

STAFF REPORT TO THE COMMISSIONER FOR A DETERMINATION OF NEED	
Applicant Name	Shields and Atrius Health PET/CT at Dedham, LLC
Applicant Address	700 Congress Street, Suite 204, Quincy, MA 02169
Filing Date	April 12, 2024
Type of DoN Application	Required Equipment
Total Value	\$273,687.00
Project Number	N/A-24031814-RE
Ten Taxpayer Groups (TTG)	None
Community Health Initiative (CHI)	\$13,684.35 (Statewide Fund)
Staff Recommendation	Approval
Delegated	Commissioner Approval
<p style="text-align: center;"><b><u>Project Summary and Regulatory Review</u></b></p> <p>Shields and Atrius Health PET/CT at Dedham, LLC (Applicant) is filing a Determination of Need Application for the establishment of a part-time mobile positron emission tomography/ computed tomography diagnostic imaging service located at the existing Shields MRI Dedham clinic at 40 Allied Drive, Suite 112, Dedham, MA 02026, to operate one day per week. The Applicant is a newly formed joint venture between Atrius MSO and Shields Imaging Services, LLC. The total value of the Proposed Project is \$273,687.00; the Community Health Initiatives (CHI) contribution is \$13,684.35 to the Statewide fund.</p> <p>This DoN application falls within the definition of DoN-Required Equipment and Services, which are reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.</p>	

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## Background

The Applicant is a newly formed joint venture between Atrius MSO and Shields Imaging Services, LLC.

**Atrius MSO, LLC** 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 Imaging Services, LLC** (Shields) is an entity affiliated with Shields Health Care Group, Inc., which established Massachusetts' first independent regional MRI center in 1986 and has been dedicated to advanced care in a local setting for more than 50 years. 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.

### Proposed Project

Shields and Atrius Health PET/CT at Dedham, LLC (Applicant) seeks to establish a part-time mobile positron emission tomography/ computed tomography (PET/CT) diagnostic imaging service located at the existing Shields MRI Dedham clinic 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 in the Primary Service Area and 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.

### Patient Panel<sup>1</sup>

The Applicant is a newly formed joint venture and does not have its own Patient Panel. Consequently, the Applicant's proposed panel is based on patients of Atrius Health to demonstrate the need for the Proposed Project.<sup>2</sup> Staff determined that this is an acceptable way for the Applicant to define its Patient Panel.

The Patient Panel data for Calendar Years (CY) 2018-2023 are provided in Table 1 below.

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<sup>1</sup> As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder. (1) If the Applicant or Holder has no Patient Panel itself, the Patient Panel includes the Patient Panel of the health care facilities affiliated with the Applicant.

<sup>2</sup> The Applicant also provides data from Atrius Health's complete Patient Panel for additional context.

**Table 1: Atrius Health Patient Panel**

	CY2018	CY2019	CY2020	CY2021	CY2022	CY2023 <sup>3</sup>
Unique Patients	470,494	427,618	417,689	381,725	385,507	414,406

The Applicant provided demographic data for the Patient Panel, which is presented in Table 2. Staff notes the following observations about these data below:

- **Age:** Approximately 75% of the Patient Panel are between the ages of 19-64.
- **Race/ Ethnicity:** The majority of the Patient Panel identifies as White (~70%), followed by Asian at 9.5%, Black at 7.9%, and Hispanic at 5.5%.
- **Patient Origin:** The top 10 towns served by Atrius Health include Boston, Quincy, Cambridge, Plymouth, Somerville, Braintree, Medford, Lowell, Dedham, Norwood.
- **Payer Mix:** The majority of patients served have Commercial HMO (46%), followed by Commercial PPO/ Indemnity at 27%, and Medicare (~14%).

**Table 2: Atrius Health Patient Panel Demographics (CY2023)**

	Totals
<b>Total Patients</b>	414,406
<b>Gender</b>	
Female	57.8%
Male	42.2%
Total	100.0%
<b>Age</b>	
0-18	0.7%
19-64	74.3%
65+	25.0%
Total	100.0%
<b>Race/ Ethnicity</b>	
Caucasian	70.4%
Black	7.9%
Asian	9.3%
Hispanic	5.5%
Native American	0.2%
Native Hawaiian	0.1%
Other	0.4%
Patient Declined	2.5%
Unavailable	3.8%
Total	100.0%
<b>Patient Origin</b>	
Boston	4.40%
Quincy	3.50%

<sup>3</sup> Data presented is through the Third Quarter of 2023.

	<b>Totals</b>
Plymouth	2.90%
Cambridge	3.00%
Somerville	2.70%
Braintree	2.10%
Medford	1.90%
Lowell	1.70%
Dedham	1.40%
Norwood	1.30%
Middlesex County	17.0%
Norfolk County	14.5%
Plymouth County	6.8%
Suffolk County	6.3%
Essex County	4.2%
Bristol County	1.0%
Barnstable County	0.5%
All other patient origins	24.8%
Total	100.0%
<b>Payer Mix<sup>4</sup></b>	
Commercial HMO	46.0%
Commercial PPO/Indemnity	27.6%
Medicaid HMO	7.1%
Medicare	13.9%
Medicare MHO	4.4%
Other Government	0.6%
Self-Pay	0.4%
Total	100.0%

### Factor 1: a) Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently addressed Patient Panel need for the Proposed Project.

#### Patient Panel Need

The Applicant notes that Atrius Health does not currently have PET/CT services and attributes Patient Panel need for the Proposed Project to the following:

- a. Growth in the number of older patients
- b. Disease burden trends for Conditions requiring PET/CT
- c. Projected volume growth

<sup>4</sup> 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.

#### a. Growth in the Number of Older Patients

As previously demonstrated in Table 2, 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. Atrius Health has seen an increase in the age 65+ population of its Patient Panel from 2020-2023, as shown in Table 3

**Table 3: Atrius Unique Patients Aged 65+**

	2020	2021	2022	2023	% Change 2020-2023
<b>65+ Population</b>	97,087	92,230	93,909	103,442	6.5%

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 (CAGR<sup>5</sup> of +4.3%). The Applicant expects that its PSA will continue to see growth in the 65+ age cohort, a population for which the need for PET/CT imaging services becomes more important for detecting, managing, and treating age-related conditions,<sup>a</sup> as discussed in the next section.

#### b. Disease Burden Trends For Conditions Requiring PET/CT

As the population expands, the percentage of Americans over age 65 is expected to double from 2000 to 2050.<sup>b</sup> This population expansion will be accompanied by a marked increase in patients requiring care for disorders with high prevalence in the elderly.<sup>c</sup> In consideration of the aging population, the Applicant quotes research stating, "imaging strongly contributes to establishing accurate and timely diagnosis, informs and guides treatment decisions, and contributes to improving treatment outcomes."<sup>d</sup> 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,<sup>e</sup> which is essential to the Applicant's aging patients with oncologic, neurologic, and cardiac concerns.

- i) *Cancer*: Imaging in oncology is used for lesion detection, lesion characterization, staging of malignant lesions and assessment of the therapeutic response. The combined PET/CT images have the potential to guide biopsies of the most metabolically active regions of tumors and provide better maps of viable cancer than CT alone, for modulating the field and dose of radiation therapy.<sup>f</sup>
- ii) *Neurological Conditions*: As the size and proportion of the Massachusetts population age 65 and older continues to increase, the number of residents with Alzheimer's or other dementias will grow. In neurology, PET/CT plays an important role in the clinical assessment of dementias, cognitive impairments, and various epileptic syndromes. The PET/CT modality has become a valuable tool in the diagnosis, treatment evaluation and follow-up of patients

<sup>5</sup> 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>

with a variety of infections and inflammatory conditions and is already the “gold standard” for some neurological indications<sup>g</sup>.

- i) *Cardiovascular Disease*: Recently, there has been significant development in PET/CT for cardiovascular disease. It has become the preferred test for patients unable to complete a diagnostic-level exercise stress test imaging study, who have known cardiovascular disease, and who meet appropriate criteria for a stress-imaging test.<sup>h</sup>

The Applicant provided research on the prevalence of oncologic, cardiac, and neurologic conditions among an aging population, and the literature reviewed can be found in Appendix II. The theme among the literature for each of these conditions is that the likelihood of each condition increases after age 65, the age 65+ population is growing in Massachusetts, and the incidences of oncologic, cardiac, and neurologic conditions is growing with continued growth expected in Massachusetts. The Applicant asserts that this growth underlies the PSA’s need for a PET/CT for efficient and accurate assessment, clinical analysis, and treatment decisions.

### c. Projected Volume Growth

The Applicant evaluated the growing need for access to PET/CT services based on the historical growth of the 65+ population of Atrius’s Patient Panel, the projected growth of an aging population in the Primary Service Area, and the associated disease burden trends. Based on these indicators, Veralon Partners Inc. (Veralon) performed an analysis of the volume forecast prepared by Shields Health Care Group for the proposed joint venture partnership. The projected volume is shown in Table 4.

**Table 4: Projected PET/CT Volume Data Within the Primary Service Area**

	Baseline 2023	Year 1 2024	Year 2 2025	Year 3 2026	Year 4 2027	Year 5 2028
<b>Total Projected PET/CT Volume</b>	<b>664</b>	<b>764</b>	<b>856</b>	<b>958</b>	<b>1,054</b>	<b>1,160</b>

### **Analysis**

Staff concurs that the Proposed Project will increase needed access to PET/CT services for the Patient Panel. The proposed siting of PET/CT imaging is designed to ensure appropriate access for the Patient Panel based on the projected growth in patients needing PET/CT services among the Patient Panel. As a result of the growth in an aging population and the associated disease burden, the volume of PET/CT scans for the Atrius Patient Panel is projected to increase by approximately 67% from 2023 numbers over the 5 years post-project implementation. The aging population in the PSA further reinforces the need for access to imaging services to aid in the diagnosis and treatment of diseases that are more prevalent in advancing age cohorts. Through the Proposed Project, the Applicant will provide local access to imaging services for the Patient Panel. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1a.

### **Factor 1: b) Public Health Value, Improved Health Outcomes and Quality of Life; Assurances of Health Equity**

In this section staff will assess if the Proposed Project adds measurable public health value in terms of improved health outcomes and quality of life for the Applicant’s existing Patient Panel, while providing reasonable assurances of health equity.

### ***Public Health Value, Health Outcomes, and Quality of Life***

The Applicant states that the Proposed Project will provide closer access to imaging services, and this will promote better health outcomes and a more positive patient experience. The Applicant states that PET/CT services are not currently available at Atrius Health and patients in the PSA seeking diagnostic imaging must travel to disparate locations across Norfolk, Suffolk, and Middlesex counties.

The Applicant asserts that both PET and CT are well established technologies that enable clinicians to appropriately diagnose and develop the most effective treatment plans earlier in the disease process across oncologic, cardiac, and neurologic specialties. Combined PET/CT scans help clinicians pinpoint abnormal metabolic activity and provide more accurate diagnoses than the two scans performed separately.<sup>i</sup> The Applicant cites a wide variety of literature that can be found in Appendix II showing that PET-CT scans are integral to the diagnosis and treatment of oncologic, cardiac, and neurological conditions. Clinical research has been instrumental in showing that, compared to a PET scan alone, PET/CT technology provides new information that can alter a patient's treatment plan to better target disease.<sup>j</sup>

The Applicant cites studies indicating that delayed access to healthcare services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.<sup>k</sup> Conversely, ease of access improves quality of life for patients because early detection and treatment of diseases improves patient outcomes.<sup>l</sup> The Applicant notes that satisfied patients are more likely to comply with their medical care plan, ultimately leading to improved outcomes and more efficient utilization of healthcare resources.<sup>m</sup> 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.<sup>n</sup> The Applicant states that establishing PET/CT services will provide the Patient Panel with easy, convenient access to imaging services and help to avoid treatment delays.

In addition to using the mobile PET/CT unit for clinical purposes, the Applicant also plans to use the diagnostic imaging unit to support four Alzheimer's clinical research trials.<sup>6</sup> 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. The Applicant's participation as the diagnostic imaging partner across these clinical trials would allow for critical community research support around Alzheimer's disease.

### ***Analysis: Public Health Value, Health Outcomes, and Quality of Life***

Staff concurs that providing timely access to imaging services contributes to improved health outcomes and patient satisfaction. Advanced imaging can improve disease detection, allow for more accurate diagnosis and treatment, and avoid more invasive and costly procedures.<sup>o</sup> Not having adequate access to advanced imaging leads to delays in diagnosis and treatment, which could negatively affect health outcomes. Staff confirms that access to PET/CT services in the PSA will be a necessary component in diagnosing and treating the growing and aging population.

### **Health Equity and Social Determinants of Health (SDoH)**

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<sup>6</sup> 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.



The Applicant states that it plans to ensure health equity to all populations, including those deemed underserved, and that the Proposed Project will not adversely affect accessibility of the Applicant's services for poor, medically indigent, and/or Medicaid eligible individuals. The Applicant accepts all forms of insurance and asserts that it will not discriminate based on ability to pay or payer source. Shields has price transparency tools so that all patients have information on current pricing, and they provide financial counselors for assistance in understanding insurance benefits. The Proposed Project will promote health equity and ensure equal access to PET/CT services for all of the Applicant's patients by providing linguistically appropriate services through a variety of translation tools, imaging services close to public transportation, and the Atrius Health Equity Steering Committee will monitor health disparities and establish plans to reduce inequities, improving equitable access to services for all Atrius Health's patients.

#### ***Analysis: Health Equity and SDoH***

Staff review of the Proposed Project's impact on equitable access to care found that the Applicant will enable access for all patients regardless of patients' ability to pay and offer financial options as well as language interpreter services. The Applicant also has equity weaved into its administrative structure in an effort to advance equitable access. Staff finds that the Applicant has sufficiently outlined a case for improved health outcomes and health equity. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1b.

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

The Applicant states that the Proposed Project will support integrated care because it will combine a strong technology infrastructure and physician engagement to ensure continuity of care, improved health outcomes, and care efficiencies.

**Technology Infrastructure:** Imaging services provided by the Applicant will be integrated with Atrius Health's EMR. 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 compile 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.

**Physician Engagement:** Utilizing the patients' medical records and relevant prior imaging can enable patients to forego incidental follow-up diagnostic imaging studies. This allows patients to avoid the incremental costs and the inconvenience associated with subsequent imaging.<sup>7</sup> 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.<sup>8</sup> Reducing repeated visits improves the efficiency of the treatment process as well as improving the patient experience.

#### ***Analysis***

Staff finds that the Applicant's care coordination and use of technology infrastructure will contribute positively to efficiency, continuity, and coordination of care. Integrated health information technology

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<sup>7</sup> 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.

systems directly impact health outcomes through reducing fragmentation and improving coordination among care providers.<sup>q</sup> Similarly other studies show that integrated health information technology systems directly affect health outcomes, as access to a single, integrated health record, can reduce errors, improve patient safety, and support better patient outcomes.<sup>r</sup> As a result, Staff finds that the Proposed Project meets the requirements of Factor 1c.

### **Factor 1: d) Consultation**

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1d.

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

The Department's Guideline<sup>8</sup> for community engagement defines "community" as the Patient Panel and requires that, at minimum, the Applicant must "consult" with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."<sup>9</sup>

The Applicant presented the Proposed Project presented to Atrius Health's Patient Family Advisory Council (PFAC) in February 2024 and also held a Community Meeting via Zoom in January 2024. The presentation covered the Applicant's proposed plans, and how the Proposed Project will benefit the Patient Panel. Following the presentation, attendees were able to share feedback and ask the presenters questions. Discussion 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 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.

### **Analysis**

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the required community engagement standard of Consult in the planning phase of the Proposed Project. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1e.

### **Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending**

The Applicant asserts that the Proposed Project will compete on the basis of competition in the Massachusetts healthcare market based on price, TME, provider costs, or other recognized measures of healthcare spending based on the following:

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<sup>8</sup> [Community Engagement Standards for Community Health Planning Guideline.](#)

<sup>9</sup> [DoN Regulation 100.210 \(A\)\(1\)\(e\).](#)

- The clinic will provide conveniently located PET/CT access that has previously been out of network for the Patient Panel in this area.
- The clinic will operate as an IDTF, which is reimbursed at lower rates than hospital-based imaging.<sup>s</sup>
- Shields' operating model allows for improved scheduling, workflow, technology, and customer service, which the Applicant asserts will have a positive impact on the cost to provide care.

The Applicant notes research suggesting that providing ease of access to care can reduce healthcare utilization and spending.<sup>t</sup> The Applicant further states that studies have detailed high costs for unnecessary repeat imaging<sup>u</sup> which could be improved through more appropriate use of all imaging, including PET/CT, and better integration of services. For the Proposed Project, the Applicant states that preventing overuse and improving service integration can lead to lower operational overhead and lower healthcare spending, which could, in turn, reduce TME.

### ***Analysis***

Staff notes that the Proposed Project has the potential to reduce costs by providing imaging services at lower costs compared to hospital-based imaging services. While advanced imaging improves clinical care, it is also the source of overuse and added healthcare costs.<sup>v</sup> The Applicant has proposed internal protocols to assess and address appropriate use of imaging and minimize overuse and tracked through the Outcome Measures in Appendix I. Staff finds that, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending have been met. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1f.

## **Summary, FACTOR 1**

As a result of the information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project meets Factor 1. The Applicant proposed specific outcome and process measures to track the impact of the Proposed Project which Staff has reviewed, and which will become a part of the reporting requirements.

## **Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation**

For Factor 2, the Applicant must demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation beyond the Patient Panel.

### **Cost Containment**

The Applicant states that the Proposed Project seeks to align with the Commonwealth's goals for cost containment by reducing repeat scans and performing the imaging in a lower cost IDTF environment, as described in Factor 1f. Reducing diagnostic and treatment delays limits the deterioration of health and lowers costs by reducing the resources required for care.<sup>w</sup> Offering PET/CT imaging services in a location that is proximate to Atrius Health's Dedham site<sup>10</sup> helps promote faster diagnosis,

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<sup>10</sup> Atrius Health has a site located at 1 Lyons Street, Dedham.

intervention, and treatment and can contribute to improving health care quality, thereby reducing the overall costs of health care.

As previously described, the addition of a mobile PET/CT will be used in part to support research studies. Research has been shown to help cut the cost of medical care.<sup>x</sup> 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 treatments<sup>11</sup> and associated side effects.<sup>y</sup> PET/CT also has the potential to reduce the cost burden over time to the health care system by identifying the most appropriate treatment,<sup>z</sup> earlier in the disease process. The Applicant states that the Proposed Project will help promote faster diagnosis, intervention, and treatment for their Patient Panel, which supports improving quality of care and thus reducing overall health care costs.

### ***Analysis: Cost Containment***

Staff finds that the Applicant has adequately explained how it aligns with the Commonwealth's cost containment goals through the expansion of high-quality, low-cost imaging services provided locally. The Proposed Project seeks to provide continued access to imaging services within a lower-cost reimbursement setting and improve the quality of such services. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the cost containment component of Factor 2.

### **Improved Public Health Outcomes**

The Applicant asserts that access to PET/CT services will allow clinicians to determine appropriate treatment options that will impact overall health outcomes in a time effective manner. As detailed in several other sections of the Staff Report, the Proposed Project will provide the Patient Panel with local access to imaging that can expedite the diagnosis and treatment process for a number of disorders. As the patient population ages, the demand for imaging services will likely grow in conjunction with the need to treat age-related conditions. The Applicant states that creating streamlined pathways for access to care will improve overall public health outcomes.

### ***Analysis: Public Health Outcomes***

Staff finds that the Proposed Project is planned to ensure timely access to more accurate imaging services has the potential to improve health outcomes and patient satisfaction. Timely access can reduce delays in diagnosis and treatment that can adversely impact health outcomes. As a result, DoN Staff can conclude that the Proposed Project will likely meet the Public Health Outcomes component of Factor 2.

### **Delivery System Transformation**

The Applicant has plans to support patients' needs around social determinants of health (SDoH) and has a SDoH screening process in place for issues related to imaging appointments. In instances where patients need support to address SDoH's, the Applicant offers access to services designed to facilitate improved care pathways influenced by social determinants of health. Specifically, the Applicant plans to implement numerous patient access tools, such as preregistration functionality, a cost transparency application, linkages to financial counselors, culturally competent staff, and a translation services program. The Applicant states that these amenities facilitate easier to access care for vulnerable and at-risk populations.

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<sup>11</sup> Such as curative intent surgery and radiation therapy in patients demonstrated by PET to have advanced disease.

### ***Analysis: Delivery System Transformation***

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant conducts pre-screens on relevant SDoH factors, and if made aware of a SDoH issue, staff will provide linkage to an appropriate community-based support to meet the identified need. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the system delivery transformation component of Factor 2.

### **Summary, FACTOR 2**

As a result of the information provided, staff finds that the Proposed Project has sufficiently met the requirements of Factor 2.

### **Factor 3: Relevant Licensure/Oversight Compliance**

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and this Factor will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

### **Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis**

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such a finding must be supported by an analysis by an independent CPA.

The Applicant submitted a CPA report compiled by Veralon Partners, Inc. The CPA assessed the reasonableness<sup>12</sup> of assumptions used in the preparation and feasibility<sup>13</sup> of the projections with regards to the Proposed Project. The CPA concluded that projections were reasonable, and that the Applicant has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel.

#### ***Factor 4 Analysis***

Staff is satisfied with the CPA's analysis of the Proposed Project's projections. As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project has met Factor 4.

### **Factor 5: Assessment of the Proposed Project's Relative Merit**

Evaluation of Factor 5 shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

The Applicant considered and rejected two alternatives to the Proposed Project.

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<sup>12</sup> Reasonableness is defined within the context of this report as supportable and proper, given the underlying information.

<sup>13</sup> Feasibility is defined as based on the assumptions used, the plan is not likely to result in insufficient funds available for capital and ongoing operating costs necessary to support the proposed project without negative impacts or consequences to the existing Patient Panel.

### **Alternative Option 1: Continue services with no PET/CT Imaging Option in the PSA**

The Applicant considered not establishing a new vendor partnership to provide access to PET/CT imaging. This alternative is not sufficient to meet the Patient Panel's growing need for accessible, low-cost PET/CT imaging in the community. 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. While no additional capital expenses would be incurred in the short term, the Applicant states that forgoing this project would greatly impact patient experience, clinician experience, and health outcomes.

### **Alternative Option 2: Atrius establishing its own PET/CT program**

The Applicant considered establishing its own PET/CT program. This was not considered a viable option due to the expense of such an undertaking. A new generation PET/CT machine can cost between \$1.5 and \$2.1 million,<sup>14</sup> depending on the level of functionality. Also, purchasing the initial system is just one factor in the total cost of acquiring a PET/CT. Several other factors for consideration include site preparation, installation, and regulatory compliance. The Applicant states that the partnership with Shields made better financial and operational sense.

### **Analysis**

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

## **Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline**

*Summary:* The Applicant plans to establish a mobile PET/CT unit at an existing Shields facility located in Dedham, Massachusetts. This project constitutes a DoN-Required Equipment acquired by an entity other than a hospital. As such, the Applicant is not required to submit CHI forms.

Shields and Atrius Health PET/CT will contribute their full CHI contribution to the Statewide Community Health and Healthy Aging Funds (CHHAF). With fulfillment of the below conditions, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

## **Findings and Recommendations**

Based upon a review of the materials submitted, Staff finds the Applicant has met each DoN Factor for the Proposed Project and recommends that the Commissioner approve this Determination of Need, subject to all applicable Standard and Other Conditions.

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<sup>14</sup> Price Guide available at: <https://directmedparts.com/pet-ct-scan-machine-cost-guide/#:~:text=A%20new%20generation%20PET%2DCT,service%20warranty%2C%20and%20applications%20training.>

## Other Conditions

1. Payment should be made out to the Massachusetts Community Health and Healthy Aging Funds in the full amount of \$13,684.35, and should be submitted within 30 days from the date of Notice of Approval to:

**Health Resources in Action, Inc., (HRiA)**

2 Boylston Street, 4th Floor

Boston, MA 02116

Attn: MACHHAF c/o Ms. Bora Toro

DoN project #: N/A-24031814-RE

2. Please also **send a PDF image of the check** (or confirmation of payment) to [DONCHI@mass.gov](mailto:DONCHI@mass.gov) and [dongrants@hria.org](mailto:dongrants@hria.org). If you should have any questions or concerns regarding payment, please contact the CHI team at [DONCHI@mass.gov](mailto:DONCHI@mass.gov).

## Appendix I: Quality Metrics

The Holder shall provide, in its annual report to the Department, the following outcome measures. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12). Reporting will include a description of numerators and denominators.

- 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%

**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.

## Appendix II: Literature Review

### Research on the prevalence of oncologic, cardiac, and neurologic conditions among an aging population

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Department of Public Health. *Massachusetts Deaths 2021*. October 2023. Available Online at: <https://www.mass.gov/doc/2021-death-report-pdf/download>

## Research on the importance of PET-CT scans to the diagnosis and treatment of oncologic, cardiac, and neurological conditions

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

Stanford Medicine Health Care. What to Expect: Advantages of a PET/CT Scan. Available online at: <https://stanfordhealthcare.org/medical-tests/p/pet-ct-scan/what-to-expect.html>

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