

STAFF REPORT TO THE COMMISSIONER FOR A DETERMINATION OF NEED

Applicant Name	Tufts Medicine: Shields PET-CT, LLC
Applicant Address	700 Congress Street, Suite 204, Quincy, MA 02169
Filing Date	October 6, 2022
Type of DoN Application	DoN-Required Equipment
Total Value	\$1,095,687.00
Project Number	#NA-22091411-RE
Ten Taxpayer Groups (TTG)	None
Community Health Initiative (CHI)	\$54,784.35 (Statewide Fund)
Staff Recommendation	Approval
Delegated	Commissioner Approval

Project Summary and Regulatory Review

Tufts Medicine: Shields PET-CT, LLC (Applicant) is filing a Determination of Need Application for the establishment of a licensed clinic to provide part-time mobile positron emission tomography – computed tomography (together PET-CT) diagnostic imaging services. The mobile PET-CT unit will be located at the MelroseWakefield Medical Building at 888 Main Street, Wakefield and will operate one day per week (Proposed Project) as an Independent Diagnostic Testing Facility. The Applicant is a newly formed joint venture between MelroseWakefield Hospital and Shields, that replaces an existing contract with another imaging vendor for the same service. The total value of the Proposed Project is \$1,095,687.00; the Community Health Initiatives (CHI) contribution is \$54,784.35 to the Statewide fund.

This DoN application falls within the definition of DoN-Required Equipment and Services, which are reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

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Background: Tufts Medicine: Shields PET-CT, LLC and Application Overview

Background

The Applicant is a newly formed joint venture between Melrose Wakefield Hospital (MWH) and Shields, named Tufts Medicine: Shields PET/CT LLC, for the establishment of a licensed clinic to provide part-time mobile PET-CT diagnostic imaging services via a mobile medical imaging unit located at 888 Main Street, Wakefield. MWH currently offers local PET-CT services to its patients through a joint venture called Montvale PET-CT. The current contract with the Montvale PET-CT is ending in Summer 2023 and the Applicant seeks to fulfill the need for continued access to PET-CT services for the Patient Panel.

The relevant parties to the transaction are:

MelroseWakefield, formerly Hallmark Health, is a coordinated system of hospitals, physician practices and community-based services providing care for communities throughout north suburban Boston. The MelroseWakefield organization includes MWH, Lawrence Memorial Hospital of Medford; Hallmark Health Medical Center, Reading; Tufts MC Community Care; and Lawrence Memorial/Regis College School of Nursing.¹ MelroseWakefield is part of Tufts Medicine, which includes Tufts Medical Center, Circle Health (Lowell General Hospital), Tufts Medicine Integrated Network, and Tufts Medicine Care at Home. MWH is a general acute care hospital offering a wide range of services including expert cardiac care, 24-hour emergency care, wound care management, and maternity services with an on-site level II special care nursery. MWH is currently licensed to operate 232 beds, is supported by over 700 affiliated physicians, and has access to advanced, specialty care through its clinical affiliation with Tufts Medical Center.

Shields Healthcare Group, Inc. (Shields) was founded in 1972 and opened its first MRI center in 1986. Shields manages multiple facilities throughout New England, offering MRI and PET-CT services. Many of these sites are joint venture partnerships with community hospitals and operate as licensed clinics but remain in close proximity to the local hospital-partner, an arrangement which improves access to care and coordination of care.

Proposed Project

PET-CT services are currently offered at MWH through an arrangement with an existing imaging vendor. The contract is coming to an end and the Applicant is proposing to establish a licensed clinic to provide PET-CT services via a mobile medical imaging unit to ensure continued access to these imaging services for the Patient Panel. Shields is both a Member of the LLC that comprises the Applicant and is slated to serve as the entity responsible for the operational and management services of the Proposed Project, which will be located in a proximate location to the MWH campus². The construction activities related to this proposed project include constructing a small-scale addition to an existing building to accommodate a corridor, and a dock/vestibule for patients to access the mobile PET-CT.

Combined PET-CT is a dual-modality diagnostic imaging technology.³ The Applicant assesses and documents the need for continuation of the existing imaging services and future demand for such

¹ For more information, visit <https://www.melrosewakefield.org>

² The PET-CT site is approximately two miles away and less than a ten-minute drive from MWH.

³ PET provides images of bio-chemical metabolic activity in the body without the anatomical structural information that CT captures. CT provides 3D images with anatomic specificity of bones and tissues within the body. When overlaid, CT images aid in defining the precise location of any metabolic abnormality identified with PET. Both modalities have been in use for several decades. Performed

imaging services based on a historical volume of scans, the increasing age 60+ age cohort in Massachusetts that will experience increased risk for age-related conditions requiring the proposed imaging services, and the projected growth in demand for PET-CT services. The Applicant states through the Proposed Project, it will meet demand for PET-CT imaging services in a cost-effective manner.

Patient Panel⁴

The Applicant is a newly formed joint venture and does not have its own Patient Panel. The Applicant reviewed both MWH’s Patient Panel to demonstrate the need for the Proposed Project and historical utilization of PET-CT diagnostic services via MWH’s current Montvale PET-CT joint venture from fiscal year (FY)2019 to FY2021⁵. Staff determined that this is an acceptable way for the Applicant to define its Patient Panel. The Patient Panel data for FY2019-2021 are provided in Table 1 below. The Applicant notes a relative 5.41% decrease in the number of unique patients from 2019 to 2021, stating the decrease is both an anomaly and a derivative of the COVID-19 pandemic.

Table 1: MWH Patient Panel, FY2019-FY2021

	FY2019	FY2020	FY2021	% Change Rate FY19-FY21
Unique Patients	109,089	94,800	103,183	-5.4%

The Applicant provided demographic data for the Patient Panel, which is presented in Table 2. Staff notes the following observations about these data below:

- **Age:** Greater than 52% of the Patient Panel is in 50+ cohort. The Applicant notes that of the 50+ cohort, ~68% of unique patients were 60 years old or over.
- **Race/ Ethnicity:** The Patient Panel largely identifies as White (~77%), followed by Other/Unknown at 12%. Those who identify as Asian comprise 5.76% and those identifying as Black or African American comprise 4.59% of the Panel.
- **Patient Origin:** The Primary Service Area includes Malden, Medford, Melrose, Saugus, Wakefield, and Stoneham, which constitutes ~50% of patient origin.
- **Payer Mix:** The majority of patients served have commercial insurance (~45%), followed by Medicare (34%) and Medicaid (15%).

Table 2: Overview of MWH Patient Population FY21

	Total
Total Patients	103,183

simultaneously, the images provide a more accurate picture since there are no changes in patient positioning that would occur if the patient had to undergo each type of scan separately at different times on different units.

⁴ As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder. (1) If the Applicant or Holder has no Patient Panel itself, the Patient Panel includes the Patient Panel of the health care facilities affiliated with the Applicant.

⁵ Fiscal year is defined as the period from October 1 to September 30.

	Total
Gender	
Female	58.41%
Male	41.53%
Unknown ⁶	0.06%
Total	100.00%
Age	
0-49	47.09%
50+	52.91%
Total	100.00%
Race/Ethnicity	
American Indian or Alaskan Native	0.07%
Asian	5.76%
Black or African American	4.59%
Other/Unknown ⁷	12.13%
White	77.45%
Total	100.00%
Patient Origin	
Malden (02148)	12.48%
Medford (02153, 02155)	10.44%
Melrose (02176)	10.03%
Saugus (01906)	7.54%
Wakefield (01880)	7.42%
Stoneham (02180)	3.08%
Revere (02151)	1.53%
Everett (02149)	1.97%
Reading (01867)	3.62%
Winthrop (02152)	1.30%
North Reading (01864, 01889)	3.99%
Lynnfield (01940)	4.12%
Outside of Primary Service Area (PSA)	32.48%
Total	100.00%
Payer Mix	
Commercial	44.96%
Medicare	34.00%
Medicaid	15.00%
Other	2.59%
Dual ⁸	2.22%
Behavioral Health ⁹	1.23%
Total	100.00%

⁶ "Unknown" were either not captured or declined to choose from the binary options provided

⁷ Since Race and Ethnicity are self-reported, there may be an inclination by the patient to not participate in the answering of the question. Patients that may identify as having more than one race may opt to choose "Other/Unknown". Also, the "Office of Management and Budget" (OMB) defines "Hispanic or Latino" as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin regardless of race. Many patients that identify with an ethnicity that meets the OMB definition of "Hispanic or Latino" may choose "Other/Unknown" as their race.

⁸ "Dual" is defined as patients who are dually eligible for Medicare and Medicaid.

⁹ "Behavioral" is defined as insurances products that are behavioral health carve out utilized by several local and national insurers.

Factor 1: a) Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently addressed Patient Panel need for the Proposed Project.

Patient Panel Need

The Applicant attributes Patient Panel need for the Proposed Project to the following:

- a. Historical PET-CT Demand
- b. Aging Population
- c. PET-CT Demand Projections

Background: MWH currently provides access to on-site mobile PET-CT services through an agreement with an Alliance Imaging that will not be renewed. The current MWH-Alliance partnership is called Montvale PET-CT. The Applicant notes that within the Applicant’s Primary Service Area, the Montvale PET-CT is the only PET-CT imaging center offering lower cost Independent Diagnostic Facility (IDTF)¹⁰ rates. Currently, MWH offers PET-CT services two days per week for a total of 22 hours through a mobile unit in the hospital parking lot. The Applicant has established a joint venture with Shields to maintain access to high-quality imaging services for the Patient Panel one day per week for 10 hours, as demonstrated in Table 3.

Table 3: PET-CT Equipment Access

	Current PET-CT Access	Proposed Project Access
Location	41 Montvale Ave, Melrose	888 Main St, Wakefield
Days/ Week of Availability	Tues 6a-5p Thurs 6a-5p	One weekday (To Be Determined) 7a-5p
Hours of Availability	22	10

The Applicant notes that the Proposed Project will enhance existing imaging capabilities with the installation of a new Siemens Horizon mCT 16, 2018 model PET-CT imaging unit to replace an antiquated machine currently in use. The updated equipment has technological advances that allow for the same number of scans to be accomplished in one day versus two. The new machine will use of Time Of Flight (TOF) algorithms that allow for increased mass accuracy and mass resolution, greater sensitivity, rapid acquisition, and increased dynamic range, thus producing higher quality images in less time. The Applicant will use a two licensed technologist model, which increases efficiency of the non-imaging time during the appointments. The Applicant has also contracted with Subtle Medical to develop an Artificial Intelligence tool to reduce patient time on the scanner. These efficiencies will allow for the number of weekly scan appointments/availability to remain the same even though the service will operate on a more limited hourly schedule.

¹⁰ An IDTF is a facility that is independent both of an attending or consulting physician’s office and of a hospital.

a. PET-CT Historical Demand

The Applicant reviewed the total number of PET-CT scans referred to Montvale PET-CT for diagnostic imaging in FY19, FY20, and FY21. Table 4 demonstrates that the number of PET-CT scans referred to Montvale PET-CT grew by 16% from FY2019-FY2021 and the number of unique patients undergoing PET-CT scans increased by 18% from FY2019-FY2021.

Table 4: Historical PET-CT Volume

	FY2019	FY2020	FY2021	Change Rate (%) FY2019-FY2021
Total Scans	450	455	522	16%
Total Unique Patients	364	359	431	18%

The Applicant provided demographic information on patients referred to Montvale PET-CT for diagnostic imaging in FY2021, which is presented in Table 5 below. Utilization of PET-CT is heavily weighted to the 65+ population and about one third of the patients are from the Medford, Malden, and Melrose areas.

Table 5: Demographic Information for Unique Patients Referred to Montvale PET-CT (FY21)

	PET-CT Unique Patients
Patients	431
Age	
18-34	2%
35-44	2%
45-64	24%
65-74	36%
75-84	29%
85+	7%
Total	100%
Race	
Caucasian	89%
Asian	3%
African American/ Black	2%
Unknown/ Not Specified	6%
Total	100%
Patient Origin	
Medford	12%
Malden	12%
Melrose	10%
Saugus	9%
Wakefield	6%
Revere	6%
Everett	6%
Stoneham	4%
Reading	3%
Winthrop	2%

	PET-CT Unique Patients
Woburn	3%
All Other	27%
Total	100%

b. Aging Population. The Applicant asserts that need for continued access to PET-CT services is supported by an aging Patient Panel and an aging population in Massachusetts. The Patient Panel data in Table 2 shows that over half (~53%) of their Patient Panel falls in the 50+ age cohort. The historical PET-CT data in Table 5 also demonstrated that 72% of patients utilizing PET-CT fall in the 65+ age cohort. The Applicant further highlighted US Census data for the Towns of Melrose and Wakefield as Primary Service Area towns for MWH. As Table 6 demonstrates, these towns have higher percentages of the over 50 age cohort compared to Massachusetts.

Table 6: Melrose, Wakefield, and Massachusetts Statewide Census Data for Residents Over 50 Years Old

Age Range	Melrose	Wakefield	Massachusetts
50-59	14.5%	14.4%	14.1%
60-69	11.2%	13.5%	11.8%
70-79	8%	7.5%	6.9%
80+	4.9%	5%	4.3%
TOTALS	38.6%	40.4%	37.1%

Additionally, the Applicant cites UMass Donohue population projections which suggest that within the next 15-20 years, the largest part of the Commonwealth’s population growth will be attributable to residents within the 50+ age cohort, and residents that are 65+ will represent 21% of the Massachusetts population.^a Assuming the demographic trends within the city of Melrose and town of Wakefield continue to mirror that of the Commonwealth, it is expected that these areas will continue to see growth in the 50+ age cohort. Supporting this prediction is the Advisory Board Company’s (Advisory Board)¹¹ forecast that the MelroseWakefield Primary Service Area for people aged 65+ is projected to increase on average by 12.9% over the next five years. The Applicant asserts that an increasing aging population will contribute to an increasing demand for healthcare services in general, and a sustained need for PET-CT services which are used in the diagnosis and treatment of conditions seen in an aging population.

c. Demand Projections

¹¹ The Advisory Board Company is a research agency specializing in the healthcare industry.

The Applicant evaluated the growing demand for continued local access to PET-CT services. In Table 7, the Applicant cites projections by the healthcare business consultants Veralon to underscore the anticipated growth in demand for PET-CT services.¹²

Table 7: Projected Growth in Shields PET-CT Scans

	Year 2023	Year 2024	Year 2025	Year 2026	Year 2027	Year 2028
Total Scan Volume¹³	605	678	746	821	862	905

The Applicant also cites recent data from the Advisory Board to further demonstrate the need for PET-CT in the proposed Primary Service Area. The Advisory Board projects that demand for PET-CT services in the freestanding and the hospital-based outpatient departments combined within the Primary Service Area will grow by 8.5% over the next five years and 15.0% over the next ten years.

An aging population will be accompanied by a marked increase in the total number of patients with cancer,^b the majority of whom will require precise diagnostic imaging. The Applicant refers to the most recent Cancer Incidence City & Town Supplement from DPH’s Office of Data Management and Outcomes Assessment,¹⁴ which provides Standardized Incidence Ratios (SIR)¹⁵ for 23 types of cancers in the cities and towns of Massachusetts over a 5-year time frame. The Applicant highlights that the towns of Melrose and Wakefield have significantly higher rates of certain cancers among its residents compared to the statewide averages, as seen in Tables 8 and 9.

Table 8: Notable Standard Incidence Ratios (SIR) of Cancer in the City of Melrose

Cancer Type	Notable SIRs for Melrose	Percentage Higher than Statewide Average
Brain and Other Nervous System	Female: 138.8	Female: 38.8%
Breast	Female: 106.7	Female: 6.7%
Colon/Rectum	Male: 137.9 Female: 125.2	Male: 37.9% Female: 25.2%
Esophagus	Male: 120.0	Male: 20%
Larynx	Male: 161.8	Male: 61.8%
Leukemia	Male: 165.7	Male: 65.7%
Liver and Intrahepatic Bile Ducts	Female: 132.6	Female: 32.6%
Lung and Bronchus	Female: 101.2	Female: 1.2%
Melanoma of Skin	Female: 127.3	Female: 27.3%
Multiple Myeloma	Male: 115.1	Male: 15.1%

¹² This is referenced in the CPA Report, which used the Shields PET standard year over year growth trend from new PET starts with Shields since 2016.

¹³ Year over year % change starting in Year 2 is 12%, Year 3 is 12%; Year 4 is 10%; Year 5 is 10%; and Year 6 is 5%. For details, please see the Statement of Profit and Loss in the Appendix of the Veralon CPA Report.

¹⁴ Available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

¹⁵ An SIR of 100 indicates that a city/town’s incidence of a certain type of cancer is equal to that expected based on statewide average age-specific incidence rates. An SIR of more than 100 indicates that a city/town’s incidence of a certain type of cancer is higher than expected for that type of cancer based on statewide average annual age specific incidence rates

Non-Hodgkin Lymphoma	Male: 124.1 Female: 142.1	Male: 24.1% Female: 42.1%
Pancreas	Male: 146.4 Female: 111.2	Male: 46.4% Female: 11.2%
Stomach	Male: 129.2	Male: 29.2%
Uteri Corpus and Uterus, NOS	Female: 122.0	Female: 22.0%
All Sites/Types	Female: 103.9	Female: 3.9%

Table 9: Notable Standard Incidence Ratios (SIR) of Cancer in the Town of Wakefield

Cancer Type	Notable SIRs for Wakefield	Percentage Higher than Statewide Average
Bladder, Urinary	Female: 118.9	Female: 18.9%
Brain and Other Nervous System	Male: 138.4 Female: 126.6	Male: 38.4% Female: 26.6%
Breast	Female: 107.2	Female: 7.2%
Esophagus	Male: 113.7	Male: 13.7%
Kidney and Renal Pelvis	Female: 128.4	Female: 28.4%
Leukemia	Male: 144.1	Male: 44.1%
Lung and Bronchus	Female: 107.0	Female: 7.0%
Melanoma of Skin	Female: 150.3	Female: 50.3%
Non-Hodgkin Lymphoma	Female: 106.2	Female: 6.2%
Oral Cavity and Pharynx	Male: 105.2 Female: 109.5	Male: 5.2% Female: 9.5%
Thyroid	Male: 103.9	Male: 3.9%
All Sites/Types	Female: 101.2	Female: 1.2%

The Applicant states that higher than average instances of oncologic conditions support the need not only for continued access to PET-CT imaging services in this catchment area, but also supports the market predictions that the demand for PET-CT services will grow in accordance with the diagnostic and treatment needs of the Patient Panel.

Analysis

Staff concurs that the Proposed Project will support ongoing access to PET-CT services for the Patient Panel. The proposed siting of PET-CT imaging is designed to ensure appropriate access for the Patient Panel based on historical utilization of these imaging services and projected demand for PET-CT services. The volume of PET-CT scan demand is projected to increase by approximately 8.5% over the next 5 years after project implementation. The aging population and prevalence of oncological conditions in certain localities of the Primary Service Area further reinforces the need for access to imaging services to aid in the diagnosis and treatment of diseases that are often more prevalent in advancing age cohorts. Through the Proposed Project, the Applicant will sustain local access to high-quality imaging services for the Patient Panel. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1a.

Factor 1: b) Public Health Value, Improved Health Outcomes and Quality of Life; Assurances of Health Equity

In this section staff will assess if the Proposed Project adds measurable public health value in terms of improved health outcomes and quality of life for the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

Public Health Value, Health Outcomes, and Quality of Life

The Applicant states that through the Proposed Project, it will maintain timely access to imaging services, and this will promote patient care and patient experience. The Applicant asserts that both PET and CT are well established technologies that enable clinicians to appropriately diagnose and develop the most effective treatment plans earlier in the disease process across oncologic, cardiac, and neurologic specialties. Combined PET-CT scans help clinicians pinpoint abnormal metabolic activity and provide more accurate diagnoses than the two scans performed separately. The Applicant cites a wide variety of literature supporting the use of PET-CT scans in the treatment of these conditions and anticipates that the Proposed Project will provide the Patient Panel with continued access to integrated PET-CT services that will positively impact health outcomes, quality of life, and patient satisfaction.

The Applicant cites studies indicating that *delayed access* to healthcare services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.^c Conversely, *ease of access* improves quality of life for patients because early detection and treatment of diseases improves patient outcomes.^d The Applicant notes that satisfied patients are more likely to be compliant with their medical care plan, ultimately leading to improved outcomes and more efficient utilization of healthcare resources.^e

Analysis: Public Health Value, Health Outcomes, and Quality of Life

Staff concur that providing timely access to imaging services contributes to improved health outcomes and patient satisfaction. Advanced imaging can improve disease detection, allow for more accurate diagnosis and treatment, and avoid more invasive and costly procedures.^f Not having adequate access to advanced imaging leads to delays in diagnosis and treatment, which can negatively affect health outcomes. Staff confirms the ongoing need for continued access to PET-CT services, especially among the 50 and over age population, which comprises more than half of the Applicant's patient population. Risk for cancer, cardiovascular disease, and Alzheimer's (the leading causes of death in Massachusetts) increase with age, and consequently demand for the proposed imaging services is likely to increase with a growing aging population.^g

Health Equity and Social Determinants of Health (SDoH)

The Applicant states that it plans to ensure health equity to all populations, including those deemed underserved, and that the Proposed Project will not adversely affect accessibility of the Applicant's services for poor, medically indigent, and/or Medicaid eligible individuals. The Applicant accepts all forms of insurance and asserts that it will not discriminate based on ability to pay or payer source. Shields has price transparency tools so that all patients have information on current pricing, and they provide financial counselors for assistance in understanding insurance benefits. The Proposed Project will promote health equity and ensure equal access to PET-CT services for all of the Applicant's patients in the following ways:

- 1) **Language Access.** The Applicant plans to implement a translation services program using Language Line and InDemand as tools to address language barriers. Language Line provides phone and video interpretation services from professional linguists in more than 240 languages, 24 hours a day, 7 days a week. InDemand is an iPad-based system which offers medical interpreting solutions, allowing clinicians to provide their limited English proficient, deaf, and hard of hearing patients with access to the ability to understand their healthcare provider. The Applicant asserts that these solutions will eliminate language barriers for patients and ensure culturally appropriate care.
- 2) **Cultural Competence Training.** The Applicant notes that the population within the Primary Service Area of the Proposed Project reflects moderate diversity that necessitates implementation of commensurate, culturally appropriate support services to ensure improved patient experience. Accordingly, the Applicant states it will employ culturally competent staff and offer ongoing education and training in culturally and linguistically appropriate care.
- 3) **Social determinants of health (SDoH).** The Applicant pre-screens patients related to certain social determinants of health (SDoH) issues, specifically those issues that are relevant to an imaging appointment. In instances where patients need support to address social determinants of health, the Applicant offers access to services designed to facilitate improved care pathways influenced by social determinants of health. These tools are explored in greater detail in Factor 2.

Analysis: Health Equity and SDoH

The DoN Staff's review assessed the Proposed Project's impact on equitable access to care. The Applicant ensures that it will enable access for all patients regardless of patients' ability to pay and offer financial options as well as language interpreter services. The Applicant will offer staff trainings on culturally and linguistically appropriate services. Staff finds that the Applicant has sufficiently outlined a case for improved health outcomes and health equity. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1b.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

The Applicant states that the Proposed Project will support integrated care because patients will be able to continue to receive PET-CT services within the MHW Healthcare System. The Proposed Project will allow the Applicant to prevent a lapse in access to imaging services once the current agreement with the existing imaging vendor ends. A lapse in access to imaging services could result in patients traveling further distances for PET-CT imaging services. By offering continued local access to PET-CT services at the MelroseWakefield Medical Building as an IDTF clinic-based service, the Applicant aims to ensure timely access to optimized, low-cost, high-quality imaging services for MWH patients.

The Applicant asserts that Shields operational model allows for improved scheduling, workflow, technology, and customer service. There are several operational efficiencies that Shields is exploring through the optimization of Artificial Intelligence (AI) and software to reduce manual efforts. Three examples that are in the beta phases of development are: 1) Plenful, which is an automation platform that cleans and connects all text-based healthcare data; and 2.) Shields has also contracted with Subtle

Medical to develop an AI tool to reduce patient time on the scanner. 3.) Shields has enlisted outside development support to continue to automate the administrative activities and improve the patient experience. These operational optimizations drive efficiency, which in turn drives down cost to provide care, allowing Shields to operate effectively under lower IDTF rates.

With MWH as a part owner of the Applicant, imaging services will be fully integrated with MWH's Health Information System. 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 MWH's patients will facilitate quick and easy access to patient images and reports.

Analysis

Staff finds that the Applicant's care coordination and use of technology infrastructure will contribute positively to efficiency, continuity, and coordination of care. Review of the literature points to evidence which suggests access to integrated health information technology systems directly impacts health outcomes through reducing fragmentation and improving coordination among care providers.^h Similarly other studies show that integrated health information technology systems directly affect health outcomes, as access to a single, integrated health record, can reduce errors, improve patient safety, and support better patient outcomes.ⁱ The Health Information System supports communication between professionals on the care team that can foster better collaboration. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1c.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with the following government agencies that have licensure, certification, or other regulatory oversight:

- Community Health Planning and Engagement Specialist, Bureau of Community Health and Prevention, Massachusetts Department of Public Health
- Health Care Interpreter Services Coordinator, Massachusetts Department of Public Health
- Determination of Need Analyst, Bureau of Health Care Safety & Quality, Massachusetts Department of Public Health

As a result, Staff finds that the Proposed Project meets the requirements of Factor 1d.

Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel

The Department's Guideline¹⁶ for community engagement defines "community" as the Patient Panel and requires that, at minimum, the Applicant must "consult" with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."¹⁷

The Applicant published a legal notice on the Shields website to raise awareness to all patients, family members, local residents, and resident groups of the Project and efforts to address access and capacity

¹⁶ [Community Engagement Standards for Community Health Planning Guideline.](#)

¹⁷ [DoN Regulation 100.210 \(A\)\(1\)\(e\).](#)

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

Presentation to MelroseWakefield Hospital’s Patient and Family Advisory Council (PFAC)

The Proposed Project was presented at MWH’s Patient Family Advisory Committee (PFAC) on June 28, 2022, with fifteen (15) members in attendance. The PFAC is comprised of current and former patients of the hospital and their family members as well as caregivers and staff of the hospital. The presentation to the PFAC offered members an overview of the current state of imaging services and the continued need for PET-CT at the MelroseWakefield Medical Building location once the current imaging vendor relationship expires in the summer of 2023. The presentation reviewed how the Proposed Project will benefit current and future patients. The PFAC members had positive reactions to the presentation of the Proposed Project and did not voice any serious concerns. Participants were engaged throughout the presentation and made several comments that generally focused on ease of access, the ease of scheduling, and the benefits of local care, as well as the advantages of new imaging equipment.¹⁸ Clarification was sought regarding the impact to the neighborhood and whether there would be additional traffic and/or noise – both matters are not contemplated to be an issue with the Proposed Project.

Presentation at a Community Meeting

The Proposed Project was also presented at a community meeting on September 8, 2022, with thirteen (13) individuals in attendance. The group was comprised of MWH patients and residents of Wakefield. The presentation generally covered the same points as the PFAC presentation. Attendees at the community meeting also had a positive reaction to the Proposed Project and did not voice any concerns. There was a question about radiation safety and a comment about local street access.

Analysis

Staff reviewed the information on the Applicant’s community engagement and finds that the Applicant has met the required community engagement standard of Consult in the planning phase of the Proposed Project. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1e.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

The Applicant asserts that the Proposed Project will compete on the basis of competition in the Massachusetts healthcare market based on price, TME, provider costs, or other recognized measures of healthcare spending based on the following:

- The clinic will operate as an IDTF, which is reimbursed at lower rates than hospital-based imaging.^j
- Shields’ operating model allows for improved scheduling, workflow, technology, and customer service, which the Applicant asserts will have a positive impact on the cost to provide care.
- The Proposed Project will allow the Applicant to continue to provide PET-CT services without a significant capital expenditure.

¹⁸ Current imaging equipment is 15+ years old.

As previously noted, historical need for PET-CT imaging and projections of future demand demonstrate the MWH catchment area has a continued need for access PET-CT services. The Applicant notes research suggesting that providing ease of access to care can reduce healthcare utilization and spending.^k The Applicant further states that studies have detailed high costs for unnecessary repeat imaging^l which could be improved through more appropriate use of all imaging, including PET-CT, and better integration of services. For the Proposed Project, the Applicant states that preventing overuse and improving service integration can lead to lower operational overhead and lower healthcare spending, which could, in turn, reduce TME.

Analysis

Staff notes that the Applicant seeks to replace an existing service that is currently provided through a different imaging vendor to provide access to imaging services that correspond to historical utilization. The Proposed Project has the potential to reduce costs by providing imaging services at lower costs compared to hospital-based imaging services. While advanced imaging improves clinical care, it is also the source of overuse and added healthcare costs.^m The Applicant reports that it will have internal protocols to assess and address appropriate use of imaging and minimize overuse, utilizing the Centers for Medicare & Medicaid Services (CMS) appropriate use criteria (AUC) and clinical decision support (CDS) tools once the mandate for these tools goes into effect. Staff finds that, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending have been met. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1f.

Summary, FACTOR 1

As a result of the information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project meets Factor 1. The Applicant proposed specific outcome and process measures to track the impact of the Proposed Project which Staff has reviewed, and which will become a part of the reporting requirements. The measures are described in Appendix 1 below.

Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation

For Factor 2, the Applicant must demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation beyond the Patient Panel.

Cost Containment

The Applicant states that the Proposed Project seeks to align with the Commonwealth's goals for cost containment by supporting continued access to high-quality PET-CT services in a cost-effective setting for the Patient Panel. As previously detailed, the Applicant states that deploying more advanced state of the art technology will decrease historic scan times. In addition, higher quality imaging reduces the need for repeat scans. State of the art imaging equipment allows Shields to use a part time mobile unit, with costs shared across multiple customers to provide access in less time. As previously mentioned, the clinic will provide PET-CT imaging locally and will operate as an IDTF, where

reimbursement rates are lower than those of a hospital. In addition, Shields has no fixed site overhead adding to the cost of services. Shields has a specialized PET-CT team scheduling patients, an efficiency that allows for more customers to be added to the system, which in turn reduces the overall cost. The Applicant states that the Proposed Project will help promote faster diagnosis, intervention, and treatment for their Patient Panel, which supports improving quality of care and thus reducing overall health care costs.

Analysis: Cost Containment

Staff finds that the Applicant has adequately explained how it aligns with the Commonwealth's cost containment goals through the expansion of high-quality, low-cost imaging services provided locally. The Proposed Project seeks to provide continued access to imaging services within a lower-cost reimbursement setting and improve the quality of such services. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the cost containment component of Factor 2.

Improved Public Health Outcomes

The Applicant asserts that access to PET-CT services will allow clinicians to determine appropriate treatment options that will impact overall health outcomes in a time effective manner. The Applicant notes that the updated equipment has a few advantages over the current unit which include:

1. Time of Flight (TOF) technology – TOF offers higher image quality for more accurate detection of masses and lesions.¹⁹
2. Higher CT slice²⁰ configuration, which helps ensure optimum image quality.
3. Dose control technology, which allows for optimization of a personalized dosage via the as low as reasonably achievable (ALARA) principle.

The Applicant posits that providing needed care more efficiently will improve public health outcomes and patient experience. The Proposed Project provides continued access to local PET-CT imaging services at a low-cost and community clinicians will have the necessary tools to appropriately diagnose and treat patients, thereby improving health outcomes for the Patient Panel. As the patient population ages, the demand for imaging services will likely grow in conjunction with the need to treat age-related conditions. The Applicant declares that creating streamlined pathways for access to care will improve overall public health outcomes.

Analysis: Public Health Outcomes

Staff finds that the Proposed Project is planned to ensure timely access to more accurate imaging services has the potential to improve health outcomes and patient satisfaction. Timely access can reduce delays in diagnosis and treatment that can adversely impact health outcomes. As a result, DoN Staff can conclude that the Proposed Project will likely meet the Public Health Outcomes component of Factor 2.

Delivery System Transformation

The Applicant has plans to support patients' needs around social determinants of health (SDoH) and has a SDoh screening process in place for issues related to imaging appointments. In instances where

¹⁹ A more accurate system gives you better information, and better information makes it easier to declare a more definitive diagnosis and pursue a more specialized treatment plan.

²⁰ PET-CT scans create cross-sectional images (slices).

patients need support to address SDoH's, the Applicant offers access to services designed to facilitate improved care pathways influenced by social determinants of health. Specifically, the Applicant plans to implement numerous patient access tools, such as preregistration functionality, a cost transparency application, linkages to financial counselors, culturally competent staff, and a translation services program. The Applicant states that these amenities facilitate easier to access care for vulnerable and at-risk populations.

The Applicant states that PET-CT service appointments and results will become embedded in MWH's established cancer care continuum and cardiac rehabilitation programs. These programs employ collaboration among a multitude of medical specialists as well as social work, dietary support, and wellness services. MWH's design of care navigation seeks to address barriers to care and long-term connections to wellness offerings.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant conducts pre-screens on relevant SDoH factors, and if made aware of a SDoH issue, staff will provide linkage to an appropriate community-based support to meet the identified need. The Applicant also has a system of embedding the imaging services into its already established multidisciplinary patient wellness programs to promote linkage to community resources for its PET-CT patients. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the system delivery transformation component of Factor 2.

Summary, FACTOR 2

As a result of information provided, staff finds that the Proposed Project has sufficiently met the requirements of Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and this Factor will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis

Under factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such finding must be supported by an analysis by an independent CPA.

The CPA examined a range of documents and information in developing its report including Tufts Medicine: Shields PET/CT, LLC (TM: Shields) six-year Financials, prepared May 12, 2022, volume assumptions, payer mix and per-case reimbursement assumptions, the Shield's company website, and

the MelroseWakefield website. Additionally, it calculated key liquidity and operating metrics²¹ to assist in determining reasonableness of the Applicant's assumptions.

Revenues

Prospective volume for TM: Shields was based on its historical volume trends plus an annual growth factor ranging from 5% to 12% annually. The prospective revenue per scan rates were determined based on actual 2021 payer mix and rates of a similar market location to MelroseWakefield.

The CPA report determined that the prospective TM: Shields volumes provided by Management were reasonable. Management provided supporting information used to prepare the Financials, including the payer mix of a similar market location to MelroseWakefield. Management based the budgeted reimbursement rate on a calculated weighted average of this location's payer mix and reimbursement rates. The CPA determined the reimbursement rates provided by Management were reasonable for TM: Shields.

The CPA found that the revenue growth estimated by Management reflects a reasonable estimation of future revenue of TM: Shields based on estimated volumes and reimbursements.

Expenses

Operating expenses include support services, billing, and bad debt expense for TM: Shields. Management projected bad debt expenses that are notably higher in 2023 to account for Medicare and Medicaid services that are not anticipated to be reimbursable for the first month of operations for the Applicant until accreditation is obtained from the American College of Radiology. The CPA calculated the compound annual growth rate (CAGR) for 2024 through 2028 of 7.6 % for the Applicant. 2023 was not included in the CAGR calculation due to the previously cited higher bad debt expenses.

Facilities and equipment-related expenses include equipment-related expenses, depreciation, and other facility & equipment expenses. No facilities-related expenses were projected in 2023 through 2028 and equipment-related expenses remain steady during the same time period.

Service-related expenses include FDG (fludeoxyglucose) charges²², specialty isotope, and other service-related expenses. These expenses are projected to increase steadily between 2023 and 2028, representing a CAGR of 9.2%.

Salaries and benefits include radiology, technologists, and operations expense. The CPA calculated a CAGR of 9.3% from 2023 through 2028 and found this to be a reasonable assumption.

SG&A expenses include support services, management fees, and other SG&A expenses. The CPA calculated a CAGR of 6.6% from 2024 through 2028. 2023 was not included in the CAGR calculation due to the estimated start-up costs of initiating operations.

The CPA noted that there was no interest expense for the Applicant.

²¹ These are standard financial metrics used in determining the financial health and feasibility of an Applicant. Liquidity ratios measure the quality and adequacy of assets to meet current obligations as they come due. Operating metrics are used to assist in the evaluation of management performance. Additionally, certain metrics can be applicable to multiple categories.

²² A contrast agent most commonly used in performing PET-CTs

The CPA found that the prospective expenses did not warrant any additional adjustment and are reasonable.

Capital Expense and Cash Flows

The CPA reviewed the capital expenditures and future cash flows to determine whether sufficient funds would be available to sustain the operation of the Applicant. For the Applicant, there are \$25,000 in capital asset acquisitions in 2023. There are no capital expenditures expected from 2024 through 2028. Accordingly, The CPA determined that the prospective capital requirements and resulting impact on the cash flows are reasonable.

Feasibility

The CPA analyzed the Financials and the associated Key Metrics and determined both to be based on reasonable assumptions. Based on a review of the Applicant's relevant documents, the CPA determined the Financials are based upon feasible assumptions. Accordingly, the CPA concluded that the Financials are feasible and sustainable and not likely to have a negative impact on the Patient Panel or result in a liquidation of assets of the Applicant.

Analysis

Staff is satisfied with the CPA's analysis of Applicants decision to proceed with the Proposed Project. As a result, Staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

Factor 5: Assessment of the Proposed Project's Relative Merit

Evaluation of 105 CMR 100.210(A)(5) 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.

The Applicant considered and rejected two alternatives to the Proposed Project.

Alternative Option 1: No new vendor contract with no identified PET-CT service provider. The Applicant considered not establishing a new vendor partnership to replace the current PET-CT imaging vendor once the contract expires in the summer of 2023, noting that they would send patients to any available PET-CTs throughout the region. This was rejected because it would overall reduce the quality of care, patient access, and continuity of care. Discontinuation of a diagnostic imaging vending partnership would result in insufficient access, which may increase the risk of poor health outcomes and health disparities. While no additional capital expenses would be incurred in the short term, this option would result in poor care coordination and barriers to accessing needed imaging services for the Patient Panel.

Alternative Option 2: No new vendor contract, imaging services performed at Shields PET-CT at Tufts Medical Center. The Applicant considered and rejected the option of not establishing a new vendor partnership to provide patients with continued local access to PET-CT services and to instead refer all

patients meeting the clinical protocols to Shields PET-CT at Tufts Medical Center located at 800 Washington Street in Boston. This alternative would force those patients to travel for the service, thus limiting local access for the Patient Panel. It is unlikely that there would be additional operating costs incurred directly by the Applicant. However, patients referred to Shields PET-CT at Tufts Medical Center may present an operational burden that could translate into increased operating costs for the Applicant's sister corporation, due to increased appointment volume and the overtime that would likely be required for clinicians/technicians to accommodate the displaced patients' imaging needs.

Analysis

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to the potential alternative. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 5.

Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline

Summary and relevant background and context for this application: This project is for DoN-regulated equipment acquired by a non-hospital entity, so the Applicant will contribute the full CHI contribution to the Massachusetts Statewide Funds.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project and recommends that the Commissioner approve this Determination of Need, subject to all applicable Standard and Other Conditions.

Other Conditions

1. The total required CHI contribution of \$54,784.35 will be directed to the Massachusetts Statewide Community Health Fund.
2. To comply with the Holder's obligation to contribute to the Massachusetts Statewide Community Health Funds, the Holder must submit the payment, a check for \$54,784.35, to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - i. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
 - ii. The Holder must promptly notify DPH (CHI contact staff) when payment has been made.

Payment should be sent to:
Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: Ms. Bora Toro

The Holder shall provide, in its annual report to the Department, the following outcome measures. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12). Reporting will include a description of numerators and denominators.

- i. **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 around the wait time for services.

Projections: As the Proposed Project is to establish a new clinic, baseline will be established following one full year of operation.

Monitoring: Any category receiving a less than exceptional rating (satisfactory level) will be evaluated quarterly and policy changes shall be instituted.

- ii. **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 forwarded to the medical records department and follow-up will be conducted to the referring physician. The radiologist will be available to answer any questions.

- i. **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. Given that the PET-CT equipment will only be available one-day per week, the next opportunity for a scan would be seven days later.

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: Baseline: 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.

ii. **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.

iii. **Provider Satisfaction – Value Assessment:** Ensuring provider satisfaction with PET-CT scans and their overall value when treating patients is necessary to assess the impact on care for patients. The Applicant will survey referring physicians to validate scan utility.

Measure: Confirmation with referral physician about the utility of PET-CT scans.

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

Monitoring: PET-CT referral physician population will be queried to validate scan utility via survey

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