SIEM DON Narrative

2. Project Description

Background:

Shields Imaging of Eastern Massachusetts, LLC ("SIEM") (“Applicant"), seeks Determination of Need ("DON") approval for the addition of five (5) days of mobile positron emission tomography ("PET/CT") services at South Shore Hospital, 55 Fogg Road, South Weymouth, MA 02190 and for the acquisition of a mobile PET/CT unit to serve that location. The Applicant is a joint venture between South Shore Health and Shields Health that operates a Department of Public Health licensed clinic at South Shore Hospital for the provision of PET/CT services.

South Shore Health is an independent, not-for-profit, regional health system, based in Weymouth, Massachusetts, offering high-value, high-quality primary, secondary and tertiary care as well as specialty care, home health, community care, emergency, urgent care and preventive and wellness services. South Shore Health is committed to providing all patients with equitable access to quality care regardless of race, ethnicity, preferred language, disability, gender identity or sexual orientation.

Shields Health was founded in 1972 in Brockton, Massachusetts. Dedication to high quality and advanced care in a local setting quickly became a signature attribute of the Shields business model. Shields Health introduced Massachusetts’ first independent regional MRI center in 1986 and, today, it manages numerous MRI and PET/CT facilities throughout New England, many of which are joint venture partnerships with community hospitals. While most Shields Health locations operate as licensed clinics, many of those clinics are either on a partner hospital’s campus or proximate to the hospital’s facilities, thereby enabling coordinated, seamless, and highly accessible care. A dedicated focus on operational and management services expertise in outpatient settings allows Shields to provide cost savings to patients, employers, insurance providers, and joint venture partners.

SIEM is both a part of, and a product of, Shields Imaging of Massachusetts, LLC, a consortium that received DON approval in 2002 for Project #4-4886, to acquire a PET/CT unit to provide services at three host sites. The consortium was comprised of Shields Imaging of Eastern Massachusetts, LLC, Shields Imaging of Worcester, LLC, and Shields Imaging of Springfield, LLC, and the host sites offering the mobile PET/CT services included South Shore Hospital, UMass Memorial Medical Center, and Baystate Medical Center. Pursuant to a DoN amendment approved on August 9, 2006, each of the host sites was licensed as a separate clinic, one for each member of the original consortium. The three licensed clinics that now hold the approval to provide PET/CT pursuant to Project #4-4886 are SIEM, UMass Memorial MRI and Imaging Center (UMMIC), and Baystate MRI and Imaging Center, LLC ("BMIC").

Pursuant to a subsequent amendment to the original DoN, dated October 1, 2018, SIEM currently operates a mobile PET/CT service two (2) days per week at South Shore Hospital--on Tuesday from 6:30 AM to 10:00 PM, and Thursday from 6:30 AM to 10:00 PM. However, demand for PET/CT services at SIEM has increased, resulting in the need for additional PET/CT capacity at the South Shore Hospital location.

Historical utilization data for the location shows a continual increase in individual patients and scans over the past four years. The Applicant performed 2,021 scans in 2022; 2,135 scans in 2023; 2,760

scans in 2024; and 2,174 scans in the first 9 months of 2025 (which, annualized, equals 2,899 scans)—meaning that the Applicant's scan volume has increased over forty-three percent over the 4 year period. SIEM has also experienced an increase in unique patients presenting for scans(unique patients means the number of patients who receive PET/CTs at the clinic in a given year, not the number of scans they receive, and an increase in unique patients indicates a growing community need). The Applicant saw 1,575 unique patients in 2022, 1,709 in 2023, 2,167 in 2024, and 1,761 (or 2,348 annualized) in the first 9 months of 2025. The Applicant's unique patient count per year has increased almost fifty percent over those 4 years.

Proposed Project:

The Applicant seeks approval for a mobile PET/CT unit, and for five additional (i.e., a total of 7) PET/CT service days, to meet the need for increased access to PET/CT services for the Applicant's patient panel. As described above and below, demand has significantly increased for PET/CT scans at SIEM over the past four years. The Applicant's data demonstrates an increased need for access to PET/CT at the clinic, a need that is underscored by the fact that the Applicant's location is currently experiencing an average wait time of 17 days from referral to the date of a scan. The Applicant also began offering amyloid brain scans in 2024 (144 scans in first year) and is anticipating 10% growth each year for those scans going forward. Further, SIEM plans to offer cardiac PET perfusion scans in 2026, anticipating 100 scans in 2026 with 10% annual growth in such scans in subsequent years.

Five additional days of service at the Applicant's location will reduce wait times for the Applicant's patients, thereby reducing delays in care and improving both quality of care and patient (and provider) satisfaction. As PET/CT is increasingly and effectively utilized to detect and monitor high acuity and progressive diseases such as cancer, heart disease, and neurological abnormalities, timely imaging is an essential element of patient treatment plans. For example, PET/CT scans are now frequently utilized at SIEM to facilitate the diagnosis or existence of solid tumors, prostate cancer, neuroendocrine cancer, cardiac sarcoidosis, Alzheimer's disease, and amyloid plaque. Moreover, cancer screening standards for lung, prostate, breast and colorectal cancer now contemplate follow up PET/CT exams post screening to determine malignancy; and patients with diagnosed malignancies are then monitored throughout their treatment using the same PET/CT technology that established the malignancy. PET/CT serves this role in a noninvasive manner and in an outpatient (generally lower cost) setting.

SIEM anticipates still further increases in demand for PET/CT services as the population of its patient panel ages, since age is the most important risk factor for cancers. Based on 2025 data, eighty percent of SIEM patients are age 65 or older and ninety-seven percent are age 50 or older.

The nature of the conditions experienced by patients who present to SIEM, and the age of those patients and SIEM's patient panel, make it especially important that SIEM be able to offer its patients timely and convenient access to PET/CT services. The additional five days of service SIEM is seeking will allow it to meet the need for patients requiring PET/CT services and will obviate the need for those patients to otherwise have to travel to another, less convenient facility or be subject to extended wait times at SIEM. The Applicant projects the five additional days of service it is seeking will result in approximately 3,549 scans in year 1 post-DON; 3,904 scans in year 2; 4,294 scans in year 3, 4,724 scans in year 4, and 5,078 in year 5. By increasing capacity five additional days per week, the Applicant will be able to accommodate the needs of its patient panel, for whom PET/CT is an integral modality as part of their diagnosis and treatment planning, particularly for cancers.

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. Patient Age:

Eighty percent of the Applicant's patients are age 65 or older and seventeen percent are age 50-64, with only three percent younger than 50, and no pediatric patients.

Age range	**FY2022**	**FY2023**	**FY2024**	**FY2025** *(9 months annualized)*
65+	1,306	1,396	1,729	1,880
50-64	222	264	385	397
18-49	47	49	53	71
TOTAL	**1,575**	**1,709**	**2,167**	**2,348**

B. Patient Gender:

Fifty-five percent of the Applicant's patients are male, and forty-five percent are female. The Applicant does not collect patient sexual orientation data.

Gender	**FY2022**	**FY2023**	**FY2024**	**FY2025** *(9 months annualized)*
Male	821	925	1,254	1,294
Female	754	784	913	1,054
Total	**1,575**	**1,709**	**2,167**	**2,348**

C. Patient Race:

The Applicant collects patient race data, however only sixteen percent of the patients provided their race. [1]

Race	**FY2022**	**FY2023**	**FY2024**	**FY2025** *(9 months annualized)*
Not collected/ declined to specify	1,449	1,357	1,695	1,972
White	126	333	445	359
Other races - grouped to meet	0	19	27	17

[1] In FY22, the "Other" category has been combined with the "Not Collected" category for HIPAA compliance.

HIPAA compliance				
Total	**1,575**	**1,709**	**2,167**	**2,348**

D. Patient Ethnicity:

The Applicant collects patient ethnicity data, however only 15% of the patients provided their ethnic backgrounds.

Ethnicity	**FY2022**	**FY2023**	**FY2024**	**FY2025** *(9 months annualized)*
Not collected/ declined to specify	1,443	1,332	1,689	2,006
Not Hispanic	120	352	423	320
Hispanic	12	25	55	22
Total	**1,575**	**1,709**	**2,167**	**2,348**

E. Patient Origin:

In 2025, the Applicant's patients resided in 7 different states with ninety-nine percent of the patients residing in Massachusetts. Seventy-six percent of the Applicant's 2025 patients live in 22 towns in Massachusetts as detailed in the table below. These 22 towns comprise the Applicant's primary service area (PSA).

Town	**FY2022**	**FY2023**	**FY2024**	**FY2025** *(9 months annualized)*
Quincy	142	153	176	201
Braintree	96	92	117	128
South Weymouth	74	81	98	120
Plymouth	56	73	111	115
Rockland	49	63	78	109
Marshfield	71	75	81	105
Hingham	77	81	84	105
Scituate	59	75	62	85
Brockton	26	50	63	81
East Weymouth	52	57	65	79
Weymouth	66	55	61	77
Hull	48	48	63	77
Abington	39	65	60	59
Hanover	58	48	51	57
Pembroke	66	49	63	57
Hanson	23	38	41	53
Whitman	27	40	53	52
North Weymouth	36	36	40	48
Randolph	35	32	43	47
Norwell	31	23	41	40
Holbrook	29	23	40	40

Town	FY2022	FY2023	FY2024	FY2025 *(9 months annualized)*
Kingston	24	31	33	39
Patients - PSA Towns	**1,184**	**1,288**	**1,524**	**1,774**
Other Patients	**391**	**421**	**643**	**574**
Total Patients	**1,575**	**1,709**	**2,167**	**2,348**

D. Payer Mix:

The Applicant's patients are predominantly covered by Medicare plans (seventy six percent in 2025) which is consistent with the patient age demographic.[2]

Payer Mix	FY2022	FY2023	FY2024	FY2025 *(9 months annualized)*
Medicare (FFS and Commercial)	1,119	1,237	1,575	1,785
Commercial	376	391	470	459
MassHealth and Managed Medicaid	80	81	122	104
TOTAL	**1,575**	**1,709**	**2,167**	**2,348**

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, the Applicant seeks approval to provide PET/CT services seven (7) days per week at South Shore Hospital. This is an increment of five (5) days of service from the current two (2) days of service.

Historical Scan Volume:

The Applicant has experienced the following scan volume over the past 4 years [3]:

[2] In FY22, FY23, FY24. and FY25, the "Other" category has been combined with the "Medicare (FFS and Commercial)" category for HIPAA compliance.

[3] The Applicant's historic volume differs slightly from the counts filed in its recently withdrawn Application for amendment, as there was an inadvertent error in that filing.

Scan Volume	FY2022	FY2023	FY2024	FY2025 *(9 months annualized)*
FDG PET/CT	1,731	1,737	2,053	2,184
PSMA PET/CT	230	362	534	516
Amyloid PET/CT			144	171
Other PET/CT	60	36	29	28
PET/CT Scans	**2,021**	**2,135**	**2,760**	**2,899**

Forecasted Scan Volume:

The Applicant projects PET/CT scan volumes for the first five years of project implementation to be as follows:

Forecasted Volume	Year 1	Year 2	Year 3	Year 4	Year 5
FDG PET/CT	2,579	2,837	3,121	3,433	3,690
PSMA PET/CT	684	752	827	910	978
Amyloid PET/CT	186	204	225	247	266
Cardiac PET/CT	100	110	121	134	144
PET/CT Scans	**3,549**	**3,903**	**4,294**	**4,724**	**5,078**

Demand Increasing Need:

The anticipated growth in PET/CT scan volume into the future is largely based on an aging patient population. Eighty percent of the Applicant's patients are age 65 or older and seventeen percent are age 50-64, with only three percent younger than 50, and no pediatric patients. While the overall population in the 22 cities and towns that comprise the Applicant's primary service area is forecasted to be relatively stable over the next 5-20 years, there is significant population growth forecasted in the population aged 65 and older over the next 5-20 years as detailed in the tables below.[4]

Applicant Primary Service Area towns	2025 Forecast	2030 Forecast	2035 Forecast	2040 Forecast	2045 Forecast
Population count (all ages)	607,710	609,637	609,091	606,626	602,376
Population count (ages >=65)	131,636	146,032	153,449	153,883	150,773

Applicant Primary Service Area towns		5 year change	10 year change	15 year change	20 year change
Population (all ages)		+0.3%	+0.2%	-0.2%	-0.9%
Population (ages >=65)		+10.9%	+16.6%	+16.9%	+14.5%

[4] UMass Donahue Institute V2024 Population Projections, May 2024, accessed excel data file online 10/27/25 https://donahue.umass.edu/business-groups/economic-public-policy-research/massachusetts-population-estimates-program/population-projections

The Applicant has been experiencing increasing wait times (date of referral to date of scan) for PET/CT scans given the limitations of its current 2 day schedule. The Applicant's average wait times for PET/CT scans have increased from 11 days in 2020 and 2021, to 14 days in 2022, 17 days in 2023, 15 days in 2024 and 17 days in 2025. Timely access to diagnosis and treatment is very important to patients and referring providers, and even more so for cancer related cases. With the expansion to a 7 day schedule, the Applicant will be able to reduce wait times to average 7 to 10 days, prioritizing the new diagnoses for closer to 7 days.

The Applicant evaluated available tumor registry data, available national and regional PET/CT trending data through the Advisory Board, as well as other industry trends to estimate increasing PET/CT demand to support the need for an additional five days of PET/CT services.

- Based on a review of CDC Tumor reporting the Applicant estimates that over 200 patients who were diagnosed locally were likely obliged to seek PET/CTs at other locations based on lack of local appointment availability. [5]
- Advisory Board data projects PET/CT utilization will grow by 9% per year for the next 5 years.
- Over 7 million people in the US, including about 1 in 9 people age 65 an older, are living with Alzheimer's.[6] This population would be the primary population seeking anti-amyloid treatment. If choosing to pursue anti-amyloid therapy, these patients would need a lumbar puncture or the preferred PET/CT scan which is less invasive.
- 10-15% of nuclear medicine stress tests result in equivocal results with respect to coronary artery disease, due to body habitus, diabetes, and being of female gender. PET/CT is the preferred imaging tool to enable this population to obtain more definitive results. South Shore Hospital provides nuclear medicine stress tests to approximately 2,500 patients per year. Of those patients, approximately 250 - 375 would be better served by PET/CT due to higher sensitivity, than the nuclear medicine stress test.
- FDA has approved Novartis radioligand therapy Pluvicto® for earlier use before chemotherapy in PSMA-positive metastatic castration-resistant prostate cancer.[7]
- Recent FDA approval of donanemab (Kisulna) for amyloid plaque removal will use serial PET/CT to evaluate treatment termination. (Leqembi treatment requires one PET/CT scan).[8]
- New imaging biomarker for renal cancer expected to have FDA approval in 2025 for PET/CT. Renal carcinoma is a new population for PET/CT. (TLX250-CDx, Zircaix®3 (89Zr-girentuximab)

F1.a.iii **<u>Competition</u>:**

[5] Massachusetts Cancer Registry *available at https://www.cancer-rates.com/*

[6] Alzheimer's Disease Facts and Figures available at https://www.alz.org/alzheimers-dementia/facts-figures

[7] FDA approves Novartis radioligand therapy Pluvicto® for earlier use before chemotherapy in PSMA-positive metastatic castration-resistant prostate cancer *available at https://www.novartis.com/news/media-releases/fda-approves-novartis-radioligand-therapy-pluvicto-earlier-use-chemotherapy-psma-positive-metastatic-castration-resistant-prostate-cancer*

[8] Implications for radiology following the FDA's approval of new Alzheimer's treatment from Eli Lilly *available at https://radiologybusiness.com/topics/healthcare-management/healthcare-economics/implications-radiology-following-fdas-approval-new-alzheimers-treatment-eli-lilly*

[8] Teliz Late-stage therapeutic pipeline *available at https://telixpharma.com/our-portfolio/pipeline/*

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 Proposed Project will not have an adverse effect on competition in the Massachusetts healthcare market based on price, TME, provider costs, or other recognized measures of health care spending. The proposed project does not introduce a new competitor into the Applicant's service area. Rather, it expands the capacity of an existing provider in order to satisfy demonstrated need, without new construction or related expenditures. At the same time, the proposed project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending because, for the foreseeable future, patients and payers will be charged for the services at the same rates as they are being charged currently.

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 the Applicant has identified.

Factor F1.a.ii outlines how the Proposed Project will meet patient panel need. As described below, the Proposed Project is also supported by evidence-based literature related to the utility of PET/CT technology and the benefits associated with receiving timely, co-located, fully integrated health care services.

A. PET/CT as a Screening Modality

PET and CT are two well-established imaging systems that have been available for clinical use for several decades. PET is a noninvasive, molecular imaging technology that measures metabolic activity via detection of radiotracers injected in a patient's bloodstream. Specifically, PET studies evaluate the metabolism of organs and tissues inside the body, providing information about how organs and tissues are functioning on a molecular and cellular level. While other diagnostic imaging procedures predominantly offer anatomical pictures, PET, as a molecular imaging modality, enables physicians to measure chemical and biological processes. Thus, PET may detect biochemical changes in an organ or tissue that indicate the onset of a disease process before symptoms, abnormalities, or anatomical changes related to the disease can be seen with other imaging processes. PET may also be used to track treatment progress and is commonly used in the fields of oncology, cardiology, and neurology/neuropsychology.[9]

While the function of PET is to provide molecular information, the function of CT scanning is to provide anatomical and structural information. A CT scan creates a three-dimensional picture of the inside of the body with an x-ray machine.[10] A computer then combines these images into a cross-sectional view that shows any tumors or physical abnormalities in tissue morphology. CT scans can be performed on every region of the body and CT images of internal organs, bones, soft tissues, and blood vessels provide greater detail and clarity compared to conventional x-ray images. CT scans

[9] SOC'Y OF NUCLEAR MED. & MOLECULAR IMAGING, *Fact Sheet: What is PET? available at https://snmmi.org/Patients/Patients/Fact-Sheets/What-is-PET.aspx*

[10] NAT'L INST. OF BIOMEDICAL IMAGING AND BIOENGINEERING; *Computed Tomography*, available at https://www.nibib.nih.gov/science-education/science-topics/computed-tomography-ct

are performed for a variety of reasons, and are useful in diagnosing disease, trauma, and abnormality; planning and guiding interventional and therapeutic procedures; treatment planning and monitoring the effectiveness of therapy; and screening purposes.

PET/CT is a dual-modality imaging technique that combines images from PET and CT scans that have been performed at the same time using the same machine. Since a PET scan reveals any abnormal metabolic activity that may be occurring on a molecular level and a CT scan provides detailed pictures of tissues and organs inside the body, combining these scans creates a more complete image than either test can offer alone. Specifically, a PET/CT scan merges the quantitative physiologic and metabolic information provided by stand-alone PET with the contextual anatomic information provided by stand-alone CT to deliver a clinically meaningful integrated data set containing accurately aligned anatomic and functional images.[11]

As discussed in further detail below, applications of PET/CT include oncologic, cardiovascular, and neurologic/neuropsychologic imaging. The influence of the combined PET/CT modality provides an unsurpassed level of patient care and patient management. In addition to contributing to increased confidence by allowing physicians to better diagnose disease, as well as plan and monitor response to treatment more effectively, a single PET/CT scan also provides convenience for both physicians and patients. Integrated PET/CT avoids scanning delays associated with separate or sequential PET and CT and reduces acquisition times, thus leading to increased patient throughput and more efficient instrument utilization.[12]

B. Clinical Applications of PET/CT Technology

As discussed in further detail below, the clinical application of PET/CT technology performed by the Applicant includes conditions that fall within the categories of oncology, cardiology, and neurology.

Oncology

The most well-known and well-documented use of the integrated PET/CT scan is in the field of oncology. The hybrid modality combines PET's incomparable ability to determine the metabolic activity of tissues with CT's high-resolution anatomic information to offer an integrated data set and improve accuracy and localization of many lesions. PET/CT is a powerful tool for many types of cancer for the following: detection; establishing staging and determining whether the cancer has spread to other parts of the body; helping physicians and patients decide on a tailored treatment plan; evaluating the effectiveness of treatments, such as chemotherapy or radiation therapy; detecting whether the disease is recurring after treatments are completed; and helping physicians locate an area for a biopsy, if necessary.[13]

Cardiology

An additional clinical application of PET/CT is cardiovascular disease, which relies on early detection

[11] David W. Townsend, *Combined Positron Emission Tomography-Computed Tomography: The HistoricalPerspective*; 29(4) SEMINARS IN ULTRASOUND CT AND MRI 232-235 (2008).
[12] Muhammad Wasif et al.*; Role and Cost Effectiveness of PET-CT in Management of Patients with Cancer*, YALE JBIOL MED. 2010;83(2):53-6; *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892773/.
[13] Landis K. Griffeth; *Use of PET-CT Scanning in Cancer Patients: Technical and Practical Considerations*; 18(4)BAYLOR UNIV. MED. CTR. PROCEEDINGS 321-30 (2005).

to treat.[14] Various PET radiotracers are capable of probing molecular processes and tracking biologic pathways inside the body, making PET a powerful technology for understanding cardiac physiology, myocardial viability, and disease processes.[15] In addition, CT produces images of cardiovascular structure. Given the utility of both PET and CT imaging systems when used independently, an integrated PET/CT modality provides significant incremental benefits to the data provided by each modality alone. Specifically, the hybrid modality's simultaneous quantification of cardiac perfusion and assessment of coronary artery anatomy allows for direct comparison of the extent of stenosis and the severity of obstructed blood flow, and therefore provides a wealth of complementary information in the evaluation of coronary artery disease ("CAD").[16] Moreover, the PET/CT scan provides improved characterization of atherosclerotic plaque and risk stratification in patients, and thus is clinically applicable in staging and managing CAD.[17]

Neurology

Finally, PET/CT has significant potential in the fields of neurology and neuropsychiatry due to the merging of metabolic and anatomic information in one examination. PET/CT can increase understanding of the pathogenesis and mechanism of various conditions, including but not limited to, epilepsy and seizures and autoimmune encephalitis ("AE").[18] With regard to epilepsy and seizures, a PET/CT scan provides information both during a seizure and between seizures. During a seizure, the hybrid scan shows the area responsible for the seizure as an area of increased glucose use, and between seizures, the hybrid scan shows a characteristic pattern of reduced glucose need.[19]

Additionally, research indicates that PET/CT may be helpful in supporting evidence of brain dysfunction in suspected patients with AE.[20]

Patient Satisfaction and Convenience

The extended availability of PET/CT services at South Shore Hospital will contribute to patient satisfaction, which is an important indicator used for measuring quality in health care.[21] Patient satisfaction enhances clinical outcomes, improves patient retention, reduces medical malpractice claims, reflects timely, efficient, and patient-centered delivery of quality health care, and is a very

[14] Anna Rosiek and Krzysztof Leksowski; *The risk factors and prevention of cardiovascular disease: the importance of electrocardiogram in the diagnosis and treatment of acute coronary syndrome*; 12 THERAPEUTICS AND CLINICAL RISKMANAGEMENT 1223-29 (2016); *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4982493/.

[15] Caitlund Q Davidson et al.; *Searching for novel PET radiotracers: imaging cardiac perfusion, metabolism andinflammation*; 8(3) AM. J. NUCLEAR MED. MOLECULAR IMAGING 200-27 (2018); *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056242/.

[16] P. Knaapen et al; *Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease*; 18(2)NETH HEART J. 90-98 (2010); *available at* https://pubmed.ncbi.nlm.nih.gov/20200615/.

[17] Patricia M Sánchez-Roa et al.; *Systemic atherosclerotic plaque vulnerability in patients with Coronary Artery Disease with a single Whole Body FDG PET-CT scan*; 8(1) ASIA OCEAN J. NUCLEAR MED. BIOL. 18-26 (2020); *availableat* https://pubmed.ncbi.nlm.nih.gov/32064279/.

[18] Julie Guerin et al.; *Autoimmune epilepsy: findings on MRI and FDG-PET*; 92 BRITISH J. RADIOLOGY 20170869(2019); *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6435058/.

[19] Ismet Sarikaya; *PET Studies in Epilepsy*; 5(5) AM J NUCL MED MOL IMAGING 416-30 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4620171/.

[20] John C. Probasco et al.; *Abnormal brain metabolism on FDG-PET-CT is a common early finding in autoimmuneencephalitis*; 4(4) *Neurol Neuroimmunol Neuroinflamm* e352 (2017); *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442608/.

[21] Bhanu Prakash, *Patient Satisfaction*, 3 J. CUTANEOUS & AESTHETIC SURGERY 151 (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3047732/.

effective indicator to measure the success of doctors and hospitals.[22] Thus, its importance cannot be overstated. Patient satisfaction will be sustained through the Proposed Project by ensuring that patients enjoy access to on-campus PET/CT services and do not need to travel elsewhere for imaging services. In sum, the Applicant anticipates that the Proposed Project will positively impact patient satisfaction and convenience, and, in turn, quality.

Expanded Access to Integrated Care

The extended availability of PET/CT services at South Shore Hospital enables patients to receive a full complement of comprehensive, integrated care within South Shore Health. When health care delivery is spread out across a number of separately located and operated providers, often the result is fragmented care.[23] Care fragmentation is considered an important source of inefficiency in the US health care system and a large concern for patients.[24] By increasing the days of access to PET/CT services at South Shore Hospital, the Applicant will be able to reduce scheduling delays and reduce the need for patients to travel outside of the community for PET/CT services, and thereby, enable the Applicant to facilitate greater access to integrated care and improved health outcomes.

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. Improving Health Outcomes and Quality of Life

The Proposed Project will provide the Applicant's patient panel with increased access to PET/CT services that will directly impact health outcomes, quality of life and patient satisfaction. Studies indicate that delayed access to healthcare services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.[25] Through the continued operation of an on-site PET/CT service at South Shore Hospital, the Applicant will provide timely access to imaging services for all South Shore Health patients.

Increased access to PET/CT services will address the needs of an aging patient panel. The Applicant's PET/CT patient panel is already comprised of a significant 65+ population, and that age cohort has been growing each year. As the 65+ age cohort grows, the demand will grow for imaging services utilized to detect and treat age-related conditions such as neurological disorders, orthopedic and musculoskeletal conditions, cancer, and cardiovascular disease.[26] Expanded access to on-campus PET/CT services will facilitate timely diagnosis and treatment, improving overall health outcomes.

[22] *Id.*

[23] Kurt C. Stange, *The Problem of Fragmentation and the Need for Integrative Solutions*, 7 ANNALS FAMILY MED. 100(2009), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2653966/.

[24] *Id.*

[25] Julia C. Prentice & Steven D. Pizer, *Delayed Access to Health Care and Mortality*, 42 HEALTH SERVICES RESEARCH644 (2007), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955366/.

[26] WORLD HEALTH ORGANIZATION, *supra* note 6.

Finally, given that South Shore Health is a part owner of the Applicant, imaging services will be part of a fully integrated medical record. Studies show that having access to integrated health information systems has a direct impact on health outcomes, as access to a single medical record for patients leads to enhanced care coordination by care teams. Additionally, an integrated medical record allows primary care physicians and specialists to have access to the same patient information, allowing for real-time care decisions, thereby reducing duplication of services and unnecessary testing. The availability of these integrated record services for the Applicant's patients will facilitate quick and easy access to patient images and reports, which will in turn affecttimely care, improved outcomes, and better quality of life.

B. Assessing the Impact of the Proposed Project

To assess the impact of the Proposed Project, the Applicant has developed the following measures of patient satisfaction, access and quality of care. The measures are discussed below:

PET/CT Measures

1. **Patient Satisfaction:** Patients that are satisfied with care are more likely to seek additional treatment when necessary. The Applicant will review patient satisfaction levels with the PET/CT imaging service.

   Measure: To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients receiving imaging services with specific questions around a) satisfaction levels with pre-appointment communication; and b) satisfaction with the wait time for services.

   Projections: Minimum response expectation: 40% of total delivered surveys. Satisfaction sore minimum expectation 95% satisfaction. Scores evaluated quarterly

   Monitoring: Any category receiving a less than exceptional rating (satisfactory level) on an annual basis will be evaluated and policy changes instituted.

2. **Quality of Care – Critical Value Reporting:** When critical values or abnormal test results are registered within an electronic medical record for a patient, the referring physician is notified via electronic communication. A benefit of having an integrated electronic medical record and PACS system is the ability to send these messages to a referring physician, so that clinical decisions may be expedited.

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

   Projections: Baseline: 100% Year 1: 100% Year 2: 100% Year 3: 100%

   Monitoring: PET/CT scans will be monitored and follow up will be conducted with the referring physician. The radiologist will be made available to answer any questions.

3. **Quality of Care – Quality of PET/CT Scan:** The quality of a PET/CT scan is imperative to its interpretation. Accordingly, the Applicant will evaluate the number of scans that need to be repeated over the course of a week to ensure radiology technicians are performing appropriate

scans.

Measure: The number of repeat PET/CT scans performed on patients within a seven-day period (day of scan to next day of scan).

Projections: 1.5% Year 1: 1% Year 2: 1% Year 3: .08%

Monitoring: PET/CT 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.

4. **Quality of Care – Peer Review Over Read Correlation:** To evaluate the accuracy of scan interpretations, the Applicant will conduct peer review readings to ensure quality outcomes for patients.

   Measure: The Applicant will have contracted radiologists conduct peer review readings on a random basis (1 case per scan day) based on the American College of Radiology ("ACR") Peer to Peer criteria and will follow-up on all discrepancies with the original reading radiologist.

   Projections: Baseline: 95% Year 1: 96% Year 2: 97% Year 3: 100%

   Monitoring: A random selection of cases based on ACR Peer to Peer criteria will be reviewed. Radiologists will evaluate scans documenting any inconsistencies and discuss outstanding issues with the original reading radiologist.

F1.b.iii **<u>Public Health Value /Health Equity-Focused</u>:**

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.

To ensure health equity to all populations in the Applicant's service area, including those deemed underserved, the Proposed Project will not adversely affect access to the Applicant's services by poor, medically indigent, and/or Medicaid eligible individuals. The Applicant will not discriminate based on payor source or ability to pay. Accordingly, as further detailed throughout this narrative, the Proposed Project will ensure access to PET/CT services for all of South Shore Health's and the Applicant's patients.

Additionally, the Applicant will provide effective, understandable, and respectful care with an understanding of patients' cultural health beliefs and practices and preferred languages. The Applicant will provide interpreter services to its patients who require such services through the Applicant's existing interpreter services program. The Applicant seeks to identify the need for interpreter services prior to the patient's appointment, so as to provide in-person interpreter services

whenever possible. On-site interpreters are available Monday – Friday. If an interpreter is not available on-site, phone or VRI services are available 24/7 for interpretation needs. The Applicant also has developed arrangements to offer ongoing education and training of staff in culturally and linguistically appropriate care. These steps will promote health equity and ensure equal access to PET/CT 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.

The Proposed Project will result in improved health outcomes and quality of life of the Applicant's patient panel through increased access to on-site PET/CT services at South Shore Hospital. These services will be provided equitably as part of a full complement of health care services available to South Shore Health patients. Dedicated focus by the Shields management team will maximize operational andscheduling efficiencies that improve patient and referring provider satisfaction. The Proposed Project will result in increased access and decreased wait times for PET/CT services at South Shore Hospital.

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 result in improved health outcomes and quality of life, ensuring continuity of care for South Shore Health and the Applicant's patients. The Applicant will increase the days of service of on-site PET/CT services to patients, ensuring timely access to imaging services that complement the clinical services patients are receiving at South Shore Hospital. Co-located services combat fragmented care, resulting in benefits such as improved access, increased collaboration among providers, better coordination of care, increased efficiency, and overall improved health outcomes. The Applicant's provision of PET/CT services on the hospital campus allows patients to schedule and attend appointments in a single location on the same day, minimizing transportation needs or other social issues that may otherwise pose a barrier to obtaining care. Additionally, co-location of services is a significant benefit for low-income and older adults, populations that are more likely to obtain the care they need if services can be accessed at a single site within their community. Accordingly, the Proposed Project's on-site PET/CT services will facilitate greater continuity of care, improved health outcomes, and enhanced quality of life for South Shore Health's and the Applicant's patients.

Importantly, the Applicant is a joint venture with South Shore Health. As such, all imaging results are part of a fully-integrated medical record, which will be available to each of the patient's primary care and specialty providers across the South Shore Health system. This medical record integration supports care coordination and collaboration among providers, leading to higher quality outcomes for patients. Accordingly, as a result of the Proposed Project, patients will have increased access to high-quality PET/CT services in the community that are co-located and integrated with the full complement of South Shore Health services.

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 Applicant sought input from a variety of stakeholders in planning the Proposed Project. The Applicant conducted a formal consultative process with individuals at various regulatory agencies regarding the Proposed Project. The following individuals are some of those consulted with regard to the Proposed Project:

- Lucy Clark, Analyst, Determination of Need Program, Department of Public Health
- Jaclyn Gagne, Chief Deputy Counsel, Department of Public Health
- Dennis Renaud, Director, Determination of Need Program, Department of Public Health
- Teryl Smith, Bureau Director HCSQ, Department of Public Health
- Katie Teague, Community Health Planning and Engagement Specialist, Determination of Need CHI Program, Bureau of Community Health and Prevention

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.**

To inform and consult the community about the Proposed Project, the Applicant engaged members of the patient panel, family members, and community members and local stakeholders that may be impacted by the Proposed Project.

The Proposed Project was presented at South Shore Hospital's Patient and Family Advisory Council ("PFAC") on December 11, 2025. The PFAC is an important forum for creating partnerships among patients, family and staff. This meeting was attended by 16 individuals, 7 South Shore Hospital PFAC staff members and 9 community PFAC members. The Applicant presented to the PFAC in order to gain feedbackon the existing and proposed PET/CT service and hours of operation, and on the impact of this service on the patient population. Discussions of the Proposed Project included the history of the service, and benefits of improved access to PET/CT services. Questions that were addressed included: how increased days would impact hours of operation; how patient satisfaction is monitored and how the joint venture is structured. The PFAC members were engaged and enthusiastic about the project, and feedback was overwhelmingly positive.

F1.e.ii **Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful 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, the Applicant took the following actions:

- Presentation to the South Shore Hospital PFAC on December 11, 2025.

For detailed information on this meeting, see **Attachment 1.**

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. **Cost Containment:**
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.

The goals for cost containment in Massachusetts are focused on the provision of low-cost care alternatives without sacrificing high quality care. The Proposed Project seeks to align with these goals by providing expanded access to high-quality PET/CT services in a cost-effective setting.

The clinic operated by the Applicant allows for PET/CT services to be provided locally. The clinic will operate as an IDTF, which is reimbursed at lower rates than the same service provided by a hospital. Through the Proposed Project, the Applicant seeks to ensure continued lower cost, high quality care to the communities served by South Shore Health.

Additionally, the Applicant highlights the cost benefits associated with access to integrated health care services. When patients delay treatment, conditions worsen, leading to critical events that often are more expensive.[27] Providing patients with accessible, high quality services to ensure that all patients receive necessary care in a timely manner is one way to promote lower care costs. Accordingly, the Proposed Project seeks to eliminate barriers to care through the availability of a full complement of services through South Shore Health, ensuring patients receive the care they need in a timely manner. By offering these services where the patient panel already goes for care, care efficiencies improve care coordination, promote faster diagnosis and intervention, and improve health care quality, thereby reducing the overall costs of health care.

F2.b **Public Health Outcomes:**
Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

The Proposed Project will improve public health outcomes and patient experience through the expansion of on-site PET/CT services in an integrated manner that promotes improved coordination of care. The incidence of many disease categories, such as cancer and cardiac- related diseases increases with age. Accordingly, the need for the PET/CT services envisioned by the Proposed Project will increase with a growing 65+ age cohort in the Applicant's patient panel--as imaging services are important for detecting, managing, and treating the referenced diseases and other conditions.

[27] Ara Ohanian, *The ROI of Addressing Social Determinants of Health*, AJMC (Jan. 11, 2018),https://www.ajmc.com/view/the-roi-of-addressing-social-determinants-of-health.

PET/CT is a powerful imaging modality that enables clinicians to better understand these disease processes and conditions and to make treatment decisions. Through expanded access to imaging services at South Shore Hospital, clinicians will have the necessary tools to appropriately diagnosis and treat patients, thereby improving health outcomes for the patient panel.

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.

Social Determinants of Health ("SDoH") are the conditions and environments in which people are born, grow, live, eat, work, play and age, that affect access to the healthcare system and a wide range of health risks and outcomes.[28] Socioeconomic status, education, employment, housing, food security, transportation, social protective factors, social support, and language/literacy are all examples of SDoH that have an impact on the physical and mental well-being of the population. The Applicant will provide programs to address issues associated with the SDoH, ensure all patients have equal access to care, and ensure linkages to social service organizations when indicated. Specifically, the Applicant plans to implement patient access tools, such as preregistration functionality, a cost transparency application, linkages to financial counselors, culturally competent staff, and a robust translation services program. These services facilitate easier access to care for vulnerable and at-risk populations.

Additionally, individuals are more likely to receive care if it is in a setting with which they are familiar and is conveniently located, such as their local community hospital--like South Shore Hospital. As a result, and the expanded operation of on-site PET/CT services at South Shore Hospital will increase the likelihood that patients in the community will access care, and it will promote communication between and among providers and caregivers regarding a patient's care. Patients will also be able to better coordinate multi-service visits on the same day due to co-located services. Accordingly, continued on-site provision of PET/CT services will reduce health inequities and positively impact quality of care. Additionally, patients of the Applicant's PET/CT services will further benefit from care coordination through access to the hospitals' system-wide support services.

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 will establish a Mobile PET/CT unit seven days per week at South Shore Hospital. The Proposed Project will expand the existing two-day mobile PET/CT imaging services currently provided by the Applicant.

[28] *Social Determinants of Health: Know What Affects Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/socialdeterminants/ (last updated Jan. 17, 2024).

Quality: The Proposed Project will result in improved quality and healthcare outcomes as patients will have more and more timely access to on-site PET/CT services at South Shore Hospital in addition to the full complement of hospital services, including emergency and inpatient. This will improve coordination of care and health outcomes.

Efficiency: The Proposed Project will improve care efficiency, as the clinic's expanded operation of the PET/CT services at South Shore Hospital will ensure patients have greater access to co-located PET/CT and other hospital services. Patients will not have to travel to other providers for PET/CT services and may coordinate other health care appointments on the same day. Moreover, the Proposed Project will result in continued integration of medical records, improving care efficiency.

Capital Expense: The Applicant will expend $1,099,871 to implement the Proposed Project.

Operating Costs: First year incremental operating costs resulting from the Proposed Project are estimated to be approximately $6,948,091

List alternative options for the Proposed Project:

Option 1
Alternative Proposal: One alternative considered for this Proposed Project would be to do nothing and maintain the current days and hours of operation with a shared mobile unit.

Alternative Quality: This alternative would result in increasing wait times for PET/CTs as the service area population expands and ages, and therefore reduced quality care from delayed diagnoses and treatments.

Alternative Efficiency: This alternative would result in longer wait times for PET/CT services onsite at South Shore Hospital and/or patients seeking PET/CT scans elsewhere, without access to care coordination and integrated medical records.

Alternative Capital Expenses: There are no capital expenses associated with continuing this arrangement.

Alternative Operating Costs: Continuing this arrangement would not result in a change in operating expenses.

Option 2
Alternative Proposal: A second alternative considered for this Proposed Project would be to offer alternate Shields Health PET/CT locations to patients.

Alternative Quality: The quality of care provided would be consistent with care provided by the Applicant, however the patients would have to travel further for their PET/CTs, causing decreased patient satisfaction and increased stress and anxiety.

Alternative Efficiency: This alternative would result in patients having to travel further for their PET/CTs, without access to care coordination and integrated medical records.

Alternative Capital Expenses: There are no capital expenses associated with continuing this

arrangement.

Alternative Operating Costs: Referring patients to alternate Shields Health PET/CT locations would not result in a change in operating expenses.