



# Massachusetts Department of Public Health Determination of Need Application Form

Version: DRAFT  
3-15-17b

**DRAFT**

Application Type:

Application Date: 07/06/2017 4:29 pm

## Applicant Information

Applicant Name:

Mailing Address:

City:  State:  Zip Code:

Contact Person:  Title:

Mailing Address:

City:  State:  Zip Code:

Phone:  Ext:  E-mail:

## Facility Information

List each facility affected and or included in Proposed Project

1 Facility Name:

Facility Address:

City:  State:  Zip Code:

Facility type:  CMS Number:

## 1. About the Applicant

1.1 Type of organization (of the Applicant):

1.2 Applicant's Business Type:  Corporation  Limited Partnership  Partnership  Trust

1.3 What is the acronym used by the Applicant's Organization?

1.4 Is Applicant a registered provider organization as the term is used in the HPC/CHIA RPO program?  Yes  No

1.5 Is Applicant or any affiliated entity an HPC-certified ACO?  Yes  No

1.6 Is Applicant or any affiliate thereof subject to M.G.L. c. 6D, § 13 and 958 CMR 7.00 (filing of Notice of Material Change to the Health Policy Commission)?  Yes  No

1.7 Does the Proposed Project also require the filing of a MCN with the HPC?  Yes  No

- 1.8 Has the Applicant or any subsidiary thereof been notified pursuant to M.G.L. c. 12C, § 16 that it is exceeding the health care cost growth benchmark established under M.G.L. c. 6D, § 9 and is thus, pursuant to M.G.L. c. 6D, §10 required to file a performance improvement plan with CHIA?  Yes  No

1.9 Complete the Affiliated Parties Form

## 2. Project Description

2.1 Provide a brief description of the scope of the project.

The Applicant is a newly formed joint venture between Berkshire Health System ("BHS") and Shields Health Care Group ("Shields") known as Shields PET-CT at Berkshire Medical Center, LLC ("Applicant"). This joint venture was formed to establish a licensed clinic to provide positron emission tomography ("PET")/computed tomography ("CT") diagnostic imaging services one day per week to BHS' patients ("Proposed Project"). Currently, BHS patients receive PET/CT imaging services through another Shields entity, Baystate MRI and Imaging Center. These services are provided at Berkshire Medical Center's ("BMC") main campus. BHS and Shields have formed a new joint venture, the Applicant, to ensure BHS' patients have access to quality imaging services that are co-located with the BMC Cancer Center to provide a continuum of cancer care services.

Through the Proposed Project, the Applicant will satisfy both existing and future patient panel needs by providing PET/CT imaging services one day per week at BMC's Hillcrest Campus, the site of its Cancer Center. The existing need for PET/CT imaging services for BHS' patient panel is demonstrated by historical volume trends for the current PET/CT provider to BHS, the growth in the number of older patients seeking care at BHS and the increased number of patients with underlying oncologic, cardiac, and neurologic conditions. National statistics indicate the prevalence of cancer, cardiovascular disease, and neurological conditions increase with age. Therefore, the need for these services is expected to expand as the Massachusetts population and BHS' patients within the 55+ age cohort increase.

To meet the need for fully integrated diagnostic cancer services, the Applicant will offer PET/CT one day per week to BHS patients. PET/CT is a dual-modality imaging technique that combines images from PET and CT scans that have been performed at the same time using the same machine. Since a PET scan reveals any abnormal metabolic activity that may be occurring on a molecular level and a CT scan provides detailed pictures of tissues and organs inside the body, combining these scans creates a more complete image than either test can offer alone. Specifically, a PET/CT scan merges the quantitative physiologic and metabolic information provided by stand-alone PET with the complementary anatomic information provided by stand-alone CT to deliver a clinically meaningful integrated data set containing accurately aligned anatomic and functional images.

The Applicant anticipates that the Proposed Project will provide BHS' patient panel with improved local access to integrated cancer services that will directly impact health outcomes and quality of life. Currently, cancer patients receive disjointed care because the PET/CT service is located at the BMC main campus while all other cancer services are at the Hillcrest Campus. The PET/CT that will be available one day per week will be co-located with BMC's Cancer Center at the Hillcrest Campus. BMC's Cancer Center is a comprehensive cancer program that is consolidated at one location providing access to highly-skilled physicians who specialize in all forms of cancer and who work with other clinical professionals to provide team-based care.

BHS' cardiac and neurology patients will also be referred to the Applicant for PET/CT services. Diagnostic technology is crucial for cardiac and neurology patients to determine what treatments are most effective with their anatomy. Given the patient panel's high acuity level around cardiac and neurological diseases, access to PET/CT services will allow clinicians to determine appropriate treatment options that will impact overall health outcomes in a time effective manner.

2.2 and 2.3 Complete the Change in Service Form

## 3. Delegated Review

- 3.1 Do you assert that this Application is eligible for Delegated Review?  Yes  No

3.1.a If yes, under what section?

## 4. Conservation Project

- 4.1 Are you submitting this Application as a Conservation Project?  Yes  No

## 5. DoN-Required Services and DoN-Required Equipment

- 5.1 Is this an application filed pursuant to 105 CMR 100.725: DoN-Required Equipment and DoN-Required Service?  Yes  No

5.2 If yes, is Applicant or any affiliated entity thereof a HPC-certified ACO?

Yes  No

5.3 See section on DoN-Required Services and DoN-Required Equipment in the Application Instructions

## 6. Transfer of Ownership

6.1 Is this an application filed pursuant to 100 CMR 100.735?

Yes  No

## 7. Ambulatory Surgery

7.1 Is this an application filed pursuant to 105 CMR 100.740(A) for Ambulatory Surgery?

Yes  No

## 8. Transfer of Site

8.1 Is this an application filed pursuant to 105 CMR 100.745?

Yes  No

## 9. Research Exemption

9.1 Is this an application for a Research Exemption?

Yes  No

## 10. Amendment

10.1 Is this an application for a Amendment?

Yes  No

## 11. Emergency Application

11.1 Is this an application filed pursuant to 105 CMR 100.740(B)?

Yes  No

## 12. Total Value and Filing Fee

Enter all currency in numbers only. No dollar signs or commas. Grayed fields will auto calculate depending upon answers above.

**Your project application is for:** DoN-Required Equipment

12.1 Total Value of this project:

\$556,454.00

12.2 Total CHI commitment expressed in dollars: (calculated)

\$27,822.70

12.3 Filing Fee: (calculated)

\$1,112.91

12.4 Maximum Incremental Operating Expense resulting from the Proposed Project:

\$851,264.00

12.5 Total proposed Construction costs, specifically related to the Proposed Project, If any, which will be contracted out to local or minority, women, or veteran-owned businesses expressed in estimated total dollars.

## 13. Factors

Required Information and supporting documentation consistent with 105 CMR 100.210

Some Factors will not appear depending upon the type of license you are applying for.

Text fields will expand to fit your response.

### Factor 1: Applicant Patient Panel Need, Public Health Values and Operational Objectives

#### F1.a.i Patient Panel:

Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measure, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status and other priority populations relevant to the Applicant's existing patient panel and payer mix.

The Applicant is a newly formed joint venture between BHS and Shields known as Shields PET-CT at Berkshire Medical Center, LLC. This joint venture was formed to establish a licensed clinic to provide PET/CT diagnostic imaging services one day per week to BHS' patients. Currently, BHS patients receive PET/CT imaging services through another Shields entity, Baystate MRI and Imaging Center. These services are provided at BMC main campus. BHS and Shields have formed a new joint venture, the Applicant, to ensure BHS' patients have access to quality imaging services that are co-located with the BMC Cancer Center to provide a continuum of cancer care services.

As the Applicant is newly formed and does not have its own patient panel, the Applicant relies on BHS' patient panel to determine the need for the Proposed Project. BHS is a private, not-for-profit organization that provides medical care through a network of affiliates, including BMC, the BMC Hillcrest Campus, Fairview Hospital, Berkshire Visiting Nurse Association, BHS physician practices, and long-term care associate, Berkshire Healthcare Systems. BHS serves a diverse patient panel as demonstrated by their demographics data collected for fiscal years ("FY") 2014-2016 (1). Over the last three years, the number of patients utilizing BHS' services has increased from 113,996 unique patients in FY2014 to 118,565 unique patients in FY2016. BHS' patient mix consists of approximately 47.5% males and 52.5% females.

In addition to Massachusetts, BHS provides care to patients from several New England area states, including Vermont, New York, and Connecticut. While there is a sizeable portion of BHS' patient panel that resides outside of Massachusetts (17%), the majority of patients reside in Massachusetts. Focusing solely on Massachusetts residents, the geographic breakdown of BHS' patient population is localized to Western Massachusetts, and more specifically to Berkshire County. Within Berkshire County, the largest number of patients reside in Pittsfield (37.0%), followed by North Adams (11.1%), Adams (6.22%), Great Barrington (6.14%), and Williamstown (5.52%).

The demographic profile for FY2014 – FY2016 shows that the majority of patients within BHS' patient population are 45 years of age or older, and that a significant portion of patients are 65 and older. Specifically, from FY2014 to FY2016, patients in the 45+ age cohort consistently represented between 59% – 61% of BHS' total patient population, and patients in the 65+ age cohort consistently represented between 26% – 29% of BHS' total patient population. These rates are in line with the Berkshire region population statistics (2010 data indicates that 32% of the region's population was 55 and older). The Berkshire region has traditionally attracted a large number retirees, accounting for the large cohort of older individuals in BHS' population. Moreover, the aging patterns of the above-specified areas within Berkshire County demonstrate that most of these areas are densely populated with individuals aged 45-64 (2).

With the addition of an increasing out-migration rate among the teen and young-adult population, it is predicted that by 2035 nearly 44% of the population within the Berkshire region will consist of individuals 55 years of age or over (3). Additionally, population projections provided by the UMass Donohue Institute demonstrate that, in 2035, it is expected that approximately 48% of the total population in Pittsfield will be over 45 years of age; North Adams, 44%; Adams, 56%; Great Barrington, 57%; and, Williamstown, 33% (4). These statistics suggest that the principal cities and towns where the majority of BHS' patients reside will experience a surge in their aging populations in the coming years, and consequently that BHS will continue to serve high percentages of adult and older adult patients in the future.

BHS' payer mix shows a few key insurance companies that provide significant coverage to their patient panel. Medicare tops the list as Medicare beneficiaries represent over 48% of the patient panel, HMO Blue covers 8.3%, and Blue Cross Blue Shield is the next largest payer, covering 5.39% of BHS patients. CHIA reports that BHS' two acute hospitals, Berkshire Medical Center and Fairview Hospital, are considered high public payer hospitals, with a public payer mix of 70% and 65.9%, respectively (5). The significant percentage of Medicare payer representation emphasizes the substantial aging population within BHS' patient panel.

Data based on patient self-reporting collected between FY2014 and FY2016 indicates that BHS' patient panel is largely reflective of a Caucasian/White population. The next largest cohorts of patients self-identify as African American or Black (3.45%) or Hispanic/Latino/Spanish (2.642%). Subsequently, 0.899% of their patients identify as Asian, 0.017% as Native Hawaiian or Pacific Islander, and 0.8862% as Other or Non-Specified. A substantial portion of the patient population (7.8%) chose to either not report their race or identified as a race that was not provided in the surveyed categories. Therefore, it is important to note that the racial composition of BHS' patient panel may be understated.

The Applicant also reviewed the number of PET/CT scans performed for BHS' patients since FY2014. The statistics for the patient panel include: 711 PET/CT scans in calendar year ("CY") 2014, 695 scans in CY2015 and 744 scans in CY2016. The clinic has also projected that 750 PET/CT scans will be conducted in CY2017.

Finally, the Applicant reviewed the number of patients that BHS served during the last three fiscal years who had an underlying oncologic, cardiovascular, or neurologic condition, as the Applicant's research supports the use of PET/CT in these areas. In FY2016, 3,093 BHS patients had an underlying cancer diagnosis, which accounted for approximately 3% of the total patient panel; 4,555 BHS patients had an underlying cardiac condition, which accounted for approximately 4% of the total patient panel; and 1,600 BHS patients had an underlying neurologic condition, which accounted for more than 1% of the total patient panel.

#### F1.a.ii **Need by Patient Panel:**

Provide supporting data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question F1.a.i that demonstrates the need that the Proposed Project is attempting to address. If an inequity or disparity is not identified as relating to the Proposed Project, provide information justifying the need. In your description of Need, consider the principles underlying Public Health Value (see instructions) and ensure that Need is addressed in that context as well.

Through the Proposed Project, the Applicant will satisfy both existing and future patient panel needs by providing PET/CT imaging services one day per week at BMC's Hillcrest Campus. The existing need for PET/CT imaging services is demonstrated by historical volume trends, the growth in the number of older patients seeking care at BHS and the increased number of patients with underlying oncologic, cardiac, and neurologic conditions. Both worldwide and national statistics indicate that the prevalence of cancer, cardiovascular disease, and neurological conditions increase with age (6). Therefore, the need for these services is expected to expand as the Massachusetts population and BHS' patients within the 55+ age cohort increase.

#### Aging Population and Need for PET/CT Services

As discussed above, statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035 (7). While overall statewide population growth will continue to grow at a consistent rate of 3.2% during this period, estimates suggest that certain age cohorts will account for a greater share of the population than others (8). Specifically, within the next 15-20 years, the largest part of the Commonwealth's population growth will be attributable to residents within the 50+ age cohort, and residents that are 65+ will represent roughly a quarter of the Massachusetts population (9). The growth trend is similar in Berkshire County, where BHS is located; by 2035, the percentage of the population in Berkshire County aged 55 and older will increase to nearly 44%, up from 32% in 2010 (10). Adults and older adults similarly comprise the bulk of BHS' patient panel (from FY2014 to FY2016, patients in the 45+ age cohort consistently represented between 59% – 61% of BHS' total patient population, and patients in the 65+ age cohort consistently represented between 26% – 29% of BHS' total patient population). Assuming that the demographic trends within BHS' patient population continue to mirror that of the surrounding region, it is expected that BHS will continue to see growth in the 55+ age cohort that it serves.

As the number of BHS' patients that fall into the 55+ age cohort continues to grow, the need for imaging services, such as PET/CT, becomes more important for detecting, managing, and treating age-related conditions. Research studies and their findings demonstrate that the prevalence of cancer increases with age (11). Persons over 65 account for 60% of newly diagnosed malignancies and 70% of all cancer deaths, the incidence of cancer in individuals over 65 is 10 times greater than in those younger than 65, and the cancer death rate is 16 times greater in patients over 65 compared to younger patients (12). Similarly, it is well-established that age is a leading risk factor for cardiovascular disease and certain neurological disorders (13). With regard to cardiovascular disease, the risk for coronary heart disease increases starting at age 45 for men and at age 55 for women (14). In the realm of neurology, statistics indicate that after age 55, the rate of epilepsy starts to increase; that the incidence of neurodegenerative conditions, such as Parkinson's Disease, increase rapidly over the age of 60 (only 4% of Parkinson's cases are under the age of 50 years); and that the incidence of stroke is greater among people 65+ (66% of people hospitalized for stroke in 2009 were 65+) (15). Accordingly, to ensure that BHS' aging patient panel has access to high quality PET/CT services with proven effectiveness in the fields of oncology, cardiology, and neurology, the Applicant seeks to establish a licensed clinic to provide PET/CT services at BMC's Hillcrest Campus.

#### Need for PET/CT Services for Cancer Patients

In Massachusetts, from 2009 through 2013, there were 183,009 newly diagnosed cases of cancer, for an average annual age-adjusted incidence rate of 480.4 cases per 100,000 persons. Overall, cancer incidence in Massachusetts slightly decreased from 2009 to 2013 (16). The most commonly diagnosed type of cancer in Massachusetts for men during this time period was prostate cancer, followed by cancers of the bronchus and lung, colon/rectum, and urinary bladder (17). Among women in Massachusetts, the most commonly diagnosed cancer types were cancers of the breast, bronchus and lung, colon/rectum, and corpus uteri (uterus). Regarding cancer deaths, from 2009 to 2013, there were 64,543 deaths from cancer among Massachusetts residents, for an average annual age-adjusted mortality rate of 162.9 deaths per 100,000 persons (18). Similar to newly diagnosed cases, cancer mortality in Massachusetts decreased

from 2009 to 2013 (19).

In Berkshire County, cancer is the second leading cause of death for residents. Similar to the state, since 2010 the rates of age-adjusted mortality for cancer have declined in Berkshire County. Specifically, mortality rates of breast, prostate, and colon cancer have continued to decline since 2008 (20). Vigorous early screening and detection programs in combination with treatment advances are thought to be contributing factors. Consequently, the cancer incidence at BHS was 2.2% in 2014 (2,472 patients), 2.1% in 2015 (2,534 patients) and 2.6% in 2016 (3,093). Nationally, PET/CT is most widely used as a diagnostic and therapeutic tool in treating and managing care for cancer patients. PET/CT images taken simultaneously have qualities that surpass that of either modality in a stand-alone imaging setting (21). Given the formation of the new joint venture, BHS will have the ability to seamlessly transition patients from diagnostic care to therapeutic care with the availability of co-located PET/CT services meeting the patient panel's need for integrated cancer services.

#### Cardiac Conditions and the Need for PET/CT Services

According to the 2015 results from the Massachusetts Behavioral Risk Factor Surveillance System, statewide, 5.7% of Massachusetts adults are diagnosed with myocardial infarction and 5.3% are diagnosed with angina or coronary heart disease annually (22). These percentages are similar to figures from previous years, representing a consistent incidence rate trend: in 2013, 5.2% of Massachusetts adults were diagnosed with myocardial infarction, and 4.7% were diagnosed with angina or coronary heart disease; and in 2014, 5.6% of Massachusetts adults were diagnosed with myocardial infarction, and 5.8% were diagnosed with angina or coronary heart disease (23). Moreover, according to the American Heart Association, 12,023 people died of heart disease in Massachusetts in 2013, making heart disease the second leading cause of death (24).

Regarding Berkshire County, circulatory diseases, including all cardiovascular diseases are the leading cause of death for residents (25). The age-adjusted coronary heart disease death rate is 90.8 (per 100,000 persons) (26). While overall cardiovascular disease deaths have shown declines in age-adjusted mortality rates since 2010, cardiovascular disease remains a major healthcare issue for Berkshire County's residents (27). Consistent with area statistics and research findings highlighting the association between age and cardiovascular changes, BHS' patient panel includes a substantial amount of patients with needs related to cardiac care. The cardiac disease incidence at BHS was 3.5% in 2014 (3,980 patients), 3.7% in 2015 (4,449 patients), and 3.8% in 2016 (4,455 patients).

PET/CT images of the heart provide comprehensive information to physicians, allowing for more enhanced management of cardiovascular disease, especially for ischemic heart disease (28). The ability for the heart to recover naturally from ischemic damage decreases with age, and makes older patients more susceptible to injury (29). Where traditional CT and PET scans have unique advantages in diagnosing coronary artery disease, a typical cause of ischemic heart disease, each have their downfalls and result in missed diagnoses or unnecessary invasive procedures (30). Combined PET/CT imaging remains the only technique that yields sufficient information in one procedure to quickly provide all of the necessary information for a physician to make a timely and proper medical decision (31). In a setting where comprehensive acute care and follow-up treatment can be appropriately provided, BHS' cardiology patients would benefit from provider access to PET/CT by allowing for efficient and accurate decision-making in critical situations.

#### Neurological Conditions and the Need for PET/CT Services

Finally, recent studies have placed an increased focus on aging and neurological diseases, such as epilepsy and Alzheimer's dementia. This research provides that the risk of having a seizure increases after the age of 60 (32). Moreover, the incidence rate of Alzheimer's also increases with age. The Alzheimer's Association states that one in ten adults over 65 years of age have Alzheimer's dementia and the incidence of Alzheimer's deaths has increased by 89% between 2000-2014 (33). Patient panel data for BHS' patients provide that 1.3% of patients were treated for neurological issues in FY14, 1.4% in FY15 and 1.4% in FY16. PET/CT has been shown to enhance a clinician's ability to diagnose and effectively treat these diseases.

#### F1.a.iii **Competition:**

Provide evidence that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending. When responding to this question, please consider Factor 4, Financial Feasibility and Reasonableness of Costs.

The Proposed Project has no material impact on provider price, total medical expenses ("TME") or provider costs as the PET/CT services provided by the Applicant are currently offered by another Shields joint venture, Baystate MRI and Imaging Center. Through this Project, PET/CT services will be shifted to a new clinic located at BMC's Hillcrest Campus and provided via a new joint venture, one day per week, allowing ready access for BHS' patients to PET/CT services at the Cancer Center.

The price of PET/CT services (34) as well as the cost (35) of providing these services will remain the same for the new joint venture as no additional imaging capacity will be created via the Applicant's new clinic. The Applicant will utilize the same contracted rates for services that have been previously negotiated for the existing Shields' clinic serving BHS. Additionally, the Applicant's TME, the amount that insurers pay to providers for healthcare services delivered to members, will not be impacted given that no change is occurring to the price or cost of PET/CT services. Furthermore, the Applicant's new clinic represents \$1,445,035 of net revenue annually, which represents

a statistically insignificant amount of the imaging services provided in the state, as well as an immaterial amount when compared to overall healthcare spending. Accordingly, this project will have little to no effect on competition in the market place.

Regarding the competitiveness of the overall capital expenditure, the Applicant received quotes for both the construction and equipment needed for the clinic. Given that the PET/CT pad is being constructed as part of a larger cancer center, the pricing for construction is more cost-effective than creating a stand-alone service. Consequently, the capital expenditure competes on the basis of cost. Additionally, the Applicant compared the overall expenses associated with the proposed joint venture model with the expenses associated with the implementation of a fixed PET/CT unit at BHS. This analysis provides that the facilities and equipment costs associated with implementing a fixed unit at BHS are \$459,395 more than the Proposed Project. For these reasons, the Applicant chose to use a joint venture model.

**F1.b.i Public Health Value /Evidence-Based:**

Provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need that Applicant has identified.

**A. PET/CT as a Screening Modality**

PET and CT are two well-established imaging systems that have been available for clinical use for several decades (36). PET is a noninvasive, molecular imaging technology that measures metabolic activity via detection of radiotracers injected in a patient's bloodstream (37). Specifically, PET studies evaluate the metabolism of organs and tissues inside the body, providing information about how organs and tissues are functioning on a molecular and cellular level (38). While other diagnostic imaging procedures predominantly offer anatomical pictures, PET, as a molecular imaging modality, allows physicians to measure chemical and biological processes (39). Thus, PET may detect biochemical changes in an organ or tissue that indicate the onset of a disease process before symptoms, abnormalities, or anatomical changes related to the disease can be seen with other imaging processes (40). PET may also be used to track treatment progress and is commonly used in the fields of oncology, cardiology, and neurology/neuropsychology (41).

While the function of PET is to provide molecular information, the function of CT scanning is to provide anatomical and structural information (42). A CT scan creates a three-dimensional picture of the inside of the body with an x-ray machine (43). A computer then combines these images into a cross-sectional view that shows any tumors or physical abnormalities in tissue morphology (44). CT scans can be performed on every region of the body and CT images of internal organs, bones, soft tissues, and blood vessels provide greater detail and clarity compared to conventional x-ray images (45). CT scans are performed for a variety of reasons, and are useful in diagnosing disease, trauma, and abnormality; planning and guiding interventional and therapeutic procedures; treatment planning and monitoring the effectiveness of therapy; and screening purposes (46).

PET/CT is a dual-modality imaging technique that combines images from PET and CT scans that have been performed at the same time using the same machine (47). Since a PET scan reveals any abnormal metabolic activity that may be occurring on a molecular level and a CT scan provides detailed pictures of tissues and organs inside the body, combining these scans creates a more complete image than either test can offer alone (48). Specifically, a PET/CT scan merges the quantitative physiologic and metabolic information provided by stand-alone PET with the complementary anatomic information provided by stand-alone CT to deliver a clinically meaningful integrated data set containing accurately aligned anatomic and functional images (49). Moreover, the contemporary acquisition of images reduces spatial differences, such as patient positioning and involuntary motion of internal organs, as well as problems due to misalignment or possible change of disease in the interval between the two imaging procedures, and therefore improves diagnostic accuracy and localization of functional abnormalities (50). As discussed in further detail below, applications of PET/CT include oncologic, cardiovascular, and neurologic/neuropsychologic imaging, areas which the Applicant has identified based on a review of BHS' patient acuity mix as three of the top incidences for which patients need care.

The influence of the combined PET/CT modality provides an unsurpassed level of patient care and patient management (51). In addition to contributing to increased confidence by allowing physicians to better diagnose disease, as well as plan and monitor response to treatment more effectively, a single PET/CT scan also provides convenience for both physicians and patients (52). Integrated PET/CT avoids scanning delays associated with separate or sequential PET and CT and reduces acquisition times, thus leading to increased patient throughput and more efficient instrument utilization (53).

**B. Applicant's Proposed Use of PET/CT**

An analysis of historical volume for PET/CT services at BHS documents that in Calendar Year ("CY") 2014, 711 PET/CT scans were performed. This number decreased slightly to 695 PET/CT scans in CY2015 and rose to 744 in CY2016. The Applicant projects 750 scans will be performed in CY2017. Accordingly, the need for the Proposed Project is established by historical volume trends and projections for future need.

The Applicant, a newly formed joint venture between BHS and Shields Health Care Group, proposes to use the integrated PET/CT unit for part-time clinical use one day per week at BMC's Cancer Center. Use of the PET/CT unit will be restricted to those patients who meet

the clinical protocols for combined PET/CT. A patient's underlying condition and diagnosis will be the basis for determining whether the patient meets appropriate clinical protocols for PET/CT. Among other clinically appropriate applications, the Applicant proposes to utilize the designated PET/CT for oncology, cardiology, and neurology/neuropsychology imaging purposes, as the patient panel data provided by BHS, as well as historical PET/CT volume indicates high oncologic, cardiologic, and neurologic/neuropsychologic disease burden, and as the Applicant's research, outlined below, supports the use of PET/CT in these areas.

### C. Research Supporting the Utility of PET/CT Technology

Research into the various uses and benefits of PET/CT has been ongoing. Studies focus on specific diseases, as well as parts of the body that may benefit from this technology.

#### Oncology

The most well-known and well-documented use of the integrated PET/CT scan is in the field of oncology. The hybrid modality combines PET's incomparable ability to determine the metabolic activity of tissues with CT's high-resolution anatomic information to offer an integrated data set and improve accuracy and localization of many lesions (54). PET/CT is a powerful tool for many types of cancer for the following: detection; establishing staging and determining whether the cancer has spread to other parts of the body; helping physicians and patients decide on a tailored treatment plan; evaluating the effectiveness of treatments, such as chemotherapy or radiation therapy; detecting whether the disease is recurring after treatments are completed; and helping physicians locate an area for a biopsy, if necessary (55).

#### Cardiology

An additional clinical application of PET/CT is cardiovascular disease, which relies on early detection to treat (56). Various PET radiotracers are capable of probing molecular processes and tracking biologic pathways inside the body, making PET a powerful technology for understanding cardiac physiology, myocardial viability, and disease processes (57). In addition, CT produces images of cardiovascular structure (58). Given the utility of both PET and CT imaging systems when used independently, an integrated PET/CT modality provides significant incremental benefits to the data provided by each modality alone (59). Specifically, the hybrid modality's simultaneous quantification of cardiac perfusion and assessment of coronary artery anatomy allows for direct comparison of the extent of stenosis and the severity of obstructed blood flow, and therefore provides a wealth of complementary information in the evaluation of coronary artery disease ("CAD") (60). Moreover, the PET/CT scan provides improved characterization of atherosclerotic plaque and risk stratification in patients, and thus is clinically applicable in staging and managing CAD (61).

#### Neurology

Finally, PET/CT has significant potential in the fields of neurology and neuropsychiatry due to the merging of metabolic and anatomic in one examination. PET/CT can increase understanding of the pathogenesis and mechanism of various conditions, including but not limited to, epilepsy and seizures and autoimmune encephalitis (AE) (62). With regard to epilepsy and seizures, a PET/CT scan provides information both during a seizure and between seizures (63). During a seizure, the hybrid scan shows the area responsible for the seizure as an area of increase glucose use, and between seizures, the hybrid scan shows a characteristic pattern of reduced glucose need (64). In this way, PET/CT imaging is useful for localizing all seizure foci for surgical resection (65). Additionally, research indicates that PET/CT may be helpful in supporting evidence of brain dysfunction in suspected patients with AE (66). Specifically, the integrated data set from the hybrid modality provides useful information regarding brain region hypometabolism and metabolic abnormalities, and thus may represent a sensitive and early biomarker for AE (67).

#### F1.b.ii **Public Health Value /Outcome-Oriented:**

Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.

#### Improving Health Outcomes and Quality of Life

The Applicant anticipates that the Proposed Project will provide BHS' patient panel with improved local access to integrated cancer services that will directly impact health outcomes and quality of life. Currently, cancer patients receive disjointed care because the PET/CT service is located at the BMC main campus while all other cancer services are at the Hillcrest Campus. As a result, patients travel to two locations to receive a full array of cancer services. The availability of PET/CT imaging services is especially advantageous for BHS' cancer patients who are in need of nuclear imaging services. The PET/CT that will be available one day per week on BMC's campus will be co-located with BMC's Cancer Center at the Hillcrest Campus. BMC's Cancer Center is a comprehensive cancer program that is consolidated at one location providing access to highly-skilled physicians who specialize in all forms of cancer and who work with other clinical professionals to provide team-based care. BMC's Cancer Center also comprises state-of-the-art radiation oncology services via two high-speed linear accelerators with robotic components which allow for the rapid creation of complex treatment plans and



customized dose distributions. Through the Proposed Project, cancer patients will be referred and have access to PET/CT technology that will allow for the detection of cancer, establishing the stage of the disease and determine if cancer has metastasized to various organs. Access to high quality, integrated care directly impacts quality outcomes for cancer patients as early detection is key in treating most forms of cancer. Moreover, it is often difficult for cancer patients to travel to different locations to receive the full complement of cancer services given their weakened physical state. Accordingly, access to integrated imaging services improves cancer patients' quality of life in that they may receive a continuum of services at one location, rather than taxing their bodies with travel for services.

BHS' cardiac and neurology patients will also be referred to the Applicant for PET/CT services. Patients that are referred to BMC's cardiology practice for consultation and diagnosis have access to cardiac catheterization and full range of diagnostic tests, as well as comprehensive out-patient care. Diagnostic technology is crucial for cardiac patients to determine what treatments are most effective with their anatomy. Given the patient panel's high acuity level around cardiac diseases and ailments, access to PET/CT services will allow clinicians to determine appropriate treatment options that will impact overall health outcomes (e.g. what procedure is most appropriate, how quickly does the procedure need to be done, etc.) in a time effective manner.

For patients with neurological issues, PET/CT allows clinicians to understand the pathogens of conditions. Access to PET/CT services for these patients allows for better quality health outcomes, as clinicians will have a better understanding of an individual's condition and will be able to provide treatment options in a timely manner. Finally, given that the Applicant is a joint venture with BHS, imaging services will be fully integrated. Studies show that having access to integrated health information technology systems, including integrated picture archiving and communication systems ("PACS") information, has a direct impact on health outcomes as access to a single medical record for patients leads to enhanced care coordination by care teams. Additionally, an integrated medical record allows primary care physicians and specialists to have access to the same patient information, allowing for real-time care decisions, thereby reducing duplication of services and unnecessary testing.

Overall, quality of life is impacted by access to integrated imaging services as patients who are sick or effected by oncology, cardiovascular or neurological clinical issues will have access to integrated services. Having imaging services that are co-located on BMC's Hillcrest Campus allows patients to receive a full complement of cancer care services in one setting. When care is integrated studies show that care outcomes are improved (given that patients access services in a timely manner) and patient satisfaction is increased.

#### Assessing the Impact of the Transaction

To assess the impact of the transaction, the Applicant has developed the following quality metrics and reporting schematic, as well as metric projections for quality indicators that will measure patient satisfaction, access and quality of care. The measures are discussed below:

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

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

Projections: Baseline: 92% Year 1: 92% Year 2: 93% Year 3: 94%

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

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

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

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

Monitoring: PET/CT scans will be forwarded to the BHS film library and follow-up will be conducted to the referring physician. The radiologist will be made available to answer any questions.

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

seven days later.

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

Projections: Baseline: 0% Year 1: 1% Year 2: 8% Year 3: 5%

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

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

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

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

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

5. Access – Backlog Reporting: The Proposed Project seeks to ensure access to PET/CT imaging services. Accordingly, the Applicant will track any backlogs associated with the service.

Measure: The number of times scanning day utilization is greater than 90% and adjustments need to be made to the schedule.

Projections: Baseline: 90% Year 1: 90% Year 2: 89% Year 3: 88%

Monitoring: Applicant’s staff will assess daily hours of service and implement adjustments if necessary.

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

Measure: Confirmation with referral physician about the utility of PET/CT Scans.

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

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

**F1.b.iii Public Health Value /Health Equity-Focused:**

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need-base, please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g. culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

To ensure health equity to all populations, including those deemed underserved, the Proposed Project will not affect accessibility of the Applicant’s services for poor, medically indigent, and/or Medicaid eligible individuals. The existing PET/CT provider does not discriminate based on ability to pay or payor source and the Applicant will continue this practice following the implementation of the Proposed Project. As further detailed throughout this narrative, the Proposed Project will increase access to PET/CT services for all of BHS’ patients.

Additionally, the Applicant will provide effective, understandable, and respectful care with an understanding of patients’ cultural health beliefs and practices and preferred languages. The Applicant has also developed arrangements to offer ongoing education and training in culturally and linguistically appropriate areas for staff. These steps will promote health equity and ensure equal access to PET/CT imaging services.

Language barriers are an emerging issue in Berkshire County, especially in accessing healthcare services with BMC’s In-Person Interpreter Program experiencing a 59% increase in use from FY2012-FY2014 (to primarily address the needs of Latino patients). Accordingly, there are a number of systems in place at BMC to access interpreter services, including access to certified translators (eleven staff and per diem interpreters in four languages) at no cost to patients with limited English proficiency (LEP) at all points of

clinical contact; additional translation services (access to over 170 languages) in less frequently encountered languages are available at all times through Language Assistance lines. Additionally, BMC provides American Sign Language interpreting, as well as in-home interpretations in Spanish, Portuguese and Russian.

Previously, programs that further health equity, such as the identified translation and navigation programs were not fully integrated into PET/CT imaging services, as BHS was not included in the model. Through the Proposed Project, patients will have access to these robust services that alleviate barriers to care. Furthermore, cancer patients will have access to co-located PET/CT and navigation services leading to improved care experiences and quality outcomes.

F1.b.iv Provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

Improved health outcomes and quality of life indicators for BHS' Patient Panel will be achieved through the integration of health information technology tools used by the Applicant, such as electronic medical records and a PACS system. With the growing need for clinical collaboration and access to patient information across modalities and locations, an integrated technology system provides necessary information to multiple clinicians in different settings at one time. Early studies around PACS integration into health information technology systems provide evidence of improvements in clinician efficiency around work practices with quick image availability leading to an impact on clinical decision making. Moreover, communication practices are enhanced allowing for expedited reaction times by clinicians, especially when a patient needs care immediately (68). Accordingly, access to clinical information in real-time leads to process and work-flow changes that improve clinical care and achieve improved health outcomes and more efficient work practices.

F1.c Provide evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, how the Proposed Project will create or ensure appropriate linkages to patients' primary care services.

To ensure continuity of care, improved health outcomes and enhanced quality of life for BHS' cancer patients, BMC has in place a robust care navigation program that provides linkages to patients primary and oncology care, as well as associated services. A cancer diagnosis significantly impacts the lives of a patient and their family/friends. When a patient is struggling to access health services, but is unable due to financial barriers, inaccurate health knowledge, mistrust of the healthcare system, language and cultural barriers or a variety of other barriers, compliance with recommended treatment is compromised. Care navigation helps to address the complexities individuals encounter when entering any health care system. A growing body of evidence suggests that navigation services improve outcomes for those diagnosed with cancer by early identification and resolution of health disparities.

Underserved cancer patients face barriers to care that include financial challenges, lack of knowledge about health screening, and where and how to access care. Many patients report problems with the medical system, including difficulties scheduling or keeping appointments due to a lack of understanding especially in non-English speaking individuals. Emotions such as fear and frustration compound these barriers.

While many programs at hospitals are dedicated to helping underserved and racial and ethnic minorities with poor access to care, even the savviest patients who have medical insurance may be daunted by the complexities of cancer care, and benefit from the help of a navigator. One of the main functions of the navigator role is to oversee and help foster patient autonomy, provide individuals with information to enhance their ability to make sound healthcare choices with the guidance of their physicians. There is an increased sense of confidence concerning risks and benefits of prescribed treatments when patients and their families take an active role. This is done in an interdisciplinary team setting. Often patients are receiving a cancer diagnosis while undergoing treatment for other conditions, utilizing multiple providers. A nurse navigator supports the team approach by empowering the patient and connecting the patient to needed resources, including tools to address the social determinants of health, testing and psycho-social supports. At BMC contact by a navigator is established at the time of a biopsy or at a new patient appointment to assess and address barriers and obstacles to receiving care. This confidential service is provided at no cost. Patients are followed through the continuum of care from diagnosis to survivorship or to end of life care. BMC's customized Distress Tool which includes practical, emotional, physical and nutritional concerns is administered by a nurse navigator at the initial visit and then again at the time of survivorship care planning. Patients receiving chemotherapy or radiation therapy are transitioned to the care of the nurses covering those services. Once treatment is completed, a nurse navigator provides a survivorship care plan that was approved by the physician to appropriate patients.

F1.d Provide evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

The Applicant sought to receive input from various stakeholders in the planning of this Project. Consequently, the Applicant carried out a formal consultative process with individuals at various regulatory agencies regarding the Proposed Project. The following individuals were consulted regarding the Project:

- Nora Mann, Esq., Director, Determination of Need Program, the Department of Public Health

- Ben Wood, Director, Office of Community Health Planning and Engagement
- Christopher King, MassHealth
- David Garbarino, MassHealth
- Health Policy Commission, Material Change Notice

F1.e.i Process for Determining Need/Evidence of Community Engagement: For assistance in responding to this portion of the Application, Applicant is encouraged to review *Community Engagement Standards for Community Health Planning Guideline*. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the Proposed Project.

Currently, the services proposed in this Project are provided by a Shields' joint venture that does not include BMC. This clinic provided 711 PET/CT scans in CY14, 695 in CY15 and 744 in CY16 and is projected to provide 750 in CY17. Accordingly, the need for the Proposed Project has been established by the existing image services. However, to inform and consult the community about the proposed Project, including a change in the provider, the Applicant sought to engage its patient panel. As a first step in the engagement process, the Proposed Project was presented to BHS' Patient and Family Advisory Council ("PFAC"). The PFAC is an important forum for understanding patient and family needs and allowing them to have a voice in the policies, programs and practices at BHS. The Applicant chose to consult the PFAC on this initiative, as the goals for this group include: (1) ensuring that care at BHS is patient and family centered; (2) improving patient safety at BHS; (3) improving collaboration between caregivers, patients and families at BHS, such that their concerns regarding quality of care are addressed promptly and effectively; and (4) providing input from a patient's perspective towards BHS' priorities and planning. During the June PFAC meeting, BHS leadership presented on the Proposed Project informing PFAC members of the need for the project and the services that will be offered by the Applicant. At this time, PFAC members expressed support for the Project, noting the benefits of having co-located imaging modalities with BMC's Cancer Center.

Furthermore, to ensure awareness within the community about the Proposed Project, BHS and Shields posted the legal notice associated with the Project prominently on their web sites. This action brings awareness of the Proposed Project to all patients, local residents and resident groups, informing them of the new availability of co-located services. It also provides an opportunity for patients to comment on the proposed project.

F1.e.ii Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value".

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

- Presentation to the BHS PFAC
- Publication of legal notice to the BHS and Shields web sites.

For detailed information on these activities, including an agenda and meeting minutes for the PFAC meeting, see Appendix 9.

To ensure appropriate engagement of the community on the Proposed Project, the Applicant developed a presentation for the June BHS PFAC meeting that outlines the imaging needs of BHS' patient panel, the services that will be offered by Shields PET-CT at Berkshire Medical Center; the process by which the organizations determined that a joint venture was the mostly clinically sound and cost-effective alternative for meeting the imaging needs of the patient panel and the impact of the transaction, including the public health value.

## Factor 2: Health Priorities

Addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

### F2.a **Cost Containment:**

Using objective data, please describe, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment.

The goals for cost containment in Massachusetts center around providing low-cost care alternatives without sacrificing high quality. The Proposed Project seeks to align with these goals by providing a lower cost option for patients in Berkshire County seeking PET/CT imaging services. The Applicant through the Proposed Project seeks to replace the existing imaging service that serves BHS. As previously discussed, the price of PET/CT services, as well as the cost of providing these services will remain the same for the new joint venture as no additional imaging capacity will be created by the Applicant's new model. Moreover, TME will not be impacted given that no change will be occurring to the price or cost of PET/CT services. Accordingly, given no overall change in price, cost or TME, the Proposed Project will not impact total healthcare expenditures within the state thereby having a negligible effect on the overall health benchmark for the state.

Additionally, the Proposed Project meets the goal of providing a lower-cost alternative for PET/CT imaging services as services will be provided by an independent diagnostic testing facility ("IDTF"), rather than a hospital-based outpatient clinic. IDTF's are a more cost-effective option as the administrative costs for these types of providers are lower. This difference in fees will allow the Applicant to provide cost-effective, quality imaging services to BHS' patients, while having a negligible impact on the overall healthcare market.

### F2.b **Public Health Outcomes:**

Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

In Massachusetts, from 2009 through 2013, there were 183,009 newly diagnosed cases of cancer, for an average annual age-adjusted incidence rate of 480.4 cases per 100,000 persons (69). Overall, cancer incidence in Massachusetts slightly decreased from 2009 to 2013 (70). To continue this trend, it is imperative that Massachusetts' residents, especially elderly residents, have access to integrated cancer care and diagnostic imaging services. Studies have shown that the prevalence of cancer increases with age (71). For elderly residents, integrated services enable and incentivize them to seek care as traveling to two locations is often not appropriate nor feasible. Through the Proposed Project, BHS' patients will have access to integrated imaging services at BMC's Cancer Center on the Hillcrest Campus. These co-located services afford patients the opportunity to receive a continuum of services in one location. Consequently, access to integrated services will have a direct impact on when patients seek treatment (e.g. wellness/prevention appointments versus when they become symptomatic) thereby allowing for early detection and treatment. When cancer is detected at an early stage, health outcomes, including mortality are improved (72). By improving health outcomes for patients in the Berkshire region, the Commonwealth will see improved health outcomes for cancer patients overall.

Similarly, access to diagnostic testing for cardiac and neurologic testing, such as PET/CT can increase understanding of the pathogenesis of various conditions. PET/CT is also a powerful clinical tool when trying to determine disease state. Accordingly, access to PET/CT after a cardiac or neurologic event allows clinicians to make timely clinical decisions that impact overall health outcomes, such as mortality. Through local access to these services, patients will be evaluated in an expedited manner, allowing for improved health outcomes in the county and the state.

### F2.c **Delivery System Transformation:**

Because the integration of social services and community-based expertise is central to goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

Over the past decade, mortality rates for most of the major disease categories have been trending downward. However, Berkshire residents are still beset by health challenges that affect their daily lives and their overall well-being. Many of these challenges are related to the social determinants of health. The social determinants of health are "the conditions and environments in which people are born, grow, live, eat, work and age, as well as their access to the healthcare system" (73). Socioeconomic status, education, employment, housing, food security, transportation and social protective factors, all have an impact on the physical and mental well-being of the population, including the circumstances people find themselves in, and in many cases the life choices they make or are forced to make, such as choosing between seeking care or purchasing food.

To address issues associated with the social determinants of health and to ensure all patients have equal access to care, BMC has developed a robust nurse navigation program that facilitates linkages to social service organizations, as well as to clinical services, such as collaborative relationships with primary care clinicians for cancer patients. In 2014, the BMC Care Navigation Department was integrated into the BMC Cancer and Infusion Center where these services have become available to all newly diagnosed oncology

patients.

One of the main functions of the nurse navigator role is to help provide individuals with information to enhance their ability to make sound health care choices with the guidance of their physicians. As part of an interdisciplinary care team, the nurse navigator helps to empower patients by fostering patient autonomy in care decisions. Additionally, nurse navigators connect patients with necessary resources, including referrals for social supports. Patients are followed through the continuum of care from diagnosis to survivorship or to end of life care. BMC's customized Distress Tool is administered by the nurse navigator at the initial visit and then again at the time of survivorship care planning.

Given the success of the nurse navigator program, through the Proposed Project, the Applicant will determine whether replicating the nurse navigation program to additional practice areas is appropriate and feasible. Additionally, BMC will determine what role the hospital's community worker program may have in assessing patient panel needs and creating linkages to social service organizations to address the social determinants of health. Once a thorough review of all options has been conducted, a determination will be made by hospital leadership as to how to refer patients to resources that may address the social determinants of health. BMC staff will then provide a recommendation to the Applicant.

### Factor 3: Compliance

Applicant certifies, by virtue of submitting this Application that it is in compliance and good standing with federal, state, and local laws and regulations, including, but not limited to M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder, and in compliance with all previously issued notices of Determination of Need and the terms and conditions attached therein .

F3.a Please list all previously issued Notices of Determination of Need

Add/Del Rows	Project Number	Date Approved	Type of Notification	Facility Name
<input type="checkbox"/> + <input type="checkbox"/> -				

**Factor 4: Financial Feasibility and Reasonableness of Expenditures and Costs**

Applicant has provided (as an attachment) a certification, by an independent certified public accountant (CPA) as to the availability of sufficient funds for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel.

**F4.a.i Capital Costs Chart:**

For each Functional Area document the square footage and costs for New Construction and/or Renovations.

Add/Del Rows	Functional Areas	Present Square Footage		Square Footage Involved in Project				Resulting Square Footage		Total Cost		Cost/Square Footage	
		Net	Gross	New Construction		Renovation		Net	Gross	New Construction	Renovation	New Construction	Renovation
				Net	Gross	Net	Gross						
+ -	Mobile PET/CT Support Areas	900	2,800	0	0	900	2,800	900	2,800	\$0.00	\$556,454.00	\$0.00	\$198.73
+ -													
+ -													
+ -													
+ -													
+ -													
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	Total: (calculated)	900	2,800	0	0	900	2,800	900	2,800	\$0.00	\$556,454.00	\$0.00	\$198.73



F4.a.ii For each Category of Expenditure document New Construction and/or Renovation Costs.				
	Category of Expenditure	New Construction	Renovation	Total (calculated)
	<b>Land Costs</b>			
	Land Acquisition Cost	\$0.	\$0.	\$0.
	Site Survey and Soil Investigation	\$0.	\$0.	\$0.
	Other Non-Depreciable Land Development	\$0.	\$0.	\$0.
	<b>Total Land Costs</b>	<b>\$0.</b>	<b>\$0.</b>	<b>\$0.</b>
	<b>Construction Contract (including bonding cost)</b>			
	Depreciable Land Development Cost	\$0.	\$0.	\$0.
	Building Acquisition Cost	\$0.	\$56000.	\$56000.
	Construction Contract (including bonding cost)	\$0.	\$229000.	\$229000.
	Fixed Equipment Not in Contract	\$0.	\$0.	\$0.
	Architectural Cost (Including fee, Printing, supervision etc.) and Engineering Cost	\$0.	\$38547.	\$38547.
	Pre-filing Planning and Development Costs	\$0.	\$2500.	\$2500.
	Post-filing Planning and Development Costs	\$0.	\$2500.	\$2500.
Add/Del Rows	Other (specify)			
<input type="checkbox"/> + <input type="checkbox"/> -	Other - IT Cost	\$0.	\$20000.	\$20000.
	Net Interest Expensed During Construction	\$0.	\$0.	\$0.
	Major Movable Equipment	\$0.	\$207907.	\$207907.
	<b>Total Construction Costs</b>	<b>\$0.</b>	<b>\$556454.</b>	<b>\$556454.</b>
	<b>Financing Costs:</b>			
	Cost of Securing Financing (legal, administrative, feasibility studies, mortgage insurance, printing, etc)	\$0.	\$0.	\$0.
	Bond Discount	\$0.	\$0.	\$0.
Add/Del Rows	Other (specify)			
<input type="checkbox"/> + <input type="checkbox"/> -		\$0.	\$0.	\$0.
	<b>Total Financing Costs</b>	<b>\$0.</b>	<b>\$0.</b>	<b>\$0.</b>
	<b>Estimated Total Capital Expenditure</b>	<b>\$0.</b>	<b>\$556454.</b>	<b>\$556454.</b>

## Factor 5: Relative Merit

F5.a.i Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant 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.

### Proposal:

The Proposed Project is for the licensure of a clinic to provide PET/CT imaging services, one day per week at BMC's Hillcrest Campus for BHS' patients. This Project will replace the existing imaging service that serves BHS' patients.

### Quality:

The Proposed Project is a superior alternative for quality PET/CT imaging services and improved health outcomes as patients will have access to co-located imaging and cancer care services at BMC's Hillcrest Campus. Providing services that are co-located improves quality in two ways: 1) Patients that seek services from two locations often delay or forgo treatment given the inconvenience. Specifically, for the large number of elderly patients within BHS' patient panel, co-located services afford access to a continuum of care locally; 2) Additionally, when diagnostic modalities are co-located with treatment services, communication is fostered between referring physicians and radiologists and this impacts care as clinicians may collaborate on treatment decisions.

### Efficiency:

The co-location of services leads to more efficient care as patients may receive all of their necessary services at one location, rather than traveling to multiple clinics for services. Additionally, administrative efficiencies are achieved through the integration of electronic medical records and the PACS system that may be accessed by BHS and Shields.

### Capital Expense:

Through the Proposed Project, the Applicant will provide PET/CT services, one day per week to BHS patients using a mobile unit. The facilities and equipment related costs for this model are \$218,782. However, if BHS were to implement a fixed unit at the hospital, the facilities and equipment costs would be approximately \$460,000, over 50% more than the joint venture model. Accordingly, the Proposed Project is more cost-effective.

### Operating Costs:

The operating costs associated with the Proposed Project are less than the costs associated with implementing a fixed PET/CT unit at BMC as the facility fees associated with running the IDTF are less than those for a hospital outpatient imaging facility. Moreover, as a member of the joint venture, BMC will receive a financial benefit from the new clinic, allowing the hospital to fund critically needed programs for the underserved. Previously, imaging services provided to BHS' patients did not include the system as a co-venturer. This new model allows BHS to more fully participate in the financial aspects of the model.

List alternative options for the Proposed Project:

### Alternative Proposal:

The alternative option for the Proposed Project would be to implement a fixed PET/CT unit at BMC operated as a hospital service.

### Alternative Quality:

This is not a superior alternative for quality purposes as the unit would be located at the main hospital, rather than co-located at the Hillcrest Campus with BMC's Cancer Center. The benefits of having co-located services are outlined in the Proposal Section above for both patients and clinicians.

### Alternative Efficiency:

A fixed PET/CT unit at BMC would provide local access to PET/CT services. However, to justify the purchase of the modality, BMC would need to provide evidence of a significant increase in utilization, which is not feasible given the documented needs of the patient panel.

### Alternative Capital Expense:

Installation and implementation of a fixed PET/CT until will be more than 50% of the costs for a mobile unit. Please see the Proposal above for additional information.

**Alternative Operating Costs:**

The creation of a IDTF to provide these PET/CT services is a lower-cost, high quality alternative to the implementation of a hospital-based outpatient imaging clinic as the facility costs associated with operationalizing an IDTF are lower that the costs for a hospital-based outpatient imaging clinic.

Add additional Alternative Project

Delete this Alternative Project

F5.a.ii Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant 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.

Please see the above section for additional information.

## Documentation Check List

The Check List below will assist you in keeping track of additional documentation needed for your application. Once you have completed this Application Form the additional documents needed for your application will be on this list. E-mail the documents as an attachment to: [DPH.DON@state.ma.us](mailto:DPH.DON@state.ma.us)

- Copy of Notice of Intent
- Affidavit of Truthfulness Form
- Scanned copy of Application Fee Check
- Affiliated Parties Table Question 1.9
- Change in Service Tables Questions 2.2 and 2.3
- Certification from an independent Certified Public Accountant
- Notification of Material Change
- Articles of Organization / Trust Agreement
- Limited Liability Company agreement
- Partnership agreement
- Trust agreement
- Current IRS Form, 990 Schedule H CHNA/CHIP and/or Current CHNA/CHIP submitted to Massachusetts AGO's Office
- Community Engagement Stakeholder Assessment form
- Community Engagement-Self Assessment form

## Document Ready for Filing

When document is complete click on "document is ready to file". This will lock in the responses and date and time stamp the form.

To make changes to the document un-check the "document is ready to file" box. Edit document then lock file and submit

Keep a copy for your records. Click on the "Save" button at the bottom of the page.

To submit the application electronically, click on the "E-mail submission to Determination of Need" button.

**This document is ready to file:**



Date/time Stamp: 07/06/2017 4:29 pm

E-mail submission to  
Determination of Need

**Application Number: -17070616-RE**

**Use this number on all communications regarding this application.**