

STAFF SUMMARY FOR DETERMINATION OF NEED
BY THE PUBLIC HEALTH COUNCIL
December 16, 2015

APPLICANT: Shields Sturdy PET-CT, LLC

PROGRAM ANALYST: Lynn Conover

LOCATION: 211 Park St
Attleboro, MA 02703

DATE OF APPLICATION: July 31, 2015

REGION: HSA V

PROJECT NUMBER: 5- 4959

PROJECT DESCRIPTION: Provide mobile PET-CT service one day per week to Sturdy Memorial Hospital.

ESTIMATED MAXIMUM CAPITAL EXPENDITURE:

Requested:	\$389,100 (July 2015 dollars)
Recommended:	\$389,100 (July 2015 dollars)

ESTIMATED FIRST YEAR INCREMENTAL OPERATING COST:

Requested:	\$338,602 (July 2015 dollars)
Recommended:	\$338,602 (July 2015 dollars)

LEGAL STATUS: A regular application for substantial changes in service pursuant to M.G.L. c.111, §.25C and the Regulations adopted thereunder.

ENVIRONMENTAL STATUS: No environmental notification form or environmental impact report is required to be submitted for this project since it is exempt under 301 Code of Massachusetts Regulations 11.00, promulgated by the Executive Office of Environmental Affairs pursuant to Massachusetts General Laws, Chapter 30, Sections 61-62H. As a result of this exemption, the project has, been determined to cause no significant damage to the environment.

OTHER PENDING APPLICATION: None

COMPARABLE APPLICANTS: Shields Signature Imaging, LLC: Project #5-4958

COMMENTS BY THE CENTER FOR HEALTH INFORMATION AND ANALYSIS: None submitted

COMMENTS BY THE DIVISION OF MEDICAL ASSISTANCE: None submitted

COMMENTS BY THE HEALTH POLICY COMMISSION: None submitted

TEN TAXPAYER GROUP(S): None

RECOMMENDATION: Approval with conditions

I. BACKGROUND AND PROJECT DESCRIPTION

Shields Sturdy PET-CT, LLC (“Shields Sturdy” or “Applicant”) has filed a Determination of Need (“DoN”) for a mobile Positron Emission Tomography-Computed Tomography (“PET-CT”) service one day per week. The project includes the renovation of 4,640 gross square feet (“GSF”) for a mobile vestibule area, reception, and bathroom, and has an associated MCE of \$389,100.

The Applicant is a Limited Liability Corporation (“LLC”) established between Sturdy Memorial Hospital (“Hospital”) and Shields Imaging, MA, LLC (“Shields”) for the purposes of providing this PET-CT service one day per week. This service is currently provided by Alliance Imaging (“Alliance”) with the Hospital renting the docking station and pad to Alliance which in turn does all of the scheduling, billing and scanning independently. According to the applicant, the current arrangement does not adequately afford the Hospital the ability to integrate PET-CT with other hospital services, most relevantly, its cancer services. Additionally, this arrangement does not afford the Hospital control over quality, management, and scheduling. As a result, the Hospital sought an experienced imaging provider, Shields, to partner with and operate a licensed clinic at their facility. Based on their current and projected demand, the applicant elected to submit this DoN.

A DoN has been filed as a substantial change in service since the LLC is a new entity even though the service has been provided at the hospital by an independent provider, Alliance Imaging.

II. STAFF ANALYSIS

The application was reviewed for compliance with the November 24, 1998, *Determination of Need Guidelines for Positron Emission Tomography* (“Guidelines”). Since the PET Guidelines were developed in 1998, a number of new clinical applications for PET-CT have been approved for reimbursement by the Center for Medicare and Medicaid Services (“CMS”), which is considered the standard for reimbursement by other third-party payors. As of January 28, 2005, the Medicare Program covers the use of PET-CT for the initial staging and subsequent restaging of a number of cancers as well as for some cardiac and neurological applications.

The combined PET-CT machine uses the capabilities of both diagnostic modalities. CT locates masses in the body, but cannot determine if they are cancerous, while PET can detect cancerous cells using radiopharmaceutical tracers, but cannot precisely pinpoint their location. The current medical literature indicates that the fusion and correlation of these two imaging modalities has resulted in improved surgical planning, assessment of therapeutic response, and radiotherapy planning.

A. Health Planning Process

Through a comprehensive long-range planning process, the member hospital determined that a comprehensive approach to oncology care was needed to better meet the needs of their patients, with PET-CT services being a component of the spectrum of care.

The planning process undertaken by the Applicant included multidisciplinary meetings among clinical and administrative staff from both LLC member parties, a review of the PET-CT medical literature, a need analysis, an estimate of projected volume at the hospital, and financial analyses.

The Guidelines also stipulate that an applicant for PET services, whether a multi-institutional system or a single hospital, involve a tertiary teaching hospital. The hospital has underscored that, while licensed as a single community hospital, it has a clinical affiliation with tertiary provider, Brigham and Women’s Hospital,

thereby providing access to a full range of services. To further assure the high quality of its services, the Applicant has developed a tertiary agreement with UMass Memorial Medical Center for planning and ongoing consultation of this service.

Based on the above analysis, Staff finds the project in conformance with the health planning process of the Guidelines.

B. Health Care Requirements

The Guidelines recommend that applicants proposing to establish a PET service document need for a statewide service area of at least 1.6 million people by demonstrating a minimum demand of 1,250 PET scans annually, and present additional data to supplement the demand analysis. However, Staff notes that in the seventeen years since the Guidelines were promulgated (November 1998), the clinical applications for PET have increased significantly, to the point that reliance on a patient population of 1.6 million to demonstrate need for a single PET unit may underestimate the number of patients who would benefit from PET services. As mentioned previously, Medicare has expanded the number of indications for PET that are reimbursable now, including coverage when participating in clinical studies for certain cancers not previously indicated.

1. Current Volume at Sturdy Memorial Hospital

Given the above mentioned changes in clinical applications and potential for increased volume, Shields Sturdy has relied solely on its actual patient volume (Table 1, below) to determine its ability to meet the minimum volume demand of 1,250 annual scans for the proposed PET unit. When applying the minimum volume requirements of the Guidelines to a one day per week mobile service, that volume is 178.6 scans per year.

Table 1

Actual Scans	
Fiscal Year	Volume
2012	206
2013	180
2014	190

As demonstrated in the table above, the Hospital's current volume exceeds the minimum standards of the Guidelines.

2. Sturdy Memorial Hospital's Service Area

The Hospital reports that it provides health care services predominately to residents of Southeastern Massachusetts and Eastern Rhode Island.

The Hospital reports that 90% of its discharges derive from 9 towns in Southeastern Massachusetts encircling Attleboro. This population of 180,044 is projected to grow 1.12% in the next five years to 182,059.

3. Estimated Number of Scans

a. Cancer Indications

To estimate the demand for PET-CT scans involving cancer patients at the Sturdy Memorial Hospital, utilization rates that are widely accepted by CMS and by the health care industry, were applied by type of cancer to actual 2013 patient encounters at the Hospital. The table below estimates the expected/potential number of scans using this methodology.

Table 2

Cancer Type	FY 2013 Patient Encounters¹	PET/CT Use Rate per Incidence²	Scans Projected
Breast	82	0.5	41
Cervical	25	0.7	17.5
Colorectal	42	1	42
Pancreas	4	1	4
Lung	49	1.8	88.2
Melanoma	13	1.8	23.4
Lymphoma	10	2	20
Esophageal	2	1.3	2.6
Head and Neck Oral Cavity	18	1.3	23.4
Thyroid	3	0.25	0.75
Brain	1	1	1
Renal	22	0.75	16.5
Myeloma	6	1	6
Other			
Total	248		286.35

As seen above, the table projected the number of potential oncology-based scans at the Hospital at 286 scans which is above the number of actual scans performed at the hospital. Therefore, Staff notes that using this historical volume with a modest projected annual increase is a reasonable approach to projecting the volume for this service. This methodology does not impact the service volume of other hospitals in the service area and will not impact market share.

¹ Number of Patients from Sturdy Hospital Tumor Registry FY 2013

² PET Use Rates based on Innovations Center, Health Care Advisory Board, New Technology Brief PET/CT Imaging, 2005 and CareCore National, Criteria for Imaging, August 13, 2014

b. Other Clinical Indications

In addition to the projected scans related to cancer patients detailed above, the Applicant anticipates it will provide PET-CT scans to patients with other clinical indications.

PET-CT imaging is a recognized modality in the diagnosis of certain neurological and psychiatric disorders including dementia and seizure disorders. In 2014, the Hospital identified 364 patients falling within these diagnostic categories. While there is not yet an accepted industry standard use-rate within these diagnoses, the Hospital's neurological and psychiatric caseload indicates that there is a patient sub-group who would benefit from PET-CT scans in addition to their oncology caseload.

Although the Hospital determined that there is cardiology based demand for PET-CT based on their existing patient encounters, the Applicant did not utilize this data to project demand because clinical best practices indicate that PET-CT scans for cardiac disease performed in a mobile device are not a reliable means for diagnosis.

c. Total Projected Scans

Table 3 below shows that the Applicant would provide an estimate of 200 PET-CT scans in FY 2016, a value exceeding the previously discussed minimum volume requirements of the Guidelines which at one day per week is 178.6 per year. Staff notes that this estimate does not include any of the potential volume of scans that could be performed for Psychiatric and Neurological patients, and therefore has determined that despite the slight decline in their current volume over two years, the projected increases, will likely occur due to the anticipated increases in efficiencies gained by the Hospital having more overall control over scheduling and service delivery.

Table 3

PET-CT Projections		
Fiscal Year	Volume	% Increase
2016	200	-
2017	220	9%
2018	242	9%
2019	254	4.7%

3. Existing Resources

Of the approximately 23 existing approved PET or PET-CT scanners in the state, 18 are hospital-based units and five are freestanding mobile units. Staff's review determined that there would be little impact on the projected volume at other hospitals, since the volume projections associated with the previous DoN approvals was based on each institution's existing case mix data specific to those projects, and did not rely on referrals from other providers to meet the minimum volume requirements. Staff has further determined that more than half of the existing PET services are located in the Greater Boston area.

4. Conclusion on Need

Based on the above analysis, Staff finds there is need for the PET-CT unit proposed by the Applicant. Staff finds that, based upon utilization rates derived from the industry practices for PET-CT, and the Hospital's historical utilization of their current contracted mobile PET-CT service, the Applicant's projections are reasonable and exceed the minimum volume of scans required by the Guidelines.

Moreover, in keeping with the non-duplication of service standards of the Guidelines, Staff notes that the proposed project should not have a negative impact on previously approved DoN PET-CT scanners, since the majority of demand for each of the approved PET-CT services, including that proposed by the Applicant, will be generated primarily by patients already served by each institution.

C. Operational Objectives

The Applicant has provided documentation that the proposed PET-CT unit will meet the Standards of the Guidelines.

Staffing Measures of the Guidelines including a Medical Director who is board certified in radiology and experienced in PET –CT technology and radiochemistry.

The service will be staffed to include appropriate levels of full-time equivalents ("FTE's") for a one day per week service that are trained in CPR and who receive ongoing education in PET-CT. Radiologic technologists with documented training in PET-CT imaging will provide support in the areas of Patient preparation, technology operation, and imaging analysis. Trained radiologists will be responsible for reviewing images and interpreting scans.

Since the Applicant's service is a mobile unit, it does not include an onsite cyclotron for preparation of radiopharmaceuticals. As such, the applicant has provided a referral agreement with an independent licensed laboratory.

The Applicant reports that a Clinical Oversight Committee for this service will have responsibilities as outlined in the Guidelines, including the task of reviewing scan quality, providing information on utilization data, clinical data and reporting on clinical efficacy. The Committee will be comprised of representatives from radiology, cardiology, neurology, and oncology with an unaffiliated physician from UMass Memorial Medical Center. None of the committee members will have an equity interest in the Applicant.

The mobile PET-CT scanner, which the Applicant plans to contract for, has received pre-market approval from the Food and Drug Administration.

Support services to patients and families during the course of treatment will be available through Sturdy Memorial Hospital. The Hospital also provides Single-photon emission computed tomography ("SPECT"), CT, Magnetic resonance imaging ("MRI"), ultrasound, diagnostic radiology, oncology, and radiation oncology services on-site, as required by the Guidelines. Additionally, all tertiary services are available through a referral agreement with Brigham and Women's Hospital.

The Applicant has indicated that all clinically appropriate patients will have access to the PET-CT unit regardless of ability to pay. To ensure patient access to the PET-CT unit, Staff is recommending a condition of approval that ability to pay or insurance status should not be considered in selecting or scheduling patients for the service.

Shields Sturdy PET-CT has agreed to work with the Office of Health Equity ("OHE") regarding medical interpreter services and specifically the Applicant shall:

- a) Submit a high priority plan that ensures their capacity to provide timely and competent interpreter services to the OHE three months prior to their inaugural;
- b) Contact the OHE to review their interpreter services operations within the first six months of operations; and,
- c) Enter into agreement with the OHE to provide language access services consistent with the recommendations of the OHE.

Staff finds that the proposed project, with adherence to a certain conditions, meets the operational objectives of the Guidelines.

D. Compliance Standards

Shields Sturdy states that its proposed PET-CT unit will meet all applicable standards of safety and operations standards. Minor renovations will be required at the hospital site which already has a docking pad for use by the mobile PET-CT unit.

Staff finds that the proposed project meets the compliance standards of the Guidelines.

E. Reasonableness of Expenditures and Cost

1. Maximum Capital Expenditure

The requested and recommended MCE is \$389,100 (July 2015 dollars) itemized as follows:

Land Acquisition Cost	\$	-
Building Acquisition Cost		66,100
Construction Contract		125,000
Fixed Equipment NOT in Contract		-
Architectural Cost		34,500
Post-filing Planning & Development		5,000
Major Movable Equipment		<u>158,500</u>
TOTAL CONSTRUCTION COSTS		\$389,100

The proposed mobile PET-CT scanner will require no major renovation other than a bathroom and docking pad upgrade. Staff finds the recommended MCE reasonable, at \$34.36 per GSF, based upon previously approved projects.

2. Reasonableness of Incremental Operating Costs

The requested and recommended incremental operating costs of \$338,602 (July 2015 dollars) for the new PET-CT scanner's first full year of operation (FY 2016), are itemized below, and were based on an estimated 200 scans.

Salaries, Wages, Fringe Benefits	\$34,799
Purchased Services ¹	21,216
Supplies and Other Expenses	249,114

Depreciation	25,950
Interest	<u>7,523</u>
Total Operating Expenses	\$338,602

Other expenses include contracted services of physicians, tertiary physician consultant, and medical physicist, as well as radiopharmaceuticals to be purchased from a licensed commercial supplier to New England area providers, Cardinal Health 414, LLC.

Staff has determined that net revenue for the proposed new PET-CT scanner will be an average of \$2,122 per scan for the first full year of operations (FY 2016). Based on a projected 200 scans, Staff has calculated a cost per scan of \$1,693 and an anticipated break-even point of 300 scans for the new PET-CT unit in its second full year of operation.

Based on the above analysis, Staff finds the requested incremental operating costs reasonable when compared with similar, previously approved projects.

F. Financial Feasibility and Capability

The Applicant will contribute \$174,600 in equity of the recommended capital expenditure of \$389,100 (July 2015 dollars). The remaining 55%, \$214,500 will be financed through a bank loan at an estimated 4% over 5 years. Staff notes that the Applicant's projected fixed charges covered ratio demonstrates a sound financial projection. Since this is a new entity, formed in 2015, no audited financial statements were provided; however, staff anticipates that the Applicant will be subject to further scrutiny from its lending institution.

Staff finds the project financially feasible and within the financial capability of the Applicant.

G. Relative Merit

The Applicant states that it considered the following alternatives to the proposed project:

1. Maintaining Status Quo: A relationship with an existing mobile provider of PET-CT services.
2. Establishing its own PET-CT Service under the hospital license.
3. A relationship with a different existing mobile provider of PET-CT services.

After exploring the potential for developing a relationship with an existing hospital PET-CT provider, the Hospital determined that this would do little to improve access within its service area. The Hospital also rejected the alternative of developing an arrangement with a different mobile PET-CT provider on the basis of the limited control it would exert over location and scheduling. The Applicant also noted concerns with conditions placed by potential providers on certain types of patients, notably inpatients and Medicaid beneficiaries.

Thus, the Hospital determined the alternative of establishing a formal LLC with a reputable PET-CT provider, Shields to be the optimal solution both in terms of improving patient coordination with their existing cancer treatment center and improved patient access.

Staff finds that the proposed PET-CT service meets the relative merit provisions of the Guidelines.

H. Community Health Initiatives

Shields Sturdy PET-CT, LLC has agreed to provide a total of \$19 455 (November 2015 dollars) in one payment to fund community health initiatives (CHI) based on a current needs assessment and in support of a community health improvement plan for the region (as defined by the Office of Community Health Planning and Engagement in collaboration with planning partners). Funds may also support the development of a regional community health assessment with multi-sector involvement. The Applicant will work with the Office of Community Health Planning and Engagement, the Office of Local and Regional Health and other planning partners named by the Office to develop a specific plan and funding allocation which will be consistent with community health improvement planning processes.

Staff found this to be consistent with the Guidelines and has included this provision as a condition of approval for this application.

V. COMPARABILITY ANALYSIS

In reviewing the two comparable applications, the Applicant's and Shields Signature Imaging, LLC, Staff found that both applicants are proposing to establish PET-CT services only one day per week service. Based on each hospital's current service volume, staff notes that each service is independent of the other and therefore finds justification for both projects.

Both of the comparable applications meet, at a minimum, all of the following review factors of the Guidelines: Health Planning Process, Health Care Requirements, Operational Objectives, Standards Compliance, Reasonableness of Expenditures and Cost, Financial Feasibility, Relative Merit and Community Health Initiatives as elaborated elsewhere; and therefore a more detailed comparability analysis was deemed unnecessary and not undertaken.

VI. STAFF FINDINGS

1. Shields Sturdy PET-CT, LLC proposes to lease a mobile Positron Emission Tomography-Computed Tomography ("PET-CT") service one day per week.
2. The project meets the health planning requirements that are consistent with *the Guidelines for Positron Emission Tomography* ("Guidelines").
3. The Applicant has demonstrated demand for the proposed PET-CT service, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The project, with adherence to certain conditions, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$389,100 (July 2015 dollars) is reasonable, based upon on similar, previously approved projects.
7. The recommended incremental operating costs of \$338,602 (July 2015 dollars) are reasonable for a mobile PET-CT unit.
8. The project is financially feasible and within the financial capability of the Applicant.
9. The project meets the relative merit provisions of the Guidelines.

10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.

12. This project is one of two comparable applications filed for single day PET-CT services. When considered alone, each of these applications is capable of being approved, since each has demonstrated demand for PET-CT services. Therefore, an extensive comparability analysis was not undertaken.

VII. STAFF RECOMMENDATION

Based on the above analysis and findings, Staff recommends approval with conditions of Project Number 5-4959 submitted by Shields Sturdy PET-CT, LLC to establish a one day per week Positron Emission Tomography-Computerized Axial Tomography (“PET-CT”) service through lease of a mobile scanner. Failure of the Applicant to comply with the conditions may result in Department sanctions, including possible fines and/or revocation of the DoN. The recommended conditions are as follows:

1. Shields Sturdy, LLC shall accept the maximum capital expenditure of \$389,100 (July 2015 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. Shields Sturdy, LLC shall make an equity contribution of \$174,600 (July 2015 dollars) toward the final approved MCE.
3. Shields Sturdy, LLC shall not consider ability to pay or insurance status in selecting or scheduling patients for PET-CT services.
4. Shields Sturdy PET-CT, LLC has agreed to provide a total of \$19 455 (November 2015 dollars) in one payment to fund community health initiatives to be agreed upon with the Office of Community Health Planning and Engagement and other planning partners named by the Office. Payment will be made in November 2016 with notification to the Office of Community Health Planning and Engagement. Shields Sturdy PET-CT, LLC will also file all reports as required by the Department.
5. Shields Sturdy, LLC shall submit to the DoN Program Director, documentation of the clinical oversight activities of its PET-CT clinical oversight committee for a period of two years following the date of project approval.
6. With regards to its Medical Interpreter Service, Shields Sturdy PET-CT, LLC shall:
 - a. Submit a high priority plan that ensures their capacity to provide timely and competent interpreter services to the Office of Health Equity three months prior to their inaugural;
 - b. Contact the OHE to review their interpreter services operations within the first six months of operations; and,
 - c. Enter into agreement with the OHE to provide language access services consistent with the recommendations of the OHE.
7. Unless otherwise approved by the Department, Shields Sturdy PET-CT, LLC shall provide services only at the approved site and only for one day indicated in this approval. Any request for change in either number of days or specific site served shall require the DoN Director’s approval.

The Applicant has agreed to these conditions.