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

DoN Project Number	17111513-HE
Applicant Name	Partners HealthCare System, Inc.
Applicant Address	800 Boylston Street, Suite 1150, Boston, MA 02199
Date Received	November 15, 2017
Type of DoN Application	Capital Expenditure
Maximum Capital Expenditure (MCE)	$73,186,747
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	$3,659,337.35
Staff Recommendation	Approval with conditions
Public Health Council (PHC) Meeting Date	March 6, 2018

PROJECT SUMMARY AND REGULATORY REVIEW

Partners HealthCare (Partners) submitted a Determination of Need (DoN) application pursuant to M.G.L. c.111, §25C and the regulations and guidelines adopted thereunder. In this Application, Partners proposes a substantial capital expenditure as that term is defined in the regulation, and the acquisition of new technology at Brigham and Women's Hospital (BWH).

Partners proposes to expand the Emergency Department (ED) at BWH to address what Partners characterizes as overcrowding and long wait times. Separately, Partners proposes to add certain DoN-Required Equipment. The two projects are proposed together to avoid disaggregation.

The proposal includes the addition of 20 ED bays (including 10 care initiation bays), 10 observation beds, two trauma bays, and ED radiology equipment. It is designed to incorporate two "regionalized" areas one for cancer care and one for behavioral health, as well as areas designed for team and family meetings. The size of the ED will increase from 25,000 GSF to 51,000 GSF. (Collectively, the ED Project).

In addition to and separate from the ED Project, Partners proposes to implement, for clinical use at BWH, three technologies that are classified as DON-required equipment. They propose to use their existing, research 7Tesla (7T) Magnetic Resonance Image Device MRI for part-time clinical use. In addition, they propose to purchase a MRI Simulator and a MRI Linear Accelerator (MRI LINAC). The transition of the 7T MRI for clinical use will require new construction of 1,567 GSF, and the MRI Simulator and LINAC requires the renovation of 4,023 GSF.

The total capital expenditure for this project is $73,186,747 of which $47,093,215 is for construction.
Applications for substantial capital expenditures and for the addition of DoN-required Equipment and Services are reviewed under the DoN regulation 105 CMR 100.000. Under the regulation, the Department must determine that the Applicant has made a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. Each of the six factors set forth in the Regulation are addressed in this Staff Report.

The Department received no public comment on the Application.

Background

The Applicant is Partners HealthCare System, Inc. (Partners), a nonprofit integrated health care system that was formed in 1994, and which now operates two tertiary care hospitals, seven community acute care hospitals in MA, one community acute care hospital in Southern New Hampshire, one facility providing inpatient and outpatient mental health services, and three facilities providing in- and outpatient services in rehabilitation medicine and long-term care. It also operates physician organizations and practices, a home health agency, nursing homes, a program for training graduate level health professionals, as well as a licensed, nonprofit managed care organization that offers health insurance products to MassHealth, Commonwealth Care, and commercial insurance populations.

Brigham and Women's Hospital (BWH), located at 75 Francis Street in the Longwood Medical area of Boston, is a tertiary care academic medical center licensed to operate 763 beds and a level one adult trauma center. BWH is an affiliate of Harvard Medical School and is a teaching and research institution operating six specialty clinical research centers, and the BWH Biomedical Research Institute (BRI). In Massachusetts, it is the second largest acute care hospital in Massachusetts.

Analysis

This analysis and recommendation reflect the purpose and objective of DoN which is "to encourage competition and the development of innovative health delivery methods and population health strategies within the health care delivery system to ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation" 105 CMR 100.001.

All DoN factors are applicable in reviewing a capital expenditure project. This Staff Report addresses each of these factors in turn. The presentation of the ED Project and of the addition of DoN Required Equipment was made separately in the Application. As a result, this Report will also address the two parts of the DoN sequentially.

Factors 1 and 2

Factor 1 of the DoN regulation requires that the Applicant address patient panel need, and demonstrate that the project will add measurable public health value in terms of improved health outcomes and quality of life for the existing patient panel, while providing reasonable assurances of health equity. Under factor 2 of the regulation, 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. This analysis will approach the requirements of factors 1 and 2 by describing each element of the proposed project and how each element complies with those parts of the regulation.

Patient Panel[1] and Need

[1] Patient panel for the purposes of DoN is defined as, "The total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant."

Partners' Patient Panel - Partners' patient panel consists of approximately 1.3 million unique patients. Its providers treat 19% of all discharges in Massachusetts. Partners draws 77% of its patients from the eastern part of the state, and 14% from out of state, including international patients. Fifty eight percent of patients are female and 41% are male. From 2014-2016 Partners saw a 4% increase in the patients it serves in the 65 and over cohort. According to the Applicant, older adults' ED care visits are typically more urgent and require longer stays with more services than other age groups.

Since the regulation defines Patient Panel as that of the Applicant, DPH considers the Proposed Project in the context of the whole Partners panel.[2] In this DoN, where the proposed project is entirely contained within BWH, the Application and analysis focuses more on the BWH panel.

BWH's Patient Panel - The BWH ED sees about 42,000 patients annually, and over the 2014 to 2016 timeframe, it saw 101,038 unique patients. The surrounding neighborhoods account for 41.3% of ED visits. To that extent, the BWH ED is the local hospital for these neighborhoods. A significant portion, 65%, of the patients seen at the BWH ED come from greater Boston (HSA 4); 17.7% are from the north and south shore regions, 6.2% are from central and western Massachusetts and 10.9% are from out of state. Females comprise 58.7%, and males, 41.3% of patients seen in the ED. Three quarters of patients seen are ages 18-64, while one quarter is 65 and over.[3]

Age of BWH's ED Patient Panel

≤17	18-64	≥65
0.4%	75.4%	24.2%

The ED payer mix over the last three fiscal years reflects the following breakdown of payers:

Commercial	Medicare/MassHealth	Self-pay	Other (government or free care)
50%	32%	3%	15%

Over the last three fiscal years, BWH reports that the portion of Medicare and MassHealth beneficiaries has increased from 26.6% in FY14 to 38.8% in FY16. The BWH ED admitted an annual average of 41,313 unique patients over the last three fiscal years. Partners reports that the BWH ED has a steady annual growth rate of 1%, and an annual average patient volume of 61,046.

Need for ED Expansion

Implementation of Team-Based Care

Partners asserts that ED process flow has changed over time and Partners intends to implement the team model of care, also referred to as a "zone" or "pod" model. "This structure assigns a team of providers to a certain number of beds in a small geographic area of the department, allowing for increased collaboration among caregivers, improved overall efficiency and better patient satisfaction. The ED team model offers a different way of distributing the workload within the ED to help improve patient flow and satisfaction. In a common team structure, one physician will be assigned to a group of adjacent rooms where he or she works with the same team of nurses for the entire shift. An ED using

[2] Partners submitted an analysis under its response to factor 4 which affirmed that Partners could support the project without negative consequences to the Partners patient panel (Donohue report)

[3] Partners provided a breakdown of the most prevalent conditions for seeking treatment in the BWH ED indicating that an average of 3.3% presented with Behavioral Health (BH) indications in FY14-16.

this model will likely have multiple teams in operation, with each team seeing patients of a certain acuity level".[4]

BWH will expand the space within the ED allowing for co-located services and patients will be placed in specific team work streams, decreasing the amount of time and steps that clinical staff takes to see patients. Research indicated that this results in improved access to care, and outcomes through improved throughput, and improved linkages with community supports related to Social Determinants of Health (SDoH).

Partners points to long ED wait times at every stage in the visit and to extended boarding times as indicators of capacity constraints within the BWH ED. Based on information provided through the Centers for Medicare & Medicaid Services' ("CMS") Hospital Compare tool BWH's wait times are higher than national and Massachusetts averages.

Comparative ED Care Times*

	BWH	MA	US
Before being seen by a Health care professional	42m	42m	29m
Before being admitted	6h 46m	6h 4m	5h 33m
Time in ED post decision to admit+	2h 38m	2h 48m	2h 16m
Before Discharge	4h 21m	3h 10m	2h 52m

*Centers for Medicare & Medicaid Services' ("CMS") Hospital Compare tool
+Boarding

During the last two years, 17% of all ED patients at BWH were cared for in hallways. According to Partners, this exceeds the national standard of fewer than 5%, Partners asserts. The "walk-out" rate for ED patients at BWH rose to 2.78% in 2015 and 2016. In an effort to address this walk-out rate, in 2017, staff increased the amount of care provided in hallways and waiting areas. This step resulted in the decrease in the rate to 1.96%. The median length of stay (LOS) for all patients increased, as did the number of patients whose visits were longer than 12 hours.[5]

[4] https://www.beckershospitalreview.com/hospital-physician-relationships/emergency-department-teams-deliver-results.html
[5] Behavioral health patients include observation patients while M/S does not.

BWH ED Data							
Year	Total Visits	Median LOS for Admitted Patients Minutes	Median LOS for Discharged Patients Minutes	# M/S Patients with Visit > 12 Hours ~	# Patients BH with Visit > 12 Hours*	BH % of Total > 12 Hours	M/S % of Total > 12 Hours
2014#	57,174	3,918	2,378	2,090	498	0.87%	3.66%
2015	61,778	4,413	2,843	2,680	507	0.82%	4.34%
2016	62,240	4,383	2,781	2,537	561	0.90%	4.08%
2017	62,004	4,436	2,555	2,735	530	0.85%	4.41%

Provided by Partners
~ Does not include Observation
* Includes Observation
# Annualized
BH= behavioral health; M/S= medical surgical (all other than BH)

According to research cited by Partners, ED overcrowding can result in increased errors, reduction in quality of patient care, delays in delivery of care, and delays in necessary testing and monitoring.[6] Additionally, because some care at the BWH ED is currently provided in hallways, staff cannot take a complete medical and psychosocial history without compromising patient privacy.

To address the long wait times, care administration in hallways and high walk-out rates, Partners proposes to add 20 ED beds to its overall capacity, plus two trauma bays, and 10 observation beds. The expansion will facilitate the team-based care, reduce patient crowding, expedite patient throughput, and ensure better patient flow resulting in improved quality and access.[7]

ED to Expand Capacity and Improve Flow

The ED expansion project contemplates significant redesign of patient flow which, in addition to supporting implementation of team-based care will afford more flexibility to adjust capacity based on patient demand.

The renovated ED will have a larger main 24/7 central pod, in which they will integrate flexible use zones including a 10-bed observation/acute care area. Partners asserts that this will allow staff to flex the use up and down according to the patient demands. Generally, acute demand is greater during day and evening hours, while observation need is greater at night.

The project also includes a 10-bed arrival/care initiation area to which patients will be admitted for registration and triage, and, for lower intensity patients, immediate treatment, rather than being moved

[6] Paul Richard Edwin Jarvis, *Improving emergency department patient flow,* 3 CLINICAL & EXPERIMENTAL EMERGENCY MED. 63, 63-68 (2016), *available at http://ceemjournal.org/journal/view.php?doi=10.15441/ceem.16.127* R. Richards et al., *Providing Care in Emergency Department Hallways: Demands, Dangers, and Deaths* https://www.hindawi.com/journals/aem/2014/495219/

[7] Partners points out that as an academic medical center with a Level 1 trauma center, BWH is often relied upon for disaster relief when larger state issues, such as terrorist attacks or fires occur. A right-sized ED, they argue, will meet the needs for timely and seamless care leading to improved health outcomes, improved quality of life and additional access to high quality ED services in the event of a local or state-wide catastrophe.

back to an area to await treatment. This area will be open during the Hospital's highest volume arrival hours and easier to open and close than their current design which is oriented towards higher acuity treatments that require planning for more complex resources. Partners argues that this will be a more efficient use of space and staff time, and improve patient satisfaction.

The proposed project also includes the addition of two trauma resuscitation bays that can accommodate necessary equipment and team based care and will, Partners suggests, address the increase in urgent and emergent visits. Urgent and emergent ED visits have increased 1.3% and 5.6% respectively (with a combined 2.9% increase) since FY15.[8] [9] Finally, the ED Project addresses ED patient throughput through expansion of space and diagnostic equipment in the ED. Partners proposes to add radiology capacity, including an additional Computed Tomography ("CT") scanner, ultrasound, and portable X-ray, to reduce delays in service during peak demand. Partners argues that having the required diagnostic imaging capacity within the ED is essential to making timely patient diagnoses, and that these additions will improve wait times and expedite patient throughput, while improving patient satisfaction.

Redesign of ED to Meet Needs of Target Populations

BWH is the inpatient provider site for patients of the Dana-Farber Cancer Institute (DFCI) which results in a significant number oncology patients seeking ED care at BWH, primarily due to reactions and toxic responses to their cancer treatment.[10] [11] In 2014, 16% (9,647) of BWH's total ED visits were oncology related. The renovation project includes two specialty regions within the ED where care teams can address, in a more efficient way, the needs of the cancer patients being treated at DFCI who experience emergent issues related to their treatment.

The cancer care region in the new ED will, Partners asserts, reduce waiting time for those cancer patients who will be seen and treated directly by trained ED-oncology staff and the designated area will more effectively address those patients' needs for isolation areas due to immunosuppression as a result of their treatment.[12]

The ED Project also includes designated clinical space within the ED for BWH's behavioral health patients, including patients with substance use disorders (SUDs), which will be designed to allow for treatment in an environment with lower stimulation than the overall ED, and will include space for substance use disorder evaluation (SUDE) for patients in a private setting. Partners asserts that this will result in improved quality of both evaluation and care and will help reduce patient agitation and the risk of violent behavior. Partners reports that 3.3% of BWH's ED population sought services for an underlying behavioral health condition (5,972 patients).[13] At the same time, however, these 3.3% of patients

[8] This terminology is based on the Emergency Severity Index, which is a five-level ED triage algorithm that provides clinically relevant stratification of patients into five groups on the basis of acuity and resource needs. ED visits for non-urgent and less urgent care have declined by 16.7% and 7.5% respectively (with a combined 8.4% decline) since FY15.

[9] In addition, Partners asserts that these care bays may address the fact that ED overcrowding resulted, in approximately 416 tertiary referrals being declined in 2017.

[10] A recent study evaluating cancer trends from 2006-2012 found that 29.5 million ED visits were related to an underlying cancer diagnosis resulting in patients seeking both palliative and routine care in the ED.

[11] Donna R. Rivera et al., Trends in Adult Cancer-Related Emergency Department Utilization, JAMA ONCOLOGY (2017). https://jamanetwork.com/journals/jamaoncology/article-abstract/2650794

[12] BWH staff is reviewing the specific types of treatment that will be offered and Partners states that there is no anticipated impact on NWH's or Emerson's cancer treatment services.

[13] A review of underlying medical conditions associated with ED visits at BWH for the last three fiscal years and the first quarter of FY2017 showed the most prevalent diagnoses were: (1) unspecified chest pain, (2) unspecified abdominal pain, (3) syncope and collapse, (4) headache, and (5) urinary tract infection at an unspecified site. In addition, 0.1% presented with a myocardial

account for 20-25% of ED care hours. In the first six months of FY 2017, patients requiring transfer to a psychiatric facility remained in the ED for an average of 23.2 hours.[14] Partners explains that their SUD patients wait in general treatment spaces and/or hallways which is a barrier to providing optimal evaluation and treatment. In summary, the renovation and expansion of the ED is expected to improve quality of care both by reducing wait time and by providing patient-centered services for cancer and BH populations.

Health Equity and Access to Care

Partners points out that the BWH ED is an essential component of the social safety net for patients with complex medical and psychosocial needs. The new ED design includes space for this multi-disciplinary team based care, with appropriate private meeting rooms for families, care coordinators and interpreters. BWH has developed a dataset that follows patients who are frequent ED users to ensure that they are connected to needed appropriate resources, including community health workers, primary and behavioral health, and case workers to address housing and food insecurity. This program, Partners asserts, has been proven to reduce hospitalizations, ED visits and total costs with a return on investment of greater than five times. As a result of the program's success, Partners plans to increase access and extend the benefits of this program to the Partners HealthCare ACO.

Community Engagement

Partners described a community engagement process that was geared towards patients, the BWH community broadly, and local resident groups that may be impacted by the transaction beginning in December 2015. BWH has a service-line Patient and Family Advisory Council (PFAC) for the ED. The ED PFAC is responsive to the Steering Committee of the PFAC and offers the opportunity for discussion with the Chief Medical officer and Chief Nursing Officer in an effort to support patient and family centered care and provide feedback. The ED PFAC has been working for six years and works closely with clinical staff to understand ED expansion needs and plans. They have planned a PFAC orientation for new nurses, are addressing gender orientation identification and the opioid crisis as those affect ED service. Specific updates including opportunities for feedback from the ED PFAC have been held. As well, BWH has worked with local residents and those resident groups who will be impacted by the proposed projects, hosting two community forums at which the projects were discussed and feedback solicited. At each forum, participants noted that expansion was necessary to alleviate long wait times.

DoN-Required Equipment

In addition to the ED Project, BWH proposes to add, for clinical use, three technologies that are classified as DON required equipment. The proposed project contemplates: the part-time clinical use of a 7T (Tesla) MRI that is currently exempt from DoN because it is used solely for research; the addition of a new MRI Radiation Therapy (RT) Simulator; and the addition of a new MRI guided LINAC. In its Application, Partners addressed the ED expansion and the proposal for this equipment separately and defined a different relevant patient panel – a subset of the Partners' panel for whom the equipment would have a specific impact.

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infarction (154 patients were symptomatic for a heart attack), 0.7% presented with stroke (1,311 patients), 8.6% presented with trauma (17,774 patients), and 83.3% presented from "other'' causes (152,644 patients).

[14] Extended wait times reflect a national trend, and the delay in transferring patients is exacerbated for Medicaid beneficiaries who are twice as likely as privately insured patients experience delays of a day or more. See, Mark D. Pearlmutter et al., Analysis of Emergency Department Length of Stay for Mental Health Patients at Ten Massachusetts Emergency Departments, 70 ANNALS OF EMERGENCY MED. 193, 193-202 (2017), available at http://www.annemergmed.com1articlelS0196-0644(16)31217-31pdf.

7 Tesla (7T) MRI Need and Public Health Value

Partners owns and operates a 7T MRI which has, until now, been used for research purposes.[15] In October 2017, the United States Food and Drug Administration (USFDA) approved its use for clinical applications including multiple sclerosis, epilepsy, cerebral vascular diseases, brain tumors, and degenerative diseases such as Alzheimer's and Parkinson's. This proposal, to convert the existing unit to part-time clinical use, is subject to review as DoN-Required Equipment. MRI is designated, under the 2017 DoN-Required Equipment and Services Guideline as equipment that warrants a case-by-case review based on DoN application-specific information due to its potential for clinically unnecessary utilization that in aggregate, can result in a significant increase in health care spending without an associated benefit to the public in terms of better health outcomes, or access to needed care. https://www.mass.gov/files/documents/2017/01/vr/guidelines-equipment-and-services.pdf. In this project, the decision to add this capacity will be analyzed like any other part of the project in the context of how the project addresses the patient panel need, public health value, and operational objectives.

This higher field strength MRI produces higher resolution images that enhance soft tissue contrast making images that are clearer than those of lower field strength and other imaging modalities. Partners cites research demonstrating that the 7T MRI provides improved value in evaluating select neurological[16] and musculoskeletal disorders (including demonstrated clinical effectiveness in the ability to image complex soft tissue structures surrounding the knee), and cites 10 novel clinical applications for the 7T MRI.[17] [18]

Partners estimates that approximately 1,500 of a total of 9,052 BWH patients (about 17%) who have epilepsy, brain tumors, Parkinson's, multiple sclerosis, Alzheimer's, traumatic brain injury, and musculoskeletal disorders, will benefit from the level of detail that 7T scans provide. Partners explains that the shift of the 7T MRI to clinical use is not generated by the need for additional capacity, but, instead, from the need to provide a more precise diagnostic imaging modality to evaluate and treat patients with challenging medical conditions.

Partners asserts that, when compared to alternative or substitute diagnostic and clinical methods, the 7T unit is the only non-invasive technology with the capability to provide soft tissue images of the

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[15] The purchase of the unit was originally exempt from DoN. BWH has been operating one of four in the US, and the only 7T MRI in Massachusetts for research purposes. It is currently located on the BWH campus in its Building for Transformative Medicine.

[16] These include including multiple sclerosis, epilepsy, cerebral vascular diseases, brain tumors, and degenerative diseases such as Alzheimer's and Parkinson's.

[17] P. Balchandani & T.P. Naidich, *Ultra-High-Field MR Neuroimaging.* 36 AM. J. NEURORADJOLOGY 1204, 1204-15 (2015), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4472608/;* Anja G.van der Kolk, Jeroen Hendrikse, Jaco J.M. Zwanenburg, Fredy Visser, Peter R. Luijten, *Clinical applications of 7 T MRI in the brain, https://www.sciencedirect.com/science/article/pii/S0720048X11006450#!;* Siegfried Trattnig et al., *Key clinical benefits of neuroimaging at 7 T,* NEUROIMAGE (2016) *http://www.sciencedirect.com/science/article/pii/S1053811916306516*

[18] These include: Detection of cortical lesions that have particular clinical importance for patients with MS; evaluation of grey-matter injury in patients with MS; discovery of central veins in white matter lesions that are essentially pathognomonic for patients with MS; imaging deep brain stimulation targets, such as the subthalamic nucleus, internal globus pallidus and substantia nigra for patients with Parkinson's disease; offering more anatomical detail in evaluation of the hippocampus and sub-structures for patients with Alzheimer's disease; more precise delineation of arterial microvasculature, as well as tumor metabolism via T2* weighted venography in patients with brain tumors; detection of small areas of cortical dysplasia or sclerosis via better spatial resolution for epilepsy patients.; detection of microbleeds is stronger at higher field strengths for patients with cerebrovascular diseases and traumatic brain injury patients; improved spatial resolution to visualize ever-smaller, arteries as well as anatomic details of aneurysms for patients with cerebrovascular diseases; and enhanced ability to perform ultra-high resolution morphological imaging, 3D T2 and T2* mapping, as well as ultra-short TE applications for patients with musculoskeletal disorders.

specificity and clarity in difficult to image areas. As such, Partners asserts, expanding the use of this unit from research to part-time clinical use will substitute for and prevent costly and unnecessary treatment and potentially reduce hospital admissions. Partners asserts that clinicians will be able to deliver an immediate and more accurate diagnosis of the patient's illness develop an expedited plan of treatment which offers improved outcomes and, further that its use of electronic health records (EHR) facilitates earlier care initiation because radiology staff can communicate directly with primary and specialty care providers as well as care coordinators.

Partners has provided measures with benchmarks to assess the impact of the project on image quality and access. These are included in Attachment 1. Partners expects that for the appropriate patients, the 7T will replace the use of lower field strength MRIs. Partners will track the degree to which the 7T is a replacement for or used in addition to lower strength MRI scans. Partners asserts that the project will not materially increase capital costs since the equipment has already been purchased[19] and is already installed and operational. Reimbursement for each scan from public and private payers will not increase; it will be the same rate as for lower field strength MRIs. For these reasons, Partners asserts, the project will have a negligible impact on the overall Massachusetts healthcare market.

DoN staff believe that improved imaging provides a benefit to the patient panel without concomitant increases in reimbursement and recognizes, as well, that in this circumstance, there will be no added capital costs because Partners is shifting to part time clinical use a unit that it already owns.

Radiation Therapy MRI Simulator (RT-MRI Simulator)

For effective treatment of cancer using radiation therapy (RT) treatment, simulation is an important first step. The patient is immobilized and imaged in the position in which they will be treated. This facilitates accurate visualization of the tumor and organs at risk, and allows the practitioner to determine and target the precise area to be treated, calculate the correct dosages, and ensure accuracy of the treatment plan.[20] Several imaging modalities have been used in RT simulation, beginning with fluoroscopic RT, then computerized axial tomography (CT) RT, and the newest is RT-MRI which is under consideration in this DoN.

RT-MRI simulator uses MRI in simulation planning. For certain soft tissue tumors, this improves the accuracy of RT planning and subsequent treatment delivery.[21] Additionally, patients are spared the exposure to additional ionizing radiation. In the proposed project, Partners proposes to replace an existing fluoroscopic RT simulator which it asserts is both beyond its useful life and "antiquated", with a RT-MRI simulator. Implementation of a MRI simulator will not provide any additional MRI capacity to either BWH or Partners. Rather, it offers improved soft-tissue contrast that allows for more precise and reliable evaluation of tumor location and volume and is particularly important for treatment planning in regions of the brain, head and neck, prostate and female reproductive organs[22] because it allows for more precise delivery of the radiation therapy. As a result, less surrounding healthy tissue is irradiated, and there is less radiation toxicity for the patient. If approved, this will be the first RT-MRI simulator in Massachusetts. Partners asserts that were the fluoroscopic RT to be replaced with the CT simulator then appropriate patients would not benefit from the additional soft tissue contrast that MRI simulation

[19] It was purchased at a reduced rate as part of a larger package of research and clinical devices during the construction of the BWH building for Transformative Medicine.

[20] Robba Rai et al., *The integration of MRI in radiation therapy: collaboration of radiographers and radiation therapists,* 64 J. MED. RADIATION SCIENCES 61, 61-68 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5355372/

[21] https://pdfs.semanticscholar.org/f8a4/d6d1d457f3647c7e03f20790bd1e8a09fb60.pdf

[22] F. Guerreiro et al., *Evaluation of* a *multi-atlas CT synthesis approach for MRI-only radiotherapy treatment planning,* http://www.physicamedica.com/article/S1120-1797(17)30045-5/pdf.

delivers. Over 3,000 simulations are performed on BWH/DFCI patients using existing CT simulators annually. Of those, in FY17, BWH/DFCI identified 1,337 patients having the types of cancers for which planning via a RT-MRI simulator would be appropriate.[23]

Partners asserts that its acquisition will have no material impact on provider price, total medical expenses ("TME")or provider costs; that costs for MRI scans obtained on the RT-MRI simulator are currently bundled into RT reimbursement codes for external beam RT planning; and therefore there is no increase to costs on a per patient basis for these therapies. Partners also asserts that the rate of reimbursement for treatment planning on a RT-MRI simulator is the same as planning performed on a CT simulator. As a result, there is no difference in reimbursement by shifting appropriate cases to a RT-MRI simulator for RT treatment planning.

Because the RT-MRI reduces radiation toxicity compared with the other RT simulation modalities DoN Staff believe that there is a public health benefit and need for this technology.

MRI-Linear Accelerator

BWH saw a 4% increase in RT treatments between 2014 and 2016 (from 32,569 in 2014 to 33,942 in 2016). A Linear Accelerator (LINAC) is the device most commonly used for external beam radiation treatments for patients with cancer. Partners proposes to add a MRI guided linear accelerator (MRI LINAC) at the BWH main campus.[24] [25]

The MRI LINAC has the benefit of not exposing the patient to additional radiation. In addition, Partners argues that it will facilitate the real-time, clearer view of soft tissue. This is, Partners asserts, particularly useful for small tumors and in regions with continuous motion (related to breathing, swallowing or digesting).[26] The MRI LINAC can provide accuracy within 1-3 millimeters versus one centimeter for conventional modalities. This will significantly reduce radiation exposure to surrounding areas and can allow for the delivery of a higher dosage to the desired area and can lead to a shorter course of treatment.[27]

In FY17, BWH identified approximately 1,207 patients in their existing panel for whom MRI guided LINAC would have been indicated and who would have benefited from this technology had it been available. Based on the disease burden of their existing patients, BWH's projections of the number of treatments that they expect to provide represent approximately 16% of treatments provided to all patients.

Radiation therapy-related toxicity rates and type of toxicity vary based on the location and dose of radiation delivered. Toxicities can lead to increased cost of care due to hospitalization Currently, BWH measures the impact of these toxicities on patient quality of life (QoL) by collecting validated patient-

[23] In addition to using this unit for cancer patients, Partners indicated it identified 120 brachytherapy procedures which could have been optimally guided with a RT-MRI simulator.
[24] This technology received FDA approval in 2017, and is not available at any other facility in MA.
[25] BWH operates four LINACs at its main campus plus one Cobalt Gamma Beam device. BWH also has one LINAC at its satellite location in Milford.
[26] Kathy Hardy, *MRI-Guided Radiation Therapy,* 15 RADIOLOGY TODAY 20 (2014), http://www.radiologytoday.net/archive/rt0914p20.shtml.
[27] S. Acharya et al., *Magnetic Resonance Image Guided Radiation Therapy for External Beam Accelerated Partial-Breast Irradiation: Evaluation of Delivered Dose and Intrafractional Cavity Motion,* 96 INT'L J. RADIATION ONCOLOGY BIOLOGY PHYSICS 785, 785-92 (2016). https://www.ncbi.nlm.nih.gov/pubmed/27788951; A.J. McPartlin et al., *MRI-guided prostate adaptive radiotherapy - A systematic review,* 119 RADIOTHERAPY & ONCOLOGY 371, 371-80 (2016), https://www.ncbi.nlm.nih.gov/pubmed/27162159.

reported outcome measures (PROMS) from all patients treated in the BWH Department of Radiation Oncology before, during and after radiation therapy. Partners has baseline data on thousands of patients with >20,000 QoL data points collected to date, which provides BWH with a baseline of toxicity rates using conventional simulators and conventional LINACs that can be compared to rates experienced from treatment with the proposed RT-MRI simulator and MRI LINAC. Partners will measure the impact of those toxicities of patient quality of life and the benefits of the RT-MRI and MRI-LINAC as compared with conventional simulators and LINACs by using the QoL data points for each.

Partners acknowledges that the capital expenses for the RT-MRI simulator and MRl-LINAC are approximately 50% more than comparable conventional CT simulators and X-ray guided LINACs. Partners asserts that there will be cost savings and avoided costs which will balance any increase in capital costs.

Factor 3

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

Factor 4

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the proposed project without negative impacts or consequences to the existing patient panel. Documentation sufficient to make such finding must be supported by an analysis by an independent CPA. Partners submitted such an analysis, dated November 1, 2017 and performed by Bernard Donohue, III, CPA (Donohue).

Because the DoN analysis looks at the cost impact on the Applicant, in this case, Partners, the scope of analysis was limited to an analysis of the five year consolidated financial projections (the Projections) prepared by Partners as well as the actual operating results for Partners for the fiscal years ended 2015 and 2016 (Base Budget), and the supporting documentation in order to render an opinion as to the reasonableness of assumptions used in the preparation and feasibility of the Projections with regards to the impact of the proposed project at BWH.

Donohue used certain key metrics which fall into three primary categories: profitability, liquidity, and solvency. Profitability metrics, such as Earnings before Interest, Depreciation and Amortization (EBIDA) expenses, EBIDA Margin, Operating Margin, Total Margin, and Debt Service Coverage Ratio are used to assist in the evaluation of management performance in how efficiently resources are utilized. Liquidity metrics, such as Unrestricted Days Cash on Hand, and Unrestricted Cash-to-Debt measure the quality and adequacy of assets to meet current obligations as they come due. Solvency metrics, such as Debt to Capitalization, and Total Net Assets, measure the company's ability to service debt obligations. Additionally, certain metrics can be applicable in multiple categories.

Donohue reported that the only revenue category on which the proposed capital projects would have an impact is net patient service revenue and therefore, analyzed net patient service revenue identified by Partners in both their historical and projected financial information. Based upon its analysis of the projected results from Fiscal Year 2017 through Fiscal Year 2021, the proposed capital projects would represent approximately 0.168% (17 one-hundredths of 1%) of Partners operating revenue beginning in FY 2019 to 0.194% (about 2 tenths of 1 %) in FY 2021. The first year in which revenue is present for any of the proposed capital projects is FY 2018 when the revenue for the proposed projects represents

approximately 0.010%. It is Donohue's opinion that the revenue growth projected by Management reflects a reasonable estimation based primarily upon the organization's historical operations.

Donohue analyzed each of the categorized operating expenses for reasonableness and feasibility as it relates to the projected revenue items and reviewed the actual operating results for Partners for the years ended 2015 and 2016 in order to determine the impact of the proposed capital projects at BWH on the consolidated entity and in order to determine the reasonableness of the Projections for the fiscal years 2017 through 2021. Based upon analysis of the projected results from Fiscal Year 2017 through Fiscal Year 2021, the proposed capital projects would represent approximately 0.132% (13 one-hundredths of 1%) of Partners operating expenses beginning in FY 2019 to 0.157% (about 16 one-hundredths of 1%) in FY 2021. Donohue opines that the growth in operating expenses projected by Management reflects a reasonable estimation based primarily upon the organization's historical operations.

Donohue reviewed certain non-operating gains/expenses and other changes in net assets and determined that there were no non-operating expenses projected for the proposed project and that the pro-forma non-operating gains/expenses and other changes in net assets are reasonable. He reviewed Partners' capital expenditures and cash flows to determine whether Partners anticipated reinvesting sufficient funds for technological upgrades and property, plant and equipment and whether the cash flow would be able to support that reinvestment. He opines, based upon discussions with Management and his review of the information provided, that the pro-forma capital expenditures and resulting impact on Partners cash flows are reasonable.

Finally, Donohue opines that the impact of the proposed capital projects at BWH represent a relatively insignificant component of the projected operating results and financial position of Partners and that, as such, Projections are not likely to result in a scenario where there are insufficient funds available for capital and ongoing operating costs necessary to support the ongoing operations of Partners. As a result, it is his opinion that the Projections are financially feasible for Partners.

Factor 5

Factor 5 requires the Applicant to "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 and addressing, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes.

ED Renovation and Expansion

The current ED was last renovated in its entirety in 1994, with minor changes being made since then, such as to their triage area. However, Partners states, since that time, many standards/practices for ED care delivery have changed and will be addressed with this project. Partners argues that the only alternative option for the ED Project would be to maintain the current ED footprint and infrastructure. This would preclude expansion or redesign of the clinical space or significant improvements to patient flow.

Analysis by a national ED consultant retained by BWH determined that the current flow-model was inefficient and time consuming for both patients and staff. The consultant recommended an expansion

and a redesign of patient flow and the implementation of specialty areas, citing studies that the changes will expedite care through rapid assessment, care initiation, and clinical specialization, and they will create operational efficiencies to improve patient outcomes and experience, as well as provider satisfaction.

Equipment - 7T MRI conversion from full-time research use to part- time clinical use

Partners argues that the clinical benefits of the 7T are the superior alternative for providing services to patients with neurologic or musculoskeletal conditions/diseases needing to advanced imaging that can improve diagnosis, treatment and expedite care delivery leading to improved health outcomes. Partners does not offer alternative modalities to providing this highly detailed imaging because, it asserts, there are none. Partners argues that the 7T MRI images will allow clinicians to determine appropriate treatment more efficiently, eliminating the need to test multiple treatment courses and saving time and money. Partners argues that declining to implement the 7T for clinical use would deny access to a known approved effective diagnostic modality and might actually increase the cost of care.

Equipment - Implementation of RT-MRI simulator and a MRI-LINAC.

Partners argues and cites literature in support of its argument that each of the RT-MRI and MRI-LINAC are superior to alternatives for certain patients undergoing radiation therapy. The qualitative impact in terms of decreasing the risk of co-morbid conditions created by the toxicity of ionization radiation used by the alternative technologies when balanced with the ability to provide potentially less invasive, more precise and more efficient care can improve recovery times. Partners asserts that cost savings including eliminating the need for (and costs of) certain invasive treatments, will outpace the initial capital and operating costs and ensure patients receive the most appropriate care for their cancer type.

Factor 6

The Community Health Initiative (CHI) component of the DoN regulation requires approval of the Applicant's plans for fulfilling its responsibilities set out in the Department's Community-based Health Initiatives Guideline (Guideline). 105 CMR 100.210(A)(6) The Guideline establishes three tiers based on the size of the CHI contribution. CHI projects ranging from $500K to $4M (which includes this project) are considered Tier II projects for which Applicants are required to submit documentation showing that the existing community health needs assessment (CHNA) and community health improvement planning (CHIP) processes both evidence a sound community engagement process and demonstrate an understanding of the DoN Health Priorities.

After approval by the Department of the DoN – before which the Applicant has provided satisfactory evidence of a community engagement process and indicated sufficient understanding of DoN Health Priorities – decisions regarding Health Priority strategies occur through submittal of the Health Priorities Strategy Selection form to DPH. Selection of the Health Priorities, and funding decisions, are conditions of the DoN and enforceable as such.

Tier II Applicants can submit a variety of documentation to establish that they are in compliance with factor 6, all as set out in the Guideline.[28] Partners submitted the following in support of its compliance with Factor 6:

- A completed Community Engagement Self-Assessment form

[28]Tier II Applicants are not required to submit a Community Engagement Plan at the time of Application.er II Applicants are not required to submit a Community Engagement Plan at the time of Application.

- 6 completed Stakeholder Assessment forms
- Brigham and Women's 2016 Community Health Needs Assessment
- A narrative overview of Brigham and Women's last CHI planning process, how that process related to the 2016 Community Health Needs Assessment and other considerations and requests (such as a modification to the prescribed timeline of actions to be taken post PHC decision on the DoN application).

CHI Review summary:

The proposed CHI Advisory Committee meets DPHs standards; that the most recent CHI planning process and 2016 CHNA reflect a thoughtful and community engaged process and that it can and should be used as the basis for CHI funding decisions. The review process also identified opportunities for improvement. Accordingly, and to ensure a robust process of engagement post approval of the DoN, BWH was required to complete a Community Engagement Plan describing the focus neighborhoods (informed by the CHNA). BWH was asked to describe community engagement plans focusing on communication plans for the CHI funding plan and evaluation of funded strategies and to describe targeted approaches to engaging different types of population groups, including how communication barriers will be reduced. The actions described in the completed Community Engagement Plan area condition of the DoN.

Staff review finds that the 2016 CHNA had a strong social determinant of health orientation and should lead to easy alignment between the priority issues identified there and the DoN Health Priorities. Noting that there are issue areas where Partners appears to be more or less comfortable supporting Social Determinant of Health level investments/strategies DPH encourages the use of this CHI opportunity to learn how to impact the social determinants of health/DoN Health Priorities in new and innovative ways.

Applicant intends to use the UMass Donahue Institute (UMDI) as its evaluation vendor. Because UMDI lead evaluation activities under the most recent CHI process, and all parties find that to be satisfactory, it is not necessary to conduct another competitive search for an evaluation vendor.

DPH finds the Community Engagement Plan (Attachment 2) satisfactory. The actions described in the Plan will be used as the basis for reporting on future community engagement activities.

CHI Condition and timeline:

- Actions described by Partners in the Community Engagement Plan will be reported to DPH.
- Up to 10% of CHI funds may be used for evaluation purposes.
- Up to 3% of CHI funds may be used for administrative purposes.
- The allocation period may be extended to 6-8 years.
- The Applicant will submit a Health Priority Strategy Selection form to DPH for review and will implement the strategies upon DPH approval according to the timeline below.

    - One-month post-approval: The Advisory Committee will begin meeting and reviewing the 2016 CHNA to commence the process of selecting Health Priorities. Partners (specifically the Center for Community Health and Health Equity (CCHHE) will seek to work with the University of Massachusetts – Donahue Institute on evaluation and serve as a technical resource to the CHI process and grantees.
    - Three months post-approval: The Advisory Committee has determined Health Priorities for funding and submits the Health Priorities Form to the Department.

- Three to four months post-approval: Allocation committee to interview key contacts within the selected health priority(s) to refine funding strategies and RFP components.
- Four to five months post-approval: The Allocation Committee is developing the RFP process and determining how this process will work in tandem with the BWH – Center for CCHHE current grant RFP process.
- Six to seven months post-approval: The RFP for funding is released.
- Eight months post-approval: Bidders conference is held on the RFP.
- Nine months post-approval: Responses are due for the RFP.
- Twelve months post-approval: Funding decisions are made, and the disbursement of funds begins.
- Fifteen months post-approval: The UMass Donahue Institute will begin impact evaluation work with grantees.

Finding – ED Project

The DoN program is designed to "ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost" 105 CMR 100.001. As required by factor 1, any DoN applicant must show that the project will add measurable public health value in terms of outcomes, quality of life, with a focus on health equity. 105 CMR 100.210(A)(1)(b).

Partners highlighted the need to address increasing demands on the aging BWH ED facility and to more effectively address ED volume, increasing case-mix acuity, and the requirements of the BH and cancer populations. Renovation is required to implement the team based model of care which will, in turn, decrease wait time, improve throughput, improve access to care, and more effectively support clinical and psycho-social needs of patients presenting in the ED.

Partners includes outcomes metrics to evaluate the impact of the ED expansion that relate to patient satisfaction and quality of life, access, process and quality, and which are detailed in Attachment 1 and will be reported on in the context of the annual reporting required of all DoN holders. These metrics include baselines and annual achievement targets that build on each previous year's progress. The ED leadership team will monitor and review the progress towards these goals quarterly.

Partners described its process of working with the community over time to address the issues and the options for addressing the wait times and overcrowding as well as implementing a proven strategy of team-based care and the implications of the project on competitiveness and with respect to costs and other recognized measures of spending. The CPA analysis supports a finding that the project is financially feasible and that operating and capital costs can be met without negative implications on the Partners patient panel. Finally, in planning for its CHI funding, Partners evidences an ability to implement plans which will become conditions to this DoN and will support and fund programs tied to the state health priorities.

Finding – Equipment

Partners addition of three units of DoN Required equipment will avoid unnecessary testing, harmful side-effects and additional hospitalization and have the capacity to offer superior clinical results. The use of the MRI enabled radiation therapy simulator and the MRI-guided LINAC will offer superior visualization of and more accurate targeting of certain tumors. Where the Applicant in this DoN is the Partners HealthCare, Inc. system, the Department is hopeful that these costly and specialized pieces of equipment will be utilized for the appropriate patients from other Partners facilities and that their acquisition and implementation at BWH will meet the need of the broader patient panel.

Recommendation

Based upon a review of the materials submitted, Staff finds that Partners has met each DoN factor and recommends that the Department approve this Determination of Need application for the ED Project and addition of DoN Required Equipment subject to all standard conditions (105 CMR 100.310), to the CHI Condition and Timeline, and subject to the other conditions set out below, pursuant to 105 CMR 100.360.

Other Conditions

1. The evaluation metrics set out in Attachment 1 shall be reported upon and the benchmarks set forth shall be considered in assessment of continuing compliance with the DoN.
2. The annual reporting required under 105CMR 100.310(J) shall track the impact of the ED expansion upon:
    a. ED boarding (as that term is defined by DPH);
    b. wait times and through-put times at all stages of care as reported to CMS, and walk-out rates;
    c. acuity appropriate usage of the ED (effectiveness of overall care coordination directing patients to appropriate levels of care including primary and urgent care)
    d. outcomes improvements and rate of medical error;
    e. utilization of the BH and cancer spaces;
    f. Partners shall report on the results of the program that follows frequent ED users. In addition, it shall report on the results of the program's extension to the Partners ACO. Specifically, for those tracked frequent users the reporting shall include the reduction in: ED visits, in unnecessary admissions and in medical expenses.
3. Using DPH guidelines for ED reporting, Partners shall report monthly ED utilization to the Department as requested, and annually to the DoN program.
4. Partners shall document the cost savings and avoided costs generated by the new equipment and commits that any additional costs (capital or operating) shall not be passed on to consumers or payers in higher rates, unnecessary utilization, or cost sharing.

Attachment 1

The Impact of the Proposed Project Metrics Proposed by the Applicant

BWH has developed the following metrics that includes a baseline and target projections for patient satisfaction, access and quality of care, as well as a reporting schematic.

ED Expansion

1. **Satisfaction** - Patient Satisfaction: Patients that are satisfied with care are more likely to seek additional treatment when necessary. BWH will review patient satisfaction levels with ED services via Press Ganey Scores.

Measure: To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all ED patients who provided a valid e-mail address and received services at BWH's ED with specific questions around (a) satisfaction levels with wait times; (b) satisfaction with services; and (c) satisfaction with clinical staff, including the physician.

Projections: Baseline: 85.30%; Year 1: 90.0%; Year 2: 91.8%; and Year 3: 92.72%

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

2. **Access Measure** - Walk-Out Rate: As previously discussed, given overcrowding issues, BWH experienced a walk-out rate of 2.78% in FY16, with an increased rate over the last two years. Through a redesigned physical space and new patient throughput processes, BWH will be able to move patients to exam rooms more quickly, reducing wait time, overcrowding and the walk-out rate.

Measure: The number of patients leaving the ED without treatment, without being seen or without an appropriate discharge.

Projections: Baseline: 2.78%; Year 1: 1.20%; Year 2: 1.18%; and Year 3: 1.16%

Monitoring: This data will be evaluated on a quarterly basis by the ED operations leadership team.

3. **Access Measure** - The Amount of Time between Registration to Being Seen by a Physician: Patients will be evaluated to determine the amount of time it takes for the individual to move from registering as a patient in the ED to being seen by a physician (or equivalent, such as a nurse practitioner).

Measure: The amount of time it takes between a patient registering in the ED to being seen by a treating clinician

Projections: Baseline: 24 minutes; Year 1: 15 minutes; Year 2: 15 minutes; and Year 3:

15 minutes

Monitoring: This data will be evaluated on a quarterly basis by the ED operations leadership team.

4. **Process Measure** - The Amount of Care Provided Outside of an ED bay: Currently, approximately 17% of care within BWH's ED is provided in areas outside of formal exam bays. This measure will be evaluated to determine the impact of the redesigned space and patient flow on overcrowding.

Measure: The number of times care is provided outside of an ED bay.

Projections: Baseline: 16.52%; Year 1: 8.00%; Year 2: 5.00%; and Year 3: 5.00%

Monitoring: This data will be evaluated on a quarterly basis by the ED operations leadership team.

5. **Quality Measure** - Early Management Bundle, Severe Sepsis/Septic Shock: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad-spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. The first three interventions should occur within 3 hours of presentation of severe sepsis, while the remaining interventions are expected to occur within 6 hours of presentation of septic shock.

Measure: Percentage of patients receiving care within the timeframe of the Measure Guidelines

Projections: Baseline: 27.32% Year 1; 60.72% Year 2: 66.79%; and Year 3: 73.47%

Monitoring: the ED's Continuous Quality Improvement ("CQI") Committee will evaluate this data on a quarterly basis.

DoN Required Equipment Metrics

7T MRI

1. **Quality of Care – Quality of the 7T Image:** The quality of a MRI scan is imperative to its interpretation. Accordingly, BWH will evaluate the number of scans that need to be repeated because of insufficient image quality over the course of 30 days to ensure radiology technicians are performing scans optimally and that the device is functioning within norms.

   Measure: The percentage of examinations that need to be repeated within 30 days due to technical inadequacy.

   Projections: Baseline: 0.5% Year 1: 0.5-1.0% Year 2: 0.5-1.0% Year 3: 0.5-1.0%

   Monitoring: This data will be provided on an annual basis.

2. **Access – Waiting Times for Patients:** The proposed Project seeks to ensure access to 7T MRI services. Accordingly, BWH will track the time to appointment, as well as the time it takes a patient to be seen upon arrival and to be scanned.

a. **Measure – Time to Next Available Outpatient Appointment:** The time (in days) to the next available outpatient appointment

   Projections: Baseline: 3 days Year 1: 3 days Year 2: 3 days Year 3: 3 days

   Monitoring: This data will be provided on an annual basis.

b. **Measure – Waiting Time after Patient Arrival:** The amount of time (in minutes) between a patient arriving at the clinic for MRI services and beginning scan services.
   Projections: Baseline: 36 minutes Year 1: 36 minutes Year 2: 36 minutes Year 3: 36 minutes

   Monitoring: This data will be provided on an annual basis.

RT-MRI Simulator

1. **Access – Increased Access to MR-guided Gynecological Brachytherapy**
   Procedures: This measure seeks to ensure that clinically eligible patients for MRI- guided brachytherapy receive treatment on the RT-MRI simulator.

   Measure: The proportion of gynecological cancer patients who are MR-eligible treated with the RT-MRI Simulator.

   Projections: Baseline: 0% Year 1: 10% Year 2: 25% Year 3: 50%

   Monitoring: This data will be provided on an annual basis.

2. **Access – Impact on Care Efficiency and Patient-Centered Care Integration:** This measure seeks to determine how integrated care may be provided to all patients.

   Measure: The proportion of clinically eligible patients whose treatment was planned on the RT-MRI simulator as part of same-day radiation planning compared to number of patients who had treatment planning on a traditional MRI scanner.

   Projections: Baseline: 0% Year 1: 10% Year 2: 25% Year 3: 50%

   Monitoring: This data will be provided on an annual basis.

MRl-LINAC

1. **Quality Care – Patients who have their RT Plan Adjusted due to Movement or Shrinkage:** This measure seeks to determine how effective the technology is at adjusting RT plans due to organ/tumor movement or shrinkage.

   Measure: Number of patients who received treatment on the MRl-LINAC and had their RT plans adjusted during treatment to account for tumor movement and/or shrinkage, and/or organ movement.

   Projections: Baseline: 0% Year 1: 10% Year 2: 25% Year 3: 50%

   Monitoring: This data will be provided on an annual basis.

2. **Quality Care – Reducing Radiation Toxicity:** This measure evaluates the impact on reducing toxicity and morbidity on cancer patients.

   Measure: The impact of reducing toxicity and morbidity by collecting patient-reported outcomes using the PRO CTCAE scales by disease site in aggregate and compared against departmental baseline data.

   Projections: Baseline: 0% Year 1: 10% Year 2: 25% Year 3: 50%

   Monitoring: This data will be provided on an annual basis.

Attachment 2

Community Engagement Plan

Massachusetts Department of Public Health
Determination of Need
Community Health Initiative
Community Engagement Plan

Version: 8-1-2017

The Community Engagement Plan is intended for those Applicants with CHIs that require further engagement above and beyond the regular and routine CHNA/CHIP processes. For further guidance, please see the *Community Engagement Standards for Community Health Planning Guidelines* and its appendices for clarification around any of the following terms and questions.

All questions in the form, unless otherwise stated, must be completed.

Approximate DoN Application Date: 11/15/2017

DoN Application Type: Hospital/Clinic Substantial Capital Expenditure

Applicant Name: Partners HealthCare System, Inc.

What CHI Tier is the project? ○ Tier 1 ◉ Tier 2 ○ Tier 3

1. Community Engagement Contact Person

Contact Person: Wanda McClain

Title: Vice President, Community Health and Health Equity, BWH

Mailing Address: 75 Francis Street

City: Boston

State: Massachusetts

Zip Code: 02115

Phone: 6172648747

Ext:

E-mail: wmcclain@bwh.harvard.edu

2. Name of CHI Engagement Process

Please indicate what community engagement process (e.g. the name DoN CHI Initiative associated with the CHI amount) the following form relates to. This will be use as a point of reference for the following questions.
(please limit the name to the following field length as this will be used throughout this form):

BWH DoN CHI 2018

3. CHI Engagement Process Overview and Synergies with Broader CHNA /CHIP

Please briefly describe your overall plans for the CHI engagement process and specific how this effort that will build off of the CHNA / CHIP community engagement process as is stated in the *DoN Community-Based Health Initiative Planning Guideline.*

In response to the Brigham and Women's Hospital ("BWH") Determination of Need application, including the required community health initiative forms ("CHI") submitted on November 15, 2017, the Department of Public Health ("Department") noted "It is clear that the last DoN process and the 2016 Community Health Needs Assessment ("CHNA") was a thoughtful and community engaged process. We (The Department) agree that the process is evidence of a sound community engagement process that led to the identification of health priorities and that it can and should be used as the basis for CHI funding decisions." (email correspondence, Ben Wood 12.22.17). Furthermore, the Department acknowledged that there was, "A lot of synergy in the CHNA approach that should lead to easy alignment between the priority issues identified and the DoN Health Priorities." (email correspondence, Ben Wood 12.22.17). Accordingly, based on this shared understanding and as requested, BWH has developed the following CHI engagement process for the "Act on What is Important" and "Evaluate Action" Stages. This is consistent with the DoN Community Engagement Guideline and leverages best practices and synergies learned and established during the CHNA process. The steps described on this form will enable a transparent, clear and mutually accountable process for decision making and communication to advisory committee members and to the wider community:

• A CHI Advisory Committee has been established which includes members that represent the various constituencies outlined in the DoN Community Engagement Guideline.

• BWH's Advisory Committee was convened on October 31, 2017 for a preparatory meeting. The objective of this meeting was to provide a general overview of the CHI process and parameters for Committee's work. The roles and responsibilities as described in the Guidelines were shared with members and, together with DPH staff member – Halley Reeves, we responded to questions from committee members. Members were also provided with a copy of the 2016 BWH CHNA/Implementation Plan that was used to develop the required DoN CHI forms. This CHNA will also be used to determine Health Priorities for CHI funding.

• The Advisory Committee will be reconvened upon approval of the DoN by the Public Health Council. The roles and responsibilities of the committee and BWH will be explicitly discussed to ensure mutual understanding and agreement to guide the committee's decision making process.

• It is anticipated that the Advisory Committee will meet at least three times to select DoN health priorities and related strategies (using the 2016 CHNA as the basis for all decisions). Once health priority decisions have been made, the Advisory Committee will submit the necessary Health Priorities Form to the Department.

• Post-approval of health priorities, all Advisory Committee members will complete a conflict of interest form to determine if they are eligible for participation in the Allocation Committee that develops a request for proposal ("RFP") for CHI funding and the allocation of all CHI monies.

Additionally, in regard to the CHI administrative fee, as outlined in Table 1: CHI Funding Tiers and Community Engagement Requirements for Hospitals in the Department's Determination of Need Community-Based Health Initiative Planning Guideline, Applicants submitting a Tier 2 CHI are eligible for a three percent (3%) administrative fee. Specifically, for this CHI, these monies ($109,780.12) if allocated over a six- to eight-year period will range from $13,000 to $18,000 per year and will be used for administrative support of the DoN CHI efforts, including but not limited to: implementation, reporting and dissemination of promising practices and lessons learned, facilitation support for the Advisory Committee and Allocation Committee, costs associated with the development of communication materials and placement of procurement information in community newspapers as described in question #11 of the Community Engagement Plan Form.

4. CHI Advisory Committee

In the CHNA/CHIP Self Assessment, you listed (or will list) the community partners that will be involved in the CHI Advisory Committee to guide the BWH DoN CHI 2018 . As a reminder:

For Tier 2 DON CHI Applicants: The CHI Advisory Committee is tasked with helping select DoN Health Priorities based on the CHNA / CHIP unless the Applicant is directed by DPH to conduct additional community engagement. If so, the advisory committee's role is to guide that additional work.

For Tier 3 DON CHI Applicants: The CHI Advisory Committee is to select DoN Health Priorities based on**, but not exclusive to,** the CHNA / CHIP. This includes the additional community engagement that must occur to develop the issue priorities.

5. Focus Communities for CHI Engagement

Within the BWH DoN CHI 2018 , please specify the target community(ies), please consider the community(ies) represented in the CHNA / CHIP processes where the Applicant is involved.

Add/Del Rows	Municipality	If engagement occurs in specific neighborhoods, please list those specific neighborhoods:
+ -	Boston	Specific neighborhoods include Dorchester, Mattapan, Mission Hill, Roxbury and Jamaica Plain

6. Reducing Barriers

Identify the resources needed to reduce participation barriers (e.g., translation, interpreters, child care, transportation, stipend). For more information on participation barriers that could exist, please see Appendix A from the *Community Engagement Standards for Community Health Planning Guidelines* http://www.mass.gov/eohhs/docs/dph/quality/don/guidelines-community-engagement.pdf

BWH has reviewed the Community Planning Toolkit to understand the barriers and
design issues that need to be considered when engaging community members. Based on this evaluation, BWH staff have developed the following solutions to overcome barriers. By working with community partners, BWH will mitigate barriers through the following approaches:

• Translation of the RFP Announcement into appropriate languages, based on community need, for inclusion in community newspapers (as noted in question #11).

• Where needed, provide interpreters in appropriate community languages as part of the evaluation process.

• Ensure access for individuals with disabilities at meetings and gatherings associated with the CHI and community engagement.

• For the evaluation process, BWH staff will confer with the CHI Advisory Committee to determine the range of options for engagement processes.

• Develop a thoughtful pre-assessment of location and time of any gatherings to maximize participation of relevant community members/groups (access to public transportation and safety for participants will also be key considerations). Additionally, BWH will provide food at these gatherings and ensure a family friendly environment that is responsive to the needs of young people and parents/ caregivers in the noted neighborhoods.

7. Communication

Identify the communication channels that will be used to increase awareness of this project or activity:

BWH is committed to a transparent process and ongoing communication to ensure stakeholders are informed, engaged and have opportunities to provide feedback and participate as partners to shape our strategy. We anticipate that this CHI process will provide an opportunity to deepen community understanding of the impact of the social determinants of health and we will take every opportunity to build these messages into our communication processes. The communication channels that will be utilized are described in detail in question #11 below and include broad email communication, a dedicated CHI email inbox, a dedicated CHI web page on the BWH web site and local media outlets that are accessed by residents and organizations in the five communities identified in question #5.

8. Build Leadership Capacity

Are there opportunities with this project or activity to build community leadership capacity? (•) Yes ( ) No

If yes, please describe how.

Throughout each aspect of the CHI process, BWH staff and the Advisory Committee, in tandem with UMDI staff, will determine what these opportunities may be and seek to work with community partners to bolster their leadership capacity. Given the procurement and evaluation aspects of the CHI, there are potential opportunities for building community leadership capacity. During the procurement phase, Allocation Committee members will be directly involved in site visits to a shortlist of potential grantees. This experience builds their capacity in the decision-making process and engages them as equal and valued partners in the effort. BWH and UMDI are committed to evaluation designs that build capacity for those involved. The 'ground up' evaluation design that we have used for the evaluation work undertaken with the Health Equity grantees (under the prior BWH DoN) is evidence of this capacity building approach. To share promising practices, we are exploring convening an annual poster session as part of this DoN CHI to disseminate learnings and to advance work on addressing the social determinants of health. We will explore available opportunities to present the DoN CHI work at relevant conferences and gatherings (e.g. APHA, the Ounce of Prevention, MPHA, ACHI) and will encourage grantees to participate in this effort.

9. Evaluation

Identify the mechanisms that will be used to evaluate the planning process, engagement outcome, and partner perception and experience:

The evaluation design for this CHI is anticipated to have specific objectives as described below. As indicated in the DoN application submitted on November 15, 2017, the University of Massachusetts Donahue Institute with extensive experience in large scale policy and program evaluation will be contracted to undertake the CHI evaluation once BWH receives DoN approval.

It is anticipated that the following four evaluation objectives will form the basis of the evaluation plan:

Objective #1 – Assess and provide data-driven feedback regarding the community engagement process and strategies used over the course of the CHI.

Objective #2- Inform future practice and innovation by monitoring and documenting the process of grant implementation of the overall DoN and the grant recipient level.

Objective #3 - Assess grant-level program health equity impacts by working with grant recipients to identify, measure, and report outcomes at key points in the grant process.

Objective #4 – To build evaluation capacity among grant recipients and awareness among DoN stakeholders.

The mechanism to be used to evaluate the planning process, engagement outcome(s), and partner perception and experience will involve collaborative consultation with advisory and allocation committee members, as well as grant recipients to develop program-specific processes and outcomes measures, data collection plans, and reporting templates. Through this collaborative consultation, evaluators will aim to build grantee capacity to engage in program evaluation and use results to inform practice(s). Mixed methods approaches will be utilized, including observation, quantitative data collection, and qualitative data collection to gather all necessary data relevant to the priority areas and key measures appropriate to the initiative at the both the overall DoN level and grant recipient level.

10. Reporting

Identify the mechanisms that will be used for reporting the outcomes of this project or activity to different groups within the community:

Residents of Color

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: Black Ministerial Alliance, NAACP (Boston Branch), the Mayor's Office of Immigrant Advancement, Community Change, Inc. Additionally, publication of a formal announcement will be made in the Bay State Banner as described in question #11.

Residents who speak a primary language other than English

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: Mayor's Office of Immigrant Advancement, Sociedad Latina, La Alianza Hispana, Asian American Women for Health, Casa Esperanza. Additionally, publication of a formal announcement will be made in El Planeta as described in question #11.

Aging population

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: Boston Commission of Affairs of the Elderly, Senior Service Providers in the five neighborhoods (including, but not limited to Ethos, Roxbury Tenants of Harvard, Kit Clark Senior Services and Central Boston Elder Services).

Youth

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: Boston Center for Youth and Families, Boston Public Schools, BEST Network, YMCA/YWCA, Apprentice Learning, Boys and Girls Clubs of Boston and Cradles to Crayons.

Residents Living with Disabilities

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: Boston Center for Independent Living, Ethos and the Multi-cultural Independent Living Center of Boston.

GLBTQ Community

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: GLAAD, BAGLEY, and PFLAG.

Residents with Low Incomes

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: Community Development Corporations that service the five noted communities, ABCD, City Life, MassHousing. Additionally, publication of a formal announcement will be made in the the Bay State Banner and El Planeta as described in question #11.

Other Residents

BWH staff will ensure communication materials are sent to the following organizations with a request to distribute among their networks: community health centers that reside in the five communities listed in question #5, the Boston Foundation and the Boston Alliance for Community Health and Jane Doe, Inc. The Advisory Committee with its diverse and multi-sector composition will also support dissemination to the groups above, as well as other residents in priority neighborhoods. BWH staff will also request that the MA Department of Public Health and the Boston Public Health Commission distribute the notification of the RFP among their networks relevant to the focus communities.

11. Engaging the Community At Large

Which of the stages of a CHNA/CHIP process will the BWH DoN CHI 2018 focus on? Please describe specific activities within each stage and what level the community will be engaged during the BWH DoN CHI 2018 . While the step(s) you focus on are dependent upon your specific community engagement needs as a result of your previous CHNA/CHIP work, for tier 3 applicants the CHI community engagement process must at a minimum include the "Focus on What's Important," "Choose Effective Policies and Programs" and "Act on What's Important" stages. (For definitions of each step, please see pages 12-14 in the *Community Engagement Standards for Community Health Planning Guidelines* http://www.mass.gov/eohhs/docs/dph/quality/don/guidelines-community-engagement.pdf).

	Inform	Consult	Involve	Collaborate	Delegate	Community - Driven / -Led
☐ Assess Needs and Resources						
☐ Focus on What's Important						
☐ Choose Effective Policies and Programs						
☒ Act on What's Important	○	○	○	◉	○	○

	Inform	Consult	Involve	Collaborate	Delegate	Community - Driven / -Led
Please describe the engagement process employed during the "Act on What's Important" phase.	BWH has a longstanding commitment to addressing the social determinants of health to advance health equity in our priority communities. The community engagement activities for this DoN CHI will promote transparency, ongoing engagement and communication throughout the process. Our experience has shown that the most effective way to engage communities is to tap into the communication 'hubs' that they access including umbrella organizations (as described in question #10), as well as using trusted community media outlets. We are committed to providing regular updates on the CHI process as in advances. Once the CHI Priorities are determined in consultation with the Community Advisory Committee, the following action steps will be taken to ensure a transparent funding and allocation process: Step 1: With the involvement of the Allocation Committee (comprised of Advisory Committee members that do not have a conflict of interest that necessitate them to recuse themselves), the CHI evaluators and BWH staff, a RFP will be developed that aligns with the DoN health priorities selected. Step 2: To ensure broad community awareness of the CHI opportunity, the RFP will be posted to a dedicated CHI web page on the BWH web site (with a sign-up option for those who wish to receive additional information). An email notification with a link to the RFP will be sent to the following groups: 1. Advisory Committee members 2. All organizations identified in question #10 3. The organizations that received notification of the Health Equity Grants (and the 88 organizations that submitted applications to the DoN funded Health Equity grants in 2016). 4. BWH staff will request that the MA Department of Public Health and the Boston Public Health Commission distribute the notification of the RFP among their networks relevant to the focus communities. Moreover, a public notice of the procurement will be posted in the Bay State Banner (a free weekly newspaper that has a strong readership with the African American community and is distributed throughout the priority communities in Question #5) and El Planeta (the largest Spanish-language newspaper in the Boston Area), as well as BWH's CCHHE newsletter and via BWH's social media. Step 3: An information session will be conducted to provide an overview of the funding opportunity RFP and requirements for submissions. Additionally, BWH will establish a dedicated email inbox receiving and responding to all communication associated with the procurement process and frequently asked questions will be posted on the web site. Step 4: The Allocation Committee will be directly involved in the selection of grant recipients including participating in site visits to grant finalists. Step 5: Communication of the final funding decisions on our website, via email to organizations above and in the relevant community media outlets. Step 6: Explore and harness opportunities to promote continuous learning and disseminate knowledge from this CHI process (described in detail in Question #8).					

	Inform	Consult	Involve	Collaborate	Delegate	Community - Driven / -Led
☒ Evaluate Actions	○	○	○	◉	○	○
Please describe the engagement process employed during the "Evaluate Actions" phase.	The evaluation plan and process for engagement is delineated in the response to question #9.					

12. Document Ready for Filing

When the document is complete, click on "document is ready to file". This will lock in the responses, and Date/Time stamp the form. To make changes to the document, un-check the "document is ready to file" box. Edit the 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 DPH" button.

This document is ready to file: ☒

E-mail submission to DPH

Date/Time Stamp: 01/09/2018 4:13 pm