

Questions for PHS Brigham and Women's Capital Expansion and Required Equipment Project

DON # PHS-17111513-HE

1. **Because the DoN regulation requires a discussion of the impact of the project on the Applicant's patient panel, please address the need as well as the public health value, continuity of care (and other elements in factor 1) relative to the Partners patient panel.**

Partners HealthCare currently operates two tertiary and seven community acute care hospitals 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. Consequently, the needs of Partners HealthCare's patient panel are broad and diverse.

A. An Aging Patient Population Needs Access to ED Services

As discussed in the Determination of Need ("DoN") narrative (page 6), the proposed Project also will allow the Applicant, and specifically BWH, to address the needs of an aging patient panel and the need for improved access to ED services. According to the University of Massachusetts' Donahue Institute's ("UMDI") *Long-Term Population Projections for Massachusetts Regions and Municipalities*, statewide population growth is projected to grow a total of 11.8% from 2010 through 2035.¹ 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 fifty (50) and older.² Moreover, between 2015 and 2035, the Commonwealth's 65+ population is expected to increase at a higher rate compared to all other age cohorts.³ By 2035, the 65+ age cohort will represent approximately a quarter of the Massachusetts population.⁴ The general trend of growth appears consistent across the counties where Partners HealthCare's affiliates are located, as well as within BWH's service area. The Applicant has seen a 4% increase in the number of patients it serves in the 65+ age cohort between FY14 and FY16. Current age demographics show that while the majority of the patients within Partners HealthCare's patient population are between the ages of 18-64 years of age (61-62% of total patient population), patients that are 65 and older make up a significant portion of the total patient population (25-28% of total patient population). As the number of patients that fall into the 65+ age cohort for BWH and Partners HealthCare continues to grow, the demand for ED services is expected to increase as well.

¹ 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. Within the past five 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.

² *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.*

³ UNIVERSITY OF MASSACHUSETTS DONAHUE INSTITUTE, *supra* note 1, 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 demonstrates that where the 65+ cohort increases from 2015 to 2035, all other cohorts are predicted to decrease. *Id.*

⁴ *Id.*

Elderly patients are one of the top three cohorts that that tend to overuse the ED for primary care services.⁵ Studies show that older adults use emergency services at a higher rate than young adults.⁶ Moreover, when an older adult presents at an ED, their visits are typically more emergent and require longer stays and increased services.⁷ These elderly patients are more likely to require repeat ED visits due to complex care needs.⁸ As previously discussed, individuals in the 65+ age cohort account for one quarter or more of the Applicant's entire patient panel. The projected increase in the older adult population necessitates the need for redesigned patient flow and care processes at BWH to allow this at-risk-population to receive quality care. However, these changes are only possible through renovations to and the expansion of the existing clinical space. Through the proposed Project, BWH will increase the overall ED footprint by 26,000 GSF, allowing for the addition of private rooms and the expansion of designated trauma bays.

B. Public Health Value of Expanded ED Services

Although the expansion of the BWH ED directly impacts the BWH patient panel, this expanded ED will also serve as a critically needed resource for all current patients in the panel, as well as all Massachusetts residents in need of emergency care. As an academic medical center ("AMC") BWH is often called upon for disaster relief and serves as a key resource for larger state issues, such as terrorist attacks. In 2013, after the Marathon bombing, BWH was a valuable resource in providing care to the injured. A right-sized ED will allow 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, such as house fires or larger scale attacks on the Commonwealth's residents.

Moreover, the proposed technology outlined in the DoN narrative will serve all patients in the system. If there is a need for services, physicians will be able to refer patients to the 7T MRI, MRI simulator and or MRI LINAC. Having access to these technologies allows for patients to receive more effective and expedited care that lead to improved health outcomes.

C. Continuity of Care

As discussed in DoN narrative, to ensure continuity of care, improved health outcomes and enhanced quality of life, through the proposed Project, information regarding patient care will be shared via the Applicant's electronic health record ("EHR") to share clinical information, images and provide follow-up information to a patient's primary care and specialty physicians. Additionally, patients will be linked with the necessary services to address social determinant of health ("SDoH") issues. Providing patients with linkages to these necessary services prevents unnecessary readmissions, ensures appropriate care management and provides the patient with the necessary resources for leading a better life.

MRI and LINAC

⁵ Doris F. Glick & Karen MacDonald Thompson, *Analysis of emergency room use for primary care needs*, 15 NURSING ECONOMICS 42 (1997).

⁶ Faranak Aminzadeh & William Burd Dalziel, *Older adults in the emergency department: A systematic review of patterns of use, adverse outcomes, and effectiveness of interventions*, 39 ANNALS OF EMERGENCY MED. 238, 238-47 (2002).

⁷ *Id.*

⁸ SR Lowenstein et al., *Care of the elderly in the emergency department*, 15 ANNALS OF EMERGENCY MED. 528, 528-35 (1986).

4. Describe the impact of these technologies on the Partner's patient panel.

As discussed in the DoN Narrative (page 2, RT-MRI Simulator and MRI-LINAC section) and above, statewide population projections provided by the University of Massachusetts' Donahue Institute suggest that population growth in Massachusetts is expected to increase through 2035.⁹ As the number of Partners HealthCare's patients in the 55+ age cohort continues to increase, the need for innovative technologies, such as a RT-MRI simulator and a MRI- LINAC are needed to meet increased demand for detecting, managing, and treating specific cancers.

Research-based findings demonstrate that the prevalence of cancer increases with age.¹⁰ Persons over 65 comprise 60% of newly diagnosed malignancies and 70% of all cancer deaths.¹¹ The incidence of cancer in individuals over 65 is 10 times greater than in those younger than 65.¹² The cancer death rate is 16 times greater in patients over 65 compared to younger patients.¹³

In Massachusetts, from 2009 through 2013, there were 183,009 newly diagnosed cases of cancer, for an average annual age-adjusted incidence rate of 480.4 cases per 100,000 persons. Overall, cancer incidence in Massachusetts slightly decreased from 2009 to 2013.¹⁴ The most commonly diagnosed type of cancer in Massachusetts for men during this time period was prostate cancer, followed by cancers of the bronchus and lung, colon/rectum, and urinary bladder.¹⁵ Among women in Massachusetts, the most commonly diagnosed cancer types were cancers of the breast, bronchus and lung, colon/rectum, and corpus uteri (uterus). From 2009 to 2013, there were 64,543 deaths from cancer among Massachusetts residents, for an average annual age-adjusted mortality rate of 162.9 deaths per 100,000 persons.¹⁶ Similar to newly diagnosed cases, cancer mortality in Massachusetts decreased from 2009 to 2013.¹⁷ However, cancer is still the leading cause of death in the Commonwealth. Accordingly, to address demand for radiation-based cancer treatment, BWH plans to acquire a RT-MRI simulator that may be used for RT treatment techniques (e.g., external beam radiation therapy and brachytherapy). In addition, BWH plans to acquire a MRI-LINAC that will provide real-time MRI imaging of a tumor during treatment. These innovative technologies will allow specific types of cancer patients across the Applicant's panel to receive better treatment resulting in higher quality care and improved health outcomes, as well as improved quality of life.

The proposed technologies will have an impact on cancer treatment that will lead to improved health outcomes and a better quality of life for cancer patients across the patient's panel that may be treated at BWH. The RT-MRI simulator provides improved visualization of certain cancers, including cancers of the brain, head and neck, prostate, as well as gynecological

⁹ 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.

¹⁰ Nathan A. Berger et al., *Cancer in the Elderly*, 117 TRANSACTIONS OF THE AM. CLINICAL & CLIMATOLOGICAL ASSOC. 147, 147-56 (2006), *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500929/pdf/tacca117000147.pdf>.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Massachusetts Cancer Statistics*, COMMONWEALTH OF MASSACHUSETTS EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES, <http://www.mass.gov/eohhs/gov/departments/dph/programs/community-health/cancer-age/massachusetts-cancer-statistics.html> (last visited Oct. 31, 2017).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

cancers. This enhanced capability leads to less radiation exposure of tissue and organs around the tumor. Moreover, use of MRI instead of CT simulation in treatment planning results in decreased overall exposure to radiation for the patient as MRI does not use radiation to produce images. Currently, the time from MRI scan to stereotactic treatment at BWH is approximately fourteen days; however, the availability of a RT-MRI simulator can reduce this timeframe and ensure patients receive care in an expedited manner. Finally, this technology can provide high-quality imaging of difficult to reach areas and differentiate between various types of soft tissue that is not possible with CT simulation. Accordingly, access to a RT-MRI simulator will provide patients with more refined treatment plans with a technology that does not expose patients to additional radiation, ultimately leading to improved health outcomes and quality of life for a subset of cancer patients.

The MRI-LINAC also enhances quality care and leads to improved patient outcomes by precisely delivering radiation that can improve disease control while reducing toxicity. Better quality outcomes are achieved through the integrated MR imager that provides pre-treatment and real-time soft tissue visualization that is not possible with current state-of-the-art conventional LINACs. Accordingly, the MRI-LINAC will improve cancer patients' health outcomes and quality of life by providing targeted radiation to better treat certain cancers.

5. Overuse of medical technologies is recognized as a cost driver. How do you determine when a technology is being overused? Do you maintain statistics on overuse/inappropriate use of services? How will you assure that only the appropriate patients are scanned/treated using these modalities? What professional organizations/bodies set the standards for which diagnoses are appropriate for treatment?

For **diagnostic imaging**, overuse/inappropriate use are determined by comparing the reasons or indications provided by the ordering professional for a specific exam to a published list of Appropriate Use Criteria (AUC) for medical imaging. Under regulations enacted by the Centers for Medicare and Medicaid Services (CMS), a small list of national professional medical societies and qualified provider-led entities have been given the authority to create and publish AUC. These organizations are required to apply for this authority, demonstrate detailed evidence-based processes for creating AUCs, and comply with provisions of the extensive regulations and underlying federal statute. Providers nationally are required to utilize one or more AUC sets published by one of the 17 current societies or qualified provider led entities approved by CMS. The Applicant utilizes the AUC published by the American College of Radiology for diagnostic imaging exams, and monitors the adherence by ordering providers with these AUC, and maintains statistics on adherence and lack of adherence. In addition to the AUC process, the Applicant maintains quality and safety programs designed to prevent the unsafe or inappropriate use of medical imaging technologies.

It is important to note that the CMS AUC program is intended to address the use of *diagnostic* imaging for patients, and it does not address **MRI simulation/planning** for radiation therapy or **MRI LINAC** for the delivery of therapeutic radiation. Radiation Oncology patients have a known diagnosis of cancer and present for MRI Simulator in order to determine the appropriate radiation treatment plan for the individual's clinical needs. The MRI Simulator is a planning system that is not intended to perform initial diagnoses, and the MRI LINAC is designed to improve the safe delivery of therapeutic radiation. The Applicant will only use these systems pursuant to orders submitted by properly credentialed providers. All such uses will comply with Applicants quality and safety programs for these systems.

Additionally, the Department of Radiation Oncology at BWH has developed and implemented clinical pathways for the majority of the common cancer diagnoses (lung, breast, prostate, GI, CNS, lymphoma, sarcoma, etc). These clinical pathways were developed using consensus recommendations from the hospital's disease site expert radiation oncologists with input from specialists from BWH surgery and DFCI medical oncology, and draw on national guidelines and appropriateness criteria from organizations including the American College of Radiology, American Society of Radiation Oncology (ASTRO), National Comprehensive Cancer Network (NCCN), American Association of Physicists in Medicine (AAPM), and the National Cancer Institute (NCI). The clinical pathways have been implemented into a clinical software that provides decision support on the appropriate use of technologies at the point of care, requires physicians to select either a consensus treatment pathway or an "off-pathway" treatment, and tracks the frequency of on-pathway treatment versus off-pathway treatments for all patients receiving radiation therapy at the hospital center. The hospital would utilize this existing infrastructure to develop a framework for measurement of appropriate use of the MRI simulator and MRI linear accelerator.

6. We understand that the 7T will be reimbursed at the same level as existing 3T machines; will the MRI simulator and MRI LINAC be reimbursed at an equal or greater level?

Procedures performed on the MRI Simulator will be coded using the same CPT codes currently used for a CT Simulator and will be reimbursed at the same rate as current CT Simulator services. Similarly, radiation treatments delivered using the MRI LINAC will be coded using the same CPT codes currently used for the hospital's existing LINACs and will be reimbursed at the same rate as the hospital's current LINAC services.