STAFF REPORT TO THE COMMISSIONER				
FOR A DETERIN	INATION OF NEED			
Applicant Name	UMass Memorial MRI and Imaging Center,			
Applicant Name	LLC			
Applicant Address	700 Congress Street, Suite 204			
Applicant Address	Boston, MA 02109			
Filing Date	November 16, 2022			
Type of DoN Application	Substantial Change in Service, DoN-required			
Type of DoN Application	Equipment			
Total Value	\$380,687.00			
Project Number	UMMIC-22062409-RE			
Ten Taxpayer Group (TTG)	None			
Community Health Initiative (CHI)	\$19,034.35			
Staff Recommendation	Approval			
Delegated Review	Commissioner Approval			

Project Summary and Regulatory Review

UMass Memorial MRI & Imaging Center, LLC (Applicant) submitted a DoN Application for a Substantial Change in Service to establish a licensed clinic to provide part-time mobile positron emission tomography (PET) — computed tomography (CT) (PET-CT) diagnostic imaging services on the UMass Memorial Health — Marlborough Hospital campus at 157 Union Street, Marlborough, MA. The Applicant is a joint venture between UMass Memorial Health Ventures, Inc. and Shields Healthcare of Worcester, LLC. The capital expenditure for the Proposed Project is \$380,687; the Community Health Initiatives (CHI) contribution is \$19,034.35.

This DoN application falls within the definition of Substantial Change in Service, 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.

Table of Contents

Application Overview	3
Patient Panel	4
Factor 1: a) Patient Panel Need	6
Factor 1: b) Public Health Value, Improved Health Outcomes And Quality Of Life; Assurances Of Hea	
Factor 1: c) Efficiency, Continuity of Care, Coordination of Care	13
Factor 1: d) Consultation	14
Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel	14
Factor 1: f) Competition On Price, Total Medical Expenses (TME), Costs And Other Measures Of Hea	
SUMMARY FACTOR 1	16
Factor 2: Cost Containment, Improved Public Health Outcomes and Delivery System Transformation	n 16
SUMMARY for FACTOR 2	17
Factor 3: Relevant Licensure/Oversight Compliance	17
Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis	17
Factor 5: Assessment of the Proposed Project's Relative Merit	20
Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application	20
Findings and Recommendations	21
Appendix I: Reporting Measures	22
REFERENCES	25

Application Overview

The relevant parties to the transaction are:

UMass Memorial MRI & Imaging Center, LLC (Applicant). A joint venture between UMass Memorial Health Ventures, Inc. and Shields Healthcare of Worcester, LLC developed for the purposes of owning and operating diagnostic radiological imaging facilities utilizing magnetic resonance imaging (MRI), PET/CT, and other advanced imaging equipment. The Applicant operates Shields MRI at UMass Memorial Shrewsbury Street (Shields MRI at UMass Memorial) with two mobile medical satellite clinics and two medical satellite clinics across Fitchburg and Worcester.

Shields. A joint venture partner and entity responsible for the operational and management services of the Proposed Project. Shields owns and operates more than 40 MRI and PET-CT facilities throughout New England, of which many are joint venture partnerships with community hospitals. Most locations operate as licensed clinics and are often located on campus or proximate to the local hospital, which the Applicant states enables coordinated and accessible care.

Marlborough Hospital. A member of UMass Memorial Health Care, and site of the Proposed Project. A 79-bed community-high public payer (HPP) hospital located in Marlborough providing a range of inpatient and outpatient medical, surgical, and ancillary services. Services include: 24/7 emergency care; comprehensive cancer care services; general, minimally invasive, and orthopedic surgery; diagnostic imaging; medical oncology and radiation oncology; and a behavioral health unit. Marlborough Hospital is a designated Primary Stroke Service (PSS) hospital by the Department of Public Health. The Applicant notes a 2016 report produced by the Massachusetts Health Policy Commission, stating that only 43 of the 351 cities and towns in Massachusetts are home to a community hospital, and Marlborough is one of them.

Proposed Project

The Applicant currently provides PET-CT imaging services in Worcester and Fitchburg.² The Applicant states that Marlborough Hospital patients travel to one of these sites to obtain PET-CT services. The Applicant proposes to install one PET-CT unit on the Marlborough Hospital campus to operate one day per week using an already existing and serviceable mobile pad at Marlborough Hospital. Patients would enter the hospital radiology department and then enter the mobile environment that is temporarily attached to the building and enclosed from the outside elements. The Proposed Project will allow Marlborough Hospital patients to obtain PET-CT services onsite at Marlborough Hospital thereby meeting existing and future demand for PET-CT services, improving access to integrated imaging services, and improving patient

¹ Community - High Public Payer (HPP) are community hospitals that are disproportionately reliant on public revenues by virtue of a public payer mix of 63% or greater. Public payers include Medicare, Medicaid, and other government payers, including the Health Safety Net.

² The Applicant states that there are 20.78 miles from Fitchburg to Marlborough in southeast direction and 25 miles by car following the I-495 S route. Additionally, Fitchburg and Marlborough are 35 minutes far apart if you drive non-stop. Distance Between Cities: https://www.distance-cities.com/distance-fitchburg-ma-to-marlborough-ma

experience. Additionally, the clinic will be licensed and reimbursed as an Independent Diagnostic Testing Facility (IDTF), and thus will be reimbursed at rates that are lower than hospital-based rates and in so doing provides a cost-effective option for PET-CT imaging services.

Patient Panel³

The Applicant relied on both UMass Memorial Health Care's (UMMHC) Patient Panel data and Marlborough Hospital's patient population data to demonstrate need for the Proposed Project because; Marlborough is part of the UMMHC system, and because the proposed PET-CT services will be located at Marlborough Hospital. Staff determined that this is an acceptable way for the Applicant to define its Patient Panel. The Applicant provided Patient Panel data and patient population data for fiscal years (FYs) 2019-2021. This is shown in Tables 1 and 2.

Table 1: UMMHC Patient Panel

FY19	FY20	FY21	Change Rate % FY19-FY21
371,488	345,864	393,429	6%

Table 2: Marlborough Hospital Patient Population

FY19	FY20	FY21	Change Rate %
			FY19-FY21
37,326	38,209	48,292	29%

Table 3 shows a comparison of the UMMHC and Marlborough Hospital patient populations, which are very similar. Staff note the following observations about these data below:

- Age The majority of UMMHC and Marlborough Hospital patients are ages 18-64; the age 65 and old population comprises almost 21% of the UMMHC patient population and 25% of the Marlborough Hospital patient population.
- Race. The majority of UMMHC (76%) and Marlborough Hospital (83%) patients identify as White.
- **Ethnicity.** A slightly larger percent of the UMMHC patient population identify as Hispanic (15%) than the Marlborough Hospital patient population (13.5%).
- **Primary Service Area.** The majority of UMMHC (90%) and Marlborough Hospital (91%) of patients originate from Central Massachusetts.

4

³ 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...(2) If the Proposed Project is for a new facility and there is no existing patient panel, Patient Panel means the anticipated patients.

⁴ Fiscal year is October to September.

Table 3: Overview of UMMHC and Marlborough Hospital Patient Populations⁵

Female 44.4% 41.7% Unknown 0.1% 0.1% Total 100% 100% Age 0-17 18.4% 8.9% 18-64 60.4% 66.3% 65+ 21.2% 24.8% Unknown 0% 0% Total 100% 100% Race American Indian or Alaska Native 0.2% 0.1% Asian 3.8% 5.5% Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander Multiracial 6/Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity Hispanic or Latino 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Unknown 2.7% 1.4% Unknown 2.7% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin 7.8 Central Mass 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 5.0% 6.9% Western Mass 2.3% 0.3%	FY21	ИММНС	Marlborough Hospital
Male 55.5% 58.2% Female 44.4% 41.7% Unknown 0.1% 0.1% Total 100% 100% Age	Patients	393,429	48,292
Female 44.4% 41.7% Unknown 0.1% 0.1% Total 100% 100% Age	Gender		
Unknown	Male	55.5%	58.2%
Total 100% 100% Age	Female	44.4%	41.7%
Age 0-17 18.4% 8.9% 18-64 60.4% 66.3% 65+ 21.2% 24.8% Unknown 0% 0% Total 100% 100% Race	Unknown	0.1%	0.1%
0-17 18.4% 8.9% 18-64 60.4% 66.3% 65+ 21.2% 24.8% Unknown 0% 0% Total 100% 100% Race American Indian or Alaska Native 0.2% 0.1% Asian 3.8% 5.5% Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander 0.0% 0.0% Multiracial ⁶ /Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 13.5% 13.5% Hispanic or Latino 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 2.0% 6.9% Central Mass 5.0% 6.9% <td>Total</td> <td>100%</td> <td>100%</td>	Total	100%	100%
18-64 60.4% 66.3% 65.5	Age		
Duknown	0-17	18.4%	8.9%
Unknown 0% 0% Total 100% 100% Race	18-64	60.4%	66.3%
Race 100% 100% American Indian or Alaska Native 0.2% 0.1% Asian 3.8% 5.5% Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander 0.0% 0.0% Multiracial ⁶ /Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 89.6% 91.1% Central Mass 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	65+	21.2%	24.8%
Race American Indian or Alaska Native 0.2% 0.1% Asian 3.8% 5.5% Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander 0.0% 0.0% Multiracial ⁶ /Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Unknown	0%	0%
American Indian or Alaska Native 0.2% 0.1% Asian 3.8% 5.5% Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander 0.0% 0.0% Multiracial ⁶ /Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 2 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Total	100%	100%
Asian 3.8% 5.5% Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander Multiracial ⁶ /Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity Hispanic or Latino 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} Central Mass 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Race		
Black or African-American 5.9% 3.3% Native Hawaiian or Other Pacific Islander 0.0% 0.0% Multiracial 6/Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity	American Indian or Alaska Native	0.2%	0.1%
Native Hawaiian or Other Pacific Islander 0.0% 0.0% Multiracial ⁶ /Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 2.7% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Asian	3.8%	5.5%
Islander	Black or African-American	5.9%	3.3%
Multiracial 6/Other/Unknown 13.5% 7.6% White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin 7,8 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Native Hawaiian or Other Pacific	0.0%	0.0%
White 75.7% 82.7% Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Hispanic or Latino 80.7% 83.6% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Islander		
Declined to Answer 0.8% 0.8% Total 100% 100% Ethnicity 15.0% 13.5% Hispanic or Latino 80.7% 83.6% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Multiracial ⁶ /Other/Unknown	13.5%	7.6%
Total 100% Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 2.3% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	White	75.7%	82.7%
Ethnicity 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Declined to Answer	0.8%	0.8%
Hispanic or Latino 15.0% 13.5% Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 2 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Total	100%	100%
Not Hispanic or Latino 80.7% 83.6% Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} 2.3% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Ethnicity		
Declined to Answer 1.6% 1.4% Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8} Central Mass 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Hispanic or Latino	15.0%	13.5%
Unknown 2.7% 1.4% Total 100% 100% Patient Origin ^{7,8}	Not Hispanic or Latino	80.7%	83.6%
Total 100% Patient Origin ^{7,8} 89.6% 91.1% Central Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Declined to Answer	1.6%	1.4%
Patient Origin ^{7,8} Central Mass 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Unknown	2.7%	1.4%
Central Mass 89.6% 91.1% Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Total	100%	100%
Eastern Mass 5.0% 6.9% Western Mass 2.3% 0.3%	Patient Origin ^{7,8}		
Western Mass 2.3% 0.3%	Central Mass	89.6%	91.1%
	Eastern Mass	5.0%	6.9%
Out of State 3.2% 1.7%	Western Mass	2.3%	0.3%
	Out of State	3.2%	1.7%

⁵ Numbers are rounded to the nearest tenth.

⁶ In the demographic category known as "Multi Racial," the patient count was <11. Therefore, those patients were accounted for in the "Other/Unknown" demographic category to ensure patient privacy.

⁷ UMMHC's Primary Service Area includes Southbridge, Sturbridge, Charlton, Dudley, Wales, Webster, Holland, and Fiskdale. Marlborough Hospital's Primary Service Area includes Hudson, Northborough, Westborough, Berlin, Framingham, Clinton, Southborough, Bolton, and Shrewsbury.

⁸ **Central Mass** is defined as all of Worcester County and the northwest corner of Middlesex County. **Eastern Mass** is defined as the Greater Boston, Cambridge, and South Shore, Cape Cod & Martha's Vineyard service areas. **Western Mass** is defined as Franklin, Hampshire, Hampden, and Berkshire counties.

Total	100%	100%
Payer Mix		
Commercial PPO/Indemnity	3.0%	0.9%
Commercial HMO/POS	26.7%	28.5%
MassHealth	17.5%	13.4%
Managed Medicaid	6.4%	8.0%
Commercial Medicare	14.8%	16.1%
Medicare FFS	28.4%	28.5%
All other		
(e.g. HSN, self-pay, TriCare)	3.2%	4.5%
Total	100%	100%

Factor 1: a) Patient Panel Need

Background

Currently, Marlborough Hospital patients travel out of Marlborough to access PET-CT services; most often, imaging is sought in Worcester, Fitchburg, and Boston. This can lead to fragmented care, and delayed diagnosis and treatment. The Applicant states that because PET-CT services do not currently exist at Marlborough Hospital, it relied on assumptions that were derived from referral volume from the top ten primary zip codes for Marlborough Hospital multiplied by the market share per zip code, as provided by the American Hospital Directory to estimate Patient Panel Need. The Applicant identified 88 Marlborough Hospital patients who received PET-CT services in Worcester, and nine who received PET-CT services in Fitchburg in the last calendar year, but the Applicant notes that this is a small subset of the larger number of patients who received or should have received PET-CT services. Through the Proposed Project, the Applicant will locate PET-CT services on the Marlborough Hospital campus and support local access to PET-CT services for the Patient Panel.

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

- Historical Volume Demand
- Increasing Aging Population
- Increase in age-related oncologic and cardiac conditions
- Projected Demand for PET-CT Services
- 1. Historical Volume. The Applicant asserts that need for local access to PET-CT services is demonstrated in historical volume demand, which is defined as the volume of patients who met the clinical protocols for PET-CT imaging. Research supports the use of PET-CT in oncology and cardiology. The most common use of PET-CT is in the detection of cancer and the evaluation of cancer treatment. PET-CT scans are performed to detect cancer and/or make a diagnosis, to determine whether a cancer has spread in the body, to assess the

⁹ PET/CT amalgamates the functional information of PET with the structural details of the CT scan, thus greatly aiding in accurate staging, therapy response assessment and early detection of recurrent disease.

effectiveness of treatment, and to determine if a cancer has returned after treatment.^b Additionally, PET-CT scans are used to evaluate the heart for disease and to determine appropriate treatment.^c

To demonstrate need for the Proposed Project, the Applicant provided the number of patients treated at Marlborough Hospital during the last three fiscal years, who had an underlying oncologic or cardiac condition This is shown in Tables 4 and 5. In Table 4, total visit volume refers to the number of patients treated at the Marlborough Hospital Cancer Clinic & Marlborough Hospital Radiology Oncology Department. Table 5 shows that the total number of patients with oncologic and cardiac diagnoses increased by 8.9% between FY19 and FY21. The Applicant expects increasing need for local access to PET-CT services as the number of patients treated for oncologic and cardiac-related conditions continues to increase.

Table 4: Oncologic Visit Volume

Fiscal Year	Total Visit Volume	Unique Patients treated	% of Total Visit Volume
	Marlborough Hospital	for an	Marlborough Hospital
	Cancer Clinic &	Oncological-related	Cancer Clinic & Marlborough Hospital
	Marlborough Hospital	Condition	Radiology Oncology Department
	Radiology Oncology	Marlborough Hospital	
	department 10	Cancer Clinic &	
		Marlborough Hospital	
		Radiology Oncology	
		Department	
FY19	1,665	740	44%
FY20	1,702	735	43%
FY21	2,465	966	39%

Table 5: Demand for PET-CT Services

Fiscal Year	Marlborough Hospital Patients treated for a cardiac-related diagnosis	Marlborough Hospital Cancer Clinic & Marlborough Hospital Radiology Oncology Department Patients Treated for an oncological- related diagnosis	Total Marlborough Hospital patients treated for oncological/cardiological-related diagnoses
FY19	2,071	1,655	3,736
FY20	1,583	1,702	3,285
FY21	1,602	2,465	4,067
Change Rate % (FY19-FY21)			8.9%

The Applicant states that the Advisory Board, a consulting firm that uses a combination of research, technology and consulting to improve the performance of health care organizations,

¹⁰ The number of patients treated at the Marlborough Hospital Cancer Clinic & Marlborough Hospital Radiology Oncology department, not all patients treated across Marlborough Hospital.

projects demand for PET-CT services within the primary service area (PSA) will increase by 8.9% over the next five years and will increase by 15.7% over the next 10 years. ¹¹ The PSA includes the following zip codes and corresponding towns/cities: Marlborough (01752); Hudson (01749); Northborough (01532); Westborough (01581); Berlin (01503); Framingham (01701); 01510 Clinton (01510); Southborough (01772); Bolton (01740); and Shrewsbury (01545).

2. Increasing aging population

The Applicant states that a growing aging population within Massachusetts will increase demand for PET-CT services. Statewide projections from UMass Donahue Institute project population growth within residents age 50 and older to be the largest part of the Commonwealth's population growth, and residents aged 65 and older will represent 23% of the Massachusetts population by 2035. Marlborough residents aged 65 and older represent 13% of the city of Marlborough population. Further, patients aged 65 and older represented 25-26% of the Marlborough Hospital patient population between FY19 and FY21. This is shown in Table 6.

Table 6: Marlborough Hospital data from FY19-FY21

	FY1	Y19 FY20		FY21		
Age	Count	%	Count	%	Count	%
0-17	3,203	9%	2,536	7%	4,287	9%
18-64	24,319	65%	25,840	68%	32,006	66%
65+	9,799	26%	9,830	25%	11,996	25%
Unknown	5	0%	3	0%	3	0%
Total	37,326	100%	38,206	100%	48,289	100%

Based on these population trends, the Applicant expects that Marlborough will continue to see growth in the age 50 and older age cohort, an age category for which the need for imaging services such as PET-CT will become more important for detecting, managing and treating age-related conditions.

3. Increasing number of patients, and older patients with underlying age-related oncologic and cardiac conditions.

The Applicant asserts that cancer and cardiac disease burden demonstrate need for advanced imaging to address conditions as PET-CT services are an important component of care for patients with oncologic and cardiac concerns. The Applicant reported on statistics related to cancer incidence and mortality and cardiovascular disease in Massachusetts to further demonstrate need for the Proposed Project. Table 7 displays age-adjusted cancer incidence and mortality for Middlesex County, the location of the Proposed Project, Massachusetts and the United States.

8

¹¹ Analytics were derived in March of 2022.

Table 7: Cancer Incidence and Mortality^f

	Incidence Rate ¹²	Mortality Rate ¹³		
Middlesex County	434.4	140.3		
Massachusetts	443.5	149.9		
United States	422	155.5		

Middlesex County has an Age-Adjusted Cancer Incidence Rate of 434 per 100,000. ^{14,g} Using Marlborough Hospital's inpatient market share by its top ten zip codes, the Applicant determined that there are a projected 164 cancer cases diagnosed each year. ¹⁵ The Applicant posits that these cases could benefit from greater access to PET-CT services that the Proposed Project would provide.

The American Cancer Society projects 42,190 new cases of cancer in Massachusetts in 2022, and an estimated 12,520 cancer related deaths in 2022. The most diagnosed cancer in Massachusetts between 2014-2018 by gender was prostate cancer for men and cancers of the breast for women. The Applicant cites research showing that lower rates of cancer screening resulting from the COVID-19 pandemic will result in increased cancer deaths over the next decade. Notably, the pandemic affected screening rates for breast, colorectal, and cervical cancers resulting in more than 9.4 million screening exams missed in 2020.

Heart disease was the second leading cause of death in Massachusetts in 2017, and in 2020, 5.0% of Massachusetts adults were diagnosed with angina or coronary heart disease.^{k,l} The Applicant states that the long term impact of the COVID-19 pandemic will affect cardiovascular health for years to come.

The Applicant asserts further that an aging population with increasing risk for cancer and cardiac conditions, also demonstrate need for local access to PET-CT services. Older adults are particularly impacted by morbidity and mortality from cancer and cardiac conditions. The prevalence of cancer increases with age, and persons aged 65 and older comprised 60% of newly diagnosed malignancies and 70% of all cancer deaths. m,n Additionally, age is a leading risk factor for cardiovascular disease.

4. Projected Demand for PET-CT Services

The Applicant anticipates Year 1 of operation to be 2023. Table 8 shows projected PET-CT volume after project implementation, and year over year growth in imaging volume is presented in Table 9.

¹² **Cancer incidence:** The number of cancer cases diagnosed, sometimes reported as the number of cases per 100,000 Massachusetts residents. This cancer incidence rate is adjusted for the age distribution of the population so rates from one location can be compared to rates in another location.

¹³ **Cancer mortality:** The number of cancer deaths, sometimes reported as the number of deaths per 100,000 Massachusetts residents. This cancer mortality rate is adjusted for the age distribution of the population so rates from one location can be compared to rates in another location.

¹⁴ Middlesex County Age-Adjusted Incidence Rate cases per 100,000 = 434.0 with a 95% Confidence Interval of (429.7-438.3).

¹⁵ Zip Codes representing the following cities/towns: Marlborough, Hudson, Northborough, Westborough, Berlin, Framingham, Clinton, Southborough, Bolton, and Shrewsbury.

Table 8: Projected PET-CT Volume¹⁶

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total Volume	165	185	207	228	251	264

Table 9: Projected Year over Year Percent Change in PET-CT Volume¹⁷

Year 2	Year 3	Year 4	Year 5	Year 6
12%	12%	10%	10%	5%

Staff inquired further about projected PET-CT volume in the context of assessing Patient Panel need for PET-CT services at Marlborough Hospital. The Applicant affirms that they have built their volume assumptions on the following:

- A. Utilizing new PET-CT start-ups that Shields has been involved in since 2016.
- B. A methodology to project referral volumes off zip codes and market share. The Applicant states that the 97 Marlborough Hospital patients that received PET-CT services in the last calendar year does not represent the entire number of eligible patients who sought a PET-CT scan, but is a subset of a larger number of patients since the analysis did not include Marlborough's prospective referring providers, as this information is not yet available.
- C. Acknowledging that it is difficult to project PET-CT volumes as Marlborough Hospital does not currently offer the service, but they do offer limited leakage volume. The Applicant states that when PET-CT services are not available locally, patients leave the market, as is seen in the 63 patients the Applicant identified who received PET-CT imaging scans at the Shields location in Framingham (FY22).¹⁸
- D. Use of alternatives to PET-CT. The Applicant states that less sensitive technology is used as an alternative when PET-CT is unavailable, such as single-photon emission computerized tomography (SPECT) scans. 19,20 When PET-CT services become available, it is expected that additional PET-CT volume will result.

Furthermore, clinical investigation has revealed that systematically applied PET scanning has a significant impact on patient management. The primary aim of the Proposed Project is for Marlborough Hospital to provide local patient access to PET-CT imaging via Shields operational acumen. In so doing, the Applicant asserts that the Proposed Project will address current and future demand for PET-CT services among the Patient Panel.

¹⁶ Reflected in the financial pro forma.

 $^{^{17}}$ For details, see the Statement of Profit and Loss in the Appendix of the CPA Report.

¹⁸ Shields MRI at Framingham.

¹⁹ A SPECT scan is a type of nuclear imaging test produces images that show how your organs are functioning. https://www.mayoclinic.org/tests-procedures/spect-scan/about/pac-20384925

²⁰ Nuclear medicine is a medical specialty that uses radioactive tracers to assess bodily functions and to diagnose and treat disease. SPECT and Positron Emission Tomography are the two most common imaging modalities in nuclear medicine. The main difference between SPECT and PET scans is the type of radiotracers used.

Analysis

Staff find that the addition of PET-CT services on the Marlborough Hospital campus will serve to increase access to care for Marlborough Hospital patients, and help to reduce delays in imaging, diagnosis, and treatment. As described above, existing volume related to cancer and cardiac diagnoses serve to support demand for additional PET-CT imaging capacity. Expanding access to PET-CT services locally, will reduce barriers to access for Marlborough Hospital patients, improving patient experience. Further, as the population grows and ages, the need for convenient local access to PET-CT services becomes more important. Staff confirms ongoing need for continued access to PET-CT services, especially among the 65 and over population which comprises about one quarter of the Applicant's patient population. Risk for cancer and cardiovascular disease, 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.^p With the operating model provided by Shields, the Applicant will be able to sustain local access to high-quality imaging services for the Patient Panel, and support continuity of care and improve patient satisfaction.

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

Public Health Value: Improved Outcomes and Quality of Life

The Applicant states 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 a number of clinical complications, the main applications of which include those within oncologic and cardiac specialties, with newer application in neurologic specialty. PET-CT scans provide more accurate diagnoses in one procedure than when the two scans are performed separately providing physicians with necessary information to make timely and appropriate medical decisions.

The Applicant asserts that these advancements will contribute to improve health outcomes by reducing wait times to access services for needed scans which may expedite diagnosis and treatment of patients, potentially reducing treatment complications and contributing to better health outcomes.

• Improved health outcomes and quality of life. The Applicants states that through the Proposed Project it will maintain timely access to imaging services, and this will promote patient care and patient satisfaction. The Applicant described the clinical applications and benefits of PET-CT imaging. Clinicians use PET-CT imaging to better understand disease processes and to make treatment decisions. Improved access to these imaging services will contribute to appropriate and timely diagnosis and treatment as well as improved health outcomes.

Patient satisfaction and convenience. The Applicant asserts the Proposed Project will
sustain patient satisfaction by ensuring access to on-campus PET-CT services so that
patients will not need to travel outside Marlborough Hospital to access PET-CT imaging
services. Patient satisfaction is linked to patient compliance with their medical care plan,
which leads to improved health outcomes.

The Centers for Medicare & Medicaid has delayed its implementation of the payment penalty phase of the appropriate use criteria (AUC) consultation mandate for Medicare advanced diagnostic imaging services.²¹ The Applicant states that once the mandate for referring providers goes into effect, Shields will have the capability of reporting the following:

- a. The percent of ordering physicians using the mechanism
- b. Data showing yearly changes in "low utility" or "marginal utility"
- c. Percent of ordering providers' response to alerts provider by CDS tools
- d. Analysis of data and policy changes instituted as a result of these data.

The Applicant has provided several measures to demonstrate impact of the Proposed Project. Staff reviewed the suggested measures which are described fully Appendix I. The measures will become part of the annual reporting to DPH.

Analysis Improved Outcomes and Quality of Life

Staff concur that providing timely access to imaging services contributes to improved health outcomes, quality of life, and patient satisfaction. Advanced imaging can improve disease detection, diagnosis and treatment allowing for more accurate diagnosis and treatment and the avoidance of more invasive and costly procedures. Not having adequate access to advanced imaging leads to delays in diagnosis and treatment, which can negatively affect health outcomes.

Public Health Value: Health Equity

The Applicant states that the Proposed Project will not adversely affect accessibility of services for poor, medically indigent, and/or Medicaid eligible individuals. Further, the Applicant will not discriminate based on ability to pay or payor source following implementation of the Proposed Project.

The Applicant offers the following services to support access to culturally and linguistically appropriate care:

- Ongoing education and training of staff in culturally and linguistically appropriate care.
- Translation services including language Line which provides phone and video interpretation services in more than 240 languages 24 hours a day, seven days a week;

²¹ CMS.gov. Appropriate Use Criteria Program. https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program

and InDemand which offers medical interpreting solutions for Limited English proficient and Deaf and Hard of Hearing patients to access care.

In order to support equitable access to imaging services, the Applicant will offer price transparency tools, which the Applicant states will ensure all patients have access to current pricing information, and the Applicant will provide patients with access to financial counselors to assist patients in understanding their insurance benefits. The Applicant states that Shields has an individualized model of care, which supports patients who are unable or uncomfortable using technology, with a customer care department to assist in understanding out-of-pocket costs and arranging transportation needs. Onsite staff are trained to provide operational assistance to patients in the event that technology is not accessible. During the referral stage of the scheduling process, Shields works with the referring office to coordinate care and to ensure that patients translation and other needs are met.

Analysis Health Equity

Staff finds that through their planned language access, cultural competence training, and care coordination, the Applicant has provided reasonable assurances of improved health equity.

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

To allow for efficient and accurate assessment, clinical analysis, and treatment decisions imaging services will be fully integrated with Marlborough Hospital Health Information System. Integrated health information systems have been shown to impact health outcomes by enhancing care coordination and improving efficiency. Integrated medical records facilitate easy access to images and reports which supports real-time decision-making regarding care, thereby reducing duplication of services and unnecessary testing.

Shields Management will provide operational and scheduling efficiencies that will increase capacity and improve patient and referring provider satisfaction. Streamlined patient access tools will interface with an electronic medical record (EMR) that offer pre-registration functionality. This will allow for access to patient health information and will allow radiologists to share patient health information with primary care physicians (PCPs) to track treatment progress.

The Applicant states that PET-CT services will be embedded within existing cancer and cardiac services to enhance care delivery. Specifically, PET-CT services will be aligned within a cancer care continuum to include access to Marlborough Hospital-based nurse navigators that guide patients through care, treatment, recovery, and grief; and with Marlborough Hospital's cardiac rehabilitation program, which includes access to social workers, dietary support, and wellness services.

Analysis

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.^{r,s} 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.^t

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report.

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

The Department's Guideline²² 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."²³

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

- Marlborough Hospital's Patient and Family Advisory Council (PFAC). June 2, 2022.
 Eleven members were in attendance. The Applicant states that it chose the PFAC, which
 is composed of former patients of the Hospital and their family members, and
 caregivers and staff of the Hospital, to fulfill its community engagement efforts, because
 it best represents patients from the proposed service area. The Applicant states that
 reaction to the presentation was positive and no concerns were expressed.
- Marlborough Hospital Board of Trustees. June 10, 2022. Sixteen members were in attendance. The Board is comprised of local influencers from a diversity of professions, a list of which is provided in the community engagement materials. The Applicant states that reaction to the presentation was positive and no concerns were expressed.
- **Legal Notice**. Published on the Shields website to bring awareness to patients, family members, residents and resident groups, and to provide an opportunity for public comment on the project.

²² Community Engagement Standards for Community Health Planning Guideline

²³ DoN Regulation 100.210 (A)(1)(e). https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf

Analysis

Staff finds that the Applicant met the minimum required community engagement standard of Consult in the planning phase of the Proposed Project.

Factor 1: f) Competition On Price, Total Medical Expenses (TME), Costs And Other Measures Of Health Care Spending

The Applicant states that the Proposed Project will complete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending through the provision of PET-CT services that meets existing and projected demand for PET-CT services. The Applicant notes several factors that make the Proposed Project cost effective:

- The proposed PET-CT unit will be located on the Marlborough Hospital campus, which will support local access to PET-CT services.
- The proposed PET-CT unit will utilize an existing and serviceable mobile pad located at Marlborough Hospital.
- The Proposed PET-CT unit will improve access to PET-CT services which can reduce healthcare utilization and spending which is supported by appropriate imaging and better integration of services.
- The proposed PET-CT services will be provided through a licensed IDTF clinic, which costs less than services reimbursed at hospital rates.
- Shields will manage the clinic, allowing the Applicant to identify opportunities to provide high-quality care and reduce costs.
- Site-of-care reviews for diagnostic imaging have been implemented by insurers to improve cost of care by directing patients to lower-cost sites of care for imaging services.²⁴

The Applicant also notes that by offering imaging services that are reimbursed at lower rates, UMMIC is helping to make access to care more affordable, and thus more equitable. Health care costs and affordability influence decision making around care seeking, and high health care costs can cause people to delay care or go without care.^u

Analysis

Staff finds that the Proposed Project has the potential to reduce costs through improving access to care, reducing delays in diagnosis and treatment thereby reducing healthcare utilization and spending. For the Proposed Project, reducing unnecessary expenditures related to inefficiencies from lack of service integration, can lead to lower operational overhead and lower healthcare spending, which may reduce TME. The proposed PET-CT unit will address increasing demand in an efficient manner and minimize excess utilization through providing mobile PET-CT services

²⁴ The Applicant notes that Site of Care Review will not occur (and therefore no additional charges will be incurred) if the imaging is performed at an IDTF, and Site of Care Review will only be done (and billed) if the procedure is requested to be performed in an outpatient hospital setting.

one day per week. Staff also notes that the given the reimbursement model, through the IDTF, is less costly to the system than a hospital-based service.

SUMMARY FACTOR 1

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f). 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 listed below in Appendix 1.

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

Cost Containment

The Applicant states that the Proposed Project aligns with the Commonwealth's cost containment goals because it seeks to provide access to high-quality imaging services at a lower cost. As mentioned above, the services will be provided at a clinic licensed as an IDTF. Additionally, siting the PET-CT services at Marlborough Hospital, with existing MRI services, will improve local access to PET-CT services, which will help to ensure timely access to PET-CT services and reduce delays in diagnosis and treatment, which in turn can reduce costs.

Analysis: Cost Containment

As described above, the Proposed Project seeks to provide access to imaging services within a lower-cost reimbursement setting and in a more effective and efficient manner. Therefore, staff can conclude that the Proposed Project will likely meet the cost containment factor.

Improved Public Health Outcomes

The Application states that enhancing access to PET-CT services, and its demonstrated clinical utility, will improve physician diagnosis and treatment, and enhance patient satisfaction and health outcomes. Additionally, demand for PET-CT services is projected to increase with an aging population with a growing need for imaging services to treat age-related conditions.

Analysis: Public Health Outcomes

As mentioned above, ensuring timely access to coordinated imaging services can reduce delays in diagnosis and treatment, which can adversely impact health outcomes, and thus contribute to improved health outcomes and patient satisfaction.

Delivery System Transformation

The Applicant states that it conducts a pre-screening process for all scheduled patients. Questions in the prescreen pertaining to certain social determinant of health (SDoH) issues and that are relevant to an imaging appointment include transportation, which the Applicant notes is one of the most important SDoH identified by the Centers for Disease Control and Prevention(CDC). When an SDoH need is identified during the pre-screen or the PET-CT appointment, staff assist the patient directly or refer the patient back to their PCP for linkage to community-based support. The Applicant provides transportation assistance to patients in the form of ride-share and cab vouchers.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. SDoH screening is integrated into the Applicant's care processes, to address health risks and improve health outcomes. Persistent disparities in a number of health outcomes, including the leading causes of death, indicate the important influence of the SDoH in prevention and disease promotion. V

SUMMARY for FACTOR 2

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project has met 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 will not be addressed further in this report.

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 six-year Financials prepared November 30, 2021, for the operation of UMass Marlborough PET-CT, volume assumptions, payer mix of a similarly sized location to Marlborough and per-case reimbursement assumptions, DPH DoN Guidelines, and the partner's respective websites.²⁵

²⁵ The CPA notes that its analysis is limited to the PET/CT services to be provided at UMASS Marlborough, so

Additionally, it calculated key liquidity and operating metrics to assist in determining reasonableness of the Applicant's assumptions utilized in preparing the Financials as well as the feasibility of UMASS Marlborough PET/CT.²⁶ The CPA report states that the Financials reflect positive operating margins and positive year-end cash balances in each of the six years presented.

Revenues

To determine the reasonableness of the prospective revenues, the CPA reviewed the underlying assumptions upon which Management relied. Prospective volume was based on service area cancer incidence and assumed rates of Shields market capture.

The PET-CT scanner will be operational one half day per week for 52 weeks of the year for the first three years. The fourth, fifth, and sixth year, the PET-CT scanner will be operational one full day per week for 52 weeks of the year. Year 1 case volumes are projected to be 165. Projected volume is expected to increase from 6.3 tests per day in Year 1 to 8.0 tests per day in Year 3. Tests are expected to decrease to 4.4 tests per day in Year 4 due to increase from half day to a full day and increase to 5.1 tests per day by Year 6.

The CPA reviewed the budgeted reimbursement rates for Years 1 through Year 6 which was based on a calculated weighted average of the location's payer mix and Shields's reimbursement rates. The per-test reimbursement rates remained constant in the projections because contractual rate increases from payers while possible, are not assured. Based upon its review, the CPA determined the Applicant's projected reimbursement rates and volumes are reasonable, and therefore that the revenue growth "reflects a reasonable estimation of future revenues of UMass Marlborough PET-CT..."

Expenses

To analyze expense categories, the CPA reviewed total expenses for each category, and a calculation of a compound annual growth rate (CAGR) to analyze year-over-year trends.

Operating Expenses include support services, billing, and bad debt expense. Projected bad debt expenses were higher in Year 1 to account for a lag in obtaining reimbursement from Medicare and Medicaid services for the first month of operations while accreditation is obtained from the American College of Radiology (ACR). Accreditation is typically obtained within two weeks, so the CPA determined that the one-month estimate to obtain accreditation is reasonable and therefore the corresponding bad debt expense is also reasonable.

the Applicant is referred to as "UMASS Marlborough PET/CT" for the purposes of the report.

²⁶ Reasonableness is defined within the context of this report as supportable and proper, given the underlying information. Feasibility is defined as based on the assumptions used, and that the plan is not likely to result in a liquidation of the underlying assets or the need for reorganization.

The CPA calculated an operating expense compound annual growth rate (CAGR) for Years 2 through Year 6 of 9% for UMass Marlborough PET-CT. Year 1 was not included in the CAGR calculation because of the higher bad debt expense.

Facilities & Equipment Related Expenses include equipment related, facilities related, depreciation, and other expenses. No facilities related expenses were projected in Years 1 through 6 and equipment-related expenses increase from \$123,960 to \$200,560 between Years 3 and 4. Management attributed this increase to the increase in operation hours.

Service-Related Expenses include Staffing, Fluorodeoxyglucose Isotope²⁷ Charges, equipment charges and other expenses. These expenses are projected to increase steadily between Years 1 to 6, representing a CAGR of 10%.

Salaries & Benefits include radiology, technologists, and operations expense. The CPA calculated a CAGR of 7% from Year 1 through Year 6 and found it to be a reasonable assumption.

Selling, General & Administrative ("SG&A") Expenses include support services, management, and other SG&A expenses. The CPA calculated a CAGR of 6% from Year 2 through Year 6. Year 1 was not included in the CAGR calculation due to the estimated start-up costs of initiating operations.

Interest Expense There is no interest expense for UMASS Marlborough PET/CT.

Based on their review, the CPA found the operating expenses estimated by the Applicant to be reasonable.

Capital Expense and Cash Flows

The CPA also reviewed the capital expenditures and future cash flows for UMass Marlborough PET-CT to determine whether sufficient funds would be available to sustain the operation of UMass Marlborough PET-CT and determined that the prospective capital requirements and resulting impact on the cash flows of UMass Marlborough PET-CT are reasonable.

CPA's Conclusion of Feasibility

The Financials exhibit a cumulative cash surplus in the Financials, after any scheduled distributions, of approximately 30% of cumulative projected revenue for the project for the six years presented in the Financials. Based upon its review the CPA determined the financial projections "are based upon feasible assumptions. Accordingly, we determined 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 UMass Marlborough PET-CT."

²⁷ A contrast agent most commonly used in performing PET-CTs.

Analysis

Staff is satisfied with the CPA's analysis of the Applicant's 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

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). 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 one alternative to the Proposed Project.

Maintain status quo. The Applicant considered not establishing an IDTF to provide PET-CT services, but dismissed this alternative because it would not address Patient Panel need for local access to high-quality imaging services at a lower cost. Limiting access to PET-CT services impacts quality of care for patients. This alternative is less efficient as it is not the best option for providing timely and accurate access to diagnostic information.

Analysis

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

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

Summary and relevant background and context for this application: This is a DoN project that will result in a Tier 1 Community-based Health Initiative (CHI). The Applicant, UMass Memorial MRI and Imaging Center, LLC (UMMIC), plans to establish a mobile PET-CT service that constitutes as DoN-Required Equipment acquired by an entity other than a hospital. As such, UMMIC's proposed project does not require the Applicant to submit CHI forms.

As an imaging center, UMMIC will contribute their full CHI contribution to the Community Health and Healthy Aging Statewide Funds (CHHAF) to fulfill Factor 6 requirements. With fulfillment of the below conditions, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

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 Department approve this Determination of Need, subject to all applicable standard and Other Conditions.

Other Conditions

- 1. The total required CHI contribution of \$19,034.35 will be directed to the Massachusetts Statewide Community Health and Healthy Aging Funds.
- 2. To comply with the Holder's obligation to contribute to the Massachusetts Statewide Community Health and Healthy Aging Funds, the Holder must submit the payment, a check for \$19,034.35, 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

Appendix I: Reporting Measures

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 numerators and denominators where applicable.

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 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.

Shields employs a digital platform called Podium²⁸ to evaluate patient satisfaction. Shields became a subscriber to Podium in February of 2022. Patients who supplied a cellular phone number receive a text request to participate in a survey to share their experience. Patient responses indicate overall satisfaction with the patient experience. The patient can also send an open text response related to his/her satisfaction. Shields leverages the responses from this tool to evaluate the effectiveness of site operations.

Response rate:

- The numerator is the number of surveys returned.
- The denominator is the total number of surveys sent.
- Net result is a percentage of responses compared to total sent surveys

Podium provides Shields with a Net Promoter Score ("NPS") that is translated as a patient satisfaction score.

- The calculation of a Net Promoter Score is a simple subtraction of the percent of detractors from the percent of promoters.
- **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

²⁸ https://www.podium.com/article/5-important-patient-experience-strategies-for-health-systems/

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.

No numerator or denominator calculation.

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. 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.

Repeat scanning is monitored through radiology feedback and reported in our patient scheduling system, eRAD.²⁹

- Numerator: number of scans repeated per given period
- Denominator: total patient scans
- Percent repeat = Numerator/Denominator x 100
- **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

_

²⁹ https://erad.com/

("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.

At least one scan a day is used for Peer Review. 30 This application is for 1 day per week of service:

- Numerator: reporting of 1 scan per service day + peer review
- Denominator: total number of days of service in the given period
- Result: Percent completion of Peer to Peer reporting

5. Provider Satisfaction – Value Assessment: Ensuring provider satisfaction with PET-CT scans and their overall value when treating patients is necessary to access 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 surveys.

Provider satisfaction follows the methodology used in the Podium platform (cited above). The provider response indicates overall satisfaction with the referring physician's experience. The provider can send an open text response related to his/her satisfaction. Shields leverages the responses from this tool to evaluate the effectiveness of the provider's experience.

Response rate:

- The numerator is the number of surveys returned
- The denominator is the total number of surveys sent
- Net result is a percentage of responses compared to total sent

Shields calculates a Net Promoter Score that is translated as a provider satisfaction score.

³⁰ The number of scans per day is not relevant.

REFERENCES

pet#:~:text=Why%20is%20PET%20performed%3F,the%20evaluation%20of%20cancer%20treatment.

institute.org/downloads/2015/new/UMDI LongTermPopulationProjectionsReport 2015%2004%20 29.pdf

^e 2018 Massachusetts Healthy Aging Community Profile. Marlborough (Middlesex).

https://mahealthyagingcollaborative.org/wp-

content/themes/mhac/pdf/community profiles/MA Towncode170 Marlborough.pdf

https://www.statecancerprofiles.cancer.gov/incidencerates/index.php?stateFIPS=25&areatype=county&cancer=0 01&race=00&sex=0&age=001&stage=999&year=0&type=incd&sortVariableName=rate&sortOrder=default&outpu t=0#results

^h American Cancer Society. Cancer Statistics Massachusetts.

 $\underline{https://cancerstatisticscenter.cancer.org/\#!/state/Massachusetts}$

¹ American Cancer Society. Cancer Statistics Massachusetts.

https://cancerstatisticscenter.cancer.org/#!/state/Massachusetts

^j National Cancer Institute. Working to Close the Cancer Screening Gap Caused by COVID.

https://www.cancer.gov/news-events/cancer-currents-blog/2022/covid-increasing-cancer-

screening#:~:text=An%20estimated%209.4%20million%20screening,more%20people%20dying%20from%20cancer

https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm

A Profile of Health among Massachusetts Adults, 2020 Results from the Behavioral Risk Factor Surveillance System. https://www.mass.gov/doc/a-profile-of-health-among-massachusetts-adults-2020/download

^m White MC, Holman DM, Boehm JE, Peipins LA, Grossman M, Henley SJ. Age and cancer risk: a potentially modifiable relationship. Am J Prev Med. 2014 Mar;46(3 Suppl 1):S7-15. doi: 10.1016/j.amepre.2013.10.029. PMID: 24512933; PMCID: PMC4544764.

ⁿ Berger NA, Savvides P, Koroukian SM, Kahana EF, Deimling GT, Rose JH, Bowman KF, Miller RH. Cancer in the elderly. Trans Am Clin Climatol Assoc. 2006;117:147-55; discussion 155-6. PMID: 18528470; PMCID: PMC1500929.

^o Sachs Sharona, MD and Bilfinger Thomas V, MD, ScD, FCCP. The Impact of Positron Emission Tomography on Clinical Decision Making in a University-Based Multidisciplinary Lung Cancer Practice. CLINICAL INVESTIGATIONS | VOLUME 128, ISSUE 2, P698-703, AUGUST 01, 2005. Available online

at: https://journal.chestnet.org/article/S0012-3692(15)50414-5/fulltext

^p CDC. Stats of the State of Massachusetts.

https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm

^q Hendee WR, Becker GJ, Borgstede JP, Bosma J, Casarella WJ, Erickson BA, Maynard CD, Thrall JH, Wallner PE. Addressing overutilization in medical imaging. Radiology. 2010 Oct;257(1):240-5. doi: 10.1148/radiol.10100063. Epub 2010 Aug 24. PMID: 20736333.

^r HealthIT.gov. Improve Care Coordination. https://www.healthit.gov/topic/health-it-basics/improve-care-coordination

^s Alain Pinsonneault, Shamel Addas, Christina Qian, Vijay Dakshinamoorthy & Robyn Tamblyn (2017) Integrated Health Information Technology and the Quality of Patient Care: A Natural Experiment, Journal of Management Information Systems, 34:2, 457-486, DOI: 10.1080/07421222.2017.1334477.

^t HealthIT.gov, https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/improved-diagnostics-patientoutcomes

^u 2 Kaiser Family Foundation. America's Challenges with Health Care Costs. December 14, 2021. Online at: https://www.kff.org/healthcosts/issue-brief/americans-challenges-with-health-care-costs/

^a Johns Hopkins Medicine. Health. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/positron-emission-tomography-

^b Radiologyinfo.org. PET-CT. https://www.radiologyinfo.org/en/info/pet

^c Radiologyinfo.org. PET-CT. https://www.radiologyinfo.org/en/info/pet

^d UMass Donahue Institute. Long-term Population Projections for Massachusetts Regions and Municipalities. March 2015. http://pep.donahue-

f Cancer in Massachusetts: A Call To Action. http://www.cancerinmass.org/

^g National Cancer Institute. State Cancer Profiles.

^k Centers for Disease Control and Prevention. Stats of the State of Massachusetts.

^v Singh GK, Daus GP, Allender M, et al. Social Determinants of Health in the United States: Addressing Major Health Inequality Trends for the Nation, 1935-2016. *Int J MCH AIDS*. 2017;6(2):139-164. doi:10.21106/ijma.236