ATTACHMENT 2 NARRATIVE

2. Project Description

South Shore Health System, Inc. (the "System" or "SSHS") located at 55 Fogg Road, Weymouth, Massachusetts 02190 is filing a Notice of Determination of Need ("Application") with the Massachusetts Department of Public Health ("Department") for the acquisition of a 3 Tesla ("3T") magnetic resonance imaging ("MRI") unit to be to be located on the main campus of South Shore Hospital (the "Hospital" or "SSH") at the same address as the System ("Proposed Project").

SSHS is a not-for-profit health care system in Southeastern Massachusetts serving Weymouth, Braintree, Quincy, Hingham, Marshfield, Plymouth, Scituate and the surrounding towns. The System provides an array of services including primary, specialty, and urgent care. Through SSH, an acute care hospital with 393 licensed beds, the System also provides emergency care and inpatient and outpatient services in the community. SSHS, including the Hospital, continues to expand its clinical services offerings through investments in physicians, employees, technology, locations, and services.

The Proposed Project seeks to expand access to MRI services for SSH's patient panel. To that end, the System proposes to acquire one 3T MRI unit to be located at the main campus of the Hospital. The 3T unit will be in addition to the Hospital's existing 1.5T unit at its main campus as well as two 1.5T units located at off-campus satellites. The Hospital's current MRI unit is operating at capacity with significant wait times. Moreover, the existing 1.5T unit is limited in the types of scans that can be performed at the Hospital. Through the Proposed Project, the Hospital will increase operating capacity as well as expand access to 3T MR imaging services.

SSHS anticipates that the Proposed Project will significantly reduce MR imaging wait times for inpatients and emergency room patients. The MRI unit will increase timely access to high-quality MR imaging services in the community. As a result, SSHS anticipates that patients will be more likely to seek and comply with treatment if they do not experience significant delays in diagnosis or referrals outside the System, contributing to improved health outcomes and quality of life.

Lastly, the Proposed Project will advance Massachusetts' goals for cost containment by providing patients with expanded MR imaging services within their community. Current demand for MR imaging at the Hospital has led to increased wait times, resulting in patient transfers to off-campus outpatient satellites of the Hospital and longer waits for MR imaging for inpatients, creating delays in diagnosis and treatment. By increasing capacity at the Hospital, patients will be scanned sooner and more efficiently. Therefore, the Proposed Project will contribute positively to the Commonwealth's goals of containing the rate of growth of total medical expenses ("TME") and total healthcare expenditures ("THCE").

As a result, the Proposed Project will provide patients of SSHS with expanded access high-quality MR imaging in their community. The expansion of MR imaging services will provide patients with additional types of MR imaging while also reducing wait times. Moreover, the addition of an MRI unit will not negatively impact the state's cost growth benchmark, and therefore will improve access to care, patient experience, and public health outcomes. Accordingly, the Proposed Project meets the factors of review for Determination of Need approval.

Factor 1: Applicant Patient Panel Need, Public Health Values and Operational Objectives

F1.a.i Patient Panel:

Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measure, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status and other priority populations relevant to the Applicant's existing patient panel and payer mix.

A. Overview of Patient Panel Selection

SSHS is a not-for-profit, regional health system compromised of an acute care hospital with multiple outpatient satellites, urgent care centers, and a physician group of more than 300 primary care doctors and specialists. As the largest independent health system in Southeastern Massachusetts, SSHS serves patients across Norfolk and Plymouth counties.

B. South Shore Health System Patient Panel

Overall Patient Panel

SSHS serves a large patient panel as demonstrated by the utilization data for the 36-month period covering Fiscal Years ("FY") 18-20.¹ The number of patients utilizing SSHS's services has increased since FY18, with 187,706 unique patients in FY18, 197,180 unique patients in FY19 and 197,808 unique patients in FY20. SSHS's patient mix consists of approximately 59% females and 41% males.

With respect to patient origin, SSHS patients mainly reside in Norfolk and Plymouth counties. More than 70% of the System's patients are from 17 communities. The following chart provides a further breakdown of the FY18-20 patient origination from each of the primary cities and towns comprising SSHS's service area.

Table 1: South Shore Health F	Patient Panel by City/Town
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City/Town	FY18	FY19	FY20
Weymouth	20,296	21,417	21,447
Hingham	11,770	12,162	12,323
Braintree	9,994	10,539	10,125
Marshfield	9,855	10,336	10,121
Plymouth	8,180	8,674	8,892
Rockland	8,064	8,426	8,430
Quincy	8,021	8,934	9,162
Scituate	7,903	8,192	8,093
Pembroke	7,824	8,119	8,036
Hanover	7,757	8,068	8,208
Duxbury	6,501	6,840	6,918

¹ Fiscal year October 1 – September 30.

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Norwell	6,032	6,315	6,338
Abington	5,633	5,806	5,938
Kingston	4,858	5,145	5,218
Hull	4,468	4,555	4,545
Whitman	4,171	4,391	4,379
Hanson	3,922	4,091	4,086

The majority of the System's patient panel is between the ages of 18-64 (58.3% in FY20). Ages 0-17 and 65+ are 18% and 23.6% respectively. Moreover, data indicates that from patients in the 18-64 age cohort increased 7% from FY18 to FY20. Based on this historical data, as well as preliminary data for FY21 and population projections provided by the University of Massachusetts Donahue Institute ("UMDI") which predict that the principal cities and towns where the majority of SSHS's patients reside will experience increases in their aging populations in coming years, the System anticipates that it will continue to see increased numbers of older adults requiring services in the coming years.²

SSHS also reviewed ethnicity data based on patient self-reporting. In FY20, 75.7% of the Applicant's patient panel identified as White; 3.4% identified as Black/African American; 2% identified as Asian/Pacific American; 14% identified as "Other"; and 4.7% chose not to report their ethnicity.

Lastly, SSSH's public payer mix included 44.5% of all patients. Commercial payers represented 48.1% of the System's patient panel and an additional 7.5% of patients used another source of payment. Preliminary data for FY20 shows similar trends.

Table 2: SSHS Patient Panel by Risk Contract

	FY18	FY19	FY20
ACO and Advanced Payment Model ("APM")	2.0%	2.8%	3.4%
Non-ACO and Non-APM	98%	97.2%	96.6%

Table 3: SSHS Patient Panel by Payer Mix

	FY18	FY19	FY20
Commercial PPO/Indemnity	14.8%	16.4%	16.8%
Commercial HMO/POS	36.1%	33.1%	31.3%
Mass Health	5.2%	3.7%	2.8%
Managed Medicaid	1.7%	1.2%	2.0%
Commercial Medicare	7.0%	8.0%	8.6%
Medicare FFS	30.3%	30.6%	31.1%
All Other	4.9%	7.0%	7.4%

² UMDI Population Projections - By 2035, 24% of the region's population will be over the age of 65, compared to 14% in 2010. Yet the Southeast will continue to attract young families, including many from the millennial generation, who will be moving into their forties by 2035.

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South Shore Health MRI Patient Panel

SSHS currently has three MRI units located at SSH and two outpatient satellites. The Proposed Project will increase access to high-quality MR imaging. Accordingly, in addition to reviewing the demographic and utilization data for the entire system, the System also conducted a focused review of its patient panel's historical MR imaging service demographic profile to determine the need for the Proposed Project.

For FY20, data indicates that most of the System's MRI patients are between the ages of 18-64 (55.7%), followed closely by patients 65+ (42.7%) and a small portion of patients between the ages of 0-18 (1.5%). Additionally, the patient mix consists of approximately 60.4% females and 39.6% males based on FY20 data.

Data indicates that the majority of SSHS's MRI patients originate from Norfolk and Plymouth counties. Specifically, in FY20, approximately 70% of MRI patients originated from the following 14 communities:

Table 4: South Shore Hospital MRI Patient Panel by City/Town

City	FY 2020
Weymouth	1192
Hingham	632
Braintree	606
Marshfield	589
Quincy	541
Rockland	462
Scituate	446
Pembroke	424
Hanover	409
Hull	335
Plymouth	318
Abington	302
Duxbury	275
Norwell	269

The data also demonstrates that SSHS's MRI patient population ethnicity composition is slightly different to the larger system-wide patient panel in terms of race. Race/ethnicity data collected in FY20 based on patient self-reporting demonstrates that 89% of the System's MRI patient population identified as While; 2.5% identified as Black/African American; 1.5% identified as Asian/Pacific Islander, 5.9% identified as "Other"; and 0.6% did not report.

F1.a.ii Need by Patient Panel:

Provide supporting data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question F1.a.i that demonstrates the need that the Proposed Project is attempting to address. If an inequity or disparity is not identified as relating to the Proposed Project, provide information justifying the need. In your description of Need, consider the principles underlying Public Health Value (see instructions) and ensure that Need is addressed in that context as well.

Through the Proposed Project, SSHS seeks to meet the existing and future needs of its patient panel by expanding access to high-quality MR imaging services. After evaluating SSHS's historical utilization, wait times, and impact on inpatients and patient transfers, it determined that an additional MRI unit is needed to address constraints on the existing capacity and meet future demand for MRI. The addition of a 3T MRI unit will address these capacity issues and meet demand by decreasing patient wait times, reducing the number of patients transferred to outpatient satellites, and providing access to additional types of MR imaging services at the Hospital.

A. Need for Additional Capacity

As discussed previously, SSHS is a comprehensive regional health system providing health care and wellness services across the care continuum. Providing all aspects of patient care allows SSHS to maximize clinical integration, operate efficiently, and deliver high-quality care. Through the Hospital, SSHS currently has three 1.5T MRI units, but demand has created significant wait times and inefficiencies for all MRI services. Accordingly, the addition of a 3T MRI unit is needed to meet current demand for high-quality MR imaging services by the patient panel.

Historic Utilization

SSHS has three 1.5T MRI units licensed to the Hospital. The units are located at the Hospital's main campus and two outpatient satellites: The Cancer Center and South Shore Orthopedics. The Hospital's historical MRI scan volume for each unit is detailed in the following chart.

	FY2018	FY2019	FY2020
South Shore Hospital Main Campus	7,497	7,471	6,497
Cancer Center	4,019	4,386	4,285
South Shore Orthopedics	3,716	3,697	3,315
Total	15,232	12,554	14,097

Table 5: South Shore Health MRI Scans by Location

The Hospital offers MR imaging to emergency room patients as well as inpatients and outpatients at the main campus. As illustrated in the table below, almost half of the scans performed at the Hospital's main campus were for outpatients.

Table 6: South Shore Health MRI Scans by Patient Status

	FY2018	FY2019	FY2020
Inpatient Scans	4,164	4,181	3,839
Outpatient Scans	11,068	11,373	10,258
Total	15,232	12,554	14,097

During the COVID-19 pandemic, MRI scans declined slightly in FY20 as a result of overall decreased health care utilization. However, wait times for MR imaging services have remained high. The current demand for MR imaging services at SSH has created significant wait times for emergency room patients, inpatients, and outpatients. For FY2020, the average wait time for an inpatient at SSH was 24 hours and 13 hours for emergency patients. For emergency room and inpatients, a significant delay to obtaining imaging often increases the length of the patient's stay which can lead to higher costs. In addition to delays, some patients are not eligible to be scanned using the current MRI unit at the Hospital and must be transported via ambulance to one of SSH's outpatient facilities or referred outside SSH. With the addition of a 3T MRI unit, fewer patients will need to be transferred for MRI or admitted longer, thereby further reducing the Hospital's costs.

Furthermore, approximately 190 patients were transported from SSH to SSH's outpatient MRI facilities for several reasons. First, some patients are not eligible for the current unit due to the unit's weight limit. Additionally, the current unit is over 18 years old and requires significant maintenance during which time it is taken out of service. Patients who are not able to be scanned at the Hospital's main campus must be transferred from the Hospital to an outpatient satellite via the Hospital-owned ambulance. This process is both costly and creates increased risks of complications for complex or high acuity patients. Moreover, patients transferred from the Hospital for MR imaging at an outpatient satellite must take an imaging appointment from a scheduled outpatient, disrupting the outpatient facility's scheduling. Accordingly, transporting patients from the main campus negatively impacts patient care and satisfaction, and adds to the costs of care.

Lastly, SSHS notes that the Hospital only has 1.5T MRI units and does not have a 3T MRI unit. With respect to clinical capabilities, as discussed in greater detail in Factor F1.b.ii., 3T MRI are increasingly indicated for diagnosis of certain conditions and diseases, such as prostate cancer, premature birth neonates, and brain and neck injuries. Because SSH does not offer 3T MRI, SSH patients whose condition is clinically indicated for 3T MRI may be referred outside SSHS for their imaging needs, often delaying their care and impacting care coordination. Accordingly, a 3T MRI is needed to provide increased access to high-quality MR imaging to SSHS's patient panel.

Projected Growth and Future Needs

The Proposed Project is needed to address and alleviate current capacity constraints impacting access to timely MR imaging services. However, SSHS also anticipates that MRI volume will return to pre-pandemic levels and steadily increase in the future. The University of Massachusetts Donahue Institute ("UMDI") projects that the 65+ age cohort will increase to 24% of the population in Southeastern Massachusetts by 2035, up from 14% in 2010.3 Additionally, UMDI expects

³ UNIVERSITY OF MASSACHUSETTS DONAHUE INSTITUTE, Long-term Population Projections for Massachusetts Regions and Municipalities available at http://pep.donahue-institute.org/UMDI Long Term Population Projections Report 2013.11.pdf (last accessed Apr. 12, 2021).

modest growth amongst Millennials⁴ who will be entering their forties in 2030.⁵ Lastly, SSH will experience some increased volume from MRI scans that are currently transferred outside SSHS because the type of MR imaging is recommended to be performed using a 3T MRI. In 2020, approximately 975 patients were referred outside of SSHS for MR imaging of the prostate.

The following chart details the number of MR imaging scans that are projected to be performed using the proposed 3T MRI unit. These projections are based on historical demand with modest growth over time.

Year 1 Year 2 Year 3 Year 4 Year 5 SSH 3T MRI 6,720 6,854 6,991 7,131 7,273 SSH 1.5T MRI 6,295 6,421 6,549 6,680 6,814 Total 13,275 13,015 13,640 13,811 14,087

Table 7: Projected MRI Scans at Main Campus

As a result of the Proposed Project, SSH patients will have greater access to high-quality, convenient, and coordinated MR imaging in their community. The additional unit will reduce wait times and patient transfers and increase access to additional types of MR imaging. Moreover, SSH will be able to meet future demand for MR imaging as demand by its patient population is expected to grow in the coming years.

F1.a.iii Competition:

Provide evidence that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending. When responding to this question, please consider Factor 4, Financial Feasibility and Reasonableness of Costs.

The Applicant's Proposed Project will compete on the basis of price, total medical expenses ("TME"), provider costs and other recognized measures of health care spending by increasing MR imaging capacity and capabilities at SSH in order to meet current and projected demand at the Hospital. The primary objective of the Proposed Project is to expand the services offered at SSH, as well as address the current demand of MR imaging services for emergency department patients and inpatients. SSH's existing MRI unit is operating at capacity with wait times up to 24 hours for inpatients. Significant wait times for imaging services needed for diagnosis or treatment may delay discharge, extending the length of inpatient admissions. Additionally, if the existing MRI unit is off-line for repairs, or other barriers to care exist, Hospital patients may be transferred to an off-campus location to receive imaging services. In that situation, patients are transported by the Hospital-owned ambulance. This practice creates additional resource constraints on Hospital personnel and the EMS, leading to increased costs.

With respect to provider and service costs, MRI services are not reimbursed depending on the machine type. Accordingly, reimbursement rates will not change as a result of the Proposed Project. However, as discussed above, SSHS anticipates operating costs will not increase

⁴ Defined as individuals ages 23-38 in 2019 by the Pew Research Center.

⁵ UMDI, *Supra* note 5.

through the Proposed Project by reducing service delays, decreasing admission length of stays, and minimizing the need to transfer and/or transport patients from the main building.

F1.b.i Public Health Value / Evidence-Based:

Provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need that Applicant has identified.

A. MRI as an Imaging Modality

MRI is a well-established, non-invasive imaging modality used to visualize internal, anatomical structures. 6 At a high level, detailed images of organs, tissues and joints are produced through the use of magnetic fields and pulses of radio waves which measure how protons in the body realign following the disruption caused by the radiofrequency current. In order to capture the image, patients are placed in the center of the scanner, which allows the magnetic field to be activated around the patient. The end result is an anatomical image of the patient, without the use of ionizing radiation, making it a safer alternative to similar imaging technologies.8

B. Use of 3T MRI

As discussed above, MRI technology requires the use of a magnetic field to produce internal images. MRI machines vary in magnetic field strength which are measured in Tesla ("T").9 Most MRI machines used for diagnosis and treatment have a magnetic field strength of 1.5T or 3T.10 A stronger magnet creates a higher "signal-to-noise" ratio which in turn is responsible for improved image quality. Therefore, the use of a stronger magnet produces images in a higher resolution, allowing physicians to see anatomical features in greater detail. 11 This is particularly beneficial for imaging involving the brain, spine, and musculoskeletal system. 12 Additionally, higher strength MRI machines require less scanning time to produce higher quality images. ¹³ This creates a better experience for patients and also allows more patients to be scanned during the same period of time. 14

⁶ Magnetic Resonance Imaging, WHO,

https://www.who.int/diagnostic imaging/imaging modalities/dim magresimaging/en/ (last accessed Feb. 19, 2021).

Magnetic Resonance Imaging (MRI), NAT'L INST. OF BIOMEDICAL IMAGING & BIOENGINEERING, https://www.nibib.nih.gov/science-education/science-topics/magnetic-resonance-imaging-mri (last visited Feb 19,

⁸ Benefits and Risks, US FOOD & DRUG ADMIN., https://www.fda.gov/radiation-emitting-products/mri-magneticresonance-imaging/benefits-and-risks (last revised Dec. 9, 2017).

⁹ What does tesla mean for an MRI and its magnet? GE HEALTHCARE, https://www.gehealthcare.com/featurearticle/w hat-does-tesla-mean-for-an-mri-and-its-magnet (Feb. 27, 2019).

10 What does tesla mean for an MRI and its magnet? Supra note 11.

¹¹ Keith Loria, Technology Trends: MRI Time to Upgrade? — Considerations for the Move From 1.5T to 3T 17 RADIOLOGY TODAY 16 (2016), available at https://www.radiologytoday.net/archive/rt0216p22.shtml

¹² Why the 3 Tesla MRI is the Best Scanner for Diagnostic Imaging, RAD. AFFILIATES MAG., https://4rai.com/blog/whythe-3-tesla-mri-is-the-best-scanner-for-diagnostic-imaging (Sept. 12, 2016).

¹³ Loria, *Supra* note 13.

¹⁴ Why the 3 Tesla MRI is the Best Scanner for Diagnostic Imaging, Supra note 14.

Neonates and Pediatric Patients

The improved imaging capabilities of a 3T machine are particularly valuable in pediatric patients. MRI is recognized as a valuable tool for detecting brain damage in premature infants. ¹⁵ However, the process of imaging premature infants is complicated by time spent outside of the Neonatal Intensive Care Unit ("NICU"). ¹⁶ Given that high-resolution images are obtainable in a shorter amount of time using a 3T MRI unit, this equates to a safer imaging process for NICU patients. ¹⁷ Additionally, the shorter scanning time is useful for young patients who may not be able to stay still for long periods of time. ¹⁸ Reducing the length of time needed for the MRI is critical for improving patient outcomes of SSH's youngest patients. ¹⁹

Brain and Musculoskeletal Imaging

Similarly, MRI is the preferred imaging modality for adult patients with respect to brain and musculoskeletal imaging and is used to help diagnose pathological conditions involving the brain, spine, and musculoskeletal system. ²⁰ As previously discussed, the higher signal-to-noise ratio of 3T MRI produces superior image quality which in turn offers greater anatomical and functional detail of the shape, size, and integrity of gray and white bran matter and structures. ²¹ Specifically, MRI is often used in initial brain tumor evaluation to locate the lesion in order to establish a treatment or biopsy plan; evaluate mass effect on the brain, ventricular system, and vasculature; and suggest a possible diagnosis. ²² In addition to its clinical application for conditions affecting the brain, MRI also provides superior clinical utility for spinal and musculoskeletal conditions due to its ability to noninvasively display high definition images of tissue contrast. This allows MRI to detect failure of the soft tissue as well as quantify physical and physiological attributes of soft tissue as in the case of diagnosing neuromuscular disease. ²³ For both brain and musculoskeletal conditions, 3T MRI scans produce greater image detail, which in turn allow radiologists to identify smaller lesions and anatomical structures that are not represented as clearly using less powerful machines, such as a 1.5T MRI. ²⁴

¹⁵ Ivan L. Hand, Renée A. Shellhaas, Sarah S. Milla and Committee on Fetus and Newborn, Section on Neurology, Section on Radiology, *Routine Neuroimaging of the Preterm Brain*, AM. ACAD. OF PED. (2020), available at https://doi.org/10.1542/peds.2020-029082 (last accessed Mar. 23, 2021).

¹⁶ Mathur, A., Neil, J., McKinstry, R., & Inder, T. (2007). *Transport, monitoring, and successful brain MR imaging in unsedated neonates*. PEDIATRIC RADIOLOGY, 38(3), 260-264. https://link.springer.com/article/10.1007/s00247-007-0705-9

¹⁷ Loria, supra note 13.

¹⁸ Govind B. Chavhan, Paul S. Babyn, Manoj Singh, Logi Vidarsson, Manohar Shroff, *MR Imaging at 3.0 T in Children: Technical Differences, Safety Issues, and Initial Experience*, Vol. 29, No. 5 (2009), *available at* https://pubs.rsna.org/doi/full/10.1148/rg.295095041 (last accessed Feb. 19, 2019).

¹⁹ Mathur et al, *supra* note 18.

²⁰ Marc C. Mabray et al., *Modern Brain Tumor Imaging*, 3 BRAIN TUMOR RESEARCH & TREATMENT 8 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4426283/.

²¹ M. Symms et al., *A review of structural magnetic resonance neuroimaging*, 75 J. NEUROLOGY, NEUROSURGERY & PSYCHIATRY 1235 (2004), *available at* http://jnnp.bmj.com/content/jnnp/75/9/1235.full.pdf; *What is fMRI?*, UC SAN DIEGO CTR. FOR FUNCTIONAL MRI, http://fmri.ucsd.edu/Research/w hatisfmri.html (last visited Jun. 24, 2019) ²² Mabray et al., *supra* note 22.

²³ Symms et al., supra note 23; What is fMRI?, supra note 23.

²⁴ Law rence N. Tanenbaum, *3T MRI in clinical practice*, 34 APPLIED RADIOLOGY 8 (2005), *available at* https://appliedradiology.com/articles/3t-mri-in-clinical-practice.

Oncology

MRI is an important tool in cancer diagnosis, staging, and treatment planning.²⁵ In particular, MRI with contrast dye is often the best way to see brain and spinal cord tumors.²⁶ Moreover, the stronger magnetic field of a 3T unit creates more detailed images that can show the difference between normal and abnormal tissue making it the preferred imaging modality for the prostate and breast.²⁷

Prostate cancer is the second most commonly diagnosed cancer in American men. ²⁸ The current standard of care following an abnormally high prostate-specific antigen (PSA) level is a biopsy guided by a transrectal ultrasound ("TRUS"). ²⁹ However, TRUS-guided biopsies are limited and cannot determine which tumors need to be treated and which do not. ³⁰ Recent advances in MRI now allow for targeted biopsy sampling, increasing the efficiency and accuracy of prostate cancer diagnoses. ³¹ The increased strength of 3T units has further improved visualization of the prostate. ³² This may improve local staging and localization accuracy in prostate cancer patients, which in turn is likely to reduce unnecessary treatment and improve not only patient outcomes, but also quality of life. ³³

MRI is also commonly used for imaging breast tissue and is recommended to screen most individuals at high risk for breast cancer.³⁴ Once breast cancer is diagnosed, MRI also frequently used for surgical planning and treatment monitoring.³⁵ Improvements in spatial and temporal resolution, as well as the greater spectral separation of fat and water enables superior fat suppression, further aiding in the visualization of enhancing lesions.³⁶ These studies suggest that 3T MRI is more accurate for pre-operative assessment of breast cancer extent, and therefore, 3T scans are a valuable guide to surgical planning and improving treatment outcomes.³⁷

²⁵ MRI for Cancer, AM. CANCER SOC'Y, https://www.cancer.org/treatment/understanding-your-diagnosis/tests/mri-for-cancer.html (last revised May 16, 2019).

²⁷ Jeannette Sabatini, *MRI's Role In Active Surveillance: 3T MRI Offers a Better Portrait of Prostate Cancer* — *and Its Risk to Men,* 16 RADIOLOGY TODAY 12, available at https://www.radiologytoday.net/archive/rt1215p12.shtml, *Accuracy of 3T versus 1.5T breast MRI for pre-operative assessment of extent of disease in newly diagnosed DCIS, Eur J Radiol.* 84(4): 611–616. (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4348176/.

Key Statistics for Prostate Cancer, Am. CANCER SOC'Y https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html (last revised Jan. 21, 2021)
 MRI and Prostate Cancer, COLUMBIA RADIOL., https://www.columbiaradiology.org/news/mri-and-prostate-cancer

²⁹ MRI and Prostate Cancer, COLUMBIA RADIOL., https://www.columbiaradiology.org/news/mri-and-prostate-cancer (last revised Sept. 9, 2019).

³⁰ Id

³¹ Sabatini, *supra* note 29.

³² Sabatini, supra note 29.

³³ Sabatini. *supra* note 29.

³⁴ Breast Cancer, AM. CANCER SOC'Y, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/breast-mri-scans.html (last revised Oct. 3, 2019); Rebecca Rakow-Penner, MS, Brian Hargreaves, PhD, Gary Glover, PhD, and Bruce Daniel, MD, Breast MRI at 3T APPLIED RADIOLOGY (2009), available at https://appliedradiology.com/articles/breast-mri-at-

³t?utm_source=TrendMD&utm_medium=cpc&utm_campaign=Applied_Radiology__TrendMD_0 (last accessed Feb. 19, 2021).

³⁵ Rakow -Penner et al., *supra* note 36.

³⁶ Rakow -Penner et al., *supra* note 36.

³⁷ Rakow -Penner et al., *supra* note 36.

F1.b.ii Public Health Value/Outcome-Oriented:

Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.

A. Expansion of Imaging Services at the Hospital

Through the Proposed Project, SSHS seeks to improve patient experience and health outcomes, and enhance quality of life for SSH patients by increasing access to high-quality MRI services. Wait times for MRI services for emergency room and admitted patients are on average 13 hours and 24 hours, respectively. Delayed access to imaging services, especially in the emergency department and inpatient setting, can lead to delayed diagnosis and treatment. Furthermore, significant delays in access to MRI for admitted patients may cause their length of stay to be extended if imaging is required prior to discharge. Alonger admission will often result in increased costs and may also negatively affect patient satisfaction and well-being. Similarly, patient satisfaction may reflect other barriers to receiving imaging services such as being transported outside the Hospital for MR imaging. The addition of a 3T MRI unit at the Hospital's main campus will allow SSHS to increase timely access to high-quality imaging services in the community, which also will improve health outcomes, patient satisfaction, and quality of life for its patients.

B. Assessing the Impact of the Proposed Project

SSH will use the following quality measures and projections to assess the impact of the Proposed Project. Along with quality indicators to measure patient satisfaction, these measures will allow SSHS to assess access and quality of care. The selected measures are discussed below:

1. Patient Experience/Satisfaction: Patients that are satisfied with care are more likely to seek additional treatment when necessary. SSH staff will review overall ratings of care with imaging services via a Press Ganey survey.

Measure: Overall rating of care using response options: Very poor, poor, fair, good, very good

Projections: SSHS will provide baseline measures and three years of projections following one full year of operation from the date of implementation of the Proposed Project.

Monitoring: Results will be benchmarked and reviewed quarterly by the Radiology Department.

2. Access - Wait Times: The Proposed Project seeks to ensure timely access to MRI services. SSH will track the time interval (in hours) from when the case was initiated for scheduling to appointment. This information will be obtained via the electronic medical record system, Epic.

Measure: Time interval (in hours) from when the case was initiated for scheduling to appointment.

Monitoring: Results will be benchmarked and reviewed quarterly by the Radiology Department.

Projections - Admitted patients: Baseline: 24 hours

Year 1: 14 hours Year 2: 12 hours Year 3: 8 hours

Projections – Emergency and Observation: Baseline: 13 hours

Year 1: 8 hours Year 2: 6 hours Year 3: 6 hours

3. Quality of Care - Reporting of Critical Value Results: SSH uses PowerScribe within EPIC to document radiology findings, including any follow-up actions required as a result of Critical or Significant findings. All Radiologists are expected to document Critical or Significant findings within the "Follow Up" tab in PowerScribe. Once an acuity of Critical or Significant is entered into the patient's medical record, a 72-hour timer is triggered for administrative staff to notify the patient's care team. If follow-up is not completed within 72-hours, an escalation alert is sent out to a specific pool of administrative imaging staff.

Measure: Number of radiologists conducting critical value reporting on cases being interpreted.

Projections: Baseline: 100%

Year 1: 100% Year 2: 100% Year 3: 100%

Monitoring: MRI scans will be forwarded to the patient's care team in order to complete follow-up as required. The radiologist will be available to answer any questions.

4. Quality of Care - Quality of MRI Scan: The quality of an MRI scan is imperative to its interpretation. Accordingly, the System will evaluate the number of scans that need to be repeated within a 48-hour period from the date of the original scan to ensure radiology technicians are performing appropriate scans.

Measure: The number of repeat MRI scans performed on patients within a 48-hour period from the date of the original scan.

Projections: Baseline: 5/month

Year 1: 4/month (20% improvement)

Year 2: 3/month (40% improvement)

Year 3: 2/month (60% improvement)

Monitoring: MRI technologists will track the number of scans that are repeated and scheduled for the next scan day. Technologists will document each case and conduct a monthly comparison to total volume to meet or exceed the metric.

F1.b.iii Public Health Value / Health Equity-Focused:

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need-base, please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g. culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

A. Nondiscrimination

In furtherance of health equity across all populations, especially those most at risk, SSHS will continue to serve uninsured, underinsured, and Medicaid-eligible individuals. The System does not discriminate on the ability to pay or payer source and will apply this policy to all services provided through the Proposed Project. Moreover, the Hospital has been deemed a Certified Application Counselor Organization. Through the certification, the Hospital trains personnel on the eligibility and benefit rules and regulations in order to certify individuals as Certified Application Counselors. These individuals are able to assist patients with enrollment in MassHealth, premium assistance payment programs offered by the Health Connector (including ConnectorCare), Health Safety Net, the Children's Medical Security Program, Medical Hardship and SSH's Financial Assistance Program. As highlighted throughout this narrative, the Proposed Project will improve access to high-quality MRI services for patients of SSH and the System.

B. Providing Culturally Competent Care and Language Accessibility

SSHS is committed to providing culturally competent care to the community. All clinical and non-clinical staff are provided with cultural and linguistic education upon hire and annually thereafter. Additionally, SSH provides extensive linguistic and cultural support to its patients, including those receiving imaging services. To help bridge linguistic and cultural gaps, SSH provides professional medical interpreters through face-to-face, telephonic, and video conference modalities. All written materials, including signs, brochure, and forms are professionally translated. Bilingual providers are required to go through proficiency testing. Interpreter services also provide services for deaf and hard of hearing patients, including American Sign Language translators and Certified Deaf Interpreters.

C. Social Determinants of Health Screening

South Shore Health System

SSHS has implemented several population health initiatives to further promote health equity. One such initiative is conducting a Social Determinant of Health ("SDoH") screening for Medicaid ACO patients. The System has adopted the THRIVE screener to facilitate conversations with patients and document areas of need. Using the tool, patients are asked about their living situation, access to food and ability to pay, transportation, and education. All responses are documented within the System's electronic medical records system, Epic, so that information is available to the patient's entire care team within the system. Additionally, SDoH screenings are documented through flowsheets in Epic by nurses, case managers and social workers using information collected by nursing, medical assistants, case managers and social workers.

If a patient screens positive for a SDoH, a referral can be initiated within Epic notifying the Population Health Team. Referrals can also be made directly to Case Management and Social Work. Through the THRIVE assessment, providers have immediate access to a listing of community resources they can discuss with the patient. Additionally, a print-out can be generated for the patient to take home with them.

Further, the Community Resources Directory can be accessed through the System's webpage. The Directory is maintained by Aunt Bertha, Inc. and allows patients and the community to privately browse a variety of programs based on location and eligibility. Individuals can search for local organizations such as food pantries, home healthcare agencies, substance abuse treatment, and legal assistance. ³⁸ This program is intended to serve the Greater South Shore community as well as SSHS patients who might need services in between appointments or who do not feel comfortable discussing their needs with their primary care provider ("PCP"). The System also hopes the directory may prompt more patients to reach out to their PCP to discuss referall services.

F1.b.iv Provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

Health outcomes and quality indicators for the Applicant's patient panel will be improved through the Proposed Project as patients will have increased access to high-quality, timely MRI services. Offering 3T MR imaging services at the Hospital will create additional MR imaging capacity, reducing service delays, as well as allowing patients to stay within the System for certain specialty imaging. The additional MRI unit also will limit the number of patients who must be transferred to an outpatient location of the Hospital, which causes delays for outpatients to be scanned, adding to the System's current capacity constraints. Increasing MR imaging capacity at the Hospital will provide patients with an improved care experience, as well as quality outcomes while assuring health equity.

F1.c Provide evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, how the Proposed Project will create or ensure appropriate linkages to patients' primary care services.

The Proposed Project will promote continuity of care, improved health outcomes, and enhanced quality of life through the use of case management that has been established throughout the SSHS network. First, SSH staff will continue to follow processes currently in place at the Hospital for linking imaging patients with case management/social work support to ensure patients have access to resources around SDoH issues. When negative SDoH are identified, SSH providers will engage SSH social workers who will collaborate with Applicant providers and with programs in the community. Facilitating provider and community linkages for the Applicant's patient panel is a crucial for furthering care management and health outcomes.

Furthermore, imaging patients at SSH will benefit from integrated medical records. Through the Proposed Project, patients will be able to receive all of their imaging services within the System,

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³⁸ https://www.southshorehealth.org/patient-resources/community-resource-directory

ensuring care continuity through the shared medical records system. An integrated health information system has been shown to impact health outcomes because of the ability to better manage care coordination through the use of a single system. This is true of the system used by SSHS, which not only enables imaging results to be available to primary care and specialty physicians across the System, but also includes capabilities that facilitate clinical decision support, peer review, and monitoring. As a result, the use of an integrated EMR ensures that SSHS's patients will benefit from appropriate care coordination, better outcomes, and improved quality of life.

F1.d Provide evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

The following individuals are some of those consulted regarding this Project:

- Rebecca Rodman, Esq., Deputy General Counsel, Department of Public Health
- Lara Szent-Gyorgyi, Director, Determination of Need Program, Department of Public Health
- Ben Wood, Director, Office of Community Health Planning and Engagement, Department of Public Health
- Jennica Allen, Office of Community Health Planning and Engagement, Department of Public Health
- Christopher King, MassHealth
- Capt. Hyosim Seon-Spada, The Centers for Medicare & Medicare
- Steven Sauter, MassHealth
- Zhao Zhang, MassHealth

F1.e.i Process for Determining Need/Evidence of Community Engagement: For assistance in responding to this portion of the Application, Applicant is encouraged to review Community Engagement Standards for Community Health Planning Guideline. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the

Proposed Project.

Through ongoing community engagement, SSHS identified the need to increase access to MRI for its patients. Additionally, the Hospitals' historical utilization data for these services demonstrates ongoing demand for MR imaging services at the hospital. SSHS engaged the community in order to more fully involve patients and families regarding the Proposed Project.

A. Patient and Family Advisory Committee

The Proposed Project was presented at the Hospital's Patient Family Advisory Committee ("PFAC") on June 25, 2020 with twenty (20) members in attendance, including twelve (12) Hospital staff and eight (8) community members. The PFAC's mission is "to create positive changes in our healthcare system by supporting an environment where patients and family members feel safe, respected, and empowered to be partners in their care." The PFAC is comprised of patients, family members, committed volunteers, and Hospital staff. The role of

PFAC is to bring the voice of patients and families to SSH's decision-making by creating a structured forum and process for SSH to learn from patients, families, and community members.

Through the presentation, the Hospital focused on the challenges of having a single MRI unit at the Hospital's main campus and sought to inform PFAC members about the purpose of the Proposed Project and what it would mean for patients. Members were presented with an overview of the Proposed Project and its associated benefits. Feedback from the PFAC was favorable and encouraged the Hospital to move forward with its plan to expand imaging services.

B. Public Meeting

Additionally, the Hospital engaged residents and resident groups through a community forum. This meeting was held on March 18, 2021 using remote technology. The meeting was attended by 15 people, including thirteen (13) Hospital staff and two (2) community members. Hospital leadership presented an overview of the Proposed Project and the benefits of expanding imaging services at the Hospital.

F1.e.ii

Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. Asuccessful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value".

To ensure sound community engagement throughout the development of the Proposed Project, SSHS took the following actions:

- Presentation to SSH's PFAC on June 25, 2020; and
- Community Forum for community members on March 18, 2021.

For detailed information on these activities, see Attachment 3.

Factor 2: Health Priorities

Addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

F2.a. <u>Cost Containment:</u>

Using objective data, please describe, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment.

In furtherance of the Commonwealth's goals for cost containment, the Proposed Project seeks to expand services at SSH without a net increase in TME. As previously discussed, the Proposed

Project is for the acquisition of a 3T MRI unit. This unit will be in addition to the existing 1.5T MRI unit on the Hospital's main campus. Adding a second unit with additional imaging capabilities will allow SSH to expand access to MR imaging services, which in turn will reduce overall wait times, the length of inpatient admissions, and patient transfers to MRI units off campus. Furthermore, MRI services are not reimbursed differently depending on machine strength so payors and patients will not be charged more for imaging services with the new machine.

Given the current demand for imaging services at SSH, there are significant wait times for emergency room patients, inpatients, and outpatients. For emergency room and admitted patients, a significant delay for imaging often increases the length of the patient's stay resulting in higher costs. In addition to delays, some patients are not eligible to be scanned using the current MRI unit. Those patients must be transported via ambulance to a SSH outpatient satellite. The cost for transport is not passed on to patients or payors, resulting in an increased operating cost to SSH. With the addition of a 3T MRI unit, fewer patients will need to be transferred to a SSH outpatient facility for MRI, thereby further reducing Hospital costs.

F2.b. <u>Public Health Outcomes:</u>

Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

Expanding MRI services at SSH to improve public health outcomes is supported first by historical imaging service volume which points to high utilization rates, and second by population projections suggesting that the demand for imaging services will grow as the Hospital's patient panel ages.³⁹ Specifically, an aging population will have an increased need for high-quality imaging services to diagnose and treat age-related conditions.

In order to adequately address current and projected demand for MR imaging services in the community, additional capacity and capability is required. Through the Proposed Project, SSHS seeks to not only increase the number of imaging appointments available, but also increase the type of MR imaging services available, such as those needed for NICU patients and certain cancers, like prostate and breast cancer. Both of these objectives will help to keep patients within the South Shore Health System, which is necessary for optimizing care coordination. Therefore, public health outcomes will be improved by providing SSHS patients timely access to high-quality 3T MRI services in the community as a result of shorter wait times for services within the Hospital, as well as 3T images for certain conditions allowing for improved diagnosis and treatment options.

F2.c. Delivery System Transformation:

Because the integration of social services and community-based expertise is central to goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

Following implementation of the Proposed Project, the System will continue to engage with patients in order to connect them with resources and social services as needed. First, patients are screened for potential communication barriers so that interpreter services can

³⁹ UMDI Population Projections - By 2035, 24% of the region's population will be over the age of 65, compared to 14% in 2010. Yet the Southeast will continue to attract young families, including many from the millennial generation, who will be moving into their forties by 2035.

be provided. Additionally, patients are screened for potential psycho-social factors that are known to impact well-being. SSHS has implemented the THRIVE screener to assess ACO patients for SDoH. Using the tool, patients are screened for housing status/stability, food security, transportation, employment, education and financial security. All responses are documented within Epic, SSHSs EMR, so that information is available to the patient's entire care team. Additionally, SDoH screenings are documented through flowsheets in Epic by nurses, case managers and social workers using information collected by nursing, medical assistants, case managers and social workers.

If a patient screens positive for a SDoH, a referral is initiated within Epic notifying the SSHS's Population Health Team. Referrals also can be made directly to Case Management and Social Work. Through the THRIVE assessment, providers have immediate access to a listing of community resources they can discuss with the patient. Additionally, a print-out can be generated for the patient to take home with them.

Further, the Community Resources Directory can be accessed through the SSHS's webpage. The Directory is maintained by Aunt Bertha, Inc. and allows patients and the community to privately browse a variety of programs based on location and eligibility. Individuals can search for local organizations such as food pantries, home healthcare agencies, substance abuse treatment, and legal assistance. ⁴⁰ This program is intended to serve the Greater South Shore community as well as SSHS patients who may need services in between appointments or who do not feel comfortable discussing their needs with their Primary Care Provider ("PCP"). SSHS also hopes the directory may prompt more patients to reach out to their PCP to discuss referall services.

Factor 5: Relative Merit

F5.a.i

Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

Proposal: The Proposed Project is for the acquisition of one 3T MRI unit.

Quality: The Proposed Project will increase the capacity of MRI services at SSH, thereby improving access by addressing demand by its patient panel. As a result, patients will experience decreased wait times and will be less likely to be transferred to another facility for imaging.

Efficiency: The Proposed Project will improve efficiency by reducing inpatient wait times for MRI. Reducing wait times will in turn provide more timely access to necessary diagnostic information, improving treatments, and will decrease length of stay for patients who remain inpatient while waiting for MRI.

⁴⁰ https://www.southshorehealth.org/patient-resources/community-resource-directory

Capital Expense: The Proposed Project will result in a one-time capital expense to purchase an additional MRI. The Maximum Capital Expenditure for the project is \$2,387,481.00.

Operating Costs: The operating expenses for Year 1 of the Proposed Project, the first full year of operation of the 3T MRI, are expected to be \$887,682.00.

List alternative options for the Proposed Project:

Option 1

Alternative Proposal: An alternative option considered was the acquisition of a mobile MRI unit.

Alternative Quality: Although image quality and capability of mobile trailers is similar to that of fixed MRI scanners, patient experience would not be equivalent due to the distance that would be required to transport the patient from the ER or their room to the MRI trailer. Additionally, the potential location of the mobile trailer would create access issues for the Hospital's Code Team in the event of an emergency. Lastly, the space available in a mobile MRI trailer is very limited as compared to an MRI scan room. This smaller area limits the amount of supplies, such as a code cart, and patient comfort items such as blanket warmers and positioning aids.

Alternative Efficiency: This option would result in decreased efficiency as the Hospital would need additional staff to operate two separate MRI areas.

Alternative Capital Expenses: This alternative considered by SSH resulted in capital expenses of approximately \$2,420,000.00.

Alternative Operating Costs: The operating cost of a mobile unit are similar to those of a fixed MRI suite if the unit can be installed directly adjacent to the main facility. If the unit cannot be directly adjacent, additional operating costs would be needed to purchase additional emergency medical service transport vehicles and hire associated staff.

Option 2

Alternative Proposal: SSH also considered not acquiring an additional MRI unit.

Alternative Quality: Quality of care and access would be further reduced under this alternative. As discussed in Factor 1, Hospital inpatients are currently experiencing wait times of up to 24 hours which often causes a delayed discharge. Alternatively, inpatients who require immediate imaging may bump a scheduled outpatient. These wait times and delays will continue to be exacerbated as the demand for quality imaging services increases with patient volumes. Additionally, the hospital would continue to refer certain patients outside the system due to lack of a 3T MRI unit.

Alternative Efficiency: SSH investigated the effects on efficiency if the facility were to continue with one on-campus MRI unit. Continuing with one MRI unit will continue to degrade the efficiency of patient flow for admitted and emergent trauma patients with MRI orders. Admitted patients currently experience delays exceeding 24 hours from time of MRI exam order to MRI exam completion. The overflow of inpatients is often transferred

to an outpatient imaging satellite which requires rescheduling outpatients. Rescheduling patients requires additional resources, increasing cost and deceasing efficiency.

Alternative Capital Expenses: There is no capital expense for this alternative.

Alternative Operating Costs: Operating costs under this alternative would increase over time as SSH will continue to transport admitted and emergency department patients to its satellites to accommodate projected patient volume. The transport of these patients would overwhelm the ability of the Hospital's emergency medical services to transport patients, requiring SSH to purchase additional transport vehicles, such as ambulances and wheelchair transport vans. Moreover, acutely ill and unstable patients would experience longer admissions until they could be transported for imaging, resulting in increased costs of care to the patient and hospital.