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Executive Office of Health and Human Services  
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October 4, 2017

Via E-mail and first class mail

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RE: Notice of Final Action  
Project No. 17070616-RE  
Shields PET-CT at Berkshire Medical Center, LLC

Dear Mr. Levine:

This shall serve as notification that, based on the information provided by the Applicant and staff analysis, and pursuant to M.G.L. c. 111, § 25C and the regulatory provisions of 105 CMR 100.000 et seq, including 105 CMR 100.725 (DoN Required Services and DoN Required Equipment), and 105 CMR 100.630(7), I hereby approve the application for Determination of Need ("DoN") filed by Shields PET-CT at Berkshire Medical Center, LLC (Shields or Applicant) to provide mobile positron emission tomography-computed tomography (PET-CT) diagnostic imaging services to patients one day per week at Berkshire Medical Center's (BMC) Hillcrest Campus, 165 Tor Court, Pittsfield, MA 02101 in Pittsfield, Massachusetts.

The project is approved with a maximum capital expenditure of \$556,454 (July 2017 dollars) and an approved gross square footage of 2,800 GSF.

This Notice of Final Action incorporates by reference the Staff Report concerning this Application and is subject to the conditions set forth therein.

Sincerely,

Monica Bharel, MD, MPH  
Commissioner

**STAFF SUMMARY FOR DETERMINATION OF NEED  
FOR DELEGATED REVIEW**

**APPLICANT:** Shields PET-CT at Berkshire Medical Center, LLC

**PROJECT NUMBER:** 17070616-RE

**LOCATION:** 165 Tor Court  
Pittsfield, MA 02101

**DATE OF APPLICATION:** July 6, 2017

**TYPE OF APPLICATION:** DoN Required Equipment (Delegated Review pursuant to 105 CMR 100.630(7))

**Maximum Capital Expenditure:** \$556,454 (July 2017 dollars)

**Project Summary and Regulatory Review**

The Applicant is a newly formed joint venture between Berkshire Health System (BHS) and Shields Health Care Group (Shields) and is known as Shields PET-CT at Berkshire Medical Center, LLC (Applicant). The Applicant requests a Determination of Need (DoN) pursuant to 105 CMR 100.725 (DoN Required Services and DoN Required Equipment)<sup>1</sup> to provide mobile positron emission tomography-computed tomography (PET-CT) diagnostic imaging services to patients one day per week at Berkshire Medical Center's (BMC) Hillcrest Campus, in Pittsfield, MA. The Hillcrest campus is the location of the BMC cancer center, where infusion, radiation therapy and other services are currently provided.

This proposal reflects the provision of PET-CT by a new joint venture which will replace the one day per week mobile PET-CT service currently provided by a different joint venture and located at BMC's main campus, also in Pittsfield, MA, and about 2.7 miles away from the Hillcrest Campus.<sup>2</sup>

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<sup>1</sup> The Department of Public Health (DPH or the Department) uses an inclusion framework (see below) in order to determine what equipment and services require a Notice of Determination of Need. The inclusion framework looks at: Quality: Meaning improved patient health outcomes; Access: Meaning a demonstrable increase in access and reasonable assurances of health equity, including but not limited to a decrease in price; and Cost: Meaning a reduction in the Commonwealth's Total Health Care Expenditure. In consideration of whether the use of specific equipment or service may result in increases in health care spending without associated benefits to the public in terms of improved patient health outcomes or improved access to health care, the Department has included PET-CT in its list of DoN Required Equipment.

<sup>2</sup> Separately, the operator of the existing service, Baystate MRI and Imaging Center ("BMIC"), will move its service from Pittsfield to Springfield, where it will provide service to the patients at the main site of BMIC.

### **Background Info**

BMC is a 298-bed hospital located in Pittsfield MA. It is part of BHS. BHS, in turn, operates facilities and services at multiple locations in Western MA. Shields operates PET-CT services at 13 different locations in Massachusetts and two in Maine. Combined PET-CT is a dual modality, diagnostic imaging technology.<sup>3</sup> The Applicant cites peer reviewed articles for the proposition that PET-CT has been proven effective in diagnosing and staging some cancers and is also clinically effective for certain neurological and cardiac conditions.

The Applicant asserts that co-locating its PET-CT services at the cancer center will improve access, convenience and continuity of care for cancer patients; enhance communication and collaboration among radiologists, oncology clinical multi-disciplinary teams, and primary care physicians; and create efficiencies which ultimately benefit patients.

Between 2014 and 2016, the number of unique individuals utilizing BHS facilities has increased by 4%. BHS attributes this increase to the growth in the 55+ age cohort. The incidence of cancer, cardio-vascular, and neurologic diseases increases with age. The 55+ age cohort is the fastest growing cohort in the region with a projected growth rate of 37.5% by 2035. The BHS patient panel draws from a large geographic area. Approximately 66% of inpatient admissions come from five towns in Berkshire County, and 17% from VT, NY and CT. In Massachusetts, the five year (2010-2014) average incidence (number of new cases) rate of all types of cancer is 462.7 per 100,000 people, and for the 50+ age cohort, it is 1,389.8 per 100,000 people. Berkshire County compares favorably to this rate; the five year average incidence rate (2010-2014) is stable at 438 per 100,000 and for the 50+ age cohort it is 1,322.9 per 100,000 for the same time period.<sup>4</sup>

The Applicant will serve that portion of the BHS patient panel that has 1) cancer, 2) heart disease, or 3) neurologic conditions. In 2016, 9,248 patients having diagnoses within one of those three broad diagnostic categories were treated at BHS as shown below.

<b><u>2016 Patient Panel Diagnosis</u></b>		
		<b>% of total</b>
<b>Diagnosis</b>	<b># Patients</b>	<b>Pt Panel</b>
Cancer	3,093	3%
Cardiac	4,555	4%
Neurologic	1,600	1%

<sup>3</sup> PET provides images of bio-chemical metabolic activity in the body without the anatomical structural information that CT captures. CT provides specificity of bones and tissues within the body which aids in defining the precise location of an abnormality. The combined 3D images provide more accurate anatomic and metabolic images since there are no changes in patient positioning from one modality to another, and, performed in one session, it eliminates the need for the patient to move off of the table to another piece of equipment for another scan, as well as the need to have additional invasive contrast agents administered.

<sup>4</sup><https://www.statecancerprofiles.cancer.gov/incidencerates/index.php?stateFIPS=25&cancer=001&race=00&sex=0&age=136&type=incd&sortVariableName=rate&sortOrder=default#results>

The Applicant refers to relevant demographic data in support of the continuing need for imaging services for a population that is, like much of the area, aging, and has consequently, increased risks for cancer, and cardiac diseases. BHS currently has one day per week service of PET-CT provided by a different PET-CT provider (see, fn. 2, above). The Applicant reports that in 2016 the existing service performed 734 scans on 545 patients. This averages out to about 14 scans per day, once a week. Of the patients utilizing the equipment, a total of 707 scans were for cancer patients, while the combined scan total of 27 were for cardiac and neurologic disorders. Of the 529 cancer patients, 137 of the patients received more than one scan, for a total of 707 scans.

#### Number of Scans by Diagnosis (2016)

Diagnosis	# Scans*	% scans	# Patients having PET/CT scans	Number of patients needing >1 Scans
Cancer	707	96%	529	137
Cardiac	23	3%	12	8
Neurologic	4	1%	4	0
<b>TOTAL</b>	<b>734</b>		<b>545</b>	<b>245</b>

\*based on scan volume from existing PET-CT service patients.

The Applicant provided three years of historical volume for PET-CT services at BHS. In calendar year (CY) 2014, 711 PET-CT scans were performed. In CY 2015, this number decreased slightly to 695 and, in CY2016, increased to 734. The Applicant estimates 750 scans will be performed in CY2017, and indicates that proposed capacity will be sufficient for projected demand in the foreseeable future.

#### Analysis

Applications for DoN Required Equipment or Services are reviewed under the DoN regulation at 105 CMA 100.100. Under the regulation, 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 of the six Determination of Need Factors set forth within 105 CMR 100.210. This staff report addresses each of the six factors in turn. The authority to review and take action upon applications for the certain DoN-required Equipment including Positron Emission Tomography (PET) equipment is delegated to the Commissioner pursuant to 105 CMR 100.630(A)(7).

#### Factors 1 and 2

Factor 1 requires that the Applicant address patient panel need, and that the project add measurable public health value in terms of improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity. Under factor 2 the Applicant must demonstrate that the project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

Income disparity and limited transportation in rural communities are, along with increasing age, factors that may impact access to health care services and health outcomes. In Berkshire County, the percentage of people 55 and over who are below the poverty line is 13%, which exceeds the statewide average of 11.6%.<sup>5</sup> This is higher than the percentage of all ages that are living below the poverty line (9.7% in Berkshire County and 8.2% in Massachusetts).<sup>6</sup> Medicare patients comprise 48% of the patient panel, HMO Blue, 8.3%, and BC/BS 5.39%. The Center for Health Information and Analysis (CHIA) reports that BHS' two acute care hospitals, BMC and Fairview, are high public payer hospitals with public payer mix of 70% and 65.9% respectively.

The significant majority of BHS patients receive scans in connection with cancer diagnosis and treatment.<sup>7</sup> By co-locating the PET-CT at the cancer center the Applicant asserts it will improve the integration of care, and ease access for over 95% of the patients receiving PET-CT who would no longer need to travel to more than one site.

The Applicant points to the BMC Nurse Navigation and Language Access Programs in support of the public health value of this project.

The Nurse Navigation Program was established 15 years ago. It operates under standardized national practice guidelines at no charge to patients. Nurse navigators work one-on-one with patients, from the time of their initial biopsy or new patient appointment to help assess and address barriers and obstacles to receiving care; to advocate for patients to help foster patient autonomy by providing patients with information; to support sound health care choices. The Applicant collects data on the number of patients receiving navigation support, and tracks certain quality metrics.

BHS describes its language access need as an emerging issue. From 2012-2014, the in-person language interpreter program experienced a 59% increase, primarily accessing Spanish interpreters. In anticipation of increasing need, BMC has 11 certified staff and per diem interpreters in four languages, with access to translators in over 170 languages.

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<sup>5</sup><https://www.statecancerprofiles.cancer.gov/map/map.withimage.php?25&001&00008&00&0&3&0&1&5&0#results>

<sup>6</sup>Id.

<sup>7</sup> Patients, other than those with cancer, who may be clinically eligible for scans, comprise less than 3% of the total PET-CT patients (16 patients total in 2016).

BHS's language access and Nurse Navigator programs, already implemented in its cancer center, will be extended to the PET-CT service provided by the Applicant and fully integrated to improve access and reduce barriers to care. As a condition of this approval, the Applicant will include, in its annual reporting, data that support this assertion.

In further support of its factor 1 compliance, the Applicant cites the integration of health information technology such as Electronic Health Records (EHR) and a Picture Archiving Communications System (PACS) which, the Applicant asserts, will improve patient care management including reduced delays for patients to obtain scans, more accurate diagnoses, faster treatment, and reduction in unnecessary other diagnostic tests. Applicant asserts that EHR and the PACS improve communication among the team of providers enabling them to more effectively coordinate care delivery and thereby improve health outcomes.

The Applicant has indicated that it will monitor quality, access, and patient-and provider satisfaction. Separately, and as a condition of approval, the Applicant will include, in its annual reporting, data that supports an assessment of the impact of coordinated care delivery on the several barriers identified by BHS in its Community Health Needs Assessment (CHNA). Those barriers include economic insecurity and transportation.

In support of sound community engagement and consultation, the Applicant states that the proposed project was presented at a monthly BHS Patient and Family Advisory Council (PFAC) meeting<sup>8</sup> and that "PFAC members expressed support for the Project, noting the benefits of having co-located imaging modalities with BMC's cancer center."

The proposed project will be constructed as a part of a separate cancer center project, for which a DoN is not required and which is proceeding through DPH licensure and plan review. As a result, the incremental cost of adding the cement pad to the project is, according to the Applicant, both negligible and competitive when compared to doing a stand-alone project, and will cost \$459,395 less than installing a fixed unit.<sup>9</sup>

The Applicant asserts that as a Medicare-certified independent diagnostic testing facility (IDTF) with lower administrative costs, it will be more cost effective than a hospital-based outpatient clinic. Medicare's fee schedule for PET/CT scans performed at IDTF's is less than at hospital based clinics. No additional capacity is being created for BHS patients, the patient panel will be unchanged from the current service, the Applicant will use the same contracted rates, and the

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<sup>8</sup> The PFAC is a forum for understanding patient and family needs that, according to the Applicant, affords them a "voice in policies, programs, and Practices at BHS." The goals of the group are to 1) ensure that care at BHS is patient and family centered; 2) improve patient safety at BHS, 3) improve collaboration among caregivers, patients and families at BHS, such that their concerns regarding quality of care are addressed promptly and effectively; and 4) provide input from a patient's perspective towards BHS' priorities and planning. The PFAC is comprised of seven patients, a community member, a family member, an Administrative Director, an Operations Director, a Clinical Manager, a Care Navigation Manager, an Oncology Social Worker and an Oncology Dietician for a total of fifteen people.

<sup>9</sup> See, discussion below of the relative merits of the proposed project as compared with other options.

Applicant has asserted that there will be no material impact on provider Total Medical Expense (TME) or costs.

The Applicant has established compliance with factors 1 and 2, in that the proposed project is responsive to patient panel need, is likely to improve coordination of care and access, will be competitive in terms of price and TME, and demonstrates its public health value in that, along with its need base, the project is outcome oriented, and will address health equity.

### Factor 3

Factor 3 requires compliance with relevant licensure, certification, or other regulatory oversight. The Applicant provided sufficient information in the form of its Affidavit of Compliance and other relevant documentation.

### Factor 4

The Applicant engaged an independent certified public accountant to analyze its five year financial projections and the reasonableness of the assumptions used in their feasibility forecast. The CPA indicated in its report to the Department that revenue growth, expenses, capital expenditures and cash flow projections were "feasible and sustainable and not likely to have a negative impact on the patient panel or result in liquidation of assets of Shields Berkshire" and were "reasonable in nature." This analysis meets the requirements of factor 4 of the DoN regulation.

### Factor 5

Factor 5 requires evidence that the Proposed Project, on balance, superior to alternative and substitute methods for meeting the existing Patient Panel needs, taking into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes.

In this case, the options presented were: continuing to provide the service at the hospital campus through the Baystate/Shields joint venture; installing a fixed PET-CT unit; or the proposal here, to co-locate cancer care and the imaging services proposed by this new Berkshire/Shields Joint Venture, at the Hillcrest campus. The Applicant asserts that this proposal will: increase quality through more timely treatment, improved communication, and better care coordination; improve efficiency as the cancer patients will receive all of their services at one location, and the service will benefit from full integration of EHR and PACS; cost significantly less than the cost of the facility and equipment for a fixed unit; and as an IDTF, will generate lower operating costs than a hospital-based fixed unit. Finally, the joint venture through which the services will be provided in this proposal includes revenue sharing between the Applicant and BHS – an arrangement that is not available through the provision of services by the current provider and results in a financial benefit that is absent in the current scenario.

The Applicant has submitted sufficient evidence that the proposed project is superior to alternative and substitute methods for meeting the existing patient panel needs identified by the Applicant, in compliance with factor 5 of the regulations.

#### Factor 6

The Applicant will be contributing \$27,822.70 to the statewide Community Health Initiative fund, in compliance with factor 6 of the regulations.

#### Finding

Based on the information provided by the applicant and staff analysis, and pursuant to 105 CMR 100.630(7), the proposed project, with an approved maximum capital expenditure of \$556,454 (July 2017 dollars) and an approved gross square footage of 2,800 GSF, for a one day per week PET- CT service to be located at 165 Tor Court, Pittsfield, MA 02101, is approved.

All standard conditions pursuant to 105 CMR 100.310 apply.

In addition to the standard conditions, the following conditions shall apply:

1. As a condition of approval, and in connection with the reporting requirement set forth in 100.310(L) the Applicant shall provide baseline numbers regarding:
  - a. the average length of time (for the past six months) that a patient has to wait for a PET-CT from the scheduling date to the date of the scan; and
  - b. the number of patients receiving navigation support.
2. As further conditions of approval, the Applicant will include in its annual reporting:
  - a. an assessment of the impact, if any on the transportation and income disparities reported on in the BHS Community Health Needs Assessment (CHNA)<sup>10</sup>;
  - b. a summary report of the cancer prevention community outreach programs conducted by the Applicant which includes measures, outcomes and monitoring; and
  - c. an update on the baseline measures reported in condition 1, above.
3. The Applicant will report annually to the Department its payer-mix in order to assess financial access to the provided service.

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<sup>10</sup> <https://www.berkshirehealthsystems.org/documents/Health%20Needs%20Assessment/Berkshire%20County%20Health%20Needs%20Assessment%20REVISED%20Nov%202015.pdf>



