PARTNERS HEALTHCARE SYSTEM, INC.
DON APPLICATION # PHS-19030610-HS
ATTACHMENTS

SUBSTANTIAL CHANGE IN SERVICE
DON-REQUIRED EQUIPMENT
BRIGHAM AND WOMEN'S FAULKNER HOSPITAL

MARCH 6, 2019

BY

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2. Project Description

Partners HealthCare System, Inc. ("Applicant" or "Partners HealthCare") located at 800 Boylston Street, Suite 1150, Boston, MA 02199 is filing a Notice of Determination of Need ("Application") with the Massachusetts Department of Public Health ("Department") for a change in service by Brigham and Women's Faulkner Hospital, Inc. ("BWFH" or "the Hospital") located at 1153 Centre Street, Boston, MA 02130. BWFH is a community acute care hospital that provides comprehensive medical, surgical and psychiatric care as well as complete emergency, ambulatory and diagnostic services. The Hospital's Radiology Department offers a variety of imaging services including computed tomography ("CT"), magnetic resonance imaging ("MRI"), ultrasound, nuclear medicine, mammography, interventional procedures and diagnostic x-ray. As part of this offering, BWFH is currently licensed to provide CT imaging via two units. The proposed project is for the expansion of imaging services at BWFH through the acquisition of a specialized extremity Cone Beam CT ("CBCT") unit ("Proposed Project").

The need for the addition of a CBCT unit at BWFH is based on the current lack of CBCT services offered at BWFH and the existing and future needs of the Applicant's patient panel. Presently, patients presenting at BWFH that would benefit from CBCT services, namely patients with musculoskeletal conditions of the extremities, are at a disadvantage as such services are not available at BWFH. This situation requires BWFH patients with conditions of the upper and lower extremities to settle for traditional x-ray imaging or imaging performed on one of BWFH's traditional CT units which, compared with the proposed CBCT unit, are not as technologically advanced and are more limited in their capability to precisely image these anatomical locations. Looking into the future, this lack of on-campus CBCT services at BWFH is not ideal. Statistics indicate that the prevalence of musculoskeletal conditions increase with age and statewide and system projections suggest that the patient population will grow into the older age cohorts through 2035. Being that CBCT is a well-established imaging tool used to diagnosis and treat age-related musculoskeletal conditions of the extremities, these findings suggest that the demand for CBCT services to treat older adult patients will expand into the future and therefore, support the need for the Proposed Project.

In terms of quality and access, the Applicant anticipates that the Proposed Project will facilitate the provision of higher quality imaging services and improve health outcomes for a subset of patients within its panel. Compared with traditional CT, the proposed CBCT unit offers improved diagnostic capabilities for patients with musculoskeletal conditions of the extremities; supports weightbearing imaging of the foot, ankle, leg and knee in addition to the non-loaded imaging of these and the upper extremities; and provides reduced radiation exposure and faster acquisition times. Through implementation of the proposed CBCT unit, clinicians will utilize higher resolution, more precise, and better-quality images to improve their ability to prescribe the optimal treatment approach. Moreover, siting the proposed CBCT unit at BWFH next to the Hospital's high-volume orthopedic center will ensure that patients with extremity conditions have access to co-located high-quality imaging, musculoskeletal, and surgical services at BWFH's campus, which will foster care coordination, improve the overall quality of the Hospital's services and promote better health outcomes.

Finally, the Proposed Project will meaningfully contribute to Massachusetts' goals for cost containment by providing cost-effective, high-quality CBCT imaging services and creating care efficiencies for patients. The proposed CBCT services will be reimbursed at the same rate as traditional CT services, and therefore will not negatively impact the cost growth benchmark set for the Commonwealth. Moreover, scans on the proposed CBCT unit often will be used as a substitute for scans on the Hospital's traditional CT units, as CBCT technology offers the unique

and differentiating ability to produce high-quality CT imaging of patients in a weightbearing stance, increasing specificity for patients with musculoskeletal conditions of the extremities. By improving the diagnostic accuracy of hard to diagnose musculoskeletal extremity conditions, reducing the need for less specific and frequently duplicative testing (which is currently necessary given the limited capability of the Applicant's existing equipment inventory to conclusively image the musculoskeletal extremities), and decreasing the potential for misdiagnoses and expensive corrective care, the Applicant anticipates that the Proposed Project will assist in decreasing overall healthcare spending in the state. Accordingly, the Proposed Project will contribute positively to the Commonwealth's goals of containing the rate of growth of total medical expenses ("TME") and total healthcare expenditures ("THCE").

In sum, the proposed expansion of imaging services at BWFH through the acquisition of a specialized extremity CBCT unit will allow patients with musculoskeletal conditions of the extremities in need of imaging services to receive high-quality care in an integrated setting. This expanded imaging capacity at BWFH will provide patients with convenient access to co-located CBCT imaging, musculoskeletal, and surgical services without negatively impacting the state's cost growth benchmark, and therefore will improve care coordination, patient experience, and public health outcomes. Accordingly, the Proposed Project meets the factors of review for Determination of Need approval.

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.

A. Partners HealthCare Patient Panel

Partners HealthCare is a not-for-profit, integrated health care system that was formed in 1994 by an affiliation between The Brigham Medical Center, Inc. (now known as Brigham Health)[1] and The Massachusetts General Hospital. Partners HealthCare currently operates two tertiary hospitals, six community acute care hospitals, and one acute care specialty hospital in Massachusetts; one community acute care hospital in Southern New Hampshire; one facility providing inpatient and outpatient mental health services; and three facilities providing inpatient and outpatient services in rehabilitation medicine and long-term care. Partners HealthCare also operates physician organizations and practices, a home health agency, nursing homes and a graduate level program for health professionals. Partners HealthCare is a non-university-based nonprofit private medical research enterprise and its academic medical centers are principal teaching affiliates of the medical and dental schools of Harvard University. Partners HealthCare provides its services to patients primarily from the Greater Boston area and eastern Massachusetts, as well as New England and beyond. Additionally, Partners HealthCare operates a licensed, not-for-profit managed care organization that provides health insurance products to the MassHealth Program (Medicaid), Commonwealth Care (a series of health insurance plans for adults who meet income and other eligibility requirements) and commercial populations.

[1] Brigham Health is composed of Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and Brigham and Women's Physicians Organization.

Partners HealthCare serves a large and diverse patient panel as demonstrated by the utilization data for the 36-month period covering Fiscal Year ("FY") 15-17 and the preliminary data available for FY18.[2] Appendix 2 provides this demographic profile for Partners HealthCare in table form. The number of patients utilizing Partners HealthCare's services has increased since FY15, with 1,347,860 unique patients in FY15, 1,377,282 unique patients in FY16 and 1,403,898 unique patients in FY17.[3] Preliminary data indicates that in FY18 Partners HealthCare had 1,498,562 unique patients. Partners HealthCare's patient mix consists of approximately 42% males and 58% females. The Massachusetts Center for Health Information and Analysis ("CHIA") reports that Partners HealthCare's patient panel represents 19% of all discharges in the Commonwealth.[4] The system's case mix adjusted discharge rate is 22%.[5]

Partners HealthCare has seen an increase in the number of patients it serves across all age cohorts between FY15 and FY17. Current age demographics show that the majority of the patients within Partners HealthCare's patient population are between the ages of 18-64 years of age (59.7-62.1% of total patient population). Patients that are 65 and older also make up a significant portion of the total patient population (26.7-27.7% of total patient population). Only 9.6-11.1% of Partners HealthCare's patients are between 0-17 years of age. Preliminary data for FY18 shows similar trends with regard to increases across age cohorts and cohort distribution.

Partners HealthCare's patient panel reflects a mix of races. Data based on patient self-reporting demonstrates that in FY17, 72.3% of the total patient population identified as White; 5.7% identified as African American or Black; 4.1% identified as Asian; 1.7% identified as Hispanic/Latino; 0.1% identified as American Indian or Alaska Native; and 0.1% identified as Native Hawaiian or Other Pacific Islander. Since patients were grouped into these categories based on how they self-identified,[6] there is a portion of the patient population (16% in FY17) that

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[2] Fiscal year October 1 – September 30. While preliminary data is available for FY18, annual comparisons are calculated using data for FY15-17 as the FY18 data has not yet been finalized and is subject to change.

[3] Entities include: Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, Massachusetts General Hospital, Newton-Wellesley Hospital, and North Shore Medical Center; Cooley Dickinson Hospital, Martha's Vineyard Hospital, McLean Hospital, and Nantucket Cottage Hospital (post-Epic data only); Massachusetts Eye and Ear Infirmary (outpatient post-Epic data only); Spaulding Rehabilitation Hospital (Telehealth, Partners Mobile Observation Unit, Home Hospital programs for GH and BWH, Stay Connected with GH, Lifeline, and CareSage programs are not included); Brigham and Women's Physicians Organization, Massachusetts General Physicians Organization, Newton-Wellesley Medical Group, and North Shore Physicians Group; Cooley Dickinson PHO (post-Epic data only); and Partners Community Physicians Organization (pre-Epic non-risk patients not included). Please note: The methodology for aggregating Partners HealthCare's patient panel data has evolved into an automated process utilizing internal data resources. Initially, in 2017, when Partners HealthCare began developing its patient panel for Determination of Need applications, such as the Change of Ownership for Massachusetts Eye and Ear and the Substantial Capital Expansion for Brigham and Women's Hospital, staff manually aggregated the necessary data. However, since these submissions, Partners HealthCare staff have developed a new automated process that allows for the collection and amalgamation of system-wide data. This refined methodology allows staff to continuously monitor and improve the way that data are aggregated. Accordingly, between June 2018 and October 2018, staff further refined the data collection processes leading to a decrease of no more than 5% in overall patient counts for the system. Staff will continue to refresh and refine the process for aggregating data across the system, leading to more exact patient panel data.

[4] *Fiscal Year 2015: Partners HealthCare System*, MASSACHUSETTS CTR. FOR HEALTH INFORMATION ANALYSIS, http://www.chiamass.gov/assets/docs/r/hospital-profiles/2015/Partners-HealthCare-System.pdf (last visited Feb. 5, 2019).

[5] *Id.*

[6] With the exception of the category "Hispanic/Latino," the race categories shown above are based on the 1997 Office of Management and Budget standards on race and ethnicity. Patients were grouped into these categories based on their responses as follows – White: "White"; African American or Black: "African American", "Black", "Black or African American"; American Indian or Alaska Native: "American Indian", "American Indian or Alaska Native"; Asian: "Asian"; Native Hawaiian or Other Pacific Islander: "Native Hawaiian or Other Pacific Islander", "Native Hawaiian/Other Pacific

either chose not to report their race or identified as a race that did not align with the above categories. Therefore, it is important to note that the racial composition of Partners HealthCare's patient panel may be understated.

Partners HealthCare provides care to patients from a broad range of geographies including all fifty states. While Partners HealthCare's patient panel resides mainly in Eastern Massachusetts, there is a sizeable portion of the patient panel that resides outside of Massachusetts (10.6%, or 148,225 patients, in FY17). By applying the Department of Public Health's ("DPH") Health Service Area ("HSA") categories to FY17 data, 45.4% of Partners HealthCare's patients reside in HSA 4 (637,347 patients); 17.6% reside in HSA 6 (247,600 patients); 15.2% reside in HSA 5 (213,127 patients); 6.4% reside in HSA 3 (89,773 patients); 3.4% reside in HSA 2 (47,480 patients); 1.0% reside in HSA 1 (13,522 patients); 0.01% reside in MA but outside of HSAs 1-6 (80 patients); and the origin of 6,744 patients or 0.5% of the panel is unknown.

B. BWFH Patient Panel

BWFH is a community acute care hospital member of the Applicant that provides comprehensive medical, surgical and psychiatric care as well as complete emergency, ambulatory and diagnostic services. Appendix 2 provides the demographic profile for BWFH in table form. Similar to Partners HealthCare, the number of patients utilizing BWFH's services increased from FY15-17, with 85,441 unique patients in FY15, 87,757 unique patients in FY16, and 89,024 unique patients in FY17. Preliminary data indicates that in FY18 BWFH had 89,359 unique patients. Of these patients, approximately 34% are male and 66% are female.

In regard to age, the majority of the patients within BWFH's patient population are between the ages of 18-64 (63.3%, or 56,359 patients, in FY17). The next largest age cohort is patients that are 65 years and older (35.2%, or 31,317 patients, in FY17). Subsequently, 1.5% of BWFH's patients are between ages 0-17 (1,347 patients in FY17). Preliminary data for FY18 shows similar trends and continued increases in the number of patients served across all age cohorts.

Moreover, BWFH's patients reflect a diversity of races. Data based on patient self-reporting demonstrate that in FY17, 71.2% of BWFH's patients identified as White; 11.1% identified as African American or Black; 5.2% identified as Hispanic/Latino; 2.2% identified as Asian; 0.2% identified as American Indian or Alaska Native; and 0.05% identified as Native Hawaiian or Other Pacific Islander. Since patients were grouped into these categories based on how they self-identified,[7] there is a portion of the patient population (10.1% in FY17) that either chose to not report their race or identified as a race that did not align with the above categories. Therefore, it is important to note that the racial composition of BWFH's patients may be understated.

Finally, Appendix 2 provides aggregated zip code data by HSA for BWFH's patient population. This data indicates that 73.4% of BWFH's patients reside in HSA 4 (65,332 patients); 12.3% reside in HSA 5 (10,984 patients); 3.1% reside in HSA 6 (2,732 patients); 3.0% reside in HSA 2 (2,682

Islander", "Pacific Islander"; Hispanic/Latino: "Hispanic"," Hispanic or Latino"," Latino"; Other/Unknown: All other responses.

[7] With the exception of the category "Hispanic/Latino", the race categories shown above are based on the 1997 Office of Management and Budget standards on race and ethnicity. Patients were grouped into these categories based on their responses as follows – White: "White"; African American or Black: "African American", "Black", "Black or African American"; American Indian or Alaska Native: "American Indian", "American Indian or Alaska Native"; Asian: "Asian"; Native Hawaiian or Other Pacific Islander: "Native Hawaiian or Other Pacific Islander", "Native Hawaiian/Other Pacific Islander", "Pacific Islander"; Hispanic/Latino: "Hispanic"," Hispanic or Latino"," Latino"; Other/Unknown: All other responses.

patients); 2.1% reside in HSA 3 (1,842 patients); and 0.7% reside in HSA 1 (624 patients).[8] Approximately 4,600 patients or 5.2% of the panel is from outside of Massachusetts, and the origin of 0.2% of the panel is unknown.

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.

Diagnostic imaging utilization, including imaging with CT, has increased significantly in the United States over the last several decades.[9] A number of factors have contributed to this increase, including technological advancements (e.g., improvements in techniques, resolution, and image acquisition time) and expansion of clinical applications (particularly to diagnose and treat age-related conditions).[10] The Applicant has been no exception to this upward trend. With regard to CT specifically, from FY16-FY18 scan volume at BWFH increased by 22% (from 14,014 scans in FY16 to 17,108 scans in FY18). Although this data gives context to the volume of CT services being provided at BWFH, as provided in greater detail below, the need for CBCT services is not based on the need for additional capacity, but rather on the technology's ability to provide novel clinical applications meeting the special needs for specific subsets of patients which are expected to grow into the future.

A. CBCT Technology

CT is a powerful, noninvasive imaging technique that has increased in technological capability and clinical application since it first became available for clinical use in the United States in the 1970s. One important aspect of improved CT capability has been the development of devices that employ CBCT technology. As further detailed in Factor F1.b.i, CBCT is a variant of traditional CT that uses a cone shaped beam, rather than a fan shaped beam, to image an extended volume of a patient in one single rotation. The use of CBCT technology is advantageous as it leads to higher quality images of certain parts of the body, as well as improvements in imaging speed, spatial resolution, and dose efficiency.

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[8] In FY17, 3 BWFH patients resided in MA but outside of HSAs 1-6.

[9] Rebecca Smith-Bindman et al., *Rising Use Of Diagnostic Medical Imaging In A Large Integrated Health System*, 27 HEALTH AFFAIRS 1491 (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2765780/pdf/nihms-137739.pdf; Rebecca Smith-Bindman et al., *Use of Diagnostic Imaging Studies and Associated Radiation Exposure For Patients Enrolled in Large Integrated Healthcare Systems, 1996–2010*, 307 JAMA 2400 (2012), *available at* https://jamanetwork.com/journals/jama/fullarticle/1182858; Robert J. McDonald et al., *The Effects of Changes in Utilization and Technological Advancements of Cross-Sectional Imaging on Radiologist Workload*, 22 ACADEMIC RADIOLOGY 1191 (2015); Michael Walter, *Feeling overworked? Rise in CT, MRI images adds to radiologist workload*, RADIOLOGY BUSINESS (Jul. 31, 2015), http://www.radiologybusiness.com/topics/quality/feeling-overworked-rise-ct-mri-images-adds-radiologist-workload; *Increases in Imaging Procedures, Chronic Diseases Spur Growth of Medical Imaging Informatics Market*, IMAGING TECHNOLOGY NEWS (Oct. 28, 2016), https://www.itnonline.com/content/increases-imaging-procedures-chronic-diseases-spur-growth-medical-imaging-informatics-market.

[10] *Rising Use Of Diagnostic Medical Imaging In A Large Integrated Health System*, *supra* note 9; *Use of Diagnostic Imaging Studies and Associated Radiation Exposure For Patients Enrolled in Large Integrated Healthcare Systems, 1996–2010*, *supra* note 9; McDonald et al., *supra* note 9; Walter, *supra* note 9; *Increases in Imaging Procedures, Chronic Diseases Spur Growth of Medical Imaging Informatics Market*, *supra* note 9.

Based on this innovation, a clinical imperative exists to utilize CBCT units and several manufacturers have produced various CBCT units in recent years. One such manufacturer, Carestream Health, has produced a CBCT unit, the OnSight 3D Extremity System, that received clearance from the United States Food and Drug Administration ("FDA") in 2016.[11] The need for the acquisition and implementation of the OnSight 3D Extremity System at BWFH is based on the technology's innovative applications when evaluating conditions affecting the musculoskeletal system. As the name suggests, the proposed CBCT unit is designed specifically to image the extremities (e.g., hands, wrists, elbows, knees, feet, ankles). Consequently, BWFH clinicians will only be able to utilize this device for evaluation of certain patients.

Novel clinical applications of the proposed CBCT unit include, but are not limited to, the following:

- Excellent visibility of bone detail and soft-tissue suitable to a broad spectrum of musculoskeletal indications;
- Ability to see the extent of arthritis or the specifics of a fracture, which can assist a surgeon in determining if surgery is required;
- Precise depiction of the degree and extent of degenerative joint changes and ability to image pathology in small joints not visible due to overlying of bony structures or the presence of a metallic screw;
- Improved visualization of occult, mal-union, and non-union bone fractures, thus eliminating an incorrect or missed diagnosis on a query fracture;
- High spatial resolution resulting in exquisite detail of bone microarchitecture and ability to more accurately assess progression of healing, which can shorten a patient's recovery time; and
- Ability to produce weightbearing images of the lower extremities, which reveal alignment abnormalities that may not be seen on non-weightbearing images produced by traditional CT units.[12]

B. Current and Future Patient Panel Needs

At present, BWFH does not have a CBCT unit. Accordingly, BWFH patients with musculoskeletal conditions of the extremities – including, but not limited to, patients referred from BWFH's high-volume orthopedic, podiatry, physiatry and rheumatology service lines – are imaged on BWFH's traditional x-ray devices or CT units, which are more limited in their capability to accurately image the extremities. This is not ideal; the inherent limitations of the Hospital's traditional units often necessitate duplicative testing in order to obtain conclusive, quality images, and thereby create a situation that is not conducive to a seamless one-stop provision of care.

The Proposed Project will allow the Applicant, and specifically BWFH, to address the needs of the patient panel and the need for access to CBCT services. The proposed CBCT unit will be located at BWFH, the site within the Brigham Health network with the highest orthopedic clinic and surgical volume, adjacent to the orthopedic center, which offers the following services: foot

[11] *OnSight 3D Extremity System*, CARESTREAM HEALTH, INC., https://www.carestream.com/en/us/medical/products/carestream-onsight-3d-extremity-system (last visited Feb. 5, 2019); Letter from Robert Ochs, Director, U.S. Food & Drug Admin., to Carolyn Wagner, Senior Supervising Manager, Carestream Health, Inc. (Aug. 30, 2016), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160723.pdf [hereinafter Letter from Robert Ochs]; *Carestream's OnSight 3D Extremity System Receives FDA 510(k) Clearance*, CARESTREAM HEALTH, INC. (Sep. 8, 2016), https://www.carestream.com/en/us/newsandevents/news-releases/2016/carestreams-onsight-3d-extremity-system-receives-fda-510k-clearan.

[12] *See infra* Factor F1.b.i.

and ankle, hand and upper extremity, joint replacement, knee replacement, podiatry, rehabilitation, and sports medicine and shoulder services. By siting the proposed CBCT unit next to BWFH's high-volume orthopedic center, the Applicant aims to provide increased access to high-quality imaging services and facilitate care coordination for patients with musculoskeletal conditions of the extremities. Specifically, upon implementation of the Proposed Project, appropriate patients will be shifted from the Hospital's traditional CT (and, in some cases, x-ray) units, which together were utilized to perform 13,944 upper and lower extremity scans in FY16, 15,185 upper and lower extremity scans in FY17, and 15,477 upper and lower extremity scans in FY18. In terms of current need, the Applicant anticipates, based on a review of the relevant CPT codes that may be impacted by the installation of the proposed extremity CBCT unit, that through the implementation of the Proposed Project, approximately 1,100 clinical patients per year will benefit from this new modality.

The Proposed Project will also meet the future needs of the Applicant's patient panel. According to the University of Massachusetts' Donahue Institute's ("UMDI") *Long-Term Population Projections for Massachusetts Regions and Municipalities*, the statewide population is projected to grow a total of 11.8% from 2010 through 2035.[13] An analysis of UMDI's projections shows that the growth of the Commonwealth's population is segmented by age sector, and that within the next 20 years, the bulk of the state's population growth will cluster around residents that are age 50 and older.[14] Moreover, between 2015 and 2035, the Commonwealth's 65+ population is expected to increase at a higher rate compared to all other age cohorts; by 2035, the 65+ age cohort will represent approximately a quarter of the Massachusetts population.[15] The general trend of growth appears consistent across the counties where Partners HealthCare's affiliates are located. Moreover, patient panel data for FY17 indicates that patients ages 18-64 already comprise 62% of the Applicant's patient panel and 63% of BWFH's patient panel and that patients ages 65+ already comprise more than quarter of the Applicant's patient panel and greater than 35% of BWFH's patient panel.

These projections are significant with regard to the Proposed Project as the proposed CBCT unit is specifically advantageous for imaging of musculoskeletal extremities and studies indicate that age is a leading risk factor for musculoskeletal conditions.[16] As the statewide population continues to age and the number of patients that fall into the 50+ and 65+ age cohorts for Partners HealthCare and BWFH continues to remain high/grow, the demand for CBCT services is expected to remain high/increase as well. Accordingly, to ensure that BWFH's patient panel has timely, convenient access to high-quality CBCT services with proven effectiveness in various

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[13] UNIVERSITY OF MASSACHUSETTS DONAHUE INSTITUTE, LONG-TERM POPULATION PROJECTIONS FOR MASSACHUSETTS REGIONS AND MUNICIPALITIES 11 (Mar. 2015), *available at* http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf. The Massachusetts Secretary of the Commonwealth contracted with the University of Massachusetts Donahue Institute (UMDI) to produce population projections by age and sex for all 351 municipalities. *Id.* at 7. In recent years, Massachusetts has been experiencing an increase in the population growth rate per year due to high immigration and low domestic outflow, which is expected to slow down in 2030. *Id.* at 12.

[14] *Massachusetts Population Projections – EXCEL Age/Sex Details*, UNIVERSITY OF MASSACHUSETTS DONAHUE INSTITUTE (2015), http://pep.donahue-institute.org/downloads/2015/Age_Sex_Details_UMDI_V2015.xls. This data has been extracted for counties where current Partners HealthCare's hospitals and affiliates are located. *Id.*

[15] UNIVERSITY OF MASSACHUSETTS DONAHUE INSTITUTE, *supra* note 13, at 14. The report uses the cohorts as defined by the U.S. Census Bureau 2010 Census Summary, which are 0-19, 20-39, 40-64, and 65+. *Id.* Figure 2.5 in the report illustrates the increase in the 65+ age cohort from 2015 to 2035. *Id.*

[16] *See infra* Factor F1.b.i.; Ramon Gheno et al., *Musculoskeletal Disorders in the Elderly*, 2 J. CLINICAL IMAGING SCI. 1 (2012), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3424705/; WORLD HEALTH ORGANIZATION, WORLD REPORT ON AGEING AND HEALTH (2015), *available at* http://apps.who.int/iris/bitstream/10665/186463/1/9789240694811_eng.pdf; AJ Freemont & JA Hoyland, *Morphology, mechanisms and pathology of musculoskeletal ageing*, 211 J. PATHOLOGY 252 (2007).

musculoskeletal fields, including orthopedics, podiatry, physiatry and rheumatology, the Applicant seeks to expand imaging services at BWFH through the acquisition of Carestream Health's OnSight 3D Extremity System.

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 will not have an adverse impact on competition in the Massachusetts health care market based on price, TME, provider costs or other recognized measures of health care spending as evidenced by the information below.

While the addition of the proposed CBCT unit represents an expansion of the Applicant's overall clinical CT equipment inventory, the Applicant anticipates that the overall impact on competition in the Massachusetts health care marketplace will be negligible. BWFH clinicians will restrict use of the CBCT unit to those subsets of patients that meet the clinical requirements for the device (e.g., patients who have lower or upper extremity musculoskeletal issues). Given that a limited number of patients qualify for CBCT scanning services (approximately 1,100 patients per year will receive scans on the proposed CBCT unit) and since scans on the proposed CBCT unit will often be used as a substitute for scans performed on BWFH's existing traditional CT units, the impact on the market will be negligible. Importantly, the rate of reimbursement for scans performed on CBCT units is the same as the rate for scans performed on traditional CT units. As a result, there is no difference in reimbursement by shifting appropriate cases to the proposed CBCT unit.

Additionally, cost savings will be generated based on care efficiencies made possible by the CBCT unit's capacity to provide high-quality, precise, low-dose imaging of the extremities (e.g., hands, wrists, elbows, knees, feet, ankles). This capacity will improve the diagnostic accuracy of hard to diagnose conditions and thereby decrease utilization of less effective and inconclusive scans and tests. Duplicative testing, which is often necessary given the capability of the Applicant's current equipment inventory in order to overcome issues with patient placement and insufficient image quality, is inefficient and costly. By decreasing the need for duplicative scanning on the Hospital's traditional units, the acquisition of the proposed CBCT unit will assist in decreasing overall healthcare spending. Additionally, the precision of the CBCT unit will lead to accurate diagnoses of musculoskeletal conditions and refined surgical planning, which in turn will allow BWFH clinicians to avoid misdiagnoses which can result in complications, extensive follow-up interventions, and increased costs of care.

Finally, regarding the competitiveness of the overall capital expenditure, the Applicant notes that it received quotes for the acquisition and installation of the proposed CBCT equipment. The capital cost for the proposed CBCT unit is approximately 1/4 - 1/5 compared to traditional CT units and renovation, installation and maintenance costs are also relatively less expensive, due to the CBCT unit's compact design and simpler configuration. Given these quotes and the fact that cost savings generated by implementation of the proposed CBCT unit will outpace the relatively less expensive capital costs, the Applicant asserts that the Proposed Project competes on the basis of provider cost.

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.

Factor F1.a.ii describes how the addition of the CBCT unit at BWFH will meet the Applicant's patient panel need. As provided in greater detail below, the Proposed Project is further supported by extensive evidence-based literature related to the efficacy of CBCT technology. As an overview, this review focuses on clinical applicability, quality of care, comprehensive access, efficiency and convenience. Cost-savings are also associated with the Proposed Project; however, these points are addressed in Factors F1.a.iii and F2.a.

A. CBCT as an Imaging Modality

CT is a well-established, non-invasive imaging system that has been available for clinical use for several decades and has gained widespread acceptance in several fields of medicine.[17] Generally speaking, CT is a diagnostic imaging test that combines the use of sophisticated x-ray technology and computer processing to provide detailed anatomical and structural information.[18] Since its introduction into clinical use in the United States in the 1970s, CT has made enormous technical and engineering advances that have led to improvements in image quality, speed, and dose reduction, and have increased the clinical utilization of the technology.[19] One particularly important innovation in CT capability has been the development of specialized CBCT devices.[20]

CBCT is a modified version of traditional CT that was first introduced in the United States in the early 2000s.[21] The main difference between traditional CT and CBCT is how the images are acquired. In traditional CT, a narrowly collimated, fan-shaped x-ray beam and a narrow detector rotate around a patient in a helical progression to acquire multiple two-dimensional images of the field of view.[22] To produce an extended volume of the patient's anatomy via traditional CT, the

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[17] Carlo Liguori et al., *Emerging clinical applications of computed tomography*, 8 MED. DEVICES 265 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467659/; Norbert J. Pelc, *Recent and Future Directions in CT Imaging*, 42 ANNALS BIOMED. ENG'G 260 (2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958932/pdf/nihms557198.pdf; *Computed Tomography*, RADIOLOGYINFO.ORG, https://www.radiologyinfo.org/en/submenu.cfm?pg=ctscan (last visited Feb. 5, 2019).

[18] Liguori et al., *supra* note 17; Pelc, *supra* note 17; *Computed Tomography*, *supra* note 17; *Computed Tomography (CT)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115317.htm (last updated Mar. 7, 2018).

[19] Liguori et al., *supra* note 17; Pelc, *supra* note 17; *Half A Century In CT: How Computed Tomography Has Evolved*, INT'L SOC'Y COMPUTED TOMOGRAPHY (Oct. 7, 2016), https://www.isct.org/computed-tomography-blog/2017/2/10/half-a-century-in-ct-how-computed-tomography-has-evolved.

[20] Pelc, *supra* note 17; John A. Carrino et al., *Dedicated Cone-Beam CT System for Extremity Imaging*, 270 RADIOLOGY 816 (2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4263642/pdf/radiol.13130225.pdf; Magdalena Posadzy et al., *Cone beam CT of the musculoskeletal system: clinical applications*, 9 INSIGHTS IMAGING 35 (2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5825310/pdf/13244_2017_Article_582.pdf.

[21] W. Zbijewski et al., *A dedicated cone-beam CT system for musculoskeletal extremities imaging: Design, optimization, and initial performance characterization*, 38 MED. PHYSICS 4700 (2011), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3172864/; Sunny Sanyal, *Cone Beam Computed Tomography (CBCT) Rivals Image Quality of Computed Tomography (CT)*, VAREX IMAGING (Mar. 20, 2016), https://www.vareximaging.com/cone-beam-computed-tomography-cbct-rivals-image-quality-computed-tomography-ct.

[22] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Chia-Ding Shih et al., *Initial Report on the Use of In-Office Cone Beam Computed Tomography for Early Diagnosis of Osteomyelitis in Diabetic Patients*, 106 J. AM. PODIATRIC MED. ASS'N 128 (2016); Beth W. Orenstein, *Imaging in the Extremities*, 18 RADIOLOGY TODAY 16 (2017), *available at* https://www.radiologytoday.net/archive/rt0317p16.shtml; CARESTREAM HEALTH, INC., THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *available at*

patient must be imaged multiple times through the fan of x-rays as it rotates and the acquired data set must then be processed by computer software which reconstructs and stacks the two-dimensional slices to obtain a three-dimensional image.[23] In contrast, in CBCT, the x-rays are emitted in a three-dimensional divergent cone-shape and detected by a large-area flat panel detector.[24] The geometrically different beam configuration of CBCT enables the acquisition of the entire field of view in a single rotation about the patient and eliminates the need for multiple rotations around the area of interest.[25]

CBCT's acquisition of the entire field of view in one rotation has many advantages. Most notably, it leads to faster acquisition times and more rapid data collection compared with traditional CT.[26] For instance, Carestream's Health's OnSight 3D Extremity System captures a 3D extremity image in a single rotation that takes only 25 seconds.[27] Moreover, the latest version of Carestream's Health's image viewing software, which is installed on new OnSight 3D Extremity Systems and will be installed on the proposed OnSight 3D Extremity System at BWFH, enables completion of a full high-resolution volume reconstruction in approximately four minutes.[28] Taken together, practices that have these systems in place report workflows of roughly 10-15 minutes from start to finish.[29] This translates into increased patient throughput, improved workflow efficiency and productivity, enhanced convenience, and shortened time from imaging to diagnosis and treatment.[30]

Another key advantage of CBCT is that images are obtained with less radiation exposure compared with traditional CT scans.[31] This is partially attributable to the technology's ability to image a patient in a single rotation.[32] Specifically, the quicker motion and decreased scan time of the CBCT compared to a traditional CT scanner makes it possible to conduct a scan using a CBCT scanner with lower doses of radiation.[33] The decreased radiation exposure is also a

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https://www.carestream.com/en/us/-/media/publicsite/products-and-solutions/radiography-and-health-it/cbct/cbctwhitepaper_ltr_2015-09-22.pdf?la=en [hereinafter THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS].

[23] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; Orenstein, *supra* note 22; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[24] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; Orenstein, *supra* note 22; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[25] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; Orenstein, *supra* note 22; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[26] Carrino et al., *supra* note 20; Orenstein, *supra* note 22; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22; Sanyal, *supra* note 21.

[27] *Growing Number of Hospitals, Orthopaedic Practices Install Carestream OnSight 3D Extremity Imaging Systems*, CARESTREAM HEALTH, INC. (Nov. 8 ,2018), https://www.carestream.com/en/us/newsandevents/news-releases/2018/orthopaedic-practices-install-carestream-onsight-3d-extremity-imaging-systems.

[28] Orenstein, *supra* note 22.

[29] Orenstein, *supra* note 22.

[30] Carrino et al., *supra* note 20; Orenstein, *supra* note 22; *FDA Clears Carestream's 3-D Extremity Cone Beam CT Imaging System*, IMAGING TECHNOLOGY NEWS (Sep. 8, 2016), https://www.itnonline.com/content/fda-clears-carestreams-3-d-extremity-cone-beam-ct-imaging-system.

[31] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; J. YORKSTON & K. TÖEPFER, CARESTREAM HEALTH, INC., DOSE CONSIDERATIONS FOR ONSIGHT 3D EXTREMITY SYSTEM (2017), *available at* https://www.itnonline.com/sites/itnonline/files/whitepaper-CBCT-Dose-Consideration%20%285%29.pdf

[32] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; Orenstein, *supra* note 22; YORKSTON & TÖEPFER, *supra* note 31.

[33] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; Orenstein, *supra* note 22; YORKSTON & TÖEPFER, *supra* note 31; Vikki Harmonay, *What Is the Difference Between a CT Scanner & a Cone Beam CT Scanner?*, ATLANTIS WORLDWIDE (Aug. 2, 2017), https://info.atlantisworldwide.com/blog/ct-scanner-or-cone-beam-ct-scanner.

function of the fact that only the affected body part is placed into the unit and imaged.[34] With regard to extremity scanning, the effective radiation dose to a patient receiving an extremity scan on a CBCT is 4-6 times lower than a traditional CT of the same body part.[35] The relatively low irradiation of CBCT is a vast improvement and makes it a safer alternative to traditional CT, as exposure to ionizing radiation is associated with a detectable increase in the risk of developing cancer.[36]

Finally, as discussed in further detail below, CBCT provides better image quality of the extremities compared with traditional CT.[37] This is due, in part, to the short scan time, which results in improved image sharpness due to reduction in a patient's external and internal movement artifacts.[38] In addition, the high-resolution flat panel detectors and optimized image processing features of CBCT allow for volumetric images of the extremities with soft-tissue contrast resolution comparable to traditional CT and greatly improved spatial resolution that is useful in distinguishing the fine grades of soft tissue and bone and, therefore, valuable in musculoskeletal extremity imaging.[39]

B. Clinical Applications of BWFH's Proposed Extremity CBCT

Although clinically available in the United States beginning in 2001, CBCT was initially limited in its use to dental, otolaryngology and breast imaging and has only recently become practical in extremity imaging (e.g., imaging of the hands, wrists, elbows, knees, feet, and ankles).[40] Within the last 5-10 years, several companies have manufactured affordable, compact CBCT systems designed specifically for extremities and CBCT extremity systems are currently installed in many radiology departments as an integral part of the imaging armamentarium.[41] Among these manufacturers, Carestream Health received clearance from the United States FDA in 2016 for its OnSight 3D Extremity System.[42] This particular unit – which received the 2016 AuntMinnie award for Best New Radiology Device and the 2016 North American Frost & Sullivan award for New Product Innovation and commercially launched in early 2017 – is a newer generation device and

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[34] YORKSTON & TÖEPFER, *supra* note 31; Brian Curtin, *The Financial Implications for Integrating the Carestream Onsight 3D Extremity System into an Orthopedic Practice*, CARESTREAM HEALTH, INC. (2016), available at https://www.carestream.com/specials//2018/extremityct/pdf/CBCTFinancialImplicationsROIModelWhitepaper.pdf; *Growing Number of Hospitals, Orthopaedic Practices Install Carestream OnSight 3D Extremity Imaging Systems*, *supra* note 27.

[35] YORKSTON & TÖEPFER, *supra* note 31.

[36] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Orenstein, *supra* note 22; YORKSTON & TÖEPFER, *supra* note 31; David J. Brenner & Eric J. Hall, *Computed Tomography — An Increasing Source of Radiation Exposure*, 357 New England J. Med. 2277 (2007), *available at* https://www.nejm.org/doi/full/10.1056/NEJMra072149; *What are the Radiation Risks from CT?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115329.htm (last updated Dec. 5, 2017).

[37] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; W. Zbijewski et al., *supra* note 21; Orenstein, *supra* note 22; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22; Sanyal, *supra* note 21.

[38] Shih et al., *supra* note 22; Orenstein, *supra* note 22.

[39] Carrino et al., *supra* note 20; Zbijewski et al., *supra* note 21; Sanyal, *supra* note 21.

[40] Zbijewski et al., *supra* note 21; Sanyal, *supra* note 21; A. Nemtoi et al., *Cone beam CT: a current overview of devices*, 42 DENTOMAXILLOFACIAL RADIOLOGY 1 (2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3922261/; Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20.

[41] Posadzy et al., *supra* note 20; Zbijewski et al., *supra* note 21; Orenstein, *supra* note 22.

[42] *OnSight 3D Extremity System*, *supra* note 11; Letter from Robert Ochs, *supra* note 11; *Carestream's OnSight 3D Extremity System Receives FDA 510(k) Clearance*, supra note 11.

is the unit proposed for implementation at BWFH.[43] Current clinical applications of CBCT involve the upper and lower extremities and are outlined below.

Upper Extremities

CBCT imaging permits noninvasive volumetric visualization of the upper extremities in unprecedented detail.[44] The excellent spatial resolution and advanced iterative reconstruction techniques available with the proposed OnSight 3D Extremity System unit enable exquisite detail of bone microarchitecture and high-resolution images of the articular cartilage surface.[45] These improved imaging methods may be applied to detect abnormalities associated with a wide range of musculoskeletal disorders, conditions and injuries.[46] Specific clinical applications for CBCT in the hand, wrist and elbow include orthopedics, physiatry and rheumatology.[47]

According to the literature, CBCT imaging is the "method of choice" for compound anatomical structures such as the wrist and hand.[48] In these anatomical locations, CBCT provides detailed mapping of bone structure, as well as accurate differentiation of bone trabeculae and minor structural changes and defects.[49] Being that it shows higher sensitivity in detection of small bone and joint trauma, CBCT imaging may visualize fractures being occult on other imaging modalities or may confirm doubtful fractures.[50] Combined with its low cost and relatively low irradiation, these capabilities make CBCT a valuable option in precisely evaluating, assessing the local extent of, and following up on finger fractures, carpal fractures (especially the scaphoid bone), acute or chronic wrist pain, and dislocations of the upper extremities.[51]

CBCT also has clinical application in osteomyelitis, which commonly affects the long bones in the upper arm.[52] With regard to osteomyelitis, visualization of early signs of bone destruction is invaluable in facilitating timely diagnosis and early surgical intervention.[53] Compared with other imaging technologies, CT offers significant benefits for imaging early osteolytic changes as it facilitates accurate depiction of bone pathology and visualization of soft tissue abscesses and sinus tracts, which allows for evaluation of the extent of infection and assists in pre-operative

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[43] *Winners of Minnies 2016 showcase mosaic of radiology*, AUNTMINNIE.COM (Oct. 26, 2016), https://www.auntminnie.com/index.aspx?sec=nws&sub=rad&pag=dis&ItemID=115394; *Frost & Sullivan Awards Carestream Top Honors for OnSight 3D Extremity System*, FROST & SULLIVAN (Oct. 20, 2016), https://ww2.frost.com/news/press-releases/frost-sullivan-awards-carestream-top-honors-onsight-3d-extremity-system/.

[44] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; W. Zbijewski et al., *supra* note 21; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[45] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[46] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[47] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS (2015), *supra* note 22.

[48] A.Yu. Vasiliev et al., *Capabilities of Cone-Beam Computed Tomography in the Assessment of the Structure of Wrist and Hand Bones*, 3 INT'L J. BIOMED.119 (2013), *available at* https://core.ac.uk/download/pdf/25820699.pdf.

[49] *Id.*; *Study Calls CBCT "Method of Choice" for Hand and Wrist Bone Assessment*, CURVEBEAM (Aug. 22, 2018), https://www.curvebeam.com/blog/cone-beam-computed-tomography-ct-capabilities-the-assessment-of-the-structure-of-wrist-and-hand-bones-studied/.

[50] Posadzy et al., *supra* note 20; A.Yu. Vasiliev et al., *supra* note 48.

[51] Posadzy et al., *supra* note 20; A.Yu. Vasiliev et al., *supra* note 48.

[52] Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; *Osteomyelitis*, NAT'L CTR. ADVANCING TRANSLATIONAL SCIENCES, https://rarediseases.info.nih.gov/diseases/7286/osteomyelitis (last visited Feb. 5, 2019).

[53] Posadzy et al., *supra* note 20; Shih et al., *supra* note 22.

planning.[54] Among CT variants, the high-resolution three-dimensional data from CBCT facilitates more quantitative analysis, such as osteolysis detection, and is particularly valuable as it provides more detailed visualization of osteolytic changes caused by infection in the presence of metallic hardware.[55] CBCT's high specificity and sensitivity for early osteolytic changes in tandem with its benefits of reduced radiation dose and faster acquisition time compared to traditional CT makes the proposed unit a valuable tool that clinicians can utilize to diagnose and treat osteomyelitis in a timely manner, thereby preventing its spread to adjacent bone and soft tissue and minimizing the amount of required surgical resection.[56]

Finally, CBCT shows promise in imaging degenerative joint disorders of the upper extremities.[57] Studies indicate that CBCT of the wrist is more sensitive than traditional CT and demonstrates more erosions in patients with rheumatoid arthritis when compared to the current gold standard of MRI.[58] With higher spatial resolution, less ionizing radiation, and fewer logistic limitations than other imaging technologies, CBCT has the potential to provide a readily accessible, cost-effective and efficient imaging alternative for rheumatoid arthritis patients and subsequently expedite treatment decisions in this population.[59] Similarly, taking into account its low radiation dose, high spatial resolution, and ability to identify bone structural remodeling even smaller than one millimeter, the evidence-based literature suggests that CBCT should be considered as a first stage method for diagnosing the characteristic changes of the hand and wrist bones and joints in patients with psoriatic arthritis.[60]

Lower Extremities and Weightbearing Capabilities

Carestream Health's OnSight 3D Extremity System also provides pristine images of the lower extremities.[61] Like the upper extremities, the proposed CBCT unit can help in diagnosing and treating a host of musculoskeletal conditions that affect the biomechanical behavior of the knees, feet and ankles such as fractures, arthritis, meniscus loss, instability and malalignment syndromes.[62] As described below, the CBCT unit's clinical applicability in the lower extremities is

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[54] Posadzy et al., *supra* note 20; Shih et al., *supra* note 22; Laura M. Fayad & Elliot K. Fishman, *Computed Tomography of Musculoskeletal Pathology*, 29 ORTHOPEDICS 1076 (2006).

[55] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; A.Yu. Vasiliev et al., *supra* note 48; Shih et al., *supra* note 22.

[56] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; A.Yu. Vasiliev et al., *supra* note 48; Shih et al., *supra* note 22.

[57] Posadzy et al., *supra* note 20; E. TRAJCEVSKA ET AL., DETECTION OF BONE EROSIONS IN RHEUMATOID ARTHRITIS WITH CONE BEAM COMPUTED TOMOGRAPHY COMPARED WITH MAGNETIC RESONANCE IMAGING (2015), *available at* https://pdfs.semanticscholar.org/c0f9/1b2d0c262b70468c297e119343d595d2a362.pdf; D.V. Makarova & K.V. Kushnyr, *A Standardized Protocol for Cone-Beam Computed Tomography of the Hand and Wrist in Rheumatoid Arthritis*, 7 CTM 135 (2015), *available at* http://stm-journal.ru/en/numbers/2015/4/1203/pdf; D. V. MAKAROVA ET AL., CONE-BEAM CT OPPORTUNITIES IN HAND AND WRIST ASSESSMENT IN PATIENTS WITH PSORIATIC ARTHRITIS (2016), *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwjY9u-T7KngAhULhuAKHYGyCnUQFjAAegQIBxAC&url=https%3A%2F%2Fposterng.netkey.at%2Fesr%2Fviewing%2Findex.php%3Fmodule%3Dviewing_posteraction%26task%3Ddownloadpdf%26pi%3D133425&usg=AOvVaw0_BdCt4f04wvdfsP4D6O-m.

[58] E. TRAJCEVSKA ET AL., *supra* note 57; Makarova & Kushnyr, *supra* note 57.

[59] E. TRAJCEVSKA ET AL., *supra* note 57.

[60] MAKAROVA ET AL., *supra* note 57.

[61] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20.

[62] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; Esa K. J. Tuominen et al., *Weight-Bearing CT Imaging of the Lower Extremity*, 200 AM. J. ROENTGENOLOGY 146 (2013), *available at* https://www.ajronline.org/doi/full/10.2214/AJR.12.8481; Gaurav K. Thawait et al., *Extremity cone-beam CT for evaluation of medial tibiofemoral osteoarthritis: Initial experience in imaging of the weight-bearing and non-weight-bearing knee*, 84 EUR. J. RADIOLOGY 2564 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4891813/; John Marzo et al., *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring*

attributable to the technology's ability to deliver high-resolution, low-dose, weightbearing images.[63]

While CT scanning has become invaluable in the evaluation and management of patients with musculoskeletal diseases, as bone and soft tissue detail is better-visualized with CT renderings compared to other imaging modalities, a significant limitation of traditional CT technology is that it involves scanning patients in a supine, relaxed position.[64] When imaging an injured knee, for instance, the leg is fully extended and the muscles are relaxed.[65] This limitation has consequences with respect to diagnosis and treatment of lower extremity musculoskeletal conditions.[66] Typically, when performing knee, foot, and ankle imaging, it is preferred to image in a natural weightbearing stance, unless there's been trauma and the patient can't bear the load, as a weightbearing image offers improved functional detail and better information regarding what's driving the problem.[67] For example, a weightbearing image of the knee provides superior depiction of joint space narrowing, meniscal positioning, and malalignment, and a weightbearing image of the foot or ankle provides a more accurate determination of the relative placement and orientation of the bones while under realistic load conditions.[68] This information not only affords more diagnostic confidence and a reduction in repeat examinations, but also leads to refined and more precise surgical planning and interventions.[69]

In the knee, research indicates the specific value of weightbearing CBCT imaging in the evaluation of medial tibiofemoral osteoarthritis.[70] Studies demonstrate that the medial tibiofemoral joint space width and meniscal extrusion are better visualized with CBCT.[71] CBCT images provide improved isotropic spatial resolution which can be reconstructed in any plane in support of accurate joint space width measurements, as opposed to plain radiographs where joint space

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Patellar Instability, 4 ORTHOPAEDIC J. SPORTS MED. 1 (2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5175415/ [hereinafter *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*]; François Lintz et al., *Weight-bearing cone beam CT scans in the foot and ankle*, 3 EFORT OPEN REVIEWS 278 (2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5994636/pdf/eor-3-278.pdf; Orenstein, *supra* note 22; *FDA Clears Carestream's 3-D Extremity Cone Beam CT Imaging System*, *supra* note 30.

[63] Posadzy et al., *supra* note 20; Tuominen et al., *supra* note 62; Orenstein, *supra* note 22; JOHN MARZO, CARESTREAM HEALTH, INC., THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS (2017), *available at* https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjM5salh6rgAhUKGt8KHWOMBK4QFjAAegQIBxAC&url=https%3A%2F%2Fwww.carestream.com%2Fen%2Fus%2F-%2Fmedia%2Fpublicsite%2Fproducts-and-solutions%2Fradiography-and-health-it%2Fcbct%2Fwhitepaper-cbct-weight-bearing-201609.pdf&usg=AOvVaw1LrMQkQWDelbr6we92Mdbg [hereinafter THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS]; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS, *supra* note 22.

[64] Tuominen et al., *supra* note 62; Orenstein, *supra* note 22; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS, *supra* note 22.

[65] Tuominen et al., *supra* note 62; Thawait et al., *supra* note 62; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging*, CARESTREAM HEALTH, INC. (Sep. 20, 2016), https://www.carestream.com/blog/2016/09/20/study-favors-weight-bearing-images-for-orthopaedic-diagnosis-and-surgery/.

[66] Tuominen et al., *supra* note 62; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging*, *supra* note 65.

[67] Tuominen et al., *supra* note 62; Orenstein, *supra* note 22; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging*, *supra* note 65.

[68] Tuominen et al., *supra* note 62; Orenstein, *supra* note 22; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; THE ADVANTAGES OF VOLUMETRIC CONE BEAM IMAGING FOR ORTHOPAEDIC EXTREMITY EXAMS, *supra* note 22.

[69] Tuominen et al., *supra* note 62; Curtin, *supra* note 34.

[70] Thawait et al., *supra* note 62.

[71] *Id.*

width measurements can be highly dependent on patient and x-ray beam positioning.[72] The availability of isotropic data enables more sophisticated analysis of contact pressure in weightbearing versus non-weightbearing images and other morphometry that may augment diagnostic accuracy and the soft tissue visualization attainable with CBCT is significant for assessment of meniscal extrusion.[73] Together, such information helps to improve understanding of the pathophysiology and progression of disease in patients with medial tibiofemoral compartment osteoarthritis and can help guide selection of appropriate follow-up care.[74]

Similarly, weightbearing CBCT imaging is favored for patellofemoral instability diagnosis and treatment given its ability to provide more functionally relevant measurement of patellofemoral alignment.[75] The conventional measures of patellofemoral alignment include tilt angle, congruence angle, and tibial tubercletrochlear groove offset distance.[76] Abnormalities in patellofemoral alignment measures are considered risk factors in patients who suffer from patellofemoral instability and are used by surgeons to plan corrective operations on the patellofemoral joint.[77] A traditional CT scan, done in full extension and non-weightbearing, may overestimate these measures and give inaccurate data to a surgeon contemplating realignment surgery.[78] Imaging in a weightbearing position is much more functionally relevant here as it places the knee in the most vulnerable position for diagnosing patellofemoral instability.[79] Specifically, CBCT technology provides more functional measurements of the patellofemoral alignment measures since imaging can be performed with the patient standing, the knee flexed, and the leg muscles active.[80] The improvements that CBCT technology offers in objective measures of patellofemoral alignment are significant as they give more accurate data to surgeons contemplating realignment surgery and therefore may lead to improved clinical and surgical care of patients with this condition.[81]

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[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.
[76] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.
[77] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.
[78] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.
[79] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.
[80] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.
[81] *Comparison of a Novel Weightbearing Cone Beam Computed Tomography Scanner Versus a Conventional Computed Tomography Scanner for Measuring Patellar Instability*, supra note 62; THE VALUE OF WEIGHT-BEARING "FUNCTIONAL" CT SCANS, *supra* note 63; *Research: Impact of Weight-bearing Images in Orthopaedic Imaging, supra* note 65.

Finally, CBCT technology has clinical application in the foot and ankle. The foot and ankle is a highly complex anatomical and biomechanical structure combining several bones in a maze of arrangements.[82] Because the appropriate understanding of how these structures interact and react under stress is essential to understanding pathology, CBCT is more advantageous than traditional CT as it can be used while a patient is standing so that the joints and bones can be imaged in the weightbearing position.[83] Given CBCT's ability to provide pristine weightbearing images and functional information about the joint biomechanics of the foot and ankle that is not possible with traditional CT, it is highly useful for evaluation of complex fractures and dislocations in this anatomical location.[84]

Older Adults

While CBCT exhibits clinical utility across all age cohorts to image various musculoskeletal conditions of the extremities, it has exceptional significance in the diagnosis and treatment of older adults, an age group that is affected by musculoskeletal issues of the upper and lower extremities at high rates.[85] Studies show a positive correlation between age and increased bone fragility, loss of cartilage resilience, reduced ligament elasticity, loss of muscular strength, fat redistribution, and loss of normal tissue function.[86] Loss of mobility and physical independence resulting from age-related orthopedic, podiatric, physiatry, and rheumatologic issues, such as fractures, arthritis, joint instability, meniscus loss, and fall-related injuries, can have an especially enduring and detrimental impact in this population and lead to increased health care utilization.[87] Particular attention is necessary in this older adult population, as an early and accurate diagnosis can help to avoid delays in treatment and extensive follow-up care, which are associated with reduced quality of life and increased morbidity and mortality.[88] CBCT holds great potential for helping to precisely diagnose and treat these conditions, as it is specifically capable, as outlined above, of providing improved, high-resolution, three-dimensional images of the bones, cartilage, and joints in the hands, wrists, elbows, knees, feet, ankles with advanced anatomical detail.[89]

C. Value of On-Campus CBCT Imaging Services at BWFH

In addition to outlining the clinical applicability of the proposed CBCT unit, the evidence-based literature also details the benefits of co-located services. Generally speaking, a variety of benefits of co-location are identified in the literature, including but are not limited to, improved access for patients, more patient/family satisfaction, greater opportunities for providers to collaborate and improve their skills and service to patients, improved referrals (appropriate, timely, and with higher completion rates), increased efficiency, and improved health outcomes.[90] With regard to imaging

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[82] Lintz et al., *supra* note 62.
[83] *Id.*
[84] Lintz et al., *supra* note 62.
[85] Gheno et al., *supra* note 16; WORLD HEALTH ORGANIZATION, *supra* note 16.
[86] Gheno et al., *supra* note 16; Freemont & Hoyland, *supra* note 16.
[87] Gheno et al., *supra* note 1685.
[88] *Id.*
[89] Carrino et al., *supra* note 20; Posadzy et al., *supra* note 20; W. Zbijewski et al., *supra* note 21; Orenstein, *supra* note 22.
[90] SUSANNA GINSBURG, ISSUE BRIEF: COLOCATING HEALTH SERVICES: A WAY TO IMPROVE COORDINATION OF CHILDREN'S HEALTH CARE? (The Commonwealth Fund 2008), *available at* https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2008_jul_colocating_health_services__a_way_to_improve_coordination_of_childrens_health_care_ginsburg_colocation_issue_brief_pdf.pdf; Dennis L. Kodner & Corinne Kay Kyriacou, *Fully integrated care for frail elderly: two American models*, 1 INT'L J. INTEGRATED CARE (2000), *available at* https://ijic.ubiquitypress.com/articles/10.5334/ijic.11/.

specifically, imaging at the point of care can provide immediate information to clinicians, eliminate the need for costly follow-up visits, allow for an earlier commencement of treatment, and thereby improve health outcomes.[91] Given the advantages of CBCT imaging as an evidence-based component of musculoskeletal extremity care, it is critical to have advanced CBCT services integrated and co-located with the Hospital's orthopedic center in order to increase access and efficiency, improve patient convenience and satisfaction, and facilitate faster diagnosis which results in implementation of a more timely and appropriate treatment regime and reduces the overall burden to the health care system.[92]

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.

A. Improving Health Outcomes and Quality of Life Through Implementation of CBCT Unit

Massachusetts residents benefit from access to premier healthcare institutions. One key aspect to healthcare in the Commonwealth is the industry's commitment to quality, innovation and leadership in patient care. This dedication to implementing new services and technology that may lead to new treatments means the quality of clinical care in the state is unsurpassed by other areas in the nation.

In particular, the field of medical imaging, as well as scientific and clinical innovation, have been "signposts" of advances in medicine, in general, and in the Commonwealth. Radiology at BWFH continues to be at the forefront of technology with the creation of a cross sectional imaging suite and the installation and implementation of some of the newest diagnostic imaging equipment available. The Hospital holds a five-star rating from Hospital Compare, which was created through the efforts of the Centers for Medicare & Medicaid Services, in collaboration with organizations representing consumers, hospitals, doctors, employers, accrediting organizations and other federal agencies, to inform consumers about the quality of care at over 4,000 Medicare-certified hospitals across the country. The Hospital Compare overall rating summarizes up to fifty-seven quality measures across seven groups of categories, including efficient use of medical imaging, into a single star rating. BWFH is one of just seven hospitals in Massachusetts and 333 hospitals in the nation to achieve a five-star rating.

The addition of the recently FDA-approved OnSight 3D Extremity System to BWFH's inventory is fitting and appropriate. As outlined above, the clinical applications of this technology will be in the fields of musculoskeletal extremity conditions, including orthopedics, podiatry, physiatry and rheumatology. Accordingly, BWFH's physicians and patients will benefit from having the CBCT unit available at BWFH, the site within the Brigham Health network with the highest orthopedic clinic and surgical volume. Based on a review of literature, analysis of the relevant upper and lower extremity CPT codes that may be impacted by the installation of the proposed extremity CBCT unit, experience and discussions with other facilities that already own a CBCT unit, BWFH staff project that in the initial phase of the CBCT program, approximately 1,100 patients will be

[91] Orenstein, *supra* note 22; *Point-of-Care Diagnostic Testing*, NAT'L INST. HEALTH, https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=112 (last updated Jun. 30, 2018); Curtin, *supra* note 34; Walter Eisner, *FDA Clears CurveBeam CT Scanner for Extremities*, ORTHOPEDICS THIS WEEK (May 12, 2017), https://ryortho.com/breaking/fda-clears-curvebeam-ct-scanner-for-extremities/.
[92] Orenstein, *supra* note 22; *Point-of-Care Diagnostic Testing*, supra note 91; Curtin, *supra* note 34; Eisner, supra note 91.

scanned annually. These scans will provide precise images of the extremities that will allow clinicians to accurately diagnose musculoskeletal extremity conditions and determine the best path for care. Through the utilization of the CBCT unit, clinical staff will have increased capacity to review a patient's scans for musculoskeletal extremity conditions, leading to improved care and ultimately to overall better health outcomes for patients.

B. Assessing the Impact of the Proposed Project

To assess the impact of the Proposed Project, BWFH 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. BWFH staff will review overall ratings of care with imaging services via Press Ganey Survey scores. BWFH staff will also review survey comments and follow up with patients reporting negative experiences who wish to be contacted.

   Measure: Mean Scores Overall Rating of Care – Response Options, include: Very Good, Good, Fair, Poor and Very Poor.

   Projections: Baseline: > 90 Year 1: > 90 Year 2: > 90 Year 3: > 90

   Monitoring: Press Ganey comments are reviewed on a weekly basis by BWFH staff. Patients who report a very negative experience are contacted if they choose to leave their name and phone number on the survey. Mean score trends are evaluated on a monthly basis, and policy changes are instituted as deemed appropriate. This data will be provided on an annual basis.

2. **Access – Wait Times:** The Proposed Project seeks to ensure timely access to CBCT services and timely reporting of results. Accordingly, BWFH will track the access to the 3rd available appointment on a weekly basis. Additionally, the time interval time from the completion of the CBCT scan to radiology report finalization will be tracked.

   a. **Measure:** On a weekly basis, the 3rd available appointment will be assessed and documented.

      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:** Median time interval from when a patient receives CBCT services at BWFH to finalization of radiology report.

      Projections: Baseline: < 6 hours Year 1: < 6 hours Year 2: < 6 hours Year 3: < 6 hours

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

3. **Quality of Care – Quality of the CBCT Image:** The quality of a CBCT scan is imperative to its interpretation. Accordingly, BWFH will evaluate the number of scans that need to be

repeated because of insufficient image quality to ensure CT technologists are performing scans optimally and that the device is functioning within norms.

Measure: Annually, the percentage of examinations that need to be repeated due to technical inadequacy.

Projections: Baseline: < 5% Year 1: < 5% Year 2: < 5% Year 3: < 5%

Monitoring: CBCT technologists will track the number of scans that are repeated and conduct a monthly comparison to total volume to meet or exceed the metric. This data will be provided on an annual basis.

4. **Quality of Care – Reporting of Critical Value Results:** To facilitate timely reporting and communication of critical test results, BWFH radiologists use a real-time radiology reporting and communication platform that enables quick, efficient generation of high-quality reports and delivery of communications concerning critical test results. Specifically, radiologists use a platform with capabilities to embed specific text in reports, detect specific text indicating critical test results, and trigger alerts regarding critical test results to the responsible physician. When an alert regarding a critical test result is triggered, the responsible physician is notified via "verifiable and timely communication." Examples of verifiable communication are by telephone or in person. Subsequently, this communication is documented, and all information is incorporated into the patient's EHR so that imaging results and information may be made available to primary care and specialty physicians both across and outside the Applicant's system (via the "Care Everywhere" feature).

   Measure: Percent of critical results acknowledged by referring physicians within specified time frames.

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

   Monitoring: Radiologists' critical CBCT scans will be documented in the department's critical results reporting software application. Follow-up will be conducted to the referring physician, who in turn, will manage the patient. The radiologist will be available to answer any questions. This data will be provided on an annual basis.

5. **Quality of Care – Peer Review Over Read Correlation:** BWFH will conduct peer review readings to evaluate the accuracy of CBCT scan interpretations and ensure quality outcomes for patients.

   Measure: Radiologists will conduct peer review readings on a random basis based on the American College of Radiology's ("ACR") peer review criteria and will follow-up on all discrepancies with the original reading radiologist.

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

   Monitoring: A random selection of cases based on ACR's peer review criteria will be reviewed. Radiologists will evaluate CBCT scans documenting any inconsistencies and discuss outstanding issues with the original reading radiologist. This data will be provided on an annual basis.

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 BWFH's services for poor, medically indigent, and/or Medicaid eligible individuals. BWFH does not discriminate based on ability to pay or payer source and this practice will continue following implementation of the Proposed Project. As further detailed throughout this narrative, the Proposed Project will increase access to high-quality CBCT services for all of the Applicant's and BWFH's patients in a number of ways.

The Applicant has also adopted the Culturally and Linguistically Appropriate Services ("CLAS") standards set forth by the United States Department of Health and Human Services Office of Minority Health for all practice sites, including BWFH. BWFH strives to provide effective, understandable, and respectful care with an understanding of patients' cultural health beliefs and practices and preferred languages. To this end, the Hospital has arrangements to offer ongoing education and training in culturally and linguistically appropriate areas for staff at all levels and across all disciplines. Additionally, BWFH has launched a variety of initiatives to address disparities, increase the percentage of employees from underrepresented groups, build trust among people of diverse backgrounds, and create an inclusive environment that values differences in race, ethnicity, national origin, linguistics, gender identity and expression, sexual orientation, age, physical and mental ability, sociological background, and religious and spiritual characteristics. For instance, the Hospital has in place the Brigham Health Hospital Without Stigma Statement, which is designed to reduce stigma and raise awareness around using unbiased and nonprejudicial language related to mental health and substance use conditions. In addition, BWFH currently supports the following groups:

- Association of Multicultural Members of Partners, a volunteer employee network whose mission is commitment to the advancement, retention, recruitment, and development of multicultural professionals into leadership roles at all levels and areas of Partners HealthCare System;
- LGBT & Allies Employee Resource Group, whose mission is to create a welcoming and affirming environment for Lesbian, Gay, Bisexual and Transgender employees, patients, families and friends;
- Diversity and Inclusion Steering Committee, which is charged with celebrating the cultural diversity of staff, supporting staff with their cultural needs, and fostering a positive and welcoming and environment for all; and
- Emerging Leaders Committee, whose mission is to foster growth, improve retention, and create a sense of community among BWFH's young professionals and early careerists.

In regard to language assistance, BWFH offers access to interpreter and translation services via several modalities at no cost to BWFH's limited-English speaking ("LEP") and hearing-impaired patients at all points of clinical contact in a timely manner. For LEP patients, as a first choice BWFH provides access to certified in-person interpreters as follows: full-time Spanish and

Russian interpreters during routine business hours, per diem interpreters for 12 additional languages with advance notice, and contracted interpreters for approximately 40 languages with advance notice. When an interpreter is not available in person, BWFH provides access to qualified interpreters skilled in 50+ languages via iPad Video Remote (Interpreters on Wheels) or via phone (Language Line). For patients that are deaf or hard of hearing, sign language interpreter services are offered through "in house" interpreters, the Hospital's list of per-diem sign interpreters, contracted agencies, and the PHS Bulfinch Temporary Services Department or, when in-person interpreters are not available, through the use of iPad Video Remote Units which allow for visual access to an interpreter on the iPad screen. The Hospital's interpreter service follows closely the recommendations of the Department, including those set forth in the guide entitled "Best Practice Recommendations for Hospital-Based Interpreter Services," and all interpreters are trained and certified in medical interpretation and BWFH hospital policies, including diversity and inclusion. These services, which are currently available at BWFH and will continue to be in place following implementation of the Proposed Project, further health equity by ensuring that all patients have meaningful access to robust health services regardless of any language limitations.

Finally, all of the Applicant's hospitals, including BWFH, participate in the American Hospital Association's #123Equity Pledge Campaign. This Campaign seeks to eliminate health and health care disparities that exist for racially, ethnically and culturally diverse individuals and identifies area for hospital and health system leaders to focus on to ensure high-quality, equitable, and safe care for everyone. Specifically, the Campaign requires hospital leaders to accelerate progress in the following areas: (1) Increasing the collection and use of race, ethnicity, language preference and other socio-demographic data; (2) Increasing cultural competency training; (3) Increasing diversity in leadership and governance; and (4) Improving and strengthening community partnerships. This Campaign will allow BWFH staff to ensure equal access to the benefits created by the Proposed Project.

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.

The Proposed Project will facilitate improved health outcomes and quality of life indicators for the Applicant's patient panel by allowing for access to CBCT services. As discussed in Factor F1.b.i, CBCT offers improved diagnostic capabilities for patients with musculoskeletal conditions, supports weightbearing imaging of the foot, ankle, leg and knee in addition to the non-loaded imaging of these and the upper extremities, and provides reduced radiation exposure and faster acquisition times as compared with traditional CT. These features allow clinicians to fully visualize the lower extremities in a "real-life" and real-time fashion (i.e. under load) and afford more accurate radiologic evaluation of both the upper and lower extremities with one CT scan, thereby precluding repeat or extensive follow-up studies and leading to refined and more precise surgical planning and interventions in a timely and safe manner.

The proposed new CBCT unit will be located immediately adjacent to the high-volume orthopedic clinic at BWFH, which the Applicant anticipates will be a primary source of referral for CBCT services in addition to podiatry, physiatry and rheumatology. Due to the rapid-processing and the co-location of the unit by the high-volume orthopedic surgery clinic, the Applicant anticipates that many patients will be able to see their providers and obtain their CT scans on the same day, allowing for improved, centralized one-stop shop patient care. By providing patients with access to conveniently located, state-of-the-art CBCT services at BWFH, the Applicant will be better able to facilitate the expedited provision of high-quality follow-up care, which will lead to a reduction in

condition-related complications and, thereby, improved patient experience, increased health outcomes, and better quality of life. Combined with the fact that BWFH does not discriminate and offers a variety of services to address social determinants of health ("SDoH") and health care disparities (e.g., CLAS standards, interpreting services, and social services), the Applicant anticipates that the Proposed Project will result in improved patient care experiences and quality outcomes while assuring health equity. For these reasons, BWFH seeks to implement CBCT services at its hospital site.

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.

The Proposed Project will ensure continuity of care, improved health outcomes and enhanced quality of life by providing better service integration and allowing BWFH staff to continue existing formal processes for providing coordination of care as well as linkages to case management/social work support for the Applicant's patients.

Currently, BWFH patients that would benefit from CBCT services do not have access to this form of diagnostic imaging. This situation requires patients presenting at BWFH that would benefit from CBCT services to rely on the Hospital's traditional CT units, which do not offer the same benefits as the proposed CBCT unit and often necessitate repeat studies to accurately diagnose musculoskeletal conditions of the extremities. The Applicant aims to provide access to CBCT imaging services, avoid duplicative testing and improve coordination by siting the proposed CBCT unit at BWFH. Specifically, through the Proposed Project, the CBCT unit will be located next to the Hospital's orthopedic clinic and BWFH radiologists will be embedded within the clinic to provide real-time interpretation and consultation while patients are in the clinic with the ordering physician. This co-location will improve interdisciplinary interactions and facilitate more integrated discussions of patient care between ordering physicians and radiology providers. Such team-based, collaborative care will afford patients a full complement of readily accessible and integrated CBCT imaging, musculoskeletal, and surgical care in one location, often with the option to have their treatment plan finalized the same day as their scan is performed and read. This will enhance efficiency, lead to a more focused and integrated musculoskeletal clinical team and promote greater patient satisfaction and better quality of life.

In addition, because BWFH is a member of the Applicant, all CBCT results for tests performed at BWFH will be integrated into the Partners HealthCare electronic health record ("EHR"). Studies show that integrated health information technology systems directly affect health outcomes as access to a single, integrated health record improves care coordination.[93] This is true of the system used by the Applicant, EPIC, which not only enables imaging results and information to be available to primary care and specialty physicians across the system, but also allows patients to authorize providers outside of Partners HealthCare to access their data, view their record, and send progress notes back for improved continuity of care via the "Care Everywhere" feature. In sum, the availability of these integrated record services ensures that patients at BWFH benefit from appropriate care coordination, better outcomes, and improved quality of life.

[93] Isla M. Hains et al., *The impact of PACS on clinician work practices in the intensive care unit: a systematic review of the literature*, 19 J. AMERICAN MED. INFORMATION ASS'N 506 (2012), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3384105/; *Improve Care Coordination: The Need for Better, Improved Care Coordination*, HEALTHIT.GOV, https://www.healthit.gov/topic/health-it-basics/improve-care-coordination (last updated Sep. 15, 2017).

Finally, CBCT patients will be linked with the necessary social work/case management services to address SDoH issues. BWFH social workers collaborate, as appropriate, with providers and staff across Partners HealthCare and with programs in the community. Providing patients with linkages to these necessary contacts and services prevents unnecessary readmissions, ensures appropriate care management, and provides the patient with the resources for leading a better life.

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.**

Since a broad range of input is valuable in the planning of a project, the Applicant carried out a diverse consultative process with individuals at various regulatory agencies regarding the Proposed Projects. The following individuals are some of those consulted regarding this Project:

- Nora Mann, Esq., Director, Determination of Need Program, Department of Public Health
- Rebecca Rodman, Esq., Deputy General Counsel, Department of Public Health
- Ben Wood, Director, Office of Community Health Planning and Engagement, Department of Public Health

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.

Following strategic internal discussions around the most effective way to provide patients with specialized CT needs with the highest quality care, the Applicant and Hospital staff developed a plan to provide CBCT services at BWFH. In contemplation of this addition of services, BWFH's leadership sought to define its community broadly and engage local residents, patients, and family members that may be impacted by the Proposed Project to obtain feedback and answer questions. These groups were engaged through various initiatives.

As a first step in the engagement process, the Proposed Project was presented to BWFH's Community Engagement Committee ("CEC" or "the Committee"). This Committee falls within the purview of the Hospital's Community Health and Wellness Department, which has a longstanding commitment to improving community access to health care and addressing SDoH issues. At its core, the CEC is committed – along with the Board of Directors, Hospital administration, and the larger Hospital community – to upholding BWFH's Community Benefits Mission, which is as follows:

- To evaluate the health status of service area neighborhoods of West Roxbury, Roslindale, Hyde Park and Jamaica Plain, and respond to identified needs;
- To pay particular attention to health and wellness concerns affecting children in local schools, the elderly, women, and diverse populations who may experience health disparities, among others;
- To provide a wide variety of free health screenings and immunizations, health education programs, and other services relating to important health issues affecting communities served;

- To seek community participation in and feedback about community benefits efforts, by involving community members in the Hospital's planning and evaluation processes and by keeping the lines of communication open;
- To engage in meaningful, active collaboration with a broad range of community residents, schools, service organizations, businesses, government agencies and others, to stay abreast of community needs, and to pool knowledge and resources in addressing those needs; and
- To periodically review and assess community benefits goals, services, and outcomes to ensure that they remain relevant to issues affecting our communities, and to allocate or reallocate community benefits resources, as needed.

To advance this commitment, the CEC, which includes representatives from a wide range of local organizations and community residents, provides an opportunity for community feedback as well as for members to offer their unique perspectives on community needs, resources and connections to implement the Hospital's Community Benefits Mission in the most efficient and effective manner. Given that the goal of the CEC is to solicit input and recommendations on how the Hospital can better serve the community and given that the members of the CEC represent the Hospital's diverse community and can offer a unique perspective on what those community members' needs are and how best to meet them, leadership determined it was appropriate to engage this Committee around the Proposed Project. Accordingly, on September 17, 2018, Brian McIntosh, Director of Radiology, and Tracy Sylven, Director of Community Health and Wellness, presented the Proposed Project to the CEC. Other co-presenters included Christopher Chiodo, MD, a surgeon within the Department of Orthopedics, and Stacy Smith, MD, Chief of Musculoskeletal Radiology. The purpose of the presentation was to educate Committee members on the utility of the CBCT, its clinical application, and the community benefit associated with acquisition and implementation of the unit. Feedback from this meeting was very positive with attendees supportive of the Proposed Project and noting a chance for greater community impact by adding the Community Health Initiative ("CHI") monies associated with the Proposed Project to the Brigham and Women's Hospital ongoing CHI. Please see Appendix 3 to review the CEC meeting materials.

In addition to engaging the CEC around the CBCT initiative, BWFH sought to engage its Patient and Family Advisory Council ("PFAC" or "the Council"). BWFH's PFAC was formed in 2009 to promote the Hospital's goal of continuous improvement in quality, access, safety and the experience of care by engaging patient and family stakeholders in organizational efforts to promote the health and well-being of individuals and families. Today, the Council is comprised of six staff members and eight patient/family advisor members and provides a forum to facilitate patient and family input in all aspects of the Hospital's operations. The philosophies that govern that work of the Council are guided by BWFH's mission statement – "Excellence in patient care services delivered in a learning environment with dignity, compassion and respect" – and by the core concepts of patient and family centered care, including dignity and respect, information sharing, participation, and collaboration. Information and recommendations from the PFAC provide BWFH leadership with an enhanced understanding of how to improve quality and patient safety, service excellence, program development, facility design, and patient and family education and satisfaction, among other things. The Council meets bi-monthly throughout the year with agenda items prioritized by members based on topics of interest, follow-up progress reports, participation in public health initiatives and standing Hospital-wide committee work, and requests from Hospital staff that wish to consult the Council.

On November 29, 2018, Brian McIntosh, Director of Radiology, and Christopher Chiodo, MD, Orthopedic Surgery, met with the PFAC to discuss the need for CBCT services at BWFH and the

community benefit associated with the Proposed Project. Overall feedback from the meeting was positive and supportive of the plan. Specifically, the group agreed that the proposed CBCT unit would offer benefits to patients in terms of lower radiation and increased patient safety; better visualization, improved detection of hidden fractures, and refined imaging of joints and bone alignment; greater accessibility for patients; and advantages and opportunities for orthopedic surgeons as well. There were no concerns expressed by this group. Please see Appendix 3 to review the PFAC meeting materials.

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 Proposed Project, the Applicant in conjunction with BWFH took the following action:

- Presentation to BWFH's CEC on September 17, 2018; and
- Presentation to BWFH's PFAC on November 29, 2018.

For detailed information on these activities, including meeting agendas, minutes and presentations, see Appendix 3.

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. **<u>Cost Containment</u>:**
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 the Commonwealth center around providing low-cost care alternatives without sacrificing high-quality. In fact, the Health Policy Commission, Massachusetts' independent state agency that develops policy to reduce health care cost growth and improve the quality of patient care, has a stated goal of bettering health care at a lower cost across the Commonwealth. The Proposed Project seeks to align with these goals and meaningfully contribute to cost containment in Massachusetts by providing cost-effective high-quality imaging services and creating care efficiencies for patients.

As previously discussed, the proposed CBCT services at BWFH will be reimbursed at the same rate as traditional CT services. Additionally, scans on the proposed CBCT unit will often be used as a substitute for scans on BWFH's traditional CT units, as CBCT technology offers higher quality images with more specificity for a certain subset of patients, allowing these individuals to avoid duplicative or repeat CT imaging. For these reasons, the Proposed Project will not negatively

impact the cost growth benchmark set for the Commonwealth. Rather, the Applicant anticipates that it will achieve cost-savings by siting the proposed CBCT unit at BWFH. As discussed, the CBCT unit's capacity to provide high-quality, precise, low-dose imaging of the extremities in fast acquisition times will improve the diagnostic accuracy of hard to diagnose conditions, lead to refined surgical planning, and allow BWFH clinicians to avoid duplicative testing and misdiagnoses which can result in complications, extensive follow-up interventions, and increased costs of care. Additionally, co-location of the proposed CBCT unit at BWFH next to the Hospital's orthopedic center will allow the Applicant to improve care coordination by providing patients with musculoskeletal conditions of the extremities a full complement of imaging, musculoskeletal and surgical services in one location. Such co-location will facilitate the immediate transmission of information to providers, allow for earlier diagnosis and commencement of treatment, and reduce overall health care utilization costs.

In sum, TME will not be impacted given that no change will occur with respect to the price of CT services. Moreover, by improving the diagnostic accuracy of hard to diagnose conditions, eliminating the need for less-effective duplicative testing (which is currently necessary given the limited capability of the Applicant's existing equipment inventory to conclusively image the musculoskeletal extremities), and decreasing the potential for misdiagnosis and related expensive follow-up corrective care, the Applicant anticipates that the Proposed Project will reduce medical expenses paid by payers to providers and patient cost-sharing amounts and, thereby, contribute to reducing THCE within the state. Accordingly, as there will not be any change in TME and with the anticipated decrease in THCE, the Proposed Project will have a negligible effect on the overall healthcare cost benchmark for the Commonwealth.

F2.b. **Public Health Outcomes:**
Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

The need to offer CBCT services at BWFH to improve public health outcomes is demonstrated by the current lack of CBCT services at the Hospital, the technology's ability to provide novel clinical applications meeting the special needs for specific subsets of patients, and population projections which suggest that conditions that will benefit from CBCT imaging will grow into the future, particularly as the older adult patient population increases and requires CBCT imaging to diagnose and treat age-related musculoskeletal extremity conditions. As discussed throughout this narrative, this technology will be used for specific patient conditions to improve care outcomes as existing imaging tools do not have the capability to provide the precision and accuracy available in a CBCT study. With this enhanced diagnostic capability, clinicians can diagnose conditions and severity sooner and develop more tailored treatment plans, ultimately leading to improved public health outcomes for this subset of the population. Accordingly, this technology will have a significant impact on patients with musculoskeletal conditions of the extremities.

In addition, as discussed, studies have documented the benefits that patients receive from co-located services. By siting the proposed CBCT unit at BWFH adjacent to its high-volume orthopedic center and embedding BWFH radiologists within the center to provide real-time interpretation and consultation, the Proposed Project will ensure that patients have increased access to integrated CBCT imaging, musculoskeletal, and surgical services. These co-located services will afford patients the opportunity to receive a continuum of care in one location and will result in improved access, increased collaboration among providers, better coordination of care, increased efficiency, expedited diagnosis and commencement of treatment, and overall improved health outcomes and quality of life. In total, by providing improved access to timely services in the

appropriate integrated care setting, the Proposed Project will improve health outcomes for Massachusetts patients and the Massachusetts health care market overall.

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.

The SDoH are the conditions in the environments in which people live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[94] Examples of SDoH that have an impact on the physical and mental well-being of the population include socioeconomic status, education, employment, housing, food security, transportation, social protective factors, social support, and language/literacy. As noted in Factors F1.b.iii and F1.c, BWFH and the Applicant have numerous programs in place to address issues associated with the SDoH and ensure linkages to social service organizations.

Most notably, BWFH offers access to a variety of language services, including access to certified/qualified interpreters and translators for LEP and hearing-impaired patients via in-person interpreters, video remote interpreting, and phone interpreting. Additionally, the Hospital participates in the American Hospital Association's #123Equity Pledge Campaign, which seeks to eliminate health and health care disparities that exist for racially, ethnically and culturally diverse individuals and has as one of its stated goals improving and strengthening community partnerships. Finally, BWFH has developed a social work/case management program that facilitates linkages to clinical services, as well as to social service organizations. The Hospital's social workers provide emotional support and assistance with communication between patients, families and healthcare providers; counseling around chronic illness, a new diagnosis or medical decision-making needs; and referral information about healthcare conditions, family issues and other stressors that impact a patient's health. Similarly, the Hospital's nurse case managers can help with information on home care services or specialized skilled nursing/rehabilitation facilities; ensuring education received regarding a patient's illness/condition; arrangement for outpatient medical treatment and equipment; directing families to community resources; and questions regarding health plan and insurance benefits. All of these services, which are currently available at BWFH and will continue to be available following implementation of the Proposed Project, promote health equity and ensure that patients have access to robust services that alleviate barriers to care and help patients lead a better life.

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**

[94] *Social Determinants of Health: Know What Affects Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/socialdeterminants/ (last updated Jan. 29, 2018).

substitutes, including alternative evidence-based strategies and public health interventions.

Proposal: The Proposed Project is for the expansion of CT imaging capacity at BWFH through the acquisition and implementation of an extremity CBCT unit.

Quality: The Proposed Project is a superior alternative for providing high-quality imaging services and improving health outcomes for patients with certain conditions as clinicians will have higher resolution, more precise, and better-quality images that will impact prescribed clinical treatments. Moreover, siting of the proposed CBCT unit at BWFH will ensure that patients with extremity conditions have access to co-located imaging, musculoskeletal, and surgical services at BWFH's campus, which will improve the overall quality of the Hospital's services and promote better health outcomes.

Efficiency: Both care and operating efficiencies may be created through implementation of the proposed CBCT unit at BWFH. The proposed CBCT unit will allow BWFH radiologists to provide higher-quality, more precise, lower-dose imaging of the extremities in faster acquisition times as compared with traditional x-ray and CT, and BWFH physicians will be able to more accurately diagnose musculoskeletal conditions and determine if specific treatments will be more effective on a patient in an expedited manner. This will eliminate the need for repeat testing and the need to try multiple treatment courses, which is an inefficient use of resources and impacts patient outcomes. Moreover, co-location of the proposed CBCT unit with BWFH's high-volume orthopedic clinic and placing BWFH musculoskeletal radiologists within the clinic to provide real-time interpretation and consultation will facilitate team-based collaborative care and enhance efficiency, as patients may receive integrated CBCT imaging, musculoskeletal, and surgical care in one location. This will allow for effective management of utilization and resources, lower costs, and higher-quality outcomes.

Capital Expense: There are capital expenses associated with the implementation of the CBCT unit. The total capital expenditure cost for this model is $495,500.

Operating Costs: These costs include staff, medical supplies and ongoing maintenance of the machine, but are minimal as many patients receiving the proposed CBCT services would be receiving scans via the Hospital's traditional imaging units if not performed on the proposed CBCT unit. Specifically, the first-year incremental operating expense of the Proposed Project is $44,600. By Year 5, operating costs are estimated at $71,061. The increase is attributable to the cost of the maintenance contract, which is not a factor in Year 1 as the proposed CBCT unit will be under warranty, as well as standard increases in staff and supply costs.

List alternative options for the Proposed Project:

Option 1

Alternative Proposal: The alternative option for the Proposed Project would be to forego acquisition and implementation of any CBCT technology and sustain the current fleet of traditional CT units at BWFH.

Alternative Quality: This is not a superior alternative for quality purposes. As discussed, the quality of care that is provided by traditional CT is less efficient and does not always provide patients with musculoskeletal conditions of the extremities with the most accurate radiologic evaluation. If the Applicant does not establish CBCT technology at BWFH,

approximately 1,100 patients per year will not have ready access to these needed imaging services that help determine more precise surgical planning and interventions in an expedited manner. Such patients will continue to have traditional imaging, which is limited with respect to imaging the extremities and frequently necessitates repeat studies to accurately diagnose musculoskeletal conditions. The benefits of the proposed CBCT unit and the benefits of having co-located CBCT imaging, musculoskeletal, and surgical care services at BWFH are outlined throughout this narrative.

Alternative Efficiency: Current CT technologies lack the efficiencies of the proposed CBCT unit, including the ability to image patients while weightbearing and provide the necessary precision to ensure accurate radiologic evaluation of joint space, possible intraarticular joint bodies, occult fractures, mal-union and non-union fractures, arthritis, and soft tissue abnormalities, among other musculoskeletal conditions. Thus, without the acquisition and implementation of the specialized CBCT unit at BWFH, patients will be forced to continue to rely on traditional imaging technology, undergo repeat testing, and try various treatments for musculoskeletal conditions, rather than having an image that will help a physician determine the best course of treatment in an expedited manner.

Alternative Capital Expenses: Although this alternative will allow the Applicant to forego construction and equipment costs, it will have an overall negative impact on access, quality of care, efficiency, and patient and provider satisfaction. Moreover, it is worth noting that the capital cost for the proposed CBCT unit is approximately 1/4 - 1/5 compared to traditional CT units. Over time, the cost savings generated by the proposed CBCT unit will outpace the initial, relatively less expensive capital costs and ensure patients receive the most appropriate care for their extremity-related condition.

Alternative Operating Costs: There would be no additional operating costs associated with sustaining the current fleet of traditional CT units and foregoing any implementation of CBCT technology at BWFH. However, as mentioned above, this alternative will not afford the Applicant with any operational efficiencies.

Attachment/Exhibit

2

Table 1: Total PHS Patient Panel

	FY15		FY16		FY17		FY18 YTD	
	Count	%	Count	%	Count	%	Count	%
PHS Total	1,347,860		1,377,282		1,403,898		1,498,562	
Gender								
Female	759,251	56.3%	805,462	58.5%	818,150	58.3%	871,575	58.2%
Male	536,077	39.8%	571,367	41.5%	585,460	41.7%	626,833	41.8%
Other/Unknown	52,532	3.9%	453	0.0%	288	0.0%	154	0.0%
Age								
0-17	129,801	9.6%	144,121	10.5%	156,506	11.1%	179,434	12.0%
18-64	804,267	59.7%	851,580	61.8%	872,365	62.1%	930,699	62.1%
65+	361,361	26.8%	381,217	27.7%	374,819	26.7%	388,385	25.9%
Unknown	52,431	3.9%	364	0.0%	208	0.0%	44	0.0%
Race								
American Indian or Alaska Native	1,456	0.1%	1,495	0.1%	1,586	0.1%	1,861	0.1%
Asian	52,650	3.9%	54,703	4.0%	57,629	4.1%	61,379	4.1%
Black or African American	75,650	5.6%	78,633	5.7%	80,044	5.7%	82,048	5.5%
Hispanic/Latino	30,594	2.3%	24,963	1.8%	23,529	1.7%	22,017	1.5%
Native Hawaiian or Other Pacific Islander	964	0.1%	1,024	0.1%	1,134	0.1%	1,135	0.1%
Other/Unknown	228,612	17.0%	216,206	15.7%	224,891	16.0%	254,147	17.0%
White	957,934	71.1%	1,000,258	72.6%	1,015,085	72.3%	1,075,975	71.8%
Patient Origin								
HSA_1	11,673	0.9%	12,547	0.9%	13,522	1.0%	90,954	6.1%
HSA_2	45,814	3.4%	47,359	3.4%	47,480	3.4%	48,961	3.3%
HSA_3	83,892	6.2%	88,382	6.4%	89,773	6.4%	95,231	6.4%
HSA_4	609,048	45.2%	624,078	45.3%	637,347	45.4%	654,527	43.7%
HSA_5	162,023	12.0%	205,287	14.9%	213,127	15.2%	203,818	13.6%
HSA_6	240,464	17.8%	247,360	18.0%	247,600	17.6%	244,517	16.3%
In MA but not in HSA 1-6	182	0.0%	102	0.0%	80	0.0%	47	0.0%
Outside of MA	132,730	9.8%	143,466	10.4%	148,225	10.6%	154,190	10.3%
Unknown	62,034	4.6%	8,701	0.6%	6,744	0.5%	6,317	0.4%

Date Pulled: 10/15/2018

Table 2: Total BWFH Patient Panel*

	FY15		FY16		FY17		FY18 YTD	
	Count	%	Count	%	Count	%	Count	%
MGH Total	85,441		87,757		89,024		89,359	
Gender								
Female	57,492	67.3%	58,398	66.5%	59,081	66.4%	59,161	66.2%
Male	27,939	32.7%	29,356	33.5%	29,940	33.6%	30,196	33.8%
Other/Unknown	10	0.0%	3	0.0%	3	0.0%	2	0.0%
Age								
0-17	1,238	1.4%	1,309	1.5%	1,347	1.5%	1,434	1.6%
18-64	51,160	59.9%	54,252	61.8%	56,359	63.3%	57,605	64.5%
65+	33,042	38.7%	32,195	36.7%	31,317	35.2%	30,319	33.9%
Unknown	1	0.0%	1	0.0%	1	0.0%	1	0.0%
Race								
American Indian or Alaska Native	146	0.2%	128	0.1%	135	0.2%	147	0.2%
Asian	1,705	2.0%	1,866	2.1%	1,994	2.2%	2,050	2.3%
Black or African American	8,931	10.5%	9,467	10.8%	9,884	11.1%	10,219	11.4%
Hispanic/Latino	5,206	6.1%	4,507	5.1%	4,606	5.2%	4,739	5.3%
Native Hawaiian or Other Pacific Islander	40	0.0%	57	0.1%	43	0.0%	52	0.1%
Other/Unknown	7,538	8.8%	8,508	9.7%	9,021	10.1%	9,251	10.4%
White	61,875	72.4%	63,224	72.0%	63,341	71.2%	62,901	70.4%
Patient Origin								
HSA_1	489	0.6%	547	0.6%	624	0.7%	639	0.7%
HSA_2	2,542	3.0%	2,658	3.0%	2,682	3.0%	2,758	3.1%
HSA_3	1,843	2.2%	1,852	2.1%	1,842	2.1%	1,834	2.1%
HSA_4	62,192	72.8%	63,768	72.7%	65,332	73.4%	65,936	73.8%
HSA_5	10,759	12.6%	11,103	12.7%	10,984	12.3%	10,930	12.2%
HSA_6	2,786	3.3%	2,727	3.1%	2,732	3.1%	2,665	3.0%
In MA but not in HSA 1-6	14	0.0%	7	0.0%	3	0.0%	1	0.0%
Outside of MA	4,605	5.4%	4,848	5.5%	4,622	5.2%	4,392	4.9%
Unknown	211	0.2%	247	0.3%	203	0.2%	204	0.2%

Date Pulled: 10/15/2018

*Excludes BWPO

Attachment/Exhibit

3

Attachment/Exhibit

A

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S
Faulkner Hospital

Community Engagement Committee

September 17, 2018
Sadowsky Conference Room, 4th floor

Objectives:

- Learn and Give Feedback to the CT DoN [redacted]
- Brief overview of CHNA/CHIP and how you can participate
- Share announcements and network

Agenda

Time	min	Agenda Item	Speaker/Notes
7:30	*5*	**Welcome and Introductions**	*Tracy Sylven*
7:35	*20*	**BWFH CT Radiology DoN**	*Brian McIntosh* *Stacy Smith* *Christopher Chiodo, MD*
7:50	*25*	[redacted]	[redacted]
8:15	*5*	**CHIP/CHNA Process** – Overview – Community Needs Survey	*Tracy Sylven*
8:25	*5*	**Other Announcements**	*All*
8:30	-	**Adjourn**	

Next Meeting: January 14, 2019; 7:30 – 8:30 a.m., 4th floor Sadowsky Conference Room

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S
Faulkner Hospital

Community Engagement Committee
Minutes

September 17, 2018

In attendance: (see sign in sheet)

BWFH CT DoN

Brian McIntosh, Chris Chiodo, MD and Stacy Smith presented the Cone Beam CT project to the group (slides attached). Comparisons to traditional CT were made and benefits to patients—including less imaging potential, lower radiation and better view of extremities for increased detection of abnormalities and fractures.

Tracy Sylven presented that with this project there is a DoN (Determination of Need) and will have approximately $27,500 to designate to community work. There were two options discussed for this allocation of funds. The first is to do an RFP and allocate the dollars as a one time grant. The other is to collaborate with BWH on their current DoN project (which focuses on housing instability). Discussion with the group included that given that there is priority community overlap with the Brigham's community work (Jamaica Plain) and a chance for much greater impact with being a part of a larger DoN, that the BWFH funds would be rolled into the BWH work.

[redacted]

CHNA—CHIP Collaborative

Tracy Sylven presented the Boston CHNA—CHIP Collaborative. She discussed the purpose and goals of the group; structure; steering committee membership; timeline and a reminder of the meeting taking place on 9/17 to learn about more ways to be involved and engaged in the process.

Launch of the Boston CHNA-CHIP Collaborative's

2019 Community Health Needs Assessment

Monday, September 17th from 6:30PM to 8PM

Bruce C. Bolling Building

2300 Washington Street, Roxbury

Light dinner will be served

Boston CHNA-CHIP Collaborative

The Boston CHNA-CHIP Collaborative is an exciting new initiative among a number of stakeholders - community organizations, health centers, hospitals and the Boston Public Health Commission - formed to undertake the first city-wide Community Health Needs Assessment (CHNA) and Community Health Improvement Plan (CHIP) for the City of Boston.

Join us on **September 17th** to....

- ✓**Learn** more about the Collaborative's work
- ✓**Meet** Collaborative members, neighbors and friends involved in this important work
- ✓**Explore** how you can become involved

Other announcements and event links:

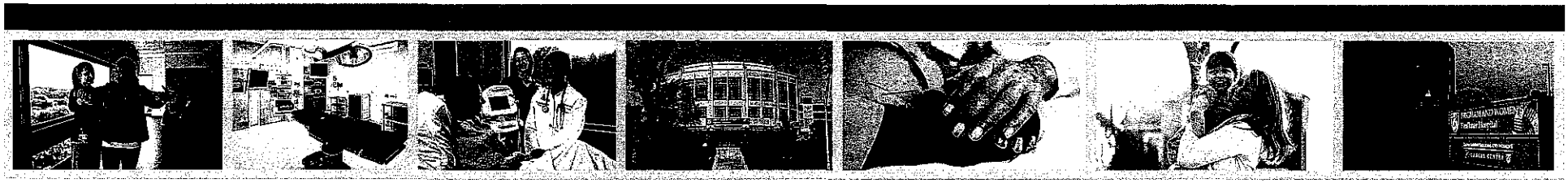
[redacted]

BRIGHAM HEALTH

BRIGHAM AND WOMEN'S
Faulkner Hospital

Cone Beam CT

Brian McIntosh
Christopher Chiodo, MD
Stacy Smith, MD
Brigham and Women's Faulkner Hospital



A MEMBER OF PARTNERS HEALTHCARE

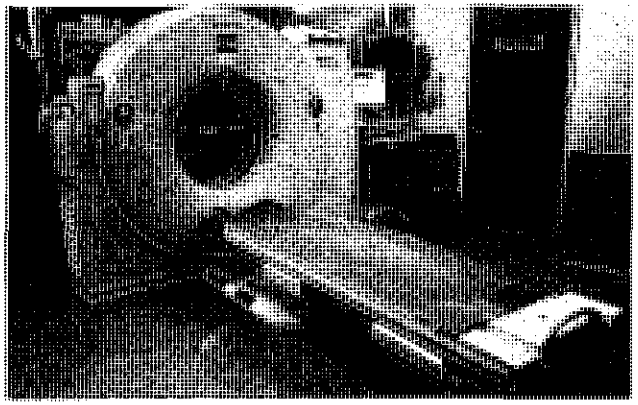
Cone Beam Extremity CT System

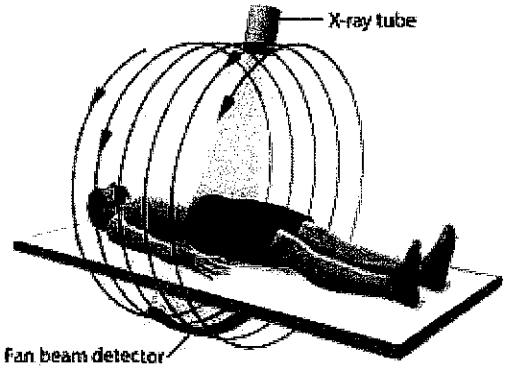
- Novel medical imaging device designed specifically for 3D x-ray imaging of extremities while the patient is in a natural weight bearing stance
  - Hand, wrist, elbow
  - Foot, ankle, knee

- Manufactured by Carestream Health, Inc.

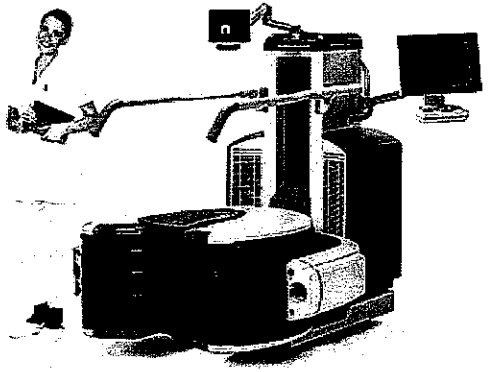
- FDA approved in 2017

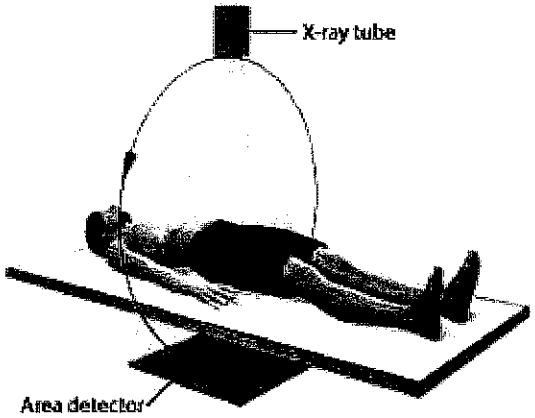
Traditional CT Unit



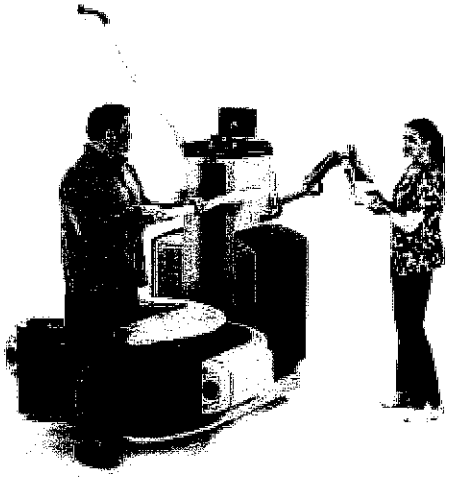


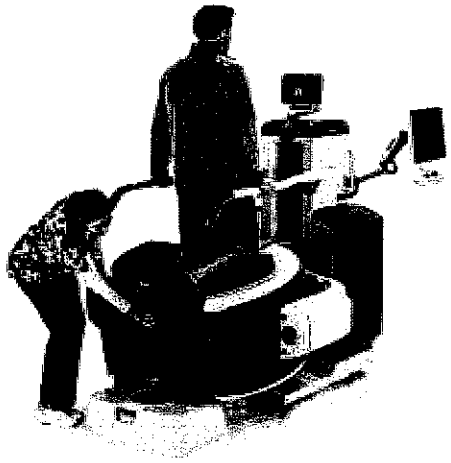
Cone Beam CT Unit

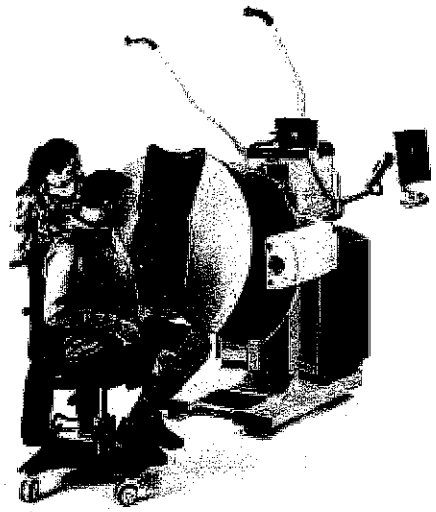




Upper and Lower Extremity Configurations







- Motorized movements and auto-positions for height, tilt and rotation
- Stepstool and positioning guides
- Patient monitor for imaging status
- Patient support handles
- Technologist touch-screen monitor with intuitive GUI
- Optional patient chair

The Best of Both Worlds

X-ray + Traditional CT

- 2D x-ray imaging today
  - Limited information compared to CT
  - Usually 2-3 x-rays of each body part
  - Weight bearing views are difficult to acquire and present safety concerns because patients need to climb stairs
- Traditional CT is 3D, *but:*
  - High acquisition costs + significant space need
  - *Unable to acquire "weight bearing" studies*
  - Increased radiation to patient

Cone Beam CT

- Combines the weight bearing capabilities inherent in traditional x-ray views with the advanced imaging capabilities of CT, but with lower radiation dose to the patient
- Lower acquisition cost + smaller space requirement
- Very quick acquisition time

Why CBCT at BWFH?

- BWFH is a lower cost more easily accessible community facility within the BH network
- BWFH has the highest orthopedic clinic and surgical volume within the BH network
- Could be the 1st in New England to place this device
- Initial projections >1100 patients in first year
- Will co-locate with our busy orthopedic department on 5th floor

Clinical Application

- Can better detect occult fractures (not seen on x-ray)
- Provides better visualization of mal-union and non-union of fractures, arthritis, flat foot, soft tissue abnormalities
- Surgical planning
- Post surgical assessment for healing, hardware
- Quote from a BWFH Orthopedic MD:
  - *"WB CT has the advantage of evaluating alignment with a three dimensional view. I anticipate using WB CT for evaluation of subtle Lisfranc injuries, subtle syndesmosis injuries, and certain cavovarus and pes planus deformities."*

Hand, Wrist and Elbow

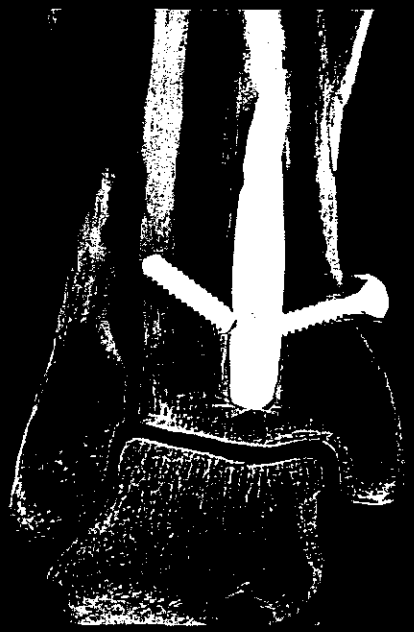
- Scaphoid fracture in cast
- Distal pole transverse fracture of scaphoid can easily seen

Weight–Bearing 3D Exams
Foot & Ankle

- Weight Bearing shows a collapsed arch

Trauma

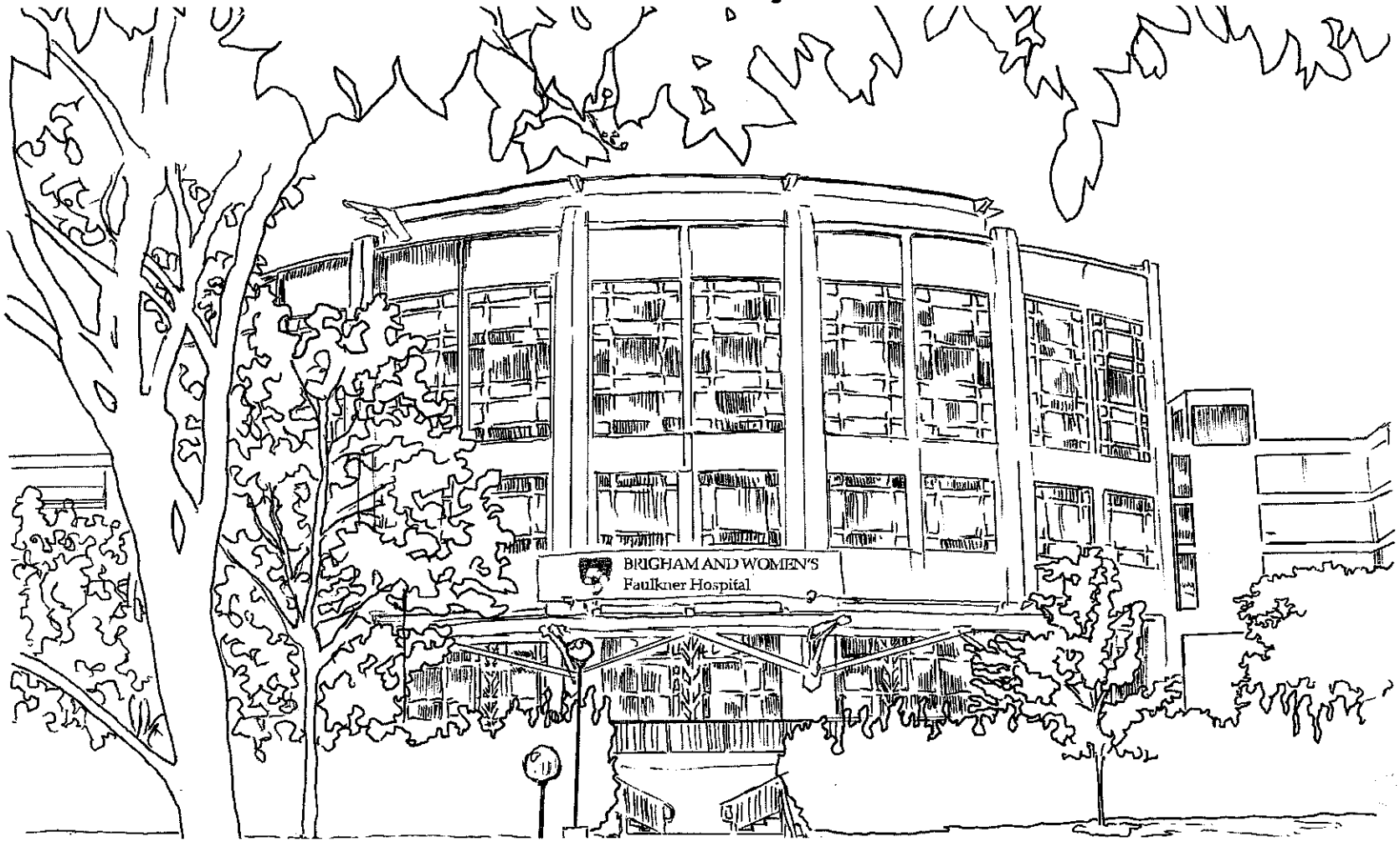
w/MAR



wo/MAR

- Tibial fracture with fixation
- Screw is broken. It is difficult to see without metal correction how many pieces the screw is broken into.
- With metal correction you can definitively make out two distinct pieces

Thank you!



CT DoN Facts

- Tier I Project
- October 7 notification deadline
- $27,400 for community allocation (5%)
- Two options:
  - New RFP
  - Collaborate with BWH (Children's/BMC)

September 17, 2018
Community Engagement Committee
Brigham and Women's Faulkner Hospital

- William Alves
- Patti Cahill
- Jacqueline Cucchiara
- Ethan d'Ablemont Burnes
- Susan Dempsey
- Lynda Giovaniello
- David Goldberg
- Heather Guarnotta
- ~~Michael Gustafson, MD~~
- Effie Ingram
- Margaret (Mimi) Jolliffee
- Leigh Kalbacker
- Michelle Keenan
- Marion Kelly
- Maryka Lier
- Cori Loescher
- Janet McGrail Spillane
- Emily Morris-Litonjua
- Bernadette Murphy
- Dan Murphy
- Susan O'Connell
- Jane O'Donnell
- Scott O'Mara
- Alysia Ordway
- John Pappas
- David Perry
- Katie Plante
- Edna Rivera Carrasco
- Raymond Santos
- Cathy Slade
- Tracy Sylven
- Josh Trautwein
- Meghan Walsh
- Ronald Warner, MD
- Brian McIntosh
- STACY SMITH

CHRIS CHIOZO

[illegible]

Attachment/Exhibit

B

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S
Faulkner Hospital

Brigham and Women's Faulkner Hospital
PATIENT AND FAMILY
ADVISORY COUNCIL

PATIENT FAMILY ADVISORY COUNCIL (PFAC) MEETING

DATE: Thursday, November 29, 2018
TIME: 4:00 – 5:30PM
LOCATION: BWFH Sadowsky Conference Room

BWFH ATTENDEES: Linda Burgoon, Peggy Duggan MD, Cori Loescher, Jaimie Paolucci,
PATIENT/FAMILY ATTENDEES: Bonnie Fallon, Jane Maier, Cynthia Murphy, Paula Santosuosso, Jeff Stone
EXCUSED: Dorothy Dorsey, David Goldberg, Diane Grallo, Annie Lewis-O'Connor, Carol Rabinovitz, Kae Santos
GUESTS: Christi Barney, Christopher Chiodo MD, Sylvia Baedorf Kassis, Tracy Lane, Brian McIntosh, Jeff Weinstock

TOPICS	DISCUSSION/ FEEDBACK	NEXT STEPS	WHO
New Medical Imaging Device: Cone Beam CT	Brian McIntosh, BS, RT (R), CRA, *Director of Radiology*, and Dr. Christopher Chiodo, MD, *Chief of Foot and Ankle Surgery Service*, discussed a new medical imaging device called the Cone Beam Extremity CT System manufactured by Carestream Health, Inc. Information on the purpose and use of this device has been presented to community engagement groups as part of the MA Determination of Need (DoN). This device is designed specifically for 3D x-ray imaging of upper and lower extremities including hand, wrist, elbow, foot, ankle and knee. It allows patients to be in a natural weight bearing stance and uses lower radiation doses during imaging in contrast to a Traditional CT. Maintenance costs associated with this device are considerably less than a Traditional CT. In addition, the acquisition time of 25 seconds is also lower, and less staff would be needed. BWFH could be the 1st in New England to have this device. It would be located on the 5th floor near the Orthopaedic Clinic. The Radiology Reading Room would be redesigned to accommodate the device. Patient/Family PFAC members inquired about whether patients receiving care in the Emergency Department will have access to the device. This will be considered but has not yet been determined. Patient/Family PFAC members also inquired about what the Traditional CT can do better than this new device. It was explained that a Traditional CT will still be used for images needed of internal organs, spine, pelvis and abdomen. Patient/Family PFAC members voiced their support for this device. They agree it would offer the following benefits: 1. Lower radiation would increase patient safety 2. Provide better visualization 3. Weight bearing stance could improve precision of the effect on lower extremity joints and alignment of bones 4. Improve detection of hidden fractures	Continue the DoN process to acquire the device	Brian McIntosh Christopher Chiodo, MD Stacy Smith, MD

	5. Ease of accessibility for patients living in the city 6. Provide access to trauma patients receiving care at BWH 7. Offer "amazing" advantages and "career-changing" opportunities for orthopaedic surgeons		
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S
Faulkner Hospital

Brigham and Women's Faulkner Hospital
PATIENT AND FAMILY
ADVISORY COUNCIL

[redacted]

BRIGHAM HEALTH

BRIGHAM AND WOMEN'S
Faulkner Hospital

Cone Beam CT

Brian McIntosh

Christopher Chiodo, MD

Stacy Smith, MD

Brigham and Women's Faulkner Hospital

A MEMBER OF PARTNERS HEALTHCARE

Cone Beam Extremity CT System

- What is it?
  - Novel medical imaging device designed specifically for 3D x-ray imaging of extremities while the patient is in a natural weight bearing stance
  - Hand, wrist, elbow
  - Foot, ankle, knee

- Who Makes It?
  - Manufactured by Carestream Health, Inc.
  - FDA approved in 2017

- Why are we here at PFAC?
  - Massachusetts requires DoN for all newly installed CT devices.
  - As part of DoN process, must engage community group
    - Answer questions about the device and use
    - Seek your endorsement.

The Best of Both Worlds

Traditional X-Ray

- Limited information compared to CT
- Usually 2-3 x-rays of each body part
- Weight bearing views are difficult to acquire and present safety concerns because patients need to climb stairs

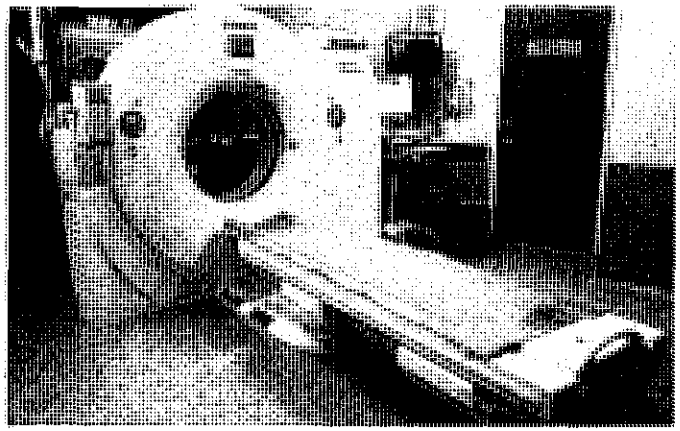
Traditional CT

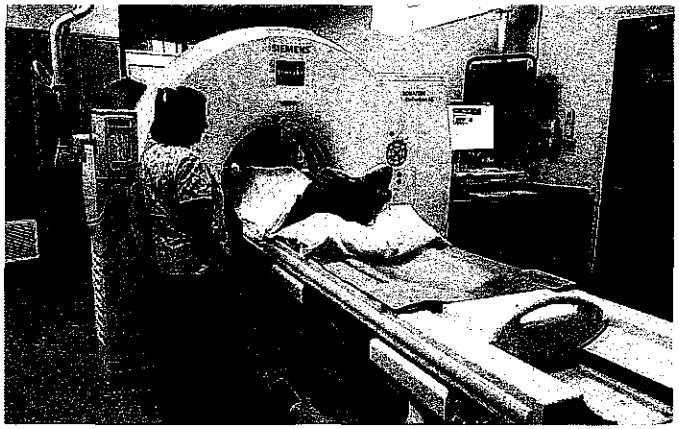
- Is 3D, but high acquisition and maintenance costs
- Significant facilities infrastructure
- *Unable to acquire "weight bearing" studies*
- *Increased radiation to patient*

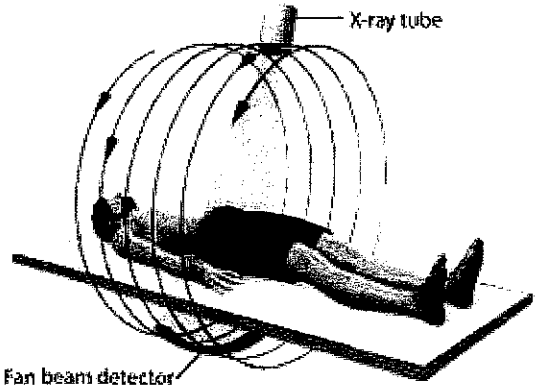
Cone Beam CT

- Combines the weight bearing capabilities inherent in traditional x-ray views with the advanced imaging capabilities of CT, but with lower radiation dose to the patient
- Lower acquisition and maintenance costs
- Plug and play
- Very quick acquisition time

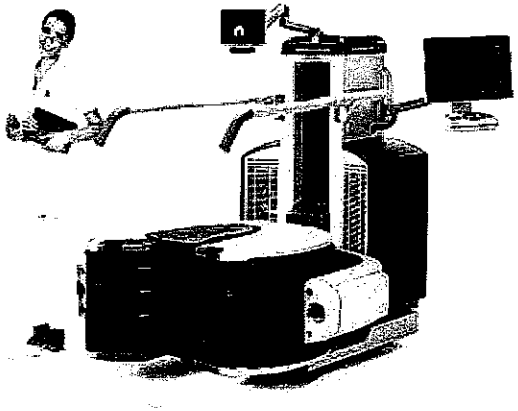
Traditional CT Unit

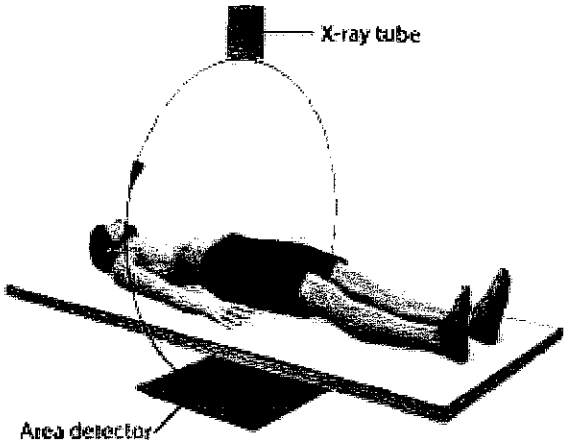




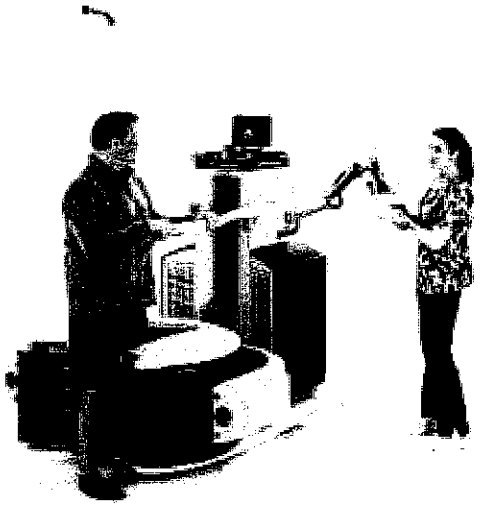


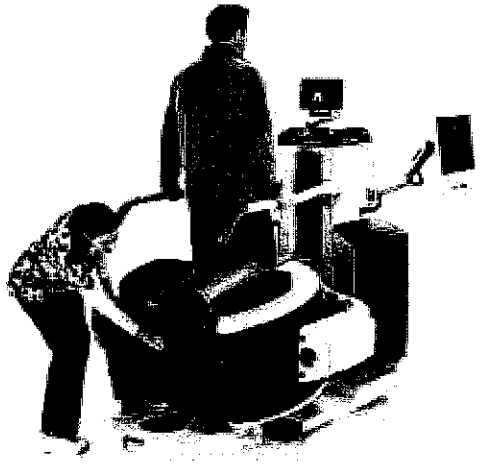
Cone Beam CT Unit

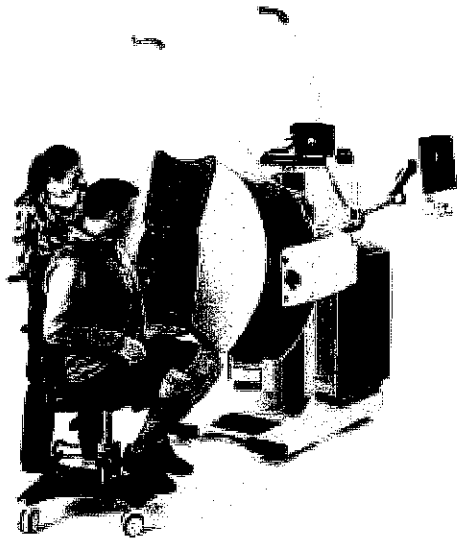




Upper and Lower Extremity Configurations



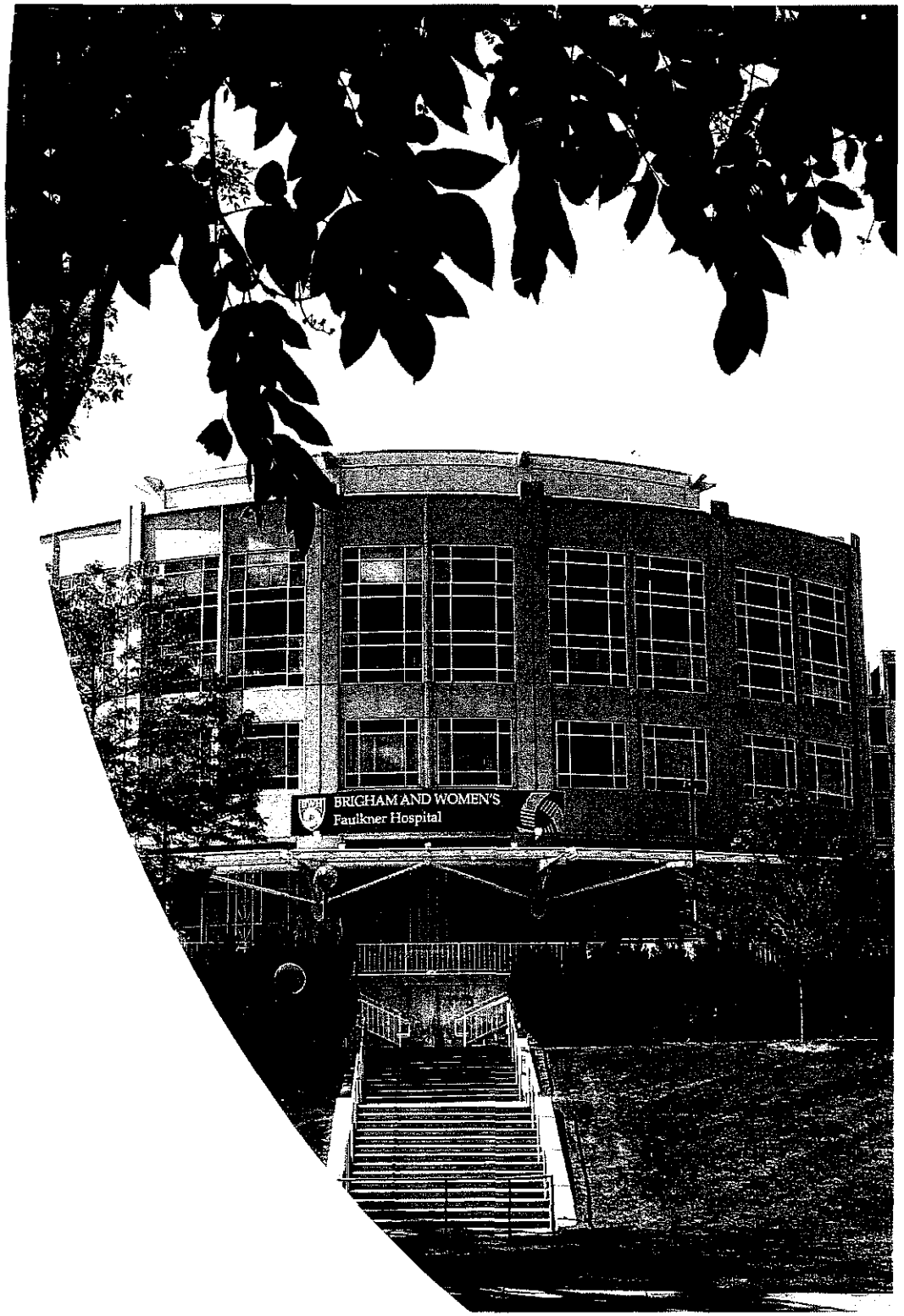


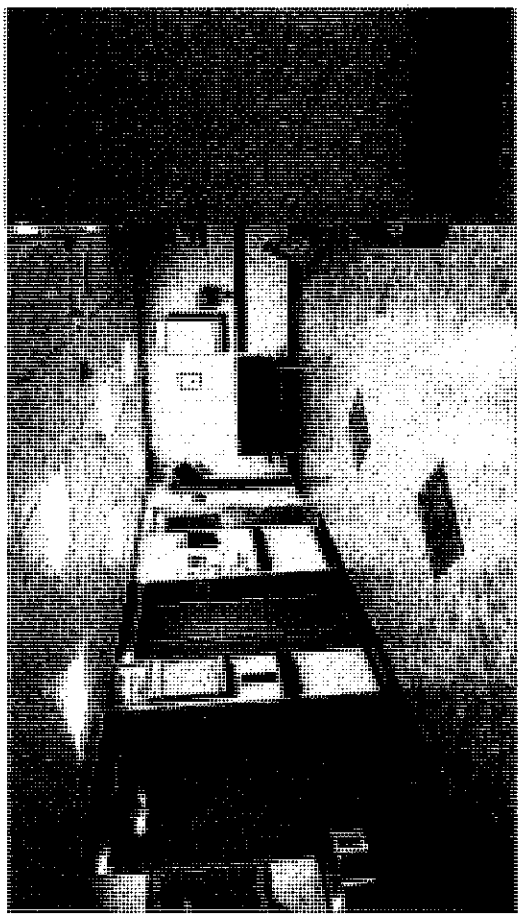


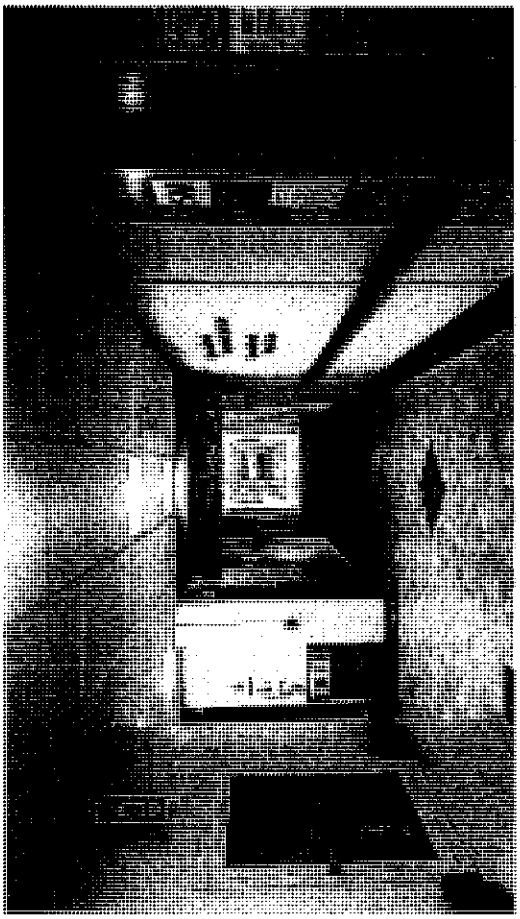
- Motorized movements and auto-positions for height, tilt and rotation
- Stepstool and positioning guides
- Patient monitor for imaging status
- Patient support handles
- Technologist touch-screen monitor with intuitive GUI
- Optional patient chair

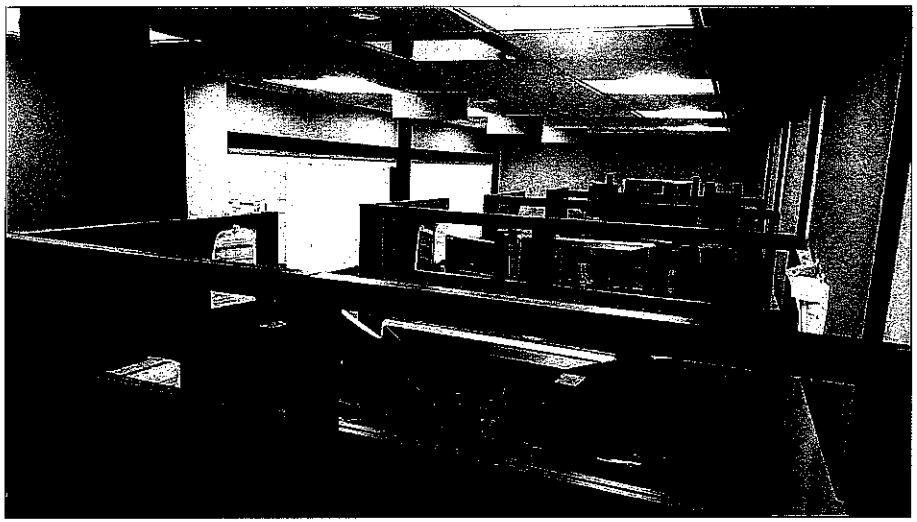
Why CBCT at BWFH?

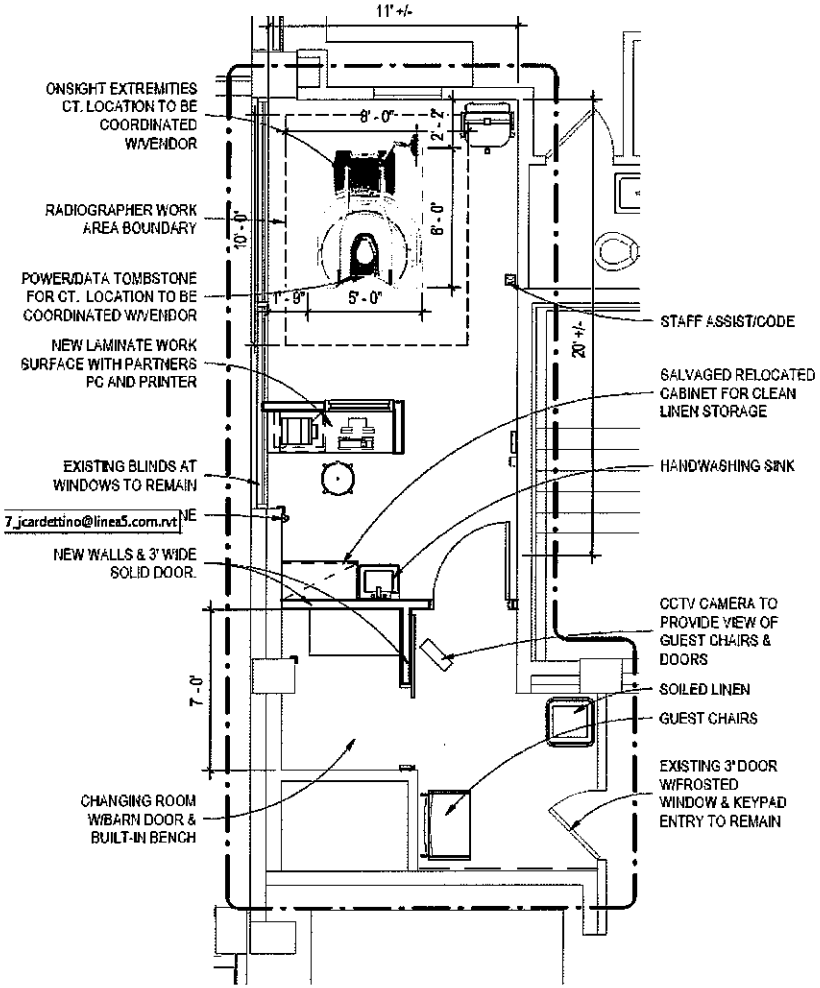
- BWFH is a lower cost more easily accessible community facility within the BH network
- BWFH has the highest orthopedic clinic and surgical volume within the BH network
- Could be the 1st in New England to place this device
- Initial projections >1100 patients in first year
- Will co-locate with our busy orthopedic department on 5th floor










11' +/-
ONSIGHT EXTREMITIES CT. LOCATION TO BE COORDINATED W/VENDOR
8' - 0"
2' - 2"
RADIOGRAPHER WORK AREA BOUNDARY
10' - 0"
6' - 0"
POWER/DATA TOMBSTONE FOR CT. LOCATION TO BE COORDINATED W/VENDOR
1' - 8"
5' - 0"
STAFF ASSIST/CODE
20' +/-
NEW LAMINATE WORK SURFACE WITH PARTNERS PC AND PRINTER
SALVAGED RELOCATED CABINET FOR CLEAN LINEN STORAGE
EXISTING BLINDS AT WINDOWS TO REMAIN
HANDWASHING SINK
7_jcardettino@linea5.com.rvt
NEW WALLS & 3' WIDE SOLID DOOR.
CCTV CAMERA TO PROVIDE VIEW OF GUEST CHAIRS & DOORS
7' - 0"
SOILED LINEN
GUEST CHAIRS
EXISTING 3' DOOR W/FROSTED WINDOW & KEYPAD ENTRY TO REMAIN
CHANGING ROOM W/BARN DOOR & BUILT-IN BENCH

Clinical Application

- Can better detect occult fractures (not seen on x-ray)
- Provides better visualization of mal-union and non-union of fractures, arthritis, flat foot, soft tissue abnormalities
- Surgical planning
- Post surgical assessment for healing, hardware
- Quote from a BWFH Orthopedic MD:
  - *"WB CT has the advantage of evaluating alignment with a three dimensional view. I anticipate using WB CT for evaluation of subtle Lisfranc injuries, subtle syndesmosis injuries, and certain cavovarus and pes planus deformities."*

Hand, Wrist and Elbow

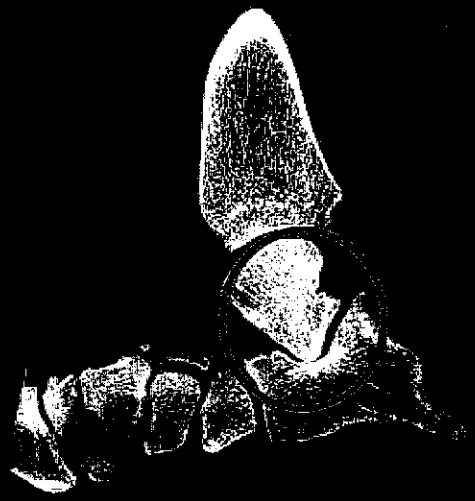
- Scaphoid fracture in cast
- Distal pole transverse fracture of scaphoid can easily seen

IMPRESSION:
Casted left distal radius fracture with radiographic findings concerning for loss of reduction.

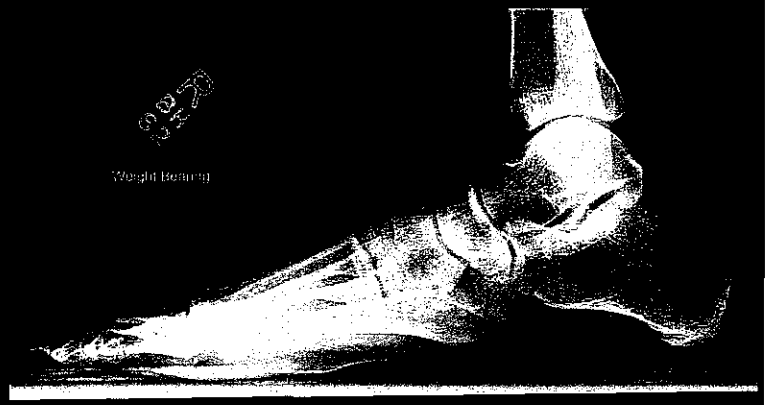
Weight–Bearing 3D Exams
Foot & Ankle

- Weight Bearing shows a collapsed arch

Non weight-bearing

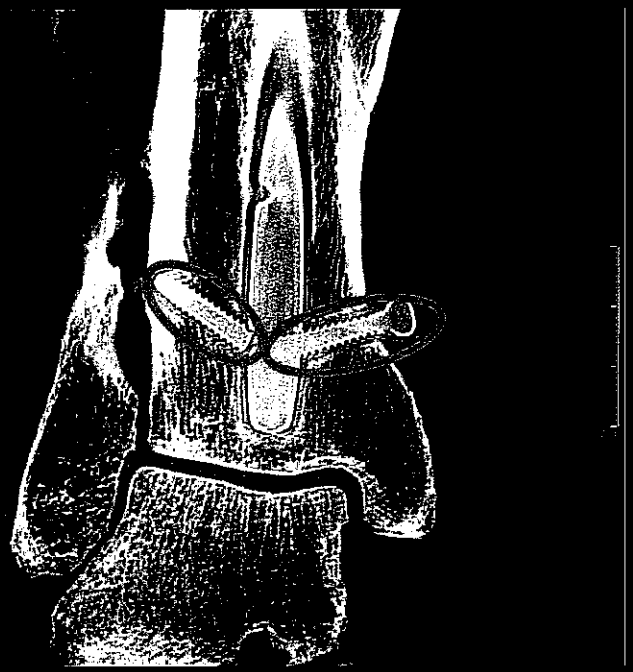


Weight-bearing



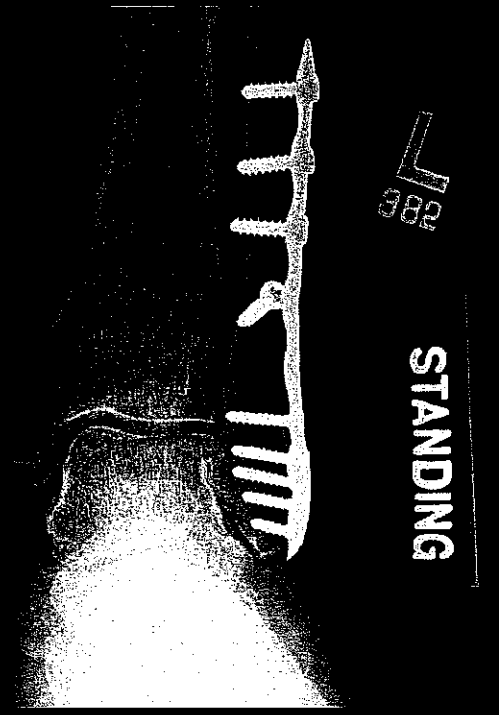
Traditional X-ray

Trauma



CBCT w/MAR

CBCT wo/MAR

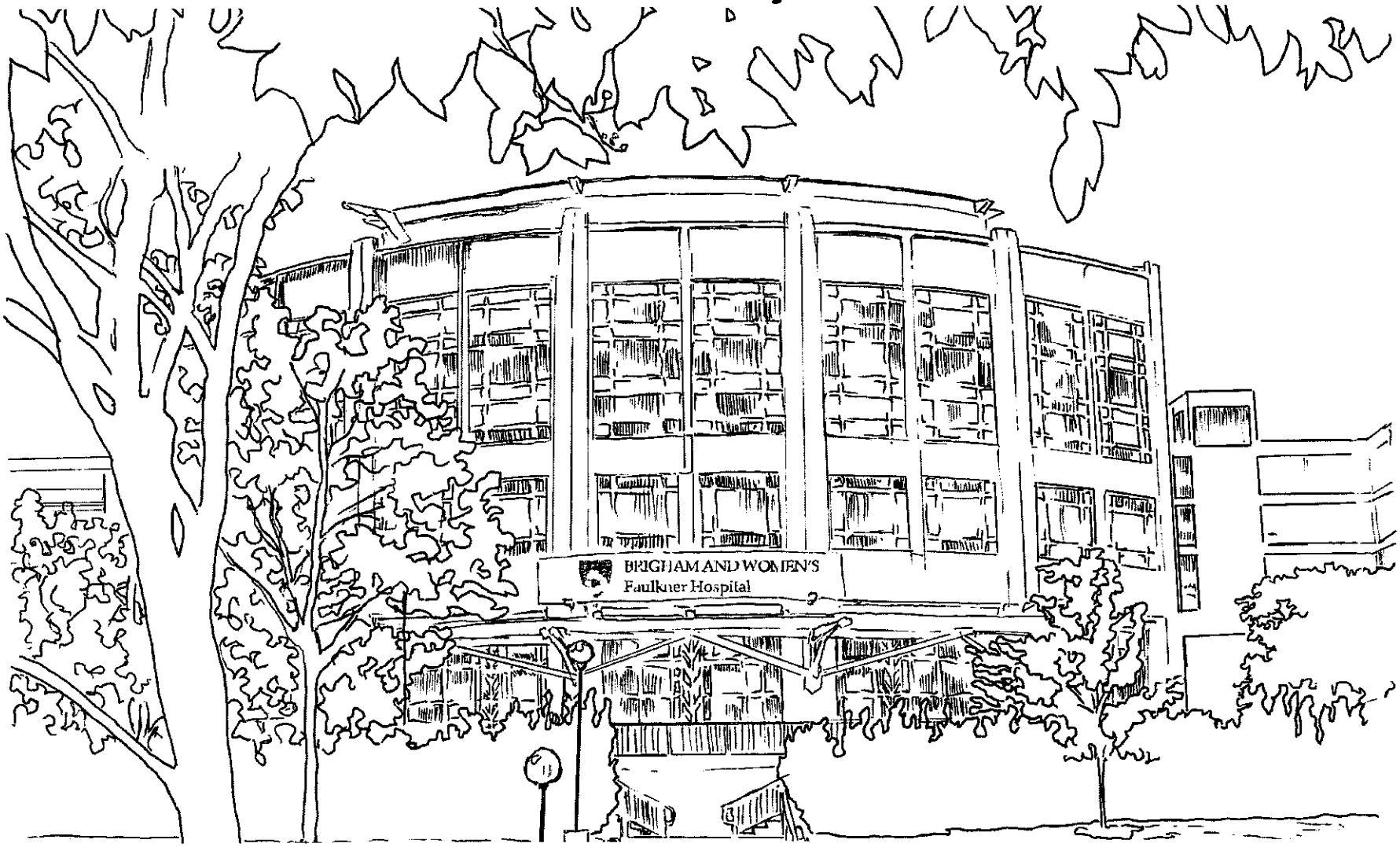


X-ray

- Tibial fracture with fixation
- Screw is broken. It is difficult to see without metal correction how many pieces the screw is broken into.
- With metal correction you can definitively make out two distinct pieces

IMPRESSION:
Status post ORIF left distal fibula with healed fracture.

Thank you!



Attachment/Exhibit

4

Attachment/Exhibit

A

Partners HealthCare System, Inc.
Brigham and Women's Faulkner Hospital, Inc. –
Extremity Cone Beam CT Determination of Need
Community Health Initiative Narrative

A. Community Health Initiative Monies

The breakdown of Community Health Initiative ("CHI") monies for the proposed Project is as follows:

- Maximum Capital Expenditure: $495,500.00
- Community Health Initiative: $24,775.00 (5% of Maximum Capital Expenditure)
- CHI Administrative Fee to be retained: $991.00 (4% of the CHI monies)
- CHI Money – less the Administrative Fee: $23,784.00

- CHI Funding for the Statewide Initiative: $2,378.40 (10% of CHI monies – less the administrative fee)
- Initial CHI Local Funding: $21,405.60 (90% of CHI monies – less the administrative fee)
- Evaluation Costs for the CHI: $2,140.56 (10% of Initial CHI Local Funding)
- Final CHI Local Funding to be Distributed via the BWH Request for Proposal Process: $19,265.04 (Initial CHI Local Funding – less the evaluation costs)

B. Background Information

The Community Health Initiative ("CHI") processes for the proposed Determination of Need ("DoN") Project will be conducted by Brigham and Women's Hospital ("BWH") and will be amalgamated to BWH's larger CHI process for its 2018 Substantial Capital Expenditure Determination of Need (DoN# 17111513-HE). Staff from Brigham and Women's Faulkner Hospital, Inc. ("BWFH") and BWH began speaking with Mr. Ben Wood, Director of the Office of Community Health Planning and Engagement at the Department of Public Health ("Department") about combining these two CHI processes in September 2018. Leaders from both hospitals thought it would be best to combine these two processes for the following reasons: 1) There is overlap in the hospitals' priority neighborhoods for community benefit work. Specifically, both hospitals share Jamaica Plain as a priority neighborhood; 2) There is a documented need for housing stabilization services (BWH's current CHI health priority) in Jamaica Plain; and 3) Given that the BWFH CHI is a smaller amount of CHI funding, it is most efficient to add these monies to the ongoing and existing processes that BWH has created for its CHI.

To combine these two CHI processes, BWFH and BWH leadership felt it was important to discuss the amalgamation of the initiatives with both the BWFH Community Engagement and Advisory Committee, as well as BWH's CHI Allocation Committee. Accordingly, in October 2018, Tracy Sylven, Director of Community Health and Wellness at BWFH brought this issue before the BWFH Community Engagement and Advisory Committee, receiving approval to move forward with combining the monies with BWH's larger CHI process. Moreover, Michelle Keenan, Program Director at BWH's Center for Community Health and Health Equity discussed the concept of combining the BWFH CHI with BWH's CHI Allocation Committee and had members vote on the on the notion. In November 2018, BWH's CHI Allocation Committee approved the amalgamation of the BWFH CHI monies with the BWH's existing CHI processes.

C. Timeline for CHI Activities and Years of Funding

The BWFH CHI monies will be amalgamated to BWH's ongoing CHI activities. Consequently, the timeline for the disbursement of these monies will follow BWH's existing timeline and years of funding.

D. Administrative and Evaluation Overview

BWH is seeking the administrative and evaluation monies associated with the BWFH CHI. Administrative monies will be used to off-set the costs associated with conducting a formal solicitation process to distribute funding to grantee(s) in Jamaica Plain. As noted in the Department's sub-regulatory CHI guidelines, a DoN Applicant may request administrative monies for a Tier 1 CHI, if the Applicant is conducting a request for proposal ("RFP") process. Accordingly, given that BWH is carrying out a formal RFP process to distribute these CHI monies, BWH is requesting administrative funds to pay for associated staff time, supplies and other costs associated with conducting a formal solicitation process. Moreover, BWH is working with the University of Massachusetts – Donahue Institute to evaluate the impact of all CHI funding. Evaluation monies from this initiative will assist in paying for these evaluation services.

Attachment/Exhibit

B

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 Core in Emergency Department Hallways: Demands, Dongers, ond 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

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[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 5UD 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.com1articleIS0196-0644(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.* 36AM.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 neuraimaging 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 M5; discovery of central veins in white matter lesions that are essentially pathognomonic for patients with M5; 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-

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[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-Breost Irradiation: Evaluation of Delivered Dose and Intrafractional Cavity Motion,* 96 INT'L J. RADIATION ONCOLOGY BIOLOGY PHYSICS 785, 78S-92 (2016). https://www.ncbi.nlm.nih.gov/pubmed/27788951; A.J. McPartlin et al., *MRI-guided prostate adaptive radiotherapy - A systemotic 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 MRI-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 5trategy 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.

MRI-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 MRI-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: ☒

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

E-mail submission to DPH

DoN # 17111513-HE
Partners HealthCare System, Inc.
BWH Capital Expenditure

ADDENDUM TO STAFF SUMMARY FOR DETERMINATION OF NEED
BY THE PUBLIC HEALTH COUNCIL
March 6, 2018

Introduction

On February 5, 2018, and pursuant to 105 CMR 100.510, the Massachusetts Department of Public Health (DPH or Department) Staff for the Determination of Need (DoN) Program (Staff) forwarded to all Parties of Record its written Staff Report relative to DoN application #17111513-HE filed by Partners HealthCare System, Inc.

In accordance with the regulation, Parties of Record were authorized to submit written comments related to the Staff's recommendation and any other conditions recommended in the Staff report.

A timely response from the Applicant was received which requested clarification of the terms several of the Conditions. The request was reviewed and, as appropriate, incorporated in the staff report that is presented to the Public Health Council (PHC) for review at its March 6, 2018 meeting.

New language *in italics,* language removed ~~in strikethrough~~.

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) *the Holder* shall track the impact of the ED expansion upon *the following at BWH*:
    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, *which is defined as the number of DPH serious reportable events that occur in the ED (related to the expansion project) divided by total ED visits*;
    e. utilization of the BH and cancer spaces;
    f. *The Holder* ~~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, *the Holder* ~~Partners~~ shall report monthly ED utilization *(registered visits)* to the Department as requested, and annually to the DoN program.
4. *The Holder* ~~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.

DoN # 17111513-HE
Partners HealthCare System, Inc.
BWH Capital Expenditure

Presented for PHC Vote:

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) the Holder shall track the impact of the ED expansion upon the following at BWH:
    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. rate of medical error, which is defined as the number of DPH serious reportable events that occur in the ED (related to the expansion project) divided by total ED visits;
    e. utilization of the BH and cancer spaces;
    f. The Holder 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, the Holder shall report monthly ED utilization (registered visits) to the Department as requested, and annually to the DoN program.
4. The Holder 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/Exhibit

5

RETURN OF PUBLICATION

I, the undersigned, hereby certify under the pains and penalties of perjury, that I am employed by the publishers of the *Boston Herald* and the following Public/Legal announcement was published in two sections of the newspaper on February 9, 2019 accordingly:

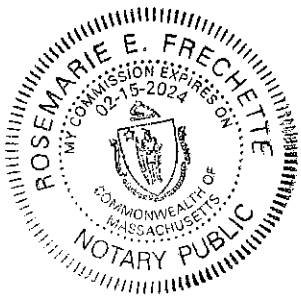
1) "Public Announcement Concerning a Proposed Health Care Project" page A24, Legal Notice Section.

2) "Public Announcement Concerning a Proposed Health Care Project" page A9, MAJORS / EDITORIAL Section.

Rosemarie E Frechette
Signature

Rosemarie E Frechette
Name

Notary Public
Title



604071.1

BY: Stephanie Pollack, Secretary and CEO, MassDOT
Jonathan L. Gulliver, Highway Administrator, MassDOT Highway Division
SATURDAY, FEBRUARY 9, 2019

LEGAL NOTICES LEGAL NOTICES LEGAL NOTICES

PUBLIC ANNOUNCEMENT CONCERNING A PROPOSED HEALTH CARE PROJECT

Partners HealthCare System, Inc. ("Applicant") located at 800 Boylston Street, Suite 1150, Boston, MA 02199 intends to file a Notice of Determination of Need ("Application") with the Massachusetts Department of Public Health for a change in service by Brigham and Women's Faulkner Hospital ("BWFH") located at 1153 Centre Street, Boston, MA 02130. The project is for the expansion of imaging services at BWFH through the acquisition of an extremity cone beam CT unit ("Project"). The total value of the Project based on the maximum capital expenditure is $495,500. The Applicant does not anticipate any price or service impacts on the Applicant's existing Patient Panel as a result of the Project. Any ten Taxpayers of Massachusetts may register in connection with the intended Application by no later than March 26, 2019 or 30 days from the Filing Date, whichever is later, by contacting the Department of Public Health, Determination of Need Program, 250 Washington Street, 6th Floor, Boston, MA 02108. This public announcement concerning the Project supersedes the public announcement published in this newspaper on February 7, 2019.

PUBLIC ANNOUNCEMENT CONCERNING A PROPOSED HEALTH CARE PROJECT

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This public announcement concerning the Project supersedes the public announcement published in this newspaper on February 7, 2019.

Attachment/Exhibit

6

Partners HealthCare System, Inc.

Analysis of the Reasonableness of Assumptions Used For and Feasibility of Projected Financials of Partners HealthCare System, Inc. For the Years Ending September 30, 2019 Through September 30, 2023

TABLE OF CONTENTS

BERNARD L. DONOHUE, III, CPA

Chestnut Green
8 Cedar Street, Suite 62
Woburn, MA 01801

(781) 569-0070
Fax (781) 569-0460

February 13, 2019

Mr. Brian Huggins
Partners HealthCare System, Inc.
399 Revolution Drive STE 645
Somerville, MA 02145

RE: Analysis of the Reasonableness of Assumptions and Projections Used to Support the Financial Feasibility and Sustainability of the Proposed Expansion of CT Services at Brigham and Women's Faulkner Hospital

Dear Mr. Huggins:

I have performed an analysis of the financial projections prepared by Partners HealthCare System, Inc. ("Partners") detailing the projected operations of Partners including the projected operations of Brigham and Women's Faulkner Hospital ("BWFH"). This report details my analysis and findings with regards to the reasonableness of assumptions used in the preparation and feasibility of the projected financial information of Partners as prepared by the management of Partners ("Management"). This report is to be included by Partners in its Determination of Need ("DoN") Application – Factor 4(a) and should not be distributed or relied upon for any other purpose.

I. EXECUTIVE SUMMARY

The scope of my analysis was limited to 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 2017 and 2018 ("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 capital projects involving and ancillary to the Brigham and Women's Faulkner Hospital Extremity Cone Beam CT unit.

The impact of the proposed capital project at BWFH, which is the subject of this DoN application, represent a relatively insignificant component of the projected operating results and financial position of Partners. As such, I determined that the 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. Therefore, it is my opinion that the Projections are financially feasible for Partners as detailed below.

II. RELEVANT BACKGROUND INFORMATION

Refer to Factor 1 of the application for description of proposed capital project at BWFH and the rationale for the expenditures.

III. SCOPE OF REPORT

The scope of this report is limited to an analysis of the Projections, 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 certain capital projects involving and ancillary to BWFH. My analysis of the Projections and conclusions contained within this report are based upon my detailed review of all relevant information (see Section IV which references the sources of information). I have gained an understanding of Partners and BWFH through my review of the information provided as well as a review of Partners website, annual reports, and the DoN application.

Reasonableness is defined within the context of this report as supportable and proper, given the underlying information. Feasibility is defined as based on the assumptions used, the plan is not likely to result in insufficient "funds available for capital and ongoing operating costs necessary to support the proposed project without negative impacts or consequences to [Partners] existing patient panel" (per Determination of Need, Factor 4(a)).

This report is based upon historical and prospective financial information provided to me by Management. If I had audited the underlying data, matters may have come to my attention that would have resulted in my using amounts that differ from those provided. Accordingly, I do not express an opinion or any other assurances on the underlying data presented or relied upon in this report. I do not provide assurance on the achievability of the results forecasted by Partners because events and circumstances frequently do not occur as expected, and the achievement of the forecasted results are dependent on the actions, plans, and assumptions of management. I reserve the right to update my analysis in the event that I am provided with additional information.

IV. PRIMARY SOURCES OF INFORMATION UTILIZED

In formulating my opinions and conclusions contained in this report, I reviewed documents produced by Management. The documents and information upon which I relied are identified below or are otherwise referenced in this report:

1. Five-Year Pro-Forma Statements for the fiscal years ending 2019 through 2023, provided December 12, 2018 and updated as of January 21, 2019;

2. Multi-Year Financial Framework of Partners Healthcare System, Inc. for the fiscal years ending 2019 through 2023 prepared as of December 6, 2018;

3. Audited Financial Statements of Partners HealthCare System, Inc. and Affiliates as of and for the years ended September 30, 2018 and 2017, prepared as of December 7, 2018;

4. Company website – www.partners.org;

5. Various news publications and other public information about the Company;

6. Determination of Need Application Instructions dated March 2017; and

7. Draft Determination of Need Factor 1, provided December 28, 2018.

V. REVIEW OF THE PROJECTIONS

This section of my report summarizes my review of the reasonableness of the assumptions used and feasibility of the Projections. The Projections are delineated between five categories of revenue and six general categories of operating expenses of Partners as well as other non-operating gains and losses for the Organization. The following table presents the Key Metrics, as defined below, of Partners which compares the results of the Projections for the fiscal years ending 2019 through 2023 to Partners historical results for the fiscal year ended 2018.

	Partners, as reported	Change in Key Metric of pro forma results compared to prior year				
	2018	**2019**	**2020**	**2021**	**2022**	**2023**
EBIDA ($)	1,164,519	19,481	120,137	49,985	42,003	55,001
EBIDA Margin (%)	8.8%	0.0%	0.5%	0.0%	-0.1%	0.0%
Operating Margin (%)	2.3%	-0.2%	0.3%	0.0%	0.0%	0.0%
Total Margin (%)	6.2%	-1.7%	0.5%	0.0%	0.0%	0.0%
Total Assets ($)	18,303,531	781,560	858,990	632,512	910,485	939,986
Total Net Assets ($)	8,972,581	742,000	767,031	792,016	819,019	845,020
Unrestricted Cash Days on Hand (days)	212.2	18.6	20.3	13.9	19.9	19.8
Unrestricted Cash to Debt (%)	132.5%	13.7%	16.9%	21.6%	18.8%	18.7%
Debt Service Coverage (ratio)	6.5	(1.8)	1.2	(2.8)	3.2	0.3
Debt to Capitalization (%)	43.3%	-2.3%	-1.8%	-2.8%	-1.5%	-1.4%

The Key Metrics fall into three primary categories: profitability, liquidity, and solvency. Profitability metrics, such as EBIDA, 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.

The following table shows how each of the Key Metrics are calculated.

Key Metric	Definition
EBIDA ($)	(Earnings before interest, depreciation and amortization expenses) - Operating gain (loss) + interest expense + depreciation expense + amortization expense
EBIDA Margin (%)	EBIDA expressed as a % of total operating revenue. EBIDA / total operating revenue
Operating Margin (%)	Income (loss) from operations / total operating revenue
Total Margin (%)	Excess (deficit) of revenue over expenses / total operating revenue
Total Assets ($)	Total assets of the organization
Total Net Assets ($)	Total net assets of the organization (includes unrestricted net assets, temporarily restricted net asset and permanently restricted net assets)
Unrestricted Cash Days on Hand (days)	(Cash & cash equivalents + investments + current portion investments limited as to use + investments limited as to use - externally limited funds) / ((Total operating expenses - non recurring charges - depreciation & amortization) / YTD days)
Unrestricted Cash to Debt (%)	Unrestricted Cash-to-Debt (%) - (Cash & cash equivalents + investments + current portion investments limited as to use + investments limited as to use - externally limited funds) / (Current portion of long-term obligations + long-term obligations)
Debt Service Coverage (ratio)	Debt service coverage ratio (ratio) - (Excess (deficit) of revenue over expenses + depreciation expense + amortization expense + interest expense) / (Principal payments + interest expense)
Debt to Capitalization (%)	Debt to Capitalization (%) - (Current portion of long-term obligation + long-term obligations) / (Current portion of long-term obligations + long-term obligations + unrestricted net assets)

In preparing the Key Metrics, Management noted the following:

- Partners has a balloon payment on long-term debt maturing in fiscal year ending 2021 and prepared the Projections to include the balloon payment.

1. Revenues

The only revenue category on which the proposed capital projects would have an impact is net patient service revenue. Therefore, I have analyzed net patient service revenue identified by Partners in both their historical and projected financial information. Based upon my analysis of the projected results from Fiscal Year 2019 through Fiscal Year 2023, the proposed capital project would represent approximately 0.001% (about 1 one-thousandths of 1%) of Partners operating revenue every year beginning in FY 2020 through FY 2023. The first year in which revenue is present for the proposed capital projects is FY 2020.

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

2. Operating Expenses

I analyzed each of the categorized operating expenses for reasonableness and feasibility as it relates to the projected revenue items. I reviewed the actual operating results for Partners for the years ended 2017 and 2018 in order to determine the impact of the proposed capital project at BWFH on the consolidated entity and in order to determine the reasonableness of the Projections for the fiscal years 2019 through 2023. Based upon my analysis of the projected results from Fiscal Year 2019 through Fiscal Year 2023, the proposed capital projects would represent approximately 0.001% (about 1 one-thousandths of 1%) of Partners operating expenses beginning in FY 2020 through FY 2023.

It is my opinion that the growth in operating expenses projected by Management reflects a reasonable estimation based primarily upon the organization's historical operations.

3. Non-Operating Gains/Expenses and Other Changes in Net Assets

The final categories of Partners Projections are various non-operating gains/expenses and other changes in net assets. The items in these categories relate to investment account activity (realized and unrealized), philanthropic and academic gifts, benefit plan funded status, fair value adjustments and other items. Because many of these items are unpredictable, nonrecurring, or dependent upon market fluctuations, I analyzed the non-operating activity in aggregate. Based upon my analysis, there were no non-operating expenses projected for the proposed capital project at BWFH. Accordingly, it is my opinion that the pro-forma non-operating gains/expenses and other changes in net assets are reasonable.

4. Capital Expenditures and Cash Flows

I reviewed Partners capital expenditures and cash flows in order 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.

Based upon my discussions with Management and my review of the information provided, I considered the current and projected capital projects and loan financing obligations included within the Projections and the impact of those projected expenditures on Partners cash flow. Based upon my analysis, it is my opinion that the pro-forma capital expenditures and resulting impact on Partners cash flows are reasonable.

VI. FEASIBILITY

I analyzed the projected operations for Partners and the changes in Key Metrics prepared by Management as well as the impact of the proposed capital project at BWFH upon the Projections and Key Metrics. In performing my analysis, I considered multiple sources of information including historical and projected financial information for Partners. It is important to note that the Projections do not account for any anticipated changes in accounting standards. These standards, which may have a material impact on individual future years, are not anticipated to have a material impact on the aggregate Projections.

Because the impact of the proposed capital project at BWFH represents a relatively insignificant portion of the operations and financial position of Partners, I determined that the Projections are not likely to result in insufficient funds available for capital and ongoing operating costs necessary to support the proposed projects. Based upon my review of the Projections and relevant supporting documentation, I determined the projects and continued operating surplus are reasonable and based upon feasible financial

assumptions. Therefore, the proposed capital project at BWFH is financially feasible and within the financial capability of Partners.

Respectively submitted,

Bernard L Donohue, III, CPA

Bernard L. Donohue, III, CPA

Attachment/Exhibit

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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 Projects 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.

		Present Square Footage		Square Footage Involved in Project				Resulting Square Footage		Total Cost		Cost/Square Footage	
				New Construction		Renovation							
Add/Del Rows	Functional Areas	Net	Gross	Net	Gross	Net	Gross	Net	Gross	New Construction	Renovation	New Construction	Renovation
	BWFH Extremity Cone Beam CT												
	Exam Room					190	210	190	210		$258,073.00		$1,228.92
	Control Room					42	52	42	52		$63,903.84		$1,228.92
	Changing Room					38	48	38	48		$58,988.16		$1,228.92
	Anteroom					78	90	78	90		$110,602.00		$1,228.91
	Total:					348	400	348	400		$491,567.00		$1,228.92

* Please note that the Applicant submits the F4.a.i Capital Costs Chart in Excel format to address the calculation related to Total Cost/Square Footage. The Department of Public Health's ("Department") Capital Costs Chart included in the Determination of Need ("DoN") Application auto-calculates Total Cost/Square Footage using a summation formula, such that the total is a sum of the cost/square footage for the various functional areas. For example, using the Department's Capital Costs Chart included in the DoN Application, the auto-calculated Total Cost/Square Footage for Renovation for the Proposed Project is a sum of the renovation cost/square footage for the Exam Room ($1,228.92) + Control Room ($1,228.92) + Changing Room ($1,228.92) + Anteroom ($1,228.91) = $4,915.67. A more accurate Total Cost/Square Footage is reached using the following calculation: Total Cost / Total Resulting Gross Square Footage. In the case of Total Cost/Square Footage for Renovation, this calculation is as follows: $491,567.00 / 400 = $1,228.92. This total is reflected in the Capital Costs Chart above.

Attachment/Exhibit

8

The Commonwealth of Massachusetts
HEALTH POLICY COMMISSION
50 MILK STREET, 8TH FLOOR
BOSTON, MASSACHUSETTS 02109
(617) 979-1400

STUART H. ALTMAN
CHAIR

DAVID M. SELTZ
EXECUTIVE DIRECTOR

December 29, 2017

Sree Chaguturu
Partners HealthCare System, Inc.
800 Boylston Street, 11th Floor
Boston, MA 02199

RE: ACO Certification

Dear Dr. Chaguturu:

Congratulations! The Health Policy Commission (HPC) is pleased to inform you that Partners HealthCare System, Inc. meets the requirements for ACO Certification. This certification is effective from the date of this letter through December 31, 2019.

The ACO Certification program, in alignment with other state agencies including MassHealth, is designed to accelerate care delivery transformation in Massachusetts and promote a high quality, efficient health system. ACOs participating in the program have met a set of objective criteria focused on core ACO capabilities including supporting patient-centered care and governance, using data to drive quality improvement, and investing in population health. Partners Healthcare System, Inc. meets those criteria.

The HPC will promote Partners HealthCare System, Inc. as a Certified ACO on our website and in our marketing and public materials. In addition, a logo is enclosed for your use in accordance with the attached Terms of Use. We hope you will use the logo to highlight the ACO Certification to your patients, payers, and others.

The HPC looks forward to your continued engagement in the ACO Certification program over the next two years. In early 2018, HPC staff will contact you to discuss any updates to your submission and to plan a site visit for later in the year.

Thank you for your dedication to providing accountable, coordinated health care to your patients. If you have any questions about this letter or the ACO Certification program, please do not hesitate to contact Catherine Harrison, Deputy Policy Director, at HPC-Certification@state.ma.us or (617) 757-1606.

Best wishes,

David Seltz
Executive Director

Attachment/Exhibit

9

Examiner

Name Approved

The Commonwealth of Massachusetts

OFFICE OF THE MASSACHUSETTS SECRETARY OF STATE
MICHAEL J. CONNOLLY, Secretary
ONE ASHBURTON PLACE, BOSTON, MASSACHUSETTS 02108

ARTICLES OF ORGANIZATION

(Under G.L. Ch. 180)

ARTICLE I

The name of the corporation is:

MGH/BRIGHAM HEALTH CARE SYSTEM, INC.

ARTICLE II

The purpose of the corporation is to engage in the following activities:

(i) To organize, operate and support a comprehensive health care system, including without limitation hospital and other health care services for all persons, and education and research for the prevention, diagnosis, treatment and cure of all forms of human illness; (ii) to improve the health and welfare of all persons; (iii) to operate for the benefit of and to support The Massachusetts General Hospital, The Brigham Medical Center, Inc., their respective affiliated corporations and such other charitable, scientific or educational organizations which are or are affiliated with teaching hospitals in the Greater Boston Area; and (iv) to carry on any other activity that may lawfully be carried on by a corporation formed under Chapter 180 of the Massachusetts General Laws which is exempt under section 501(c)(3) of the Internal Revenue Code.

93-349060

C ☐
P ☑
M ☐
R.A. ☐

10

P.C.

Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on separate 8½ x 11 sheets of paper leaving a left hand margin of at least 1 inch. Additions to more than one article may be continued on a single sheet so long as each article requiring each such addition is clearly indicated.

ARTICLE III

If the corporation has one or more classes of members, the designation of such classes, the manner of election or appointments, the duration of membership and the qualification and rights, including voting rights, of the members of such class, may be set forth in the by-laws of the corporation or may be set forth below:

The designation of classes of members, if any, the manner of election or appointment, the term of office, and the qualifications and rights of members are set forth in the by-laws of the Corporation.

ARTICLE IV

* Other lawful provisions, if any, for the conduct and regulation of the business and affairs of the corporation, for its voluntary dissolution, or for limiting, defining, or regulating the powers of the corporation, or of its directors or members, or of any class of members, are as follows:

See Continuation Sheets IV-A through IV-D attached hereto and incorporated herein by reference.

* If there are no provisions, state "None".

Note: The preceding four (4) articles are considered to be permanent and may ONLY be changed by filing appropriate Articles of Amendment.

IV. Other Lawful Provisions for Conduct and Regulation of the Business and Affairs of the Corporation, for its Voluntary Dissolution, and for Limiting, Defining and Regulating the Powers of the Corporation and of its Trustees and Members.

4.1. The corporation shall have in furtherance of its corporate purposes all of the powers specified in Section 6 of Chapter 180 and in Sections 9 and 9A of Chapter 156B of the Massachusetts General Laws (except those provided in paragraph (m) of said Section 9) as now in force or as hereafter amended, and may carry on any operation or activity referred to in Article 2 to the same extent as might an individual, either alone or in a joint venture or other arrangement with others, or through a wholly or partly owned or controlled corporation; provided, however, that no such power shall be exercised in a manner inconsistent with said Chapter 180 or any other chapter of the Massachusetts General Laws or which would deprive it of exemption from federal income tax as an organization described in Section 501(c)(3) of the Internal Revenue Code.

4.2. The by-laws may authorize the trustees to make, amend or repeal the by-laws in whole or in part, except with respect to any provision thereof which by law, the articles of organization or the by-laws requires action by the members.

4.3. Meetings of the members may be held anywhere in the United States.

4.4. No trustee or officer of the corporation shall be personally liable to the corporation or its members for monetary damages for breach of fiduciary duty as such trustee or officer notwithstanding any provision of law imposing such liability, except to the extent that such exemption from liability is not permitted under Chapter 180 of the Massachusetts General Laws.

4.5.(a) The corporation shall, to the extent legally permissible, indemnify each person who serves as one of its members, trustees or officers, or who serves at its request as a member, trustee or officer of another organization or in a capacity with respect to any employee benefit plan (each such person being called in this Section 4.5 a "Person") against all liabilities and expenses, including amounts paid in satisfaction of judgments, in compromise or as fines and penalties, and

counsel fees, reasonably incurred by such Person in connection with the defense or disposition of any action, suit or other proceeding, whether civil or criminal, in which such Person may be involved or with which such Person may be threatened, while in office or thereafter, by reason of being or having been such a Person, except with respect to any matter as to which such Person shall have been adjudicated in any proceeding not to have acted in good faith in the reasonable belief that his or her action was in the best interests of the corporation or, to the extent that such matter relates to service at the request of the corporation for another organization or an employee benefit plan, in the best interests of such organization or of the participants or beneficiaries of such employee benefit plan. Such best interests shall be deemed to be the best interests of the corporation for the purposes of this Section 4.5.

(b) Notwithstanding the foregoing, as to any matter disposed of by a compromise payment by any Person, pursuant to a consent decree or otherwise, no indemnification either for said payment or for any other expenses shall be provided unless such compromise shall be approved as in the best interests of the corporation, after notice that it involves such indemnification, (a) by a disinterested majority of the trustees then in office; or (b) by a majority of the disinterested trustees then in office, provided that there has been obtained an opinion in writing of independent legal counsel to the effect that such Person appears to have acted in good faith in the reasonable belief that his or her action was in the best interests of the corporation; or (c) by a majority of the disinterested members entitled to vote, voting as a single class.

(c) Expenses, including counsel fees, reasonably incurred by any Person in connection with the defense or disposition of any such action, suit or other proceeding may be paid from time to time by the corporation in advance of the final disposition thereof upon receipt of an undertaking by such Person to repay the amounts so paid if such Person ultimately shall be adjudicated to be not entitled to indemnification under this Section 4.5. Such an undertaking may be accepted without reference to the financial ability of such Person to make repayment.

(d) The right of indemnification hereby provided shall not be exclusive. Nothing contained in this Section shall affect any other rights to indemnification to which any Person or other corporate personnel may be entitled by contract or otherwise under law.

(e) As used in this Section 4.5, the term "Person" includes such Person's respective heirs, executors and administrators, and

a "disinterested" member, trustee or officer is one against whom in such capacity the proceeding in question, or another proceeding on the same or similar grounds, is not then pending.

4.6.(a) No person shall be disqualified from holding any office by reason of any interest. In the absence of fraud, any trustee, officer or member of this corporation, or any concern in which any such trustee, officer or member has any interest, may be a party to, or may be pecuniarily or otherwise interested in, any contract, act or other transaction (collectively called a "transaction") of this corporation, and

(1) such transaction shall not be in any way invalidated or otherwise affected by that fact; and

(2) no such trustee, officer, member or concern shall be liable to account to this corporation for any profit or benefit realized through any such transaction;

provided, however, that such transaction either was fair at the time it was entered into or is authorized or ratified either (i) by a majority of the trustees who are not so interested and to whom the nature of such interest has been disclosed, or (ii) by vote of a majority of each class of members of the corporation entitled to vote for trustees, at any meeting of members the notice of which, or an accompanying statement, summarizes the nature of such transaction and such interest. No interested trustee or member of this corporation may vote or may be counted in determining the existence of a quorum at any meeting at which such transaction shall be authorized, but may participate in discussion thereof.

(b) For purposes of this Section 4.6, the term "interest" shall include personal interest and also interest as a trustee, officer, stockholder, shareholder, director, member or beneficiary of any concern; and the term "concern" shall mean any corporation, association, trust, partnership, firm, person or other entity other than this corporation.

(c) No transaction shall be avoided by reason of any provisions of this paragraph 4.6 which would be valid but for such provisions.

4.7. No part of the assets or net earnings of the corporation shall inure to the benefit of any member, officer or trustee of the corporation or any individual; no substantial part of the activities of the corporation shall be the carrying on of propaganda, or otherwise attempting, to influence legislation except to the extent permitted by Section 501(h) of the Internal Revenue Code; and the corporation shall not participate in, or

intervene in (including the publishing or distributing of statements), any political campaign on behalf of (or in opposition to) any candidate for public office. It is intended that the corporation shall be entitled to exemption from federal income tax as an organization described in Section 501(c)(3) of the Internal Revenue Code and shall not be a private foundation under Section 509(a) of the Internal Revenue Code.

4.8. If and so long as the corporation is a private foundation (as that term is defined in Section 509 of the Internal Revenue Code), then notwithstanding any other provisions of the articles of organization or the by-laws of the corporation, the following provisions shall apply:

A) the income of the corporation for each taxable year shall be distributed at such time and in such manner as not to subject the corporation to the tax on undistributed income imposed by Section 4942 of the Internal Revenue Code, and

B) the corporation shall not engage in any act of self dealing (as defined in Section 4941(d) of the Internal Revenue Code), nor retain any excess business holdings (as defined in Section 4943(c) of the Internal Revenue Code), nor make any investments in such manner as to subject the corporation to tax under Section 4944 of the Internal Revenue Code, nor make any taxable expenditures (as defined in Section 4945(d) of the Internal Revenue Code).

4.9. Upon the liquidation or dissolution of the corporation, after payment of all of the liabilities of the corporation or due provision therefor, all of the assets of the corporation shall be disposed of pursuant to Massachusetts General Laws, Chapter 180, Section 11A, to The Massachusetts General Hospital and The Brigham Medical Center, Inc. if exempt from taxation as organizations described in Section 501(c)(3) of the Internal Revenue Code or, if both are not, to one or more organizations with similar purposes and similar tax exemption.

4.10. All references herein: (i) to the Internal Revenue Code shall be deemed to refer to the Internal Revenue Code of 1986, as now in force or hereafter amended; (ii) to the General Laws of The Commonwealth of Massachusetts, or any chapter thereof, shall be deemed to refer to said General Laws or chapter as now in force or hereafter amended; and (iii) to particular sections of the Internal Revenue Code or said General Laws shall be deemed to refer to similar or successor provisions hereafter adopted.

MGH/BRIGHAM HEALTH CARE SYSTEM, INC.

Continuation Sheet VII(b)

	Name	Residence or Post Office Address
Officers		
Vice-President	J. Robert Buchanan, M.D.	25 Commonwealth Avenue Boston, MA 02116
President	H. Richard Nesson, M.D.	565 Boylston Street Brookline, MA 02146
Treasurer	Richard A. Spindler	210 Schoolmaster Lane Dedham, MA 02026
Clerk	David M. Donaldson	22 Weston Road Lincoln Center, MA 01773
Trustees	W. Gerald Austen, M.D.	163 Wellesley Street Weston, MA 02193
	Eugene Braunwald, M.D.	75 Scotch Pine Road Weston, MA 02193
	J. Robert Buchanan, M.D.	25 Commonealth Avenue Boston, MA 02116
	Francis H. Burr	44 Prince Street Beverly, MA 01915
	Ferdinand Colloredo-Mansfeld	Winthrop Street Hamilton, MA 01982

MGH/BRIGHAM HEALTH CARE SYSTEM, INC.

Continuation Sheet VII(b)

Name	Residence or Post Office Address
John H. McArthur	Fowler 10 Soldiers Field Boston, MA 02134
H. Richard Nesson, M.D.	565 Boylston Street Brookline, MA 02146
Richard A. Spindler	210 Schoolmaster Lane Dedham, MA 02026

ARTICLE V

By-laws of the corporation have been duly adopted and the initial directors, president, treasurer and clerk or other presiding, financial or recording officers, whose names are set out below, have been duly elected.

ARTICLE VI

The effective date of organization of the corporation shall be the date of filing with the Secretary of the Commonwealth or if a later date is desired, specify date, (not more than 30 days after date of filing).

The information contained in ARTICLE VII is NOT a PERMANENT part of the Articles of Organization and may be changed ONLY by filing the appropriate form provided therefor.

ARTICLE VII

a. The post office address of the initial principal office of the corporation IN MASSACHUSETTS is:

c/o Ropes & Gray, One International Place, Boston, MA 02110

b. The name, residence and post office address of each of the initial directors and following officers of the corporation are as follows:

	NAME	RESIDENCE	POST OFFICE ADDRESS
President:	See Continuation Sheet VII(b) attached hereto and incorporated herein by reference.		
Treasurer:			
Clerk:			

Directors: (or officers having the powers of directors).

NAME	RESIDENCE	POST OFFICE ADDRESS
See Continuation Sheet VII(b) attached hereto and incorporated herein by reference.		

c. The fiscal year of the corporation shall end on the last day of the month of: September

d. The name and BUSINESS address of the RESIDENT AGENT of the corporation, if any, is:

I/We the below-signed INCORPORATORS do hereby certify under the pains and penalties of perjury that I/We have not been convicted of any crimes relating to alcohol or gaming within the past ten years. I/We do hereby further certify that to the best of my/our knowledge the above-named principal officers have not been similarly convicted. If so convicted, explain.

IN WITNESS WHEREOF and under the pains and penalties of perjury, I/WE, whose signature(s) appear below as incorporator(s) and whose names and business or residential address(es) ARE CLEARLY TYPED OR PRINTED beneath each signature do hereby associate with the intention of forming this corporation under the provisions of General Laws Chapter 180 and do hereby sign these Articles of Organization as incorporator(s) this 9th day of December, 19 93

David M. Donaldson

David M. Donaldson

Ropes & Gray
One International Place
Boston, MA 02110

NOTE: If an already-existing corporation is acting as incorporator, type in the exact name of the corporation, the state or other jurisdiction where it was incorporated, the name of the person signing on behalf of said corporation and the title he/she holds or other authority by which such action is taken.

SECRETARY OF STATE
RECEIVED
1993 DEC 15 PM 1:39
CORPORATION DIVISION

449104

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF ORGANIZATION

GENERAL LAWS, CHAPTER 180

I hereby certify that, upon an examination of the within-written articles of organization, duly submitted to me, it appears that the provisions of the General Laws relative to the organization of corporations have been complied with, and I hereby approve said articles; and the filing fee in the amount of $35.00 having been paid, said articles are deemed to have been filed with me this 15TH day of December 1993.

Effective date

Michael Joseph Connolly

MICHAEL J. CONNOLLY
Secretary of State

A PHOTOCOPY OF THESE ARTICLES OF ORGANIZATION SHALL BE RETURNED

TO: David M. Donaldson, Esq.
Ropes & Gray
One International Place, Boston, MA 02110

Telephone: (617) 951-7250

FEE: $15.00

The Commonwealth of Massachusetts

MICHAEL J. CONNOLLY
Secretary of State
ONE ASHBURTON PLACE, BOSTON, MASS. 02108

FEDERAL IDENTIFICATION NO. 000449104

ARTICLES OF AMENDMENT

General Laws, Chapter 180, Section 7

811

This certificate must be submitted to the Secretary of the Commonwealth within sixty days after the date of the vote of members or stockholders adopting the amendment. The fee for filing this certificate is $15.00 as prescribed by General Laws, Chapter 180, Section 11C(b). Make check payable to the Commonwealth of Massachusetts.

We, H. Richard Nesson, President/Vice President, and David M. Donaldson, Clerk/Assistant Clerk of

MGH/BRIGHAM HEALTH CARE SYSTEM, INC.
(Name of Corporation)

Name Approved

located at One International Place, Boston, MA 02110

do hereby certify that the following amendment to the articles of organization of the corporation was duly adopted at a meeting held on March 14, 1994, by vote of all members/

That the Articles of Organization of this corporation be and they hereby are amended to change the name of the corporation to "Partners HealthCare System, Inc."

C

3

P.C.

Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on separate 8½ x 11 sheets of paper leaving a left hand margin of at least 1 inch for binding. Additions to more than one article may be continued on a single sheet so long as each article requiring each such addition is clearly indicated.

The foregoing amendment will become effective when these articles of amendment are filed in accordance with Chapter 180, Section 7 of the General Laws unless these articles specify, in accordance with the vote adopting the amendment, a later effective date not more than thirty days after such filing, in which event the amendment will become effective on such later date.

IN WITNESS WHEREOF AND UNDER THE PENALTIES OF PERJURY, we have hereto signed our names this 18th day of March, in the year 1994

H. Richard Nesson ..... President/~~Vice President~~

..... Clerk/~~Assistant Clerk~~

781

459052

SECRETARY OF STATE
RECEIVED

1994 MAR 18 PM 4:10

CORPORATION DIVISION

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF AMENDMENT

(General Laws, Chapter 180, Section 7)

I hereby approve the within articles of amendment and, the filing fee in the amount of $ 15 having been paid, said articles are deemed to have been filed with me this 18th day of March, 1994.

Michael Joseph Connolly

MICHAEL J. CONNOLLY
Secretary of State

TO BE FILLED IN BY CORPORATION
PHOTO COPY OF AMENDMENT TO BE SENT

To: John L. Beard
Ropes & Gray
One International Place, Boston 02110

Telephone 617-951-7411

Copy Mailed

FEDERAL IDENTIFICATION NO. 042 0035
Fee: $15.00

Examiner

Name Approved

The Commonwealth of Massachusetts

William Francis Galvin
Secretary of the Commonwealth
One Ashburton Place, Boston, Massachusetts 02108-1512

042
041

ARTICLES OF AMENDMENT
(General Laws, Chapter 180, Section 7)

We, Samuel O. Thier, M.D., *President / ~~Vice President~~,

and Ernest M. Haddad, Secretary ~~Assistant Clerk~~,

of Partners HealthCare System, Inc.,
(Exact name of corporation)

located at 800 Boylston Street, Suite 1150, Boston, MA 02199,
(Address of corporation in Massachusetts)

do hereby certify that these Articles of Amendment affecting articles numbered:

II and IV
(Number those articles 1, 2, 3, and/or 4 being amended)

of the Articles of Organization were duly adopted at a meeting held on May 4, 1998, by vote of:

277 members, ~~of the corporation having shareholders~~

being at least two-thirds of its members/directors legally qualified to vote in meetings of the corporation ~~or the holders of at least two-thirds of the capital stock having the right to vote thereon~~

1. Delete Article II and insert in place thereof the following:

Article II

(i) To organize, operate and support a comprehensive health care system, including without limitation hospital and other health care services for all persons, and education and research for the prevention, diagnosis, treatment and cure of all forms of human illness: (ii) to improve the health and welfare of all persons: (iii) to operate for the benefit of and to support The Massachusetts General Hospital, The Brigham Medical Center, Inc., The North Shore Medical Center, Inc., their respective affiliated corporations, such other hospitals, charitable, scientific or educational organizations, and their affiliated corporations that become affiliated with Partners HealthCare System, Inc.

C ☐
P ☐
M ☐
N.A. ☐

3
P.C.

*Delete the inapplicable words.
Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on one side only of separate 8 1/2 x 11 sheets of paper with a left margin of at least 1 inch. Additions to more than one article may be made on a single sheet so long as each article requiring each addition is clearly indicated.

(collectively, the "Partners Affiliated Corporations") and such other charitable, scientific or educational organizations which are or are affiliated with teaching hospitals in the Greater Boston Area; and (iv) to carry on any other activity that may lawfully be carried on by a corporation formed under Chapter 180 of the Massachusetts General Laws which is exempt under Section 501(c)(3) of the Internal Revenue Code; and in furtherance of the foregoing purposes to:

(a) Serve as the controlling and coordinating organization for the Partners Affiliated Corporations in order to assure the consistency and appropriateness of their respective missions, activities, governance and administration;

(b) Solicit and receive devises of real property and grants, donations and bequests of money and other property to be used to further the foregoing purposes and those of the Partners Affiliated Corporations; and

(c) Support the Partners Affiliated Corporations by loan, lease or donation of funds or other assets, by guaranty of obligations or by other action.

2. Delete Section 4.5. of Article IV.

The foregoing amendment(s) will become effective when these Articles of Amendment are filed in accordance with General Laws, Chapter 180, Section 7 unless these articles specify, in accordance with the vote adopting the amendment, a *later* effective date not more than *thirty days* after such filing, in which event the amendment will become effective on such later date.

[redacted] _____.

SIGNED UNDER THE PENALTIES OF PERJURY, this 29TH day of May, 1998.

_____, *President [redacted]

_____, Secretary *[redacted]

*Delete the inapplicable words.

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF AMENDMENT

(General Laws, Chapter 180, Section 7)

$18710

SECRETARY OF THE COMMONWEALTH
98 JUN -2 AM 9:52

I hereby approve the within Articles of Amendment and, the filing fee in the amount of $ 15.00 having been paid, said articles are deemed to have been filed with me this 2nd day of June 19 98.

Effective date: _____

William Francis Galvin

WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth

TO BE FILLED IN BY CORPORATION
Photocopy of document to be sent to:

Ernest M. Haddad, Esq.
Partners HealthCare System, Inc.
800 Boylston Street, Ste. 1150
Boston, MA 02199

Telephone: (617) 278-1065

AACR.6

FEDERAL IDENTIFICATION NO. 043230035
Fee: $15.00

Examiner

N/A
Name Approved

The Commonwealth of Massachusetts

William Francis Galvin
Secretary of the Commonwealth
One Ashburton Place, Boston, Massachusetts 02108-1512

ARTICLES OF AMENDMENT

042

(General Laws, Chapter 180, Section 7)

We, Samuel O. Thier, M.D., *President / ~~Vice President~~

and Ernest M. Haddad, Secretary ~~Assistant Secretary~~

of Partners HealthCare System, Inc.,
(Exact name of corporation)

located at 800 Boylston Street, Suite 1150, Boston, MA 02199,
(Address of corporation in Massachusetts)

do hereby certify that these Articles of Amendment affecting articles numbered:

II
(Number those articles 1, 2, 3, and/or 4 being amended)

of the Articles of Organization were duly adopted at a meeting held on May 3, 19 99, by vote of:

293 members, ~~of the directors of the corporation~~

being at least two-thirds of its members/directors legally qualified to vote in meetings of the corporation ~~(or, if the only class of corporation having capital stock, by the holders of at least two-thirds of the capital stock having the right to vote thereon)~~:

Delete Article II and insert in place thereof the following:

Article II

The purpose of the corporation is to engage in the following activities:

(i) To organize, operate, coordinate and support a comprehensive integrated health care delivery system (the "System") that provides, without limitation, hospital, physician and other health care services for all persons and education and research for the prevention, diagnosis, treatment and cure of all forms of human illness; (ii) to improve the health and welfare of all persons; (iii) to serve as the controlling and coordinating organization for the System and its member institutions and entities including Brigham and Women's/Faulkner Hospitals, Inc., The Massachusetts General Hospital, The North Shore Medical Center, Inc., Newton-Wellesley Health Care System, Inc., and such other hospital, physician, charitable, scientific, educational,

C ☐
P ☐
M ☐
R.A. ☐

3

**Delete the inapplicable words.*
Note: If the space provided under any article or item on this form is insufficient, additions shall be set forth on one side only of separate 8 1/2 x 11 sheets of paper with a left margin of at least 1 inch. Additions to more than one article may be made on a single sheet so long as each article requiring each addition is clearly indicated.

research and other institutions and entities that are controlled, directly or indirectly, through sole corporate membership, stock ownership or otherwise, by the Corporation (collectively, the "Affiliated Organizations"); (iv) to assist and support the Affiliated Organizations in fulfilling their respective purposes, missions and objectives in a manner consistent with the purposes, missions and objectives of the Corporation and the System; and (v) to carry on any other activity that may lawfully be carried on by a corporation formed under Chapter 180 of the Massachusetts General Laws which is exempt under Section 501(c)(3) of the Internal Revenue Code; and in furtherance of the foregoing purposes to:

(a) Solicit and receive devises of real property and grants, donations and bequests of money and other property to be used to further the foregoing purposes; and

(b) Support the Affiliated Organizations by loan; lease or donation of funds or other assets; and

(c) Support the Affiliated Organizations by guaranty of the obligations of the Affiliated Organizations or by other action.

The foregoing amendment(s) will become effective when these Articles of Amendment are filed in accordance with General Laws, Chapter 180, Section 7 unless these articles specify, in accordance with the vote adopting the amendment, a *later* effective date not more than *thirty days* after such filing, in which event the amendment will become effective on such later date.

~~Later effective date:~~ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

SIGNED UNDER THE PENALTIES OF PERJURY, this 24th day of May, 19 99,

[signature], *President/~~Vice President~~,

[signature] Secretary ~~Clerk/Assistant Clerk~~

**Delete the inapplicable words.*

660922

THE COMMONWEALTH OF MASSACHUSETTS

ARTICLES OF AMENDMENT

(General Laws, Chapter 180, Section 7)

I hereby approve the within Articles of Amendment and, the filing fee in the amount of $ 15.00 having been paid, said articles are deemed to have been filed with me this 24th day of May 19 99.

99 MAY 26 AM 8:24

Effective date: _____

William Francis Galvin

WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth

TO BE FILLED IN BY CORPORATION
Photocopy of document to be sent to:

Mary LaLonde

Partners HealthCare System

Office of the General Counsel
50 Stanford St., 10th floor
Boston, MA 02114

Telephone:
617-726-5315

The Commonwealth of Massachusetts
William Francis Galvin

Minimum Fee: $15.00

Secretary of the Commonwealth, Corporations Division
One Ashburton Place, 17th floor
Boston, MA 02108-1512
Telephone: (617) 727-9640

Articles of Amendment
(General Laws, Chapter 180, Section 7)

Identification Number: 043230035

We, BRENT L. HENRY __ **President** X **Vice President,**

and MARY C. LALONDE __ **Clerk** X **Assistant Clerk**,

of PARTNERS HEALTHCARE SYSTEM, INC.
located at: 800 BOYLSTON ST., SUITE 1150 BOSTON, MA 02199 USA

do hereby certify that these Articles of Amendment affecting articles numbered:

__ Article 1 X Article 2 __ Article 3 __ Article 4

(Select those articles 1, 2, 3, and/or 4 that are being amended)

of the Articles of Organization were duly adopted at a meeting held on 4/19/2016, by vote of: 197 members, 0 directors, or 0 shareholders,
being at least two-thirds of its members/directors legally qualified to vote in meetings of the corporation (or, in the case of a corporation having capital stock, by the holders of at least two thirds of the capital stock having the right to vote therein):

ARTICLE I

The exact name of the corporation, ***as amended***, is:
(Do not state Article I if it has not been amended.)

ARTICLE II

The purpose of the corporation, ***as amended***, is to engage in the following business activities:
(Do not state Article II if it has not been amended.)

THE PURPOSE OF THE CORPORATION IS TO ENGAGE IN THE FOLLOWING ACTIVITIES: (I) TO ORGANIZE, OPERATE, COORDINATE AND SUPPORT A COMPREHENSIVE INTEGRATED HEAL TH CARE DELIVERY SYSTEM (THE "SYSTEM") THAT PROVIDES, WITHOUT LIMITATION, HOS PITAL, PHYSICIAN AND OTHER HEALTH CARE SERVICES FOR ALL PERSONS AND EDUCATI ON AND RESEARCH FOR THE PREVENTION, DIAGNOSIS, TREATMENT AND CURE OF ALL FO RMS OF HUMAN ILLNESS; (II) TO IMPROVE THE HEALTH AND WELFARE OF ALL PERSONS A ND TO CONDUCT AND SUPPORT EDUCATION, RESEARCH AND OTHER ACTIVITIES RELATIN G THERE TO, (III) TO SERVE AS THE CONTROLLING AND COORDINATING ORGANIZATION F OR THE SYSTEM AND ITS MEMBER INSTITUTIONS AND ENTITIES INCLUDING BRIGHAM AN D WOMEN'S HEALTH CARE, INC., THE MASSACHUSETTS GENERAL HOSPITAL, NSMC HEALT HCARE, INC., NEWTON WELLESLEY HEALTH CARE SYSTEM, INC., PARTNERS COMMUNITY PHYSICIANS ORGANIZATION, INC., PARTNERS CONTINUING CARE, INC., NEIGHBORHOOD HEALTH PLAN, INC. AND SUCH OTHER HOSPITAL, PHYSICIAN, CHARITABLE, SCIENTIFIC, E

DUCATIONAL, RESEARCH AND OTHER INSTITUTIONS AND ENTITIES THAT ARE CONTROLLED, DIRECTLY OR INDIRECTLY, THROUGH SOLE CORPORATE MEMBERSHIP, STOCK OWNERSHIP OR OTHERWISE, BY THE CORPORATION (COLLECTIVELY, THE "AFFILIATED ORGANIZATIONS"); (IV) TO ASSIST AND SUPPORT THE AFFILIATED ORGANIZATIONS IN FULFILLING THEIR RESPECTIVE PURPOSES, MISSIONS AND OBJECTIVES IN A MANNER CONSISTENT WITH THE PURPOSES, MISSIONS AND OBJECTIVES OF THE CORPORATION AND THE SYSTEM; AND (V) TO CARRY ON ANY OTHER ACTIVITY THAT MAY LAWFULLY BE CARRIED ON BY A CORPORATION FORMED UNDER CHAPTER 180 OF THE MASSACHUSETTS GENERAL LAWS WHICH IS EXEMPT UNDER SECTION 501(C)(3) OF THE INTERNAL REVENUE CODE; AND IN FURTHERANCE OF THE FOREGOING PURPOSES TO: (A) SOLICIT AND RECEIVE DEVISES OF REAL PROPERTY AND GRANTS, DONATIONS AND BEQUESTS OF MONEY AND OTHER PROPERTY TO BE USED TO FURTHER THE FOREGOING PURPOSES; AND (B) SUPPORT THE AFFILIATED ORGANIZATIONS BY LOAN, LEASE OR DONATION OF FUNDS OR OTHER ASSETS; AND (C) SUPPORT THE AFFILIATED ORGANIZATIONS BY GUARANTY OF THE OBLIGATIONS OF THE AFFILIATED ORGANIZATIONS OR BY OTHER ACTION.

ARTICLE III

A corporation may have one or more classes of members. ***As amended,*** the designation of such classes, the manner of election or appointments, the duration of membership and the qualifications and rights, including voting rights, of the members of each class, may be set forth in the by-laws of the corporation or may be set forth below:

ARTICLE IV

As amended, other lawful provisions, if any, for the conduct and regulation of the business and affairs of the corporation, for its voluntary dissolution, or for limiting, defining, or regulating the powers of the business entity, or of its directors or members, or of any class of members, are as follows:
(If there are no provisions state "NONE")

The foregoing amendment(s) will become effective when these Articles of Amendment are filed in accordance with General Laws, Chapter 180, Section 7 unless these articles specify, in accordance with the vote adopting the amendment, a *later* effective date not more than *thirty days* after such filing, in which event the amendment will become effective on such later date.

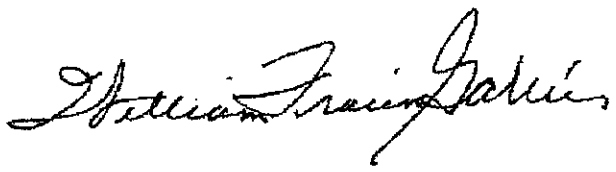
Later Effective Date:

Signed under the penalties of perjury, this 20 Day of April, 2016, BRENT L. HENRY , its , President / Vice President,
MARY C. LALONDE , Clerk / Assistant Clerk.

THE COMMONWEALTH OF MASSACHUSETTS

I hereby certify that, upon examination of this document, duly submitted to me, it appears that the provisions of the General Laws relative to corporations have been complied with, and I hereby approve said articles; and the filing fee having been paid, said articles are deemed to have been filed with me on:

April 20, 2016 04:09 PM



WILLIAM FRANCIS GALVIN

Secretary of the Commonwealth

Attachment/Exhibit

10

Massachusetts Department of Public Health
Determination of Need
Affidavit of Truthfulness and Compliance with Law and Disclosure Form 100.405(B)

Version: 7-6-17

Instructions: Complete information below. When complete check the box "This document is ready to print:". This will date stamp and lock the form. Print Form. Each person must sign and date the form. When all signatures have been collected, scan the document and e-mail to: **dph.don@state.ma.us** Include all attachments as requested.

Application Number: PHS-19030610-HS

Original Application Date: 03/06/2019

Applicant Name: Partners HealthCare System, Inc.

Application Type: Hospital/Clinic Substantial Change in Service

Applicant's Business Type: (•) Corporation ( ) Limited Partnership ( ) Partnership ( ) Trust ( ) LLC ( ) Other

Is the Applicant the sole member or sole shareholder of the Health Facility(ies) that are the subject of this Application? (•) Yes ( ) No

The undersigned certifies under the pains and penalties of perjury:

1. The Applicant is the sole corporate member or sole shareholder of the Health Facility[ies] that are the subject of this Application;
2. I have* ~~read~~ 105 CMR 100.000, the Massachusetts Determination of Need Regulation;
3. I understand and agree to the expected and appropriate conduct of the Applicant pursuant to 105 CMR 100.800;
4. I have* ~~read~~ this application for Determination of Need including all exhibits and attachments, and ~~certify that~~** all of the information contained herein is accurate and true;
5. I have submitted the correct Filing Fee and understand it is nonrefundable pursuant to 105 CMR 100.405(B);
6. I have submitted the required copies of this application to the Determination of Need Program, and, as applicable, to all Parties of Record and other parties as required pursuant to 105 CMR 100.405(B);
7. I have caused, as required, notices of intent to be published and duplicate copies to be submitted to all Parties of Record, and all carriers or third-party administrators, public and commercial, for the payment of health care services with which the Applicant contracts, and with Medicare and Medicaid, as required by 105 CMR 100.405(C), et seq.;
8. I ~~have caused~~** proper notification and submissions to the Secretary of Environmental Affairs pursuant to 105 CMR 100.405(E) and 301 CMR 11.00; will be made if applicable
9. If subject to M.G.L. c. 6D, § 13 and 958 CMR 7.00, I have submitted such Notice of Material Change to the HPC - in accordance with 105 CMR 100.405(G);
10. Pursuant to 105 CMR 100.210(A)(3), I certify that both the Applicant and the Proposed Project are in material and substantial compliance and good standing with relevant federal, state, and local laws and regulations, as well as with all ~~previously issued~~ Notices of Determination of Need ~~and the terms and Conditions attached therein~~***;
11. I have* ~~read~~ and understand the limitations on solicitation of funding from the general public prior to receiving a Notice of Determination of Need as established in 105 CMR 100.415;
12. I understand that, if Approved, the Applicant, as Holder of the DoN, shall become obligated to all Standard Conditions pursuant to 105 CMR 100.310, as well as any applicable Other Conditions as outlined within 105 CMR 100.000 or that otherwise become a part of the Final Action pursuant to 105 CMR 100.360;
13. Pursuant to 105 CMR 100.705(A), I certify that the Applicant has Sufficient Interest in the Site or facility; and
14. Pursuant to 105 CMR 100.705(A), I certify that the Proposed Project is authorized under applicable zoning by-laws or ordinances, whether or not a special permit is required; or,
    a. If the Proposed Project is not authorized under applicable zoning by-laws or ordinances, a variance has been received to permit such Proposed Project; or,
    b. The Proposed Project is exempt from zoning by-laws or ordinances.

Corporation:

Attach a copy of Articles of Organization/Incorporation, as amended

David F. Torchiana, M.D.	David Torchiana	2/28/19
CEO for Corporation Name:	Signature:	Date
Scott M. Sperling		
Board Chair for Corporation Name:	Signature:	Date

*been informed of the contents of
**have been informed that
***issued in compliance with 105 CMR 100.000, the Massachusetts Determination of Need Regulation effective January 27, 2017 and amended December 28, 2018

Massachusetts Department of Public Health
Determination of Need
Affidavit of Truthfulness and Compliance with Law and Disclosure Form 100.405(B)

Version: 7-6-17

Instructions: Complete information below. When complete check the box "This document is ready to print:". This will date stamp and lock the form. Print Form. Each person must sign and date the form. When all signatures have been collected, scan the document and e-mail to: **dph.don@state.ma.us** Include all attachments as requested.

Application Number: PHS-19030610-HS

Original Application Date: 03/06/2019

Applicant Name: Partners HealthCare System, Inc.

Application Type: Hospital/Clinic Substantial Change in Service

Applicant's Business Type: (•) Corporation ( ) Limited Partnership ( ) Partnership ( ) Trust ( ) LLC ( ) Other

Is the Applicant the sole member or sole shareholder of the Health Facility(ies) that are the subject of this Application? (•) Yes ( ) No

The undersigned certifies under the pains and penalties of perjury:

1. The Applicant is the sole corporate member or sole shareholder of the Health Facility(ies) that are the subject of this Application;
2. I have ~~read~~* 105 CMR 100.000, the Massachusetts Determination of Need Regulation;
3. I understand and agree to the expected and appropriate conduct of the Applicant pursuant to 105 CMR 100.800;
4. I have ~~read~~* this application for Determination of Need including all exhibits and attachments, and ~~certify that~~** all of the information contained herein is accurate and true;
5. I have submitted the correct Filing Fee and understand it is nonrefundable pursuant to 105 CMR 100.405(B);
6. I have submitted the required copies of this application to the Determination of Need Program, and, as applicable, to all Parties of Record and other parties as required pursuant to 105 CMR 100.405(B);
7. I have caused, as required, notices of intent to be published and duplicate copies to be submitted to all Parties of Record, and all carriers or third-party administrators, public and commercial, for the payment of health care services with which the Applicant contracts, and with Medicare and Medicaid, as required by 105 CMR 100.405(C), et seq.;
8. I ~~have caused~~** proper notification and submissions to the Secretary of Environmental Affairs pursuant to 105 CMR 100.405(E) and 301 CMR 11.00; will be made if applicable
9. If subject to M.G.L. c. 6D, § 13 and 958 CMR 7.00, I have submitted such Notice of Material Change to the HPC - in accordance with 105 CMR 100.405(G);
10. Pursuant to 105 CMR 100.210(A)(3), I certify that both the Applicant and the Proposed Project are in material and substantial compliance and good standing with relevant federal, state, and local laws and regulations, as well as with all ~~previously issued~~ Notices of Determination of Need ~~and the terms and Conditions attached thereto~~***;
11. I have ~~read~~* and understand the limitations on solicitation of funding from the general public prior to receiving a Notice of Determination of Need as established in 105 CMR 100.415;
12. I understand that, if Approved, the Applicant, as Holder of the DoN, shall become obligated to all Standard Conditions pursuant to 105 CMR 100.310, as well as any applicable Other Conditions as outlined within 105 CMR 100.000 or that otherwise become a part of the Final Action pursuant to 105 CMR 100.360;
13. Pursuant to 105 CMR 100.705(A), I certify that the Applicant has Sufficient Interest in the Site or facility; and
14. Pursuant to 105 CMR 100.705(A), I certify that the Proposed Project is authorized under applicable zoning by-laws or ordinances, whether or not a special permit is required; or,
    a. If the Proposed Project is not authorized under applicable zoning by-laws or ordinances, a variance has been received to permit such Proposed Project; or,
    b. The Proposed Project is exempt from zoning by-laws or ordinances.

Corporation:

Attach a copy of Articles of Organization/Incorporation, as amended

David F. Torchiana, M.D.		
CEO for Corporation Name:	Signature:	Date
Scott M. Sperling		02/28/2019
Board Chair for Corporation Name:	Signature:	Date

*been informed of the contents of
**have been informed that
***issued in compliance with 105 CMR 100.000, the Massachusetts Determination of Need Regulation effective January 27, 2017 and amended December 28, 2018.

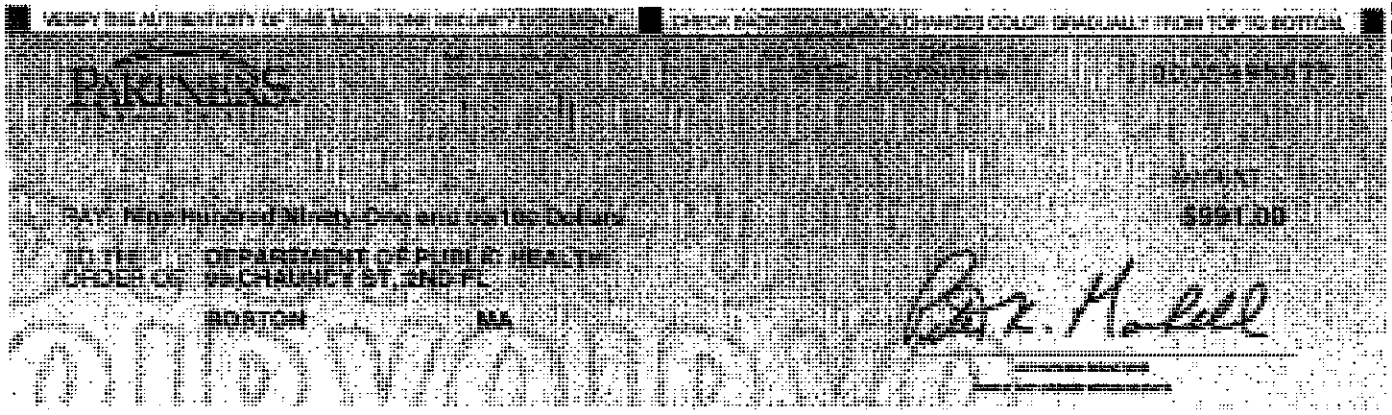
Attachment/Exhibit

11

DATE						CHECK NO
02/26/2019						0005995675
VOUCHER: INVOICE NUMBER		INVOICE DATE	PO NUMBER	GROSS AMOUNT	DISCOUNT	NET AMOUNT
27442836 220119		02/06/2019		991.00	0.00	991.00

MM Client Services (617) 726-2142	AP	2810	FH6303	780661	TOTAL AMOUNT	DISCOUNT	NET AMOUNT
					991.00	0.00	991.00

To Remove Document Fold and Tear Along This Perforation



See Reverse Side For Easy Opening Instructions

PARTNERS P.O. Box 9127
Boston, MA 02129-9127

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