

STAFF REPORT TO THE COMMISSIONER OF PUBLIC HEALTH FOR A DETERMINATION OF NEED

Applicant Name	Shields PET-CT at Emerson Hospital
Applicant Address	700 Congress St., Suite 204, Quincy MA 02169
Filing Date	October 16, 2020
Type of DoN Application	DoN Required Equipment- Expansion of Service
Total Value	\$265,687
Project Number	20081410-RE
Ten Taxpayer Group (TTG)	No
Community Health Initiative (CHI)	\$14,645.35
Staff Recommendation	Approval
Public Health Council	Delegated

Project Summary and Regulatory Review

Shields PET-CT at Emerson Hospital submitted a DoN Application for a mobile positron emission tomography-computed tomography (PET-CT) imaging service and limited associated renovations. This is a newly formed joint venture between Shields Health Care Group and Emerson Hospital that replaces an existing contract with a different vendor for the same service. The capital expenditure for the Proposed Project is \$265,687; the Community Health Initiatives (CHI) contribution is \$14,645.35.

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.

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APPLICATION OVERVIEW

Background

The Applicant, Shields PET-CT at Emerson Hospital, was formed in 2020 as a joint venture between and Shields Health Care Group (Shields) and Emerson Hospital (Emerson, the Hospital) for the purpose of establishing a licensed clinic to provide PET-CT imaging services at an existing site approximately one mile from the Hospital at 54 Baker Avenue Extension, Suite 104 in Concord that will operate one day per week.

Emerson Hospital is a full service regional medical center providing multispecialty services to residents of 25 towns. The Hospital operates 179 beds, with over 300 primary care, and specialty physicians. It has outpatient facilities in Westford, Sudbury and Concord. Emerson currently provides PET-CT services for its patients through a contractual agreement with a mobile vendor, and through this Application, proposes to transition its patients to the new clinic.

Shields owns and operates more than 40 MRI and PET-CT imaging sites throughout New England, of which many are joint venture partnerships with community hospitals. Approximately one third of their New England locations are for Pet-CT in Massachusetts. Many of these sites, as this one will be, are served one or more days per week by mobile units, whereby each site operates under a separate license.

As described further herein, combined PE-CT is a dual modality, diagnostic imaging technology.¹ The Applicant cites peer reviewed articles confirming that PET-CT has been proven effective in diagnosing and staging many cancers and is also clinically effective for diagnosing certain neurological and cardiac conditions. The Applicant documents the need for the service based on existing volume of scans, the disease burden, and demographic projections.

¹ PET provides images of bio-chemical metabolic activity in the body without the anatomical structural information that CT captures. CT provides 3D images with anatomic specificity of bones and tissues within the body. When overlaid, CT images aid in defining the precise location of any metabolic abnormality identified with PET. Both modalities have been in use for several decades. Performed simultaneously, the images provide more accurate picture since there are no changes in patient positioning that would occur if the patient had to undergo each type of scan separately at different times on different units.

OVERVIEW of PROPOSED PROJECT AND FACTOR REVIEW: Shields PET-CT at Emerson Hospital

Description of Proposed Project Component	What's Needed to Meet Factor 1: Demonstration of need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending.	What's Needed to Meet Factor 2: Demonstration of cost containment, improved public health outcomes, and delivery system transformation.	Factors 3, 4 & 5 ²	What's Needed to Meet Factor 6: Demonstration of plans for fulfilling ... responsibilities ... in the DPH Community-based Health Initiatives Guideline.
	Staff Report finds			
	MEETS w/ CONDITIONS	MEETS w/ CONDITIONS	MEETS	MEETS
Proposal of change of service provider for PET-CT to Emerson by Applicant. (Service is currently provided through a different vendor) to address existing Patient Panel needs.	- Report on use of clinical decision support tool - Report on other standard outcome measures including reporting on an efficiency measure designed to limit Low Value Scans.		✓	✓

² 3: Sufficient evidence of compliance and good standing with federal, state, and local laws and regulations

4: Sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Project without negative impacts or consequences to the Applicant's existing Patient Panel.

5: The ... Project, on balance, is superior to alternative and substitute methods for meeting ... Patient Panel needs

Patient Panel³

As stated herein, the Applicant is a newly-formed joint venture and does not have its own patient panel. However, since Emerson is a member of the Applicant and since the proposed service will continue to be operated at the same location as the existing service to ensure continued access for its patients, the Applicant relies on Emerson's patient panel to demonstrate the need for PET-CT services. Emerson and its affiliated physicians are the referral base for the PET-CT service.

Demographic Profile

The patient population to be served by the Applicant is ~100,000 per year. Table 1 below presents Fiscal Year 2019 patient information. The volume of patients served has grown ~4% since 2017 the Applicant reports.

Table 1: Overview of Patient Population

Annual Total Patients (FY19)	100,707
Gender (FY18)	
Male	38%
Female	62%
Age (FY18)	
0-49	49%
50+	51%
Race/Ethnicity (FY18)⁴	
White	95.0%
Other	5.0%
PSA comprised of 18 communities	75%

Staff notes the following observations about these data below:

- **Age** - The 50+ age cohort comprises 51% of patients, and 31% of patients are 60 and older which was the fastest growing age cohort of the patient panel from 2017-2019. The 60 and older patients are the most frequent users of PET-CT services, representing 50% in 2019 and the Applicant reports that the Advisory Board's Demographic profiler projects it will increase 20% by 2024.⁵ The Applicant reports that nearly 50% of all scans are paid by Medicare.⁶
- **Primary Service Area** - The patient panel draws from more than 18 towns. The Applicant reported that ~75% of patients live in Emerson's 18 patient origin communities.⁷

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...(2) If the Proposed Project is for a new facility and there is no existing patient panel, Patient Panel means the anticipated patients

⁴ Based on self-reporting

⁵ Reported by the Applicant

⁶ Typically patients aged 65 and older

⁷ Acton, Westford, Concord, Sudbury, Maynard, Littleton, Groton, Chelmsford, Stow, Bedford, Pepperell, Ayer, Hudson, Boxborough, Harvard, Carlisle, Leominster, and Townsend

- **Race/Ethnicity** - ~95% of the patient population served identifies as white while ~5% identifies as Asian, Asian/Indian, Black or African American.

The payer mix for PET-CT is shown in Table 2 below. The public payer mix including all MassHealth and Medicare, comprises ~40% of all payments. The payment categories *ACO* and *All Other* account for ~3.1% and 4.9% of payments respectively.

Table 2: Payer Mix for PET-CT

	CY17	CY18	CY19	CY20
Non-ACO and Non-APM Contracts				
Commercial PPO/Indemnity	21.1%	20.2%	22.3%	16.9%
Commercial HMO/POS	27.7 %	31.2%	30.9%	36.1%
MassHealth	5.5%	3.9%	1.6%	1.2%
Managed Medicaid ⁸	0.7%	0.2%	0.0%	0.0%
Commercial Medicare	14.0%	11.6%	14.1%	9.2%
Medicare FFS	24.2%	24.6%	24.4%	28.6%
All Other	5.6%	5.5%	5.4%	4.9%
Accountable Care Organization				
ACO/APM	1.2%	2.8%	1.3%	3.1%
Total	100%	100%	100%	100%

Factor 1: Patient Panel

In this section, we assess if the Applicant has sufficiently addressed patient panel need, public health value, competitiveness and cost containment, and community engagement for the PET-CT service. We also evaluate whether the Applicant has demonstrated that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

Factor 1: a) Patient Panel Need

Patient Panel Need

The Applicant attributes the need for PET-CT to two interrelated factors.

1. Need to accommodate Emerson's current PET-CT volume; and
2. Need to address anticipated volume growth resulting from
 - i) A growing aging population which has a higher incidence of those conditions where a scan is indicated.

⁸ For purposes of Payer Data, Managed Medicaid refers to Managed Care Organizations which were largely replaced by Accountable Care Organizations beginning in 2018.

- ii) An increasing incidence of oncologic, cardiovascular and neurologic conditions where PET-CT scans aid in diagnosis and treatment,

1. Need to accommodate existing PET-CT volume

As described in Background section, the current mobile PET-CT services are available one day per week through an existing service contract. As Table 3 below shows, over the three year period 2017-2019, the site experienced a growth in demand for PET-CT services, particularly between 2018 and 2019 when volume increased by 12%.

Table 3: Current PET-CT Volume

Calendar Year	2017	2018	2019	Overall growth rate (2017-2019)
# Scans	350	357	402	14.9%

2. Need to address anticipated volume growth due to:

- i. **Growth in the aging population** - The Applicant asserts there are increasing needs with the aging population whose present conditions may benefit from the use of PET-CT.
 - a. Patients age 50 and older currently make up a significant percentage of overall patients (~50%). Further, by 2035, in Massachusetts, the 65 and older population will represent a quarter of the population.^a
- ii. **Aging increases risk for the following conditions and diseases**
 - a. cancer
 - b. cardiac disease
 - c. neurologic diseases

The Applicant reports the disease burden for the above three risk areas at Emerson Hospital in Table 4 below, noting that nearly 9% of the patient population in Fiscal Year 2019 had underlying cardiovascular conditions while nearly 4% of the patient population had underlying oncologic or neurologic conditions in Fiscal 2019. The majority of scans were performed on oncologic patients.

Table 4: Patients Within Three Specialties Where PET-CT Can Be Selectively Beneficial		
Patient's Condition	# of Patients	% of Total Patient Panel
Oncologic	3,644	4%
Cardiovascular	8,841	9%
Neurologic	3,897	4%
Growth in patients from previous 3 year period 12%		

The five-year utilization projections reflect Shields' historical experience in providing PET-CT at other sites as applied to Emerson's patient panel. Based on feedback from referring physicians and clinical experts, Shields has determined that PET-CT is underutilized in some specialties for diagnosing patients. Based on this information, the Applicant projects an average annual growth rate of 8.2% over 5 years, leveling off at 527 scans in year 5, shown in Table 5 below.

Table 5: Projected PET-CT Volume and Growth Rate

Year	1	2	3	4	5	Avg. Annual % Change
# PET-CT Scans	385	423	465	502	527	8.2%

The current unit, which is operating one day a week, for 8 hours a day,⁹ performs ~402 scans annually which the Applicant reports represents 96% operating capacity. Given that scan volume is projected to increase to 527, and the current unit is near capacity, DoN Staff inquired how this volume could be accommodated. The Applicant responded that the PET- CT unit used for this new joint venture will be more efficient reducing scan times by 40-50%, thereby creating more capacity within the same one day per week time frame. Consequently, the Applicant states, the new joint venture will allow it to better accommodate current and anticipated volume growth.

⁹ Average scan time on the current unit is ~one hour.

Analysis

Staff notes that this volume supports the ongoing need for the provision of a PET-CT service, regardless of which provider is operating the service. The Proposed Project will result in benefits for Emerson, and for patients.

- For Emerson, the Proposed Project will replace one vendor with another, whereby the Hospital has a vested interest in the operations of the facility, which presents opportunities for better efficiencies and integration of services (discussed further under 1c).
- For patients, who through the Proposed Project, gain more timely access to PET-CT services because of the improved throughput of the more efficient unit.

As a result, Staff finds it reasonable to conclude that more appointment slots will be available and improve patient access. Additionally, Staff finds that the historic volume plus the anticipated changes in the patient population, demonstrate sufficient need for the PET-CT service at Emerson Hospital.

Based on a review of the literature and other DoN applications, staff concurs that the majority of demand lies in the 50+ population as incidences of cancer, neurologic, and cardio-vascular conditions increase as the population ages. Further, as the population grows and ages, the need for convenient local access to services becomes more important. As noted earlier within this Report, about one half of Emerson's Patient Panel is over the age of 50 and this cohort is also growing.

Factor 1: b) Public Health Value, Improved Health Outcomes And Quality Of Life; Assurances Of Health Equity

The Applicant states 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 a number of clinical complications, including those within oncologic, cardiac, and neurologic specialties.

The Applicant asserts that the new service will enable it to meet increasingly needed PET-CT services, through the availability of additional time slots from the faster, more advanced technology of the new unit. Applicant asserts that these advancements will contribute to improved health outcomes by reducing wait times to access services for needed scans which may expedite diagnosis and treatment^b of patients, potentially reducing treatment complications and contributing to better health outcomes.^c

The Applicant states that it ensures appropriate use of PET-CT through:

- **Providing the ordering physician with access to the National Comprehensive Cancer Network (NCCN) guidelines** on when to use PET/CT. Shields provides care path algorithms derived from the NCCN guidelines that result in standardized protocols and in turn eliminate redundant testing and ultimately improve patient outcomes.
- **Educational initiatives for referring providers** about the optimal use of PET/CT services to improve care delivery and outcomes. Shields works with providers to help them use the most appropriate and diagnostically accurate tools.

- **Potentially replacing other imaging modalities that provide less specificity.** For example, for patients with suspicious pulmonary nodules, the implementation of PET imaging and/or CT guided core biopsy could help improve diagnostic accuracy and reduce unnecessary surgical procedures¹⁰.

Analysis

The Applicant cites the clinical benefits of access to PET-CT imaging, which is used to diagnose conditions across numerous specialties, including but not limited to cancer, neurologic, and cardiologic disease. Staff confirms these ongoing growing needs, especially for the 65 and over population which comprises about one-third of their patient population:

Staff's research notes the following:

- **Cancer** is the leading cause of death in Massachusetts, with a mortality rate of 142.8/100,000 in 2018.¹¹ Over 80% of new cancer cases are diagnosed in people aged 45-84, with 25% of new cancer cases being diagnosed in people aged 65-74. The median age for a cancer diagnosis is 66.¹³ PET-CT is used to screen for specific cancers, provide information about the stage of a cancer, and to help plan and monitor treatment. Over the 2012-2016 time period, cancer incidence in Massachusetts was 449.7 per 100,000, which is higher than the national average (448.0).¹²
- **Cardiovascular disease** is the second leading cause of death in Massachusetts. PET-CT is used to evaluate a wide range of heart diseases including cardiac masses, and myocardial ischemia or infarction. From 2013-2015, annual rates of myocardial infarction and angina/coronary heart disease diagnosis among adults in MA ranged from 5.2-5.7%, and 4.7-5.8% respectively.²⁴ In 2018, 10.2% of the 65+ age cohort in Massachusetts had coronary artery disease, nearly double the rate of the overall population.²⁵
- **Neurologic diseases** Stroke and Alzheimer's are the fifth and sixth leading causes of death in Massachusetts^d and the United States respectively.^e In Massachusetts, the rate of stroke is 26.5 and the rate of Alzheimer's is 19.9 per 100,000.^f As with all causes of dementia, the risk of Alzheimer's disease increases with age.^{g,h,11} 3% of people age 65-74, 17% of people age 75-84 and 32% of people age 85 or older have Alzheimer's dementia.ⁱ Pet-CT is used to determine the extent and types of neurological diseases brain tumors, epilepsy, Parkinson's and movement disorders, strokes and neuronal Plasticity, dementias including Alzheimer's, neuro-psychology, neuropharmacology.^j

With the implementation of this project, staff finds potential improvement in outcomes for many health conditions that can result from timely access to imaging services, and through using these imaging modalities, early and accurate diagnosis^k. Additional benefits are potential reduced time lost from work and

¹⁰ Nuclear Medicine *Communications*. 2019 May 40 (5) Cost-effectiveness of second-line diagnostic investigations in patients included in the DANTE trial: a randomized controlled trial of lung cancer screening with low-dose computed tomography

¹¹ <https://www.radiologyinfo.org/en/pdf/alzheimers.pdf>

other activities, and, for rapidly changing conditions, valuable clinical information that alters the course of treatment. As a result, patients may have a better healthcare experience.

However, Staff notes that the American College of Radiology has included certain PET-CT uses for post treatment monitoring to its list of potentially overused^l imaging tests whose “necessity should be questioned and discussed” by physicians and patients. Such overuse of imaging may translate into lower quality care as a result of worry, and unnecessary healthcare interventions including follow-up tests, treatments, visits, hospitalizations, and new diagnoses for benign conditions.⁵ These “cascades” clearly present potential harms for patients.^m Staff notes the Applicant has systems in place to ensure that orders have preauthorization. While the Applicant reports that Clinical Decision Support Mechanism (CDSM) guidelines are in use to ensure appropriate scans are ordered, Staff points out that the NCCN guidelines apply to cancer diagnoses only and as described in this report PET-CT has shown clinical utility in other specialties as well. Further, beginning in 2022,¹² providers who order advanced diagnostic imaging services under Medicare Part B will be required to utilize appropriate use criteria (AUC)ⁿ through a qualified CDSM.¹³

Consequently, staff recommends the Applicant report on utilization of the CDSM as required reporting on the impact of the project, to ensure appropriate use of PET-CT imaging. This is described more fully under required reporting at the end of this report.

The Applicant has provided several measures, including wait times to appointments, which may indicate improved outcomes. Staff reviewed the suggested measures and has provided revised annual reporting measures, described fully under Conditions that will become part of the annual reporting to DPH.

Health Equity and Social Determinants of Health (SDOH)

The Applicant provided assurances around health equity and SDOH, within Emerson Hospital services.

Health Equity

The Applicant and its members are committed to the Culturally and Linguistically Appropriate Services (“CLAS”) standards as well as cultural, linguistic, and health equity. The Applicant supports the adoption of the CLAS standards at this new clinic in accordance with the six categories provided in DPH’s guide to CLAS.^o All employees are required to complete CLAS training and testing, and will be required to complete a training course.

The patient’s identified interpreter and translation program needs will be fully integrated into their EHR and accessible to all Emerson providers. All patients will have access to these interpreter services, which alleviate barriers to care and advance health equity. The Applicant describes a number of systems that it utilizes to ensure access to culturally competent staff and interpreter services for all of its patients, including access to certified/qualified interpreters and translators at no cost to patients at all points of clinical contact. Finally, Shields Healthcare Group will add this licensed site to its electronic tracking system

¹² Due to COVID-19, this mandate has been delayed for over one year, it was to have begun on July 1 2020..

¹³ CDSM that is a tool accessible through an online ordering portal which can be integrated with electronic health record (“EHR”) systems.

for patient demographic data collection and annual reporting to the Department. The Applicant anticipates that these activities in toto will help ensure that its clinical and language access services are meeting the needs of its patient population.

Social Determinants of Health (SDoH)

The Applicant will conduct a pre-screening process with all scheduled patients to evaluate SDoH issues relevant to the scan appointment. If a patient states that they require transportation assistance, the Applicant will utilize Roundtrip, which is an all-in-one ride ordering solution designed for care teams. The transportation will be booked at the same time that the appointment is made via the Applicant's scheduling department. Furthermore, if the Applicant's staff is made aware of any other SDoH issue, they will confirm that a request for assistance is needed and refer the patient back to his/her primary care physician ("PCP") for linkage to community-based support (e.g., in the case of hunger and access to food). When applicable, the Applicant will work with the physician hospital organization (PHO) to utilize the services of social workers, counselors and other community-based support services.

Analysis: Health Equity and SDoH

Staff finds that through their planned language access, the Applicant has provided reasonable assurances of improved health equity at its site. Staff notes that the Applicant's CLAS Language Access and Assistive Services Plan, as a new site, must comply with all the requirements and timelines set forth by the Office of Health Equity.

The Applicant has sufficiently described how patients are screened for certain social related health needs. Access to transportation is an important social determinant of health as its availability affects a person's ability to gain access to appropriate well-coordinated healthcare and other services that impact health. The populations most likely to need transport are the elderly, those with disabilities including veterans, and those with low incomes.^p

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

The Applicant reports that it will "combine physician engagement with a strong technology infrastructure to ensure continuity of care, improved health outcomes and care efficiencies." This technology infrastructure encompasses the following:

- Patient access tools that offer pre-registration and price transparency;
- Interface with the hospitals electronic medical record ("EMR") system to amalgamate necessary patient health information, such as medical history, allergies and medications;
- Sharing of pertinent diagnostic information among radiologists and the care teams, so that all physicians, including PCPs may track a patient's treatment and progress.
- Sharing of relevant SDOH information.

Combined, these features reduce inefficiencies of referencing disparate medical records, and help ensure continuity and coordination of care via scheduling and coordination calls, thereby improving the patient experience and referring provider satisfaction.

Analysis

The benefits of better care coordination and integration of EHR across care providers include greater opportunities for providers to collaborate, improve skills, serve patients, increase efficiency and improve health outcomes. As noted above, the Applicant's EHR system will be integrated into the Hospital's system which will enable imaging results and information to be available to primary care and specialty physicians across providers, including PCPs. Review of the literature points to evidence which suggests access to integrated health information technology systems directly impacts health outcomes through reducing fragmentation and improving coordination among care providers.¹⁴ 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.¹⁵

Staff concurs that through the Proposed Project, a reduction in time between physician's office and scan appointments will improve, and records are likely to be better integrated. This should make continuity and coordination of care more efficient, thereby ensuring that timely diagnosis and staging can occur. Additionally, by combining the strengths of existing technological and human resources such as case management and appointment scheduling of both Shields Health Care and Emerson Hospital, the complex individual care needs of patients most likely to use the service, can be addressed more efficiently ensuring better outcomes and improved quality of life.

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 Guideline¹⁴ 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."¹⁵

To ensure sound community engagement throughout the development of the Proposed Project, the Applicant took the following actions:

- Presentation to the Emerson Patient Family Advisory Council (PFAC) on June 25, 2020; and
- Publication of legal notice to the Shields and Emerson websites.

The Proposed Project was presented at Emerson Hospital's Patient Family Advisory Committee ("PFAC") in June, 2020 which seven (7) members attended. The PFAC is comprised of patients of the hospital and their

¹⁴ Community Engagement Standards for Community Health Planning Guideline

¹⁵ DoN Regulation 100.210 (A)(1)(e). <https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf>

family members as well as hospital staff. The discussion included the plans to transition the mobile PET-CT services to a licensed clinic while maintaining the partnership with North Bridge Imaging for reading services; the Applicant's presentation indicated that services would continue to be performed by Emerson staff and patients would not experience any differences during their appointments. However they will see a change in the billing source to reflect the Applicant, and that it will include a lower Independent Diagnostic Treatment Facility IDTF patient charge than they see now with the current hospital-licensed service rates.

Additionally, Emerson sought to engage residents and resident groups through an open community forum. This meeting was held on July 30, 2020 using remote technology. The meeting was attended by 44 people, of which six (6) were Emerson staff, four (4) were members of Emerson's Board of Directors, and 34 were community members. Through the open meeting, the Applicant engaged patients, families and community members in discussions and questioning regarding the Proposed Project.

The Applicant reports that feedback from the PFAC and community forum meetings was positive. Members expressed support for the Proposed Project and did not express any concerns. To ensure appropriate awareness within the community about the Proposed Project, the Applicant also posted the legal notice of the Proposed Project prominently on their websites and reports that to date no comments were received.

Analysis

Staff finds that the Applicant met the minimum required community engagement standard of *Consult* in the planning phase of the Proposed Project.

Factor 1: f) Competition On Price, Total Medical Expenses (TME), Costs And Other Measures Of Health Care Spending

The Applicant asserts that the Project, will not negatively impact TME because the service is an existing service, that will now be licensed differently, as an IDTF clinic, and thus will be reimbursed at rates that are lower than hospital-based rates. Further the Applicant states that the lower IDTF rates offer payers the opportunity to lower patients' deductibles and which lowers TME overall. Consequently, under the proposed arrangement, the Applicant anticipates that TME will decrease.

The service will be managed by Shields as it asserts it is able to operate effectively under lower IDTF rates because their "... operational model allows for improved scheduling, workflow, technology, and customer service. These front-end/access focused optimizations drive efficiency, which in turn drives down cost to provide care, allowing Shields to operate effectively under lower IDTF rates."

The Applicant also asserts that this Proposed Project will have limited effect on costs in the state because by year five, the clinic represents just \$1.2M of annual net revenue, which is a statistically insignificant amount when compared to overall health care spending.

Analysis

It has been established that improving access to care is likely to reduce healthcare utilization and spending.^{s,t} Numerous studies have detailed high costs for unnecessary repeat imaging^u which may be

ameliorated through more appropriate use of all imaging including PET-CT, and better integration of services. For the Proposed Project, reducing unnecessary expenditures related to inefficiencies from lack of service integration, can lead to lower operational overhead and lower healthcare spending, which may reduce TME.

Staff also notes that this project is the replacement of an existing service that is already offered by a different provider, and is not an expansion of days of service. As a result, TME should not increase given the reimbursement model, through the IDTF, is less costly to the system than its current license status as a hospital based service, because for Medicare and most insurances, the new services will be billed and paid through the physician fee schedule.

However, staff notes that excessive imaging remains a concern in the Commonwealth. “Massachusetts ranks 4th in the nation in Medicare spending for imaging..... Some of these imaging services have been shown to have no diagnostic value for certain conditions.^v As noted above, the American College of Radiology has also identified certain use of PET-CT for follow-up monitoring in its list for potentially overused^w imaging tests. One study found that the two year survival rate for patients with esophageal and lung cancers who were asymptomatic but monitored using PET-CT scans to determine if their cancer had returned, showed no difference in survival than those who did not receive scans.^x Staff notes that Medicare pays for three scans during treatment and does not pay for follow-up monitoring unless the physician can demonstrate additional need. One way of assessing the use of unnecessary imaging is evaluating the use of the CDSM.

Staff finds that, while difficult to measure on an individual service-specific level, 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.

Recommended Conditions, and Proposed Measures for FACTOR 1

As a result of information provided by the Applicant and additional analysis, staff finds that with the standard reporting requirements outlined below, the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f). The Applicant proposed specific outcome, and process measures to track the impact of the Proposed Project which staff has reviewed and revised. Staff recommends adding specific reporting measures, described fully under Conditions related to annual reporting on the use of Clinical Decision Support Mechanisms in order to monitor potential overuse of PET-CT imaging.

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

The Applicant discussed how the Proposed Project will align with the Commonwealth’s goal for cost containment, as well as contribute to improved public health outcomes.

Cost Containment

The Applicant states that with the change in service provider for Emerson PET-CT patients, reimbursement rates will be reduced and as a result, total medical expenses (TME) will be reduced. Additionally, it states that cost savings will be realized at the clinic as a result of improved operational efficiencies and the reduction of wait-times due to added appointment slots, which can lead to more timely diagnosis and treatment. The Applicant also asserts that for patients, the Proposed Project may reduce out of pocket expenses if cost savings are passed down by insurers.

Analysis: Cost Containment

Generally, within a facility or system, cost containment can occur in two ways: a) by designing and implementing efficient processes that minimize resource use, including staff time and supplies, thereby controlling per procedure/service operating expenses; and/or b) reducing unnecessary utilization that includes eliminating low value testing while ensuring timely access to the appropriate diagnostic and testing tools. Each of these strategies saves patients and providers time and money, and much of this has already been reviewed in Analysis of Factor 1(f) above. Staff believes the Proposed Project has the potential for the Applicant to maintain or lower certain operating costs through the means described above.

Cost containment on a statewide level is impacted through pricing, which is a function of what providers charge payers and what payers agree to pay. While payment contracts between individual providers and commercial payers are confidential, those among providers and Medicare and Medicaid are relatively transparent. As a result, staff assessed the likelihood that the Applicant's contracts with payers will increase reimbursement rates and due to the relatively¹⁶ small volume of business, found that to be unlikely.

As highlighted in the analyses throughout this report, Staff believes that the project, which is relatively small, may marginally impact healthcare expenditures due to the benefits of better care integration and the provision of services in less expensive setting where the global outpatient IDTF fee is likely less than that of a hospital-based service. Staff also considered the Applicant's assertions around existing strategies to reduce low value utilization through the use of CDSM, radiologist reviews of orders, and precertification. Thus, DoN Staff can conclude that expanding services through the relatively small Proposed Project will likely meet the cost containment factor.

Further, while it is clear that appropriate diagnostic use of advanced imaging can lead to improvements in patient health outcomes for many healthcare conditions, some imaging procedures have been identified as low value care.¹⁷ Because of their high procedural costs, in these instances, imaging procedures can contribute to potentially unnecessary spending on the part of patients and payers. The challenge is to determine the appropriate mechanism to ensure that inappropriate utilization does not drive up costs. As already noted, staff recommends a Condition of reporting on the effectiveness of the CDSM tool and recommends that the required measures for annual reporting include a report on one CMS Outpatient

¹⁶ Given that service is only one day per week.

¹⁷ by the *Choosing Wisely Campaign* <https://www.choosingwisely.org/our-mission/> The mission of Choosing Wisely is to promote conversations between clinicians and patients by helping patients choose care that is: a) Supported by evidence, b) Not duplicative of other tests or procedures already received, c) Free from harm, d) Truly necessary

Imaging Efficiency outcome (conditions 3 and 4). These Conditions may also help ensure inappropriate utilization does not drive up costs.

Improved Public Health Outcomes

The Applicant notes that more available timeslots will improve access to this diagnostic tool and can lead to more appropriate and timely treatments which in turn may reduce morbidity and mortality for numerous diseases and conditions

Analysis: Public Health Outcomes

As detailed elsewhere in this Report, while it is clear that improvements in patient health outcomes result from appropriate diagnostic use of PET-CT for many healthcare conditions, some imaging procedures have been identified as low value care. As noted above, one way of assessing the use of unnecessary imaging is evaluating the effectiveness of the CDSM, for which we have already recommended a Condition.

Delivery System Transformation

As already noted above, the Applicant prescreens patients for social needs relevant to their imaging appointment, and when a patient screens positive for other needs, they are referred back to their PCP for assistance and/or needed referrals. Moreover and as previously stated, this PET-CT service may be more cost effective for patients and ensure better coordination of their care.

Analysis: Delivery System Transformation

Central to the goal of **Delivery System Transformation** is the integration of social services and community-based expertise. The Applicant has described how patients are screened for social related needs during the pre-registration process, and how linkages to social services organizations are created. This process has the potential to improve at least one commonly identified issue related to transportation to and from care. Further, the integration of medical records with the existing PACS system may improve continuity of care for PET-CT patients.

Recommended Conditions, and Description of Proposed Measures, FACTOR 2

As a result of information provided by the Applicant and additional analysis, staff finds that with the standard reporting conditions, 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 finding must be supported by an analysis by an independent CPA.

The CPA examined a range of documents and information in developing its report including Shields Emerson PET-CT DoN six-year Financials prepared July 2, 2020, Shields Emerson payer mix and per-case reimbursement assumptions, Shields Emerson volume assumptions, and the partner's respective websites. Additionally, it calculated key liquidity and operating metrics¹⁸ to assist in determining reasonableness of the Applicant's assumptions.

Revenues

To determine the reasonableness of the prospective revenues, the CPA reviewed the underlying assumptions upon which Management relied. The projected volume was based on a Tumor Registry Analysis, the payer mix was based on Emerson's actual operating results, and reimbursement rates were based on Shields's historical experience. The daily volume of scans are projected to increase from 7.4 to 10.1 (year 5) and then remain steady in Year 6.

The CPA reviewed the budgeted reimbursement rate which was based on a calculated weighted average of Emerson's payer mix and Shields's reimbursement rates. The per-test reimbursement rates remained constant in the projections because contractual rate since increases from payers while possible, are not assured. Based upon its review, the CPA determined the Applicant's projected reimbursement rates and volumes are reasonable, and therefore that the revenue growth "reflects a reasonable estimation of future revenues of Shields Emerson..."

Operating Expenses

The CPA reviewed several expense items including Staffing, Fluorodeoxyglucose Isotope¹⁹ Charges, Support Services, and Marketing Services. It tested them by increasing the expense per case figures by two to three percent annually to evaluate the impact on net income and cash reserves and found this did not have a material impact on the net income or cash reserves.

The equipment, the largest fixed expense, representing ~20 percent of operating revenue annually, will remain constant in years 1 through 6 and, on average, represent 20 percent of operating revenue annually. The financial projections also included bad debt expenses that was higher in the first year to account for a

¹⁸ These are standard financial metrics used in determining the financial health and feasibility of an Applicant. Liquidity ratios measure the quality and adequacy of assets to meet current obligations as they come due. Operating metrics are used to assist in the evaluation of management performance. Additionally, certain metrics can be applicable to multiple categories.

¹⁹ A contrast agent most commonly used in performing PET-CTs.

lag in obtaining reimbursement from Medicare and Medicaid services during the first few weeks of operations while awaiting accreditation from the American College of Radiology (“ACR”).²⁰ Based on their review, the CPA found the operating expenses estimated by the Applicant to be reasonable.

Capital Expenditures and Cash Flows

The CPA also reviewed the capital expenditures and future cash flows for Shields Emerson to determine whether sufficient funds would be available to sustain the operation of Shields Emerson and determined that the prospective capital requirements and resulting impact on the cash flows of Shields Emerson are reasonable.

CPA’s Conclusion of Feasibility

The Financials exhibit an operating margin ranging from 36 percent in year 1 (FY 2021) to 54 percent in year 6 (FY 2026) and positive end of year cash balances in each of the six years presented in the Financials. Based upon its review the CPA determined the financials projections “are based upon feasible assumptions. Accordingly, we determined that the Financials are feasible and sustainable and not likely to have a negative impact on the patient panel or result in a liquidation of assets of Shields Emerson.”

Analysis

Staff is satisfied with the CPA’s analysis of Applicants decision to proceed with the Proposed Project. As a result, Staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

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

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(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 one alternative to the Proposed Project.

- **Maintain the status quo of the existing mobile PET-CT unit.** This was rejected because it would have an overall negative impact on access, efficiency, quality of care, and patient and provider satisfaction. Patients would have fewer appointments available to schedule scans. Additionally, with the old unit there are higher operating costs and no possibility for decreased payer/patient costs that the new unit presents through lower IDTF reimbursement.

²⁰ The Applicant affirms that this is usually obtained within two weeks. <https://www.acr.org/Clinical-Resources/Accreditation>

Analysis

Staff agrees that the improved scan speed of the new unit create more timeslots that improve efficiency and access that improves the patient experience that may reduce time to diagnosis and treatment and could improve outcomes and patient satisfaction with lower costs related.

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

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

Summary and relevant background and context for this application: This DoN project is one of two current DoN Applications under consideration at Emerson Hospital. Given that CHI related activities would be implemented concurrently, the Applicant and DPH have agreed to one Factor 6 analysis for both DoN projects where the combined CHI financial contribution is a Tier 1 CHI project. While there is one CHI analysis, this Staff Report includes only the CHI contribution for the Shields PET-CT at Emerson in the conditions of Approval.

To fulfill Factor 6 for both DoN projects, the Applicant submitted its existing Community Health Needs Assessment (CHNA) for Emerson Hospital, the Hospital's Self-Assessment (combined for streamlining purposes), Stakeholder Assessments, and a CHI Narrative.

The Community Health Needs Assessment was conducted in 2018 by Emerson Hospital, the entity that will implement CHI activities. The final CHNA utilized secondary data sources and primary data gathered from qualitative interviews with key informants and describes data collection methods for each. It also outlines key findings and themes from the service area and participating communities which include barriers to positive outcomes, populations of focus, and health conditions. The CHNA also shares the Hospital's Community Benefits Implementation Plan, based on the Key Finding Issues: Lack of Transportation, At-Risk Adolescents, Growing Aging Population, Cancer, and Mental Health and Domestic Violence.

The Applicant's Self-Assessment provided a summary of community engagement processes and socio-demographic information, data, and highlights related to topics and themes of community needs. Through data analysis, existing surveys, and key informant interviews, the participating community groups and residents identified the key concerns outlined in the 2018 CHNA.

Stakeholder Assessments submitted provided information on the individuals' engagement levels (e.g. their personal participation and role), and their assessment of how the Applicant engaged the community in the community health improvement planning processes. The information provided in these forms was largely consistent with the Applicant's self-assessment.

The Applicant's CHI Narrative provided background and overview information for the CHI processes. The narrative also outlines duties for the advisory and allocation committees, with the planned use of funding

for evaluation and administrative activities. Additionally, the narrative outlines the breakdown of CHI funds and the anticipated timeline for CHI activities.

Staff notes that the timeline, RFP processes, and use of evaluation and administrative funds are all appropriate and in line with CHI planning guidelines. There are however, differences in approach and alignment between the Applicant's existing Community Benefits Implementation Plan and CHI principles. If used as a guide for choosing CHI strategies, the activities outlined in the Implementation Plan will not suffice for meeting Health Priority guideline principles around identifying needs and implementing activities at the root cause level. Based on strategies funded in the Applicant's Implementation Plan, staff has determined, and the Applicant agrees to additional activities to ensure ongoing work with the Community Benefits Advisory Committee (CBAC) aligns with the Health Priorities Guideline. The Applicant will recruit for missing constituencies on the existing CBAC, and DPH will work with it to ensure the group's make up is sufficient to help with decision-making that aligns with Health Priority principles. The Applicant will need additional touchpoints with DPH staff to establish a process for planning and implementation work moving forward. Specifically, DPH will work with the Applicant on community engagement in further needs assessment and outreach, decision making structure, outlining future CBAC meetings, and review of community engagement and RFP processes. Regarding the implementation of specific CHI strategies, DPH will work with the Applicant in moving upstream, and identifying needs at the root cause to support sustainable systems level solutions.

The anticipated timeline for CHI activities includes the first meeting of the Advisory Committee six weeks post approval, identifying the Health Priorities Strategies three months post approval, and releasing an RFP six months post approval, with funding awarded to successful RFP applicants 3-4 months thereafter.

With respect to the administrative funds, the applicant's early plans are to support consultant time, external facilitation, communication, reporting and dissemination of lessons learned and best practices.

Summary Analysis: As a result of information provided by the Applicant and additional analysis, staff finds that with the conditions outlined below, and the ongoing communication on items for improvement outlined above, 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 that, with the addition of the recommended conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project, and recommends that the Department approve this Determination of Need, subject to all applicable standard and Other Conditions.

Conditions

1. Of the total required CHI contribution of \$14,645.35
 - a. \$1,405.95 will be directed to the CHI Statewide Initiative
 - b. \$12,653.58 will be dedicated to local approaches to the DoN Health Priorities
 - c. \$585.82 will be designated as the administrative fee.
2. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$1,405.95 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - a. The Holder must submit the funds to HRIA within 30 days from the date of the Notice of Approval.
 - b. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

The Holder shall provide, in its annual report to the Department, reporting on the following measures, #3 below. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12).

3. In order to demonstrate appropriate use of PET-CT the Holder will report on ordering providers' use of the American College of Radiology (ACR) Clinical Decision Support Mechanism "ACR Select" for Adult imaging orders (or any subsequent CDSM). Holder shall provide, at minimum:
 - a. Percent of all orders where the CDSM was used (denominator = all orders; numerator = those where utilization of the CDSM was documented.)
 - b. Annual data on changes in the use of PET-CT by specialty,
 - c. Include any policy changes instituted as a result of these data (in a, and b).

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