

2. Project Description

Tufts Medicine: Shields PET-CT, LLC (“Applicant”) located at 700 Congress Street, Suite 204, Quincy, Massachusetts 02169 is filing a Determination of Need Application (“Application”) with the Massachusetts Department of Public Health (“DPH”) for the establishment of a licensed clinic to provide part-time mobile positron emission tomography (“PET”) – computed tomography (“CT”) (together “PET-CT”) diagnostic imaging services. Specifically, the mobile PET-CT unit will be located at the MelroseWakefield Medical Building whose address is 888 Main Street, Wakefield (the “PET/CT Site”) and will operate one day per week (“Proposed Project”).

The Applicant is a newly formed joint venture between MelroseWakefield Hospital (“MWH”) and Shields, named Tufts Medicine: Shields PET/CT LLC (“TM: Shields”). MWH currently offers local PET-CT services to its patients through a joint venture called Montvale PET/CT, with another partner. It is significant to note that the current joint venture will cease operations in the summer of 2023.

The Applicant seeks to ensure that MWH patients have continued access to the highest quality imaging services in the most efficient and cost-effective manner. Through the Proposed Project, the Applicant seeks to satisfy both existing and future patient panel needs by continuing to provide local access to PET-CT imaging services, at a proximate location to the MWH campus.¹ The Proposed Project will be reimbursed as an Independent Diagnostic Testing Facility (“IDTF”) licensed as a clinic.

Through the Proposed Project, the Applicant will satisfy both existing and future patient panel needs by continuing to provide local access to PET-CT imaging services one day per week. The existing and future need for continued local PET-CT imaging access is further demonstrated by historical volume demand, projected volume, and disease burden trends, in addition to the growth in the number of older patients seeking care at MWH. There is also an increased number of patients with underlying age-related oncologic, cardiac, and neurologic conditions for which PET-CT has proven clinical applicability.² National statistics indicate the increasing prevalence of cancer and cardiovascular disease.³ Therefore, the need for these services is expected to expand as MWH’s aging patient population increases.

The Applicant proposes to use the integrated PET-CT unit for part-time clinical use at the MelroseWakefield Medical Building. Use of the proposed PET-CT unit will be restricted to patients who meet the clinical protocols for combined PET-CT. A patient’s underlying condition and diagnosis will be the basis for determining whether the patient meets appropriate clinical protocols for PET-CT imaging.

Imaging plays a critical role in establishing the diagnoses for innumerable conditions and it is used routinely in nearly every branch of medicine.⁴ Among other clinically appropriate applications, the

¹ The PET-CT site is approximately two miles away and less than a ten-minute drive from MWH.

² Jaul E, Barron J. Age-Related Diseases and Clinical and Public Health Implications for the 85 Years Old and Over Population. *Front Public Health*. 2017;5:335. Published 2017 Dec 11. doi:10.3389/fpubh.2017.00335 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5732407/> & Anand SS, Singh H, Dash AK. Clinical Applications of PET and PET-CT. *Med J Armed Forces India*. 2009;65(4):353-358. doi:10.1016/S0377-1237(09)80099-3 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4921358/>

³ 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.

⁴ 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/>

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 and neurologic 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 continued local access to integrated cancer services that will directly impact health outcomes and quality of life. Cardiac and neurologic patients will also be referred to the Applicant's clinic for PET-CT services. Diagnosis has important implications for patient care, research, and policy.⁵ 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 currently available to MWH's patient population via their current Montvale imaging partnership, which is slated to end in the summer of 2023. The Applicant's Proposed Project will allow for uninterrupted local patient access to PET-CT imaging services. These services will be reimbursed on an IDTF fee schedule – rates that are lower than hospital-based rates. IDTF's maintain lower costs by focusing on one service with much less overhead.⁶ 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. 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.⁷

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.

⁵ *Ibid.*

⁶ Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIewAiY-yMHCMetjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

⁷ 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:****A. Overview of Applicant's Joint Venture**

The Applicant is a newly formed joint venture between MelroseWakefield Hospital (“MWH”) and Shields, named Tufts Medicine: Shields PET/CT LLC (“TM: Shields”). The Applicant’s business purpose is to offer positron emission tomography - computed tomography (“PET/CT”) services via a mobile medical imaging unit located at 888 Main Street, Wakefield (the “PET/CT Site”) and engage in activities related to the accomplishment of such purposes. Shields is both a Member of the LLC that comprises the Applicant and is slated to serve as the entity responsible for the operational and management services of the Proposed Project which will be located on the MWH campus.

MelroseWakefield, formerly Hallmark Health, is a coordinated system of hospitals, physician practices and community-based services providing care for communities throughout north suburban Boston. The MelroseWakefield organization includes MWH, Lawrence Memorial Hospital of Medford; Hallmark Health Medical Center, Reading; Tufts MC Community Care; and Lawrence Memorial/Regis College School of Nursing.⁸ MelroseWakefield is part of Tufts Medicine, which includes Tufts Medicinal Center, Circle Health (Lowell General Hospital), Tufts Medicine Integrated Network, and Tufts Medicine Care at Home. MWH is a general hospital offering a wide range of services including expert cardiac care, 24-hour emergency care, wound care management, and maternity services with an on-site level II special care nursery. To address growing demand for health care services, MWH maintains 232 beds and is supported by over 700 affiliated physicians and has access to advanced, specialty care with its clinical affiliation with Tufts Medical Center. MWH’s core mission has always been to make high-quality health care more accessible to those who live and work in the community.

Shields was founded in 1972 in Brockton, Massachusetts. Dedication to high quality and advanced care in a local setting quickly became a signature attribute of the Shields business model, continuing with Massachusetts’ first independent regional MRI center in 1986. Today, Shields has expanded to 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.

B. Applicant's Patient Panel

The Applicant is a newly formed joint venture and therefore does not [yet] have its own patient panel. MWH is a member of Tufts Medicine: Shields PET-CT LCC, and the proposed PET-CT clinic will be brought online to allow [continued] local access to PET-CT services to MWH’s patients when the current joint venture partnership with Montvale PET-CT ends in the summer of 2023. The Applicant relies, both on MWH’s patient panel to demonstrate the need for the Proposed Project and historical utilization of PET-CT diagnostic services via MWH’s current joint venture partner to demonstrate the need for the Proposed Project.

⁸ For more information, visit <https://www.melrosewakefield.org>

Overall Demographic Profile

The MWH patient panel is demonstrated in the demographic data collected for fiscal years (“FY”) 2019-2021.⁹ Over the last three fiscal years, MWH has provided services to the following numbers of unique patients:

Fiscal Year (FY)	Unique Patients
FY19	109,089
FY20	94,800
FY21	103,183

*FY2019-FY2021 variance = -5.41%

There has been a relative decrease in the number of unique patients from 2019 to 2021 that the Applicant notes is both an anomaly and a derivative of the COVID-19 pandemic.

In FY19-FY21 MWH’s patient panel originated from the following towns:

City/Town	FY19 #	FY19 %	FY20 #	FY20 %	FY21 #	FY21 %
Malden	13,884	12.73%	12,065	12.73%	12,878	12.48%
Medford	12,047	11.04%	10,346	10.91%	10,776	10.44%
Melrose	10,502	9.63%	9,365	9.88%	10,351	10.03%
Saugus	8,279	7.59%	7,484	7.89%	7,782	7.54%
Wakefield	8,546	7.83%	7,550	7.96%	7,657	7.42%
Stoneham	3,775	3.46%	3,152	3.32%	3,173	3.08%
Revere	1,741	1.60%	1,504	1.59%	1,577	1.53%
Everett	2,211	2.03%	1,919	2.02%	2,037	1.97%
Reading	4,314	3.95%	3,736	3.94%	3,731	3.62%
Winthrop	1,493	1.37%	1,313	1.39%	1,345	1.30%
North Reading	4,742	4.35%	4,011	4.23%	4,117	3.99%
Lynnfield	4,411	4.04%	3,911	4.13%	4,243	4.11%
Outside PSA	33,144	30.38%	28,444	30.00%	33,516	32.48%
Total	109,089	100.00%	94,800	100.00%	103,183	100.00%

The following zip codes / towns comprise MWH’s Primary Service Area (“PSA”):

Zip Code	City/Town
02148	Malden
02153	Medford
02155	Medford
02176	Melrose
01906	Saugus
01880	Wakefield

⁹ Fiscal year is defined as the period from October 1 to September 30.

The following zip codes / towns comprise MWH’s Secondary Service Area (“SSA”)

Zip Code	City/Town
01940	Lynnfield
01864	North Reading
01889	North Reading
01867	Reading
02180	Stoneham
02149	Everett
02151	Revere
02152	Winthrop

The following table displays data regarding the number of MWH unique patients by age, as well as the corresponding percentages of unique patients who were 0-49 years old from FY19-FY21:

FY	0-49	%
FY19	53,152	48.7%
FY20	44,188	46.6%
FY21	48,870	47.4%

*The % reflects the subset of the total number of unique patients recited above in the “Overall Demographic Profile” section

The following table displays data regarding the number of MWH unique patients by age, as well as the corresponding percentages of unique patients who were 50 years old or over from FY19-FY21:¹⁰

FY	50+	%
FY19	55,937	51.3%
FY20	50,612	53.4%
FY21	54,313	52.91%

*The % reflects the subset of the total number of unique patients recited above in the “Overall Demographic Profile” section

The following table displays data regarding the number of MWH unique patients by age, as well as the corresponding the percentages of unique patients who were 60 years old or over from FY19-FY21:¹¹

FY	#	%
FY19	37,213	34.1%
FY20	34,125	36.0%
FY21	36,507	35.4%

*The % reflects the subset of the total number of unique patients recited above in the “Overall Demographic Profile” section

According to Census data, made available through the Advisory Board Demographic profiler, within MelroseWakefield Hospital’s Primary Service Area (“PSA”), the population aged 65 and over is projected to increase on average by +12.9% over the next five (5) years (CAGR of +2.5%).

¹⁰ FY2019-FY2021 % variance = -2.9%

¹¹ FY2019-FY2021 % variance = -1.9%

The following tables display MWH patient gender demographics over the last three years:

FY19

Gender	#	%
F- Female	64,073	58.735%
M -Male	45,012	41.262%
Unknown	<11 ¹²	0.004%
Total	109,089	100.000%

FY20

Gender	#	%
F- Female	55,770	58.829%
M -Male	39,026	41.167%
Unknown	<11 ¹³	0.004%
Total	94,800	100.000%

FY21

Gender	#	%
F- Female	60,271	58.412%
M -Male	42,855	41.533%
Unknown	57	0.055%
Total	103,183	100.000%

The following tables display MWH patients by race over the last three years:

FY19

Category	#	%
American Indian or Alaskan Native	72	0.07%
Asian	6,249	5.73%
Black or African American	5,192	4.76%
Other/Unknown	10,599	9.72%
White	86,977	79.73%
Total	109,089	100.00%

FY20

Category	#	%
American Indian or Alaskan Native	68	0.07%
Asian	5,361	5.66%
Black or African American	4,457	4.70%
Other/Unknown	8,744	9.22%
White	76,170	80.35%
Total	94,800	100.00%

¹² To ensure patient privacy, we have used the notation "<11" in any instance where the patient count for a demographic category included less than 11 individuals.

¹³ To ensure patient privacy, we have used the notation "<11" in any instance where the patient count for a demographic category included less than 11 individuals.

FY21

Category	#	%
American Indian or Alaskan Native	69	0.07%
Asian	5,946	5.76%
Black or African American	4,739	4.59%
Other/Unknown	12,516	12.13%
White	79,913	77.45%
Total	103,183	100.00%

It is noteworthy that the MelroseWakefield Hospital Community Health Needs Assessment (CHNA)¹⁴ reveals that compared to Massachusetts as a whole, the MWH community benefits service area¹⁵ has a smaller Hispanic population (8%, compared to 11% in MA) and larger populations of Asian residents (9%, compared to 6% in MA) and Black/African-American residents (9%, compared to 7% in MA).

Breaking it down by community, more variation is observed. Malden has the highest rate of people describing themselves as Asian (24%, compared to a MA rate of 6%), and Everett has the highest rates of people identifying as Hispanic (23%, versus MA rate of 11%) and Black/African-American (19%, versus a MA rate of 6%).

PET-CT-Specific Overview

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

	FY19 #scans	FY20 #scans	FY21 #scans
Total Scans	450	455	522

C. Payer Mix

The Product/Payer mix for MWH from FY19 to FY21 is demonstrated in the tables below:

Case percentages by Product¹⁶

Product	FY 2019	FY 2020	FY 2021	Grand Total
Commercial	45.26%	44.99%	44.63%	44.96%
Medicare	34.66%	34.33%	33.03%	34.00%
Medicaid	14.69%	14.74%	15.54%	15.00%
Other	2.45%	2.19%	3.06%	2.59%
Dual	2.01%	2.36%	2.31%	2.22%
Behavioral Health	0.93%	1.37%	1.43%	1.23%
Total	100.00%	100.00%	100.00%	100.00%

¹⁴ The MelroseWakefield Hospital’s Community Health Needs Assessment is available [here](#).

¹⁵ Please note that the community benefits service area evaluated for purposes of the CHNA differs slightly from the MWH Primary Service Area.

¹⁶ The Applicant does not have data to reflect the patient panel broken down by payer category with respect to the number of PET-CT scans completed over the last 36 months.

F1.a.ii Need by Patient Panel:

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

A. Overview

Through the Proposed Project, the Applicant will satisfy both existing and future patient panel needs by continuing to provide local access to PET-CT imaging services, at a proximate location to the MWH campus. As mentioned previously in this narrative, MWH currently offers PET-CT services to its patients through a joint venture with their Montvale partner – that joint venture will cease operations in the summer of 2023. The existing and future need for continued local PET-CT imaging access is further demonstrated by historical volume demand, operational capacity limitations, projected volume, and disease burden trends, in addition to the growth in the number of older patients seeking care at MWH, and the increased number of patients with underlying age-related oncologic, cardiac, and neurologic conditions for which PET-CT has proven clinical applicability.¹⁷

Access to healthcare emerged as a concern among community survey respondents in MWH's most recent Community Health Needs Assessment – 34% of respondents thought that access to care was one of the top health concerns in their community.

To further 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.¹⁸ 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.¹⁹

B. Need for Additional Services

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

Historical Volume

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

¹⁷ Jaul E, Barron J. Age-Related Diseases and Clinical and Public Health Implications for the 85 Years Old and Over Population. *Front Public Health*. 2017;5:335. Published 2017 Dec 11. doi:10.3389/fpubh.2017.00335 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5732407/> & Anand SS, Singh H, Dash AK. Clinical Applications of PET and PET-CT. *Med J Armed Forces India*. 2009;65(4):353-358. doi:10.1016/S0377-1237(09)80099-3 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4921358/>

¹⁸ 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>

¹⁹ According to John Simon, MD, founder and CEO of SimonMed Imaging.

	FY19 #scans	FY20 #scans	FY21 #scans
Total Scans	450	455	522

It is noteworthy that within the Applicant’s PSA²⁰ the Montvale PET-CT clinic is the only PET-CT imaging center offering Independent Diagnostic Facility (IDTF) rates. This is significant given that IDTF services are reimbursed at lower rates than hospital-based rates.²¹ The MWH/Montvale joint venture partnership ceases in 2023 leaving an opportunity for the Applicant to maintain the local PET-CT imaging service offering under different operational management.

Projected Volume

The Applicant evaluated the growing demand for continued local access to PET-CT services – the Veralon financial pro forma reveals the following.²²

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total Volume ²³	605	678	746	821	862	905

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

The Applicant also relies on recent data from the Advisory Board Company ("Advisory Board"), to further demonstrate the need for PET-CT in the proposed Primary Service Area ("PSA"). The Advisory Board projects that demand for PET-CT services in the freestanding and the hospital-based outpatient departments (HOPDs) combined, within the PSA will grow by +8.5% over the next five (5) years and +15.0% over the next 10 years.

The freestanding market alone reveals even more growth -- the Advisory Board projects that demand for freestanding PET-CT services within the PSA will grow by +14.8% over the next five (5) years and +28.6% over the next 10 years.

Patients who could benefit from PET-CT

The Applicant evaluated the number of patients that MWH treated during the last three fiscal years who had an underlying oncologic, cardiovascular, and neurological conditions, as evidence-based research supports the use of PET-CT in these areas²⁴ (please see table below). The Applicant also assessed the number of patients that MWH treated over the last three fiscal years who had an underlying urological condition, as PET-CT has a current and growing future role in the management of urological conditions,

²⁰ 02148; 02153; 02155; 02176; 01906; and 01880

²¹ Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIEiwAiY-yMHCMEtjEV0at0jsHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

²² These projections were derived by Veralon, health care business valuation and consultants, who drafted the CPA report using the Shields Pet standard year over year growth trend from new PET starts with Shields since 2016.

²³ Year over year % change starting in Year 2 is 12%, Year 3 is 12%; Year 4 is 10%; Year 5 is 10%; and Year 6 is 5%. For details, please see the Statement of Profit and Loss in the Appendix of the Veralon CPA Report.

²⁴ Johns Hopkins Medicine. Available online at: <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/positron-emission-tomography-pet>

especially urological cancer (kidney, bladder, urinary tract, prostate, adrenal gland, and testicular cancer).

Service Line	2019	2020	2021	Total
Cancer	3,007	2,656	2,671	8,334
Cardiovascular	9,373	8,087	8,014	25,474
Neurological	7,000	5,989	6,484	19,473
Urological	5,529	4,421	4,694	14,644
Total	24,909	21,153	21,863	67,925

*These are unique patients who are only counted once per category per year.²⁵

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

Melrose

The city of Melrose’s demographic profile is demonstrated by data collected from the most recent U.S. Census Bureau, which was released in 2021. As of July 1, 2021, the population of Melrose was reported to be 29,312; this is a 10.5% increase since April of 2010.²⁶ The median age of the population of Melrose is 41.7, over 2 years older than the median age of the total population of Massachusetts, 39.6.²⁷

Currently, 18.9% of the Melrose population is older than 65.²⁸ The table below compares the percent of the population in four (4) age ranges for three (3) different locations: the town of Melrose, the Boston-Cambridge-Newton, MA-NH Metro are, and the state of Massachusetts. As presented in the table, Melrose has higher percentages than the other two locations for the age ranges of 50-59, 70-79, and 80+.²⁹

Age Range	Melrose	Boston-Cambridge-Newton, MA-NH Metro Area	Massachusetts
50-59	14.5%	14.1%	14.1%
60-69	11.2%	11.3%	11.8%
70-79	8.0%	6.6%	6.9%
80+	4.9%	4.1%	4.3%

Wakefield

The town of Wakefield’s demographic profile is demonstrated by data collected from the most recent U.S. Census Bureau, which was released in 2021. As of July 1, 2021, the population of Wakefield was reported to be 27,104; this is an 8.71% increase since April

²⁵ There has been a relative decrease in the number of unique patients from 2019 to 2021 across these service line that the Applicant notes is both an anomaly and a derivative of the COVID-19 pandemic.

²⁶ United States Census Bureau. (2021). *U.S. Census Bureau QuickFacts: Melrose city, Massachusetts*. [www.census.gov](https://www.census.gov/quickfacts/melrosecitymassachusetts). Available online at: <https://www.census.gov/quickfacts/melrosecitymassachusetts>

²⁷ Census Reporter. (2021). *Census profile: Melrose, MA*. Census Reporter. <https://censusreporter.org/profiles/16000US2540115-melrose-ma/>

²⁸ *Ibid.*

²⁹ Census Reporter. (2021). *Census profile: Melrose, MA*. Census Reporter. <https://censusreporter.org/profiles/16000US2540115-melrose-ma/>

of 2010.³⁰ The median age of the population of Wakefield is 42.7, over 3 years older than the median age of the total population of Massachusetts, 39.6.³¹

Currently, 17.6% of the Wakefield population is older than 65.³² The table below compares the percent of the population in four (4) age ranges for three (3) different locations: the town of Wakefield, the Boston-Cambridge-Newton, MA-NH Metro are, and the state of Massachusetts. As presented in the table, Wakefield has higher percentages than the other two locations for all age ranges.

Age Range	Wakefield	Boston-Cambridge-Newton, MA-NH Metro Area	Massachusetts
50-59	14.4%	14.1%	14.1%
60-69	13.5%	11.3%	11.8%
70-79	7.5%	6.6%	6.9%
80+	5.0%	4.1%	4.3%

Melrose / Wakefield

The top three causes of death in both Melrose and Wakefield are: dementia; chronic ischemic heart disease; and lung cancer.³³ Clinical use of PET-CT is well established in neurodegenerative disorders,³⁴ cardiac conditions,³⁵ and oncologic disease states,³⁶ for its capacity to identify and diagnosis of specific conditions as discussed in further detail later in this narrative.

Statewide

Statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035.³⁷ 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-

³⁰ U.S. Census Bureau. (2021). *U.S. Census Bureau QuickFacts: Wakefield CDP, Massachusetts*. [www.census.gov](https://www.census.gov/quickfacts/fact/table/wakefieldcdpmassachusetts). Online at: <https://www.census.gov/quickfacts/fact/table/wakefieldcdpmassachusetts>

³¹ Census Reporter. (2021b). *Census profile: Wakefield, MA*. Census Reporter. <https://censusreporter.org/profiles/16000US2572250-wakefield-ma/>

³² U.S. Census Bureau. (2021). *U.S. Census Bureau QuickFacts: Wakefield CDP, Massachusetts*. [www.census.gov](https://www.census.gov/quickfacts/fact/table/wakefieldcdpmassachusetts). Online at: <https://www.census.gov/quickfacts/fact/table/wakefieldcdpmassachusetts>

³³ MelroseWakefield Healthcare Community Health Needs Assessment 2019. Prepared in collaboration with MelroseWakefield Healthcare by the Institute for Community Health. Pages 95 & 120.

³⁴ Berti V, Pupi A, Mosconi L. PET/CT in diagnosis of dementia. *Ann N Y Acad Sci*. 2011 Jun;1228:81-92. doi: 10.1111/j.1749-6632.2011.06015.x. PMID: 21718326; PMCID: PMC3692287. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3692287/>

³⁵ Knaapen P, de Haan S, Hoekstra OS, Halbmeijer R, Appelman YE, Groothuis JG, Comans EF, Meijerink MR, Lammertsma AA, Lubberink M, Götte MJ, van Rossum AC. Cardiac PET-CT: advanced hybrid imaging for the detection of coronary artery disease. *Neth Heart J*. 2010 Feb;18(2):90-8. doi: 10.1007/BF03091744. PMID: 20200615; PMCID: PMC2828569. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828569/>

³⁶ Czernin J, Allen-Auerbach M, Nathanson D, Herrmann K. PET/CT in Oncology: Current Status and Perspectives. *Curr Radiol Rep*. 2013 May 3;1(3):177-190. doi: 10.1007/s40134-013-0016-x. PMID: 24883234; PMCID: PMC4034170. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4034170/#:~:text=In%20summary%2C%20PET%2FCT%20is,therapy%20monitoring%2C%20and%20treatment%20stratification.>

³⁷ Online at: http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf

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.³⁸

Assuming the demographic trends within the Melrose/Wakefield area continue to mirror that of the state, it is expected that these areas will continue to see growth in the 50+ age cohort that the Applicant hopes to serve. Also compelling is the Advisory Board's forecast that the Melrose/Wakefield PSA for people aged 65+ is projected to increase on average by +12.9% over the next five (5) years (CAGR of +2.5%). As the number of patients that fall into that age cohort continues to grow, the need for imaging services, such as PET-CT, becomes more important for detecting, managing, and treating age-related conditions,³⁹ as discussed in further detail later in this narrative.

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

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

In consideration of the aging population, "imaging strongly contributes to establishing accurate and timely diagnosis, informs and guides treatment decisions and contributes to improving treatment outcomes."⁴⁰ 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,⁴¹ which is essential to the Applicant's aging patients with oncologic, cardiac, and/or neurological concerns. Following the concept of value-based healthcare, a multi-society statement was recently published to elucidate the value that radiology provides to patients and healthcare.⁴²

³⁸ Online at: <https://www.mass.gov/files/documents/2016/07/wb/healthy-aging-data-report.pdf>

³⁹ 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>

⁴⁰ Guy Frija, Ivana Blažić, Donald P. Frush, Monika Hierath, Michael Kawooya, Lluís Donoso-Bach, et al. How to improve access to medical imaging in low- and middle-income countries. eClinical Medicine, Part of The Lancet Discovery Science. VOLUME 38, 101034, AUGUST 01, 2021. Online at: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(21\)00314-X/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00314-X/fulltext)

⁴¹ *Ibid.*

⁴² 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>.

Oncologic Conditions and the Need for PET-CT

Research studies and their findings demonstrate that the prevalence of cancer increases with age.⁴³ 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.⁴⁴ Furthermore, even with a progressive decrease in the cancer incidence and death rate, aging of the population will be accompanied by a marked increase in the total number of patients with cancer,⁴⁵ the majority of whom will require the most precise diagnostic imaging.

In Middlesex County, where MWH and the proposed PET-CT facility are located, the age adjusted annual incidence of cancer rate was 436.5 - 462.3 per 100,000 persons.⁴⁶ According to the American Cancer Society, there is projected to be 42,190 new cases of cancer in Massachusetts in 2022,⁴⁷ and 12,520 cancer related deaths.⁴⁸ 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).⁴⁹

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*.⁵⁰ 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.⁵¹

Patient panel data for MWH's patients provide that 3,007 patients were treated for oncological-related issues in FY19; 2,656 patients in FY20; and 2,671 in FY21.

⁴³ 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>

⁴⁴ 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/>

⁴⁵ *Ibid.*

⁴⁶ Online at: <http://www.cancerinmass.org/uploads/1/1/9/4/119429235/macancer-report2018.pdf>

⁴⁷ Increased from 36,990 cases in 2020.

⁴⁸ Increased from 12,430 in 2020.

⁴⁹ Online at: <https://cancerstatisticscenter.cancer.org/#/state/Massachusetts>

⁵⁰ 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>

⁵¹ *Ibid.*

Furthermore, in the realm of expanded uses for PET-CT, several new PET tracers are under investigation for potential use in urological oncology.⁵² There is a future role for PET-CT in the management of urological malignancies, including testicular, kidney, bladder, and prostate cancer.⁵³ There is increasing evidence that PET-CT influences urological treatment decisions by the detection and localization of recurrent disease that is often missed by using conventional imaging methods.⁵⁴

Patient panel data for MWH's patients provide that 5,529 patients were treated for urological-related issues in FY19; 4,421 patients in FY20; and 4,694 in FY21.

Cancer Rates for Melrose and Wakefield

As part of the Massachusetts cancer registry, the Office of Data Management and Outcomes Assessment and the Department of Public Health releases a Cancer Incidence City & Town Supplement.⁵⁵ This report provides standardized incidence ratios (SIRs) for 23 types of cancers in the 351 cities and towns in Massachusetts over a 5-year time frame. The most recent report contains information from 2011-2015.⁵⁶

As stated in the report, the measurement tool, known as the Standardized Incidence Ratio (SIR), is an indirect method of adjustment for age and sex that describes in numerical terms how a city/town's cancer experience in a given time period compares with the state as a whole. An SIR of 100 indicates that a city/town's incidence of a certain type of cancer is equal to that expected based on statewide average age-specific incidence rates. An SIR of more than 100 indicates that a city/town's incidence of a certain type of cancer is higher than expected for that type of cancer based on statewide average annual age specific incidence rates.⁵⁷

⁵² Isabel Rauscher, Matthias Eiber, Wolfgang A Weber, Jürgen E Gschwend, Thomas Horn and Tobias Maurer. Positron-emission tomography imaging in urological oncology: Current aspects and developments. *International Journal of Urology*. 2018. 25. Online at: <https://onlinelibrary.wiley.com/doi/10.1111/iju.13779>

⁵³ *Ibid.*

⁵⁴ *Ibid.*

⁵⁵ Available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

⁵⁶ Available online at: <https://www.mass.gov/doc/cancer-incidence-in-massachusetts-citytown-supplement-2011-2015>

⁵⁷ For example, an SIR of 105 indicates that a city/town's cancer incidence is 5% higher than expected based on statewide average annual age-specific incidence rates. An SIR of less than 100 indicates that a city/town's incidence of a certain type of cancer is lower than expected based on statewide average age-specific incidence rates. For example, an SIR of 85 indicates that a city/town's cancer incidence is 15% lower than expected based on statewide average annual age-specific incidence rates.

Notable SIRs for Melrose

Cancer Type	Notable SIRs for Melrose	Percentage Higher than Statewide Average
Brain and Other Nervous System	Female: 138.8	Female: 38.8%
Breast	Female: 106.7	Female: 6.7%
Colon/Rectum	Male: 137.9 Female: 125.2	Male: 37.9% Female: 25.2%
Esophagus	Male: 120.0	Male: 20%
Larynx	Male: 161.8	Male: 61.8%
Leukemia	Male: 165.7	Male: 65.7%
Liver and Intrahepatic Bile Ducts	Female: 132.6	Female: 32.6%
Lung and Bronchus	Female: 101.2	Female: 1.2%
Melanoma of Skin	Female: 127.3	Female: 27.3%
Multiple Myeloma	Male: 115.1	Male: 15.1%
Non-Hodgkin Lymphoma	Male: 124.1 Female: 142.1	Male: 24.1% Female: 42.1%
Pancreas	Male: 146.4 Female: 111.2	Male: 46.4% Female: 11.2%
Stomach	Male: 129.2	Male: 29.2%
Uteri Corpus and Uterus, NOS	Female: 122.0	Female: 22.0%
All Sites/Types	Female: 103.9	Female: 3.9%

Notable SIRs for Wakefield

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

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

Cardiological Conditions and the Need for PET-CT

It is well-established that age is a leading risk factor for cardiovascular disease and the risk for coronary heart disease increases starting at age 45 for men and at age 55 for

women.⁵⁸ 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.⁵⁹ 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.⁶⁰

In addition, heart disease⁶¹ 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.⁶² 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.⁶³

Patient panel data for MWH's patients provide that 9,373 patients were treated for cardiac-related diagnoses in FY19; 8,087 in FY20; and 8,014 in FY21.

Neurological Conditions and the Need for PET-CT

Recent studies have placed an increased focus on aging and neurological diseases, such as epilepsy and Alzheimer's dementia. Additionally, the risk of having a seizure increases after the age of 60.⁶⁴ Moreover, the incidence rate of Alzheimer's also increases with age.⁶⁵ Millions of Americans have Alzheimer's or other dementias.⁶⁶ As the size and proportion of the U.S. population age 65 and older continues to increase, the number of Americans with Alzheimer's or other dementias will grow. This number will escalate rapidly in coming years, as the population of Americans aged 65 and older is projected to grow from 55 million in 2019 to 88 million by 2050.⁶⁷

The baby boom generation has already begun to reach age 65 and beyond, the age range of greatest risk of Alzheimer's dementia. The oldest members of the baby boom

⁵⁸ 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/>

⁵⁹ Online at: <https://www.mass.gov/doc/a-profile-of-health-among-massachusetts-adults-2018/download>

⁶⁰ Online at: <https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm>

⁶¹ Stroke is also included in this statistic.

⁶² 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>

⁶³ *Ibid.*

⁶⁴ Acharya JN, Acharya VJ. Epilepsy in the elderly: Special considerations and challenges. *Ann Indian Acad Neurol*. 2014;17(Suppl 1):S18-S26.

doi:10.4103/0972-2327.128645. Online at: <https://pubmed.ncbi.nlm.nih.gov/24791083/>

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

⁶⁶ *Ibid.*

⁶⁷ *Ibid.*

generation turned age 73 in 2019 and by 2030, all Baby Boomers will be aged 65 or older.⁶⁸

The impact of Alzheimer's is projected to rise, and the most recent data show: 130,000 people aged 65 and older are living with Alzheimer's in Massachusetts.⁶⁹ Furthermore, 9.3% of people aged 45 and older have subjective cognitive decline.⁷⁰ An early diagnosis [from a timely screening], opens the door to future care and treatment and helps people to plan while they are still able to make important decisions on their care and support needs and on financial and legal matters.⁷¹ It also helps them and their families to receive practical information, advice, and guidance as they face new challenges.⁷²

Patient panel data for MWH's patients provide that 7,000 patients were treated for neurological-related issues in FY19, 5,989 in FY20, and 6,484 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 continued access to PET-CT imaging to meet current and projected demand. The Applicant's primary objectives with the Proposed Project are to maintain local access when the existing PET-CT joint ventures ceases operations in 2023, accommodate current and future volume demands, and provide high quality, low cost, PET-CT services to MelroseWakefield patients.⁷³ The proposed PET-CT unit will utilize a new mobile pad that will be integrated into the existing interior of the MelroseWakefield Medical Building and integrate into the patient flow of this multi-specialty medical office space.⁷⁴

As noted in Factor F1.a.ii, historical need for PET-CT imaging and other indicators of future demand demonstrate a continued need for PET-CT services in the MWH catchment area. Providing ease of access to care has been documented to reduce healthcare utilization and spending.⁷⁵ Studies have detailed high

⁶⁸ Online at: <https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html>

⁶⁹ Alzheimer's Association. Massachusetts State Overview. Available online at: <https://www.alz.org/professionals/public-health/state-overview/massachusetts#:~:text=The%20impact%20of%20Alzheimer's%20is,of%20the%20disease%20in%20Massachusetts.>

⁷⁰ *Ibid.*

⁷¹ Why early diagnosis of dementia is important. Available online at: <https://www.scie.org.uk/dementia/symptoms/diagnosis/early-diagnosis.asp>

⁷² *Ibid.*

⁷³ MWH currently offers PET-CT services to its patients through a joint venture with their Montvale partner – that joint venture will cease operations in 2023.

⁷⁴ Located at 888 Main Street in Wakefield.

⁷⁵ 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>

costs for unnecessary repeat imaging⁷⁶ which could be improved through more appropriate use of all imaging, including PET-CT, and better integration of services. For the Proposed Project, preventing unnecessary expenditures related to inefficiencies from lack of service integration,⁷⁷ can lead to lower operational overhead and lower healthcare spending, which could, in turn, reduce TME.

The Proposed Project will not negatively impact TME, as the PET-CT services will be provided through a licensed IDTF clinic, where the PET-CT services costs less.⁷⁸ The clinic will be managed by Shields, which will seek to identify optimization opportunities to further drive down the cost to provide care, while simultaneously ensuring the highest quality of care possible.

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

Furthermore, many national insurers have implemented site-of-care reviews for diagnostic imaging.⁷⁹ 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 (or be billed) if the procedure is performed in a hospital-based setting.

Furthermore, the Applicant's clinic represents approximately \$2.3M of net revenue annually by year 6 of operation,⁸⁰ a statistically insignificant amount when compared to overall health care spending.⁸¹

Accordingly, this Proposed Project will have minimal effect on costs in the state.

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

⁷⁶ 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/>

⁷⁷ The World Health Organization defines integrated service delivery as the "the management and delivery of health services so that clients receive a continuum of preventive and curative services, according to their needs over time and across different levels of the health system". See integrated health services - what and why? Technical Brief No.1, 2008, World Health Organization. Available from: http://www.who.int/healthsystems/service_delivery_techbrief1.pdf

⁷⁸ 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/>

⁷⁹ 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](#)

⁸⁰ Please note that the years of operation are based on when the Applicant receives regulatory approval.

⁸¹ Please see Verilon Report Statement of Profit and Loss (Appendix).

Combined PET-CT scans help clinicians pinpoint abnormal metabolic activity and provide more accurate diagnoses than the two scans performed separately.⁸² A PET scan measures important body functions, such as metabolism.⁸³ It helps doctors evaluate how well organs and tissues are functioning.⁸⁴ CT imaging uses special x-ray equipment, and in some cases a contrast material, to produce multiple images of the inside of the body.⁸⁵ A radiologist views and interprets these images on a computer monitor. CT imaging provides excellent anatomic information.⁸⁶

The main applications of PET-CT have been in the oncologic and in the cardiovascular domains where the combined technique has allowed improved all-in one imaging protocols that have been proven beneficial.⁸⁷ 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.⁸⁸

The results of a significant Danish study⁸⁹ 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.⁹⁰ 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.⁹¹ 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”).⁹² 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.⁹³ Cancer screening is considered routine care for individuals starting

⁸² Available at RadiologyInfo.org for patients. Online at: <https://www.radiologyinfo.org/en/info/pet>

⁸³ *Ibid.*

⁸⁴ *Ibid.*

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*

⁸⁷ 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>

⁸⁸ *Ibid.*

⁸⁹ 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 Lysegård 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.sninjournals.org/content/58/7/1058>

⁹⁰ *Ibid.*

⁹¹ *Ibid.*

⁹² 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>

⁹³ 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>

as early as age 25.⁹⁴ CDC supports screening for breast, cervical, colorectal (colon), and lung cancers as recommended by the U.S. Preventive Services Task Force.⁹⁵

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

Oncologic Conditions

As the population expands, over the period from 2000 to 2050, the number and percentage of Americans over age 65 is expected to double.⁹⁶ This population expansion will be accompanied by a marked increase in patients requiring care for disorders with high prevalence in the elderly.⁹⁷ 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.⁹⁸

Cancer studies have shown that early detection yields better outcomes for patients – and diagnostic imaging plays an essential role.⁹⁹ Studies have shown that PET-CT has become an established nuclear imaging modality that has proved especially useful in oncology.¹⁰⁰ 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.¹⁰¹

PET-CT imaging in urological oncology remains in its burgeoning phases but is proving to be more and more useful as an imaging modality. To date, the use of F-FDG¹⁰² has been limited by a generally low tumor uptake and physiological F-FDG excretion by the urinary system,¹⁰³ but other

⁹⁴ 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>

⁹⁵ CDC website. Available online at: <https://www.cdc.gov/cancer/dccp/prevention/screening.htm>

⁹⁶ 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/>

⁹⁷ *Ibid.*

⁹⁸ *Ibid.*

⁹⁹ 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/>

¹⁰⁰ “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>

¹⁰¹ 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/>

¹⁰² Fluorodeoxyglucose F 18 is a radiotracer used in PET imaging. Also written F-FDG¹⁸

¹⁰³ Farolfi, Andreea; Koschel, Samantha; Murphy, Declan G.b.c; Fanti, Stefano. PET imaging in urology: a rapidly growing successful collaboration. *Current Opinion in Urology: September 2020 - Volume 30 - Issue 5 - p 623-627*

radiotracers are increasing the urologist's portfolio allowing imaging of several biochemical pathways.¹⁰⁴ Theragnostic¹⁰⁵ possibilities are also under investigation thanks to PSMA-based tracers.^{106,107}

According to the U.S. Cancer registry, Middlesex County has a cancer incidence of 441 cases per 100,000. Improvements in accuracy and confidence in lesion localization, it stands to reason that a significant percentage of the cases diagnosed per year could be positively impacted with 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.¹⁰⁸ The ability for the heart to recover naturally from ischemic damage decreases with age and makes older patients more susceptible to injury.¹⁰⁹ 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. 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.¹¹⁰

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.¹¹¹ 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.¹¹² There are many viability tests and noninvasive assessment of

doi: 10.1097/MOU.0000000000000800. Online at : https://journals.lww.com/co-urology/Abstract/2020/09000/PET_imaging_in_urology_a_rapidly_growing.2.aspx

¹⁰⁴ *Ibid.*

¹⁰⁵ Theragnostics is a treatment strategy that combines therapeutics with diagnostics. It associates both a diagnostic test that identifies patients most likely to be helped or harmed by a new medication, and targeted drug therapy based on the test results.

¹⁰⁶ Prostate specific membrane antigen radiotracer (PSMA radiotracer) is a medicinal compound, called a radiopharmaceutical, that is used in PET/CT imaging.

¹⁰⁷ *Ibid* -- Note 22

¹⁰⁸ 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/>

¹⁰⁹ 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/>

¹¹⁰ 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/>

¹¹¹ 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/>

¹¹² 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/>

cardiac glucose use, however the PET-CT scan is considered the most accurate technique for detecting viable myocardial tissue.¹¹³

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).¹¹⁴ 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.¹¹⁵

When compared with cardiac Magnetic Resonance Imaging (MRI), the PET-CT was able to detect a more impaired yet viable myocardium.¹¹⁶ In another study focused on cardiac sarcoidosis (inflammatory condition that affects different areas of the heart), the researchers noted differences between the two modalities, and they found that PET-CT was more efficient at detecting elevated serum angiotensin converting enzyme (ACE) levels, which suggests that this type of scan may be more useful for active disease assessment and for following treatment response.¹¹⁷

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.¹¹⁸

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

Neurological Conditions

¹¹³ 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/>

¹¹⁴ 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/>

¹¹⁵ 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/>

¹¹⁶ 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/>

¹¹⁷ 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/>

¹¹⁸ *Ibid.*

PET-CT has been shown to enhance a clinician's ability to diagnose and effectively treat neurological diseases. In neurology, PET-CT plays an important role in the evaluation of various epileptic syndromes as well as in the clinical assessment of patients with a multitude of other disorders, including cognitive impairment and dementias.¹¹⁹ The PET-CT modality has become a valuable tool in the diagnosis, treatment evaluation and follow-up of patients with a variety of infections and inflammatory conditions and is already the gold standard for some neurological indications.¹²⁰

PET (alone) has long been a part of the assessment of brain physiology and pathology. Its early applications were more academic and scientific rather than clinical. PET-CT have been proven as a superior scanning technique in oncological or cardiovascular disorders, but emerging research suggests that PET-CT could be an integral part in neuroradiological settings, such as vascular diseases such as carotid artery disease, which is a cause of stroke.¹²¹

Current standards for taking images for dementia treatment include CT, MRI, or both to exclude masses and vascular lesion, identify and monitor disease and its severity. The addition of PET-CT scans in dementia cases can provide complementary data on the cerebral glucose metabolism, which is a key indicator in the diagnosis and treatment of dementia.¹²² A study that focused on the diagnosis of Autoimmune Encephalitis, an inflammatory neurological disease, found that when compared with MRI, PET-CT may be a better technique in providing an earlier diagnosis of the disease.¹²³

According to the Alzheimer's Association, Alzheimer's disease is a growing public health crisis in Massachusetts and the impact of Alzheimer's is projected to rise.¹²⁴ In fact, 130,000 people aged 65 and older are living with Alzheimer's in Massachusetts and 9.3% of people aged 45 and older have subjective cognitive decline.¹²⁵ Studies suggest that PET imaging is valuable in the assessment of patients with dementia and can help in differentiating Alzheimer's from other causes of dementia such as frontotemporal dementia and dementia of Lewy body.¹²⁶

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

¹¹⁹ Zhuang H, Codreanu I. Growing applications of FDG PET-CT imaging in non-oncologic conditions. J Biomed Res. 2015;29(3):189-202. doi:10.7555/JBR.29.20140081. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449487/>

¹²⁰ *Ibid.*

¹²¹ 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>

¹²² Zukotynski, K., Kuo, P. K., Mikulis, D., Rosa-Neto, P., Strafella, A. P., Subramaniam, R. M., & Black, S. E. (2018, August). PET/CT of Dementia . Retrieved February 22, 2022. Online at: <https://www.ajronline.org/doi/pdfplus/10.2214/AJR.18.19822>

¹²³ Solnes, L. B., Jones, K. M., Rowe, S. P., Pattanayak, P., Nalluri, A., Venkatesan, A., Probasco, J. C., & Javadi, M. S. (2017). Diagnostic Value of 18F-FDG PET/CT Versus MRI in the Setting of Antibody-Specific Autoimmune Encephalitis. Journal of nuclear medicine : official publication, Society of Nuclear Medicine, 58(8), 1307–1313. Online at: <https://pubmed.ncbi.nlm.nih.gov/28209905/>

¹²⁴ Available online at : <https://www.alz.org/professionals/public-health/state-overview/massachusetts>

¹²⁵ *Ibid.*

¹²⁶ Marcus C, Mena E, Subramaniam RM. Brain PET in the diagnosis of Alzheimer's disease. Clin Nucl Med. 2014 Oct;39(10):e413-22; quiz e423-6. doi: 10.1097/RLU.0000000000000547. PMID: 25199063; PMCID: PMC4332800. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4332800/>

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

A. Improving Health Outcomes and Quality of Life

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

Studies indicate that *delayed access* to healthcare services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.¹²⁷ Conversely, *ease of access* improves quality of life for patients because early detection and treatment of diseases improves patient outcomes.¹²⁸ 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.¹²⁹

Through the continued access locally of PET-CT services at the MelroseWakefield Medical Building¹³⁰ via IDTF clinic-based service, the Applicant aims to ensure timely access to optimized, low-cost, high-quality imaging services for MWH patients. Access to such PET-CT services for these patients – particularly for patients who are sick or effected by oncological, cardiovascular, and/or neurological issues – allows for better quality health outcomes, as it allows clinicians to have a better understanding of an individual's condition and provide appropriate comprehensive treatment options in a timely manner. Along with providing better imaging data, PET-CT notably increases patient comfort and convenience by reducing the number of scanning sessions a patient must undergo.¹³¹

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.¹³² 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.¹³³ In this case, transmission scans are not required because the CT data are used for attenuation correction.¹³⁴ It has been estimated that patient output has increased by approximately 40 percent.¹³⁵ 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.¹³⁶

¹²⁷ 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/>

¹²⁸ American College of Radiology. *Early Action Boosts Patient Satisfaction*. Online at: <https://www.acr.org/Practice-Management-Quality-Informatics/Imaging-3/Case-Studies/Quality-and-Safety/Early-Action-Boosts-Patient-Satisfaction>

¹²⁹ 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/>

¹³⁰ Located at 888 Main Street in Wakefield.

¹³¹ Online at: <https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html>

¹³² 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/>

¹³³ *Ibid.*

¹³⁴ *Ibid.*

¹³⁵ *Ibid.*

¹³⁶ 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:

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.¹³⁷

Moreover, given that MWH is a part owner of the Applicant, imaging services provided by the Applicant will be fully integrated with MWH'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.¹³⁸

Poor coordination of care has negative consequences for patients and contributes to higher medical costs.¹³⁹ 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 MWH's patients will facilitate quick and easy access to patient images and reports, which will in turn effect timely care, improved outcomes, and better quality of life.

B. Assessing the Impact of the Proposed Project

To assess the impact of the Proposed Project, the Applicant has developed the following quality metrics and reporting schematic, as well projections for quality indicators that will measure patient satisfaction, access, and quality of care.¹⁴⁰ 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.

https://Images.philips.com/is/content/PhilipsConsumer/Campaigns/HC20140401_DG/Documents/PEX_in_Imaging_research_11Oct17_FINAL.pdf

¹³⁷ Bhanu Prakash, Patient Satisfaction, 3 J. CUTANEOUS & AESTHETIC SURGERY 151 (2010), online at:

<https://pubmed.ncbi.nlm.nih.gov/21430827/>

¹³⁸ 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>

¹³⁹ 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/>

¹⁴⁰ Shields is now using a platform called Podium – a text-based program for patient experience.

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

Monitoring: PET-CT technologists will track the number of scans that are repeated and scheduled for the next scan day. Technologists will document each case and conduct a monthly comparison to total volume to meet or exceed the metric.

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

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

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

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

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

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

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

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

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

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

To ensure health equity to all populations, including those deemed underserved, the Proposed Project will not adversely affect accessibility of MWH'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 survey¹⁴¹ 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.¹⁴² The Applicant is addressing this disparity by offering imaging services that are reimbursed at lower, IDTF rates – IDTF's maintain costs by focusing on one service with much less overhead.¹⁴³

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

¹⁴¹ 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/>

¹⁴² *Ibid.*

¹⁴³ Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIEiwAiY-vMHCMEtjEV0at0isHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

multiple tools to address language barriers, including Language Line¹⁴⁴ and InDemand interpreting to provide multiple options for translation services.¹⁴⁵ Language Line provides quality phone and video interpretation services from highly trained professional linguists in more than 240 languages 24 hours a day, 7 days a week, facilitating more than 35 million interactions a year. InDemand offers leading-edge medical interpreting solutions, which allows clinicians to provide their limited English proficient, deaf, and hard of hearing patients with access to the highest quality healthcare. Together, these solutions will eliminate language barriers for patients and ensure culturally appropriate care.

Lastly, the Proposed Project will provide the opportunity for patients to receive the highest quality imaging at a proximate location to the MWH campus, thus preventing barriers to this service locally.¹⁴⁶ To date, MWH patients seeking PET-CT imaging have not had to travel to receive a scan. This is an essential component of maintaining the continuity of care and ensuring that the most direct path to diagnosis and treatment is not disrupted. 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.¹⁴⁷ These consequences may lead to poorer management of chronic illness and ultimately poorer health outcomes.¹⁴⁸

The Applicant's Proposed Project will help continue to 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 just as convenient and efficient as the existing service, made possible through operational discipline and focus that cannot be achieved under traditional hospital oversight. Dedicated focus by the Shields management team offers insight on operational and scheduling efficiencies that increase capacity and improve patient and referring provider satisfaction. The Applicant also plans to implement numerous amenities, including patient access tools, such as preregistration functionality and a cost transparency application, to improve patient experience and ensure patient satisfaction.

¹⁴⁴ Language Line Solutions phone interpreting may also be used in the event the In Demand system is not functioning properly.

¹⁴⁵ 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.

¹⁴⁶ "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/>

¹⁴⁷ 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/>

¹⁴⁸ *Ibid.*

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.

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.¹⁴⁹ Certain questions in the pre-screen relate to certain SDoH issues, namely those issues that are relevant to an imaging appointment such as transportation.¹⁵⁰ 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:

- 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

¹⁴⁹ Centers for Disease Control and Prevention. Online at: <https://www.cdc.gov/socialdeterminants/index.htm>

¹⁵⁰ Access to transportation is one of the most important social determinants of health (SDOH), according to the CDC.

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 MWH patients. The Applicant's data for these services demonstrates the demand. Additionally, demand for local PET-CT services is likely to increase as the region's population ages. The Applicant engaged the community to involve patients and families more fully regarding the proposed transition.

The Proposed Project was presented at MWH's Patient Family Advisory Committee ("PFAC") on June 28, 2022, with fifteen (15) members in attendance. The PFAC is comprised of current and former patients of the hospital and their family members as well as caregivers and staff of the hospital. Because patients of the proposed service will continue to be MWH patients, it was decided that the PFAC would best represent patients from the proposed service area. The presentation sought to inform PFAC members about the purpose of the Proposed Project and what it would mean for patients.

The presentation to the PFAC offered members an overview of current state of imaging services and the continued need for PET-CT at the MelroseWakefield Medical Building location once the current imaging vendor relationship expires in the summer of 2023. It reviewed how the Proposed Project will benefit current and future patients. This project will use a combination of inside space and a mobile PET-CT unit aligned with the building one day per week. PET-CT services will complement the cancer treatment and breast services currently provided at MWH. 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 serious concerns. Participants were engaged throughout the presentation and made several comments that generally focused ease of access, the ease of scheduling, and the benefits of local care, as well as the advantages of new imaging equipment.¹⁵¹ Clarification was sought regarding the impact to the neighborhood and whether there would be additional traffic and/or noise – both matters are not contemplated to be an issue with the proposed project.

The Proposed Project was also presented at a community meeting on September 8, 2022 – there were thirteen (13) individuals in attendance. The group was comprised of MWH patients and residents of Wakefield. The presentation contained the substantially similar information as the PFAC presentation.¹⁵²

Attendees at the community meeting also had a positive reaction to the Proposed Project and did not voice any concerns. There was a question about radiation safety and a comment about local street access.

To ensure appropriate awareness within the community about the Proposed Project, the legal notice associated with the Proposed Project was published both on the Shields website¹⁵³ and on the MWH website.¹⁵⁴ This was done to bring awareness of the Proposed Project to all patients, family members,

¹⁵¹ Current imaging equipment is 15+ years old.

¹⁵² A copy of the presentation is included herein with this submission.

¹⁵³ Published August 31, 2022 on the Shields website: <https://shields.com/location/shields-petct-tufts-medical-center/>

¹⁵⁴ Published August 31, 2022 on MelroseWakefield Hospital website: <https://www.melrosewakefield.org/news/public-announcement-concerning-a-proposed-health-care-project/>

residents, and resident groups. It also provides an opportunity for public comment on the Proposed Project.

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

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

- Presentation to MWH's PFAC on June 28, 2022; and
- Community meeting on September 8, 2022.¹⁵⁵

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 Melrose/Wakefield PSA/SSA seeking local PET-CT imaging services. Through the Proposed Project, the Applicant seeks to enhance existing imaging capabilities by installing a new PET-CT imaging unit to replace an antiquated machine and to update the diagnostic imaging vendor relationship when the current joint venture expires in the summer of 2023. The new service will be conveniently located in a medical services building, proximately located to MWH.

As previously discussed, the cost of providing these services will be mitigated via the IDTF clinic model. Furthermore, potential savings are associated with PET-CT as a result of avoiding additional imaging examinations or invasive procedures and by helping clinicians make the optimum treatment decisions.¹⁵⁶ The Proposed Project meets the goal of providing a lower-cost alternative for PET-CT imaging services, as

¹⁵⁵ For detailed information regarding these activities, please see attached exhibit.

¹⁵⁶ 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/>

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.¹⁵⁷ This difference will allow the Applicant to provide cost-effective, quality imaging services to MWH'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 follow-up imaging studies (usually CT scans) are required.¹⁵⁸ If patients undergo both examinations in one session, in addition to having more accurate results, costs will be lower.¹⁵⁹

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. Reducing diagnostic and treatment delays limits deterioration of health and lowers costs by reducing the resources required for care.¹⁶⁰ By offering PET-CT imaging services where the patient panel has historically gone for diagnostic imaging, helps promote faster diagnosis, intervention, and treatment and can contribute to improving health care quality, thereby reducing the overall costs of health care.

F2.b Public Health Outcomes:

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

Providing needed care in a more efficient and effective manner will improve public health outcomes and patient experience. As is outlined in detail throughout this narrative, PET-CT imaging is a powerful modality that allows clinicians to better understand the disease process and make treatment decisions. If the Proposed Project is approved, the patient panel will continue to enjoy access to local PET-CT imaging services at a low-cost and community clinicians will have the necessary tools to appropriately diagnose and treat patients, thereby improving health outcomes for the patient panel.

As the patient population ages, the demand for imaging services will likely grow. An aging population will have an increased need for high-quality imaging services to diagnose and treat age-related conditions. In fact, on average, the geriatric patient uses 50% more lab/imaging services than younger populations.¹⁶¹

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

¹⁵⁷ 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/>

¹⁵⁸ 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/>

¹⁵⁹ *Ibid.*

¹⁶⁰ Robert S. Kaplan and Michael E. Porter. The Big Idea: How to Solve the Cost Crisis in Health Care. Harvard Business Review Magazine. 2011. Available online at: <https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care>

¹⁶¹ 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

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 MWH's PSA/SSA. In instances where patients need support to address social determinants of health,¹⁶² 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 MWH's well-established cancer care continuum including access to board-certified cancer specialists who take a team approach to personalized cancer treatment plans for each patient. MWH surgeons, radiation oncologists, pathologists, oncologists/hematologists, nutritionists, primary care physicians, oncology nurses, and social workers collaborate to deliver the best possible care. PET-CT services will also align with MWH's comprehensive, cardiac rehabilitation program.¹⁶³ 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.

The Applicant's enhanced service offerings are not limited to staffing and programmatic functionality – care has also been taken for the physical space where the PET-CT services will be offered. Research shows that a safe and well-designed clinical space helps to improve patient outcomes.¹⁶⁴ The MelroseWakefield Medical Building is a state-of-the-art building constructed in 2016 and erected in compliance with the Americans with Disabilities Act ("ADA") design standards. The building hosts over 27,000 square feet of convenience and offers a patient-centered design, ample free parking, walking distance to Greenwood commuter rail stop, extended hours, and on-site laboratory services. The PET-CT area will optimize a combination of inside space and a mobile PET-CT unit aligned with the building. To access diagnostic imaging, patients will enter the mobile environment that is temporarily attached to the building, enclosed from the outside elements.

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

¹⁶² MWH is committed to improving the quality of healthcare we provide to our communities wherever we provide care for them. We dedicate resources to benefit our communities by working to: promote health to our communities and patients; educate the community about health issues and prevention strategies; identify and address health needs with community partners; provide essential services; and reduce health disparities.

¹⁶³ MWH is growing as a regional center of excellence, working collaboratively with Tufts Medical Center to bring more expert services to the community. MWH is a teaching program for Tufts Medical Center fellowship students and many of our providers hold teaching appointments at Tufts University School of Medicine.

¹⁶⁴ Nelson KM, Helfrich C, Sun H, et al. Implementation of the patient-centered medical home: associations with patient satisfaction, quality of care, staff burnout, and hospital and emergency department Use. *JAMA Intern Med.* 2014;174(8):1350–8. Available online at: <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/1881931>

Factor 5: Relative Merit

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

A. Proposal

To continue to provide PET-CT services to the local, MelroseWakefield patient panel, through the new partnership established between MelroseWakefield Hospital and Shields (the Tufts Medicine: Shields PET-CT, LLC). The physical clinic will be located in a pre-existing space in the MelroseWakfield Medical Building. Patients would enter a mobile environment that is temporarily attached to the building, enclosed from the outside elements. Services will be reimbursed as an IDTF to enhance efficiency and effectiveness of care delivery.

B. Quality

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

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

C. Efficiency

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

D. Capital Expense

Establishing a new diagnostic imaging vendor partnership that leverages an IDTF fee schedule will result in minimal capital expense. There are only minimal expenses attributable to facility build out, as the proposed mobile PET/CT unit will utilize a mobile pad to be located at the MelroseWakefield Medical Building. There are only \$25,000 capital asset acquisitions in 2023.¹⁶⁵ There are no capital expenditures expected from 2024 through 2028.¹⁶⁶

¹⁶⁵ Please see Veralon's Capital Expenditures findings in section III of the attached CPA report.

¹⁶⁶ *Ibid.*

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) CAGR¹⁶⁷ for Years 2 through 6 is 7.6%. Year 1 was not included in the CAGR calculation.¹⁶⁸ These expenses for the Proposed Project in Year 6 are projected to be \$62,441.¹⁶⁹

F. Alternative Option for the Project

a. Option 1

i. Alternative Proposal

The Applicant considered not establishing a new vendor partnership to replace the current PET-CT imaging vendor once the contract expires in the summer of 2023. In this scenario, patients would not be able to continue to enjoy local access to diagnostic imaging services conveniently located at the MelroseWakefield Medical Building – a location proximately located to where patients currently receive the rest of their integrated care services at the MelroseWakefield Hospital.

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 allows those patients who meet the clinical protocols for combined PET-CT to receive the service locally, thus enhancing access for the patient panel. Discontinuation of a diagnostic imaging vending partnership would result in insufficient access. Insufficient access may increase the risk of poor health outcomes and health disparities.¹⁷⁰

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

¹⁶⁷ Compound Annual Growth Rate.

¹⁶⁸ 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").

¹⁶⁹ For reference, the operating expenses for Year 1 are calculated to be \$108,193. Please see CPA analysis for further content.

¹⁷⁰ Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care. Smedley BD, Stith AY, Nelson AR, editors. Unequal treatment: confronting racial and ethnic disparities in health care. Washington (DC): National Academies Press (US); 2002. Access to this study is referenced online at: <https://wayback.archive-it.org/5774/20220414155345/https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/access-to-health#2>

manner. Expanding access to health services is an important step toward reducing health disparities.¹⁷¹

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 maintain a local PET-CT service offering would deprive the patient panel of an important diagnostic imaging tool for the community. While no additional capital expenses would be incurred in the short term, forgoing this project would greatly impact patient experience, clinician experience, and health outcomes.

v. Alternative Operating Costs

Taking no action to maintain a local PET-CT service offering would not result in any significant near term changes in operating costs.

b. Option 2

i. Alternative (2) Proposal

The Applicant considered not establishing a new vendor partnership to provide patients with continued local access to PET-CT services and to instead refer all patients meeting the clinical protocols for PET-CT to Shields PET-CT at Tufts Medical Center located at 800 Washington Street in Boston. In this scenario, patients would need to travel a half an hour (or more) to downtown Boston to receive PET-CT scans for their oncologic, cardiac, and neurologic conditions, rather than receiving those scans at the location where they receive the rest of their integrated care services.

ii. Alternative (2) 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. This alternative would force 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. Appointment availability for MWH patients would also be difficult due to already existing volumes and lack of capacity available at Tufts Medical Center. Insufficient access effects the quality of care for the patients served.

¹⁷¹ Office of Disease Prevention and Health Promotion. Healthy People 2020. Access to Health Services. Available online at: <https://wayback.archive-it.org/5774/20220414155345/https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/access-to-health#2>

Ready access to PET-CT services is not only more convenient for the patients, but also it will allow clinicians to determine appropriate treatment options that will impact overall health outcomes in a time effective manner.

iii. Alternative (2) Efficiency

Not maintaining a local PET-CT service offering, would not help improve efficiency because it deprives patients of the most timely and accurate access to necessary diagnostic information.

iv. Alternative (2) Capital Expense

Taking no action to maintain a local PET-CT service offering would maintain the status quo and no additional capital expenses would likely be incurred for the Applicant.

v. Alternative (2) Operating Costs

Taking no action to maintain a local PET-CT service offering would maintain the status quo and no additional operating costs would likely be incurred directly by the Applicant. However, it is notable that the patients who would be referred to Shields PET-CT at Tufts Medical Center may present an operational burden that could translate into increased operating costs for the Applicant's sister corporation, due to increased appointment volume and the overtime that would likely be required for clinicians/technicians to accommodate the displaced patients' imaging needs.

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.