



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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August 9, 2019

Andrew Levine, Esq.
Barrett & Singal
One Beacon Street, Suite 1320
Boston, MA 02108-3106

VIA EMAIL

RE: Notice of Final Action DoN # PHS-19030610-HS

Dear Mr. Levine:

This shall serve as notification that, based on the information provided by the Applicant and staff analysis, and pursuant to M.G.L. c. 111, § 25C and the regulatory provisions of 105 CMR 100.000 et seq, including 105 CMR 100.715(B)(1) Substantial Change in Service (DoN-required Services and DoN-required Equipment) and 105 CMR 100.630(A)(6), I hereby approve the application for Determination of Need ("DoN") filed by Partners HealthCare System, Inc. (Partners or Applicant) to add a cone beam CT (CBCT) scanner at Brigham and Women's Faulkner Hospital (BWFH). The capital expenditure for the Proposed Project is \$495,500.00 (March 2019 dollars). The CHI commitment is \$24,775.00.

In compliance with the provisions of 105 CMR 100.310(A)(2) and (11) the Holder shall submit an acknowledgment of receipt to the Department (attached) and also include a written attestation of participation or intent to participate in MassHealth.

In compliance with the provisions of 105 CMR 100.310(A)(12), which require a report to the Department, at a minimum on an annual basis, including the measures related to achievement of the DoN factors for a period of five years from completion of the Proposed Project, the Holder shall address its assertions with respect to all the factors.

On July 10, 2019, DoN Program forwarded to all Parties of Record its written Staff Memorandum. A comment was received from the Applicant on July 19, 2019 requesting new language regarding annual reporting in Condition 3. In its comments to the Department, the Applicant explained that the data that is used to determine the percentage of lives covered in the Partners' risk contracts will differ from the Partners' Patient Panel data because the risk contract data is based on primary care lives and the Patient Panel data, as defined in the DoN regulation, is based on the number of patients that received care at Partners' acute care hospitals, including referrals. The Applicant stated

that health delivery system transformation will be demonstrated through growth in patients covered under managed risk/ACO contracts and proposed to provide the percentage of primary care lives within the Patient Panels of the Partners' PCPs that are covered under risk contracts (Partners bears risk).

DoN Program Staff agreed with the Applicant's comments and made changes to Condition 3. DoN Program Staff clarified all categories in the table and incorporated the Applicant's suggestion for new language to track participation by the Applicant in risk contracts. The final conditions, as they have been amended, are provided below.

This Notice of Final Action incorporates by reference the Memorandum concerning this Application and is subject to the conditions set forth therein, pursuant to the amendment provided in this Notice of Final Action.

Other Conditions:

In order to demonstrate that the Proposed Project will add measurable public health value in terms of improved health outcomes and quality of life of the Applicant's Patient Panel, the Holder shall, on a yearly basis:

1. Report on the measures outlined in Attachment 1.
2. Demonstrate a reduction in repeat X-ray and or CT scans and scans using multiple modalities. In its annual report to the Department, the Holder will report yearly on upper and lower extremity scan volumes for orthopedic conditions for which CBCT is indicated for diagnostic purposes, further broken out as follows: (1) upper and lower extremity x-ray volume; (2) upper and lower extremity CT volume; (3) upper and lower extremity x-ray repeats; (4) upper and lower extremity CT repeats; and (5) CBCT volume.
3. Demonstrate continued transformation and ongoing growth in the percentage of patients covered under managed risk/ACO contracts. In addition, provide payer mix of the Patient Panel for Applicant and BWFH as follows.

Patient Panel Payer Mix-List percentages (must =100%)
<ol style="list-style-type: none"> 1. Commercial <i>If possible, by</i> <ul style="list-style-type: none"> ○ <i>Commercial PPO/Indemnity</i> ○ <i>Commercial HMO/POS</i> 2. MassHealth 3. Managed Medicaid (<i>Private Medicaid/Medicaid MCOs</i>) 4. Commercial Medicare (<i>Private Medicare/Medicare Advantage</i>) 5. Medicare FFS 6. All other (e.g. HSN, self-pay, TriCare)

CHI Conditions of the DoN

4. Of the total required CHI contribution of \$24,775.00
 - a. \$2,378.40 will be directed to the CHI Statewide Initiative
 - b. \$22,396.60 will be dedicated to local approaches related to the DoN Health Priorities
 - i. The Holder may use up to 4% of this total amount for administrative purposes designed to support implementation of the CHI and provide up to 10% to support the ongoing evaluation of DoN# 17111513-HE.
 - c. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$2,378.40 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - i. The Holder must submit the funds to HRiA within 30 calendar days from the date of the Notice of Approval.
 - ii. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.
5. The Holder will provide all required local CHI resources to support the Health Priority Strategies approved on September 2018 under DoN# 17111513-HE. The approved strategies contain two "Housing Stabilization Support" components.

Ongoing compliance with the conditions and all terms of the DoN is, pursuant to the Regulation, a precondition to the filing of any future DoN by the Holder.

Sincerely,



Monica Bharel, MD, MPH
Commissioner

cc: Sherman Lohnes, Director, Division of Health Care Facility Licensure and Certification
Rebecca Rodman, Deputy General Counsel
Daniel Gent, Health Care Facility Licensure and Certification
Mary Byrnes, Center for Health Information and Analysis
Stephen Sauter, MassHealth
Katherine Mills, Health Policy Commission
Eric Gold, Office of the Attorney General

Memorandum to the Commissioner

Applicant	Partners HealthCare System, Inc.
Applicant Address	800 Boylston Street, Suite 1150 Boston, MA 02199
Project Number	PHS-19030610-HS
Project Type	Substantial Change in Service, DoN-required Equipment
Date of Application	March 6, 2019
Delegated Review	Final action by the Commissioner
<p>Project Summary</p> <p>Partners HealthCare System, Inc. (Partners or the Applicant) submitted a Determination of Need (DoN) application for one extremity cone beam CT (CBCT) unit at Brigham and Women's Faulkner Hospital (BWFH). The total value of the Project is \$495,500.00. This is a Tier 1 project with a CHI commitment of \$24,775.00.</p> <p>This request falls within the definition of DoN-Required Equipment and Services, which are reviewed under the DoN regulation 105 CMR 100.000. Pursuant to 105 CMR 100.630. This Application has been delegated by the Department for review and Final Action by the Commissioner.</p> <p>Under the regulation, the Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need factor set forth within 105 CMR 100.210. This staff memorandum addresses each of the six factors set forth in the regulation.</p>	

Background

The Applicant is Partners HealthCare System, Inc. (Partners), a nonprofit integrated health care system that was formed in 1994.¹ Partners is a Health Policy Commission (HPC) certified Accountable Care Organization (ACO).^a Partners HealthCare Accountable Care Organization, LLC, manages Medicare (Next Generation ACO) and MassHealth (Partners HealthCare Choice) ACO programs. Brigham and Women's Faulkner Hospital (BWFH), the site of the Proposed Project, is a community acute care hospital member of Partners providing comprehensive medical, surgical and psychiatric care and complete emergency, ambulatory and diagnostic services.^{2,3}

¹ Partners operates two tertiary care 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 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.

² BWFH is part of Brigham Health, which is composed of Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and Brigham and Women's Physicians Organization.

³ BWFH is located at 1153 Centre Street in Boston and is licensed to operate 171 beds: M/S = 133, ICU=14, Psychiatric Service=24.

The Proposed DoN Project

Through the Proposed Project, the Applicant will add one extremity cone beam CT (CBCT) unit at BWFH to address the imaging needs of patients with musculoskeletal conditions of the extremities. The Applicant will co-locate the CBCT unit within the hospital's orthopedic center and shift appropriate patients from CT and X-ray imaging to the CBCT unit. The Applicant states that the CBCT unit is a cost-efficient means of increasing patient panel access to higher-quality, more precise imaging of the extremities, and this will improve diagnosis and treatment of musculoskeletal conditions.

CT 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 the 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.^b

Factor 1 & 2: Patient Panel Need

In this section, staff assess if the Applicant has sufficiently addressed patient panel need, public health value, competitiveness and cost containment, and community engagement for the Proposed Project. Staff also assesses whether the Applicant has demonstrated that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

Factor 1: a) Patient Panel⁴

The number of patients utilizing Partners services increased from about 1.3 million unique patients in FY15 to about 1.4 million in FY17. About 60% of the patient panel was female. The Applicant points to patient panel data which shows that patients age 65 and older make up 27% of its patient panel. Self-reported data on race/ethnicity includes White (72%), African American (6.0%), Asian (4%), and Hispanic/Latino (2%). Almost half of the patient panel originated from health service area (HSA) 4.⁵ The FY17 payer mix was Commercial (~60%), Managed Medicaid (~5%), MassHealth (~4%), Commercial Medicare (~4%), Medicare FFS (~23%), and Other (~5%).⁶

The Applicant also provided patient panel data for BWFH to demonstrate patient panel need for the Proposed Project. At BWFH, the number of patients also increased during this same time period from ~ 85,000 unique patients in FY15, to ~89,000 unique patients in FY17. The patient panel was 66% female. The Applicant notes that 35% of the BWFH patient panel is age 65 and over. Self-reported data on race/ethnicity includes White (71%), African American (11%), Asian (2%), and

⁴ As defined in 105 CMR 100.100, Patient Panel is 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 or Holder.

⁵ Health Service Area 4 consists of the following cities/town: Acton, Arlington, Ashland, Bedford, Belmont, Boston, Boxborough, Braintree, Brighton, Brookline, Burlington, Cambridge, Canton, Carlisle, Chelsea, Cohasset, Concord, Dedham, Dover, Dorchester, Foxborough, Framingham, Hingham, Holbrook, Holliston, Hopkinton, Hudson, Hull, Lexington, Lincoln, Littleton, Marlborough, Maynard, Medfield, Millis, Milton, Natick, Needham, Newton, Norfolk, Northborough, Norwell, Norwood, Quincy, Randolph, Revere, Roslindale, Scituate, Sharon, Sherborn, Somerville, Southborough, Stow, Sudbury, Walpole, Waltham, Watertown, Wayland, Wellesley, Westborough, Weston, Westwood, Weymouth, Wilmington, Winchester, Winthrop, Woburn, and Wrentham.

⁶ Reflects aggregate Partners HealthCare revenue for 2016-2018

Hispanic/Latino (5%). Almost 75% of the patient panel originated from HSA 4. The FY17 payer mix was Commercial (52%), Managed Medicaid (~6%), MassHealth (~4%), Commercial Medicare (~5 %%%), Medicare FFS (~29%), and Other (3%).

Imaging Services and Access to Cone Beam CT (CBCT)

The Applicant proposes to add one extremity cone beam CT (CBCT) unit at BWFH-- a site with high orthopedic clinic and surgical volume -- to address the existing and future needs of the patient panel with **musculoskeletal conditions of the upper and lower extremities** (e.g., hands, wrists, elbows, knees, feet, ankles). The Applicant outlined two main needs for this equipment:

- **Avoiding unnecessary repeat and/or multiple modality scans for patients with musculoskeletal conditions of the upper and lower extremities.** Currently, these patients are imaged with a standard X-ray, which uses radiation to produce two-dimensional images of the body and/or with traditional CT, which combines X-rays with computer technology to produce more detailed three-dimensional images of the body. In order to obtain conclusive quality images, repeat x-rays and/or multimodality imaging is often necessary; this increases radiation exposure, increases the cost of care and can prevent the delivery of timely and appropriate care.
 - In FY 2017, there were a total of ~660 upper and lower extremity CT scans and ~22,500 upper and lower extremity X-rays at BWFH. The Applicant estimates that the Proposed Project would allow for the replacement of 100 unnecessary CT scans and ~500 X-rays. That same year, 282 patients with conditions of the upper and lower extremities received scans using multiple imaging modalities. The Applicant further estimates that the Proposed Project would allow for a reduction in patients requiring imaging by multiple modalities.
- **Addressing the needs of an aging population at risk for musculoskeletal conditions.** The Applicant argues that the increasing aging population in the state will lead to additional need for CBCT services. The literature shows that age is a leading risk factor for musculoskeletal conditions and the Applicant cites this to show a correlation between the increasing aging population and the Patient Panel's growing need for CBCT services.^{c,d,e,f} The age 65 and older population will represent a quarter of the Massachusetts population by 2035.^g As noted above, about 1/3 of patient panel is over age 65.

Analysis

Staff finds that the information provided by the Applicant demonstrates sufficient need by their Patient Panel for CBCT services to reduce unnecessary repeat/and or multi-modality imaging. The literature has shown that CBCT scans allow for more precise imaging of the extremities.^h Moreover, the FDA has stated that CBCT technology allows for scanning the imaged anatomy in a single rotation with very good spatial detail while providing patient radiation doses that are typically lower as compared to conventional CT.ⁱ

Factor 1: b) Measurable public health value, improved health outcomes and quality of life; assurances of health equity

The Applicant outlined improvements in access and outcomes for the proposed CBCT unit:^{7,j,k,8}

- **Improved Access.** The proposed CBCT unit offers improved diagnostic capabilities. CBCT leads to higher quality images of certain parts of the body and supports weight bearing imaging of the foot, ankle, leg and knee. Moreover, the Applicant reports state that the CBCT unit will result in shortened time from imaging to diagnosis and that this will allow treatment to start sooner.¹ As noted above, the Applicant states that BWFH clinicians will use the CBCT unit as a substitute for scans on existing BWFH CT or X-ray machines. The CBCT unit will reduce the number of unnecessary scans for patients currently imaged on X-ray and CT units and increase their access to higher-quality imaging.^m
- **Improved Outcomes.** In terms of outcomes and quality of life, the Applicant maintains that the addition of a CBCT unit will improve the diagnostic accuracy of hard to diagnose musculoskeletal extremity conditions, reduce the need for less specific and repeat testing, and reduce potential for misdiagnosis and expensive corrective care.

The Applicant provided specific outcome measures they plan to use to assess the impact of Proposed Project (Attachment 1). These include:

- **Patient Satisfaction.** Review patient ratings of care with imaging services
- **Access to CBCT Services.** Review appointment availability and wait times for timely reporting of results
- **Quality of Care.** Review repeat examinations, reporting results and follow-up in reporting software, and accuracy of CBCT scan interpretations.

Health Equity and Social Determinants of Health

The Applicant outlined the following services and processes in place at BWFH that will address potential barriers to care and support equal access to CBCT services:

- **Language Interpretation.** BWFH offers access to interpreter and translation services via several modalities to BWFH's limited-English speaking (LEP) and hearing-impaired patients at all points of clinical contact in a timely manner. All interpreters are trained and certified; hospital-wide policies for interpreter services will also be followed for the CBCT scans. BWFH publicizes LEP and hearing-impaired services offered through posters, a guide, and on the BWFH websites.

⁷ The Applicant describes the main difference between traditional CT and CBCT is how the images are captured. Traditional CT uses a fan-shaped X-ray beam to image a narrow slice of a patient and therefore, multiple rotations around the patient are required to image an extended volume; CBCT uses cone-shaped X-ray beams to image an extended volume of the patient in a single rotation. Because CBCT uses cone-shaped X-ray beams, images are acquired faster and with less radiation exposure to the patient. (<https://www.carestream.com/blog/2015/11/05/white-paper-advantages-of-volumetric-cone-beam-imaging-for-orthopaedic-extremity-exams/>)

⁸ The Applicant states that the system captures a 3D extremity image in a single rotation that takes 25 seconds; the imaging software that will be installed will enable completion of a full-high resolution volume reconstruction in approximately four minutes, resulting in a workflow of 10-15 minutes.

- **Staff Training.** The Applicant states that BWFH offers ongoing education and training in culturally and linguistically appropriate services for staff at all levels and across all disciplines.⁹
- **Social Determinants of Health (SDOH).** The Applicant states that BWFH has developed social work/case management and continuity of care programs that link patients to clinical services and to social service organizations.¹⁰ In addition, the Applicant states that BWFH partners with programs in the community to address the needs of patients experiencing social determinant of health issues. The Applicant maintains that these services will reduce unnecessary readmissions and ensure appropriate care management.

Public Health Value, improved health outcomes, and quality of life: Analysis

Staff reviewed the literature provided by the Applicant on CBCT services and found that innovations in CT technology through the proposed CBCT¹¹ will likely improve imaging services for a subset of the Patient Panel. Staff also reviewed existing CT and X-ray volume to understand the potential impact of the CBCT unit on repeat and multiple modality scans, and found that the data presented sufficiently demonstrate need for the Proposed Project. The metrics provided in Attachment 1 will become part of DoN annual reports.

Health Equity: Analysis

Staff finds that through providing access to interpretation and translation services, staff training, and social workers/case managers, the Applicant has sufficiently outlined a case for improved health outcomes and has provided reasonable assurances of health equity.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

Radiologists will be embedded within the clinic to provide real-time interpretation and consultation to allow patients to have access to integrated CBCT imaging, musculoskeletal, and surgical services. The CBCT unit will be located adjacent to the orthopedic center which offers foot and ankle, hand and upper extremity, joint replacement, knee replacement, podiatry, rehabilitation, and sports medicine and shoulder services. According to the Applicant, co-location will allow for imaging at the point of care and allow for an early commencement of treatment.ⁿ

The Applicant states that CBCT results will be integrated into the Partners HealthCare electronic health record (EHR). The Applicant uses EPIC as its EHR, which enables imaging results and information to be available to primary care and specialty physicians across Partners and includes the

⁹BWFH began offering cultural competency training in March 2015; ~97% of employees have attended some form of cultural competence training and ~90% have attended an instructor-led class.

¹⁰ BWFH's social workers provide emotional support, assistance communicating with providers, counseling around chronic illness, a new diagnosis or medical decision-making needs, and referral information about health conditions, family issues, and other matters that impact patient health. Social work services are arranged for patients who present to radiology from the inpatient setting and for ambulatory patients who present to the ED. Ambulatory patients receiving same day scans are referred to their primary care practice for those services. Nurse case managers provide information on home care services or specialized skilled nursing/rehabilitation facilities, medical treatment and equipment, community resources, and they respond to questions regarding health plans and insurance benefits.

¹¹ CareStream Health, the manufacturer of the proposed OnSight 3D Extremity System, received 501(k) clearance with the US Food and Drug Administration (FDA) in 2016; similar technology was cleared more recently. This clearance is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.

“Care Everywhere” feature, which allows patients to authorize providers outside of Partners HealthCare system to access their data, view their record, and send progress notes.

Analysis

Staff finds that the Applicant provided sufficient information to support efficiency, continuity and coordination of care. In addition to co-locating the CBCT unit next to the orthopedic center, the integration of CBCT services into the EHR will achieve greater efficiencies, continuity of care and care coordination. These improvements have been well-documented in the literature and include such benefits as better message tracking among the provider team, alerts for prescription renewals, and easier access to laboratory results leading to reduced duplication of testing. All of these can lead to time-savings for patients and clinicians, and reductions in medical errors and improved quality of care with better outcomes.

Factor 1: d) Consultation:

The Applicant has provided sufficient evidence it has appropriately consulted with Government Agencies; it will not be addressed further in this report.

Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel

The Department’s Guideline¹² for community engagement defines “community” as the Patient Panel, and requires that at minimum, the Applicant must “consult” with groups representative of the Applicant’s Patient Panel. During the planning phase of the Proposed Project, the Applicant met with the BWFH Community Engagement Committee (CEC) and the BWFH Patient and Family Advisory Council (PFAC)¹³ to discuss the need and community benefit of the Proposed Project. The Applicant states that overall feedback obtained was positive and supportive and no concerns were expressed.

Analysis

Staff finds that the Applicant met the required community engagement standard of *Consult* in the planning phase of the Proposed Project.

Factor 1: f) Competition on Price, TME, costs and other measures of health spending

The Applicant asserts that the proposed CBCT unit is competitive on the basis of price because CBCT scans will be reimbursed the same rate as traditional CT scans. The CBCT unit is also competitive because it will contribute to reductions in healthcare spending; as noted above, CBCT imaging will improve the diagnostic accuracy of hard to diagnose conditions and this will allow clinicians to avoid repeat testing and misdiagnoses, which can lead to complications, extensive follow-up interventions and increased healthcare spending. The Applicant argues that the reductions in unnecessary imaging and healthcare utilization will reduce medical expenses paid by payers to providers and patient cost-sharing amounts and contribute to a reduction of total health care expenditures (THCE).

¹² Community Engagement Standards for Community Health Planning Guideline

¹³ The CEC solicits input and recommendations on how the BWFH can better serve the community; it includes representatives from a wide range of local organizations and community residents. The BWFH PFAC provides a forum to facilitate patient and family input in all aspects of the hospital’s operations. It is comprised of six staff members and eight patient/family advisor members.

Analysis

Staff finds that on balance, the requirement that the project compete on the basis of price, total medical expenses (TME), provider costs, and other measures of health care spending have been met through the Applicant's demonstration that the addition of a CBCT unit has the potential to reduce healthcare costs through improving diagnosis and appropriate treatment for a subset of the Patient Panel making it a competitive alternative to existing imaging modalities for these patients.

Summary Analysis of Factor 1

Staff finds that with the Proposed Project, the Applicant will likely provide higher-quality imaging services to address the needs of the Patient Panel. Reports show that musculoskeletal conditions are associated with pain and impaired physical function, reduced ability to work, and lower quality of life.^{9P} Musculoskeletal conditions are also costly in the form of treatment, missed work and lost productivity.⁹ The Proposed Project will improve the diagnosis of musculoskeletal conditions which will likely lead to earlier and more appropriate treatment and better health outcomes. In addition, providing treatment more quickly can reduce the pain, disability, and costs that are associated with these conditions. The Project will likely improve coordination of care and provide linkages to services; this will further support continuity of care and improved health outcomes for the Patient Panel.

With the required post-DoN reporting under the standard conditions, staff believes that the Applicant has met the standards of compliance with factor 1.

Factor 2: Cost containment, improved public health outcomes and delivery system transformation

The Applicant provides three reasons to demonstrate that the addition of the CBCT unit will align with Commonwealth's goal for cost containment (to provide better quality care at a lower-cost⁹):

- The addition of a CBCT unit will increase access to higher-quality imaging services without increasing the cost of CT imaging. The DoN-required Equipment and Services Guideline inclusion criteria (cost, quality and access) are intended to support innovative and new technology that has added value for the patient (lower costs of care with improved outcomes). The CBCT unit is not intended to address a need for additional capacity but instead is intended to take advantage of innovations in CT technology that have improved imaging for patients with musculoskeletal conditions of the upper and lower extremities.
- As stated above, the CBCT unit will reduce repeat imaging that creates additional costs for the patient and the healthcare system.
- There will be appropriate limits on the use of the CBCT unit. Only appropriate patients will be shifted from the hospital's traditional CT (and in some cases X-ray) units to the CBCT unit. Additionally, there are several mechanisms in place (EHR, ACR select, pre-authorization, multi-step reviews, among others) that can help prevent unnecessary or inappropriate scanning.

In addressing public health outcomes, the Applicant states the higher-quality imaging achieved through the CBCT unit will improve diagnosis and lead to more appropriate treatment. Coordinated care will also create more opportunities for provider collaboration to improve patient care. Finally, the Applicant appears to address delivery system transformation through including access to BWFH

resources that support coordinated care and address SDOH issues, which has been shown to improve health outcomes.⁸

Analysis

Staff finds that the Proposed Project is likely to improve health outcomes of the patient panel through expanding access to higher-quality imaging that reduces the need for duplicate testing.

Staff notes that Massachusetts ranks in the nation in Medicare spending for imaging and in the nation for utilization of imaging services; such expenditures contribute to high overall healthcare costs in Massachusetts.¹⁴ Staff inquired about the potential for inappropriate utilization of CT imaging as a result of the additional capacity that will be obtained through the Proposed Project, and reviewed strategies listed by the Applicant to reduce inappropriate imaging against studies reporting on their varying levels of effectiveness.¹⁵ There are a number of clinical decision support mechanisms in use, such as those described above as well as one proposed by the Center for Medicare and Medicaid Services.¹⁴ However, as summarized by a review by the Alliance for Academic Internal Medicine, “Clinical decision support strategies have demonstrated modest reductions in overall utilization of diagnostic imaging tests, but it is unknown if these interventions are lasting”.¹⁶ In order to completely address cost containment under Factor 2, staff suggests conditions requiring the annual reporting of X-ray, CT, and CBCT volume, as outlined below.

Central to the goal of delivery system transformation is the integration of social services and community-based expertise. Staff finds that the Applicant has sufficiently described how the needs of their patient panel are assessed and how linkages to social services organizations are created. In order to ensure that managed risk contracts continue to grow in the Proposed Project, staff recommends tracking payers by type, also outlined below.

Factor 3 Relevant Licensure/ Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and will not be addressed further in this report.

Factor 4: Demonstration of Sufficient Funds as supported by an Independent CPA Analysis

The CPA analysis reviewed the financial projections for Partners HealthCare System, Inc. (Applicant) for the fiscal years (FY) ending 2019 through 2023 (Projection Period), operating results for Partners for the fiscal years ended 2017 and 2018 (Base Budget) and supporting documentation. The report included an analysis of key metrics (profitability, liquidity, and solvency) of Partners comparing the results of the Projections to Partners historical results for the fiscal year ended 2018.

The Projections show the Proposed Project would represent approximately 0.001% of Partners operating revenue every year and approximately 0.001% of Partners operating expenses beginning in FY2020 through FY2023. He found the projected revenue growth and growth in operations to be reasonable estimations based primarily upon the organization’s historical operations. He reviewed Partners projections of non-operating gains/expenses and other changes in net assets and Partners capital expenditure and cash flow and found them to be reasonable. Donohue concluded that “the

¹⁴As one example, starting 1/1/ 2021 - the Protecting Access to Medicare Act (PAMA) requires referring providers to consult appropriate use criteria (AUC) prior to ordering advanced diagnostic imaging services (ADIS) — CT, MR, Nuclear Medicine and PET — for Medicare patients. (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>)

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

Staff finds the CPA analysis to be acceptable.

Factor 5: Assessment regarding Proposed Project’s superiority to alternative

The Applicant considered one alternative to the Proposed Project, which was to sustain the current fleet of traditional CT units at BWFH. The Applicant dismissed this alternative because of the benefits of the Proposed Project, which include improved access, quality of care, efficiency, and patient and provider satisfaction. The Applicant noted the capital cost for the proposed CBCT unit is 1/4-1/5 compared to traditional CT units. In addition, operating costs for the CBCT unit, which includes staff, medical supplies, and ongoing maintenance of the machine, are minimal (\$44,600 in the first year and \$71,061 by year five due to the cost of the maintenance contract and standard increases in staff and supply costs).

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes.

Factor 6: Fulfillment of DPH Community based Health Initiatives Guideline

This is a Tier 1 project in which the Applicant must submit documentation showing that the existing community health needs assessment (CHNA) and community health improvement planning (CHIP) processes both

- a. evidence a sound community engagement process and
- b. demonstrate an understanding of the DoN Health Priorities sufficient for selecting strategies to fund and implement following approval of the DoN project

For the Proposed project the Applicant, following an agreement with DPH, will be adding the required CHI resources to the Health Priority strategies approved as part of a Brigham and Women’s Hospital’s (BWH) approved in 2018 (DoN# 17111513-HE). This was agreed upon 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 and the focus of approved Health Priority Strategies) in Jamaica Plain; and
3. The small size of the Applicant’s CHI requirement and the existing relationship between the Applicant and BWH made this the most efficient and reasonable course of action. Accordingly, the Applicant was not required to submit any application materials normally part of the CHI application review.

Analysis

Staff finds that the Applicant is in compliance with the requirements of the CHI planning process for the purposes of Factor 6, subject to the Conditions and pursuant to 105 CMR 100.310(j).

Based upon a review of the materials submitted, Staff finds that, with the addition of certain conditions described below, the Applicant has met each DoN factor and recommends that the Department approve this Determination of Need Application for the addition of a CBCT unit at BWFH, subject to all applicable standard and other conditions (105 CMR 100.310, 105 CMR 100.360(A) and (B)).

Additional Conditions:

In order to demonstrate that Proposed Project will add measurable public health value in terms of improved health outcomes and quality of life of the Applicant's Patient Panel, the Holder shall, on a yearly basis:

1. Report on the measures outlined in Attachment 1.
2. Demonstrate a reduction in repeat X-ray and or CT scans and scans using multiple modalities. In its annual report to the Department, the Holder will report on yearly on upper and lower extremity scan volumes for orthopedic conditions for which CBCT is indicated for diagnostic purposes, further broken out as follows: (1) upper and lower extremity x-ray volume; (2) upper and lower extremity CT volume; (3) upper and lower extremity x-ray repeats; (4) upper and lower extremity CT repeats; and (5) CBCT volume.
3. Demonstrate that the proposed project is contributing to Health Delivery System Transformation by ensuring growth in patients under managed risk contracts for the Partners and BWFH Patient Panel. Separate out payers in both ways:

Managed Risk Contracts List percentages	Payer Mix-List percentages
<ul style="list-style-type: none"> • ACO and Managed Risk Contracts • Non- ACO and Managed Risk Contracts 	<ul style="list-style-type: none"> • MassHealth (Private Medicaid/Medicaid MCOs) • Private Medicare/Medicare Advantage • Private Medicaid/Medicaid MCOs • Commercial PPO/Indemnity • Commercial HMO/POS • Other

CHI Conditions of the DoN

4. Of the total required CHI contribution of \$24,775.00
 - a. \$2,378.40 will be directed to the CHI Statewide Initiative
 - b. \$22,396.60 will be dedicated to local approaches related to the DoN Health Priorities
 - i. The Holder may use up to 4% of this total amount for administrative purposes designed to support implementation of the CHI and provide up to 10% to support the ongoing evaluation of DoN# 17111513-HE.
 - c. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$2,378.40 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).

- i. The Holder must submit the funds to HRiA within 30 calendar days from the date of the Notice of Approval.
 - ii. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.
- 5. The Holder will provide all required local CHI resources to support the Health Priority Strategies approved on September 2018 under DoN# 17111513-HE. The approved strategies contain two "Housing Stabilization Support" components.

Attachment 1

Measures proposed by the Applicant

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 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 higher-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.

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