**Project Summary and Regulatory Review**

Partners HealthCare System, Inc. (Partners or the Applicant) submitted a Determination of Need (DoN) application for a substantial capital expenditure to expand ambulatory surgical services at Mass General Waltham (MG Waltham), which is located at 40 Second Avenue in Waltham. MG Waltham is a licensed satellite of Mass. General Hospital. Partners intends to build out, within the existing building, six additional ambulatory surgery operating rooms, 21 perioperative bays with support space, and 9,881 gross square feet (GSF) of additional shell space for future build-out as demand warrants. The capital expenditure for the Proposed Project is $30,504,587.

Applications for substantial capital expenditures are reviewed under the DoN regulation 105 CMR 100.000. 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 report addresses each of the six factors set forth in the regulation.

The Department received no public comment on the application.
**Background**

MG Waltham is a licensed satellite of Massachusetts General Hospital (MGH) which is, in turn, an affiliate of Partners HealthCare System, Inc. (Partners). Partners is the Applicant for this DoN. The MG Waltham site currently houses physician services that include: advanced imaging, primary care, and specialty physician services as well as hospital satellite-based services: including oncology/infusion, blood laboratory, pharmacy, rheumatology, vascular, physical and occupational therapies, and ambulatory surgery services for orthopedics, plastic surgery and pain management. There are four operating rooms on the second floor where these surgeries are performed. If approved, the Applicant proposes to build-out six additional ambulatory surgery operating rooms, and 21 perioperative bays with support space along with 9,881 gross square feet (GSF) of additional shell space for future build-out as demand warrants (together, the “Proposed Project”).

The Proposed Project will add capacity to enable MG Waltham to offer 750 additional types of lower-acuity outpatient-appropriate procedures across gynecology, urology, general surgery, orthopedics, surgical oncology, and interventional radiology. These are all procedures that are currently performed at MGH’s main campus but not currently offered at MG Waltham’s Ambulatory Surgery Center (ASC) location and which Partners proposes to shift to MG Waltham. The Applicant asserts that approval of the Proposed Project will allow it to meet the increased demand from its patient panel for a broad range of approved outpatient surgical procedures in a setting that is more efficient, convenient and lower cost than at the hospital outpatient department (HOPD) at the MGH main campus.

**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 Proposed Project. This Staff Report addresses each of these factors in turn.

**Factors 1 and 2**

Factor 1 of the DoN regulation asks that the Applicant address patient panel need, public health value, and operational objectives of the Proposed Project, while Factor 2 focuses on health priorities. Under factor 1, the Applicant must provide evidence of consultation with government agencies who have licensure, certification or other regulatory oversight which, in this case, has been done and so will not be addressed further in this staff report. This analysis will approach the remaining 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, Need, and Projected Growth*

In 2016, Partners’ patient panel consisted of approximately 1.3 million patients, which represented 19% of all discharges in Massachusetts that year. Most of Partners patients (77%) reside in the eastern part of the

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1 Partners operates another outpatient satellite nearby. That facility, a licensed satellite of the Newton-Wellesley Hospital, is located in a leased building. Partners states that it does not have the ability to expand at that site because of lease terms as well as parking capacity.
state. Partners’ patient mix is approximately 41% male and 58% female; based upon self-reporting, the racial mix is largely Caucasian, with 4% identifying as African American-Black and 17% not reporting at all. Sixty-one percent of the patient panel is between ages 18 and 64, and 26% is 65 years or older.

Partners maintains that the growing demand for outpatient procedures is driven, in part, by improvements in the administration of anesthesia and analgesics and the development and expansion of many minimally invasive or non-invasive procedures across many specialties.  

Partners argues that providing access to a broader range of high-quality surgical services in an ASC, rather than at the MGH main campus, will be more efficient, cost-effective and convenient and will result in higher patient and provider satisfaction. Partners looked at types of surgeries performed at MGH and determined which of those would have been clinically appropriate for an ASC. This analysis indicated that annually, over 11,000 patients who received outpatient surgery in oncology, gynecology, orthopedics, urology, and general surgery could have been treated in an ASC.

Partners also argues that its patient panel need for outpatient surgery will increase as a result of population forecasts; that by 2035, approximately a quarter of the population will be age 65 and older; and that approximately half of the population over the age of 65 will require surgery at least once in their lifetime. Approximately 53% of all surgical procedures are performed on patients age 65 or older. Partners asserts that this cohort of older patients is likely to experience a higher incidence of a broad range of lower acuity conditions for which treatment in an ambulatory surgery setting is beneficial to patients, and generally at a lower cost.

Partners states that the projected increased need by its patient panel has driven its efforts to expand access for outpatient-appropriate services at an ASC, and for that ASC to serve as a community-based alternative to the existing HOPDs located at MGH and system-wide. Since the existing ambulatory surgical capacity at MG Waltham was not sufficient to accommodate the projected increase in demand and types of procedures, Partners determined that shell space at the MG Waltham site could be effectively and efficiently built-out to accommodate that projected increase and that doing so met other quality and cost goals.

Public Health Value

The DoN regulation requires the Applicant to demonstrate that the Proposed 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.

Partners maintains that by having sufficient capacity to meet the outpatient surgery needs of their patient panel in a lower cost ASC rather than a hospital-based setting, it will increase access, maintain high quality,

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2 At the same time, the Centers for Medicare and Medicaid Services (CMS) approved Medicare reimbursement for ambulatory surgery performed both at Hospital Outpatient Departments (HOPDs) and ambulatory surgery centers (ASCs).
4 Of the identified surgeries performed that could have been shifted to an outpatient setting nearly 30% of were for the 65+ age cohort. Partners expects this percentage to increase as the range of lower acuity procedures offered in the ASC setting expands.
5 University of Massachusetts Donahue Institute http://www.donahue.umassp.edu/business-groups/economic-public-policy-research/massachusetts-population-estimates-program/population-projections
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offer continued care coordination, including connection with primary care, and improve efficiency for patients and providers.

The ASC model is centered on uniformity of procedures performed within a scheduled block of time. Generally, one surgeon works with the same clinical team for the entire block of time performing multiple, very similar types of procedures. The team develops a specialized skill-set and works in a facility designed and equipped to meet the specific needs of ambulatory surgical patients, which, Partners says, generates efficiencies and cost-savings due to reduced procedure times as compared to a similar procedure performed in a HOPD.8

Partners asserts that mixing the lower acuity surgeries with higher acuity procedures at the MGH campus can result in delays when acute cases take precedence over elective procedures for operating room time. These delays can lead to unnecessary expenses; anxiety and inconvenience for patients and their families; compromise plans for the care of patients upon discharge; and result in inefficiencies in the use of resources. Partners argues that having the majority of the lower acuity, outpatient appropriate procedures located at MG Waltham will remove barriers to access related to scheduling and transportation, save money, improve efficiencies and result in improved outcomes and greater patient and family satisfaction.9

Competitiveness and Cost Containment

Partners asserts that the expansion of surgical services at MG Waltham and shifting lower acuity patients from the HOPD at MGH will reduce health care spending. Patients at an ASC spend most of the time preparing for and recovering from surgery (rather than having surgery) and thus, the organization, staffing and specialization at an ASC can result in cost differences between ASCs and HOPDs.10

Partners asserts that reducing the time per procedure will generate cost savings as well as more effectively manage utilization of system-wide resources. Partners states that on average, procedures performed in ASCs take 25% less time relative to the mean procedure time at a HOPD. Citing a 2014 study published in Health Affairs that suggests that ASCs are a lower-cost alternative to hospitals for outpatient surgical procedures,11 Partners asserts that shifting outpatient appropriate surgery from the HOPD to an ASC will reduce delays, reduce costs, and increase capacity.

Community Engagement

Prior to submitting a DoN application, the DoN Regulation requires applicants to have engaged and consulted with the community. The Community Engagement Guide describes community engagement processes on a continuum from “Inform” and “Consult” through “Community driven-led.”12 For the purposes of factor 1, engagement defines “community” as the Patient Panel, and requires that the minimum level of engagement for this step is “Consult.”13 During the planning phase of the Proposed Project, MGH engaged patients, local residents, and resident groups affected by the Proposed Project by hosting a community forum and through presenting the Proposed Project at the Patient Perspective on

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8 AMBULATORY SURGERY CENTERS: A POSITIVE TREND IN HEALTH CARE (Ambulatory Surgery Center Ass’n), available at http://www.ascassociation.org/advancingsurgicalcare/aboutascs/industryoverview/apositivetrendinhealthcare
9 While the goal is to shift most of the patients to Waltham, some will continue to be served at the main campus.
11 Id.
13 Id at Page 13
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Perioperative Care Committee at MGH.\textsuperscript{14} Partners reports that feedback was positive and supportive of the plan, and the group expressed no concerns. Don staff reviewed the slides and minutes of these meetings and found that in the context of factor 1 the Applicant met the community engagement standards in the planning phase of the Proposed Project.

**Factor 3**

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

**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 effects or consequences to the existing patient panel. Documentation sufficient to make such finding must be supported by an analysis by an independent CPA. The Applicant submitted such an analysis performed by Bernard L. Donohue, III, CPA, (Donohue) dated January 4, 2018 (CPA Report).

In order to assess the reasonableness of assumptions used, and the feasibility of the projections for the construction and build-out, the CPA Report reflects a review and analysis of the Applicant’s draft audited financial statements, current financial position, and other public information about the organization. Five-year \textit{pro forma} financial projections were reviewed in relation to the most current two-year financial performance of Partners and MG Waltham and were determined by Donohue to be based on reasonable assumptions. In review of the net patient service revenue (NPSR), Donohue reports that the Proposed Project would represent approximately 0.073\% and 0.166\% in 2020 and 2022 respectively, of Partners’ NPSR. Donohue also analyzed each category of operating expenses for reasonableness and feasibility and concluded that the operating expenses from the Proposed Project represent approximately 0.109\% and 0.171\% respectively in 2020 and 2022.

Donohue found both the revenue and operating expense projections to be reasonable. The impact of adding six additional operating rooms and 21 perioperative bays are projected to increase total operating margins for Partners’ overall by 0.1\% in 2022. Donohue also analyzed the capital expenditures and cash flows to determine whether Partners would have sufficient funds and cash flow for the Proposed Project, in light of its other financial obligations. Based on that review, Donohue stated that the capital obligations, expenditures, and resulting impact on cash flows are reasonable.

The CPA Report found that because the impact of the proposed capital project represents a relatively insignificant portion of the operations and financial position of Partners, it determined that the projections are not likely to result in insufficient funds available for any capital and ongoing operating costs necessary

\textsuperscript{14} The Perspective on Perioperative Care Committee is comprised of patients and members from MGH’s General Patient Family Advisory Council (“G-PFAC”), and is dedicated to fostering a partnership among patients, families, and staff to support the strategic goals and initiatives of MGH. The MGH G-PFAC was formed in 2011 to advance patient experience and promote patient and family involvement in all aspects of hospital operations. It has an enterprise-wide focus, including in and outpatient operations, across the continuum of care, and is comprised of a dedicated group of patient and family members who have experienced many different aspects of care and services at MGH and who volunteer their time, expertise and input, to make care even better. Meeting monthly throughout the year, the Council is co-chaired by a patient member and staff, and as part of its oversight, G-PFAC members participate in committees and task forces at MGH.
to support the Proposed Project. Therefore, it determined that the Proposed Project is financially feasible, within the financial capability of Partners and based upon feasible financial assumptions.

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.”

The Proposed Project is a build-out within an existing multi-use clinical structure at MG Waltham. The Applicant looked at the relative merit of building the additional ORs and perioperative space at each of MGH main campus and Charles River plaza as well as expanding the hours of operation at the main campus site. Expansion at the main campus or at the Charles River plaza site were dismissed as capital and operating costs would have been significantly higher at either site; accessibility to the sites would be difficult; and the reduced costs, and added convenience and efficiencies of a free-standing site would not be achieved. The Applicant asserts that the Proposed Project is the superior option because it meets anticipated increased demand, and it will continue to provide efficient, high quality services in a site specifically designed and equipped for the surgeries to be provided with a specialized team. With more capacity, Partners argues, more patients will gain greater access to the multi-specialty services that the site offers such as onsite free parking, pharmacy and cost effective care with efficient patient flow.15

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). This is a Tier 2 project in which the Applicant is required to and did 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, the Applicant (then Holder of a DoN) will work with its Community Health Initiatives Advisory Board to select Health Priority strategies and funding. These processes, selection of the Health Priorities and funding decisions are conditions of the DoN and enforceable as such. Partners HealthCare, after consultation with DPH, is using the CHNA/CHIP processes from Newton-Wellesley Hospital (NWH) as the basis for planning and decision-making.16

In compliance with the requirements of the Guideline, and based on their own analysis, Partners HealthCare submitted the following: a completed Community Engagement (CE) Self-Assessment form; four completed Stakeholder Assessment forms; a completed Community Engagement Plan (CEP); and NWH’s 2015 CHNA/CHIP. At the time of this Application, NWH had recently begun a new CHNA/CHIP (to be published in 2018), and it is that 2018 CHNA/CHIP that will serve as the basis for Health Priority Strategy Selection and implementation. Upon review of the CEP submitted at the time of Application, DPH

15 See, FN1, supra for an explanation of why expansion at this site was the superior alternative to expanding the existing ambulatory surgery capacity at the nearby Newton-Wellesley Hospital satellite.
16 MG Waltham is a satellite of an acute care hospital and therefore is not required to comply with community benefits related CHNA/CHIP processes as determined by the IRS or the Massachusetts Attorney General’s Office. Newton-Wellesley Hospital (NWH) has overlapping service areas with MG Waltham and is the most relevant hospital within the Partners system for any community health planning activity. DPH has agreed that this and future Community Health Initiatives arising from MG Waltham will use the CHNA/CHIP processes of NWH.
determined that the Applicant needed to and did complete a new CEP which would focus on the first two stages of the CHNA/CHIP process: “Assess Needs and Resources”; and “Focus on What’s Important”. By doing this, the Applicant is describing the CE process they will undergo for the completion of the 2018 CHNA. The Applicant will then (as a Holder of a DoN) submit revised CEP detailing community engagement activities for the latter stages of the CHNA/CHIP process.

DPH staff found that the revised CEP (Attachment 1) meets minimum standards and will be used as the basis for actions and reporting post-PHC approval of the DoN project. Compliance with the CEP is a condition to this DoN.

**CHI Conditions to the DoN**

1. Of the total CHI contribution of $1,525,229 an Administrative Allowance of $45,756 (for community engagement activities and management of RFP related processes) will be taken by the Applicant. An additional $369,868 will be directed to the CHI Statewide Initiative and $1,109,604 will be dedicated to local approaches to the DoN Health Priorities. To comply with the Holder’s obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $369,868 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative). The Holder must submit the funds within one month from the date of this Notice of Approval. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

2. For this DoN CHI, the Applicant and the Department have agreed to certain post PHC approval steps and a timeline (Attachment 2). The timeline is based upon certain assumptions:
   a. The timeline assumes NWH completes its’ CHNA in mid-2018 and,
   b. Reflects discussions with the Applicant of plans for another and forthcoming DoN Application that will be based at Mass General Waltham and for which the Applicant/Holder will engage in a combined CHI planning process for both projects.

   If that Application is not received or it is not approved, the timeline will be revised to be in line with the timelines described in the CHI Planning Guideline. Compliance with the timeline agreed to with DPH staff is a condition of this DoN.

3. The Applicant will implement the Community Engagement Plan attached hereto as Attachment 1.

**Findings and Recommendations**

The Applicant has provided evidence that the Proposed Project is likely to improve patient access to care in a lower cost setting by accommodating both the current demand for a broad range of lower acuity procedures that are now performed at MGH’s main campus, and anticipated demands of the aging patient panel for the surgical procedures offered. The Applicant complies with factor 3; based upon the CPA analysis, the Proposed Project is financially feasible in the context of factor 4; expansion within an existing facility is, on balance, the superior alternative for meeting the existing Patient Panel needs from the perspective of quality, efficiency, and capital and operating costs as required by factor 5; and the Applicant is in compliance with the requirements of the CHI planning process for the purposes of factor 6 subject to the CHI Conditions and Timeline and the Community Engagement Plan pursuant to 105 CMR 100.310(J).

Based upon a review of the materials submitted, Staff finds that the Applicant has met each DoN factor and recommends that the Department approve this Determination of Need application for an operating room expansion including pre and post-operative care rooms and shell space subject to all standard conditions (105 CMR 100.310). In compliance with the provisions of 105 CMR 100.310(L) and (Q), 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 the cost and quality and access benefits of outpatient
surgery, as well as the shift of lower acuity procedures from MGH main campus to MG Waltham, with
specificity and with associated metrics.
ATTACHMENT 1

Community Engagement Plan
ATTACHMENT 2

CHI Timeline

- Four weeks post-approval or sooner (July): NWH will submit an updated Community Engagement Plan Form to the Department of Public Health outlining CHI engagement activities for the “Choose Effective Policies and Procedures”, “Act on What’s Important” and “Evaluate Actions” phases. At that time, Newton-Wellesley Hospital will report on the community engagement activities described in the Community Engagement Plan.
- Six weeks post-approval (late July): The NWH 2018 community health needs assessment (“CHNA”) will be finalized with Health Resources in Action (“HRiA”) reporting to the Community Benefits Committee (“CBC”) on the key findings from the assessment and overall recommendations for focus areas. Additionally, NWH will direct HRiA to conduct a Dissemination of Results meeting with the Advisory Committee and the community at large to receive feedback on the findings.
- Two months post-approval (mid-August): The CHI Advisory Committee (as constituted and described in the Applicant’s Self-Assessment Form (Attachment 2) will begin meeting and reviewing the 2018 CHNA to commence the process of selecting Health Priorities.
- Three to four months post-approval (mid-September to mid-October): NWH will seek to work with an evaluator that will serve as a technical resource to applicants and grantees during the solicitation process, as well as evaluate planning processes.
- Three to four months post-approval (mid-September to mid-October): The Advisory Committee will meet at least three times to discuss health priorities. After these meetings, the Advisory Committee will select the final health priorities for funding.
- Four to five months post approval (mid-October to mid-November): The Advisory Committee completes a conflict of interest process to determine which members are eligible to participate in the Allocation Committee. The Allocation Committee reviews the health priorities and selects strategies for CHI funding. The Health Priorities and Strategies Form is returned to the Department of Public Health for review and approval.
- Six to seven months post-approval (mid-December to mid-January): Upon approval of the Health Priorities and Strategies Form from the Department of Public Health, the Allocation Committee begins developing the request for proposal (“RFP”) process and determining how this process will work in tandem with NWH’s current grant efforts.
- Eight to ten months post-approval (mid-February to mid-April): The RFP for funding is released.
- Eleven months post-approval (mid-May): Bidders conferences are held on the RFP with technical assistance resources present.
- Twelve months post-approval (mid-June): Responses are due for the RFP.
- Thirteen months post-approval (with allowance for an additional two months if Committee Members are not available in summer months post-approval (mid-July): Funding decisions are made, and the disbursement of funds begins.
- Ongoing: Evaluation of CHI and Reporting to the Department on an annual basis.