

STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	UMass Memorial MRI & Imaging Center, LLC
Applicant Address	700 Congress Street, Suite 204, Quincy, Massachusetts 02169
Filing Date	January 17, 2023
Type of DoN Application	Required Equipment
Total Value	\$700,687.00
Project Number	UMMIC-22103111-RE
Ten Taxpayer Groups (TTG)	None
Community Health Initiative (CHI)	\$35,034.35
Staff Recommendation	Approval
Review	Delegated

Project Summary and Regulatory Review

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

The total value of the Proposed Project is \$700,687.00; the Community Health Initiatives (CHI) contribution is \$35,034.35 to the Statewide fund.

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 in the regulation.

Table of Contents

Background and Application Overview	3
Patient Panel	4
Factor 1.....	6
Factor 1(a) Patient Panel Need.....	6
Factor 1(b) Public Health Value: Improved Health Outcomes and Quality of Life; Assurances of Health Equity	11
Factor 1(c) Efficiency, Continuity of Care, Coordination of Care.....	13
Factor 1(d) Consultation	14
Factor 1(e) Evidence of Sound Community Engagement through the Patient Panel.....	14
Factor 1(f) Competition on Price, Total Medical Expenses (TME), Costs and Other Measures of Health Care Spending	15
Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation.....	17
Factor 3: Relevant Licensure/Oversight Compliance	19
Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis.....	19
Factor 5: Assessment of the Proposed Project's Relative Merit	21
Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline	22
Findings and Recommendations.....	22
Conditions to the DoN	22
APPENDIX 1: Measures for Annual Reporting.....	23

Background and Application Overview

The Applicant, UMass Memorial MRI & Imaging Center, LLC (UMMIC), is a joint venture between UMass Memorial Health Ventures, Inc. and Shields Healthcare Worcester, LLC. (Shields). It currently operates at the following locations:

Location	Imaging Modality
214 Shrewsbury Street, Worcester, MA	MRI and PET-CT
UMass Memorial Medical Center, Memorial Campus, Worcester, MA	MRI
UMass Memorial Medical Center, University Campus, Worcester, MA	MRI
UMass Memorial Health-Alliance Hospital, Fitchburg, MA	PET-CT
UMMIC- Marlborough ¹	PET-CT

Shields Health was originally founded in 1972 as a family owned and operated nursing home. In 1986, Shields opened its first MRI center, and now Shields manages more than 40 MRI and PET-CT facilities throughout New England, many of which are joint venture partnerships with community hospitals in addition to freestanding ambulatory surgery centers.

The site of the Proposed Project, UMass Memorial Health - Harrington Hospital at Southbridge (Harrington Hospital, Harrington) previously Harrington HealthCare System officially became a part of the UMass Memorial Health Care, Inc. ("UMMHC") system in July of 2021. Harrington Hospital is a licensed 119-bed not-for-profit community hospital in Southbridge, that provides medical and surgical inpatient and outpatient family-based care, including emergency services to patients in Southbridge, Sturbridge, Brimfield, Charlton and beyond. The Hospital offers a comprehensive array of services including Oncology and Cardiac care, advanced diagnostic imaging, adult inpatient care, including intensive care unit, an eICU,² a state-of-the-art monitoring system, a 16 bed Co-occurring Disorders Unit (CDU), a 24 bed Adult Psychiatric Unit (APU), nutrition counseling, primary and specialty care offices, physical and occupational therapy, and same-day pediatric patients care.

Proposed Project

The Applicant states that Harrington Hospital currently meets its patients' PET-CT needs through an affiliation with a *non*-Shields diagnostic imaging vendor – a relationship that is set to expire in 2023. Since Harrington is now a member of UMMHC, which is a partner in UMMIC, switching vendors will enhance integration into the UMMHC system and improve care coordination.

With the current vendor, patients enter a mobile environment that is temporarily attached to the building and is enclosed from the outside elements. The new satellite clinic will utilize this existing space at Harrington. If approved, the Proposed Project, will be added to the UMMIC license, thus

¹ Received DoN Approval 2.27.23

² Find details online at: https://www.harringtonhospital.org/services/emergency_care_center/eicu/

increasing the total number of diagnostic imaging sites under this license, from to five (5) sites to six (6).

The Applicant asserts the Proposed Project will increase access to care and encourage cost containment through the provision of timely care in an appropriate setting; all of which the Applicant posits may reduce mortality and morbidity for chronic conditions and will translate to better quality outcomes and reduced costs.

Patient Panel ³

Since Harrington Hospital is part of the UMMHC system, the Applicant provided Harrington Hospital's patient demographic data along with UMMHC Patient Panel as it relates to the need for the Proposed Project,⁴ because the proposed PET-CT services will be located at Harrington. Table 1 reflects a patient population data for fiscal years (FYs) 2019-2022⁵ that is fluctuating due to the impacts of the COVID-19 pandemic.

Table 1: UMMHC Patient Panel and Harrington Hospital Patient Population

	FY19	FY20	FY21	FY22
UMMHC	371,488	345,864	393,429	383,617
Harrington	66,037	62,406	83,030	63,514

Table 2: Demographic Overview of UMMHC and Harrington Hospital Patients⁶

	UMMHC	Harrington Hospital
Gender		
Male	55.5%	53.5%
Female	44.4%	46.4%
Unknown	0.1%	0.1%
Total	100%	100.0%
Age		
0-17	18.4%	20.0%
18-64	60.4%	60.5%
65+	21.2%	19.5%
Total	100%	100.0%
Race		
American Indian or Alaska Native	0.2%	0.1%
Asian	3.8%	0.9%

³ 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.

⁴ The Applicant sought counsel from the DPH Determination of Need Program's leadership to determine that this was the appropriate course of action.

⁵ Fiscal year is October to September.

⁶ Numbers are for 2021, the most recent year available for both parties.

	UMMHC	Harrington Hospital
Black or African American	5.9%	1.5%
Native Hawaiian/Other Pacific Islander	0.0%	0.02%
Multiracial ⁷ /Other/Unknown	13.5%	17.6%
White	75.7%	78.5%
Declined to Answer	0.8%	1.4%
Total	100%	100.0%
Ethnicity		
Hispanic or Latino	15.0%	10.3%
Not Hispanic or Latino	80.7%	NA
Declined to Answer	1.6%	NA
Unknown	2.7%	90.8%
Total	100%	100.0%
Patient Origin^{8,9}		
Central Mass	89.6%	80.7%
Eastern Mass	5.0%	2.5%
Western Mass	2.3%	7.7%
Out of State	3.2%	9.1%
Total	100%	100%

Table 2 compares the key demographics for the UMMHC and Harrington Hospital patient populations, which are very similar. Staff note the following observations about these data:

- **Age:** The majority of UMMHC and Harrington Hospital patients are ages 18-64; the age 65 and older population comprises ~21% of the UMMHC patient population and ~20% of the Harrington Hospital patient population.
- **Race:** The majority of UMMHC (76%) and Harrington Hospital (75%) patients identify as White.
- **Ethnicity:** A slightly larger percent of the UMMHC patient population identify as Hispanic (15%) than the Harrington Hospital patient population (13.5%).
- **Primary Service Area:** The majority of UMMHC (90%), and of Harrington Hospital (91%) patients originate from Central Massachusetts.

Table 3: Payer Mix for UMMHC and for Harrington Hospital

Payer Mix	UMMHC	Harrington Hospital
Commercial PPO/Indemnity	3.5%	29.1%
Commercial HMO/POS	25.0%	12.9%
MassHealth	18.1%	9.9%

⁷ In the category known as “Multi Racial,” the patient count was <11. Those patients were added to the “Other/Unknown”

⁸ UMMHC’s Primary Service Area (PSA) includes Southbridge, Sturbridge, Charlton, Dudley, Wales, Webster, Holland, and Fiskdale. Harrington Hospital’s Primary Service Area includes Hudson, Northborough, Westborough, Berlin, Framingham, Clinton, Southborough, Bolton, and Shrewsbury.

⁹ **Central Mass** is defined as all of Worcester County and the northwest corner of Middlesex County. **Eastern Mass** is defined as the Greater Boston, Cambridge, and South Shore, Cape Cod & Martha’s Vineyard service areas. **Western Mass** is defined as Franklin, Hampshire, Hampden, and Berkshire counties.

Managed Medicaid	6.5%	16.8%
Commercial Medicare	16.3%	12.5%
Medicare FFS	27.0%	14.2%
All other (e.g. HSN, self-pay, TriCare)	3.6%	4.6%
Total	100%	100%

- **Payer Mix:** Table 3 shows that Harrington has ~40% commercial payers compared to UMMHC's 28.5%; Harrington has ~26.7% MassHealth/Managed Medicaid vs UMMHC's ~24.6%; Harrington's Medicare payments account for ~26.7% while UMMHC's are ~43.3%.

Factor 1

Factor 1(a) Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently demonstrated need for the Proposed Project by the Applicant's Patient Panel.

Through the Proposed Project, that replaces the current vendor, the Applicant will ensure existing and future patient needs are met by continuing to provide local access to PET-CT imaging one day per week, at the Harrington Hospital campus.¹⁰ The Applicant attributes need for this replacement service to:

1. Need to ensure local access- Capacity constraints due to the outmoded equipment in use by the current vendor
 2. Population growth- and the growing aging population
 3. The disease burden – Cancer, Cardiology, and Neurological Conditions
 4. Historical Scan Volume and Projections
1. Need to ensure Local Access- Capacity constraints due to the outmoded equipment in use by the current vendor

The Applicant asserts that there are no other PET-CT facilities available to its patients within the Applicant's primary service area. The closest competitor's site is >17 miles away in Connecticut and is out of network for its patients. The closest competitor's site in Massachusetts is >31 miles away in Worcester. The Applicant states this is significant for two reasons: 1) Harrington Hospital's current vending relationship ceases in 2023, creating an opportunity for the Applicant's service to assume operations of the local PET-CT imaging service; and 2) the Applicant plans to provide this PET-CT service as a freestanding mobile independent diagnostic testing facility (IDTF), and as such, it will be reimbursed at lower rates than hospital-based rates,¹¹ enhancing efficiencies and cost-effectiveness.

¹⁰ Patients will enter the mobile unit through an enclosure (protecting them from outside elements) via the hospital radiology department.

¹¹ because inpatient facilities cost more than mobile sites to operate.

Though the Proposed Project the Applicant will not expand the number of days the mobile unit will be on site; however, it will utilize newer updated PET-CT technology that is quicker and that yields superior lesion detection, disease characterization, more accurate quantitation,^{12, 13} and therefore, will increase the number of scans performed.

The current vendor provides mobile PET-CT imaging services one day a week onsite at Harrington Hospital. The Applicant reports that due to recent capacity limitations, overflow imaging volume has been referred to UMMC imaging sites in Worcester and Fitchburg,¹⁴ and consequently, a portion of the Harrington Hospital patients needing PET-CT must travel 20- 40 miles to attain these services. In 2021 only one referral was made, while in 2022, ~70 referrals were sent to sister locations outside the PSA¹⁵ that the newer PET-CT will be able to accommodate according to the Applicant.

The importance of local access has been demonstrated in studies that show that patient's challenges related to access to health care often result in unmet health care needs, including a lack of preventive screening services and the treatment of illnesses.^a

2. Population growth- the growing aging population

Statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035.^b While overall statewide population growth will continue to grow at a consistent rate of 3.2%, within the next 15-20 years, the largest part of the Commonwealth's population growth will be attributable to residents within the 50+ age cohort, and residents that are 65+ will represent a 21% of the Massachusetts population.^c

At the site of the Proposed Project, the city of Southbridge's population was reported to be 17,657.^{d, 16} The median age of the population of Southbridge is 40.2, which is older than the median age of the total population of Massachusetts, 39.6.^e The Southbridge population has higher percentages of residents than the State in the age cohorts of 50-59 and 60-69.^f It is expected that the 50+ age cohort will continue to grow. The Advisory Board forecasts that the Harrington Hospital PSA or people aged 65+ is projected to increase on average by +16.5% over the next five (5) years (CAGR of +3.1%).

¹² 2019 Siemens Biograph mCT 40.

¹³ Aide, Nicolas & Lasnon, Charline & Desmonts, Cédric & Armstrong, Ian & Walker, Matthew & McGowan, Daniel. (2021). Advances in PET-CT technology: An update. Seminars in Nuclear Medicine. 52. 10.1053/j.semnuclmed.2021.10.005.

Available online at: https://www.researchgate.net/publication/356449596_Advances_in_PET-CT_technology_An_update

¹⁴ There are 20.3 miles between Southbridge and Worcester

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

and 46.8 miles between Southbridge and Fitchburg

<https://www.google.com/maps/dir/Southbridge,+Massachusetts/Fitchburg,+Massachusetts+01420/@42.3307916,-72.1572953,10z/data=!3m1!4b1!4m14!4m13!1m5!1m1!1s0x89e6a1ef1c20680b:0x980c7ac63d58cf11!2m2!1d-72.0333905!2d42.0751065!1m5!1m1!1s0x89e3e654c92294d1:0x71c57d04deaac42b!2m2!1d-71.8022955!2d42.5834228!3e0>

¹⁵ PSA zip codes include Southbridge 01550; Webster 01570; Charlton 01507; Sturbridge 01566; Dudley 01571; Brimfield 01010; Spencer 01562; Holland 01521; Fiskdale 01518; and Brookfield 01506.

¹⁶ as of July 1, 2021

As the number of patients that fall into the 50 plus age cohort continues to grow, the importance of maintaining access to imaging services, such as PET-CT for detecting, managing, and treating age-related conditions,^g is underscored. The Applicant notes that seniors surveyed in Harrington Hospital's 2019 Community Health Needs Assessment reported that cancer, heart disease, and degenerative neurological conditions like Alzheimer's and Dementia were chief among their health concerns.

3. Disease Burden

Disease Burden Oncologic Conditions

Given the aging population, the total number of patients with cancer will increase,^h and the majority will require precise diagnostic imaging which may include PET-CT.¹⁷ Expanded uses for PET-CT are likely as several new PET tracers are under investigation for potential use in urological oncologyⁱ including testicular, kidney, bladder, and prostate cancer.^j PET-CT increasingly is influencing urological treatment decisions by the detection and localization of recurrent disease that is often missed by using conventional imaging methods.^k

According to recent research published in *Cancer*,^l the COVID-19 pandemic led to lower rates of cancer screening for breast, colorectal, lung, and cervical cancers in the U.S. where more than 9.4 million screening exams were missed in 2020. These missed screenings will likely lead to increased cancer deaths over the next decade.

In Worcester County, where Harrington Hospital and the proposed PET-CT facility are located, the age adjusted annual incidence of cancer rate was 473.57 – 486.21 per 100,000 persons.^m

The Applicant provided data on cancer incidence from the Massachusetts cancer registry for Southbridge,¹⁸ which standardizes incidence ratios (SIRs) for 23 types of cancers in the 351 cities and towns in Massachusetts over a 5-year time frame relative to the State's as a whole. Table 4 shows percentages of certain oncologic conditions relative to the statewide averages. Of the ten (10) Cancer SIR's provided by the Applicant, Southbridge had higher SIR's in all but three categories: females-breast, female colon/rectum, female lung/bronchus, which points to the ongoing need for regional access to PET-CT imaging.

Table 4: Notable SIRs for Southbridge¹⁹

Cancer Type	Notable SIRs * for Southbridge	Percentage Higher than Statewide Average
Breast	Female: 79.9	Female: (20.1%)
Colon/Rectum	Male: 112.4 Female: 98.8	Male: 12.4% Female: (1.2%)
Leukemia	Male: 102.8	Male: 2.8%
Liver and Intrahepatic Bile Ducts	Female: 177.7	Female: 77.7%
Lung and Bronchus	Female: 75.0	Female: (25%)
Multiple Myeloma	Male: 184.3	Male: 84.3%

¹⁷ depending on the type of cancer

¹⁸ The most recent age and sex adjust data is from 2011-2015, from Office of Data Management and Outcomes Assessment and the Department of Public Health, available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

¹⁹ Available online at: <https://www.mass.gov/lists/cancer-incidence-city-town-supplement>

Non-Hodgkin Lymphoma	Male: 117.2 Female: 146.6	Male: 17.2% Female: 46.6%
Pancreas	Male: 139.0	Male: 39%
Stomach	Male: 153.3	Male: 53.3%
Uteri Corpus and Uterus, NOS	Female: 116.0	Female: 16%

**An SIR of 100 indicates that a city/town's incidence of a certain type of cancer is equal to the expected rate based on statewide average age-specific incidence rates; while an SIR of more than 100 indicates an incidence of a certain type of cancer is higher than the incidence of that type of cancer is than the statewide average when adjusted for age.²⁰ (Accordingly, one that is below 100 indicates a lower-than-average incidence rate.)*

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

Disease burden Cardiological Conditions

The risk for coronary heart disease increases starting at age 45 for men and at age 55 for women.ⁿ According to the 2018 results from the Massachusetts Behavioral Risk Factor Surveillance System, statewide, 5.6% of Massachusetts adults are diagnosed with myocardial infarction and 4.7% are diagnosed with angina or coronary heart disease annually.²¹ According to the American Heart Association, 12,140 people died of heart disease in Massachusetts in 2017, making heart disease the second leading cause of death.²²

In addition, heart disease²³ 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.²⁴ That trend is likely to continue for years to come as the long-term impact of the novel coronavirus will directly affect cardiovascular health, according to the American Heart Association.²⁵

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

Disease Burden Neurological Conditions

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.^o

²⁰ SIR of 105 indicates that a city/town's cancer incidence is 5% higher than the statewide average annual age-specific incidence rates. An SIR of 85 indicates that a city/town's cancer incidence is 15% lower than expected based on statewide average annual age-specific incidence rates.

²¹ Online at: <https://www.mass.gov/doc/a-profile-of-health-among-massachusetts-adults-2018/download>

²² Online at: <https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm>

²³ Stroke is also included in this statistic.

²⁴ 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>

²⁵ Ibid.

Moreover, the incidence rate of Alzheimer's also increases with age.²⁶ The prevalence of Alzheimer's is projected to rise, and the most recent data show: 130,000 people aged 65 and older are living with Alzheimer's in Massachusetts.^p Additionally, 9.3% of people aged 45 and older have subjective cognitive decline.^q Early diagnosis, using such diagnostic tools as PET-CT, allows patients and families to plan for care and treatment while they are still able to make important decisions on supports, financial and legal matters.^r It also helps them and their families to receive practical information, advice, and guidance as they face new challenges.^s

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

4. Historical Volume and Projections

Patients who potentially *could* benefit from PET-CT- Since evidence-based research supports the use of PET-CT in clinical areas^t including cancer, cardiology, and neurology, the Applicant evaluated the number of patients that Harrington Hospital treated during the last three fiscal years who had these underlying conditions (Table 5); a smaller subset of clinically appropriate patients who could benefit from PET-CT will be drawn from this pool of patients.

Table 5: Number of Patients at Harrington Hospital with Cancer, Cardiac and Neurologic Conditions, and Percent of Total Patient Population²⁷

Fiscal Year (FY)	Cancer*	Cancer %	Cardiology*	Cardiology %	Neurology*	Neurology %
FY19	10,033	15.19%	25,798	39.07%	15,621	23.65%
FY20	10,225	16.38%	25,706	41.19%	16,054	25.73%
FY21	9,750	11.74%	24,453	29.45%	15,207	18.32%

*Patients and are counted once per category per year.

The Applicant notes the decrease in the number of patients from 2019 to 2020 across all three service lines that it attributes primarily to the COVID-19 pandemic.

Historical Volume and Projections

In planning for the Proposed Project, the Applicant reviewed the historical number of PET-CT scans referred to the current vendor for diagnostic imaging in FY19, FY20, and FY21. These data are provided in Table 6 and demonstrate the ongoing need for local PET-CT imaging access.

Table 6: Historical Volume of Scans as reported by the Current Vendor

FY 19 # scans	FY 20 # scans	FY 21 # scans	FY 22 # scans
183	215	260	N/A from current vendor ²⁸

²⁶ Age is the greatest of these the risk factors. 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>

²⁷ Total Patients- see Table 1

²⁸ The current vendor would not supply more updated data.

In order to assess future demand for PET-CT services (Table 7), the Applicant relies on the projections of its consultant, Veralon,²⁹ that combine Shields' historical experience of PET-CT growth,³⁰ with market shares³¹ of the top ten referral zip codes in Harrington's service area, and the Advisory Board Company ("Advisory Board") market projections that demand for PET-CT services will grow by +10.3% over the next five (5) years and +18.3% over the next 10 years.³² Based on the Advisory Board's experience with PET-CT scanning, the shares of patient scans by specialty is expected to be ~88% Oncologic, ~7.7% Cardiac, and ~4.3% neurologic.

Table 7: Six-year PET-CT Scan Volume Projections

Annual Scans	Year 1*	Year 2	Year 3	Year 4	Year 5	Year 6
Total Scans³³	297	333	366	403	423	444
% Growth		12.1%	9.9%	10.1%	4.9%	4.9%

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

Analysis

The Harrington Hospital numbers of patients with underlying oncologic, cardiac, and neurologic conditions for which PET-CT has proven clinical applicability,^u supports the need for local ongoing access to PET-CT imaging via the Proposed Project which replaces an existing vendor without adding additional days of service. The Applicant's projection of 444 total scans (year 6) should still be achievable with one day of service.³⁴

National and regional statistics show an increasing prevalence of cancer, cardiovascular disease, and cognitive decline,³⁵ along with the evolving and expanded clinical applications of PET-CT support the Proposed Project.

As a result of information provided by the Applicant and with additional analysis, Staff finds the Applicant has met the requirements of Factor 1(a).

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

²⁹ Veralon, health care business valuation and consultants, using the Shields PET-CT standard year over year growth trend from new Shield's PET-CT new sites since 2016.

³⁰ from Shield's PET-CT sites since 2016

³¹ from The American Hospital Directory AHD.com

³² Combines demand in both freestanding and hospital-based outpatient departments (HOPDs). This methodology is consistent with the recently approved UMMIC-Marlborough DoN Application.

³³ See Statement of Profit and Loss in the Appendix of the Veralon CPA Report.

³⁴ Assuming 50 weeks of operation per year, staff calculates it would equate to ~ 9 scans per day. Depending on the area being scanned, a scan can take 30-60 minutes with an additional time for preparations.

³⁵ A study by the Centers of Disease Control and Prevention titled "[Chronic Disease and Cognitive Decline – A Public Health Issue](#)," projects by 2030 about 20% of Americans will be 65 years and older.

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

- **Improved Health Outcomes**-The Applicant provided extensive documentation of the clinical utility of combined PET-CT advanced imaging which contribute to improved health outcomes through timely accurate diagnosis. PET-CT helps clinicians pinpoint abnormal metabolic activity and provide more accurate diagnoses than the two scans performed separately;³⁶ while PET scans measure metabolic activity to evaluate body functions, CT imaging is necessary to identify the precise location of any PET-identified abnormal activity since CT provides excellent anatomic definition.³⁷ Therefore, PET-CT can help doctors evaluate how well organs and tissues are functioning.³⁸

As discussed under Factor 1(a) Disease burden, PET-CT has proven to be a useful clinical tool initially for Oncology patients for diagnosis, staging, treatment planning, and evaluation. For some anatomic sites, PET-CT enables target size reduction for administering radiation therapy by enabling more focused higher doses target, sparing normal tissue. This has significantly affected radiation therapy administration.^v

Additionally, while its use in clinical oncology, continues to expand, PET-CT is finding expanded clinical applications in cardiology, neurology, general internal medicine, infectious diseases, surgery, traumatology, orthopedics, pediatrics, endocrinology, rheumatology, psychiatry, neuropsychology, and cognitive neuroscience.^w

- **Improved patient satisfaction, convenience and quality of life.** The Applicants states that through the Proposed Project it will maintain timely access to imaging services, and this will promote patient satisfaction. By ensuring access to on-campus PET-CT services patients will not face the burden of travel outside Harrington Hospital's service area to access PET-CT imaging services. Patient satisfaction is linked to patient compliance with their medical care plan, which leads to improved health outcomes.

The Applicant has provided several measures to demonstrate impact of the Proposed Project. Staff reviewed the suggested measures which are described fully Appendix I. The measures will become part of the annual reporting to DPH.

Improved Health Equity and Social Determinants of Health (SDoH)

The Applicant states it believes that health equity is tied to the affordability of the health care services and cited a Kaiser Family Foundation survey^x finding 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 and about one in eight said their medical condition got worse. Health care costs top the list of expenses that people report difficulty affording.^y

³⁶ Available at RadiologyInfo.org for patients. Online at: <https://www.radiologyinfo.org/en/info/pet>

³⁷ *Ibid.*

³⁸ *Ibid.*

The Applicant states, the Proposed Project will not adversely affect accessibility of Harrington Hospital's services for poor, medically indigent, and/or Medicaid eligible individuals. To further ensure health equity and address disparities to all, the applicant will implement the following measures:

1. The Applicant asserts it will not discriminate based on ability to pay or payer source, and that it accepts all forms of insurance, will offer pre-registration and price transparency tools to ensure that all patients have access to current pricing information, and will provide financial counselors for assistance in understanding insurance benefits. It will address affordability by offering imaging services that are reimbursed at lower, IDTF rates.²
2. The Applicant asserts that it will implement culturally appropriate support services to ensure improved patient experience and higher quality outcomes. The Applicant offers ongoing education and training for staff in culturally and linguistically appropriate care. In addition, translation services including Language Line which provides phone and video interpretation services in more than 240 languages 24 hours a day, seven days a week; and InDemand which offers medical interpreting solutions for limited English proficient (LEP) and deaf and hard of hearing patients.
3. While the Applicant also provides transportation assistance via ride-share and cab vouchers when needed by a patient, local access is an essential component of maintaining continuity of care and ensuring that the most direct path to diagnosis and treatment is available, thus promoting health equity within the community.

Analysis

Staff concur that providing timely access to appropriate imaging services contributes to improved health outcomes, quality of life, and patient satisfaction. There is a body of literature stating that delays in the delivery of care have been linked to significant patient harm, including morbidity and mortality related to delays in diagnosis and treatment for both high- and low-acuity patients, increased adverse events, higher costs, and decreased patient satisfaction.^{aa}

The Interpreter Services and affordability tools (described further under Factor 1(c)) demonstrate UMMIC Harrington's commitment to promoting health equity. Together, the service, when implemented) should eliminate language barriers for patients and ensure culturally appropriate care. As a standard condition of approval of the Proposed Project, as set out in DoN regulation 105 CMR 100.310, all Determination of Need Holders must provide a plan for approval by the Office of Health Equity for the development and improvement of language access and assistive services provided to individuals with disabilities, non-English speaking, LEP, and American Sign Language (ASL) patients.

Staff finds that with the reporting measures in Appendix 1, and the standard conditions, the Applicant has sufficiently outlined a case for improved health outcomes and quality of life for its patients. As a result of information provided by the Applicant and with additional analysis, Staff finds the Applicant has met the requirements of Factor 1(b).

Factor 1(c) Efficiency, Continuity of Care, Coordination of Care

The Applicant notes its delivery model is as convenient as the existing vendor's service. However, through the Shields management team's operational discipline and scheduling efficiencies it will increase patient throughput and improve patient and referring provider satisfaction.

To ensure that the Proposed Project furthers continuity and coordination of care that improves engagement among the clinical team and patients, the Applicant will use its existing integrated technology infrastructure including:

- Pre-registration
- Cost transparency
- Affordability tools
- The electronic medical record (EMR)

These tools interface within the EMR to amalgamate necessary patient health information, such as medical history, allergies, and medications. Additionally, the EMR also allows radiologists to efficiently share pertinent diagnostic information with PCPs and specialists, so they may coordinate and track a patient's clinical findings and treatment progress.

Analysis

Staff finds that the Applicant's care coordination tools and processes will contribute positively to continuity, and coordination of care and thereby improve efficiency. Review of the literature suggests access to integrated health information technology systems directly impacts health outcomes through reducing fragmentation and improving coordination among care providers.^{bb, cc} 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.^{dd}

As a result of information provided by the Applicant and with additional analysis, Staff finds the Applicant has met the requirements of Factor 1(c).

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.

Factor 1(e) Evidence of Sound Community Engagement through the Patient Panel

The Department's Guideline 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."

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

- Virtual Community Forum; and
- Presentation to Harrington Hospital’s Family Advisory Committee (PFAC).³⁹

The PFAC is comprised of current and former patients of the hospital and their family members as well as staff of the hospital. Because the proposed service will serve Harrington Hospital patients, it was decided that the PFAC would best represent patients. The Proposed Project was presented at Harrington Hospital’s PFAC on November 28, 2022, with eight (8) individuals in attendance. The presentation sought to inform PFAC members about the Proposed Project and how it would benefit patients, offered members an overview of the continued need for PET-CT at Harrington’s Main Campus once the current imaging vendor relationship expires in 2023. It emphasized how PET-CT services will complement the cancer treatment and breast services currently provided at Harrington Hospital and how by operating as a freestanding IDTF, the fee schedule will help lower the cost of services.

Participants were engaged and made several comments that focused on the importance of access and timeliness of an imaging appointment, and the importance of receiving imaging results as quickly as possible.⁴⁰ One member communicated a concern about the quality of the scans conducted by the *current* vendor recounting a recent personal experience was subpar and hoped that patient experience would be improved under the Applicant. In response to this comment, the suggestion was made to Hospital administration that effective communications regarding the vendor transition may be helpful. The participants expressed general support for the Proposed Project.

The Applicant also advertised a virtual community meeting regarding the Proposed Project on Harrington Hospital social media three weeks in advance of another the forum, which was scheduled for November 28, 2022,⁴¹ however, no one from the community joined the virtual meeting.⁴² To ensure appropriate awareness and provide opportunity to comment within the community about the Proposed Project, the legal notice associated with the Proposed Project was published on the Shields website⁴³ and on the Harrington Hospital website.⁴⁴

Analysis

Staff finds that the Applicant has sufficiently addressed the community engagement in the planning phase of the Proposed Project. As a result of information provided by the Applicant and with additional analysis, Staff finds the Applicant has met the requirements of Factor 1(e).

Factor 1(f) Competition on Price, Total Medical Expenses (TME), Costs and Other Measures of Health Care Spending

³⁹ For detailed information regarding these activities, please see attached exhibit.

⁴⁰ Shields’ turnaround time for imaging results is approximately 24 hours.

⁴¹ A copy of the social media flyer is included in Exhibit B.h

⁴² A copy of the presentation is included herein with the DoN Application.

⁴³ Published November 4, 2022 on the Shields website: <https://shields.com/location/shields-mri-umass-memorial-memorial-campus/>

⁴⁴ Published November 9, 2022 on Harrington Hospital website: <https://www.harringtonhospital.org/news/public-announcement-concerning-a-proposed-health-care-project-3/>

The Applicant asserts that the Proposed Project will compete based on price, total medical expenses (TME), provider costs, and other recognized measures of health care spending through several means:

- Providing ease of access to care has been documented to reduce healthcare utilization and spending.^{ee} Studies have detailed high costs for unnecessary repeat imaging^{ff} which could be improved through more appropriate use of all imaging, including PET-CT, and better integration of services.
- Shields' operating model allows for improved scheduling, workflow, technology, and customer service. The Applicant asserts these front-end/access focused optimizations drive efficiency, which in turn drives down cost to provide care, allowing Shields to operate effectively.
- The clinic will operate as an independent diagnostic testing facility (IDTF) which is reimbursed at lower rates than hospital-based imaging.⁴⁵ The Applicant states the lower IDTF rates offer payers the opportunity to lower deductibles for patients and improve access to high quality care resulting in lower TME overall. Payers like United Healthcare, Cigna, and Anthem/BCBS have all implemented site-of-care review policies to push patients to lower cost sites of care for imaging.⁴⁶
- For the Proposed Project, preventing expenditures related to inefficiencies from lack of service integration,⁴⁷ can lead to lower overhead costs, which could, in turn, reduce TME. Harrington is leveraging the recent merger with UMass to fully integrate this service into UMMIC.
- The Proposed Project will allow the Applicant to provide PET-CT services without a significant capital expenditure since it is replacing an existing mobile service, it will park on an existing pad with an existing power connection.

Analysis

The Proposed Project will replace an existing service to provide access to imaging services one day per week, which corresponds to historical utilization. While advanced imaging improves clinical care, it can also be overused and add to healthcare costs.^{gg} The Applicant affirms it has protocols in place to support appropriate use of imaging.

Staff notes that CMS Clinical Decision Support Mechanism (CDSM) mandate which will require new compliance measures when healthcare professionals order outpatient advanced imaging, has been delayed due to COVID.⁴⁸

⁴⁵ An IDTF is a facility that is independent both of an attending or consulting physician's office and of a hospital. [Available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICN909060-IDTF-Fact-Sheet.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICN909060-IDTF-Fact-Sheet.pdf)

⁴⁶ If a procedure is to be performed at an IDTF, a site of care review will not occur (and therefore no additional charges will be incurred). The review will only occur (or be billed) if the procedure is performed in a hospital-based setting. Links to site of care policies: [United Healthcare Site of Service Review for MRI Services](#); [Cigna Site of Service Review for MRI Services](#); and [Anthem/BCBS Site of Service Review for MRI Services](#)

⁴⁷ The World Health Organization defines integrated service delivery as "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

⁴⁸ The penalty phase was set to begin Jan. 1, 2022, but CMS proposed delaying implementation of the payment penalty phase of the Appropriate Use Criteria program to the later of Jan. 1, 2023, or the Jan. 1 to follow the end of the COVID-19 public health emergency.

Staff also notes that excessive imaging remains a concern in the Commonwealth since Massachusetts ranks fourth in the nation in Medicare spending for imaging.^{hh} As described herein, Staff finds that the Applicant described distinct means whereby the Proposed Project will likely compete on the basis of price, TME, provider costs and other recognized measures of health care spending.

As a result of information provided by the Applicant and with additional analysis, Staff finds the Applicant has met the requirements of Factor 1(f).

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

The Applicant stresses that potential savings to patients are associated with PET-CT its ability to provide the clinical information that aids physicians to make the optimum treatment decisions which reduces supplemental imaging examinations and invasive procedures.ⁱⁱ

Further, the Proposed Project meets the goal of providing a lower-cost options for PET-CT imaging, as services will be provided by an IDTF, rather than a higher reimbursed hospital-based outpatient clinic. IDTFs are a more cost-effective option as the administrative costs for these types of providers are lower.^{jj} This difference will allow the Applicant to provide cost-effective, quality imaging services to Harrington Hospital's patients, while having a negligible impact on overall healthcare costs.⁴⁹

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.^{kk} If patients undergo both examinations in one session, in addition to having more accurate results, costs will be lower.^{ll}

Continued access to low-cost, high-quality PET-CT imaging services can ensure that eligible patients receive essential care in a timely manner and also promotes cost containment goals. Reducing diagnostic and treatment delays can lower costs through earlier detection and can reduce resource use when treating sicker patients.^{mm}

⁴⁹ The Proposed Project's IDTF fee schedule is the same as the current IDTF fee schedule as the public payers have standardized the fees nationwide.

Improved Public Health Outcomes

Providing needed care in a more efficient and effective manner will improve public health outcomes and the patient experience, as is outlined in detail in Factor 1(b). PET-CT imaging is a minimally-invasive diagnostic modality that allows clinicians to better understand the disease process and make treatment decisions earlier in the disease process. Through the Proposed Project patients will have access to local PET-CT imaging services at a low-cost, and community- based clinicians will have the tools to appropriately diagnose and treat patients, thereby eliminating a patient's need to travel for services.

The Proposed Project will address ongoing need, for coordinated, integrated PET-CT services to diagnose and treat conditions that disproportionately occur in the aging population. On average, geriatric patients use 50% more lab/imaging services than younger populations.ⁿⁿ Creating pathways for coordinated, convenient access to high value care can improve overall public health outcomes.

Delivery System Transformation

As described throughout this narrative, the Proposed Project will ensure that access to high-value, low-cost PET-CT imaging services will continue to be offered to the community served by Harrington Hospital while improving integration within the UMMHC system. In instances where patients need support to address social determinants of health,⁵⁰ the Applicant offers enhanced access to services designed to facilitate improved care pathways taking into account social determinants of health. Specifically, the Applicant states its plans to implement numerous tools that facilitate access to care for vulnerable and at-risk populations including tools for patient access, such as preregistration, a cost transparency application, linkages to financial counselors, culturally competent staff, and a translation services program.

The Applicant asserts that PET-CT services will align with Harrington Hospital's well-established cancer care continuum. The Cancer Center at Harrington (the Center) provides infusion services (chemotherapy) and is staffed by board certified oncology physicians and oncology nurses, has its own pharmacy suite, and has a comfortable library-like setting⁵¹ where patients and their families can access literature and use a computer to learn more about cancer treatment. Harrington Hospital surgeons, radiation oncologists, pathologists, oncologists/hematologists, nutritionists, primary care physicians, oncology nurses, and social workers collaborate to deliver coordinated care.

The Applicant also asserts that PET-CT services will align with Harrington Hospital's comprehensive, cardiac rehabilitation program. These programs include access to individualized treatment to patients,

⁵⁰ The Applicant states that care management is designed to assist patients and their support systems in managing medical conditions and psycho-social issues by communicating effectively. The Applicant states its goal is to improve a patient's functional health status through enhancing coordination of care with available resources in a timely and cost-effective manner. Case managers and social workers provide individualized services including: inpatient care management; support to inpatients and family members; crisis intervention and grief support; educating and assisting with discharge planning. Harrington Hospital offers a wide variety of information available to its community.

⁵¹ The American Cancer Society Resource Room, which is sponsored by the American Cancer Society

including participation in exercise, strength-training, counseling, and education sessions with the goal of returning to better health.⁵²

Harrington Hospital participates in the MassHealth Disability Access Incentive Program which provides financial rewards when hospitals demonstrate progress in obtaining accessible medical diagnostic equipment.⁵³ Research shows that a safe and well-designed clinical space helps to improve patient outcomes. As previously noted, to access the PET-CT, patients will enter the mobile environment that is attached to the building and enclosed from the outside elements.

The Applicant asserts that patients' needs have been thoughtfully assessed in developing the Proposed Project and as a result it is confident that integration of services will improve public health outcomes.

Factor 2 Analysis

For the Proposed Project, cost savings are achieved through efficient, timely access to necessary services in the appropriate setting. Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant has described tools targeting its SDOH needs of its patients that will be integrated into their electronic health record.

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 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 will not be addressed further in this report.

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.

⁵² Program also includes: Assisting individuals to identify and modify their risk factors, increase their physical activity and return to an active and satisfying lifestyle; A team approach to your care, involving primary care doctors, cardiologists, nurses, physical and occupational therapist, social workers and nutritionists; Individualized, multi-phase approach to cardiac rehabilitation care.

⁵³ The first phase required hospitals to complete an inventory of their accessible equipment; then hospitals to conduct a survey measuring whether patients with disabilities had to wait longer for diagnostic procedures, like x-rays, due to lack of accessible equipment or provider training. Now in its third year, hospitals must evaluate the results from previous surveys and expand future surveys to include other types of diagnostic equipment. This will help develop a methodology for tracking health care barriers for patients with disabilities.

In developing its report, the CPA reviewed and relied upon the following documents and information to prepare its report:

- UMass Harrington Southbridge PET-CT six-year Financials, prepared July 19, 2022;
- Volume assumptions;
- Payer mix of a similar market location to Harrington and per-case reimbursement assumptions;
- The MA DPH DoN Guidelines (105 CMR 100.000);
- Shields company website (www.shields.com); and
- Harrington website: (<https://www.harringtonhospital.org/about-harrington/>)

The review included analysis of key metrics that fall into three categories: profitability, liquidity, and solvency.⁵⁴

Revenues

To determine the reasonableness of the revenues, the CPA reviewed the underlying assumptions upon which Management relied to develop its financial projections. Revenue is a product of volume, payor-mix and reimbursements from the various payors. Volume projections were based on an analysis of the Applicant's 2021 PET-CT volume and an annual growth factor ranging from 5-12% annually.

The revenue per scan rates were determined based on actual 2021 payer-mix and rates of an Applicant's similar market location to Harrington. The budgeted reimbursement rate on a calculated weighted average of this location's payer-mix and reimbursement rates. In the revenue projections, the Applicant maintained the per-test reimbursement rates constant⁵⁵ since contractual rate increases from their payers are possible, but not guaranteed.

Following a review of volumes, payor-mix and reimbursement mechanisms, the CPA report determined that the projections reflect a reasonable estimate of future revenues for the Applicant.

Operating Expenses

The CPA analyzed each expense category for reasonableness which included a review of the total expenses for each category, a calculation of a compound annual growth rate ("CAGR") to analyze year-over-year trends, and finally a consideration to the extent that each expense item is tied to volume or more fixed in nature. Operating expense (including support services, billing, and bad debt expense) CAGR for 2024 through 2028 of 7.6 percent for the Applicant. Salaries and wages reflect a CAGR of 7.8 percent from 2023 through 2028.

Service Expenses related to the contrast agents necessary to complete a PET-CT scan reflect the category with the highest growth rate between 2023 through 2028, with a CAGR of 10.3 percent.

⁵⁴ Profitability metrics, such as EBIDA, EBIDA Margin, Operating Margin, Total Margin, and Debt Service Coverage Ratio are used to assist in the evaluation of management performance in how efficiently resources are utilized. Liquidity metrics, such as Unrestricted Cash Days on Hand and Unrestricted Cash to Debt, measure the quality and adequacy of assets to meet current obligations as they come due. Solvency metrics, such as Debt to Capitalization, Total Assets and Total Net Assets, measure the company's ability to service debt obligations.

⁵⁵ except 2028 per test rates are 0.8% higher than 2023 per test rates

The CPA's review of prospective expenses for the Proposed Project, did not find that the underlying inputs warranted adjustment, and concluded that the operating expenses estimated by Management are reasonable.

Capital Expenditures and Cash Flows

In each of the six years, the financial projections show cash surpluses following all scheduled cash distributions and discussions with Management, indicate that distributions could be reduced in the event of a business downturn or interruption to increase the cash reserves of the Applicant.

Factor 4 Analysis

The CPA reported the following assessment: *"Based on our review of the relevant documents and analysis of the Financials, we determined the assumptions used in the preparation of the Financials to be reasonable. Accordingly, we determined that the Proposed Project is feasible and sustainable, and not likely to have a negative impact on the patient panel or result in a liquidation of assets of the Applicant."*

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

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

Under Factor 5 the Applicant shall consider, 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 one alternative to the Proposed Project, continuation of the status quo, which would entail extending the mobile PET-CT contract with the current vendor.

This option was rejected by the Applicant because the status quo does not meet Harrington Hospital patient care standards. It does not meet the efficiency and quality standards that it believes the Proposed Project will provide.

The current vending relationship is not integrated into the UMass operational platform or its electronic medical record (EMR) system, which creates a gap in efficiency. Since Harrington has recently been integrated into UMass, through the Proposed Project there are more opportunities for coordination of care and efficiencies.

The Applicant maintains that retaining the current vending relationship would result in a patient experience that does not meet Harrington Hospital satisfaction, while Shields' operational platform allows for the provision of additional screenings during the same one-day timeframe and the images will be taken on a current generation imaging system so that patients benefit from the higher quality PET-CT scans using this technology.

The Applicant stresses that expanding access to health services is an important step toward reducing health disparities.^{oo} UMMIC's existing technology infrastructure includes streamlined patient access tools that offer pre-registration functionality, and interface with the EMR system that amalgamate necessary patient health information (such as medical history, allergies, and medications). EMR integration allows radiologists to share pertinent diagnostic information with the patient's care team, thereby allowing physicians to track a patient's treatment progress. As such, through the Proposed Project, the Applicant will ensure continuity of care, improved care efficiencies, which can lead to improved health outcomes. Forgoing the opportunity to improve operational efficiency and alignment with the established UMass system, would not yield the most optimal outcomes for patients.

While no additional capital and operating expenses would be incurred in the short term with maintaining the current vending relationship, this option would not allow for the previously described improved care coordination and access barriers for needed imaging services. The Proposed Project will have minimal capital expenditures attributable to a facility buildout, because the mobile PET-CT unit will utilize an existing mobile pad located in a at Harrington Hospital.

Factor 5 Analysis

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project and recognizes that the integration of the Harrington Hospital PET-CT patients into the UMMIC system is the optimal alternative. As a result of information provided by the Applicant and with additional analysis, Staff finds the Applicant has met the requirements of Factor 5.

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

This is a DoN project that will result in a Tier 1 Community-based Health Initiative (CHI). The Applicant, UMass Memorial MRI and Imaging Center, LLC (UMMIC), plans to establish a mobile PET-CT service that constitutes as DoN-Required Equipment acquired by an entity other than a hospital. As such, UMMIC's proposed project does not require the Applicant to submit CHI forms.

As an imaging center, UMMIC will contribute their full CHI contribution to the Community Health Statewide Funds to fulfill Factor 6 requirements. 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 and with the addition of certain conditions, set out below and imposed pursuant to 105 CMR 100.360(A), the Department finds that the Applicant has met each DoN factor and recommends approval of this Application for Determination of Need.

Conditions to the DoN

1. The total required CHI contribution of \$35,034.35 will be directed to the Massachusetts Statewide Community Health Fund.
2. To comply with the Holder's obligation to contribute to the Massachusetts Statewide Community Health Fund, the Holder must submit the payment, a check for \$35,034.35, to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - i. Payment should be sent to:
Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: Ms. Bora Toro
 - ii. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
 - iii. The Holder must promptly notify DPH (CHI contact staff) when payment has been made.

APPENDIX 1: Measures for Annual Reporting

To assess the impact of the Proposed Project, the Applicant has developed the following outcome measures, as well projections for quality indicators that will measure patient satisfaction, access, and quality of care.⁵⁶ The Applicant will report this information to the Department's DoN Program staff as part of its annual report required by 105 CMR 100.310(A)(12) following implementation of the Proposed Project. For all measures, the Applicant will provide to the program a baseline upon implementation of each project component, along with updated projections, which the program will use for comparison with the annual data submitted.

The measures are discussed below:

1. Patient Satisfaction: Patients that are satisfied with care are more likely to seek additional treatment when necessary. The Applicant will review patient satisfaction levels with the PET-CT imaging service.

Measure: To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients receiving imaging services with specific questions around a) satisfaction levels with pre-appointment communication; and b) satisfaction around the wait time for services.

Projections: As the Proposed Project is to establish a new clinic, baseline will be established following one full year of operation.

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

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

⁵⁶ Shields is now using a platform called Podium – a text-based program for patient experience.

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

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

Monitoring: PET-CT scans will be forwarded to the medical records department and follow-up will be conducted to the referring physician. The radiologist will be available to answer any questions.

3. Quality of Care – Quality of PET-CT scan: The quality of a PET-CT scan is imperative to its interpretation. Accordingly, the Applicant will evaluate the number of scans that need to be repeated over the course of a week to ensure radiology technicians are performing appropriate scans. Given that the PET-CT equipment will only be available one-day per week, the next opportunity for a scan would be seven days later.

Measure: The number of repeat PET-CT scans performed on patients within a seven-day period (day of scan to next day of scan)

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

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

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

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

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

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

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

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

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

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

^a 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>

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

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

- ^d U.S. Census Bureau. (2021). *U.S. Census Bureau QuickFacts: Southbridge Town city, Massachusetts*. Www.census.gov. <https://www.census.gov/quickfacts/fact/table/southbridgetowncitymassachusetts/PST045221>
- ^e Census Reporter. (2021b). *Grid View: Table B01001 - Census Reporter*. Censusreporter.org. https://censusreporter.org/data/table/?table=B01001&primary_geo_id=06000US2502763345&geo_ids=06000US2502763345
- ^f U.S. Census Bureau. (2021). *U.S. Census Bureau QuickFacts: Southbridge Town city, Massachusetts*. Www.census.gov. <https://www.census.gov/quickfacts/fact/table/southbridgetowncitymassachusetts/PST045221>
- ^g 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>
- ^h *Ibid.*
- ⁱ Isabel Rauscher, Matthias Eiber, Wolfgang A Weber, Jürgen E Gschwend, Thomas Horn and Tobias Maurer. Positron-emission tomography imaging in urological oncology: Current aspects and developments. *International Journal of Urology*. 2018. 25. Online at: <https://onlinelibrary.wiley.com/doi/10.1111/iju.13779>
- ^j *Ibid.*
- ^k *Ibid.*
- ^l 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>
- ^m Online at: <https://www.cancer-rates.info/ma/>
- ⁿ 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/>
- ^o 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/>
- ^p 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>
- ^q *Ibid.*
- ^r Why early diagnosis of dementia is important. Available online at: <https://www.scie.org.uk/dementia/symptoms/diagnosis/early-diagnosis.asp>
- ^s *Ibid.*
- ^t Johns Hopkins Medicine. Available online at: <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/positron-emission-tomography-pet>
- ^u Jaul E, Barron J. Age-Related Diseases and Clinical and Public Health Implications for the 85 Years Old and Over Population. *Front Public Health*. 2017;5:335. Published 2017 Dec 11. doi:10.3389/fpubh.2017.00335 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5732407/> & Anand SS, Singh H, Dash AK. Clinical Applications of PET and PET-CT. *Med J Armed Forces India*. 2009;65(4):353-358. doi:10.1016/S0377-1237(09)80099-3 Online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4921358/>
- ^v Michael J. McKay, Kim L. Taubman, Farshad Foroudi, Sze Ting Lee, Andrew M. Scott, Molecular Imaging Using PET-CT for Radiation Therapy Planning for Adult Cancers: Current Status and Expanding Applications, *International Journal of Radiation Oncology* Biology* Physics*, Volume 102, Issue 4, 2018, Pages 783-791, ISSN 0360-3016, <https://doi.org/10.1016/j.ijrobp.2018.03.013>.
- ^w Zhuang H, Codreanu I. Growing applications of FDG PET-CT imaging in non-oncologic conditions. *J Biomed Res*. 2015 May;29(3):189-202. doi: 10.7555/JBR.29.20140081. Epub 2015 Mar 8. PMID: 26060443; PMCID: PMC4449487.
- ^x 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/>
- ^y *Ibid.*
- ^z Available online at: https://advis.com/services/independent-diagnostic-testing-facilities/?gclid=CjwKCAiAvaGRBhBIEiWAIY-yMHCMEtjEV0at0jsHbWkZwKZYWZI-ZUwUwvPraR98eltokq-f5V7OwhoCmWwQAvD_BwE
- ^{aa} Forero, et al., supra note 42; Sonis, et al., supra note 44; Bernstein, et al., supra note 44; Kelen, et al., Emergency Department Crowding: The Canary in the Health Care System, *NEJM CATALYST* (2021), available at <https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217>.
- ^{bb} HealthIT.gov. Improve Care Coordination. <https://www.healthit.gov/topic/health-it-basics/improve-care-coordination>

^{cc} Alain Pinsonneault, Shamel Addas, Christina Qian, Vijay Dakshinamoorthy & Robyn Tamblyn (2017) Integrated Health Information Technology and the Quality of Patient Care: A Natural Experiment, *Journal of Management Information Systems*, 34:2, 457-486, DOI: 10.1080/07421222.2017.1334477.

^{dd} HealthIT.gov, <https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/improved-diagnostics-patientoutcomes>

^{ee} 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>

^{ff} 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/>

^{gg} Hendee WR, Becker GJ, Borgstede JP, Bosma J, Casarella WJ, Erickson BA, Maynard CD, Thrall JH, Wallner PE. Addressing overutilization in medical imaging. *Radiology*. 2010 Oct;257(1):240-5. doi: 10.1148/radiol.10100063. Epub 2010 Aug 24. PMID: 20736333.

^{hh} Massachusetts Health Policy Commission. 2018 Annual Health Care Cost Trends Report. Available at <https://www.mass.gov/files/documents/2019/02/20/2018%20Cost%20Trends%20Report.pdf>

ⁱⁱ 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/>

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

^{kk} 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/>

^{ll} *Ibid*.

^{mm} 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>

ⁿⁿ 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

^{oo} 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>