

## 2. Project Description

UMass Memorial MRI & Imaging Center, LLC (“Applicant” and “UMMIC”) located at 700 Congress Street, Suite 204, Quincy, Massachusetts 02169 is filing a Determination of Need Application (“Application”) with the Massachusetts Department of Public Health (“DPH”) for the establishment of a licensed clinic to provide part-time mobile positron emission tomography (“PET”) – computed tomography (“CT”) (together “PET-CT”) diagnostic imaging services. Specifically, the mobile PET-CT unit will be located at UMass Memorial Health - Harrington Hospital at Southbridge (“Harrington Hospital”) at 100 South Street, Southbridge, MA 01550 and will operate one day per week (“Proposed Project”).

In July of 2021, Harrington HealthCare System officially became a part of the UMass Memorial Health Care, Inc. (“UMMHC”) system. Built into the hospitals’ affiliation agreement was a commitment to systemness – meaning, the merger was consummated to help drive operational and cost consistency across the entire healthcare system. Harrington Hospital currently meets its patient panel diagnostic needs via an affiliation with a *non*-Shields diagnostic imaging vendor – a relationship that is set to expire in 2023; however, through UMMIC, UMMHC has an established relationship for certain diagnostic imaging procedures with Shields Health Care Group, Inc. (“Shields”) and one of its affiliated companies. To help meet the goal of systemness, and to ensure Harrington Hospital patients have continued, local access to the highest quality PET-CT imaging services in the most efficient and cost-effective manner, it follows that UMass could leverage its existing vending relationship with Shields to meet ongoing patient needs after the current affiliation terminates.

The Applicant, UMMIC,<sup>1</sup> is the contracting entity chosen to effectuate the above-referenced systemness strategy for purposes of this Determination of Need application, as it currently operates at the following locations:

Location	Imaging Modality
214 Shrewsbury Street, Worcester, MA	MRI and PET-CT
UMass Memorial Medical Center, Memorial Campus, Worcester, MA	MRI
UMass Memorial Medical Center, University Campus, Worcester, MA	MRI
UMass Memorial Health-Alliance Hospital, Fitchburg, MA	PET-CT

The Proposed Project, if approved, would be added to the UMMIC license, thus increasing the total number of diagnostic imaging sites under this license, from four (4) to five (5).

Through the Proposed Project, the Applicant will satisfy both existing and future patient panel needs by providing local access to PET-CT imaging services one day per week, onsite at the Harrington Hospital campus.<sup>2</sup> The existing need for PET-CT imaging services for the Harrington Hospital patient panel is demonstrated by historical volume demand, disease burden trends, the growth in the number of older

<sup>1</sup> UMMIC is a joint venture between UMass Memorial Health Ventures, Inc. and Shields Healthcare Worcester, LLC.

<sup>2</sup> Patients would enter the hospital radiology department and would enter the mobile environment that is temporarily attached to the building, enclosed from the outside elements.

patients seeking care at Harrington Hospital, and the number of patients with underlying oncologic, cardiac, and neurologic conditions. National statistics indicate an increasing prevalence of cancer and cardiovascular disease.<sup>3</sup> Therefore, the need for these services is expected to expand as Harrington Hospital's patients within the 65+ age cohort increases.

The Applicant proposes to use the integrated PET-CT unit for part-time clinical use at the Harrington Hospital campus. Use of the PET-CT unit will be restricted to patients who meet the clinical protocols for combined PET-CT. A patient's underlying condition and diagnosis will be the basis for determining whether the patient meets appropriate clinical protocols for PET-CT imaging. Imaging plays a critical role in establishing the diagnoses for innumerable conditions and it is used routinely in nearly every branch of medicine.<sup>4</sup> Among other clinically appropriate applications, the Applicant proposes to utilize the designated PET-CT primarily for oncology imaging purposes, as well as for cardiologic and neurologic disease burdens as well. This, in addition to historic and projected volume data reveal the need for continued local PET-CT diagnostic imaging for this patient population.

Diagnostic technology is crucial to determine what treatments are most effective with patients' anatomy. Ready access to PET-CT services allows clinicians to diagnose and determine appropriate treatment options that will impact overall health outcomes in a time effective manner. Diagnosis has important implications for patient care, research, and policy.<sup>5</sup> The Proposed Project aims to both preserve local access to PET-CT imaging and supplement Harrington Hospital's integrated health care services, which will directly impact health outcomes and quality of life for the local patient population.

Finally, the Proposed Project will compete on the basis of provider price, costs, and total medical expenses ("TME") for several reasons. First, PET-CT services are currently available via another diagnostic imaging vendor – the Proposed Project helps ensure that the patient panel retains access to local PET-CT services. The services will be reimbursed as an Independent Diagnostic Testing Facility ("IDTF"). IDTF services are typically reimbursed at lower rates than hospital-based rates – IDTF's maintain lower costs by focusing on one service with much less overhead.<sup>6</sup> Second, the use of a part time mobile model allows for local patient access, but that also divides the cost of the fixed asset across regional relationships seeking similar imaging services – said differently, the cost of the equipment is distributed more efficiently.<sup>7</sup> Lastly, the transition will allow Shields to implement both operational optimization initiatives to further drive down cost and allow the team to leverage use of centralized patient management services across the Shields network of service partnerships. This scalable model keeps infrastructure costs low.<sup>8</sup>

Accordingly, the Proposed Project will provide patients with continued, local access to high-quality PET-CT services while also meaningfully contributing to Massachusetts' goals for cost containment.

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<sup>3</sup> According to a study by the Centers of Disease Control and Prevention titled "[Chronic Disease and Cognitive Decline – A Public Health Issue](#)," people are living longer and by 2030 about one in five Americans will be aged 65 years and older. Although increased longevity brings with it many benefits, not all adults necessarily experience good health and well-being as they age. Older adults are at a significant risk of having multiple chronic diseases, also known as comorbidities or multi-morbidities, and associated functional impairment.

<sup>4</sup> Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine; Balogh EP, Miller BT, Ball JR, editors. Improving Diagnosis in Health Care. Washington (DC): National Academies Press (US); 2015 Dec 29. 2, The Diagnostic Process. Online at: <https://www.ncbi.nlm.nih.gov/books/NBK338593/>

<sup>5</sup> *Ibid.*

<sup>6</sup> Available online at: [https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIeiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD\\_BwE](https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIeiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE)

<sup>7</sup> The proposed project will leverage existing equipment.

<sup>8</sup> Infrastructure as a Platform Smart Hospital Infrastructure Best Practices. Global Technology Briefing. Online at: <https://www.anixter.com/content/dam/anixter/resources/brochures/anixter-iaap-healthcare-best-practices-report-en.pdf>

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

### F1.a.i Patient Panel:

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

#### **A. Overview of the Applicant's Joint Venture Partners**

The business purpose of UMMIC's (the Applicant) limited liability company is to own and operate diagnostic radiological imaging facilities utilizing MRI, PET-CT. Shields Health Care Group, Inc. ("Shields") will serve as the entity responsible for the operational and management services of the Proposed Project which will be located on the Harrington Hospital Southbridge campus.

Dedication to high quality and advanced care in a local setting has been a signature attribute of the Shields business model for more than 50 years. Shields established Massachusetts' first independent regional MRI center in 1986. Today, Shields' affiliated companies have expanded to operate and manage more than 40 MRI and PET-CT facilities throughout New England, many of which are joint venture partnerships with community hospitals. Most Shields locations operate as licensed clinics and are often located on campus or proximate to the local hospital, thereby enabling coordinated, seamless, and highly accessible care.

Harrington Hospital<sup>9</sup> in Southbridge provides medical and surgical inpatient and outpatient care, including emergency services to patients in Southbridge, Sturbridge, Brimfield, Charlton and beyond.<sup>10</sup> The Hospital offers a comprehensive list of family-based health care, including advanced diagnostic imaging, adult inpatient care, and outpatient cardiac rehabilitation. Harrington Hospital hosts a 16 bed Co-occurring Disorders Unit (CDU) and a 24 bed Adult Psychiatric Unit (APU), as well as laboratory services, nutrition counseling, primary and specialty care offices, physical and occupational therapy, and more. Harrington's adult medical/surgical inpatient floors are equipped to handle post-operative patients, admitted patients from emergency visits, illness, respiratory, cardiac, and other conditions. The hospital also has capacity for same-day pediatric patients. Harrington has a staffed intensive care unit, coupled with an eICU,<sup>11</sup> a state-of-the-art monitoring system designed to improve support to patients.

#### **B. Applicant's Patient Panel**

As previously mentioned, Harrington Hospital is part of the UMass Memorial Health Care, Inc. ("UMMHC") system. The mobile PET-CT unit's proposed location is Harrington Hospital's Southbridge campus,<sup>12</sup> where it will provide continued local access to PET-CT imaging services once the service

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<sup>9</sup> While Harrington Hospital is not the Applicant or one of the Members of the Applicant's Company, it is relevant in the context of the patient panel analysis.

<sup>10</sup> The hospital has received numerous quality awards and achievements over the past several years, including top scores for patient safety and exceeding clinical outcomes.

<sup>11</sup> Find details online at: [https://www.harringtonhospital.org/services/emergency\\_care\\_center/eicu/](https://www.harringtonhospital.org/services/emergency_care_center/eicu/)

<sup>12</sup> The Southbridge location is considered the Main Campus of UMass Memorial Health – Harrington Hospital.

agreement with the current imaging vendor expires in 2023. The Applicant relies on both UMMHC's and Harrington Hospital's patient panel data to help demonstrate the need for the Proposed Project.<sup>13</sup>

#### Overall Demographic Profile of UMMHC

UMMHC's patient panel is demonstrated by the demographic data collected for fiscal years ("FY")<sup>14</sup> 2019-2021. Between FY19 and FY21 UMMHC the patient panel combined, equaled 615,105 patients.<sup>15</sup> Related to that figure over the same period, 87.5% of the patient panel originated from Central Massachusetts,<sup>16</sup> 5.7% from Eastern Massachusetts,<sup>17</sup> 2.5% from Western Massachusetts,<sup>18</sup> and 4.3% were from out of state, as demonstrated in the table below.

Pt Origin	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
Central Mass	334,998	90.2%	313,051	90.5%	352,496	89.6%	538,356	87.5%
Eastern Mass	14,363	3.9%	13,932	4.0%	19,587	5.0%	34,905	5.7%
Western Mass	8,434	2.3%	7,650	2.2%	8,881	2.3%	15,648	2.5%
Out of State	13,693	3.7%	11,231	3.2%	12,465	3.2%	26,196	4.3%
<b>Total</b>	<b>371,488</b>	<b>100.0%</b>	<b>345,864</b>	<b>100.0%</b>	<b>393,429</b>	<b>100.0%</b>	<b>615,105</b>	<b>100.0%</b>

Throughout FY19 to FY21, 20% of UMMHC's patient panel was between the ages of 0-17; 60.5% of the patient panel was between 18-64; and 19.5% was older than 65, as demonstrated in the table below.<sup>19</sup>

Age	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
0-17	71,193	19.2%	62,821	18.2%	72,425	18.4%	122,876	20.0%
18-64	220,271	59.3%	206,373	59.7%	237,664	60.4%	372,311	60.5%
65+	80,007	21.5%	76,662	22.2%	83,332	21.2%	119,897	19.5%
Unknown	17	0.0%	8	0.0%	8	0.0%	21	0.0%
<b>Total</b>	<b>371,488</b>	<b>100.0%</b>	<b>345,864</b>	<b>100.0%</b>	<b>393,429</b>	<b>100.0%</b>	<b>615,105</b>	<b>100.0%</b>

<sup>13</sup> The Applicant sought counsel from the DPH Determination of Need Program's leadership to determine that this was the appropriate course of action.

<sup>14</sup> The definition of Fiscal Year in the context of this narrative/application is October to September.

<sup>15</sup> This count reflects the number of patients, not the number of visits to a UMMHC facility.

<sup>16</sup> Central Mass is defined as all of Worcester County and the northwest corner of Middlesex County.

<sup>17</sup> Eastern Mass is defined as the Greater Boston, Cambridge, and South Shore, Cape Cod & Martha's Vineyard service areas.

<sup>18</sup> Western Mass is defined as Franklin, Hampshire, Hampden, and Berkshire counties.

<sup>19</sup> UMMHC Demographic results – actual. To ensure patient privacy, we have used the notation "<11" in any instance where the patient count for a demographic category included less than 11 individuals.

Between FY19 and FY21, 53.5% of the patient panel was female; 46.4% were male; and 0.1% were unknown, as demonstrated in the table below.

Gender	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
Female	208,885	56.2%	194,323	56.2%	218,434	55.5%	328,811	53.5%
Male	161,945	43.6%	151,096	43.7%	174,530	44.4%	285,455	46.4%
Unknown	658	0.2%	445	0.1%	465	0.1%	839	0.1%
<b>Total</b>	<b>371,488</b>	<b>100.0%</b>	<b>345,864</b>	<b>100.0%</b>	<b>393,429</b>	<b>100.0%</b>	<b>615,105</b>	<b>100.0%</b>

During this same timeframe, 0.2% of the patient panel self-defined as American Indian or Alaskan Native; 3.8% self-defined as Asian; 6.1% self-defined as Black or African American; 14.3% Multi Racial / Other / Unknown;<sup>20</sup> and 74.7% self-defined as White, and the rest of the panel declined to answer this question, as demonstrated in the table below.

Race	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
American Indian or Alaska Native	820	0.2%	749	0.2%	894	0.2%	1,370	0.2%
Asian	12,622	3.4%	11,220	3.2%	15,024	3.8%	23,399	3.8%
Black or African American	22,274	6.0%	20,595	6.0%	23,378	5.9%	37,477	6.1%
Native Hawaiian or Other Pacific Islander	139	0.0%	127	0.0%	190	0.0%	272	0.0%
Multi Racial/ Other/Unknown	50,589	13.6%	48,913	14.1%	52,988	13.5%	87,788	14.3%
White	282,786	76.1%	262,362	75.9%	297,680	75.7%	459,396	74.7%
Declined	2,258	0.6%	1,898	0.5%	3,275	0.8%	5,403	0.9%
<b>Total</b>	<b>371,488</b>	<b>100.0%</b>	<b>345,864</b>	<b>100.0%</b>	<b>393,429</b>	<b>100.0%</b>	<b>615,105</b>	<b>100.0%</b>

Furthermore, with respect to ethnicity, 15% self-defined as Hispanic or Latino; 80.7% self-defined as Not Hispanic or Latino; 1.6% declined to answer; and 2.7% are unknown, as demonstrated in the table below.

Ethnicity	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
Hispanic or Latino	53,935	14.5%	51,607	14.9%	59,041	15.0%	92,349	15.0%
Not Hispanic or Latino	307,105	82.7%	282,540	81.7%	317,480	80.7%	496,482	80.7%
Decline	5,460	1.5%	4,930	1.4%	6,472	1.6%	9,828	1.6%
Unknown	4,988	1.3%	6,787	2.0%	10,436	2.7%	16,446	2.7%
<b>Total</b>	<b>371,488</b>	<b>100.0%</b>	<b>345,864</b>	<b>100.0%</b>	<b>393,429</b>	<b>100.0%</b>	<b>615,105</b>	<b>100.0%</b>

<sup>20</sup> 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.

### Overall Demographic Profile of UMass Memorial Health - Harrington Hospital

Harrington Hospital's patient panel is demonstrated by the demographic data collected for fiscal years ("FY") 2019-2021.<sup>21</sup> Between FY19 and FY21 the Harrington Hospital patient panel combined, equaled 211,473 patients. Related to that figure over the same period, 80.65% of Harrington Hospital's patient panel originated from Central Massachusetts, 1.67% from Eastern Massachusetts, 7.88% from Western Massachusetts, and 9.8% were from out of state, as demonstrated in the table below.

Pt Origin	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
Central Mass	53,388	80.85%	50,157	80.37%	67,006	80.70%	170,551	80.65%
Eastern Mass	745	1.13%	761	1.22%	2,036	2.45%	3,542	1.67%
Western Mass	5,355	8.11%	4,888	7.83%	6,415	7.73%	16,658	7.88%
Out of State	6,549	9.92%	6,600	10.58%	7,573	9.12%	20,722	9.80%
<b>Total</b>	<b>66,037</b>	<b>100.0%</b>	<b>62,406</b>	<b>100.0%</b>	<b>83,030</b>	<b>100.0%</b>	<b>211,473</b>	<b>100.0%</b>

Harrington Hospital's Primary Service Area (PSA) includes the following zip codes:

Town / City	Zip Code
Southbridge	01550
Webster	01570
Charlton	01507
Sturbridge	01566
Dudley	01571
Brimfield	01010
Spencer	01562
Holland	01521
Fiskdale	01518
Brookfield	01506

Throughout FY19 to FY21, 10.77% of Harrington Hospital's patient panel was between the ages of 0-17; 64.23% of the patient panel was between 18-64; and 25% was older than 65, as demonstrated in the table below.

<sup>21</sup> The Harrington Hospital Fiscal Year runs from October to September.

Age	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
0-17	8,382	12.69%	6,629	10.62%	7,759	9.34%	22,770	10.77%
18-64	42,301	64.06%	40,312	64.23%	53,221	64.10%	135,834	64.23%
65+	15,354	23.25%	15,465	24.78%	22,050	26.56%	52,869	25.00%
<b>Total</b>	<b>66,037</b>	<b>100.0%</b>	<b>62,406</b>	<b>100.0%</b>	<b>83,030</b>	<b>100.0%</b>	<b>211,473</b>	<b>100.0%</b>

According to Census data, made available through the Advisory Board Demographic profiler, within Harrington Hospital's Primary Service Area ("PSA"), the population aged 65 and over is projected to increase on average by +16.5% over the next five (5) years (CAGR<sup>22</sup> of +3.1%).

Between FY19 and FY21, 54.62% of the patient panel was female; 45.37% were male; and .01% were unknown, as demonstrated in the table below.

Gender	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
Female	36,233	54.87%	34,185	54.78%	45,079	54.29%	115,497	54.62%
Male	29,800	45.13%	28,212	45.21%	37,941	45.70%	95,953	45.37%
Unknown	4	0.01	9	0.01	10	0.01	23	0.01%
<b>Total</b>	<b>66,037</b>	<b>100.0%</b>	<b>62,406</b>	<b>100.0%</b>	<b>83,030</b>	<b>100.0%</b>	<b>211,473</b>	<b>100.0%</b>

During this same timeframe, 0.14% of the patient panel self-defined as American Indian or Alaskan Native; 0.79% self-defined as Asian; 1.45% self-defined as Black or African American; 0.02% self-identified as Native Hawaiian or Other Pacific Islander; 15.94% were Multi Racial/Other/Unknown,<sup>23</sup> 79.52% self-defined as White; and, the rest of the panel declined to answer this question, as demonstrated in the table below.

Race	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
American Indian or Alaska Native	105	0.16%	81	0.13%	102	0.12%	288	0.14%
Asian	450	0.68%	441	0.71%	774	0.93%	1,665	0.79%
Black or African American	966	1.46%	889	1.42%	1205	1.45%	3,060	1.45%
Native Hawaiian or Other Pacific Islander	16	0.02%	11	0.02%	16	0.02%	43	0.02%
Multi Racial / Other/Unknown	9,693	14.68%	9,440	15.13%	14,570	17.55%	33,703	15.94%
White	53,449	80.94%	49,476	79.28%	65,245	78.58%	168,170	79.52%
Declined	1,358	2.06%	2,068	3.31%	1,118	1.35%	4,544	2.15%
<b>Total</b>	<b>66,037</b>	<b>100.0%</b>	<b>62,406</b>	<b>100.0%</b>	<b>83,030</b>	<b>100.0%</b>	<b>211,473</b>	<b>100.0%</b>

<sup>22</sup> Compound Annual Growth Rate

<sup>23</sup> 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.

Furthermore, with respect to ethnicity between FY19 and FY21, 9.93% self-defined as Hispanic or Latino and 90.07% are unknown, as demonstrated in the table below.

Ethnicity	FY2019		FY2020		FY2021		FY2019-2021 Combined	
Hispanic or Latino <sup>24</sup>	6,827	10.34%	6,511	10.43%	7,670	9.24%	21,008	9.93%
Unknown	59,210	89.66%	55,895	89.57%	75,360	90.76%	190,465	90.07%
<b>Total</b>	<b>66,037</b>	<b>100.0%</b>	<b>62,406</b>	<b>100.0%</b>	<b>83,030</b>	<b>100.0%</b>	<b>211,473</b>	<b>100.0%</b>

### C. Payer Mix

The payer mix for Harrington Hospital<sup>25</sup> from FY19 to FY21 is demonstrated in the table below:

Payer Mix-List	FY2019		FY2020		FY2021	
	Count	%	Count	%	Count	%
Commercial PPO/Indemnity	17,721	26.83%	16,622	26.64%	24,409	29.40%
Commercial HMO/POS	8,548	12.94%	7,299	11.70%	11,659	14.04%
MassHealth	5,699	8.63%	4,622	7.41%	6,194	7.46%
Managed Medicaid <sup>26</sup>	9,603	14.54%	9,404	15.07%	11,327	13.64%
Managed Medicare <sup>27</sup>	6,099	9.24%	6,443	10.32%	6,937	8.35%
Medicare FFS	9,719	14.72%	8,905	14.27%	13,776	16.59%
All other (e.g. HSN, self-pay, TriCare)	8,648	13.10%	9,111	14.60%	8,728	10.51%
<b>Total</b>	<b>66,037</b>	<b>100.0%</b>	<b>62,406</b>	<b>100.0%</b>	<b>83,030</b>	<b>100.0%</b>

#### F1.a.ii Need by Patient Panel:

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

#### A. Overview

Through the Proposed Project, the Applicant will satisfy both existing and future patient panel needs by continuing to provide local access to PET-CT imaging services, onsite at the Harrington Hospital's Southbridge campus. The current vendor provides mobile PET-CT imaging services one day a week

<sup>24</sup> There were no individuals who self-identified as Not Hispanic or Latino

<sup>25</sup> Harrington Hospital is a non-profit community-High Public Payer (HPP) hospital according to the Center of Health Information and Analysis' FY 2019 Massachusetts Hospital Profiles published in March of 2021.

<sup>26</sup> Private Medicaid / Medicaid MCOs

<sup>27</sup> Private Medicare/Medicare Advantage



onsite at Harrington Hospital. Due to more recent operational capacity limitations, overflow imaging volume has been referred to UMMIC imaging sites in Worcester and Fitchburg<sup>28</sup> – consequently, a portion of the Harrington Hospital patient panel who meet the clinical qualifications of for a PET-CT image must travel to attain these services.

The existing and future need for continued local PET-CT imaging access is further demonstrated by historical volume demand, projected volume, and disease burden trends, in addition to the growth in the number of older patients seeking care at Harrington Hospital, the increased number of patients with underlying age-related oncologic, cardiac, and neurologic conditions for which PET-CT has proven clinical applicability,<sup>29</sup> as well as the fact that there are no other PET-CT facilities available to the patient panel within the Applicant's PSA.<sup>30</sup>

It is noteworthy that seniors surveyed in Harrington Hospital's 2019 Community Health Needs Assessment, reported that cancer, heart disease, and degenerative neurological conditions like Alzheimer's and Dementia were chief among their health concerns.

To further underscore the importance of local access, it is significant to note that barriers, such as challenges related to access to health care often result in unmet health care needs, including a lack of preventive and screening services and treatment of illnesses.<sup>31</sup> For example, 80% of the women who should have an annual mammography exam will not, because they are unable to find a mammography facility that is conveniently located.<sup>32</sup>

## B. Need for Additional Services

- i. The need for local PET-CT imaging services is demonstrated by historical volume demand, operational capacity limits, projected volume, and disease burden trends.

### Historical Volume

The Applicant reviewed the total number of PET-CT scans referred to the current vendor for diagnostic imaging in FY19, FY20, and FY21. These data are provided in the table below.

<sup>28</sup> There are 20.3 miles between Southbridge and Worcester

<https://www.google.com/maps/dir/Southbridge,+Massachusetts/Worcester,+Massachusetts/@42.1687581,-72.0734668,11z/data=!3m1!4b1!4m14!4m13!1m5!1m1!1s0x89e6a1ef1c20680b:0x980c7ac63d58cf11!2m2!1d-72.0333905!2d42.0751065!1m5!1m1!1s0x89e406585a2a8b0d:0x9e137dd87fca4d6d!2m2!1d-71.8022934!2d42.2625932!3e0>

and 46.8 miles between Southbridge and Fitchburg

<https://www.google.com/maps/dir/Southbridge,+Massachusetts/Fitchburg,+Massachusetts/@42.3307916,-72.1572953,10z/data=!3m1!4b1!4m14!4m13!1m5!1m1!1s0x89e6a1ef1c20680b:0x980c7ac63d58cf11!2m2!1d-72.0333905!2d42.0751065!1m5!1m1!1s0x89e3e654c92294d1:0x71c57d04deaac42b!2m2!1d-71.8022955!2d42.5834228!3e0>

<sup>29</sup> Jaul E, Barron J. Age-Related Diseases and Clinical and Public Health Implications for the 85 Years Old and Over Population. *Front Public Health*. 2017;5:335. Published 2017 Dec 11. doi:10.3389/fpubh.2017.00335 Online at:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5732407/> & Anand SS, Singh H, Dash AK. Clinical Applications of PET and PET-CT. *Med J Armed Forces India*. 2009;65(4):353-358. doi:10.1016/S0377-1237(09)80099-3 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4921358/>

<sup>30</sup> The closest competitive service site is located out of network at Day Kimball Hospital in Putnam, CT (>17 miles away). The closest competitive site in MA is located at St. Vincent's Hospital in Worcester (>31 miles away).

<sup>31</sup> Keith Loria. Accessible Care: Challenges and Opportunities Related to Radiology Services in Rural Areas. *Radiology Today*. Vol. 20 No. 12 P. 22. Online at: <https://www.radiologytoday.net/archive/rt1219p22.shtml>

<sup>32</sup> According to John Simon, MD, founder and CEO of SimonMed Imaging.

	FY19 #scans	FY20 #scans	FY21 #scans
Total Scans	183	215	260

The vendor has recently started to refer overflow volume to UMass imaging sites in Worcester and Fitchburg. In 2021 only 1 referral was made, but to date in 2022, 70 referrals have been sent to sister locations outside the PSA.<sup>33</sup>

It is noteworthy that within the Applicant's PSA the current Independent Diagnostic Testing Facility (IDTF) clinic is the only diagnostic imaging facility offering PET-CT in the local market. This is significant for two reasons: 1) Harrington Hospital's current vending relationship is slated to cease in 2023, leaving an opportunity for the Applicant to maintain the local PET-CT imaging service offering under different operational management; and 2) the Applicant plans to provide these diagnostic imaging services as a freestanding mobile IDTF clinic, and as such will be reimbursed at lower rates than hospital-based rates.<sup>34</sup>

### Projected Volume

The Applicant evaluated the growing demand for continued local access to PET-CT services – the Veralon financial pro forma reveals the following.<sup>35</sup>

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total Volume <sup>36</sup>	297	333	366	403	423	444

\*The Applicant did not assign a specific start year, as it dependent on regulatory approval – for this project, Shields anticipates that Year 1 will be 2023.

The Applicant also relies on recent data from the Advisory Board Company ("Advisory Board"), to further demonstrate the need for PET-CT in the proposed Primary Service Area ("PSA"). The Advisory Board projects that demand for PET-CT services in the freestanding and the hospital-based outpatient departments (HOPDs) combined, within the PSA will grow by +10.3% over the next five (5) years and +18.3% over the next 10 years.

<sup>33</sup> PSA zip codes include Southbridge 01550; Webster 01570; Charlton 01507; Sturbridge 01566; Dudley 01571; Brimfield 01010; Spencer 01562; Holland 01521; Fiskdale 01518; and Brookfield 01506.

<sup>34</sup> Diagnostic imaging conducted in a hospital setting costs more [in part] because inpatient facilities cost more than mobile sites to operate.

<sup>35</sup> These projections were derived by Veralon, health care business valuation and consultants, who drafted the CPA report using the Shields Pet standard year over year growth trend from new PET starts with Shields since 2016.

<sup>36</sup> Year over year % change starting in Year 2 is 11.6%; Year 3 is 11.2%; Year 4 is 10%; Year 5 is 5.5%; and Year 6 is 4.5%. For details, please see the Statement of Profit and Loss in the Appendix of the Veralon CPA Report.

### Patients who *could* benefit from PET-CT

The Applicant evaluated the number of patients that Harrington Hospital treated during the last three fiscal years who had an underlying oncologic, cardiovascular, and neurological condition, as evidence-based research supports the use of PET-CT in these areas<sup>37</sup> (please see table below).

Fiscal Year (FY)	Unique Patients	Cancer	Cancer %	Cardiac	Cardiac %	Neuro	Neuro %
FY19	66,037	10,033	15.19%	25,798	39.07%	15,621	23.65%
FY20	62,406	10,225	16.38%	25,706	41.19%	16,054	25.73%
FY21	83,030	9,750	11.74%	24,453	29.45%	15,207	18.32%

\*These are unique patients who are only counted once per category per year.<sup>38</sup>

This patient population stands to benefit not only from the continued access to PET-CT diagnostic imaging, but also from the benefit of the Applicant's intent to utilize a 2019 Siemens Biograph mCT 40.<sup>39</sup> Newer technology yields superior lesion detection, disease characterization, more accurate quantitation, and quicker scans.<sup>40</sup>

- ii. The growing number of older patients helps define the need to maintain local PET-CT imaging services.

### Southbridge

The city of Southbridge's demographic profile is demonstrated by data collected from the most recent U.S. Census Bureau, which was released in 2021. As of July 1, 2021, the population of Southbridge was reported to be 17,657.<sup>41</sup> The median age of the population of Southbridge is 40.2, which is slightly older than the median age of the total population of Massachusetts, 39.6.<sup>42</sup>

Currently, 14.5% of the Southbridge population is older than 65.<sup>43</sup> The table below compares the percent of the population in four (4) age ranges for two (2) different locations: the town of Southbridge and the Commonwealth of Massachusetts. As

<sup>37</sup> Johns Hopkins Medicine. Available online at: <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/positron-emission-tomography-pet>

<sup>38</sup> There has been a relative decrease in the number of unique patients from 2019 to 2020 across these service line that the Applicant notes is both an anomaly and a derivative of the COVID-19 pandemic.

<sup>39</sup> Biograph mCT provides all the functionalities of a high-end, standalone CT — plus a range of CT configurations and options — for maximum system utilization. Online at: <https://www.siemens-healthineers.com/en-us/molecular-imaging/pet-ct/biograph-mct>

<sup>40</sup> Aide, Nicolas & Lasnon, Charline & Desmonts, Cédric & Armstrong, Ian & Walker, Matthew & McGowan, Daniel. (2021). Advances in PET-CT technology: An update. Seminars in Nuclear Medicine. 52. 10.1053/j.semnuclmed.2021.10.005. Available online at: [https://www.researchgate.net/publication/356449596\\_Advances\\_in\\_PET-CT\\_technology\\_An\\_update](https://www.researchgate.net/publication/356449596_Advances_in_PET-CT_technology_An_update)

<sup>41</sup> U.S. Census Bureau. (2021). U.S. Census Bureau QuickFacts: Southbridge Town city, Massachusetts. Www.census.gov. <https://www.census.gov/quickfacts/fact/table/southbridgetowncitymassachusetts/PST045221>

<sup>42</sup> Census Reporter. (2021b). Grid View: Table B01001 - Census Reporter. Censusreporter.org. [https://censusreporter.org/data/table/?table=B01001&primary\\_geo\\_id=06000US2502763345&geo\\_ids=06000US2502763345](https://censusreporter.org/data/table/?table=B01001&primary_geo_id=06000US2502763345&geo_ids=06000US2502763345)

<sup>43</sup> Census Reporter. (2021c). Grid View: Table B01001 - Census Reporter. Censusreporter.org. [https://censusreporter.org/data/table/?table=B01001&primary\\_geo\\_id=06000US2502763345&geo\\_ids=06000US2502763345](https://censusreporter.org/data/table/?table=B01001&primary_geo_id=06000US2502763345&geo_ids=06000US2502763345)

presented in the table, Southbridge has higher percentages than Massachusetts for the age ranges of 50-59 and 60-69.<sup>44</sup>

Age Range	Southbridge	Massachusetts
50-59	15.6%	14.1%
60-69	12.1%	11.8%
70-79	6.0%	6.9%
80+	3.3%	4.3%

### Statewide

Statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035.<sup>45</sup> While overall statewide population growth will continue to grow at a consistent rate of 3.2% during this period, estimates suggest that certain age cohorts will account for a greater share of the population than others. Specifically, 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 a 21% of the Massachusetts population.<sup>46</sup>

Assuming the demographic trends within the Southbridge area continue to mirror that of the state, it is expected that these areas will continue to see growth in the 50+ age cohort that the Applicant hopes to serve. Also compelling is the Advisory Board's forecast that the Harrington Hospital PSA for people aged 65+ is projected to increase on average by +16.5% over the next five (5) years (CAGR of +3.1%). As the number of patients that fall into that age cohort continues to grow, the need for imaging services, such as PET-CT, becomes more important for detecting, managing, and treating age-related conditions,<sup>47</sup> as discussed in further detail later in this narrative.

To ensure that the Harrington Hospital patient panel's aging population has continued access to high quality PET-CT services with proven effectiveness in the fields of oncology, cardiology, and neurology, the Applicant seeks to establish a licensed IDTF clinic to replace and maintain PET-CT imaging services within the serviceable catchment area.

- iii. The increased number of patients, especially older patients, with underlying age-related oncologic, cardiac, and neurologic conditions supports the need for PET-CT imaging services.

<sup>44</sup> U.S. Census Bureau. (2021). *U.S. Census Bureau QuickFacts: Southbridge Town city, Massachusetts*. [www.census.gov](https://www.census.gov).

<https://www.census.gov/quickfacts/fact/table/southbridgetowncitymassachusetts/PST045221>

<sup>45</sup> Online at: [http://pep.donahue-institute.org/downloads/2015/new/UMDI\\_LongTermPopulationProjectionsReport\\_2015%2004%20\\_29.pdf](http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf)

<sup>46</sup> Online at: <https://www.mass.gov/files/documents/2016/07/wb/healthy-aging-data-report.pdf>

<sup>47</sup> Medically reviewed by Megan Soliman, MD, written by Yvette Brazier. What are PET scans, and what are their uses? Medical New Today.

Updated on December 16, 2021. Online at: <https://www.medicalnewstoday.com/articles/154877#what-it-is>

In consideration of the aging population, “imaging strongly contributes to establishing accurate and timely diagnosis, informs and guides treatment decisions and contributes to improving treatment outcomes.”<sup>48</sup> Imaging is used for precise planning of radiotherapy procedures as well as for real-time visualization of different image-guided interventions and is essential in tumor sampling for pathology work-up,<sup>49</sup> which is essential to the Applicant’s aging patients with oncologic, cardiac, and/or neurological concerns. Following the concept of value-based healthcare, a multi-society statement was recently published to elucidate the value that radiology provides to patients and healthcare.<sup>50</sup>

### Oncologic Conditions and the Need for PET-CT

Research studies and their findings demonstrate that the prevalence of cancer increases with age.<sup>51</sup> Persons over 65 account for 60% of newly diagnosed malignancies and 70% of all cancer deaths, the incidence of cancer in individuals over 65 is 10 times greater than in those younger than 65, and the cancer death rate is 16 times greater in patients over 65 compared to younger patients.<sup>52</sup> Furthermore, even with a progressive decrease in the cancer incidence and death rate, aging of the population will be accompanied by a marked increase in the total number of patients with cancer,<sup>53</sup> the majority of whom will require the most precise diagnostic imaging.

In Worcester County, where Harrington Hospital and the proposed PET-CT facility are located, the age adjusted annual incidence of cancer rate was 473.57 – 486.21 per 100,000 persons.<sup>54</sup> According to the American Cancer Society, there is projected to be 42,190 new cases of cancer in Massachusetts in 2022,<sup>55</sup> and 12,520 cancer related deaths.<sup>56</sup> The most diagnosed type of cancer in Massachusetts for men between 2014-2018 was prostate cancer, followed by cancers of the bronchus and lung, colon/rectum, and urinary bladder. Among women in Massachusetts during that same period, the most diagnosed cancer types were cancers of the breast, bronchus and lung, colon/rectum, and corpus uteri (uterus).<sup>57</sup>

Lower rates of cancer screening caused by the COVID-19 pandemic will likely translate into increased cancer deaths over the next decade, according to recent research

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<sup>48</sup> Guy Fria, Ivana Blažić, Donald P. Frush, Monika Hierath, Michael Kawooya, Lluís Donoso-Bach, et al. How to improve access to medical imaging in low- and middle-income countries. *eClinical Medicine*, Part of The Lancet Discovery Science. VOLUME 38, 101034, AUGUST 01, 2021. Online at: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(21\)00314-X/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00314-X/fulltext)

<sup>49</sup> *Ibid.*

<sup>50</sup> Brady, A.P., Bello, J.A., Derchi, L.E. et al. Radiology in the era of value-based healthcare: a multi-society expert statement from the ACR, CAR, ESR, IS3R, RANZCR, and RSNA. *Insights Imaging* 11, 136 (2020). <https://doi.org/10.1186/s13244-020-00941-z>.

<sup>51</sup> 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;46(3 Suppl 1):S7-S15. doi:10.1016/j.amepre.2013.10.029. Online at: <https://www.sciencedirect.com/science/article/pii/S0749379713006429>

<sup>52</sup> 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. Online at: <https://pubmed.ncbi.nlm.nih.gov/18528470/>

<sup>53</sup> *Ibid.*

<sup>54</sup> Online at: <https://www.cancer-rates.info/ma/>

<sup>55</sup> Online at: <https://cancerstatisticscenter.cancer.org/#/state/Massachusetts>

<sup>56</sup> *Ibid.*

<sup>57</sup> *Ibid.*

published in the journal *Cancer*.<sup>58</sup> The report shows how the pandemic affected screening rates for breast, colorectal, lung, and cervical cancers in the U.S. – more than 9.4 million screening exams were missed in 2020 – and underscores the effort needed to tackle the problem, according to a group led by Dr. Rachel Joung of Northwestern University in Chicago.<sup>59</sup>

Patient panel data for Harrington Hospital's patients provide that 10,033 patients were treated for oncological-related issues in FY19; 10,225 patients in FY20; and 9,750 in FY21.

Furthermore, in the realm of expanded uses for PET-CT, several new PET tracers are under investigation for potential use in urological oncology.<sup>60</sup> There is a future role for PET-CT in the management of urological malignancies, including testicular, kidney, bladder, and prostate cancer.<sup>61</sup> There is increasing evidence that PET-CT influences urological treatment decisions by the detection and localization of recurrent disease that is often missed by using conventional imaging methods.<sup>62</sup>

### Cancer Rates for Southbridge

As part of the Massachusetts cancer registry, the Office of Data Management and Outcomes Assessment and the Department of Public Health releases a Cancer Incidence City & Town Supplement.<sup>63</sup> This report provides standardizes incidence ratios (SIRs) for 23 types of cancers in the 351 cities and towns in Massachusetts over a 5-year time frame. The most recent report contains information from 2011-2015.<sup>64</sup>

As stated in the report, the measurement tool, known as the Standardized Incidence Ratio (SIR), is an indirect method of adjustment for age and sex that describes in numerical terms how a city/town's cancer experience in a given time period compares with the state as a whole. 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.<sup>65</sup>

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<sup>58</sup> Joung, RH, Nelson, H, Mullett, TW, Kurtzman, SH, Shafir, S, Harris, JB, Yao, KA, Brajcich, BC, Bilimoria, KY, Cance, WG. A national quality improvement study identifying and addressing cancer screening deficits due to the COVID-19 pandemic. *Cancer*. 2022. Online at: <https://doi.org/10.1002/cncr.34157>

<sup>59</sup> *Ibid.*

<sup>60</sup> Isabel Rauscher, Matthias Eiber, Wolfgang A Weber, Jürgen E Gschwend, Thomas Horn and Tobias Maurer. Positron-emission tomography imaging in urological oncology: Current aspects and developments. *International Journal of Urology*. 2018. 25. Online at: <https://onlinelibrary.wiley.com/doi/10.1111/iju.13779>

<sup>61</sup> *Ibid.*

<sup>62</sup> *Ibid.*

<sup>63</sup> Available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

<sup>64</sup> Available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

<sup>65</sup> For example, an SIR of 105 indicates that a city/town's cancer incidence is 5% higher than expected based on statewide average annual age-specific incidence rates. An SIR of less than 100 indicates that a city/town's incidence of a certain type of cancer is lower than expected based on statewide average age-specific incidence rates. For example, an SIR of 85 indicates that a city/town's cancer incidence is 15% lower than expected based on statewide average annual age-specific incidence rates.

Notable SIRs for Southbridge<sup>66</sup>

Cancer Type	Notable SIRs for Southbridge	Percentage Higher than Statewide Average
Breast	Female: 79.9	Female: -20.1%
Colon/Rectum	Male: 112.4 Female: 98.8	Male: 12.4% Female: -1.2%
Leukemia	Male: 102.8	Male: 2.8%
Liver and Intrahepatic Bile Ducts	Female: 177.7	Female: 77.7%
Lung and Bronchus	Female: 75.0	Female: -25%
Multiple Myeloma	Male: 184.3	Male: 84.3%
Non-Hodgkin Lymphoma	Male: 117.2 Female: 146.6	Male: 17.2% Female: 46.6%
Pancreas	Male: 139.0	Male: 39%
Stomach	Male: 153.3	Male: 53.3%
Uteri Corpus and Uterus, NOS	Female: 116.0	Female: 16%
All Sites/Types	Female: 92.6	Female: -7.4%

The table above illustrates substantial data that reveal percentages of certain oncologic conditions that are higher than statewide averages in the PSA – this information further demonstrates the need for continued access to PET-CT imaging services in this catchment area.

Cardiological Conditions and the Need for PET-CT

It is well-established that age is a leading risk factor for cardiovascular disease and the risk for coronary heart disease increases starting at age 45 for men and at age 55 for women.<sup>67</sup> According to the 2018 results from the Massachusetts Behavioral Risk Factor Surveillance System, statewide, 5.6% of Massachusetts adults are diagnosed with myocardial infarction and 4.7% are diagnosed with angina or coronary heart disease annually.<sup>68</sup> Moreover, according to the American Heart Association, 12,140 people died of heart disease in Massachusetts in 2017, making heart disease the second leading cause of death.<sup>69</sup>

In addition, heart disease<sup>70</sup> continues to kill more people in the U.S. than any other cause, despite, or perhaps even likely due to the impact of the COVID-19 pandemic over the last few years, according to 2021 provisional data released from the U.S Centers for Disease Control and Prevention.<sup>71</sup> That trend is likely to continue for years to come as the long-term impact of the novel coronavirus will directly affect cardiovascular health, according to the American Heart Association.<sup>72</sup>

<sup>66</sup> Available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

<sup>67</sup> Hajar R. Risk Factors for Coronary Artery Disease: Historical Perspectives. Heart Views. 2017;18(3):109-114.

doi:10.4103/HEARTVIEWS.HEARTVIEWS\_106\_17. Online at: <https://pubmed.ncbi.nlm.nih.gov/29184622/>

<sup>68</sup> Online at: <https://www.mass.gov/doc/a-profile-of-health-among-massachusetts-adults-2018/download>

<sup>69</sup> Online at: <https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm>

<sup>70</sup> Stroke is also included in this statistic.

<sup>71</sup> Heart disease #1 cause of death rank likely to be impacted by COVID-19 for years to come

American Heart Association Report – Annual Statistical Update. Available online at: <https://newsroom.heart.org/news/heart-disease>

<sup>72</sup> *Ibid.*



Patient panel data for Harrington Hospital's patients provide that 25,798 patients were treated for cardiac-related diagnoses in FY19; 25,706 in FY20; and 24,453 in FY21.

### Neurological Conditions and the Need for PET-CT

Recent studies have placed an increased focus on aging and neurological diseases, such as epilepsy and Alzheimer's dementia. Additionally, the risk of having a seizure increases after the age of 60.<sup>73</sup> Moreover, the incidence rate of Alzheimer's also increases with age.<sup>74</sup> Millions of Americans have Alzheimer's or other dementias.<sup>75</sup> As the size and proportion of the U.S. population age 65 and older continues to increase, the number of Americans with Alzheimer's or other dementias will grow. This number will escalate rapidly in coming years, as the population of Americans aged 65 and older is projected to grow from 55 million in 2019 to 88 million by 2050.<sup>76</sup>

The baby boom generation has already begun to reach age 65 and beyond, the age range of greatest risk of Alzheimer's dementia. The oldest members of the baby boom generation turned age 73 in 2019 and by 2030, all Baby Boomers will be aged 65 or older.<sup>77</sup>

The impact of Alzheimer's is projected to rise, and the most recent data show: 130,000 people aged 65 and older are living with Alzheimer's in Massachusetts.<sup>78</sup> Furthermore, 9.3% of people aged 45 and older have subjective cognitive decline.<sup>79</sup> An early diagnosis [from a timely screening], opens the door to future care and treatment and helps people to plan while they are still able to make important decisions on their care and support needs and on financial and legal matters.<sup>80</sup> It also helps them and their families to receive practical information, advice, and guidance as they face new challenges.<sup>81</sup>

Patient panel data for Harrington Hospital's patients provide that 15,621 patients were treated for neurological-related issues in FY19, 16,054 in FY20, and 15,207 in FY21.

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<sup>73</sup> Acharya JN, Acharya VJ. Epilepsy in the elderly: Special considerations and challenges. *Ann Indian Acad Neurol*. 2014;17(Suppl 1):S18-S26. doi:10.4103/0972-2327.128645. Online at: <https://pubmed.ncbi.nlm.nih.gov/24791083/>

<sup>74</sup> Age is the greatest of these the risk factors. As noted in the Prevalence section, the percentage of people with Alzheimer's dementia increases dramatically with age: 3% of people age 65-74, 17% of people age 75-84 and 32% of people age 85 or older have Alzheimer's dementia. Source: 2020 Alzheimer's disease facts and figures. March 10, 2020. Online at: <https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/alz.12068>

<sup>75</sup> *Ibid.*

<sup>76</sup> *Ibid.*

<sup>77</sup> Online at: <https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html>

<sup>78</sup> Alzheimer's Association. Massachusetts State Overview. Available online at: <https://www.alz.org/professionals/public-health/state-overview/massachusetts#:~:text=The%20impact%20of%20Alzheimer's%20is,of%20the%20disease%20in%20Massachusetts.>

<sup>79</sup> *Ibid.*

<sup>80</sup> Why early diagnosis of dementia is important. Available online at: <https://www.scie.org.uk/dementia/symptoms/diagnosis/early-diagnosis.asp>

<sup>81</sup> *Ibid.*



**F1.a.iii Competition:**

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

The Applicant's Proposed Project will compete on the basis of price, total medical expenses ("TME"), provider costs, and other recognized measures of health care spending by providing continued access to PET-CT imaging to meet current and projected demand. The Applicant's primary objectives with the Proposed Project are to maintain local access when the existing PET-CT vending relationship ceases operations in 2023, accommodate current and future volume demands, and provide high quality, low cost, PET-CT services to Harrington Hospital patients. The proposed PET-CT unit will utilize an existing mobile pad and will integrate into the patient flow of the existing space.

As noted in Factor F1.a.ii, historical need for PET-CT imaging and other indicators of future demand demonstrate a continued need for PET-CT services in the Applicant's catchment area. Providing ease of access to care has been documented to reduce healthcare utilization and spending.<sup>82</sup> Studies have detailed high costs for unnecessary repeat imaging<sup>83</sup> which could be improved through more appropriate use of all imaging, including PET-CT, and better integration of services. For the Proposed Project, preventing unnecessary expenditures related to inefficiencies from lack of service integration,<sup>84</sup> can lead to lower operational overhead and lower healthcare spending, which could, in turn, reduce TME.

The Proposed Project will not negatively impact TME, as the PET-CT services will be provided through a licensed IDTF clinic, where the PET-CT where services will continue to be reimbursed at freestanding IDTF rates. The clinic will be managed by Shields, which will seek to identify optimization opportunities to further drive down the cost to provide care, while simultaneously ensuring the highest quality of care possible.

Shields operational model allows for improved scheduling, workflow, technology, and customer service. These front-end/access focused optimizations drive efficiency, which in turn drives down cost to provide care, allowing Shields to operate effectively under lower IDTF rates. The lower IDTF rates offer payers the opportunity to require lower deductibles for patients and the opportunity for lower TME overall, thus also improving access to high quality care.

Furthermore, many national insurers have implemented site-of-care reviews for diagnostic imaging.<sup>85</sup> Payers like United Healthcare, Cigna, and Anthem/BCBS have all implemented these policies as an attempt to push patients to lower cost sites of care for imaging. If a procedure is to be performed at an IDTF, a site

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<sup>82</sup> World Health Organization, Early cancer diagnosis saves lives, cuts treatment costs, February 3, 2017, <https://www.who.int/news-room/detail/03-02-2017-early-cancer-diagnosis-saves-lives-cuts-treatment-costs> & Robert Wood Johnson Foundation, How can Early Treatment of Serious Mental Illness Improve Lives and Save Money? March 26, 2013, <https://www.rwjf.org/en/library/research/2013/03/how-can-early-treatment-of-serious-mental-illness-improve-lives-.html>

<sup>83</sup> Jung HY, Vest JR, Unruh MA, Kern LM, Kaushal R; HITEC Investigators. Use of Health Information Exchange and Repeat Imaging Costs. J Am Coll Radiol. 2015 Dec;12(12 Pt B):1364-70. Online at: <https://pubmed.ncbi.nlm.nih.gov/26614881/>

<sup>84</sup> The World Health Organization defines integrated service delivery as the "the management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system". See integrated health services - what and why? Technical Brief No.1, 2008, World Health Organization. Available from: [http://www.who.int/healthsystems/service\\_delivery\\_techbrief1.pdf](http://www.who.int/healthsystems/service_delivery_techbrief1.pdf)

<sup>85</sup> Links to site of care policies: [United Healthcare Site of Service Review for MRI Services](#); [Cigna Site of Service Review for MRI Services](#); and [Anthem/BCBS Site of Service Review for MRI Services](#)

of care review will not occur (and therefore no additional charges will be incurred). The review will only occur (or be billed) if the procedure is performed in a hospital-based setting.

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

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

#### **A. Overview**

Combined PET-CT scans help clinicians pinpoint abnormal metabolic activity and provide more accurate diagnoses than the two scans performed separately.<sup>86</sup> A PET scan measures important body functions, such as metabolism.<sup>87</sup> It helps doctors evaluate how well organs and tissues are functioning.<sup>88</sup> CT imaging uses special x-ray equipment, and in some cases a contrast material, to produce multiple images of the inside of the body.<sup>89</sup> A radiologist views and interprets these images on a computer monitor. CT imaging provides excellent anatomic information.<sup>90</sup>

The main applications of PET-CT have been in the oncologic and in the cardiovascular domains where the combined technique has allowed improved all-in one imaging protocols that have been proven beneficial.<sup>91</sup> However, it is noteworthy that some newer applications are emerging that can re-center PET-CT clearly in the neuroradiological world such as the investigation of vascular diseases.<sup>92</sup>

The results of a significant Danish study<sup>93</sup> published in the Journal of Nuclear Medicine revealed that implementation of PET-CT as the *first-line imaging* modality *instead of CT alone*, should be considered. The positive predictive value was 83% for PET-CT but only 54% for CT.<sup>94</sup> In addition, in the subgroups in which the initial imaging modality showed a suggestion of malignant disease, there was a significantly longer time to final diagnosis in the CT group than in the PET-CT group.<sup>95</sup> This study strongly suggests that PET-CT can support patients receiving the proper diagnosis in less time, which allows for clinicians to focus their energies into treatment and recovery.

Moreover, medical care delay or avoidance may well increase morbidity and mortality risk associated with treatable and preventable health conditions and might contribute to reported

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<sup>86</sup> Available at RadiologyInfo.org for patients. Online at: <https://www.radiologyinfo.org/en/info/pet>

<sup>87</sup> *Ibid.*

<sup>88</sup> *Ibid.*

<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> Lövsblad, K.-O., Bouchez, L., Altrichter, S., Ratib, O., Zaidi, H., & Vargas, M. I. (2019, August). Pet-CT in Neuroradiology . Clinical and Translational Neuroscience. Retrieved February 16, 2022. Online at: <https://journals.sagepub.com/doi/full/10.1177/2514183X19868147>

<sup>92</sup> *Ibid.*

<sup>93</sup> Whole-Body 18F-FDG PET/CT Is Superior to CT as First-Line Diagnostic Imaging in Patients Referred with Serious Nonspecific Symptoms or Signs of Cancer: A Randomized Prospective Study of 200 Patients. Anne-Mette Lebech, Anne Gaardsting, Annika Loft, Jesper Graff, Elena Markova, Anne Kiil Bertelsen, Jan Lysgård Madsen, Kim Francis Andersen, Eric von Benzön, Morten Helms, Lars R. Mathiesen, Kim P. David, Gitte Kronborg, Andreas Kjaer. Journal of Nuclear Medicine Jul 2017, 58 (7) 1058-1064; DOI: 10.2967/jnumed.116.175380. Online at: <https://jnm.snmjournals.org/content/58/7/1058>

<sup>94</sup> *Ibid.*

<sup>95</sup> *Ibid.*

excess death, according to the Centers for Disease Control and Prevention (“CDC”).<sup>96</sup> Overall, an estimated 40.9% of U.S. adults have avoided medical care during the pandemic because of concerns about COVID-19, including 12.0% who avoided urgent or emergency care and 31.5% who avoided routine care.<sup>97</sup> Cancer screening is considered routine care for individuals starting as early as age 25.<sup>98</sup> CDC supports screening for breast, cervical, colorectal (colon), and lung cancers as recommended by the U.S. Preventive Services Task Force.<sup>99</sup>

In addition to the broader public health value benefits discussed above, the Applicant’s patient panel will enjoy the continued benefit of local access to PET-CT services that complement the cancer treatment, and the cardiological and neurological services currently provided at Harrington Hospital.

The Cancer Center at Harrington is a two-story, oncology and hematology center on the edge of the main Harrington Hospital campus in Southbridge. The center offers comprehensive treatments, tailored to patient’s individual needs. The first floor offers the latest in radiology treatments, such as Intensity Modulated Radiation Therapy (IMRT) and Image-Guided Radiation Therapy (IGRT), which focuses the radiation treatment on the tumor and spares the normal tissue. The second floor offers infusion and chemotherapy services, hematology services, care management and many other support services.

Harrington Hospital offers preventive and general cardiology services on an outpatient basis. Cardiology consults are also offered as part of their inpatient service, in the Intensive Care Unit, and through the cardiac rehabilitation program.

Harrington Hospital also offers comprehensive outpatient neurological consultations and diagnostic testing, where clinicians provide treatment for disorders of the nervous system.

## **B. PET-CT as a Clinical Modality for Oncologic, Cardiac, and Neurologic Conditions**

### Oncologic Conditions

As the population expands, over the period from 2000 to 2050, the number and percentage of Americans over age 65 is expected to double.<sup>100</sup> This population expansion will be accompanied by a marked increase in patients requiring care for disorders with high prevalence in the elderly.<sup>101</sup> Since cancer incidence increases exponentially with advancing age, it is expected that there will

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<sup>96</sup> Czeisler MÉ, Marynak K, Clarke KE, et al. Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1250–1257. Available online at: <http://dx.doi.org/10.15585/mmwr.mm6936a4>

<sup>97</sup> Czeisler MÉ, Marynak K, Clarke KE, et al. Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1250–1257. Available online at: <http://dx.doi.org/10.15585/mmwr.mm6936a4>

<sup>98</sup> According to the American Cancer Society, regular screenings can help find and treat pre-cancers and cancers early, before they have a chance to spread. Available online at: <https://www.cancer.org/healthy/find-cancer-early/american-cancer-society-guidelines-for-the-early-detection-of-cancer.html>

<sup>99</sup> CDC website. Available online at: <https://www.cdc.gov/cancer/dcpc/prevention/screening.htm>

<sup>100</sup> 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. Online at: <https://pubmed.ncbi.nlm.nih.gov/18528470/>

<sup>101</sup> *Ibid.*

be a surge in older cancer patients that will challenge both healthcare institutions and healthcare professionals.<sup>102</sup>

Cancer studies have shown that early detection yields better outcomes for patients – and diagnostic imaging plays an essential role.<sup>103</sup> Studies have shown that PET-CT has become an established nuclear imaging modality that has proved especially useful in oncology.<sup>104</sup> Major clinical advantages of PET-CT include better localization of activity to normal vs. abnormal structures, better identification of inflammatory lesions, discovery of serendipitous abnormalities, confirmation of unusual or abnormal sites, and improved localization for biopsy or radiotherapy. Studies to date typically have shown a 4% to 15% improvement in overall accuracy of staging/restaging and a 30% to 50% improvement in the confidence of lesion localization. PET-CT has become the standard of imaging care for many oncology patients.<sup>105</sup>

PET-CT imaging in urological oncology remains in its burgeoning phases but is proving to be more and more useful as an imaging modality. To date, the use of F-FDG<sup>106</sup> has been limited by a generally low tumor uptake and physiological F-FDG excretion by the urinary system,<sup>107</sup> but other radiotracers are increasing the urologist's portfolio allowing imaging of several biochemical pathways.<sup>108</sup> Theragnostic<sup>109</sup> possibilities are also under investigation thanks to PSMA-based tracers.<sup>110111</sup>

According to the Massachusetts Cancer registry, Worcester County has a cancer incidence of approximately 479 cases per 100,000.<sup>112</sup> Improvements in accuracy and confidence in lesion localization, it stands to reason that a significant percentage of the cases diagnosed per year could be positively impacted with continued access to a local and convenient PET-CT diagnostic imaging.

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<sup>102</sup> *Ibid.*

<sup>103</sup> Rachel Lynch. The Role of Diagnostic Imaging in Early Detection of Cancer. Carestream. Online at: <https://www.carestream.com/blog/2017/12/26/diagnostic-imaging-and-early-detection-of-cancer/>

<sup>104</sup> “Clinical research has shown that in comparison to a PET scan alone, PET/CT technology provides new information that can alter a patient's treatment plan to better target the cancer in approximately one-third of the cases. In one example, the PET/CT scan of a lung cancer patient revealed not only the original tumor on the lung—which a previous CT scan had found—but an additional tumor the CT missed: a small, early stage lesion in the neck. Based on the CT alone, the doctor would have recommended surgery, but the additional tumor found by PET/CT indicated that the cancer had spread and was inoperable. Based on this information, the doctor proceeded with radiation therapy, giving the patient a better chance of survival.” Case study reference from Sanford Health available online at: <https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html>

<sup>105</sup> Griffeth LK. Use of PET-CT scanning in cancer patients: technical and practical considerations. Proc (Bayl Univ Med Cent). 2005;18(4):321-330. doi:10.1080/08998280.2005.11928089. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1255942/>

<sup>106</sup> Fluorodeoxyglucose F 18 is a radiotracer used in PET imaging. Also written F-FDG<sup>18</sup>

<sup>107</sup> Farolfi, Andreaa; Koschel, Samanthab; Murphy, Declan G.b,c; Fanti, Stefanoa. PET imaging in urology: a rapidly growing successful collaboration. Current Opinion in Urology: September 2020 - Volume 30 - Issue 5 - p 623-627

doi: 10.1097/MOU.0000000000000800. Online at : [https://journals.lww.com/co-urology/Abstract/2020/09000/PET\\_imaging\\_in\\_urology\\_a\\_rapidly\\_growing.2.aspx](https://journals.lww.com/co-urology/Abstract/2020/09000/PET_imaging_in_urology_a_rapidly_growing.2.aspx)

<sup>108</sup> *Ibid.*

<sup>109</sup> Theragnostics is a treatment strategy that combines therapeutics with diagnostics. It associates both a diagnostic test that identifies patients most likely to be helped or harmed by a new medication, and targeted drug therapy based on the test results.

<sup>110</sup> Prostate specific membrane antigen radiotracer (PSMA radiotracer) is a medicinal compound, called a radiopharmaceutical, that is used in PET/CT imaging.

<sup>111</sup> *Ibid* -- Note 22

<sup>112</sup> Available online at: <https://www.cancer-rates.info/ma/>

## Cardiac Conditions

PET-CT images of the heart provide comprehensive information to physicians, allowing for more enhanced management of cardiovascular disease, especially for ischemic heart disease.<sup>113</sup> The ability for the heart to recover naturally from ischemic damage decreases with age and makes older patients more susceptible to injury.<sup>114</sup> Where traditional CT and PET scans have unique advantages in diagnosing coronary artery disease, a typical cause of ischemic heart disease, each has its downfalls and can result in missed diagnoses or unnecessary invasive procedures. Combined PET-CT imaging remains the only technique that yields sufficient information in one procedure to quickly provide all the necessary information for a physician to make a timely and proper medical decision.<sup>115</sup>

In addition, the applications of PET-CT are expanding, and its uses are being employed for assessing patients with cardiac pathology. In the heart, free fatty acid and glucose are major energy sources, however when there is a blockage of blood flow such as in a patient with myocardial ischemia, there is a metabolic change that occurs so that a new energy source is found usually in a process known as anaerobic glycolysis.<sup>116</sup> These metabolic changes can be detected by PET/CT scans and evaluations of them can provide information regarding the functionality of the myocardium (the muscular layer of the heart), which can provide important data for surgery such as heart transplantation.<sup>117</sup> There are many viability tests and noninvasive assessment of cardiac glucose use, however the PET-CT scan is considered the most accurate technique for detecting viable myocardial tissue.<sup>118</sup>

Aside from its ability to assess cardiac glucose use, PET-CT can be used to determine overall left ventricular function and calculate important cardiac function data including end-diastolic volume (EDV), end-systolic volume (ESV) and left ventricular ejection fraction (LVEF).<sup>119</sup> When a patient is experiencing the chronic phase of severe myocardial infarction, researchers found that PET-CT was useful for selecting candidates that were suitable for cell therapy.<sup>120</sup>

<sup>113</sup> Slomka, P., Berman, D.S., Alexanderson, E. et al. The role of PET quantification in cardiovascular imaging. *Clin Transl Imaging* 2, 343–358 (2014). Online at: <https://pubmed.ncbi.nlm.nih.gov/26247005/>

<sup>114</sup> Strait JB, Lakatta EG. Aging-associated cardiovascular changes and their relationship to heart failure. *Heart Fail Clin*. 2012;8(1):143–164. doi:10.1016/j.hfc.2011.08.011. Online at: <https://pubmed.ncbi.nlm.nih.gov/22108734/>

<sup>115</sup> Knaapen P, de Haan S, Hoekstra OS, et al. Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease. *Neth Heart J*. 2010;18(2):90–98. doi:10.1007/BF03091744. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828569/>

<sup>116</sup> Visser F. C. (2001). Imaging of cardiac metabolism using radio-labelled glucose, fatty acids and acetate. *Coronary artery disease*, 12 Suppl 1, S12–S18. Online at: <https://pubmed.ncbi.nlm.nih.gov/11286301/>

<sup>117</sup> Zhuang, H., & Codreanu, I. (2015). Growing applications of FDG PET-CT imaging in non-oncologic conditions. *Journal of biomedical research*, 29(3), 189–202. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449487/>

<sup>118</sup> Bax, J. J., Patton, J. A., Poldermans, D., Elhendy, A., & Sandler, M. P. (2000). 18-Fluorodeoxyglucose imaging with positron emission tomography and single photon emission computed tomography: cardiac applications. *Seminars in nuclear medicine*, 30(4), 281–298. Online at: <https://pubmed.ncbi.nlm.nih.gov/11105929/>

<sup>119</sup> Zhuang, H., & Codreanu, I. (2015). Growing applications of FDG PET-CT imaging in non-oncologic conditions. *Journal of biomedical research*, 29(3), 189–202. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449487/>

<sup>120</sup> Maureira, P., Tran, N., Djaballah, W., Angioi, M., Bensoussan, D., Didot, N., Fay, R., Sadoul, N., Villemot, J. P., & Marie, P. Y. (2012). Residual viability is a predictor of the perfusion enhancement obtained with the cell therapy of chronic myocardial infarction: a pilot multimodal imaging study. *Clinical nuclear medicine*, 37(8), 738–742. Online at: <https://pubmed.ncbi.nlm.nih.gov/22785499/>

When compared with cardiac Magnetic Resonance Imaging (MRI), the PET-CT was able to detect a more impaired yet viable myocardium.<sup>121</sup> In another study focused on cardiac sarcoidosis (inflammatory condition that affects different areas of the heart), the researchers noted differences between the two modalities, and they found that PET-CT was more efficient at detecting elevated serum angiotensin converting enzyme (ACE) levels, which suggests that this type of scan may be more useful for active disease assessment and for following treatment response.<sup>122</sup>

Additionally, a PET-CT scan may be even more useful in such patients for evaluating the full extent of cardiac sarcoidosis by detecting unsuspected lesions and identification of potential biopsy sites.

This type of scan is particularly more practical since many patients with this disease have implanted cardiac devices such as pacemakers or defibrillators that interfere with MRI scans due to the magnets that are used.<sup>123</sup>

In a setting where comprehensive acute care and follow-up treatment can be appropriately provided, Harrington Hospital's cardiology patients will benefit from continued access to PET-CT by allowing for efficient and accurate assessment, clinical analysis, and treatment decisions.

### Neurological Conditions

PET-CT has been shown to enhance a clinician's ability to diagnose and effectively treat neurological diseases. In neurology, PET-CT plays an important role in the evaluation of various epileptic syndromes as well as in the clinical assessment of patients with a multitude of other disorders, including cognitive impairment and dementias.<sup>124</sup> The PET-CT modality has become a valuable tool in the diagnosis, treatment evaluation and follow-up of patients with a variety of infections and inflammatory conditions and is already the gold standard for some neurological indications.<sup>125</sup>

PET (alone) has long been a part of the assessment of brain physiology and pathology. Its early applications were more academic and scientific rather than clinical. PET-CT have been proven as a superior scanning technique in oncological or cardiovascular disorders, but emerging research suggests that PET-CT could be an integral part in neuroradiological settings, such as vascular diseases such as carotid artery disease, which is a cause of stroke.<sup>126</sup>

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<sup>121</sup> Wang, L., Yan, C., Zhao, S., & Fang, W. (2012). Comparison of (99m)Tc-MIBI SPECT/18F-FDG PET imaging and cardiac magnetic resonance imaging in patients with idiopathic dilated cardiomyopathy: assessment of cardiac function and myocardial injury. *Clinical nuclear medicine*, 37(12), 1163–1169. Online at: <https://pubmed.ncbi.nlm.nih.gov/23154474/>

<sup>122</sup> Yu, J. Q., Doss, M., Codreanu, I., & Zhuang, H. (2012). PET/CT in Patients with Sarcoidosis or IgG4 Disease. *PET clinics*, 7(2), 191–210. Online at: <https://pubmed.ncbi.nlm.nih.gov/27157236/>

<sup>123</sup> *Ibid.*

<sup>124</sup> Zhuang H, Codreanu I. Growing applications of FDG PET-CT imaging in non-oncologic conditions. *J Biomed Res*. 2015;29(3):189-202. doi:10.7555/JBR.29.20140081. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449487/>

<sup>125</sup> *Ibid.*

<sup>126</sup> Lövblad, K.-O., Bouchez, L., Altrichter, S., Ratib, O., Zaidi, H., & Vargas, M. I. (2019, August). Pet-CT in Neuroradiology . *Clinical and Translational Neuroscience*. Retrieved February 16, 2022. Online at: <https://journals.sagepub.com/doi/full/10.1177/2514183X19868147>



Current standards for taking images for dementia treatment include CT, MRI, or both to exclude masses and vascular lesion, identify and monitor disease and its severity. The addition of PET-CT scans in dementia cases can provide complementary data on the cerebral glucose metabolism, which is a key indicator in the diagnosis and treatment of dementia.<sup>127</sup> A study that focused on the diagnosis of Autoimmune Encephalitis, an inflammatory neurological disease, found that when compared with MRI, PET-CT may be a better technique in providing an earlier diagnosis of the disease.<sup>128</sup>

According to the Alzheimer's Association, Alzheimer's disease is a growing public health crisis in Massachusetts and the impact of Alzheimer's is projected to rise.<sup>129</sup> In fact, 130,000 people aged 65 and older are living with Alzheimer's in Massachusetts and 9.3% of people aged 45 and older have subjective cognitive decline.<sup>130</sup> Studies suggest that PET imaging is valuable in the assessment of patients with dementia and can help in differentiating Alzheimer's from other causes of dementia such as frontotemporal dementia and dementia of Lewy body.<sup>131</sup>

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

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

#### **A. Improving Health Outcomes and Quality of Life**

The Applicant anticipates that the Proposed Project will provide the Applicant's patient panel with a low-cost option for continued access to integrated PET-CT services that will directly impact health outcomes, quality of life, and patient satisfaction.

Studies indicate that *delayed access* to healthcare services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.<sup>132</sup> Conversely, *ease of access* improves quality of life for patients because early detection and treatment of diseases improves patient outcomes.<sup>133</sup> 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.<sup>134</sup>

<sup>127</sup> Zukotynski, K., Kuo, P. K., Mikulis, D., Rosa-Neto, P., Strafella, A. P., Subramaniam, R. M., & Black, S. E. (2018, August). PET/CT of Dementia . Retrieved February 22, 2022. Online at: <https://www.ajronline.org/doi/pdfplus/10.2214/AJR.18.19822>

<sup>128</sup> Solnes, L. B., Jones, K. M., Rowe, S. P., Pattanayak, P., Nalluri, A., Venkatesan, A., Probasco, J. C., & Javadi, M. S. (2017). Diagnostic Value of 18F-FDG PET/CT Versus MRI in the Setting of Antibody-Specific Autoimmune Encephalitis. *Journal of nuclear medicine : official publication, Society of Nuclear Medicine*, 58(8), 1307–1313. Online at: <https://pubmed.ncbi.nlm.nih.gov/28209905/>

<sup>129</sup> Available online at : <https://www.alz.org/professionals/public-health/state-overview/massachusetts>

<sup>130</sup> *Ibid.*

<sup>131</sup> Marcus C, Mena E, Subramaniam RM. Brain PET in the diagnosis of Alzheimer's disease. *Clin Nucl Med*. 2014 Oct;39(10):e413-22; quiz e423-6. doi: 10.1097/RLU.0000000000000547. PMID: 25199063; PMCID: PMC4332800. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4332800/>

<sup>132</sup> Julia C. Prentice & Steven D. Pizer, Delayed Access to Health Care and Mortality, 42 HEALTH SERVICES RESEARCH 644 (2007), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1955366/>

<sup>133</sup> American College of Radiology. *Early Action Boosts Patient Satisfaction*. Online at: <https://www.acr.org/Practice-Management-Quality-Informatics/Imaging-3/Case-Studies/Quality-and-Safety/Early-Action-Boosts-Patient-Satisfaction>

<sup>134</sup> Otani K, Ye S, Chumbler NR, Judy Z, Herrmann PA, Kurz RS. The impact of self-rated health status on patient satisfaction integration process. *Journal of Healthcare Management*. 2015;60(3):205-218. Online at: <https://pubmed.ncbi.nlm.nih.gov/26554265/>

Through continued access to local PET-CT services at Harrington Hospital via IDTF clinic-based service, the Applicant aims to ensure low-cost, high-quality imaging services for its patient panel. Access to such PET-CT services for these patients – particularly for patients who are sick or effected by oncological, cardiovascular, and/or neurological issues – allows for better quality health outcomes, as it allows clinicians to have a better understanding of an individual’s condition and provide appropriate comprehensive treatment options in a timely manner. Along with providing better imaging data, PET-CT notably increases patient comfort and convenience by reducing the number of scanning sessions a patient must undergo.<sup>135</sup>

A study evaluating the efficacy of combined PET-CT imaging revealed that PET (on its own) is a quite lengthy procedure, as it requires both emission and transmission scans.<sup>136</sup> However, the study found that image fusion between PET and CT has resulted in an average time savings of 20 to 30 minutes per patient.<sup>137</sup> In this case, transmission scans are not required because the CT data are used for attenuation correction.<sup>138</sup> It has been estimated that patient output has increased by approximately 40 percent.<sup>139</sup> Time savings (as demonstrated above) directly correlates to patient satisfaction according to a 2017 Philips Research Report surveying patient responses to recent imaging procedures – the report found that 61% of patients reported that an accurate scan in the least amount of time to reduce physical discomfort was an “extremely important” aspect of the imaging procedure.<sup>140</sup>

Given that patients will continue to be able to access local PET-CT services in a timely, low-cost, and high-quality manner, patient satisfaction, health outcomes and quality of life will improve. Patient satisfaction is an important indicator used for measuring quality in health care.<sup>141</sup>

Moreover, imaging services provided by the Applicant will be fully integrated with Harrington Hospital’s Health Information System (“HIS”), which is an integration feature that is *not* a part of the current vendor’s service offerings. Studies show that having access to integrated health information systems, including integrated picture archiving and communication systems (“PACS”) information has a direct impact on health outcomes as access to a single medical record for patient’s leads to enhanced care coordination<sup>142</sup> by care teams and improved efficiency with respect to workflows.<sup>143</sup>

<sup>135</sup> Online at: <https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html>

<sup>136</sup> Saif MW, Tzannou I, Makrilia N, Syrigos K. Role and cost effectiveness of PET/CT in management of patients with cancer. *Yale J Biol Med*. 2010 Jun;83(2):53-65. PMID: 20589185; PMCID: PMC2892773. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892773/>

<sup>137</sup> *Ibid.*

<sup>138</sup> *Ibid.*

<sup>139</sup> *Ibid.*

<sup>140</sup> The Patient Experience in Imaging Study was conducted in the summer of 2017 by Kantar TNS, in the Netherlands per order of Philips. It was based on prior qualitative research conducted in April-May 2017. Available online at: [https://images.philips.com/is/content/PhilipsConsumer/Campaigns/HC20140401\\_DG/Documents/PEX\\_in\\_Imaging\\_research\\_11Oct17\\_FINAL.pdf](https://images.philips.com/is/content/PhilipsConsumer/Campaigns/HC20140401_DG/Documents/PEX_in_Imaging_research_11Oct17_FINAL.pdf)

<sup>141</sup> Bhanu Prakash, Patient Satisfaction, 3 J. CUTANEOUS & AESTHETIC SURGERY 151 (2010), online at: <https://pubmed.ncbi.nlm.nih.gov/21430827/>

<sup>142</sup> Care Management is designed to assist patients and their support systems in managing medical conditions and related psycho-social issues by communicating effectively. Harrington Hospital’s goal is to improve a patient’s functional health status through enhancing the coordination of care with available resources in a timely and cost-effective manner. Hospital case managers and social workers provide individualized services including: inpatient care management; support to inpatients and family members, including crisis intervention and grief support; and educating and assisting with discharge planning. Harrington Hospital offers a wide variety of information available to the public and our community.

<sup>143</sup> Hanan Aldosari, Basema Saddik, Khulud Al Kadi. Impact of picture archiving and communication system (PACS) on radiology staff, *Informatics in Medicine Unlocked*, Volume 10, 2018. Online at: <https://www.sciencedirect.com/science/article/pii/S2352914817301958>



Poor coordination of care has negative consequences for patients and contributes to higher medical costs.<sup>144</sup> An integrated medical record allows primary care physicians (“PCPs”) 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 Harrington Hospital’s patients will facilitate quick and easy access to patient images and reports, which will in turn effect timely care, improved outcomes, and better quality of life.

## **B. Assessing the Impact of the Proposed Project**

To assess the impact of the Proposed Project, the Applicant has developed the following quality metrics and reporting schematic, as well projections for quality indicators that will measure patient satisfaction, access, and quality of care.<sup>145</sup> The measures are discussed below:

**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.

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

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

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

**Monitoring:** PET-CT scans will be 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.

**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

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<sup>144</sup> O'Malley AS, Grossman JM, Cohen GR, Kemper NM, Pham HH. Are electronic medical records helpful for care coordination? Experiences of physician practices. *J Gen Intern Med.* 2010;25(3):177-185. doi:10.1007/s11606-009-1195-2. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2839331/>

<sup>145</sup> Shields is now using a platform called Podium – a text-based program for patient experience.

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.

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

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

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

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

**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.

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

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

To ensure health equity to all populations, including those deemed underserved, the Proposed Project will not adversely affect accessibility of Harrington Hospital's services for poor, medically indigent, and/or Medicaid eligible individuals. The Applicant will not discriminate based on ability to pay or payer source

following implementation of the Proposed Project. As further detailed throughout this narrative, the Proposed Project will provide continued access to high-quality PET-CT services for all patients by offering a low-cost alternative in the community setting where patients are already seeking care.

The Applicant ascribes importance to the notion that health equity is tied to the affordability of the health care service being provided. A Kaiser Family Foundation survey<sup>146</sup> found that half of U.S. adults say they or a family member put off or skipped health care or dental care or relied on an alternative treatment because of the cost. As a result, about one in eight said their medical condition got worse as a result. Health care costs top the list of expenses that people report difficulty affording.<sup>147</sup> The Applicant is addressing this disparity by offering imaging services that are reimbursed at lower, IDTF rates – IDTF's maintain costs by focusing on one service with much less overhead.<sup>148</sup>

The Applicant will not discriminate based on ability to pay or payer source following implementation of the Proposed Project. The Applicant accepts all forms of insurance. In addition, the Applicant will offer price transparency tools to ensure that all patients have access to current pricing information. By providing this information patients may determine if specific procedures are affordable. The Applicant also will provide financial counselors for assistance in understanding insurance benefits.

If the Proposed Project is approved, the Applicant shall implement culturally appropriate support services to ensure improved patient experience and higher quality outcomes. Accordingly, the Applicant will employ culturally competent staff and plans to implement a robust translation services program.

The Applicant offers ongoing education and training of staff in culturally and linguistically appropriate care and offers several tools to accommodate patients' needs and preferences. The Applicant will offer multiple tools to address language barriers, including Language Line<sup>149</sup> and InDemand interpreting to provide multiple options for translation services.<sup>150</sup> Language Line provides quality phone and video interpretation services from highly trained professional linguists in more than 240 languages 24 hours a day, 7 days a week, facilitating more than 35 million interactions a year. InDemand offers leading-edge medical interpreting solutions, which allows clinicians to provide their limited English proficient, deaf, and hard of hearing patients with access to the highest quality healthcare. Together, these solutions will eliminate language barriers for patients and ensure culturally appropriate care.

Lastly, the Proposed Project will provide the opportunity for patients to continue receive the highest quality imaging on location at the Harrington Hospital's Southbridge campus, thus preventing barriers to this service locally.<sup>151</sup> To date, several<sup>152</sup> Harrington Hospital patients seeking PET-CT imaging have had to

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<sup>146</sup> Kaiser Family Foundation. *America's Challenges with Health Care Costs*. December 14, 2021. Online at: <https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/>

<sup>147</sup> *Ibid*.

<sup>148</sup> Available online at: [https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIEiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD\\_BwE](https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIEiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE)

<sup>149</sup> Language Line Solutions phone interpreting may also be used in the event the In Demand system is not functioning properly.

<sup>150</sup> Designated iPads are used for the In Demand interpreting which provides the following: real-time, full motion video and audio over a dedicated high-speed internet connection, wide and width video connection or wireless connection that delivers high quality video images; a sharply delineated image large enough to display the interpreter's face and the participating individual's face; a clear, audible transmission of voices; a choice of female or male interpreter, based on patient preference if requested; adequate training to users on the operation of the video remote interpreting system; and phone interpreting services when needed.

<sup>151</sup> "A relationship between travelling further and having worse health outcomes cannot be ruled out and should be considered within the healthcare services location debate." Kelly C, Hulme C, Farragher T, Clarke G. Are differences in travel time or distance to healthcare for adults in global north countries associated with an impact on health outcomes? A systematic review. *BMJ Open*. 2016;6(11):e013059. Published 2016 Nov 24. doi:10.1136/bmjopen-2016-013059. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5178808/>

<sup>152</sup> To date, 70 patients.

travel to receive a diagnostic imaging scan and this number has been increasing by 10-12 patients each month over the last several months. Local access is an essential component of maintaining the continuity of care and ensuring that the most direct path to diagnosis and treatment is available. Transportation barriers are often cited as barriers to healthcare access, and it often leads to delayed care and missed or delayed medication use, among other things.<sup>153</sup> These consequences may lead to poorer management of chronic illness and ultimately poorer health outcomes.<sup>154</sup>

The Applicant's Proposed Project will help continue to ensure continued access to local PET-CT imaging services thus promoting health equity in the community.

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

The Proposed Project will allow for the continued provision of high-value, low-cost, local PET-CT services in the community setting. This delivery model is just as convenient and efficient as the existing service, made possible through operational discipline and focus that cannot be achieved under traditional hospital oversight. Dedicated focus by the Shields management team offers insight on operational and scheduling efficiencies that increase capacity and improve patient and referring provider satisfaction. The Applicant also plans to implement numerous amenities, including patient access tools, such as preregistration functionality and a cost transparency application, to improve patient experience and ensure patient satisfaction.

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

Through the Proposed Project, the Applicant will combine physician engagement with a strong technology infrastructure to ensure continuity of care, improved health outcomes and care efficiencies. The technology infrastructure for the Proposed Project encompasses streamlined patient access tools that offer pre-registration functionality. These tools interface with electronic medical record ("EMR") systems to amalgamate necessary patient health information, such as medical history, allergies, and medications. EMR functionality also allows radiologists to share pertinent diagnostic information with PCPs, so both physicians may track a patient's treatment progress.

The applicant plans to conduct a pre-screening process for all scheduled patients. Social Determinants of Health ("SDoH") are defined as conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life risks and outcomes.<sup>155</sup> Certain questions in the pre-screen relate to certain SDoH issues, namely those issues that are relevant to an imaging appointment such as transportation.<sup>156</sup> If, during this pre-screen process or at any time during a patient's PET-CT appointment,

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<sup>153</sup> Syed ST, Gerber BS, Sharp LK. Traveling towards disease: transportation barriers to health care access. J Community Health. 2013;38(5):976-993. doi:10.1007/s10900-013-9681-1. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265215/>

<sup>154</sup> *Ibid.*

<sup>155</sup> Centers for Disease Control and Prevention. Online at: <https://www.cdc.gov/socialdeterminants/index.htm>

<sup>156</sup> Access to transportation is one of the most important social determinants of health (SDOH), according to the CDC.

the Applicant's staff is made aware of an SDoH issue, staff will confirm that a request for assistance is needed and either assist the patient directly (e.g., in the case of transportation) or refer the patient back to his/her primary care physician ("PCP") for linkage to community-based support (e.g., in the case of hunger and access to food). The Applicant also provides transportation assistance via ride-share and cab vouchers when needed by a patient.

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

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

- Dennis Renaud, Director, Determination of Need Program
- Jennica F. Allen Community Health Planning and Engagement Specialist, Department of Public Health
- Lucy Clarke, Analyst, Determination of Need Program, Massachusetts Department of Public Health
- Monica Sawhney, Chief of Staff at MassHealth
- Samuel Louis, M.P.H., Coordinator, Health Care Interpreter Services, Department of Public Health, Health Care Interpreter Services

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

The Applicant identified the need to continue to provide high-quality, cost-effective PET-CT services for Harrington Hospital patients. The Applicant's data for these services demonstrates the demand. Additionally, demand for local PET-CT services is likely to increase as the region's population ages. The Applicant engaged the community to involve patients and families more fully regarding the proposed transition.

The Proposed Project was presented at Harrington Hospital's Family Advisory Committee ("PFAC") on November 28, 2022, with eight (8) individuals in attendance. The PFAC is comprised of current and former patients of the hospital and their family members as well as staff of the hospital. Because patients of the proposed service will continue to be Harrington Hospital patients, it was decided that the PFAC would best represent patients from the proposed service area. The presentation sought to inform PFAC members about the purpose of the Proposed Project and what it would mean for patients.

The presentation to the PFAC offered members an overview of current state of imaging services and the continued need for PET-CT at the hospital on location at the Main Campus once the current imaging vendor relationship expires in 2023. It reviewed how the Proposed Project will benefit current and future patients. This project will use a combination of inside space and a mobile PET-CT unit aligned with the

building one day per week. PET-CT services will complement the cancer treatment and breast services currently provided at Harrington Hospital. The service will operate on a freestanding IDTF fee schedule which will help lower the cost of services.

The PFAC members had a generally very positive reaction 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 the importance of access and timeliness of the imaging appointment. A few of the members made comments regarding the importance of receiving imaging results as quickly as possible.<sup>157</sup> One member of the group sought clarification regarding the current state of PET-CT imaging at Harrington Hospital and the hospital administration's impetus to change vendors. The primary concern with this comment was that a patient may question the quality of recent imaging and have some concern for his/her health. In response to this comment, the suggestion was made to Hospital administration that effective communications regarding the vendor transition may be helpful. Another member of the group communicated concern about the quality of the scans conducted by the *current* vendor – this individual suggested that a recent personal experience was subpar and hoped that under Shields operation, patient experience would be improved.

The Applicant also advertised a virtual community meeting regarding the Proposed Project on Harrington Hospital social media three weeks in advance of the forum, which was scheduled for November 28, 2022.

<sup>158</sup> The Applicant opened the meeting forum and waited for attendees, but no one from the community joined the virtual meeting.<sup>159</sup>

To ensure appropriate awareness within the community about the Proposed Project, the legal notice associated with the Proposed Project was published both on the Shields website<sup>160</sup> and on the Harrington Hospital website.<sup>161</sup> This was done to bring awareness of the Proposed Project to all patients, family members, residents, and resident groups. It also provides an opportunity for public comment on the Proposed Project.

**F1.e.ii Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value."**

To ensure sound community engagement throughout the development of the Proposed Project, the following meetings were scheduled:

- Virtual Community Forum on November 28, 2022; and

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<sup>157</sup> Shields' turnaround time for imaging results is approximately 24 hours.

<sup>158</sup> A copy of the social media flyer is included in Exhibit B.h

<sup>159</sup> A copy of the presentation is included herein with this submission.

<sup>160</sup> Published November 4, 2022 on the Shields website: <https://shields.com/location/shields-mri-umass-memorial-memorial-campus/>

<sup>161</sup> Published November 9, 2022 on Harrington Hospital website: <https://www.harringtonhospital.org/news/public-announcement-concerning-a-proposed-health-care-project-3/>

- Presentation to Harrington Hospital's PFAC on November 28, 2022.<sup>162</sup>

## Factor 2: Health Priorities

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

### F2.a. Cost Containment:

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

The goals for cost containment in Massachusetts center around providing low-cost care alternatives without sacrificing high quality. The Proposed Project seeks to align with these goals by providing continued access to a lower cost option for patients in and around the Harrington Hospital PSA/SSA seeking local PET-CT imaging services.

As previously discussed, the cost of providing these services will be mitigated via the IDTF clinic model. Furthermore, potential savings are associated with PET-CT as a result of avoiding additional imaging examinations or invasive procedures and by helping clinicians make the optimum treatment decisions.<sup>163</sup> The Proposed Project meets the goal of providing a lower-cost alternative for PET-CT imaging services, as services will be provided by an IDTF, rather than a hospital-based outpatient clinic. IDTFs are a more cost-effective option as the administrative costs for these types of providers are lower.<sup>164</sup> This difference will allow the Applicant to provide cost-effective, quality imaging services to Harrington Hospital's patients, while having a negligible impact on the overall healthcare market.<sup>165</sup>

According to a study in the Yale Journal of Biology and Medicine, there are savings from the integration of PET and CT in one system. There are several occasions in which PET leads to equivocal findings, and follow-up imaging studies (usually CT scans) are required.<sup>166</sup> If patients undergo both examinations in one session, in addition to having more accurate results, costs will be lower.<sup>167</sup>

Providing patients with continued access to accessible, low-cost, high-quality PET-CT imaging services and helping ensure that all patients receive essential care in a timely manner, is another way to promote cost containment goals. Reducing diagnostic and treatment delays limits deterioration of health and lowers

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<sup>162</sup> For detailed information regarding these activities, please see attached exhibit.

<sup>163</sup> Saif MW, Tzannou I, Makrilia N, Syrigos K. Role and cost effectiveness of PET/CT in management of patients with cancer. Yale J Biol Med. 2010 Jun;83(2):53-65. PMID: 20589185; PMCID: PMC2892773. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892773/>

<sup>164</sup> Daniel I. Levin, CFA, ASA and Nicholas J. Janiga, ASA. 2020 Outlook: Diagnostic Imaging Centers and Radiology Practices. Healthcare Appraisers. July 21, 2020, Business Valuation, Compensation Valuation. Online at: <https://healthcareappraisers.com/2020-outlook-diagnostic-imaging-and-radiology-practices/>

<sup>165</sup> The Proposed Project's IDTF fee schedule is the same as the current IDTF fee schedule as the public payers have standardized the fees nationwide.

<sup>166</sup> Saif MW, Tzannou I, Makrilia N, Syrigos K. Role and cost effectiveness of PET/CT in management of patients with cancer. Yale J Biol Med. 2010 Jun;83(2):53-65. PMID: 20589185; PMCID: PMC2892773. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892773/>

<sup>167</sup> Ibid.

costs by reducing the resources required for care.<sup>168</sup> By offering PET-CT imaging services where the patient panel has historically gone for diagnostic imaging, helps promote faster diagnosis, intervention, and treatment and can contribute to improving health care quality, thereby reducing the overall costs of health care.

## **F2.b Public Health Outcomes:**

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

Providing needed care in a more efficient and effective manner will improve public health outcomes and patient experience. As is outlined in detail throughout this narrative, PET-CT imaging is a powerful modality that allows clinicians to better understand the disease process and make treatment decisions. If the Proposed Project is approved, the patient panel will continue to enjoy 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. An aging population will have an increased need for high-quality imaging services to diagnose and treat age-related conditions. In fact, on average, the geriatric patient uses 50% more lab/imaging services than younger populations.<sup>169</sup>

PET-CT services managed under Shields operating platform will provide access to patients residing within the PSA/SSA. Increasing demand as outlined in Factor 1 will be met with greater access to the highest quality diagnostic imaging. Creating streamlined pathways for access to high value care will improve overall public health outcomes.

## **F2.c Delivery System Transformation:**

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

Through the Proposed Project, access to high-value, low-cost PET-CT imaging services will continue to be offered to the community served within Harrington Hospital's PSA/SSA. In instances where patients need support to address social determinants of health,<sup>170</sup> the Applicant offers enhanced access to services designed to facilitate improved care pathways influenced by social determinants of health. Specifically,

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<sup>168</sup> Robert S. Kaplan and Michael E. Porter. The Big Idea: How to Solve the Cost Crisis in Health Care. Harvard Business Review Magazine. 2011. Available online at: <https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care>

<sup>169</sup> The Geriatric Emergency Department Guidelines Task Force, Geriatric Emergency Department Guidelines. American College of Emergency Physicians, The American Geriatrics Society, Emergency Nurses Association, and the Society for Academic Emergency Medicine. Online at: [https://www.acep.org/globalassets/uploads/uploaded-files/acep/clinical-and-practice-management/resources/geriatrics/geri\\_ed\\_guidelines\\_final.pdf](https://www.acep.org/globalassets/uploads/uploaded-files/acep/clinical-and-practice-management/resources/geriatrics/geri_ed_guidelines_final.pdf)

<sup>170</sup> Care Management is designed to assist patients and their support systems in managing medical conditions and related psycho-social issues by communicating effectively. Our goal is to improve a patient's functional health status through enhancing the coordination of care with available resources in a timely and cost-effective manner. Our case managers and social workers provide individualized services including: Inpatient care management; Support to inpatients and family members, including crisis intervention and grief support; and Educating and assisting with discharge planning. Harrington Hospital offers a wide variety of information available to its community.



the Applicant plans to implement numerous amenities, including patient access tools, such as preregistration functionality, a cost transparency application, linkages to financial counselors, culturally competent staff, and a robust translation services program. These amenities facilitate easier to access care for vulnerable and at-risk populations.

PET-CT services will align with Harrington Hospital's well-established cancer care continuum. The Cancer Center at Harrington, operated by Harrington Hospital, provides infusion services (chemotherapy) and is staffed by oncology physicians and oncology nurses. To optimize patient safety, the Cancer Center at Harrington has its own pharmacy suite. The American Cancer Society Resource Room, which is sponsored by the American Cancer Society, provides a comfortable library-like setting where patients and their families can access literature and use a computer to learn more about cancer treatment. The room is staffed by volunteers who can assist in the research. The care continuum includes access to board-certified cancer specialists who take a team approach to personalized cancer treatment plans for each patient. Harrington Hospital surgeons, radiation oncologists, pathologists, oncologists/hematologists, nutritionists, primary care physicians, oncology nurses, and social workers collaborate to deliver the best possible care.

PET-CT services will also align with Harrington Hospital's comprehensive, cardiac rehabilitation program. These programs include access to individualized treatment to patients, including participation in exercise, strength-training, counseling, and education sessions with the goal of returning to better health.<sup>171</sup>

The Applicant's enhanced service offerings are not limited to staffing and programmatic functionality – care has also been taken for the physical space where services will be offered. Harrington Hospital participates in the MassHealth Disability Access Incentive Program which provides financial rewards when hospitals demonstrate progress toward getting accessible medical diagnostic equipment.<sup>172</sup> Research shows that a safe and well-designed clinical space helps to improve patient outcomes. The PET-CT area will optimize a combination of inside space and a mobile PET-CT unit aligned with the building. To access diagnostic imaging, patients will enter the mobile environment that is temporarily attached to the building, enclosed from the outside elements.

The needs of the Applicant's patient panel have been thoughtfully assessed in contemplation of the Proposed Project and as a result the Applicant is confident that integration of social services and community-based needs will be enhanced, should this project be approved.

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<sup>171</sup> Program also includes: Assisting individuals to identify and modify their risk factors, increase their physical activity and return to an active and satisfying lifestyle; A team approach to your care, involving primary care doctors, cardiologists, nurses, physical and occupational therapist, social workers and nutritionists; Individualized, multi-phase approach to cardiac rehabilitation care.

<sup>172</sup> The first phase required hospitals to complete an inventory of their accessible equipment. Then hospitals did a survey measuring whether patients with disabilities had to wait longer for diagnostic procedures, like x-rays, due to lack of accessible equipment or provider training. Now in its third year, the program is requiring hospitals to evaluate the results from previous surveys and expand future surveys to include other types of diagnostic equipment. This will help develop a methodology for tracking health care barriers for patients with disabilities.

## Factor 5: Relative Merit

**F5.a.i Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.**

### A. Proposal

To continue to provide PET-CT services to the local, Harrington Hospital patient panel, via the expansion of UMMIC's current operations. The physical clinic will be located in a pre-existing space at Harrington Hospital, where the previous vendor located its mobile facility. Patients would enter a mobile environment that is temporarily attached to the building, enclosed from the outside elements. Services will be reimbursed as an IDTF to enhance efficiency and effectiveness of care delivery.

### B. Quality

Maintaining PET-CT imaging capability for cancer staging, Alzheimer's disease evaluation, cardiac applications (amongst other things) to the patient panel at Harrington Hospital will allow for continued access to the highest quality diagnostic imaging services with the added benefit that patients will be receiving care at the same convenient location, and at a competitive IDTF price point.

Care provided at Shields' operated imaging centers are high-quality, with clinical outcomes that are equal to or better than hospital-based services for the same procedures.

### C. Efficiency

Care provided in an IDTF setting allows for greater focus on a specialized service. Highly trained staff and the ability to maintain a uniform schedule due to the PET-CT's ambulatory location allows for greater efficiencies and lower costs.

### D. Capital Expense

Establishing a new diagnostic imaging vendor partnership that leverages an IDTF fee schedule will result in some capital expense. There are expenses attributable to facility build out, as the proposed mobile PET-CT unit will utilize a mobile pad to be located in a pre-existing space at Harrington Hospital.<sup>173</sup>

### E. Operating Costs

As noted above, greater efficiencies will be identified, thus reducing operating costs, savings from which should be passed along to patients through lower premiums and deductibles, subject to third-party payer adjustments to new market conditions.

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<sup>173</sup> Please see Veralon's Capital Expenditures findings in section III of the attached CPA report.

The calculated operating expenses (including support services, billing, and bad debt expense) CAGR<sup>174</sup> for 2024 through 2028 of 7.6 percent for the Applicant. 2023 was not included in the CAGR calculation due to the previously cited higher bad debt expenses.<sup>175</sup> Bad debt expense for the Applicant in 2028 was \$18,803.<sup>176</sup>

No facilities-related expenses were projected in 2023 through 2028 and equipment-related expenses remain steady at \$246,060 during 2024 through 2028.

Service-related expenses include FDG (fludeoxyglucose) charges, specialty isotope, and other service-related expenses. These expenses are projected to increase steadily between 2023 through 2028, representing a CAGR of 10.3 percent.

Salaries and benefits include radiology, technologists, and operations expense. Veralon calculated a CAGR of 7.8 percent from 2023 through 2028 and found this to be a reasonable assumption.

Selling, General & Administrative (“SG&A”) expenses include support services, management fees, and other SG&A expenses. Veralon calculated a CAGR of 5.9 percent from 2024 through 2028. 2023 was not included in the CAGR calculation due to the estimated start-up costs of initiating operations, such as legal fees, and Community Health Needs Assessment (“CHNA”), etc.

The Maximum Incremental Operating Expense resulting from the Proposed Project is \$703,695.00.

## **F. Alternative Option for the Project**

### **a. Option 1**

#### **i. Alternative Proposal**

Harrington Hospital considered retaining the current diagnostic imaging vendor relationship. In this scenario, patients would retain local access to diagnostic imaging services on an IDTF fee schedule, however this option fails on several fronts. First, the quality of the services provided by the current vending relationship has not met with Harrington Hospital’s standard of care over the last few years. Secondly, the current vendor’s operational platform does not have the functionality to interface with the hospital’s electronic medical records (EMR) system. Lastly, maintaining the current vendor fails to meet the newly established operational principles instituted with the recent merger between Harrington Hospital and UMass Memorial Health system. UMass has an established vending relationship in place with Shields across their system. It is a priority to Harrington Hospital to preserve consistency both from a patient care perspective and an operational vantage point, therefore allowing the current vending relationship to expire in 2023 and expanding the partnership with Shields became the most appropriate option.

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<sup>174</sup> Compound Annual Growth Rate.

<sup>175</sup> Please see Profit and Loss Statement in the attached CPA report.

<sup>176</sup> The projected bad debt expenses that are notably higher in Year 1 account for Medicare and Medicaid services that are not anticipated to be reimbursable for the first month of operations of the Proposed Project until accreditation is obtained from the American College of Radiology (“ACR”).

**ii. Alternative Quality**

Retaining the current vending relationship would result in subpar patient experience – the status quo does not meet Harrington Hospital patient care standards. On the other hand, Shields’ operational platform will allow for the provision of additional screenings during the same one-day timeframe and the images will be taken on a current generation photomultiplier tube (PMT)-based imaging system. Expanding access to health services is an important step toward reducing health disparities,<sup>177</sup> and patients will benefit from the output quality of diagnostic imaging with the Siemens Biograph mCT 40.

**iii. Alternative Efficiency**

The current vending relationship is not integrated into the UMass operational platform or its electronic medical record (EMR) system, which creates a gap in efficiency.

Through the Proposed Project, the Applicant will combine physician engagement with a strong technology infrastructure to ensure continuity of care, improved health outcomes and care efficiencies. The technology infrastructure for the Proposed Project encompasses streamlined patient access tools that offer pre-registration functionality. These tools interface with the EMR system to amalgamate necessary patient health information, such as medical history, allergies, and medications. EMR functionality also allows radiologists to share pertinent diagnostic information with PCPs, so both physicians may track a patient's treatment progress.

**iv. Alternative Capital Expense**

Taking no action to update the current vending relationship would not have a per se negative impact from a financial vantage point. While no additional capital expenses would be incurred in the short term, forgoing the opportunity to improve operational efficiency and alignment from UMass as a system perspective, would not yield the most positive outcomes for patients or the operational infrastructure.

**v. Alternative Operating Costs**

Taking no action to update the current vending relationship would not result in any significant near-term changes in operating costs for Harrington Hospital.

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<sup>177</sup> Office of Disease Prevention and Health Promotion. Healthy People 2020. Access to Health Services. Available online at: <https://wayback.archive-it.org/5774/20220414155345/https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/access-to-health#2>

**Factor 6: Community Based Health Initiatives**

The Determination of Need Community-Based Health Initiative Planning Guidelines recite that the obligation to the Community-Based Health Initiative ("CHI") Program for proposed projects that classify as DoN-Required Equipment acquired by an entity other than a hospital will fulfill such obligations through a payment to the CHI Statewide Initiative at such time that the Applicant receives project approval.

The Applicant's proposed project falls into the category of DoN Required Equipment and is not a hospital and as such, will not submit CHI forms with this application.