

2. Project Description

The Applicant, “Shields and Atrius Health PET/CT at Dedham, LLC”, is a joint venture between Atrius MSO, LLC (“Atrius MSO”) and Shields Imaging Services, LLC (“Shields”) located at 700 Congress Street, Suite 204, Quincy, Massachusetts 02169. The Applicant is filing a Determination of Need Application (“Application”) with the Massachusetts Department of Public Health (“DPH”) for the establishment of a part-time mobile positron emission tomography (“PET”) – computed tomography (“CT”) (together “PET/CT”) diagnostic imaging service. Specifically, the mobile PET/CT unit will be located at an existing Shields facility at 40 Allied Drive, Suite 112, Dedham, MA 02026,¹ and will operate one day per week (“Proposed Project”).

The Proposed Project is a new installation but will utilize an existing and serviceable mobile pad aligned with the existing building. The Applicant seeks to address the absence of standard-of-care diagnostic PET/CT imaging. The Applicant also seeks to support clinical trial research by adding this part-time mobile PET/CT imaging tool. As a clinic, the Proposed Project will be reimbursed as an Independent Diagnostic Testing Facility (“IDTF”) for all diagnostic imaging services.

The Applicant seeks to ensure that patients within the Primary Service Area (PSA) have access to the highest quality imaging services delivered efficiently and cost-effectively. Currently, those patients seeking diagnostic imaging must travel to disparate locations across Norfolk, Suffolk, and Middlesex counties. The Proposed Project will enhance patient access and the patient experience by offering PET/CT imaging services via this diagnostic imaging joint venture partnership between Shields and Atrius MSO.

Through the Proposed Project, the Applicant will satisfy patient panel needs by providing access to PET/CT imaging services one day per week, onsite at the Dedham location. The existing need for PET/CT imaging services for the Applicant’s patient panel is demonstrated by volume demand,² growth in the number of older patients, disease burden trends, and the increasing number of patients with underlying oncologic, cardiac, and neurologic conditions. National statistics indicate the increasing prevalence of cancer and cardiovascular disease.³ Therefore, the need for these services is expected to expand as patients within the 65+ age cohort, increases.

The Applicant proposes to use the mobile PET/CT unit for part-time clinical use as well as part-time use as the diagnostic imaging unit supporting four (4) Alzheimer’s clinical research trials.⁴ Use of the PET/CT unit will be restricted to patients who meet either clinical protocols or the Alzheimer’s research inclusion criteria for combined PET/CT.

Imaging plays a critical role in establishing the diagnoses for innumerable conditions and it is used routinely in nearly every branch of medicine.⁵ Among other clinically appropriate applications, the Applicant proposes to utilize the designated PET/CT primarily for oncologic, cardiac, and neurologic

¹ <https://shields.com/location/shields-mri-dedham/>

² Volume demand is defined for purposes of this Narrative as the volume of patients who met the clinical protocols for PET/CT imaging.

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 The diagnostic imaging support for the clinical research is made possible by Shields’ established contractual relationships with the entities listed here: Boston Center for Memory; Adams Clinical; MedVadis Research; and Cognito Therapeutics. These contractual relationships are proprietary, and as such the Applicant is only providing the requisite details for the purposes of this narrative.

⁵ Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine; Balogh EP, Miller BT, Ball JR, editors. Improving Diagnosis in Health Care. Washington (DC): National Academies Press (US); 2015 Dec 29. 2, The Diagnostic Process. Online at: <https://www.ncbi.nlm.nih.gov/books/NBK338593/>

imaging purposes. The Applicant anticipates that the Proposed Project will provide the patient panel with access to diagnostic imaging services that will directly impact health outcomes and quality of life. Diagnosis has important implications for patient care, research, and policy.⁶ Diagnostic *technology* is crucial to determine what treatments are most effective with patients' anatomy. Access to PET/CT services will allow clinicians to determine appropriate treatment options that will positively impact overall health outcomes in a time-effective manner.

The Applicant's participation as the diagnostic imaging partner across four Alzheimer's clinical trials would allow for critical community research support around Alzheimer's disease. According to the Association of American Medical Colleges, Alzheimer's is the seventh leading cause of death in the United States and has long burdened the scientific community.⁷ Though research over the decades has identified characteristics of the disease — such as the presence of amyloid plaques between neurons and the buildup, known as tangles, of another toxic protein, tau, inside neurons — questions remain about what causes the disease and how best to treat it in a clinically meaningful way.⁸ Scientists are making great strides in identifying potential new ways to help diagnose, treat, and even prevent Alzheimer's and related dementias.⁹ These advances are possible because thousands of people have participated in clinical trials¹⁰ and PET/CT is well-established as a valuable tool in the detection of neurodegenerative disorders.¹¹

The Proposed Project will compete on the basis of provider price, costs, and total medical expenses ("TME") for several reasons. First, PET/CT services are not currently available at Atrius Health.¹² The Proposed Project will allow the Applicant's patients the opportunity to seek care inside the Atrius Health system and benefit from care coordination efforts. Services will be reimbursed as an IDTF. IDTF services are reimbursed at lower rates than hospital-based rates — IDTFs maintain lower costs by focusing on one service with much less overhead.¹³ Second, the use of a part-time mobile model allows for enhanced patient access and this model 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.¹⁴ Third, research can help cut the cost of medical care.¹⁵ PET/CT has shown important promise for reducing the cost of cancer management by improving the accuracy of both diagnosis and staging, thereby helping to avoid expensive, futile treatments¹⁶ and associated side effects.¹⁷ PET/CT also can potentially reduce the cost burden over time to the health care system by identifying the most appropriate treatment,¹⁸ earlier in the disease process. Lastly, this joint venture partnership will allow Shields to implement both operational optimization initiatives to further drive down cost and allow the team to leverage the use of

⁶ *Ibid.*

⁷ Article available online at: <https://www.aamc.org/news/recent-breakthroughs-alzheimer-s-research-provide-hope-patients>

⁸ *Ibid.*

⁹ Article available online at: <https://www.nia.nih.gov/health/alzheimers/dementia-research-and-clinical-trials>

¹⁰ *Ibid.*

¹¹ 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. Available online at <https://pubmed.ncbi.nlm.nih.gov/21718326/>

¹² Please see page 3 for an overview of the Applicant's Joint Venture Partners.

¹³ Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIeWAIY-yMHCMETjEV0at0isHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

¹⁴ The proposed project will leverage existing equipment, which will also be leveraged across six other locations.

¹⁵ Warwick Anderson, "With the right kind of research, we can reduce health-care costs." *The Conversation.* July 28, 2014. Available online at: <https://theconversation.com/with-the-right-kind-of-research-we-can-reduce-health-care-costs-28898>

¹⁶ Such as curative intent surgery and radiation therapy in patients demonstrated by PET to have advanced disease.

¹⁷ Fischer BM, Siegel BA, Weber WA, von Bremen K, Beyer T, Kalemis A. PET/CT is a cost-effective tool against cancer: synergy supersedes singularity. *Eur J Nucl Med Mol Imaging.* 2016 Sep;43(10):1749-52. doi: 10.1007/s00259-016-3414-5. Epub 2016 May 13. PMID: 27178271; PMCID: PMC4969342. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969342/>

¹⁸ *Ibid.*

centralized patient management services across the Shields network of service partnerships. This scalable model keeps infrastructure costs low.¹⁹

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.

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

F1.a.i Patient Panel:

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

A. Overview of the Applicant's Joint Venture Partners

The Applicant is a joint venture between Atrius MSO ("Atrius MSO") and Shields Imaging Services, LLC ("Shields"), an entity affiliated with Shields Health Care Group, Inc. The purpose of the joint venture is to own and operate a Department of Public Health licensed clinic for the provision of positron emission tomography / computed tomography ("PET/CT") services to patients in the service area utilizing a mobile PET/CT unit. In connection with the provision of services at the clinic, the Applicant plans to enter into a Management Services/Support Agreement with Shields and a Professional Services Agreement with Atrius Health, Inc. a nonprofit multispecialty Massachusetts-based group practice.

Atrius MSO is a Delaware Limited Liability Company registered with the Secretary of the Commonwealth as a foreign limited liability company. Atrius MSO is owned by Optum Care, a subsidiary of Optum, Inc., which, in turn, is a subsidiary of UnitedHealth Group, Incorporated. Atrius MSO provides its affiliate, Atrius Health, Inc., a multispecialty group practice organized as a Chapter 180 nonprofit corporation ("Atrius Health"), certain non-clinical assets and administrative and non-clinical support services under an administrative services agreement. Atrius Health operates over 30 locations providing its adult and pediatric patients with a range of clinical services and an effective system of connected care for its adult and pediatric patients. Atrius Health physicians collaborate closely with hospital partners, other community specialists, and post-acute facilities to provide high-quality, patient-centered, coordinated, and cost-effective care to its patient population.

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

¹⁹ 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-health-care-best-practices-report-en.pdf>

B. Applicant's Patient Panel

The Applicant was established to offer the patient panel low-cost, high-quality advanced diagnostic imaging. As a newly formed joint venture, it does not have its own patient panel. Consequently, the Applicant's proposed panel is based on certain patients of Atrius Health to demonstrate the need for the Proposed Project.²⁰ In addition to patient panel data from Atrius Health, the Applicant relies upon specific service line historic claims data from the Advisory Board Company ("Advisory Board"), to further demonstrate the need for advanced diagnostic imaging services in the proposed Primary Service Area ("PSA").

The PSA for the Proposed Project is defined by cities and towns representing approximately a third of the patients currently served by Atrius Health. The top 15 towns from which Atrius Health has patients are Boston, Quincy, Cambridge, Plymouth, Somerville, Braintree, Medford, Lowell, Dedham, Norwood, Peabody, Dorchester, Arlington, Watertown, and Brockton as demonstrated in Table 1, below.

Table 1: Top 15 Cities and Towns²¹

	2020		2021		2022		2023	
	Count	%	Count	%	Count	%	Count	%
Patient Origin (Top 15)								
Boston	18,162	4.3%	15,745	4.1%	16,098	4.2%	18,164	4.4%
Quincy	17,725	4.2%	13,189	3.5%	13,114	3.4%	14,418	3.5%
Plymouth	13,073	3.1%	12,610	3.3%	12,721	3.3%	12,013	2.9%
Cambridge	12,415	3.0	11,047	2.9%	11,055	2.9%	12,256	3.0%
Somerville	11,205	2.7%	10,127	2.7%	9,912	2.6%	11,138	2.7%
Braintree	9,766	2.3%	7,938	2.1%	7,878	2.1%	8,580	2.1%
Medford	8,038	1.9%	7,546	2.0%	7,570	2.0%	8,008	1.9%
Lowell	7,151	1.7%	6,756	1.8%	7,023	1.8%	7,072	1.7%
Dedham	6,485	1.6%	6,173	1.6%	5,842	1.5%	5,812	1.4%
Norwood	5,916	1.4%	5,515	1.4%	5,322	1.4%	5,516	1.3%
Peabody	6,560	1.6%	5,645	1.5%	5,629	1.5%	5,505	1.3%
Dorchester	5,407	1.3%	4,955	1.3%	4,882	1.3%	4,973	1.2%
Arlington	5,074	1.2%	4,868	1.3%	4,864	1.3%	5,247	1.3%
Watertown	4,605	1.1%	4,421	1.2%	4,460	1.2%	4,715	1.1%
Brockton	3,542	0.8%	3,335	0.9%	3,391	0.9%	4,943	1.2%

²⁰ The Applicant also provides data from Atrius Health's complete patient panel for additional context.

²¹ Corresponding zip codes: Boston (02110, 02118, 02126, 02109, 02113, 02130, 02121, 02119, 02115, 02163, 02135, 02199, 02124, 02132, 02114, 02108, 02136, 02111); Plymouth (02330, 02332, 02345, 02360, 02361, 02362); Quincy (02169, 02170, 02171, 02184, 02186, 02191, 02269, 02368); Cambridge (02138, 02139, 02140, 02141, 02142, 02238, 02239); Somerville (02129, 02143, 02144, 02145); Braintree (02184, 02185, 02368); Medford (02153, 02155, 02156); Lowell (01850, 01851, 01852, 01853, 01854); Dorchester (02121, 02122, 02125); Weymouth (02043, 02188, 02189, 02190, 02191); Dedham (02026, 02027, 02090); Peabody (01960, 01961); Norwood (02062, 02090); Brockton (02301, 02302, 02303, 02304, 02305); and Watertown (02471, 02472, 02477).

Overall Unique Patient Demographic Profile of Atrius Health

The patient panel is demonstrated by the demographic data collected for calendar years (“CY”) 2020 through Q3 of 2023. The patient panel count for the period of January 1, 2020, through Q3 of 2023 was 1,597,327 unique patients; Table 2 shows the historic total patient panel volume per year, starting from 2020.

Table 2: Patient Panel CY2020-CY2023

	2020	2021	2022	2023
Unique number of patients served	417,689	381,725	383,507	414,406

**2023 data reported through Q3*

Patient Panel – Age

The age demographics for the Atrius Health patient panel from CY20 through Q3 of CY23 are demonstrated in Table 3 below.

Table 3: Patient Panel – Age

	2020	2021	2022	2023
Age				
0-18	2,747	2,741	2,750	3,045
19-64	317,855	286,754	286,848	307,919
65+	97,087	92,230	93,909	103,442
Total	417,689	381,725	383,507	414,406

Similar to the statewide experience reported by the UMass Donahue Institute, Atrius Health has seen increases in the aging population evidenced by the increasing percentage of the patient panel over the age of 65.²²

According to Census data, made available through the Advisory Board Demographic profiler, within Atrius Health’s top fifteen (15) cities and towns, the population aged 65 and over is projected to increase on average by +23.6% over the next five (5) years (CAGR²³ of +4.3%).

Patient Panel – Gender

The gender demographics for the Atrius Health patient panel from CT20 through Q3 of CY23 are demonstrated in Table 4 below.

²² Available online at: <https://www.mass.gov/doc/population-projections-methods-umdi-massdot/download>

²³ According to Investopedia, the compound annual growth rate (CAGR) is the [rate of return](#) (RoR) that would be required for an investment to grow from its beginning balance to its ending balance, assuming the profits were reinvested at the end of each period of the investment’s life span. Available online at: <https://www.investopedia.com/terms/c/cagr.asp>

Table 4: Patient Panel – Gender

	2020	2021	2022	2023
Gender				
Female	243,513	221,401	222,818	239,527
Male	174,176	160,325	160,689	174,879
Total	417,689	381,725	383,507	414,406

Patient Panel – Race/Ethnicity

The race/ethnicity demographics for the Atrius Health patient panel from CT20 through Q3 of CY23 are demonstrated in Table 5 below.

Table 5: Patient Panel – Race/Ethnicity²⁴

	2020	2021	2022	2023
Race/Ethnicity				
Caucasian	284,382	258,246	258,620	291,563
Black	28,067	27,231	28,014	32,707
Asian	27,601	25,784	28,174	38,416
Hispanic	14,209	13,761	14,538	22,752
Native American	358	331	317	1,006
Native Hawaiian	164	174	186	313
Other	14,637	13,512	13,829	1,662
Patient Declined	17,552	15,468	15,415	10,237
Unavailable	30,719	27,218	24,414	15,750
Total	417,689	381,725	383,507	414,406

C. Payer Mix

The payer mix for Atrius Health from CY20 through Q3 of CY23 is demonstrated in Table 6 below:

Table 6: Patient Panel – Payor Mix²⁵

	2020	2021	2022	2023
Payor Mix				
Commercial HMO	207,330	203,436	213,962	213,286
Commercial PPO/Indemnity	111,681	118,967	135,439	128,103
Medicaid HMO	29,213	32,308	32,909	33,083
Medicare	55,870	54,716	62,849	64,444
Medicare MHO	19,799	19,112	20,157	20,619
Other Government	3,173	3,001	5,141	2,638
Self-Pay	2,758	1,930	3,860	1,722
Total	429,824	433,470	474,317	463,895

²⁴ Please note that the percentages were rounded to the nearest decimal.

²⁵ Please note that payor mix data reflects activity for all Atrius Health patients seen. Atrius Health sees patients with outside PCPs, therefore, the payor mix data totals for each year are larger than the unique patient demographic data.

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 patient panel needs by providing access to PET/CT imaging services one day per week, onsite at an existing Shields location in Dedham. To underscore the importance of 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.²⁶

The existing need for PET/CT imaging services for the Applicant's patient panel is demonstrated by projected volume demand, growth in the number of older patients, disease burden trends, and the increasing number of patients with underlying oncologic, cardiac, and neurologic conditions for which PET/CT has proven clinical applicability.

In addition, the Applicant proposes to use the mobile PET/CT unit for part-time use as the diagnostic imaging unit supporting four (4) Alzheimer's clinical research trials. Clinical research has been instrumental in showing 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 disease.²⁷

Need for Additional Services

- i. The need for local PET/CT imaging services is demonstrated by projected volume.

Projected Volume

The Applicant evaluated the growing demand for access to PET/CT services within the service area. These volume assumptions include both Shields and Atrius Health's data – please see Table 8 for the volume projection data.²⁸

²⁶ 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>

²⁷ Advantages of a PET/CT scan. Available online at: <https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html#:~:text=Clinical%20research%20has%20shown%20that%20in%20comparison%20to,the%20cancer%20in%20approximately%20one-third%20of%20the%20cases.>

²⁸ Veralon Partners Inc. ("Veralon") performed an analysis of the prospective financial schedules and associated volume forecast prepared by Shields Health Care Group for the proposed joint venture partnership to establish a PET/CT clinic in Dedham, Massachusetts.

Table 8: Projected Volume Data

	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Total PET/CT Volume	664	764	856	958	1,054	1,160
Shields	364	419	470	525	578	636
Atrius Health	300	345	386	433	476	524

Table 9 below displays the Shields projected scan volume breakdown with respect to the volume data provided above.

Table 9: Shields Breakdown

Total Volume	364	419	470	525	578	636
Neurological Research	182	182	197	220	233	257
Specialty scan	182	182	211	236	257	277
Fluorodeoxyglucose ²⁹ ("FDG") scan	0	55	62	69	88	102

The Applicant also relies on recent data from the Advisory Board Company ("Advisory Board"),³⁰ to further demonstrate the need for PET/CT in the proposed Primary Service Area ("PSA"). The Advisory Board projects that demand for PET/CT within the PSA will grow by + 13.7% over the next five (5) years and +22.0% over the next 10 years.

- ii. The growth in the number of older patients helps define the need to establish PET/CT diagnostic imaging services.

Adults (19-64) and older adults (65-84) comprise the overwhelming bulk of the Applicant's total patient panel between CY20 to Q3 of CY23. Adult patients in the 19-64 cohort represented about 76% of the total patient population, and older adult patients in the 65+ age cohort represented about 23% of the total patient population.

The U.S. Census Bureau's American Community Survey reveals that the Massachusetts population aged 65 years and above was 1,156,031 as of September 2023 – this subset population is 16.53% of the entire Massachusetts population.

The population of both Massachusetts and the Applicant's PSA that is aged 65 and older helps demonstrate the need for local PET/CT imaging services. Additionally, statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035.³¹ 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

²⁹ FDG PET scans involve a specialized sugar that shows up on PET scans. This sugar is injected into your body. And since most tumors will take up more of it, it allows the tumor to show up on the PET scan. Information is available online at: <https://anticancer360.com/what-is-a-fdg-pet-scan-and-why-does-it-matter/>

³⁰ Analytics were derived in January of 2024.

³¹ Online at: http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf

greater share of the population than others. Specifically, within the next 15-20 years, the largest part of the Commonwealth's population growth will be attributable to residents within the 50+ age cohort, and residents who are 65+ will represent 21% of the Massachusetts population.³²

The Applicant's PSA is defined by cities and towns representing approximately a third of the patients currently served by Atrius Health. Please see Table 9 below for the number of residents aged 65 and older as of September 2023.

Table 9: Residents Aged 65 and Older

Town/City ³³	Number of Residents Aged 65 and older ³⁴
Arlington	7,385
Boston	79,459
Braintree	6,341
Brockton	13,942
Cambridge	13,218
Dedham	4,957
Dorchester ³⁵	11,879
Lowell	13,040
Medford	9,017
Norwood	5,032
Peabody	12,408
Plymouth	14,069
Quincy	16,878
Somerville	7,491
Watertown	6,129

Assuming the demographic trends within the Applicant's patient population continue to mirror that of the state, it is expected that the Applicant's PSA will continue to see growth in the 65+ age cohort that it serves. As the Applicant's patients age into the 65+ age cohort, the need for imaging services, such as PET/CT, becomes more important for detecting, managing, and treating age-related conditions,³⁶ as discussed in further detail below.

To ensure that the Applicant's aging patient panel has access to high-quality PET/CT services with proven effectiveness in the fields of oncology, cardiology, and neurology³⁷ the Applicant seeks to establish a licensed IDTF satellite clinic to provide PET/CT imaging services at the Shields Dedham location.

³² Online at: <https://www.mass.gov/files/documents/2016/07/wb/healthy-aging-data-report.pdf>

³³ Alphabetically ordered.

³⁴ As per the U.S. Census Bureau's American Community Survey – September 2023.

³⁵ Dorchester is the largest neighborhood in Boston – this number is included in the Boston total.

³⁶ 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>

³⁷ The Cleveland Clinic. PET Scan. Online at: <https://my.clevelandclinic.org/health/diagnostics/10123-pet-scan>

- iii. Disease burden trends and the increased number of patients, especially older patients, with underlying age-related oncologic, cardiac, and neurologic conditions support the need for PET/CT imaging services.

As the population expands, over the period from 2000 to 2050, the number and percentage of Americans over age 65 is expected to double.³⁸ This population expansion will be accompanied by a marked increase in patients requiring care for disorders with high prevalence in the elderly.³⁹

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 and 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 neurologic concerns.

Oncologic Conditions and the Need for PET/CT

Research studies and their findings demonstrate that the prevalence of cancer increases with age.⁴² Persons over 65 account for 60 percent of newly diagnosed malignancies and 70 percent of all cancer deaths.⁴³ 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, the 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.

Cancer incidence nationwide is on the rise for many common cancers. In 2024, the American Cancer Society is expecting to hit a bleak milestone – for the first time, new cases of cancer in the US are expected to cross the 2-million mark, which is nearly 5,500

³⁸ 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/>

³⁹ *Ibid.*

⁴⁰ Guy Frijia, 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 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>

⁴³ 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. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500929/>

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://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500929/>

⁴⁵ *Ibid.*

cancer diagnoses a day.⁴⁶ In 2024, over 611,000 deaths from cancer are projected for the US.⁴⁷ That's more than 1,600 deaths from cancer each day.⁴⁸

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*.⁴⁹ 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.⁵⁰

According to the American Cancer Society, the estimated number of new cancer cases in Massachusetts is projected to be 44,040 (all sites) and the estimated number of deaths is projected to be 12,410.⁵¹ The Cancer Incidence Statewide Reports show that Breast cancer was the leading cancer among Massachusetts females between 2015 and 2019, followed by lung and bronchus, corpus uteri & uterus, colon and rectum, and thyroid cancers.⁵² Among males, prostate cancer was the leading cancer, followed by lung and bronchus, colon and rectum, urinary bladder, and melanoma cancers.⁵³

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

Cardiac 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.⁵⁴ Heart disease⁵⁵ 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.⁵⁶ That trend is likely to continue for years to come as the long-

⁴⁶ Sonya Collins. 2024—First Year the US Expects More than 2M New Cases of Cancer. January 17, 2024. Available online at: <https://www.cancer.org/research/acs-research-news/facts-and-figures-2024.html>

⁴⁷ *Ibid.*

⁴⁸ *Ibid.*

⁴⁹ 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>

⁵⁰ *Ibid.*

⁵¹ Information available online at: <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2024-cancer-facts-figures.html>

⁵² Data available online at: <https://www.mass.gov/lists/cancer-incidence-statewide-reports#2015-2019->

⁵³ Data available online at: <https://www.mass.gov/lists/cancer-incidence-statewide-reports#2015-2019->

⁵⁴ 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/>

⁵⁵ Stroke is also included in this statistic.

⁵⁶ 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>

term impact of the novel coronavirus will directly affect cardiovascular health, according to the American Heart Association.⁵⁷

According to the 2022 results from the Massachusetts Behavioral Risk Factor Surveillance System, statewide, 11.8% of Massachusetts adults were diagnosed with myocardial infarction, and 12.8% were diagnosed with angina or coronary heart disease annually.⁵⁸ Moreover, according to Massachusetts' Population Health Information Tool (PHIT) dataset, 11,954 people died of heart disease in Massachusetts in 2021. This data makes heart disease the second leading cause of death in the Commonwealth.⁵⁹

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

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 60.⁶⁰ Moreover, the incidence rate of Alzheimer's also increases with age.⁶¹ Millions of Americans have Alzheimer's or other dementias.⁶² 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 the coming years, as the population of Americans aged 65 and older is projected to grow from 55 million in 2019 to 88 million by 2050.⁶³

The baby boom generation has already begun to reach age 65 and older, which is the age range of greatest risk of Alzheimer's dementia. The oldest members of the baby boom generation turned age 73 in 2019 and by 2030, all Baby Boomers will be aged 65 or older.⁶⁴

The impact of Alzheimer's is projected to rise, and the most recent data show that 130,000 people aged 65 and older are living with Alzheimer's in Massachusetts.⁶⁵ Furthermore, 9.3% of people aged 45 and older have subjective cognitive decline.⁶⁶

⁵⁷ *Ibid.*

⁵⁸ Available for download online at: <https://www.mass.gov/behavioral-risk-factor-surveillance>

⁵⁹ Data available online at: https://www.cdc.gov/nchs/pressroom/sosmap/heart_disease_mortality/heart_disease.htm

⁶⁰ 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/>

⁶¹ 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>

⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ Online at: <https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html>

⁶⁵ 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.>

⁶⁶ *Ibid.*

According to the Alzheimer's Impact Movement ("AIM"), an estimated 150,000 people aged 65 and older in Massachusetts will be suffering the same diagnosis by 2025.⁶⁷

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 regarding their care and support needs and financial and legal matters.⁶⁸ Early diagnosis also helps them and their families to receive practical information, advice, and guidance as they face new challenges.⁶⁹

According to a report from the Department of Public Health entitled Massachusetts Deaths 2021,⁷⁰ Alzheimer's is rated sixth on the list of the top ten leading underlying causes of death in Massachusetts for people between the ages of 75-84 and is rated the seventh cause of death across all ages.⁷¹

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

As previously mentioned, the Proposed Project will serve as part-time clinical use as well as part-time use as the diagnostic imaging unit supporting several Alzheimer's clinical research trials, thus positively contributing to not just diagnosis, but also to the ever-growing collection of research data that will help inform trends in treatment and diseases progression, among other things.

F1.a.iii Competition:

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

The Applicant's Proposed Project will compete on the basis of price, total medical expenses ("TME"), provider costs, and other recognized measures of health care spending by providing access to PET/CT imaging capacity to meet projected demand.⁷² The Applicant's primary objectives with the Proposed Project are to increase access to high-quality, low-cost diagnostic imaging, accommodate future volume

⁶⁷ Facts 2020. State sheet. Massachusetts. Available at: www.alz.org

⁶⁸ Why early diagnosis of dementia is important. Available online at: <https://www.scie.org.uk/dementia/symptoms/diagnosis/early-diagnosis.asp>

⁶⁹ *Ibid.*

⁷⁰ Published in October 2023.

⁷¹ The report from the Department of Public Health entitled Massachusetts Deaths 2021 is issued pursuant to Section 2 of Chapter 111 of the Massachusetts General Laws.

⁷² The cost of a PET/CT scan will vary greatly between inpatient and outpatient facilities. The national average cost for the procedure at inpatient facilities is \$7,275, while the same procedure at outpatient facilities averaged \$2,550. Available online at: <https://www.newchoicehealth.com/pet-scan/cost#:~:text=outpatient%20facility%20cost%20differences,at%20outpatient%20facilities%20averaged%20%242%2C550>

demands, and perform diagnostic imaging to support Alzheimer's clinical research trials through the operation of a PET-CT unit at an existing Shields facility in Dedham.

As noted in Factor F1.a.ii, the projected volume needs for PET/CT imaging and other indicators demonstrate a need for PET/CT services. Providing access to care has been documented to reduce health care utilization and spending.⁷³ Studies have detailed high costs for unnecessary repeat imaging⁷⁴ which could be improved through more appropriate use of all imaging, including PET/CT, and better integration of services. For the Proposed Project, reducing unnecessary expenditures related to inefficiencies from lack of service integration⁷⁵ can lead to lower operational overhead and lower health care 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 PET/CT imaging services cost less.⁷⁶ The clinic will be operationally 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 the cost of providing care, allowing Shields to operate efficiently and effectively under the lower, IDTF rates. A pricing comparison conducted by Health care Financial Management Solutions ("HFMA") found that average hospital prices were up to 208 percent higher in the field of nuclear medicine⁷⁷ than the average prices at free-standing imaging centers.⁷⁸ The lower IDTF rates offer payers the opportunity to require lower patient cost-sharing and the opportunity for lower TME overall, thus also improving access to high-quality care.

Furthermore, many national insurers have implemented site-of-care reviews for diagnostic imaging.⁷⁹ Payers like United Health Care, Cigna, and Anthem/BCBS have all implemented these policies as an attempt to push patients to lower-cost sites of care for imaging. If a procedure is to be performed at an IDTF, a site of care review will not occur (and therefore no additional charges will be incurred). The review will only occur (and be billed) if the procedure is performed in a hospital-based setting.

⁷³ 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>

⁷⁴ 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/>

⁷⁵ 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

⁷⁶ Health care Appraisers, 2020 Outlook: Diagnostic Imaging Centers and Radiology Practices. July 21, 2020. Online at: <https://healthcareappraisers.com/2020-outlook-diagnostic-imaging-and-radiology-practices/>

⁷⁷ Positron emission tomography, also called PET imaging or a PET scan, is a type of nuclear medicine imaging. Available online at <https://www.radiologyinfo.org/en/info/pet>

⁷⁸ Identifying the Gap Between Hospital and Free-standing Prices, Jamie Cleverly, February 14, 2017, HFMA. Available online at: <https://www.hfma.org/payment-reimbursement-and-managed-care/pricing/52656/>

⁷⁹ Links to site of care policies: [United Health care 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](#)

Finally, there is evidence that research can help cut the cost of medical care.⁸⁰ PET/CT has shown important promise for reducing the cost of cancer management by improving the accuracy of both diagnosis and staging, thereby helping to avoid expensive, futile treatments⁸¹ and associated side effects.⁸² PET/CT also has the potential to reduce the cost burden over time to the health care system by identifying the most appropriate treatment,⁸³ earlier in the disease process.

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.

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

The use of computed tomography (CT) in conjunction with PET is a remarkable technical improvement for this imaging modality.⁸⁴ Combined PET/CT scans help clinicians pinpoint abnormal metabolic activity and provide more accurate diagnoses than the two scans performed separately.⁸⁵ A PET scan measures important body functions, such as metabolism.⁸⁶ It helps doctors evaluate how well organs and tissues are functioning.⁸⁷ CT imaging uses special X-ray equipment and in some cases a contrast material, to produce multiple images of the inside of the body.⁸⁸ A radiologist views and interprets these images on a computer monitor. CT imaging provides excellent anatomic information.⁸⁹

The main applications of PET/CT have been in the oncologic, cardiac, and neurologic domains where the combined technique has allowed improved all-in-one imaging protocols that have been proven beneficial.⁹⁰

⁸⁰ Warwick Anderson, "With the right kind of research, we can reduce health-care costs." *The Conversation*. July 28, 2014. Available online at: <https://theconversation.com/with-the-right-kind-of-research-we-can-reduce-health-care-costs-28898>

⁸¹ Such as curative intent surgery and radiation therapy in patients demonstrated by PET to have advanced disease.

⁸² Fischer BM, Siegel BA, Weber WA, von Bremen K, Beyer T, Kalemis A. PET/CT is a cost-effective tool against cancer: synergy supersedes singularity. *Eur J Nucl Med Mol Imaging*. 2016 Sep;43(10):1749-52. doi: 10.1007/s00259-016-3414-5. Epub 2016 May 13. PMID: 27178271; PMCID: PMC4969342. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969342/>

⁸³ *Ibid.*

⁸⁴ 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. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3692287/>

⁸⁵ Available at RadiologyInfo.org for patients. Online at: <https://www.radiologyinfo.org/en/info/pet>

⁸⁶ *Ibid.*

⁸⁷ *Ibid.*

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ Lövlblad, 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>. 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.

The results of a significant Danish study⁹¹ published in the Journal of Nuclear Medicine revealed that the implementation of PET/CT as the *first-line imaging modality instead of CT alone*, should be considered. The positive predictive value was 83 percent for PET/CT but only 54 percent for CT.⁹² 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.⁹³ This study strongly suggests that PET/CT can support patients receiving the proper diagnosis in less time, which allows clinicians to focus their energies on treatment and recovery.

Moreover, medical care delay⁹⁴ may well increase morbidity and mortality risk associated with treatable and preventable health conditions and might contribute to reported excess deaths, according to the Centers for Disease Control and Prevention (“CDC”).⁹⁵ Overall, an estimated 40.9 percent of U.S. adults have avoided medical care during the pandemic because of concerns about COVID-19, including 12 percent who avoided urgent or emergency care and 31.5 percent who avoided routine care.⁹⁶ Cancer screening is considered routine care for individuals starting as early as age 25.⁹⁷ Additionally, the CDC supports screening for breast, cervical, colorectal (colon), and lung cancers as recommended by the U.S. Preventive Services Task Force.⁹⁸

PET/CT as a modality also has the potential to increase a patient’s quality-adjusted life years (QALYs) and reduce the cost burden over time to the healthcare system by identifying the most appropriate treatment.⁹⁹

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

PET/CT as a Clinical Modality for Oncologic Conditions

Cancer studies have shown that early detection yields better outcomes for patients – and diagnostic imaging plays an essential role.¹⁰⁰ Studies have shown that PET/CT has become an

⁹¹ 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 Benzön, Morten Helms, Lars R. Mathiesen, Kim P. David, Gitte Kronborg, Andreas Kjaer. Journal of Nuclear Medicine Jul 2017, 58 (7) 1058-1064; DOI: 10.2967/jnumed.116.175380. Online at: <https://jnm.snmjournals.org/content/58/7/1058>

⁹² *Ibid.*

⁹³ *Ibid.*

⁹⁴ Or avoidance.

⁹⁵ 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>

⁹⁶ 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>

⁹⁷ 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>

⁹⁸ CDC website. Available online at: <https://www.cdc.gov/cancer/dccp/prevention/screening.htm>

⁹⁹ Fischer BM, Siegel BA, Weber WA, von Bremen K, Beyer T, Kalemis A. PET/CT is a cost-effective tool against cancer: synergy supersedes singularity. Eur J Nucl Med Mol Imaging. 2016 Sep;43(10):1749-52. doi: 10.1007/s00259-016-3414-5. Epub 2016 May 13. PMID: 27178271; PMCID: PMC4969342. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969342/>

¹⁰⁰ 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/>

established nuclear imaging modality that has proved especially useful in oncology.¹⁰¹ 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 percent to 15 percent improvement in the overall accuracy of staging/restaging and a 30 percent to 50 percent improvement in the confidence of lesion localization. PET/CT has become the standard of imaging care for many oncology patients.¹⁰²

PET/CT has brought groundbreaking changes in improving cancer care for patients. These include improved detection of previously unrecognizable disease, ability to identify oligometastatic status enabling more aggressive treatment strategies when the disease burden is lower, its use in better-defining treatment targets in radiotherapy, ability to monitor treatment responses early and thus improve the ability for early interventions of non-responding tumors, and as a prognosticating tool as well as outcome predicting tool.¹⁰³

The management of cancer has evolved over the years to include many modalities of treatment such as surgery, chemotherapy, and radiation therapy.¹⁰⁴ Proper management requires accurate diagnosis and evaluation of the spread of the tumor and the PET/CT scanner provides sophisticated imaging to assess the original tumor as well as metastatic disease.¹⁰⁵

PET/CT as a Clinical Modality for 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.¹⁰⁶ The ability of the heart to recover naturally from ischemic damage decreases with age and makes older patients more susceptible to injury.¹⁰⁷ Where traditional CT and PET scans have unique advantages in diagnosing coronary artery disease, a typical cause of ischemic heart disease, each has its downfalls and may result in missed diagnoses or unnecessary [and costly] invasive procedures. Combined PET/CT imaging remains the only technique that yields sufficient

¹⁰¹ "Clinical research has shown that in comparison to a PET scan alone, PET/CT technology provides new information that can alter a patient's treatment plan to better target the cancer in approximately one-third of the cases. In one example, the PET/CT scan of a lung cancer patient revealed not only the original tumor on the lung—which a previous CT scan had found—but an additional tumor the CT missed: a small, early stage lesion in the neck. Based on the CT alone, the doctor would have recommended surgery, but the additional tumor found by PET/CT indicated that the cancer had spread and was inoperable. Based on this information, the doctor proceeded with radiation therapy, giving the patient a better chance of survival." Case study reference from Sanford Health available online at: <https://stanfordhealth.care.org/medical-tests/p/pet-ct-scan/what-to-expect.html>

¹⁰² Griffith 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/>

¹⁰³ Vijayakumar S, Yang J, Nittala MR, Velazquez AE, Huddleston BL, Rognath NA, Adari N, Yajurvedi AK, Komanduri A, Yang CC, Duggar WN, Berlin WP, Duszak R, Vijayakumar V. Changing Role of PET/CT in Cancer Care With a Focus on Radiotherapy. *Cureus*. 2022 Dec 22;14(12):e32840. doi: 10.7759/cureus.32840. PMID: 36694538; PMCID: PMC9867792. Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9867792/>

¹⁰⁴ Stanford Medicine Health Care on the role of PET/CT scans in oncology. Online at: <https://stanfordhealth.care.org/medical-tests/p/pet-ct-scan/what-to-expect/pet-ct-scan-for-cancer.html>

¹⁰⁵ *Ibid*.

¹⁰⁶ 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/>

¹⁰⁷ 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/>

information in one procedure to quickly provide all the necessary information for a physician to make a timely and proper medical decision.¹⁰⁸

PET/CT provides a highly accurate assessment of obstructive coronary artery disease (“CAD”).¹⁰⁹ Importantly, noninvasive imaging plays a pivotal role in assessing coronary artery anatomy, myocardial perfusion, and ventricular function in patients with known or suspected cardiovascular diseases.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 assessments of 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 (an 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

¹⁰⁸ 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/>

¹⁰⁹ Ahmed I, Devulapally P. Nuclear Medicine PET Scan Cardiovascular Assessment, Protocols, and Interpretation. [Updated 2023 Jul 30]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK570631/>.

¹¹⁰ *Ibid*.

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/>

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

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/>

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

PET/CT as a Clinical Modality for Neurological Conditions

PET/CT has been shown to enhance a clinician's ability to diagnose and effectively treat neurological diseases. In neurology, PET/CT plays an important role in the evaluation of various epileptic syndromes as well as in the clinical assessment of patients with a multitude of other disorders, including cognitive impairment and dementias.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 has been proven as a superior scanning technique in oncological or cardiovascular disorders, but emerging research suggests that PET/CT could be an integral part of neuroradiological settings, such as vascular diseases such as carotid artery disease, which is a cause of stroke.¹²¹ 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.¹²²

PET/CT is a powerful functional modality that can differentiate dementia types and influence disease management.¹²³ Current imaging standards for dementia treatment include CT, PET/CT, MRI, or a combination of these imaging modalities to exclude masses and vascular lesions and identify and monitor disease and its severity. The addition of PET/CT scans in dementia cases can provide complementary data concerning cerebral glucose metabolism, which is a key indicator in

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.*

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

¹²² 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/>

¹²³ Katherine Zukotynski, Phillip H. Kuo, David Mikulis, Pedro Rosa-Neto, Antonio P. Strafella, Rathan M. Subramaniam, and Sandra E. American Journal of Roentgenology; Volume 211 | Issue 2 | August 2018. Available online at: <https://www.ajronline.org/doi/10.2214/AJR.18.19822>

the diagnosis and treatment of dementia.¹²⁴ Studies suggest that PET imaging is also 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.¹²⁵

PET/CT is used as a problem-solving tool, most commonly with the radiotracer 18F-FDG, a radioactive glucose analog.¹²⁶ Dementia is characterized by loss of neuronal metabolism, often in specific regions of the brain, and is detected by specific topographic patterns of decreased 18F-FDG uptake.¹²⁷ Studies have shown that metabolic changes in signature regions of the brain can be detected with 18F-FDG PET/CT *before* anatomic changes are visible on MRI.¹²⁸

Overall, PET/CT has proven to be a highly effective diagnostic tool; evidence that that provides a solid argument for the addition of this imaging modality in this service area.

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

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

A. Improving Health Outcomes and Quality of Life

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

Studies indicate that *delayed access* to health care services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.¹²⁹ Conversely, *ease of access* improves the quality of life for patients because early detection and treatment of diseases improves patient outcomes.¹³⁰ Satisfied patients are more likely to be compliant with their medical care plan, ultimately leading to improved outcomes and more efficient utilization of health care resources.¹³¹

¹²⁴ 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>

¹²⁵ 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/>

¹²⁶ Zukotynski K, Kuo PH, Mikulis D, Rosa-Neto P, Strafella AP, Subramaniam RM, Black SE. PET/CT of Dementia. AJR Am J Roentgenol. 2018 Aug;211(2):246-259. doi: 10.2214/AJR.18.19822. Epub 2018 Jun 27. PMID: 29949415. Available online at: <https://pubmed.ncbi.nlm.nih.gov/29949415/>

¹²⁷ *Ibid.*

¹²⁸ *Ibid.*

¹²⁹ 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/>

¹³⁰ 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>

¹³¹ 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 Health care Management. 2015;60(3):205-218. Online at: <https://pubmed.ncbi.nlm.nih.gov/26554265/>

The addition of PET/CT diagnostic imaging services in the town of Dedham via an IDTF mobile clinic at an existing and serviceable docking pad helps the Applicant to ensure timely access to optimized, low-cost, high-quality imaging services for the patient panel. In addition, as mentioned previously in this narrative, health research has high value to society¹³² and the diagnostic research completed in these trials will provide important information about Alzheimer's disease trends and risk factors.

Access to such diagnostic imaging services for these patients – particularly for patients who are sick or affected 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.¹³³

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.¹³⁴ 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.¹³⁵ In this case, transmission scans are not required because the CT data are used for attenuation correction.¹³⁶ It has been estimated that patient output has increased by approximately 40 percent.¹³⁷

Time savings (as demonstrated above) directly correlates to patient satisfaction, according to a 2017 Philips Research Report that surveyed patient responses to recent imaging procedures. The report found that 61 percent 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.¹³⁸

The fact that patients will be able to access PET/CT services in a timely, low-cost, and high-quality manner will enhance patient satisfaction, health outcomes, and quality of life. Patient satisfaction is an important indicator used for measuring quality in health care.¹³⁹

Moreover, given that Atrius MSO is a part owner of the Applicant, imaging services provided by the Applicant will be integrated with Atrius Health's Electronic Medical Records (“EMR”). Studies show that having access to integrated health information systems, including integrated picture archiving and communications systems (“PACS”) information has a direct impact on health outcomes, as access

¹³² Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule; Nass SJ, Levit LA, Gostin LO, editors. Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research. Washington (DC): National Academies Press (US); 2009. 3, The Value, Importance, and Oversight of Health Research. Available online at: <https://www.ncbi.nlm.nih.gov/books/NBK9571/>

¹³³ Online at: <https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html>

¹³⁴ 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/>

¹³⁵ *Ibid.*

¹³⁶ *Ibid.*

¹³⁷ *Ibid.*

¹³⁸ The Patient Experience in Imaging Study was conducted in the summer of 2017 by Kantar TNS, in the Netherlands per order of Philips. It was based on prior qualitative research conducted in April-May 2017. Available online at:

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

¹³⁹ Bhanu Prakash, Patient Satisfaction, 3 J. CUTANEOUS & AESTHETIC SURGERY 151 (2010), online at: <https://pubmed.ncbi.nlm.nih.gov/21430827/>

to a single medical record for patients helps facilitate enhanced care coordination by care teams and improved efficiency with respect to workflows.¹⁴⁰

Poor coordination of care has negative consequences for patients and contributes to higher medical costs.¹⁴¹ An integrated EMR 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 patients will facilitate quick and easy access to patient images and reports, which will in turn affect 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 as projections for quality indicators that will measure patient satisfaction, access, and quality of care.¹⁴² The measures are discussed below:

1. Patient Satisfaction: Patients who 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, the baseline will be established following one full year of operation.

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

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

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

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

¹⁴⁰ 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>

¹⁴¹ 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/>

¹⁴² Shields is now using a platform called Podium – a text-based program for patient experience.

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, document 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 assess the impact on care for patients. The Applicant will survey referring physicians to validate scan utility.

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

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

Monitoring: PET/CT referral physician population will be queried to validate scan utility via 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 for all populations, including those deemed underserved, the Proposed Project will not adversely affect the accessibility of services for poor, medically indigent, and/or Medicaid-eligible individuals. The Applicant will not discriminate based on the 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 a community setting.

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 survey¹⁴³ 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 worsened. Health care costs top the list of expenses that people report difficulty affording.¹⁴⁴ 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.¹⁴⁵

The Applicant will not discriminate based on the 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 will also provide financial counselors for assistance in understanding insurance benefits.

The Proposed Project will improve affordability for lower-income residents by offering imaging services at a lower cost than hospital-based imaging, which will reduce out-of-pocket expenses for patients with cost-sharing obligations for these services and it will help address inequities in access and cost of care.

The population within the service area of the Proposed Project reflects moderate diversity that necessitates the 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 plan to implement a robust translation services program.

The Applicant respects and honors the cultural differences among its patient panel and staff. The Atrius Health, Health Equity Steering Committee is charged with monitoring health disparities and establishing plans to reduce inequities, improving equitable access to services for all Atrius Health’s patients. The scope of the Health Equity Steering Committee is broad and includes ancillary and imaging services, including those imaging services to be provided under the Proposed Project.

The Applicant is sensitive to matters regarding diversity, equity, and inclusion (“DEI”) and offers ongoing education and training of staff in culturally and linguistically appropriate care, along with several tools to accommodate patients’ needs and preferences. The Applicant will offer multiple tools to address language

¹⁴³ 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/>

¹⁴⁴ *Ibid.*

¹⁴⁵ Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIEiwAiY-yMHCMEtjEV0at0isHbWkZwKZyWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE

barriers, including Language Line¹⁴⁶ and InDemand interpreting to provide multiple options for translation services.¹⁴⁷ 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 allow clinicians to provide their limited English proficient, deaf, and hard-of-hearing patients with access to the highest quality health care. Together, these solutions will eliminate language barriers for patients and ensure culturally appropriate care.

Imaging services provided by the Applicant will be integrated with Atrius Health's EMR. Utilizing the patients' medical records and appropriate, pertinent prior imaging, can, in some cases, enable patients to forgo incidental follow-up diagnostic imaging studies, which allows patients to avoid the incremental costs and the inconvenience associated with subsequent imaging.¹⁴⁸ According to research from Tine Health, many patients report that there are significant logistical challenges associated with any type of doctor's appointment due to problems taking time off work, childcare, cost, and not having transportation to and from their appointments.¹⁴⁹

The Proposed Project will provide the opportunity for patients to receive the highest quality imaging at an existing location in Dedham that is nearby to public transportation services.¹⁵⁰ Being located near public transportation helps prevent barriers to health care (and in this case, diagnostic imaging.)¹⁵¹ Transportation barriers are often cited as barriers to health care access, and they often lead to delayed care and missed or delayed medication use, among other things.¹⁵² These consequences may lead to poorer management of chronic illness and ultimately poorer health outcomes.¹⁵³ In cases where a patient cannot use public transportation or a personal mode of transport, the Applicant provides transportation assistance via ride-share and cab vouchers.

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, PET/CT services in the community setting. This delivery model is made possible through operational discipline and focus that cannot be achieved under traditional hospital oversight. Dedicated focus by the Shields management

¹⁴⁶ Language Line Solutions phone interpreting may also be used in the event the In Demand system is not functioning properly.

¹⁴⁷ 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.

¹⁴⁸ Atrius Health has documented in its radiology e-consult program that nearly 50 percent of follow-up CTs and MRIs recommended by external imaging facilities can be canceled based on a more comprehensive review of the patient's medical record and prior imaging.

¹⁴⁹ Why Patients Miss Doctor Appointments & How to Decrease No-Shows. Available online at: <https://tinehealth.com/2018/01/18/why-patients-miss-doctor-appointments-how-to-decrease-no-shows/>

¹⁵⁰ 40 Allied Drive is a short walk from the Foxboro Event Service and the Franklin/Foxboro Line at the Dedham Corporate Center stop. The 34E Walpole Center – Forest Hills Bus Station is also walking distance from the Shields MRI Dedham.

¹⁵¹ "A relationship between travelling further and having worse health outcomes cannot be ruled out and should be considered within the health care services location debate." Kelly C, Hulme C, Farragher T, Clarke G. Are differences in travel time or distance to health care 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/>

¹⁵² 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/>

¹⁵³ *Ibid*.

team offers insight into 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. In addition, the interpretation of the PET/CT imaging is conducted internally by the Applicant. Shields radiologists have access to Atrius Health's EMR system thus enabling seamless, real-time documentation and continuity of care.

The response to Factor F1.b.iii above describes the expected quality of life improvements resulting from the Proposed Project. The response to F1.b.iii summarizes the Applicant's approach to health equity, culturally and linguistically appropriate care, mitigation of cost, and reduction in wasteful incidental follow-up imaging. These factors contribute to the patient's ability to take less time off from work, the opportunity to conserve child and elder care expenses, and the capacity to either eliminate or mitigate travel time and expenses – all of which are benefits associated with the fewer conducted studies. Also, Atrius Health's, Health Equity Steering Committee oversees all of Atrius Health's services, including those imaging services to be provided under the Proposed Project.

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 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 Atrius Health's 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.

According to an article published in Cureus¹⁵⁴ last year regarding the role of Social Determinants of Health¹⁵⁵ ("SDoH") in promoting health equity, most reports show that SDoH has a more impactful effect on health than other factors.¹⁵⁶ The Applicant plans to conduct a pre-screening process for all scheduled patients. Certain questions in the pre-screen relate to certain SDoH issues, namely those issues that are relevant to an imaging appointment such as transportation.¹⁵⁷ 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.

¹⁵⁴ Cureus is an Open Access medical journal for a new generation of doctors, researchers and patients. Available online at: <https://www.cureus.com/about>

¹⁵⁵ Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. Definition available online at: <https://health.gov/healthypeople/priority-areas/social-determinants-health>

¹⁵⁶ Chelak K, Chakole S. The Role of Social Determinants of Health in Promoting Health Equality: A Narrative Review. Cureus. 2023 Jan 5;15(1):e33425. doi: 10.7759/cureus.33425. PMID: 36751221; PMCID: PMC9899154. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9899154/>

¹⁵⁷ Access to transportation is one of the most important social determinants of health (SDOH), according to the CDC.

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

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

- Dennis Renaud, Program Director Determination of Need Program
- Rebecca Kaye, Esq., Senior Deputy General Counsel
- Jennica F. Allen Community Health Planning and Engagement Specialist, Department of Public Health
- Katelyn Teague, Community Health Planning and Engagement Specialist, Bureau of Community Health and Prevention

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

The Applicant identified the need to provide high-quality, cost-effective PET/CT services for the Applicant's patients within the service area. 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 Atrius Health's Patient Family Advisory Committee ("PFAC") on February 5, 2024. 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 Atrius Health 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 the implications for patients. The presenter explained that 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 Atrius Health's oncology program offered at its Dedham location.¹⁵⁸ The service will operate on an outpatient, IDTF fee schedule which will lower the cost of services.

The PFAC members had generally positive reactions to the presentation of the Proposed Project and did not voice any significant concerns. Participants were engaged throughout the presentation and made several comments that generally focused on the benefit of increased access, cost clarification with respect to the fee schedule, and the comfort and aesthetics of the physical space inside the mobile unit. Participants inquired about the possibility of expanding the number of days per week that the PET/CT

¹⁵⁸ Location information available online at: <https://www.atriushealth.org/locations/dedham>

would be available and remarked that they would support additional PET/CT projects, given the benefits of the technology. The PFAC members unanimously agreed that the proposed location of the PET/CT would be conveniently located and easy to access via the highway and public transportation.

Additionally, a virtual Zoom community meeting was advertised for January 24, 2024. Community event flyers were sent to one hundred (100) randomly selected Atrius Health adult patients who have a PCP in a Dedham or a Norwood practice¹⁵⁹ and Shields emailed event flyers to fifty (50) randomly selected patients who previously received care at its Dedham location. There were no individuals in attendance on the evening of the event.

To ensure appropriate awareness within the community about the Proposed Project, both the community Zoom meeting invitation¹⁶⁰ and the legal notice associated with the Proposed Project were published on the Shields website.¹⁶¹ This was done to bring awareness of the Proposed Project to all patients, family members, residents, and resident groups. It also provides an opportunity for public comment on the Proposed Project.

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

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

- Invitation to a Virtual Community Zoom meeting on January 24, 2024¹⁶²
- Presentation to Atrius Health's PFAC on February 5, 2024

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.

¹⁵⁹ A copy of the flyer is included herein with this submission.

¹⁶⁰ Published on the Shields website at: <https://shields.com/location/shields-mri-dedham/>

¹⁶¹ Published on the Shields website at: <https://shields.com/location/shields-mri-dedham/>

¹⁶² For detailed information regarding these activities, please see attached exhibit.

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, yet high-quality diagnostic imaging option for patients in the service area.

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.¹⁶³ The Proposed Project meets the goal of providing a lower-cost alternative for PET/CT imaging services, as services will be provided by an IDTF, rather than a hospital-based outpatient clinic. IDTFs are a more cost-effective option as the administrative costs for these types of providers are lower.¹⁶⁴ This difference will allow the Applicant to provide cost-effective, high-quality imaging services to the Applicant's patients while having a negligible impact on the overall health care 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.¹⁶⁵ If patients undergo both examinations in one session, in addition to having more accurate results, costs will be lower.¹⁶⁶

Providing patients with accessible, low-cost, high-quality PET/CT imaging services and helping ensure that all patients receive essential care promptly, is another way to promote cost containment goals. Reducing diagnostic and treatment delays limits the deterioration of health and lowers costs by reducing the resources required for care.¹⁶⁷ Offering PET/CT imaging services in a location that is proximate to Atrius Health's Dedham site,¹⁶⁸ helps promote faster diagnosis, intervention, and treatment and can contribute to improving health care quality, thereby reducing the overall costs of health care.

Research can also help cut the cost of medical care.¹⁶⁹ PET/CT has shown important promise for reducing the cost of cancer management by improving the accuracy of both diagnosis and staging, thereby helping to avoid expensive, futile treatments¹⁷⁰ and associated side effects.¹⁷¹ PET/CT also has the potential to reduce the cost burden over time to the health care system by identifying the most appropriate treatment,¹⁷² earlier in the disease process.

F2.b Public Health Outcomes:

¹⁶³ 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/>

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

¹⁶⁵ 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/>

¹⁶⁶ *Ibid.*

¹⁶⁷ 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>

¹⁶⁸ Atrius Health has a site located at 1 Lyons Street, Dedham.

¹⁶⁹ Warwick Anderson, "With the right kind of research, we can reduce health-care costs." The Conversation. July 28, 2014. Available online at: <https://theconversation.com/with-the-right-kind-of-research-we-can-reduce-health-care-costs-28898>

¹⁷⁰ Such as curative intent surgery and radiation therapy in patients demonstrated by PET to have advanced disease.

¹⁷¹ Fischer BM, Siegel BA, Weber WA, von Bremen K, Beyer T, Kalemis A. PET/CT is a cost-effective tool against cancer: synergy supersedes singularity. Eur J Nucl Med Mol Imaging. 2016 Sep;43(10):1749-52. doi: 10.1007/s00259-016-3414-5. Epub 2016 May 13. PMID: 27178271; PMCID: PMC4969342. Available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969342/>

¹⁷² *Ibid.*

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

Providing needed care more efficiently and effectively will improve public health outcomes and patient experience. As is outlined in detail throughout this narrative, PET/CT imaging is a powerful modality that allows clinicians to better understand the disease process and make treatment decisions. If the Proposed Project is approved, the patient panel will enjoy access to 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, geriatric patients use 50 percent more lab/imaging services than younger populations.¹⁷³

PET/CT services managed under the Shields operating platform, supported by Atrius Health's EMR system will provide access to patients residing within the service area. Increasing demand as outlined in Factor 1 will be met with greater access to the highest quality diagnostic imaging. Creating streamlined pathways for access to high-value care will improve overall public health outcomes.

F2.c Delivery System Transformation:

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

The Proposed Project will provide access to high-value, low-cost PET/CT imaging services to the community served within the Applicant's service area. In instances where patients need support to address SDoH,¹⁷⁴ 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.

The Applicant's enhanced service offerings are not limited to staffing and programmatic functionality – care has also been taken concerning the physical space where the PET/CT services will be offered.

¹⁷³ 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

¹⁷⁴ Atrius Health partners with its patients to support care for the entire family across the spectrum of the care they provide. Most of Atrius Health's practice sites have a care facilitator on staff who can connect patients with community-based resources. They also have community health workers, nurse case managers, and social workers on staff who can assist patients with their needs. Some examples of assistance that Atrius Health has provided for their patients include: coordinating multiple medical appointments to cut down on the number of trips a patient has to make to Atrius Health offices or the hospital; helping patients get on a waitlist for affordable housing; providing information on how and where to access food banks; assisting families in obtaining SNAP benefits (food stamps) or getting benefits reinstated if they've lost access; arranging transportation to and from medical appointments (if eligible); and helping with securing emergency shelter.

Research shows that a safe and well-designed clinical space helps to improve patient outcomes.¹⁷⁵ The Shields Dedham site complies with the Americans with Disabilities Act (“ADA”) design standards. The building offers a patient-centered design, ample free parking, walking distance to both commuter rail as well as a bus stop, and extended hours. 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.

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

The Applicant seeks to offer PET/CT diagnostic imaging through a new joint venture partnership established between Atrius MSO and Shields. This project will use a combination of inside space and a mobile PET/CT unit aligned with the existing building one day per week. The Proposed Project would address the need for access to PET/CT diagnostic imaging and facilitate imaging to support Alzheimer’s clinical trial research. Diagnostic services will be reimbursed as an IDTF to enhance the efficiency and effectiveness of care delivery.

B. Quality

Providing PET/CT imaging capability for cancer staging, cardiac applications, and Alzheimer’s disease evaluation (amongst other things) to the Applicant’s patient panel will allow for additional access to the highest quality diagnostic imaging services with the added benefit that patients will be receiving care at a convenient, existing location, and services will be rendered at a competitive IDTF price point.

Care provided at Shields’ operated imaging centers is 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.

¹⁷⁵ 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>

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 Project will use a combination of inside space and a mobile PET/CT unit aligned within the existing building located at Shields MRI Dedham. There are only \$25,000 capital asset acquisitions at the commencement of the project.¹⁷⁶ There are no capital expenditures expected in the out years.¹⁷⁷

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) CAGR¹⁷⁸ for Years 2 through 6 is 8.7%. Year 1 was not included in the CAGR calculation.¹⁷⁹ These expenses for the Proposed Project in Year 6 are projected to be \$106,746.¹⁸⁰

F. Alternative Option for the Project**a. Option 1****i. Alternative Proposal**

The Applicant considered not establishing a vendor partnership to create a new PET/CT imaging option in the service area. In this scenario, patients would not be able to access the benefits of access to PET/CT diagnostic imaging services conveniently located at an existing facility in Dedham. This alternative option would also prevent patient participation in PET/CT imaging to support Alzheimer's clinical trial research.

ii. Alternative Quality

This alternative is not sufficient to meet the combined patient panel's need for accessible, low-cost, and high-quality PET/CT imaging in the community. The Proposed Project would allow those patients who meet the clinical protocols for combined PET/CT to receive the service at a convenient, pre-existing location, thus enhancing access for the patient panel.

It has been well-documented throughout this narrative, that access to diagnostic imaging services directly impacts health outcomes and quality of life. Diagnosis has important implications for patient care, research, and policy. Diagnostic technology is crucial to determine what treatments are most effective with patients' anatomy. Access to PET/CT services will allow clinicians to determine appropriate treatment options that will impact overall health outcomes in a time-

¹⁷⁶ Please see Veralon's Capital Expenditures findings in section III of the attached CPA report.

¹⁷⁷ *Ibid.*

¹⁷⁸ Compound Annual Growth Rate.

¹⁷⁹ 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").

¹⁸⁰ For reference, the operating expenses for Year 1 are calculated to be \$69,577. Please see CPA analysis for further content.

effective manner. Insufficient access may increase the risk of poor health outcomes and health disparities.¹⁸¹

Access to comprehensive, quality health care services is important for promoting and maintaining health, preventing and managing disease, reducing disability and premature death, decreasing health disparities, and achieving health equity.¹⁸² Important components of access include timeliness of care and accessibility of primary and preventive health care services, among other factors.¹⁸³

Timely access to care is important for ensuring desirable health outcomes, reducing the financial burden from seeking non-network care and possibly more distant healthcare, and improving patients' perception of need and experience with the healthcare system.¹⁸⁴ Expanding access to health services is an important step toward reducing health disparities.¹⁸⁵

Where access is so intricately linked with positive health outcomes and quality of life, *not* providing a PET/CT imaging service at this location does not make sense for the community or the patient panel within the service area.

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 create local a PET/CT service offering would deprive the patient panel of an important diagnostic imaging option and clinical trial tool for the community and the patient panel within the service area. 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

¹⁸¹ 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>

¹⁸² Access to Health Services Workgroup a program of the US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Information available online at: <https://health.gov/healthypeople/about/workgroups/access-health-services-workgroup#about>

¹⁸³ *Ibid.*

¹⁸⁴ 2021 National Healthcare Quality and Disparities Report [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2021 Dec. ACCESS TO HEALTHCARE AND DISPARITIES IN ACCESS. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK578537/>

¹⁸⁵ 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>

Taking no action to add a PET/CT diagnostic imaging service would not result in any significant near-term changes in operating costs.

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.