

## PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION

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

#### PETITIONER

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#### STATEMENT OF THE PROPOSED CHANGE

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

#### REASON FOR THE REQUESTED ADJUSTMENT

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

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

##### **1. Low volume growth trends**

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

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

\*Compound Annual Growth Rate.

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

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

**2. Low population with minimal growth**

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

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

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

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

### **3. Sufficient MRI capacity**

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

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

#### **SAMC Fixed and Mobile MRI Scanner Volume**

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

Source: 2020 and 2021 *SMFPs*.

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

#### **4. Difficulty meeting CON rules**

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

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

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

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

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

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

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

Source: 2007-2009 SMFPs.

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

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

Source: 2010 - 2012 SMFPs.

As a result, SAMC (at the time not part of Sentara Healthcare) decided not to develop the second fixed MRI scanner and relinquished its Certificate of Need. With 4,330 scans performed in FY 2019, SAMC’s MRI volume is 13 percent lower than the highest volume year, 2007, when the sole fixed MRI scanner at SAMC performed 4,877 scans<sup>1</sup>. SAMC does not currently expect MRI volume in the service area to exceed this historical level in the near future; thus, the existing fixed MRI at SAMC is sufficient to meet the current and expected future need in the service area.

## **6. Impacts of novel coronavirus**

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

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

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

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

Source: SAMC internal data.

However, as shown above, beginning in May 2020, total MRI volume began to increase, returning to near pre-pandemic volume by June 2020. Moreover, as discussed above, the four counties in the multi-county service area have relatively smaller populations, most of which are dispersed throughout rural coastal areas. As a result, the residents of the service area make up less than one percent of the state’s population ( $91,991/10,630,691 = 0.0087$  or 0.87 percent) and only 0.41 percent of all the state’s confirmed COVID-19 cases as of July 20, 2020<sup>2</sup> ( $409/99,975 = 0.0041$  or 0.41 percent), as shown below.

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

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

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

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

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

**ADVERSE EFFECTS IF PETITION IS NOT APPROVED**

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

**ALTERNATIVES CONSIDERED**

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

**UNNECESSARY DUPLICATION**

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

**BASIC PRINCIPLES**

Safety and Quality

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

Access

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

Value

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

**CONCLUSION**

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



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