently has established relationships with local healthcare and social service providers.
- Sentara has established relationships with area physician practices and rural health clinics, in which SAIS-Moyock will participate.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

#### NA Both Applications

Neither of the applicants projects to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, neither of the applicants projects to provide the proposed services to a substantial number of persons residing in other states that are not

adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
  - (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

### NA

#### Both Applications

Neither of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

С

### Both Applications

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP.

In Section K, page 119, the applicant states the project involves renovating 2,996 square feet of space in an existing building that the applicant will lease. Line drawings are provided in Exhibits K-2.1 and K-2.2.

On page 119, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the proposed project involves renovation of existing space, which is more cost-effective than new construction.
- The applicant states the proposed location is cost-effective because it will be convenient for patient access.
- The applicant provides a letter from a licensed architect in Exhibit K-2.3 certifying the cost for renovation.

On page 120, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the proposed project will reduce the cost of MRI services in the service area since it will be developed in existing space and will be a freestanding facility.
- The applicant states CDIC and CRH have extensive experience in designing and building diagnostic imaging centers like the one proposed in this application. This experience ensures the proposed facility will be developed to ensure efficient design and compliance with all applicable federal, state and local building codes, particularly those codes related to energy efficiency and consumption.

On pages 120-121, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

In Section K, page 79 the applicant states the project involves renovating 1,131 square feet of space on the second floor of an existing medical office building. Line drawings are provided in Exhibit C.1-1.

On pages 79-80, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the proposed project involves renovation of existing space, which is more cost-effective than new construction.
- The applicant provides a letter from a licensed architect in Exhibit F.1 certifying the cost for renovation.

On page 80, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the proposed project will reduce the cost of MRI services in the service area since it will be developed in existing space and will be a freestanding facility.
- The applicant states payors will incur a lower charge structure in the proposed freestanding facility, which lowers the cost of services to the patient.

On pages 80-82, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the healthrelated needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and persons with disabilities, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
  - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

#### NA-CRIC C-SAIS

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

SAIS is owned by Sentara, the parent company of Sentara Albemarle Medical Center. In Section L, page 83, the applicant states that is Criterion is not applicable because the proposed freestanding diagnostic center does not currently exist; however, the applicant is a subsidiary of Sentara Albemarle Medical Center. The project analyst examined the 2022 License Renewal Application for Sentara Albemarle Medical Center and calculated the following percentages:

Payor Category	Acute Care Services as Percent of Total
Self-Pay	6.6%
Medicare	66.1%
Medicaid	10.3%
Insurance	15.1%
Other (specify)	1.9%
Total	

Source: 2022 Hospital License Renewal Application, page 8

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

#### C Both Applications

## R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 125, the applicant states that, as a subsidiary of CRH, a non-government run public health system, CDIC complies with all applicable federal, state and local regulations regarding provision of uncompensated care, community service and equal access to minorities and persons with disabilities.

In Section L, page 127, the applicant states that no patient civil rights access complaints have been filed against CDIC.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

## R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 85, the applicant states that it has no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities. The applicant states it does and will provides care to persons in need of medical services, including the underserved.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

#### С **Both Applications**

### R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

In Section L, page 128, the applicant projects the following payor mix for the proposed MRI services during the third full fiscal year of operation following project completion, as shown in the table below:

CDIC-ELIZABETH CITY		
PROJECTED PAYOR MIX, FY 2027		
PAYOR CATEGORY	PERCENTAGE OF TOTAL MRI	
	PATIENTS SERVED	
Self-Pay	1.0%	
Charity Care	2.6%	
Medicare*	35.3%	
Medicaid*	5.8%	
Insurance*	41.8%	
Workers Comp	4.8%	
TRICARE	8.7%	
Total	100.0%	
*Including any managed care plans		

CDIC EUZADETU CITV

Including any managed care plans

On page 128, the applicant states charity care includes patients in all payor groups whose obligations are written off as charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.0% of total services will be provided to self-pay patients, 2.6% to charity care patients, 35.3% to Medicare patients and 5.8% to Medicaid patients.

On page 128, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for CDIC.

The Agency reviewed the:

- Application •
- Exhibits to the application •

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

### R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

In Section L, page 86, the applicant projects the following payor mix for the proposed MRI services during the third full fiscal year of operation following project completion, as shown in the table below:

PROJECTED PAYOR MIX, FY 2028			
PAYOR CATEGORY	PERCENTAGE OF TOTAL		
	MRI PATIENTS SERVED		
Self-Pay	3.7%		
Charity Care^			
Medicare*	38.0%		
Medicaid*	8.8%		
Insurance*	43.8%		
Other (includes TRICARE and Workers Compensation	5.7%		
Total	100.0%		

SAIS-IMOYOCK	
PROJECTED PAYOR MIX, FY 20	28

.....

\*Including any managed care plans

^The applicant states on page 86 that Sentara internal data does not include Charity Care, but patients in all payor categories can and do receive charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.7% of total services will be provided to self-pay patients, 38.0% to Medicare patients and 8.8% to Medicaid patients.

On page 86 and in Section C, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix for MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

#### С **Both Applications**

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

In Section L, page 129, the applicant adequately describes the range of means by which patients will have access to the proposed MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

# R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

In Section L, page 88, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

#### С

## Both Applications

**Both Applications.** In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that all of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all of the applications are conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.

- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

#### С

#### Both Applications

The 2022 SMFP defines the service area for a fixed MRI scanner as "the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county." Therefore, for the purpose of this review, the fixed MRI service area includes Pasquotank, Camden, Currituck and Perquimans counties. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Pasquotank, Camden, Currituck and Perquimans counties service area, summarized from Table 17E-1, page 356 of the 2022 SMFP:

Fixed Wiki Scamers in Pasquotank, Canden, Currituck and Perquimans Counties					
PROVIDER	# OF FIXED SERVICE TYPE TOTAL MRI ADJUSTED				
	SCANNERS		SCANS	TOTAL	
Sentara Albemarle Medical Center	1	Hospital Fixed	3,634	4,224	

#### Fixed MRI Scanners in Pasquotank, Camden, Currituck and Perquimans Counties

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner in Pasquotank County pursuant to the need determination in the 2022 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 132, the applicant states:

"Sentara Albemarle Medical Center is the only existing provider of MRI services for the four-county service area. ... Because Sentara is the only provider of MRI services in the service area, there is currently no competition. The proposed project will create competition with regard to MRI that does not currently exist in the service area."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 132, the applicant states:

"This competition will bring numerous positive effects to the community. First, it provides a cost-effective alternative to hospital-based imaging. ... Medicare and commercial [plans] pay far less for MRI services provided in a freestanding setting. ... Lower charges also mean lower payments for patients when the MRI falls into their deductible or other patient responsibility situations. .... CRIC-Elizabeth City will provide the service area with a freestanding option that will provide cost-effective, convenient, and accessible MRI imaging closer to home."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 133, the applicant states:

"The addition of CRIC-Elizabeth City will have a positive impact on quality MRI services for the service area. Like CDIC's existing locations, CRIC-Elizabeth City and its imaging equipment will be fully accredited b the American College of Radiology ..., undergoing periodic quality review to assure it meets the highest standards for diagnostic imaging centers."

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 132, the applicant states:

"CRIC-Elizabeth City will provide more capacity, a convenient and accessible setting, and will allow more than 2,000 patients from the service area who are currently leaving the area for MRI services to stay closer to home for their MRI scan each year."

See also Sections L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

# R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 91, the applicant states:

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality and access to freestanding diagnostic imaging services, which currently do not exist in the service area."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 91, the applicant states:

"... Sentara is proposing to develop the MRI scanner in a lower cost, freestanding setting, which will improve the cost-effectiveness of MRI services in the area for those that do not need a hospital-based setting. By locating the proposed scanner in a county currently without MRI services, the proposed project will also minimize the costs incurred by patients who must travel to Elizabeth City or eave the service area or state to access care."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 91, the applicant references Section B.20, pages 27-30. See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 91, the applicant references Section B.20, pages 27-30. See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

# **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

## NA – CRIC-Elizabeth City C – SAIS-Moyock

# R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP.

Neither the applicant nor any related entities own, operate, or manage an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this application.

# R-12271-22/ Sentara Advanced Imaging Solutions, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at a new diagnostic center, Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County. In Section Q, Form O, the applicant identifies one facility, Sentara Albemarle Medical Center, which is the only facility owned, operated or managed by the applicant or a related entity.

In Section O.5, page 94, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in that facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in that facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

## **C-Both Applications**

The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

# SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

## 10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
  (1) identify the misting fixed MBI segments around or expected by the applicant on a value of the segment of the segm
  - (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -NA- **CRIC-Elizabeth City.** Neither the applicant nor any related entity owns or operates a fixed MRI scanner in the proposed fixed MRI scanner service area.
- -C- **SAIS-Moyock.** In Section C, page 63 the applicant states Sentara Healthcare, the parent company to SAIS, owns one fixed MRI scanner located at Sentara Albemarle Medical Center in the fixed MRI scanner service area.

- (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;
- -NA- **CRIC-Elizabeth City.** Neither the applicant nor any related entity has been approved to own or operate a fixed MRI scanner in the proposed fixed MRI scanner service area.
- -NA- **SAIS-Moyock.** Neither the applicant nor any related entity has been approved to own or operate a fixed MRI scanner in the proposed fixed MRI scanner service area.
  - (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;
- -NA- **CRIC-Elizabeth City.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner in the proposed fixed MRI scanner service area.
- -C- **SAIS-Moyock.** In Section C, page 64 the applicant states Sentara Advanced Imaging Solutions owns and operates one mobile MRI scanner located at Sentara Albemarle Medical Center, which is in the proposed fixed MRI scanner service area during the 12 months before application deadline.
  - (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;
- -NA- **CRIC-Elizabeth City.** Neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- -NA- **SAIS-Moyock.** Neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
  - (5) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;
- -C- **CRIC-Elizabeth** City. In Section C, page 76 and in Section Q, Form C.2b, page 146, the applicant provides projected utilization for its proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.
- -C- **SAIS-Moyock.** In Section C, page 64 and in Section Q, Form C.2b, the applicant provides projected utilization for its existing fixed MRI scanner and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion. The applicant does not project utilization of its existing mobile MRI scanner, because it states it

will eliminate the existing mobile MRI scanner once this proposal is approved and operate two fixed MRI scanners in the fixed MRI scanner service area.

- (6) provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;
- -C- **CRIC-Elizabeth City.** In Section Q, "Assumptions to Projected Utilization", the applicant provides projected utilization of the proposed fixed MRI scanner through the first three full fiscal years of operation following project completion.
- -C- SAIS-Moyock. In Section Q, *"Form C Assumptions and Methodology"*, the applicant provides the assumptions and methodology used to project utilization of its existing and proposed MRI scanners.
  - (7) project that the fixed MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:
    - (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
    - (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;
    - (C) 2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;
    - (D) 2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
    - (E) 1,201 or more adjusted MRI procedures per fixed MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area.

There is currently one existing fixed MRI scanner in the fixed MRI scanner service area; thus, Subparagraph (D) applies to this review.

- -C- **CRIC-Elizabeth City.** In Section C, page 85, the applicant projects to provide 3,540 adjusted MRI procedures during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- **SAIS-Moyock.** In Section C, page 65, the applicant projects to provide 4,999 adjusted MRI procedures during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
  - (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,328 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operations following completion of the project.

- -NA- **CRIC-Elizabeth City.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner in the proposed fixed MRI scanner service area.
- -NA- **SAIS-Moyock.** The applicant has an existing mobile MRI scanner. The applicant states throughout the application that it will terminate the mobile MRI program if approved for the fixed MRI scanner proposed in this application; therefore, the applicant does not project utilization of its existing mobile MRI scanner.
- (b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
  - (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;
  - (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;
  - (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
  - (4) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;*
  - (5) *identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner;*
  - (6) provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;
  - (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;
  - (8) project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,328 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and
  - (9) project that the fixed MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:

- (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;
- (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;
- (C) 2,883 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;
- (D) 2,643 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
- (E) 1,202 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners in the fixed MRI scanner service area.
- -NA- **CRIC-Elizabeth** City. The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- -NA- **SAIS-Moyock.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.

## **COMPARATIVE ANALYSIS**

Pursuant to G.S. 131E-183(a)(1) and the 2022 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for the multi-county service area of Camden, Currituck, Pasquotank and Perquimans counties in this review. Because the two applications in this review collectively propose to develop two additional fixed MRI scanners to be located in multi-county service area, both of the applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review:

• R-12266-22/ Chesapeake Diagnostic Imaging Centers, LLC/Acquire one fixed MRI scanner

Chesapeake Diagnostic Imaging Centers, LLC proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Chesapeake Regional Imaging Centers-Elizabeth City (CRIC-Elizabeth City), a freestanding imaging center to be located in Elizabeth City, in Pasquotank County.

• **R-12271-22**/ Sentara Albemarle Medical Center, LLC /Acquire one fixed MRI scanner Sentara Albemarle Medical Center, LLC proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2022 SMFP, to be located at Sentara Advanced Imaging Solutions-Moyock (SAIS-Moyock) in Moyock, Currituck County, an existing medical office building that will be renovated to accommodate the proposed fixed MRI scanner.

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

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

## **Geographic Accessibility (Location within the Service Area)**

There is currently only one existing fixed MRI scanner located in the multi-county fixed MRI service area and it is located at SAMC in Elizabeth City in Pasquotank County. **CRIC-Elizabeth City** proposes to locate the fixed MRI scanner in Elizabeth City in Pasquotank County. **SAIS-Moyock** proposes to locate the fixed MRI scanner in Moyock in Currituck County. Therefore, with regard to expanding geographic accessibility to fixed MRI scanner services, the application submitted by **SAIS-Moyock** is the more effective alternative.

## **Competition**

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service

area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. **CRIC-Elizabeth City** would be a new provider of MRI services in the service area. Therefore, with regard to increasing competition for MRI services in the multi-county fixed MRI service area, the application submitted by **CRIC-Elizabeth City** represents a more effective alternative.

#### Access by Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

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

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

#### **Projected Medicare**

The following table shows each applicant's percentage of gross revenue (charges) projected to be provided to Medicare patients in the applicant's third full fiscal year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage to services to Medicare patients is the more effective alternative with regard to this comparative factor.

	Medicare Gross Total Gross		Medicare % of Total
Applicant	Revenue	Revenue	Gross Revenue
CRIC-Elizabeth City	\$1,842,860	\$5,265,314	35.0%
SAIS-Moyock	\$1,410,926	\$3,714,002	38.0%

Services to	Medicare	Patients -	Proiect	Year 3

Source: Form F.2 for each applicant.

As shown in the table above, the application submitted by **SAIS-Moyock** projects that 38% of its MRI services will be provided to Medicare patients. The application submitted by **CRIC-Elizabeth City** projects that 35% of its fixed MRI services will be provided to Medicare patients. Therefore, with regard to service to Medicare patients, the application submitted by **SAIS-Moyock** is the more effective alternative.

#### **Projected Medicaid**

The following table shows each applicant's percentage of gross revenue (charges) projected to be provided to Medicaid patients in the applicant's third full year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section

Q. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

	Medicaid Gross	Total Gross	Medicaid % of Total
	Revenue	Revenue	Gross Revenue
CRIC-Elizabeth City	\$263,266	\$5,265,314	5.0%
SAIS-Moyock	\$325,769	\$3,714,002	8.8%

#### Services to Medicaid Patients - Project Year 3

Source: Form F.2 for each applicant.

As shown in the table above, the application submitted by **SAIS-Moyock** projects that 8.8% of its MRI services will be provided to Medicaid patients. The application submitted by **CRIC-Elizabeth City** projects that 5.0% of its MRI services will be provided to Medicaid patients. Therefore, with regard to service to Medicaid patients, the application submitted by **SAIS-Moyock** is the more effective alternative.

#### Projected Average Net Revenue per Weighted MRI Procedure

The following table compares the projected average net revenue per weighted MRI procedure for the third year of operation following project completion for all the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally regarding this factor, the application proposing the lowest average net revenue per MRI procedure is the more effective alternative.

	Net Revenue	# of Weighted MRI Procedures	Average Net Revenue/Weighted MRI Procedure
CRIC-Elizabeth City	\$1,310,505	3,540	\$370
SAIS-Moyock	\$892,169	2,684	\$332

#### Net Revenue per Weighted MRI Procedure - Project Year 3

Source: Form F.2 for each application.

As shown in the table above, the application submitted **by SAIS-Moyock** projects the lowest net revenue per MRI procedure in the third operating year. However, SAIS-Moyock excluded professional fees from their revenue projections. Therefore, this comparison is inconclusive.

#### **Projected Average Operating Expense per Weighted MRI Procedure**

The following table compares the projected average operating expense per weighted MRI procedure in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form F.2). Generally, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative with regard to this comparative factor.

	Operating Expenses	# of Weighted MRI Procedures	Average Net Revenue/Weighted MRI Procedure
CRIC-Elizabeth City*	\$912,810	3,540	\$258
SAIS-Moyock	\$811,105	2,684	\$358

#### Projected Operating Expense per Weighted MRI Procedure - Project Year 3

Source: Form F.2 for each application.

\*Professional fees were deducted from the operating expenses for CDIC-Elizabeth City.

As shown in the table above, the application submitted by **CRIC-Elizabeth City** projects the lowest average operating expense per MRI procedure in the third operating year. Therefore, the application submitted by **CRIC-Elizabeth City** is the most effective application with respect to operating expense per MRI procedure.

#### <u>Summary</u>

The following table lists the comparative factors and indicates whether each application was more effective or less effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	CRIC-Elizabeth City	SAIS-Moyock
Conformity with Review Criteria	Yes	Yes
Geographic Accessibility	Less Effective	More effective
Competition (Access to new or alternate provider)	More effective	Less effective
Access by Medicare Patients	Less effective	More effective
Access by Medicaid Patients	Less effective	More Effective
Average Net Revenue per MRI Procedure	Inconclusive	
Average Operating Expense per MRI Procedure	More Effective	Less effective

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus all applications are approvable standing alone. However, collectively they propose a total of two fixed MRI scanners in the multi-county service area that includes Camden, Currituck, Pasquotank and Perquimans counties but the need determination in the 2022 SMFP is for only one fixed MRI scanner. Therefore, only one fixed MRI scanner in the service area can be approved.

As shown in the table above, **SAIS-Moyock** was determined to be a more effective alternative for the following three factors:

- Geographic Accessibility
- Access by Medicare Patients
- Access by Medicaid Patients

As shown in the table above, **CRIC-Elizabeth** City was determined to be a more effective alternative for the following two factors:

- Competition
- Projected average operating expense per weighted MRI procedure

## DECISION

Each application is individually conforming to the need determination in the 2022 SMFP for one fixed MRI scanner in the multi-county service area that includes Camden, Currituck, Pasquotank and Perquimans counties, as well as individually conforming to all statutory and regulatory review criteria. However, 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.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved:

• Project I.D. # R-12271-22 / Sentara Albemarle Medical Center, LLC / Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

And the following application is denied:

• Project I.D. # R-12266-22 / Chesapeake Diagnostic Imaging Centers, LLC/ Develop one fixed MRI scanner pursuant to the 2022 SMFP need determination

Project I.D. # R-12271-22 / Sentara Albemarle Medical Center, LLC is approved subject to the following conditions:

- 1. Sentara Albemarle Medical Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2022 SMFP to be located in a medical office building in Moyock in Currituck County.
- 3. Progress Reports:
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
  - b. The certificate holder shall complete all sections of the Progress Report form.

- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
- d. The first progress report shall be due on August 1, 2023.
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.
- 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
  - a. Payor mix for the services authorized in this certificate of need.
  - **b.** Utilization of the services authorized in this certificate of need.
  - c. Revenues and operating costs for the services authorized in this certificate of need.
  - d. Average gross revenue per unit of service.
  - e. Average net revenue per unit of service.
  - f. Average operating cost per unit of service.
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.