UMass Memorial MRI & Imaging Center, LLC
Determination of Need Application

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Determination of Need

Narrative

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 on the UMass Memorial Health – Marlborough Hospital ("Marlborough Hospital") campus at 157 Union Street, Marlborough, MA 01752 and will operate one day per week ("Proposed Project"). The proposed PET-CT unit is a new installation but will utilize an already existing and serviceable mobile pad at Marlborough Hospital.

The Applicant currently operates Shields MRI at UMass Memorial-Shrewsbury Street ("Shields MRI at UMass Memorial") with two (2) mobile medical satellite clinics and two (2) medical satellite clinics across Fitchburg and Worcester. The Applicant seeks to address the absence of standard of care diagnostic imaging to support local treatment programs available at Marlborough Hospital by adding a part-time mobile medical satellite clinic to the UMMIC license, thus increasing the total number of satellite clinics under this license, from four (4) to five (5).

The Applicant, which is a joint venture between UMass Memorial Health Ventures, Inc., and Shields Healthcare of Worcester, LLC seeks to ensure Marlborough Hospital patients have access to the highest quality imaging services in the most efficient and cost-effective manner. Currently, the Applicant provides PET-CT imaging services in Worcester and Fitchburg[1] – consequently, Marlborough Hospital patients must travel to attain these services. The Proposed Project will enhance patient access and the patient experience by offering PET-CT imaging services onsite at Marlborough Hospital. The Proposed Project will be reimbursed as an Independent Diagnostic Testing Facility ("IDTF") licensed as a satellite clinic.

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 Marlborough Hospital campus.[2] The existing need for PET-CT imaging services for the Marlborough patient panel is demonstrated by historical volume demand,[3] disease burden trends, the growth in the number of older patients seeking care at Marlborough Hospital, and the increasing number of patients with underlying oncologic and cardiac conditions. National statistics indicate the increasing prevalence of cancer and cardiovascular disease.[4] Therefore, the need for these services is expected to expand as Marlborough 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 Marlborough 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

[1] There are 20.78 miles from Fitchburg to Marlborough in southeast direction and 25 miles (40.23 kilometers) by car, following the I-495 S route. Available online at: https://www.distance-cities.com/distance-fitchburg-ma-to-marlborough-ma

[2] 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.

[3] Historical volume demand is defined for purposes of this Narrative as the volume of patients who met the clinical protocols for PET-CT imaging.

[4] 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.

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.[5] Among other clinically appropriate applications, the Applicant proposes to utilize the designated PET-CT primarily for oncology imaging purposes, as the patient panel data indicate an elevated oncologic incidence. PET-CT imaging will also prove useful for cardiologic disease burdens as well. This, in addition to the historic and projected volume data reveal the need for PET-CT imaging for this patient population.

The Applicant anticipates that the Proposed Project will provide the patient panel with local access to integrated cancer services that will directly impact health outcomes and quality of life. Cardiac patients will also be referred to the Applicant's satellite clinic for PET-CT services. Diagnosis has important implications for patient care, research, and policy.[6] Diagnostic *technology* is crucial to determine what treatments are most effective with patients' anatomy. Ready access to PET-CT services will allow clinicians to determine appropriate treatment options that will impact overall health outcomes in a time effective manner.

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 not currently available at Marlborough – the Proposed Project will shift to an on-campus service, where services will be reimbursed as an IDTF. IDTF services are reimbursed at lower rates than hospital-based rates – IDTF's maintain lower costs by focusing on one service with much less overhead.[7] 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.[8] 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.[9]

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

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[5] 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/

[6] *Ibid.*

[7] Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBlEiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

[8] The proposed project will leverage existing equipment.

[9] 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 the Applicant's limited liability company is to own and operate diagnostic radiological imaging facilities utilizing MRI, PET/CT and/or other advanced medical imaging equipment at various sites and to engage in all activities related to operation of the same. Shields Health Care Group, Inc. will serve as the entity responsible for the operational and management services of the Proposed Project which will be located on the Marlborough Hospital 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.

Marlborough Hospital[10] has been a community resource since 1890.[11] It is served by one-hundred forty-eight (148) medical staff, along with just over six hundred (600) employees including two hundred (200) nurses. The hospital provides a wide range of inpatient and outpatient medical, surgical, and ancillary services including: 24/7 emergency care; comprehensive cardiac services; general, minimally invasive, and orthopedic surgery; diagnostic imaging; medical oncology and radiation oncology; and a behavioral health unit. As a member of UMass Memorial Health Care, Marlborough Hospital provides patients with a direct link to the advanced medical resources of UMass Memorial Medical Center in Worcester. Marlborough Hospital is fully accredited by the Joint Commission and is certified as a primary stroke service by the Massachusetts Department of Public Health.

B. Applicant's Patient Panel

Marlborough Hospital is a part of the UMass Memorial Health Care, Inc. ("UMMHC") system. The mobile PET-CT unit's proposed location is Marlborough Hospital's campus, which will provide access

[10] While Marlborough 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.

[11] According to a 2016 report produced by the Massachusetts Health Policy Commission, only forty-three (43) of the three-hundred fifty-one (351) cities and towns in Massachusetts are home to a community hospital. Marlborough is one of the few.

to PET-CT imaging services. The Applicant relies on both UMMHC's and Marlborough Hospital's patient panel data to help demonstrate the need for the Proposed Project.[12]

Overall Demographic Profile of UMMHC

UMMHC's patient panel is demonstrated by the demographic data collected for fiscal years ("FY")[13] 2019-2021. Between FY19 and FY21 UMMHC the patient panel combined, equaled 615,105 patients.[14] Related to that figure over the same period, 87.5% of the patient panel originated from Central Massachusetts,[15] 5.7% from Eastern Massachusetts,[16] 2.5% from Western Massachusetts,[17] 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%
Total	**371,488**	**100.0%**	**345,864**	**100.0%**	**393,429**	**100.0%**	**615,105**	**100.0%**

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.

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%
Total	**371,488**	**100.0%**	**345,864**	**100.0%**	**393,429**	**100.0%**	**615,105**	**100.0%**

According to Census data, made available through the Advisory Board Demographic profiler, within UMMHC's Primary Service Area ("PSA"), the population aged 65 and over is projected to increase on average by +16.4% over the next five (5) years (CAGR of +3.1%).

[12] The Applicant sought counsel from the DPH Determination of Need Program's leadership to determine that this was the appropriate course of action.

[13] The definition of Fiscal Year in the context of this narrative/application is October to September.

[14] This count reflects the number of patients, not the number of visits to a UMMHC facility.

[15] Central Mass is defined as all of Worcester County and the northwest corner of Middlesex County.

[16] Eastern Mass is defined as the Greater Boston, Cambridge, and South Shore, Cape Cod & Martha's Vineyard service areas.

[17] Western Mass is defined as Franklin, Hampshire, Hampden, and Berkshire counties.

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%
Total	**371,488**	**100.0%**	**345,864**	**100.0%**	**393,429**	**100.0%**	**615,105**	**100.0%**

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;[18] and 74.7% self-defined as White, 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%
Total	**371,488**	**100.0%**	**345,864**	**100.0%**	**393,429**	**100.0%**	**615,105**	**100.0%**

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	
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%
Total	**371,488**	**100.0%**	**345,864**	**100.0%**	**393,429**	**100.0%**	**615,105**	**100.0%**

[18] 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 Marlborough Hospital

Marlborough Hospital patient panel is demonstrated by the demographic data collected for fiscal years ("FY") 2019-2021. Between FY19 and FY21 the Marlborough Hospital patient panel combined, equaled 86,189 patients. Related to that figure over the same period, 89.7% of Marlborough Hospital's patient panel originated from Central Massachusetts, 7.3% from Eastern Massachusetts, 0.4% from Western Massachusetts, and 2.6% were from out of state. Marlborough Hospital's Primary Service Area (PSA) includes the following: Marlborough (01752); Hudson (01749); Northborough (01532); Westborough (01581); Berlin (01503); Framingham (01701); Clinton (01510); Southborough (01772); Bolton (01740); and Shrewsbury (01545); as demonstrated in the table below.

Pt Origin	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
Central Mass	34,582	92.6%	35,246	92.2%	43,989	91.1%	77,319	89.7%
Eastern Mass	1,693	4.5%	2,131	5.6%	3,317	6.9%	6,309	7.3%
Western Mass	113	0.3%	110	0.3%	145	0.3%	334	0.4%
Out of State	938	2.5%	722	1.9%	841	1.7%	2,227	2.6%
Total	**37,326**	**100.0%**	**38,209**	**100.0%**	**48,292**	**100.0%**	**86,189**	**100.0%**

Throughout FY19 to FY21, 9.6% of Marlborough Hospital's patient panel was between the ages of 0-17; 67.7% of the patient panel was between 18-64; and 22.7% was older than 65, as demonstrated in the table below.

Age	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
0-17	3,203	8.6%	2,536	6.6%	4,287	8.9%	8,243	9.6%
18-64	24,319	65.2%	25,840	67.6%	32,006	66.3%	58,360	67.7%
65+	9,799	26.3%	9,830	25.7%	11,996	24.8%	19,581	22.7%
Unknown	5	0.0%	3	0.0%	3	0.0%	5	0.0%
Total	**37,326**	**100.0%**	**38,209**	**100.0%**	**48,292**	**100.0%**	**86,189**	**100.0%**

According to Census data, made available through the Advisory Board Demographic profiler, within Marlborough's Primary Service Area ("PSA"), the population aged 65 and over is projected to increase on average by +15.6% over the next five (5) years (CAGR of +2.9%).

Between FY19 and FY21, 56.0% of the patient panel was female; 43.9% 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	22,703	60.8%	22,945	60.1%	28,102	58.2%	48,245	56.0%
Male	14,545	39.0%	15,199	39.8%	20,134	41.7%	37,832	43.9%
Unknown	78	0.2%	65	0.2%	56	0.1%	112	0.1%
Total	**37,326**	**100.0%**	**38,209**	**100.0%**	**48,292**	**100.0%**	**86,189**	**100.0%**

During this same timeframe, 0.1% of the patient panel self-defined as American Indian or Alaskan Native; 4.8% self-defined as Asian; 3.6% self-defined as Black or African American; 83% self-defined as White; and 7.8% were Multi Racial/Other/Unknown,[19] as demonstrated in the table below.

Race	FY2019		FY2020		FY2021		FY2019-2021 Combined	
	Count	%	Count	%	Count	%	Count	%
American Indian or Alaska Native	48	0.1%	38	0.1%	62	0.1%	118	0.1%
Asian	1,389	3.7%	1,314	3.4%	2,650	5.5%	4,135	4.8%
Black or African American	1,146	3.1%	1,317	3.4%	1,599	3.3%	3,136	3.6%
Native Hawaiian or Other Pacific Islander	12	0.0%	14	0.0%	22	0.0%	34	0.0%
Multi Racial/Other/Unknown	1,984	5.3%	2,677	7.0%	3,661	7.6%	6,696	7.8%
White	32,626	87.4%	32,690	85.6%	39,929	82.7%	71,522	83.0%
Declined	121	0.3%	159	0.4%	369	0.8%	548	0.6%
Total	**37,326**	**100.0%**	**38,209**	**100.0%**	**48,292**	**100.0%**	**86,189**	**100.0%**

Furthermore, with respect to ethnicity between FY19 and FY21, 12.7% self-defined as Hispanic or Latino; 84.8% self-defined as Not Hispanic or Latino; 1.3% are unknown; and 1.2% declined to answer, as demonstrated in the table below.

Ethnicity	FY2019		FY2020		FY2021		FY2019-2021 Combined	
Hispanic or Latino	3,666	9.8%	4,389	11.5%	6,536	13.5%	10,958	12.7%
Not Hispanic or Latino	33,204	89.0%	33,098	86.6%	40,387	83.6%	73,131	84.8%
Unknown	255	0.7%	414	1.1%	670	1.4%	1,102	1.3%
Decline	201	0.5%	308	0.8%	699	1.4%	998	1.2%
Total	**37,326**	**100.0%**	**38,209**	**100.0%**	**48,292**	**100.0%**	**86,189**	**100.0%**

[19] 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.

C. Payer Mix

The payer mix for Marlborough Hospital from FY19 to FY21 is demonstrated in the table below:

Payer Mix-List	FY2019	FY2020	FY2021
Commercial PPO/Indemnity	1.4%	1.1%	0.9%
Commercial HMO/POS	30.6%	27.3%	28.5%
MassHealth	11.7%	13.0%	13.4%
Managed Medicaid[20]	6.6%	8.3%	8.0%
Commercial Medicare[21]	15.0%	15.6%	16.1%
Medicare FFS	29.8%	29.7%	28.5%
All other (e.g. HSN, self-pay, TriCare)	4.8%	5.1%	4.5%
Total	**100.0%**	**100.0%**	**100.0%**

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 providing local access to PET-CT imaging services one day per week, onsite at the Marlborough Hospital campus. To underscore the importance of local access, it is noteworthy 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.[22] For example, 80% of the women who should have an annual mammography exam won't because they are unable to find a mammography facility that is conveniently located.[23]

The existing and future need for local PET-CT imaging services is demonstrated by historical volume demand[24] and disease burden trends, the growth in the number of older patients seeking care at Marlborough, and the increased number of patients with underlying age-related oncologic and cardiac conditions for which PET-CT has proven clinical applicability.[25]

[20] Private Medicaid / Medicaid MCOs

[21] Private Medicare/Medicare Advantage

[22] 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

[23] According to John Simon, MD, founder and CEO of SimonMed Imaging.

[24] Historical volume demand is defined for purposes of this Narrative as the volume of patients who met the clinical protocols for PET-CT imaging.

[25] 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:

B. Need for Additional Services

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

The Applicant reviewed the number of patients that Marlborough Hospital treated during the last three fiscal years who had an underlying oncologic condition, as evidence-based research overwhelmingly supports the use of PET-CT in this area.[26] In FY19 Marlborough Hospital cared for 740 unique patients with an underlying cancer diagnosis, which accounted for approximately 44%[27] of the total visit volume;[28] in FY20 Marlborough hospital cared for 735 unique patients with an underlying cancer diagnosis, which accounted for approximately 43%[29] of the total visit volume; and in FY21 Marlborough Hospital cared for 966 unique patients with an underlying cancer diagnosis, which accounted for approximately 39%[30] of the total patient volume.[31]

The Applicant also reviewed the overall number of Marlborough Hospital patients who were treated for oncologic and cardiac- related conditions since FY19. This data indicates that between FY19 and FY21, the incidence of patients with these conditions grew by 331 patients or 8.2%. Specifically, the table below demonstrates the increase in the number of oncologic and cardiac cases at Marlborough Hospital over the last three fiscal years.

Demand for PET-CT Services

Fiscal Year	# Total patients treated for oncological/cardiological-related diagnosis
FY19	3,736
FY20	3,285
FY21	4,067

The Applicant evaluated the growing demand for local access to PET-CT services – the financial pro forma reveals the following.[32]

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total Volume[33]	165	185	207	228	251	264

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/

[26] 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/

[27] FY19 total visit volume = 1665

[28] Please note that total visit volume refers to the number of patients treated at the Marlborough Hospital Cancer Clinic & Marlborough Hospital Radiology Oncology department, not all patients treated across Marlborough Hospital.

[29] FY20 total visit volume = 1702

[30] FY21 total visit volume = 2465

[31] FY22 total visit volume = 822 & Total unique patient volume = 505 (FY22 is Oct21 – Jan22)

[32] These projections were derived using the Shields Pet standard year over year growth trend from new PET starts with Shields since 2016.

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

The Applicant also relies on recent data from the Advisory Board Company ("Advisory Board"),[34] to further demonstrate the need for PET-CT in the proposed Primary Service Area ("PSA").[35] The Advisory Board projects that demand for PET-CT within the PSA will grow by +8.9% over the next five (5) years and +15.7% over the next 10 years.

ii. The growth in the number of older patients seeking care at Marlborough Hospital helps define the need to establish of PET-CT imaging services.

Marlborough is a city with 5,307 residents aged 65 or older.[36] Marlborough residents have disease rates that are worse than total state averages on several indicators including cataract, chronic kidney disease, anemia, hypothyroidism, **ischemic heart disease**, hypertension, chronic obstructive pulmonary disease, diabetes, Alzheimer's disease, substance use disorder, depression, and obesity.[37]

The aging population of both Massachusetts and Marlborough demonstrates the need for local PET-CT imaging services. Statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035.[38] 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.[39]

Adults and older adults similarly comprise the bulk of Marlborough's patient panel. In fact, from FY19 to FY21, patients in the 65+ age cohort consistently represented between 24% and 26% of the total patient population – please see table below.[40]

	FY19		FY20		FY21	
Age	**Count**	**%**	**Count**	**%**	**Count**	**%**
18-64	24,319	65.2%	25,840	67.6%	32,006	66.3%
65+	9,799	26.3%	9,830	25.7%	11,996	24.8%

[34] Analytics were derived in March of 2022.

[35] PSA includes the following zip codes -- towns/cities: 01752 Marlborough; 01749 Hudson; 01532 Northborough; 01581 Westborough; 01503 Berlin; 01701 Framingham; 01510 Clinton; 01772 Southborough; 01740 Bolton; 01545 Shrewsbury

[36] Online at: https://mahealthyagingcollaborative.org/wp-content/themes/mhac/pdf/community_profiles/MA_Towncode170_Marlborough.pdf

[37] *Ibid.*

[38] Online at: http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf

[39] Online at: https://www.mass.gov/files/documents/2016/07/wb/healthy-aging-data-report.pdf

[40] Source: Marlborough Hospital data from FY2019-FY2021.

Assuming the demographic trends within Marlborough's patient population continue to mirror that of the state, it is expected that Marlborough will continue to see growth in the 50+ age cohort that it serves. As the number of Marlborough's 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,[41] as discussed in further detail below.

To ensure that Marlborough's aging patient panel has access to high quality PET-CT services with proven effectiveness in the fields of oncology and cardiology,[42] the Applicant seeks to establish a licensed IDTF satellite clinic to provide PET-CT imaging services at Marlborough Hospital's main campus.

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

In consideration for the aging population, "imaging strongly contributes to establishing accurate and timely diagnosis, informs and guides treatment decisions and contributes to improving treatment outcomes."[43] 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,[44] which is essential to Marlborough Hospital's aging patients with oncologic and cardiac 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.[45]

Oncologic

Research studies and their findings demonstrate that the prevalence of cancer increases with age.[46] 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.[47] Furthermore, even with a progressive decrease in the cancer incidence and death rate, aging of the population will be accompanied by a marked

[41] 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

[42] The Cleveland Clinic. PET Scan. Online at: https://my.clevelandclinic.org/health/diagnostics/10123-pet-scan

[43] Guy Frija, Ivana Blažić, Donald P. Frush, Monika Hierath, Michael Kawooya, Lluis 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

[44] *Ibid*.

[45] 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.

[46] 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

[47] 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/

increase in the total number of patients with cancer,[48] the majority of whom will require the most precise diagnostic imaging.

In Middlesex County, where Marlborough is located, the age adjusted annual incidence of cancer rate was 436.5 - 462.3 per 100,000 persons.[49] According to the American Cancer Society, there is projected to be 42,190 new cases of cancer in Massachusetts in 2022,[50] and 12,520 cancer related deaths.[51] 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).[52]

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 published in the journal *Cancer*.[53] 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.[54]

Patient panel data for Marlborough Hospital's patients provide that 1,665 patients were treated for oncological-related issues in FY19; 1,702 patients in FY20; and 2,465 in FY21.

Cardiac

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.[55] 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.[56] 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.[57]

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[48] *Ibid.*

[49] Online at: http://www.cancerinmass.org/uploads/1/1/9/4/119429235/macancer-report2018.pdf

[50] Increased from 36,990 cases in 2020.

[51] Increased from 12,430 in 2020.

[52] Online at: https://cancerstatisticscenter.cancer.org/#!/state/Massachusetts

[53] 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

[54] *Ibid.*

[55] 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/

[56] Online at: https://www.mass.gov/doc/a-profile-of-health-among-massachusetts-adults-2018/download

[57] Online at: https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm

In addition, heart disease[58] 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.[59] 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.[60]

Patient panel data for Marlborough Hospital's patients provide that 2,071 patients were treated for cardiac-related diagnoses in FY19; 1,583 in FY20; and 1,602 in FY21.

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 access to PET-CT imaging capacity to meet current and projected demand.[61] The Applicant's primary objectives with the Proposed Project are to increase access, accommodate volume demands, provide high quality, low cost, PET-CT services to Marlborough patients through operation of a PET-CT unit that would be located on the Marlborough Hospital campus. The proposed PET-CT unit will utilize an already existing and serviceable mobile pad at Marlborough Hospital.

As noted in Factor F1.a.ii, historical need for PET-CT imaging and other indicators of future demand demonstrates a need for PET-CT services *on location* at Marlborough Hospital. Providing access to care has been documented to reduce healthcare utilization and spending.[62] Studies have detailed high costs for unnecessary repeat imaging[63] which could be improved through more appropriate use of all imaging, including PET-CT, and better integration of services. For the Proposed Project, reducing unnecessary expenditures related to inefficiencies from lack of service integration,[64] can lead to lower operational overhead and lower healthcare spending, which could, in turn, reduce TME.

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[58] Stroke is also included in this statistic.

[59] 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

[60] *Ibid.*

[61] The cost of a PET/CT scan will vary greatly between inpatient and outpatient facilities. The national average cost for the procedure at inpatient facilities is $7,275, while the same procedure at outpatient facilities averaged $2,550. Available online at: https://www.newchoicehealth.com/pet-scan/cost#:~:text=outpatient%20facility%20cost%20differences,at%20outpatient%20facilities%20averaged%20%242%2C550

[62] 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

[63] 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/

[64] 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".

The Proposed Project will not negatively impact on TME, as the PET-CT services will be provided through a licensed IDTF clinic, where the PET-CT services costs less.[65] 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 patient cost-sharing 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.[66] 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 of care review will not occur (and therefore no additional charges will be incurred). The review will only occur (and 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.[67] A PET scan measures important body functions, such as metabolism.[68] It helps doctors evaluate how well organs and tissues are functioning.[69] CT imaging uses special x-ray equipment, and in some cases a contrast material, to produce multiple images of the inside of the body.[70] A radiologist views and interprets these images on a computer monitor. CT imaging provides excellent anatomic information.[71]

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

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

[65] HealthCare Appraisers, 2020 Outlook: Diagnostic Imaging Centers and Radiology Practices. July 21, 2020. Online at: https://healthcareappraisers.com/2020-outlook-diagnostic-imaging-and-radiology-practices/

[66] 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

[67] Available at RadiologyInfo.org for patients. Online at: https://www.radiologyinfo.org/en/info/pet

[68] *Ibid.*

[69] *Ibid.*

[70] *Ibid.*

[71] *Ibid.*

proven beneficial.[72] 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.[73]

The results of a significant Danish study[74] 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.[75] 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.[76] 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 excess death, according to the Centers for Disease Control and Prevention ("CDC").[77] 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.[78] Cancer screening is considered routine care for individuals starting as early as age 25.[79] CDC supports screening for breast, cervical, colorectal (colon), and lung cancers as recommended by the U.S. Preventive Services Task Force.[80]

B. PET-CT as a Clinical Modality for Oncologic and Cardiac 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.[81] This population expansion will be accompanied

[72] 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

[73] *Ibid.*

[74] 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 Benzon, 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

[75] *Ibid.*

[76] *Ibid.*

[77] 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

[78] 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

[79] 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

[80] CDC website. Available online at: https://www.cdc.gov/cancer/dcpc/prevention/screening.htm

[81] 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/

by a marked increase in patients requiring care for disorders with high prevalence in the elderly.[82] Since cancer incidence increases exponentially with advancing age, it is expected that there will be a surge in older cancer patients that will challenge both healthcare institutions and healthcare professionals.[83]

Cancer studies have shown that early detection yields better outcomes for patients – and diagnostic imaging plays an essential role.[84] Studies have shown that PET-CT has become an established nuclear imaging modality that has proved especially useful in oncology.[85] 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.[86]

According to the U.S. Cancer registry[87] Middlesex County has a cancer incidence of 456 cases per 100,000. Using Marlborough Hospital's top 10 patient zip code market share, it is estimated that 164 cancer cases are diagnosed per year. Applying the above-mentioned statistics with respect to improvement 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 access to a local and convenient PET-CT diagnostic imaging.

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.[88] The ability for the heart to recover naturally from ischemic damage decreases with age and makes older patients more susceptible to injury.[89] Where traditional CT and PET scans have unique advantages in diagnosing coronary artery disease, a typical cause of ischemic heart disease, each have their downfalls and result in missed diagnoses or unnecessary invasive procedures.

[82] *Ibid.*

[83] *Ibid.*

[84] 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/

[85] "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 Sandford Health available online at: https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html

[86] 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/

[87] National Cancer Institute. State Cancer Profiles. 2020. Online at: https://www.statecancerprofiles.cancer.gov/incidencerates/

[88] 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/

[89] 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/

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.[90]

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.[91] 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.[92] 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.[93]

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).[94] 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.[95]

When compared with cardiac Magnetic Resonance Imaging (MRI), the PET-CT was able to detect a more impaired yet viable myocardium.[96] 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

[90] 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/

[91] 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/

[92] 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/

[93] 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/

[94] 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/

[95] Maureira, P., Tran, N., Djaballah, W., Angioï, 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/

[96] 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/

type of scan may be more useful for active disease assessment and for following treatment response.[97]

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.[98]

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

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 Marlborough Hospital's patient panel with a low-cost option for 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.[99] Conversely*, ease of access* improves quality of life for patients because early detection and treatment of diseases improves patient outcomes.[100] 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.[101]

Through the operation of an on-site PET-CT service at Marlborough Hospital via IDTF clinic-based service, the Applicant aims to provide timely access to optimized, low-cost, high-quality imaging services for Marlborough Hospital patients. Access to such PET-CT services for these patients – particularly for patients who are sick or effected by oncology and/or cardiovascular 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

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[97] 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/

[98] *Ibid.*

[99] 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/

[100] American College of Radiology. *Early Action Boots Patient Satisfaction*. Online at: https://www.acr.org/Practice-Management-Quality-Informatics/Imaging-3/Case-Studies/Quality-and-Safety/Early-Action-Boosts-Patient-Satisfaction

[101] 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/

providing better imaging data, PET-CT notably increases patient comfort and convenience by reducing the number of scanning sessions a patient must undergo.[102]

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.[103] 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.[104] In this case, transmission scans are not required because the CT data are used for attenuation correction.[105] It has been estimated that patient output has increased by approximately 40 percent.[106] 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.[107]

Given that patients will 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.[108]

Moreover, imaging services provided by the Applicant will be fully integrated with Marlborough Hospital's Health Information System ("HIS"). 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 by care teams and improved efficiency with respect to workflows.[109]

Poor coordination of care has negative consequences for patients and contributes to higher medical costs.[110] 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 Marlborough 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.

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[102] Online at: https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html

[103] 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/

[104] *Ibid.*

[105] *Ibid.*

[106] *Ibid*.

[107] 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

[108] Bhanu Prakash, Patient Satisfaction, 3 J. CUTANEOUS & AESTHETIC SURGERY 151 (2010), online at: https://pubmed.ncbi.nlm.nih.gov/21430827/

[109] 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

[110] 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/

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.[111] 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 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: 0% Year 1: 1% Year 2: 8% Year 3: 5%

[111] Shields is now using a platform called Podium – a text-based program for patient experience.

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 UMMHC'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 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[112] 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.[113] UMMIC 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.[114]

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.

The population within the PSA of the Proposed Project reflects moderate diversity that necessitates implementation of commensurate, 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[115] and InDemand interpreting to provide multiple options for translation services.[116] 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. lnDemand 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 receive the highest quality imaging onsite at Marlborough Hospital, thus removing barriers to this service locally.[117] To date,

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[112] 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/

[113] *Ibid.*

[114] Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBlEiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

[115] Language Line Solutions phone interpreting may also be used in the event the In Demand system is not functioning properly.

[116] 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.

[117] "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/

Marlborough Hospital patients seeking PET-CT imaging must travel to receive a scan,[118] thus fragmenting the continuity of care and disrupting the most direct path to diagnosis and treatment. 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.[119] These consequences may lead to poorer management of chronic illness and ultimately poorer health outcomes.[120]

The Applicant's Proposed Project will help ensure ready 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 expansion of high-value, low-cost, local PET-CT services in the community setting. This delivery model is more convenient and efficient than the existing service,[121] made possible through operational discipline and focus that cannot be achieved under traditional hospital oversite. 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 an electronic medical record ("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.

[118] Most often, imaging is sought in Worcester, Fitchburg, and Boston.

[119] 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/

[120] *Ibid.*

[121] The Joint Venture between UMASS Memorial and Shields Health Care Group has current services located in Worcester and Fitchburg, which is where many patients currently seek imaging services.

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.[122] Certain questions in the pre-screen relate to certain SDoH issues, namely those issues that are relevant to an imaging appointment such as transportation.[123] If, during this pre-screen process or at any time during a patient's PET-CT appointment, 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:

- Lara Szent-Gyorgyi, Director, Determination of Need Program, Department of Public Health[124]
- Jennica F. Allen Community Health Planning and Engagement Specialist, Department of Public Health
- Samuel Louis, M.P.H., Coordinator, Health Care Interpreter Services, Department of Public Health, Health Care Interpreter Services
- Nazmim Borna Bhuiya, Researcher/Evaluator, Determination of Need Bureau of Health Care Safety & Quality, Massachusetts Department of Public Health
- Ruth Blodgett, Director of the Bureau of Community Health, and Prevention via Juanita Woods, Program Assistant, Bureau of Community Health, and Prevention

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

The Applicant identified the need to provide high-quality, cost-effective PET-CT services for Marlborough patients. Marlborough Hospital'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.

[122] Centers for Disease Control and Prevention. Online at: https://www.cdc.gov/socialdeterminants/index.htm

[123] Access to transportation is one of the most important social determinants of health (SDOH), according to the CDC.

[124] *Former* Director, Determination of Need Program, Department of Public Health

The Proposed Project was presented at Marlborough Hospital's Patient Family Advisory Committee ("PFAC") on June 2, 2022, with eleven (11) members in attendance. The PFAC is comprised of current and former patients of the hospital and their family members as well as caregivers and staff of the hospital. Because patients of the proposed service will continue to be Marlborough 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 need for PET-CT on location. It reviewed how the Proposed Project will benefit current and future patients. This project will share existing imaging space with the mobile MRI service on its dormant day (Sunday). PET-CT services will complement the cancer treatment and breast services currently provided at Marlborough Hospital. The service will operate on an outpatient fee schedule which will lower the cost of services.

The PFAC members had positive reactions to the presentation of the Proposed Project and did not voice any concerns. Participants were very engaged throughout the presentation and asked several follow-up questions that generally focused on how convenient the service would be for patients and how local access would assist the patients in reducing their levels of stress around traveling and waiting longer to have their diagnostic imaging performed.[125] Clarification was sought regarding where patients currently receive diagnostic imaging.

The Proposed Project was also presented at the Marlborough Hospital Board of Trustees on June 10, 2022, with sixteen (16) members in attendance. The Board of Trustees is comprised of local influencers from a diversity of professions.[126] The presentation contained the same information that was offered to the PFAC.

Members of the Board of Trustees also had a positive reaction to the Proposed Project and did not voice any concerns. One member asked about the possibility of having more than just one day of access to the local diagnostic imaging.

To ensure appropriate awareness within the community about the Proposed Project, the legal notice associated with the Proposed Project was published on the Shields website. 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."

[125] One of the PFAC members is an employee who works at the Cancer Center and in her role, she helps schedule PET-CTs for patients. She spoke from first-hand experience about the value of having PET-CT located onsite at Marlborough Hospital.

[126] Please see a list of current Board of Trustee Members in Exhibit B.h

To ensure sound community engagement throughout the development of the Proposed Project, the following actions were taken:

- Presentation to Marlborough Hospital's PFAC on June 2, 2022; and
- Presentation to Marlborough Hospital's Board of Trustees on June 10, 2022.

For detailed information regarding these activities and a list of current Board of Trustee Members, please see attached exhibits.

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 a lower cost option for patients in and around the Marlborough PSA seeking local PET-CT imaging services. Through the proposed project, the Applicant seeks to enhance existing imaging capabilities by added the capability to perform PET-CT scans onsite at Marlborough Hospital.

As previously discussed, the cost of providing these services will be reduced through the IDTF clinic model. Furthermore, potential savings also 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.[127]

Additionally, 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.[128] This difference will allow the Applicant to provide cost-effective, quality imaging services to Marlborough's patients, while having a negligible impact on the overall healthcare market.

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

[127] 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/

[128] 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/

follow-up imaging studies (usually CT scans) are required.[129] If patients undergo both examinations in one session, in addition to having more accurate results, costs will be lower.[130]

Providing patients with 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. By offering PET-CT imaging services where the patient panel has historically gone for clinical service, 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 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.[131]

PET-CT services managed under Shields operating platform will provide access to patients residing within the PSA. 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 be expanded to the community served within Marlborough's PSA. In instances where patients need support to address

[129] 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/

[130] *Ibid*.

[131] 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

social determinants of health,[132] the Applicant offers enhanced access to services designed to facilitate improved care pathways influenced by social determinants of health. Specifically, 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 a well-established cancer care continuum including access to Marlborough-based nurse navigators to guide patients through care, treatment, recovery, and in some instances, grief. PET-CT services will also align with Marlborough Hospital's comprehensive, cardiac rehabilitation program. These programs include access to social work, dietary support, and wellness services. The design of care navigation specifically deals with barriers to care and long-term connections to wellness offerings. PET-CT appointments and results will become embedded in these programs.

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

Provide PET-CT services to local, Marlborough patient panel, via the existing UMass Memorial clinic license. The physical clinic will be co-located in a pre-existing shared space with a Mobile MRI at Marlborough Hospital, and services will be reimbursed as an IDTF to enhance efficiency and effectiveness of care delivery.

B. Quality

Bringing PET-CT imaging capability for cancer staging, Alzheimer's disease evaluation, cardiac applications (amongst other things) to the patient panel at Marlborough Hospital will provide access to the highest quality diagnostic imaging services with the added benefit that patients will be receiving care at the same convenient location, but at a lower 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.

[132] UMass Memorial Health Care is committed to improving the health status of all those it serves, and to addressing the health problems of the poor and other medically underserved populations. In addition, nonmedical conditions that negatively impact the health and wellness of the community are addressed. The Mission incorporates the World Health Organization's broad definition of health defined as "a state of complete physical, mental and social well being and not merely the absence of disease."

C. Efficiency

Care provided in an IDTF setting allows for greater focus on a specialized service within the broader scope of services provided on the main campus of Marlborough. Highly trained staff and the ability to maintain a uniform schedule allows for greater efficiencies and lower costs.

D. Capital Expense

Establishing the IDTF will result in minimal capital expense because there are no expenses attributable to facility build out projected in years one through six (1-6), as the proposed mobile PET/CT unit will utilize an already existing and serviceable mobile pad located at Marlborough Hospital. There are only minor equipment-related expenses.

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.
The calculated operating expenses (including support services, billing, and bad debt expense) CAGR[133] for Years 2 through 6 of nine (9) percent for the Proposed Project. Year 1 was not included in the CAGR calculation.[134] These expenses for the Proposed Project in Year 6 were $22,047.[135]

F. Alternative Option for the Project

a. Option 1

i. Alternative Proposal

The Applicant considered not establishing an IDTF to provide patients with access to PET-CT services. In this scenario, patients would need to continue to travel to Worcester and Fitchburg to receive PET-CT scans for their oncologic and cardiac conditions, rather than receiving those scans at the location where they receive the rest of their integrated care services.

ii. Alternative Quality

This alternative is not sufficient to meet the combined patient panel's need for highly accessible, low cost and high-quality PET-CT imaging in the community. The current arrangement forces those patients who meet the clinical protocols for combined PET-CT to travel to receive the service, thus limiting local access for the patient panel. Insufficient access effects the quality of care for the patients served.

On the other hand, ready access to PET-CT services is not only more convenient for the patients, but also it will allow clinicians to determine appropriate

[133] Compound Annual Growth Rate.

[134] 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").

[135] For reference, the operating expenses for Year 1 are calculated to be $33,311. Please see CPA analysis in Exhibit B.g for further content.

treatment options that will impact overall health outcomes in a time effective manner.

iii. **Alternative Efficiency**
Not establishing the PET-CT service offering, which represents a superior imaging alternative at a convenient location for the patients, would not help improve efficiency because it deprives patients of the most timely and accurate access to necessary diagnostic information.

iv. **Alternative Capital Expense**
Taking no action to establish a PET-CT service offering would maintain the status quo and no additional capital expenses would likely be incurred.

v. **Alternative Operating Costs**
Taking no action to establish a PET-CT service offering would maintain the status quo and no additional operating costs would likely be incurred.

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.