STAFF REPORT TO THE PUBLIC HEALTH COUNCIL **FOR A DETERMINATION OF NEED**	
Applicant Name	Partners HealthCare System, Inc.
Applicant Address	800 Boylston Street, Suite 1150, Boston, MA, 02199
Date Received	April 26, 2019
Type of DoN Application	Substantial Capital Expenditure and Substantial Change in Service
Total Value	$102,204,696[1]
Project Number	PHS–19040915-HE
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	$5,110,234.80
Staff Recommendation	Approval
Public Health Council	October 16, 2019

Project Summary and Regulatory Review Partners HealthCare submitted an application for a Proposed Project at Massachusetts General Hospital consisting of four component parts: expansion of the Emergency Department, expansion of Endoscopy service and Electrophysiology lab, addition of PET-MRI, and limited additional renovations. The capital expenditure for the Proposed Project is $102,204,696; $1,277,558.70 will be directed to the CHI Statewide Initiative and $3,832,676.10 will be dedicated to local approaches to the DoN Health Priorities.

Review of Applications for Capital Expenditures and Substantial Changes in Service is under the DoN regulation 105 CMR 100.000. 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.

The summary, 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 Substantial Capital Expenditure and Substantial Change in Service DoN Applications. This Staff Report addresses each of these factors in turn.

[1] Renovation costs: Electrophysiology Lab: $30,314,692.00, Endoscopy: $29,646,923.00, Emergency Department $16,825, 180.00, PET/MR: $8,025,886.00.

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APPLICATION OVERVIEW

Background (Partners and MGH)

The Applicant is Partners HealthCare System, Inc. (Partners), a nonprofit integrated health care system that was formed in 1994 by an affiliation between The Brigham Medical Center, Inc. (now known as Brigham Health) and Massachusetts General Hospital.[2] Partners HealthCare System had 19% of all acute care hospital discharges in Massachusetts in FY17.[a]

Partners HealthCare Accountable Care Organization is a Health Policy Commission (HPC) certified Accountable Care Organization (ACO).[b] The ACO manages Medicare (Next Generation ACO) and MassHealth (Partners HealthCare Choice) ACO programs.

Massachusetts General Hospital (MGH), the site of the Proposed Project, is one of the founding members of Partners HealthCare and the original teaching hospital of Harvard Medical School. MGH is an academic medical center (AMC) with 1,035 licensed beds at its main campus in Boston, making it the largest hospital in Massachusetts.[3] MGH offers services to patients through various hospital satellite and clinical locations across Eastern Massachusetts. In FY17, MGH had ~53,000 inpatient discharges (2.5% increase since FY 2013), ~900,000 outpatient visits (4.7% increase since FY 2013), and ~107,000 emergency department visits (1.9% decrease since FY16).[c] As noted below, roughly 50% of the MGH Patient Panel resides in Health Service Area (HSA) 4[4] and almost 20% reside in HSA 6.[5]

Proposed Project Component I: Proposed Emergency Department Renovation and Behavioral Health Expansion

MGH's Emergency Department (ED) is a Level I trauma center treating the most critical patients, adults and children, including burns. The Applicant states the project will address overcrowding, long wait times and improve workflow. It will include:

- renovation of space for the medical needs by adding 4 bays to improve patient flow, better address high acuity needs and address the growth and needs of the aging population;
- add a secure unit for behavioral health needs by renovating space and adding 14 bays (for a total of 20 bays), where treatment can commence in a private, calm environment with lower stimulation, critical for behavioral health patients. The project will also address a 4-year, 7% growth rate and overcrowding in the Behavioral Health unit in the ED.

[2] 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.

[3] MGH is licensed to operate 1,035 beds: M/S=789, ICU=101, Coronary Care Unit=16, Burn Unit=7, Pediatric Service=44, Pediatric Intensive Care Unit=13, Maternal Newborn=27, Neonatal Intensive Care Unit=14, Psychiatric=24.

[4] Health Service Area 4 consists of the following cities/towns: Acton, Arlington, Ashland, Bedford, Belmont, Boston, Boxborough, Braintree, 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.

[5] Health Service Area 6 consists of the following cities/towns: Beverly, Danvers, Essex, Everett, Gloucester, Hamilton, Ipswich, Lynn, Lynnfield, Malden, Manchester, Marblehead, Medford, Melrose, Middleton, Nahant, North reading, Peabody, Reading, Rockport, Salem, Saugus, Stoneham, Swampscott, Topsfield, Wakefield and Wenham.

Proposed Project Component II: Endoscopy Renovation and Expansion

MGH's Division of Gastroenterology is a collaborative practice of gastroenterologists and endoscopists dedicated to the prevention, diagnosis, treatment and management of digestive diseases. The Proposed Project Component will renovate and expand the Endoscopy Unit to increase procedural and pre- and post-procedure space, create concentric circles of multidisciplinary care, and concentrate specialized complex care. The Applicant is proposing to

- increase the number of treatment rooms from 10 to 13 to increase access to endoscopy services and to allow clinicians to perform both interventional and routine endoscopy procedures;
- increase pre- and post-procedural bays from 21 to 31 bays to reduce overcrowding and improve patient privacy and satisfaction; and
- renovate administrative space (such as workstations) to make clinical care more efficient.

MGH's Endoscopy unit opened 20 years ago and the Applicant states MGH can no longer accommodate increasing volume and certain endoscopy procedures; the Proposed Project Component will enable it to expand endoscopy capacity at its main campus to improve Patient Panel access to treatment options, to reduce wait times for endoscopy procedures, and improve health outcomes.

Proposed Project Component III: Electrophysiology Lab

The Cardiac Arrhythmia Service at the Corrigan Minehan Heart Center treats a wide range of cardiovascular conditions and performs a variety of procedures to diagnose cardiac arrhythmias. Many patients require EP services to help manage arrhythmias.[6] The EP Lab is thirty years old and requires renovation to address/accommodate the changing demand for services, care processes, and surgical intervention methodologies. The proposed component will renovate and expand the Lab to increase access to EP services, which help to diagnose and manage arrhythmias. The Applicant is proposing to

- increase the number of treatment rooms from three to five (for cardiac ablations and implantable devices);
- expand the number of recovery bays from one to ten to reduce overcrowding and eliminate patient transfers to the inpatient setting for recovery services; and
- renovate administrative offices and waiting rooms.

The Proposed Project Component will enable the Applicant to meet current and future demand for EP Lab services.

[6] Such as catheter ablation (cryoablation and radiofrequency ablation), complicated ablation procedures and pulmonary vein isolations, implantable cardioverter defibrillators ("ICDs") and pacemaker insertion, cardiac resynchronization therapy ("CRT") and electrical cardioversion.

Proposed Project Component IV: Addition of PET/MR and MR Capacity

The MGH Department of Radiology provides comprehensive diagnostic imaging and interventional services. Through the Proposed Project, MGH plans to add PET/MR, a "hybrid"[d] diagnostic modality, to address the high incidence of patients within the Applicant's patient panel, and beyond having oncologic, cardiovascular, pediatric, and potentially neurologic, musculoskeletal and gastrointestinal conditions.

PET/MR, like PET-CT, combines the two established[7] technologies into one new integrated unit. This allows two different types of scans to be performed in sequence while the patient is in the same position; the two images are fused to ideally have enhanced images of the targeted area. The first machine was cleared by the FDA in 2011,[8] and payment by CMS and other insurers is limited since much of its use is still considered investigational.[9] If the Project is approved, it will be the first PET/MR in Massachusetts.

The Applicant is proposing to add this technology to its imaging department and to utilize it for three distinct purposes:

- for research,[10]
- PET/MR clinical diagnostic use; and
- for MRI alone

[7] have been in clinical practice for over three decades

[8] 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.

[9] CMS approves PET/MR use in limited cases. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=261 (see Background) and for Medicare National Coverage Determinations Manual https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf (section 220.6) CMS allows MACs to determine coverage within their respective jurisdictions for oncologic imaging

[10] Projects related to research are exempt from Determination of Need requirements under M.G.L. c.111, s.25C; review is limited to the two clinical components.

OVERVIEW of PROPOSED PROJECT AND FACTOR REVIEW

Description of Proposed Project Component	**What's Needed to Meet Factor 1**: **Demonstration of** need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending.	**What's Needed to Meet Factor 2: Demonstration of** cost containment, improved public health outcomes, and delivery system transformation	Factors 3, 4 & 5[11]	**What's Needed to Meet Factor 6**: **Demonstration of** plans for fulfilling … responsibilities … in the DPH Community-based Health Initiatives Guideline.
	Staff Report finds			
	MEETS W/ CONDITIONS	**MEETS W/ CONDITIONS**	**MEETS**	**MEETS W / CONDITION**
Proposed Emergency Department Renovation and Behavioral Health Expansion: will add 4 bays to improve patient flow and address the growth of the aging population for medical ED and add 14 bays for behavioral health services. Component aims to address overcrowding, long wait times and to improve workflow; will also address particular needs for additional Behavioral Health Capacity**.**	• Reduction in wait times, boarding, LWBS, among other standard CMS measures, revised from Applicant's proposed list • Reduction in lower acuity visits • Other standard outcome measures revised from Applicant proposed list	• Reduction in re-admission rates for all patients, by APS and patients over 65	✓	Detailed plan for use of administrative funds to focus on addressing barriers to public participation in the CHI process within three months of the Notice of Approval.
Proposed renovation and expansion of the Endoscopy Unit: will increase procedural and pre- and post-procedure space in order to reduce overcrowding improve patient privacy and satisfaction, reduce wait times for procedures, and improve health outcomes.	• Reporting on programs to reduce patient risk factors for CRCs and/or increase CRC screening or rescreening behaviors according to appropriate intervals • Reporting on asymptomatic patients receiving screening colonoscopy or sigmoidoscopy at regular intervals, by age and race. • Other standard outcome measures revised from Applicant proposed list	• Reporting on colorectal cancer education and outreach programs to reduce colon cancer risk factors in the community, as well as efforts to increase screening rates among minority and low income populations	✓	

[11] 3)Sufficient evidence of compliance and good standing with federal, state, and local laws and regulations
4) Sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Project without negative impacts or consequences to the Applicant's existing Patient Panel.
5) The … Project, on balance, is superior to alternative and substitute methods for meeting … Patient Panel needs

Description of Proposed Project Component	**What's Needed to Meet Factor 1**: **Demonstration of** need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending.	**What's Needed to Meet Factor 2: Demonstration of** cost containment, improved public health outcomes, and delivery system transformation	Factors 3, 4 & 5[11]	**What's Needed to Meet Factor 6**: **Demonstration of** plans for fulfilling … responsibilities … in the DPH Community-based Health Initiatives Guideline.
	MEETS w/ CONDITIONS	**MEETS w/ CONDITIONS**	**MEETS**	
Proposed renovation and expansion of the Electrophysiology (EP) Lab: will increase access to EP for diagnosis and management of arrhythmias, reduce overcrowding and eliminate patient transfers to the inpatient setting for recovery.	• Reporting on programs to either reduce risk factors for CVD and/or assist patients in managing their CVD • Other standard outcome measures revised from Applicant proposed list	• Reporting on programs on CVD risk reduction and outreach programs, and in particular among minority and low income populations	✓	**MEETS w/ CONDITION AS ABOVE**
Proposed PET/MR: Combines two established technologies into one new integrated unit, allowing for two different types scans to be performed in sequence while the patient is in the same position. Will be used for three distinct purposes: for research; for clinical diagnostic use; and for MRI alone to address needed additional capacity. If approved, it will be the first PET/MR in Massachusetts.	• Limit on use of new technology, as well as standard MRI, in order to assess potential overuse • Report on protocols to inform patients about potential insurance denials for use of PET/MR		✓	

Patient Panel Information

Table 1 below presents Patient Panel[12] information for the Applicant (Partners), MGH (the site of the Proposed Projects), and each service included in the DoN Application.
Staff notes the following observations about the Patient Panel data presented in Table 1:

- **Gender** – The percentage of males in the EP Lab patient panel (66%) is slightly higher when compared to the other Patient Panels where males account for roughly 42-51% of the patient panels.
- **Age** – The 18-64 age cohort comprises the majority (~60%) of patients except in the EP Lab Patient Panel where patients ages 65 and above represent the majority (62%) of the patient panel.
- **Race** - The racial makeup of the Patient Panels is fairly consistent across each panel. There is a higher proportion of patients identifying as Black or African American (10%) in the ED Patient Panel compared to the MGH Patient Panel (5%).
- **Patient Origin** - The geographic composition is similar across Patient Panels with the largest proportion of patients within each Patient Panel residing in HSA 4.
- **Payer Mix** – There is a slightly higher percentage of MassHealth and Managed Medicaid (MassHealth ACO) at MGH as compared to Partners; Medicare Fee For Service is slightly higher at MGH than Partners.
- **ACO and Managed Care Contracts** -The Applicant is itself an ACO and in CY2018, 57.9%[13] of the Partners primary care lives were covered in risk contracts.[14] The Applicant notes that this percentage is derived from the number of primary care lives within the Patient Panels of the Partner's primary care physicians (PCPs) that are covered under risk contracts (Partners bears risk).

[12] 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.
[13] This percentage differs from the Patient Panel described in the DoN Application
[14] The number of risk members is for CY2018 and includes members from the following risk contracts: Medicare ACO - NextGen, BCBS AQC and BCBS PPO, HPHC, TAHP, AllWays Commercial, and Medicaid ACO. The total number of patients within a PCP's panel are for FY 2017 adult and pediatric patients.

Table 1: Overview of Applicant Patient Panel, Patients at MGH, and Patients Seeking Services within each Project

	Partners	MGH	EP Lab	ED	Endoscopy	PET/ MRI[15]
Patient Panel 2016-18	4,281,773	1,693,803	7,241	228,408	70,042	
Total Unique Patients (FY18)	1,500,670	566,357	2,980	76,401	23,884	
Gender (FY18)						
Male	41.7.%	44.8%	66%	51%	48%	
Female	58.3%	55.2%	34%	49%	52%	
Age (FY18)						
0-17	11.9%	14.3%	1%	12%	6%	
18-64	62.0%	59.3%	38%	65%	61%	
65+	26.1%	26.4%	62%	23%	33%	
Race (FY18)[16]						
White	72%	73.0%	88%	67%	80%	
Black or African American	5.5%	5.2%	3%	10%	5%	
Asian	4.1%	5.2%	2%	5%	5%	
Hispanic/Latino	1.5%	0.8%	0%	1%	1%	
Native Hawaiian or Other Pacific Islander	0.1%	0.1%	0%	0%	0%	
American Indian or Alaska Native	0.1%	0.1%	0%	0%	0%	
Other/Unknown	16.8%	15.7%	7%	13%	6%	
Unavailable				3%	2%	
Declined				1%	1%	
Patient Origin (FY18)[17]						
HSA 1	6.1%	1.3%	1%	1%	1%	
HSA 2	3.3%	3.2%	4%	2%	3%	
HSA 3	6.4%	5.8%	7%	4%	6%	
HSA 4	43.6%	49.2%	43%	62%	58%	
HSA 5	13.6%	8.6%	11%	6%	9%	
HSA 6	16.3%	17.3%	18%	15%	14%	
Outside of MA	10.3%	14.1%	15%	10%	9%	
International				1%		
Unknown	0.4%	0.5%				
Payer Mix[18] (FY17)			Not provided			
Commercial[19]	59.6%	50%				
Managed Medicaid	5.3%	8%				
MassHealth	3.8%	9%				
Commercial Medicare	3.8%	4%				
Medicare FFS	22.7%	28%				
Other[20]	4.8%	2%				

[15] This is the first PET/MR unit on the MGH campus, so there is no historical volume data available and no Patient Panel data available.
[16] Based on self-reporting
[17] Aggregated zip code data by HSA
[18] Reflects aggregate Partners HealthCare revenue for 2016-2018.
[19] Commercial = Allways Health Commercial, Blue Cross Blue Shield, Commercial National Carriers, Commercial Other, Connector Care Plans, Harvard Pilgrim Health Plan, International, Qualified Health Plans, Tufts Health Plan.
[20] Other = Government Other, Other Payor, Self-Pay, Workers Comp, Unknown Summary Payor.

Factors 1 & 2: Patient Panel Need

In this section, we assess if the Applicant has sufficiently addressed patient panel need, public health value, competitiveness and cost containment, and community engagement for each of the 4 Proposed Project Components. We also assess whether the Applicant has demonstrated that the Proposed Project Component will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

Factor 1: a) Patient Panel Need: Emergency Department

Since the Hospital is a Level 1 trauma center, the ED draws patients from all around the Commonwealth. While the majority (62%) comes from greater Boston, 25% come from eastern Massachusetts communities, 10% come from outside of Massachusetts, 3% come from central and western Massachusetts. It is also the local ED for the North and West Ends and Beacon Hill.[21] The Applicant reports treating approximately 76,000 unique patients annually. Utilization data also indicates that the number of Black/African Americans seen in the ED is 10% while the number reflected in the overall MGH patient panel is 5%. In response to staff inquiry, Applicant noted that it is unclear why there is a differential use of the ED by African Americans. The Applicant mentioned MGH's work to identify and address health disparities, including the creation of the Disparities Solution Center (DSC) [22] and patient experience surveys[23] that may help them further understand why African American patients may differentially access care in the ED.

The utilization data for the ED shows that the number of annual patient visits averaged 107,191 with minor fluctuations over the past three years, resulting in 1.4 visits per patient on average. While the younger age cohorts have remained steady, the 65+ age cohort increased 1% per year.

The Applicant reports that due to current and projected growth in demand within certain segments of their Patient Panel as discussed herein, the ED needs to expand through renovations of contiguous space and it needs a more efficient design to improve the delivery of care.

a) **Need For Additional Behavioral Health Capacity**

MGH's Acute Psychiatric Service (APS) treats both psychiatric and substance use disorders. The unit has consistently had an overflow from its 6 secure bays. It has an average daily census (ADC) of 15 patients and, at peak times it can rise to 25. Comprising ~6% of total ED visits, it has a 4-year growth rate of 7% (FY14-18),[24] and the Applicant projects a 16% growth over the next 7 years (FY 18-25).

Once a medical assessment has occurred, anywhere from 6-19 APS patients may be placed in spaces not appropriately designed for behavioral health patients. Patients overflow into the main ED and hallways, which may lead to privacy violations, additional use of resources for security personnel, and pose potential security risks.

The number of patients visiting the ED with mental health concerns has increased exponentially in recent years for both children and adults.[e] In Massachusetts, patients with mental health concerns waited an average of 16.5-21.5 hours for an admission or transfer, as compared to patients with physical health concerns waiting ~4 hours, with MassHealth and uninsured patients waiting significantly longer.[f] The Applicant also noted the Massachusetts EOHHS Expedited Psychiatric Inpatient Admissions (EPIA) Policy, underscoring the need to move behavioral health patients from the ED to more appropriate care settings.

[21] Included in the Overview's Patient Panel data for HSA IV are Beacon Hill and the North and West Ends, since they are a small part of that HSA IV.
[22] The DSC is an action-oriented center moving the issue of disparities in health care beyond research and into the arenas of policy and practice.
[23] Survey focused on the experiences of minority populations and was expanded to include Haitian Creole and Russian.
[24] There were 6,082 and 6,530 visits in 2014 and 2018 respectively.

In response to staff questions, the Applicant provided supporting documentation on the disposition of its APS patients for MGH's fiscal years 2016-2018:

- ~18% are admitted to MGH, and 42-51% of patients are admitted to another psychiatric facility
- The length of stay in the ED for APS admitted patients ranges from 15.6-19.3 hours
    - Patients discharged to home comprise 28-34% of the total, and experience a length of stay of ~9.6 hours, (the range 9.0-10.2 hours)

A secure and separate unit for APS can reduce agitation, violent behavior and the potential of leaving without being seen (LWBS).[g] When patients leave the ED prior to screening and treatment, there is an increased risk of self- harm and suicide.[h] The Applicant reports that approximately 2% of APS patients leave against medical advice (which includes LWBS).

b) **Need for Additional Overall Capacity, Greater Throughput, and Care Efficiencies**
To better serve its Patient Panel, the Applicant states it needs to improve throughput and gain efficiencies by creating designated areas based on acuity levels. This can be achieved by renovating portions of the ED, including the area vacated by the APS expansion, to create a fast-track area, and add four bays equipped with medical gasses[25, i] and cardiac monitoring to treat more complex patients.

The Applicant provided data illustrating current needs, including:

- **Patients who left without being seen *(LWBS).*** The monthly range is 0.7% - 1.6% of all patients[26]
- **The amount of time from the decision to admit until the patient is discharged to a floor.** This ranges from 2.4 to 5.9 hours[30]. During this time, patients are left in halls and patient bays.
- **Data from CMS, some of which appears in Table 3 below**

While *moderate severity* and *low to moderate severity* patients only comprise ~36% and ~10% of the total number of ED patients respectively,[27] the Applicant notes the importance of creating designated treatment areas based on acuity. When EDs are crowded with lower acuity patients it prevents more acute patients from receiving timely care with potential negative consequences.[j] To further address overcrowding in the ED, Applicant notes that in addition to thisrenovation, its providers have taken steps to reduce unnecessary use of the ED by expanding availability of walk-in clinics, the number of practitioners in the primary care practice, and extending office hours in order to reduce unnecessary ED usage.

c) Need to better address aging population needs
The Applicant states that the ED expansion will also address the increased demand for services posed by of the growing aging population, and when planning this service expansion it is important to take their unique needs into consideration. Those ages 65 and over comprise ~23% of total visits; and that age cohort has experienced a 1% annual ED volume growth over the past three years.

The Applicant reports that Patients within the 65+ age cohort are among the highest users of the ED for primary care services,[k] and use the ED at a higher rate than young adults.[l] When an older adult presents at an ED, the visit often is more emergent, requires longer stays and uses more services.[m] Further, due to complex care needs these patients are more likely to make repeat ED visits.[n] Moreover, the Applicant notes that older patients have different medical conditions[28] and underlying pathophysiologic responses to illness than younger

[25] Medical gasses include medical air, oxygen, carbon dioxide, nitrogen, and nitrous oxide.
[26] October 2016-May 2019
[27] as measured by professional billing levels shown in the supplemental information provided by the Applicant.
[28] These include potential medication side effect profiles; risk and benefit profiles of diagnostic tests, interventions, and treatments; and evaluations may be affected by acute or chronic cognitive impairment.

age cohorts. The Applicant also noted that the elderly population requires more intensive discharge care coordination, which will be addressed in the new design.

Analysis

Staff finds that the information provided by the Applicant demonstrates sufficient need for the expansion of ED services by their Patient Panel through volume growth of their APS patients, and of the 65+ age cohort. Dedicated behavioral health bays, addressing the needs of more complex patients and creating new flow-patterns for specific acuity levels of care are models that are well-documented nationally.[o] There is also strong evidence in the literature of the need to develop ED services to address the specific needs of the older adults.[p] Older patients require significantly more emergency care resources than younger adults due to higher number of visits and the use of more complex resources, due to the higher number of existing co-morbidities.

Since long wait times delay care delivery and can have a negative impact on quality, Staff examined CMS Hospital Compare to view MGH's ED wait times compared to the statewide and national averages; they are appreciably higher, as shown in Table 2 below.[q] These times support the need for improving patient throughput, improving patient flow and adding capacity. It should be noted that these times do not differentiate by behavioral health and medical care services.

TABLE 2: "Very High Volume" Hospitals EDs
CMS Measures[r]- FY 2018

	MGH	**MA**	**US**
Average (median) time patients spent in the emergency department, before they were admitted to the hospital as an inpatient – Minutes CMS Measure: ED-1b	**580**	393	334
Average (median) time patients spent in the emergency department, after the doctor decided to admit them as an inpatient before leaving the emergency department for their inpatient room –Minutes CMS Measure: ED-2b	**283**	191	144
Average (median) time patients spent in the emergency department before leaving from the visit-Minutes CMS Measure: OP-18b	**202**	188	172

Factor 1: a) Patient Panel Need: Endoscopy

The Applicant notes a high demand for GI services and cites an increase (4% from FY16 to FY18) in the number of patients in the Endoscopy panel (87% of all procedures were done on an outpatient basis). The Applicant notes 33% of the Endoscopy Patient Panel was age 65 and older. There were no notable differences between the Endoscopy and other component Patient Panels.

Endoscopy Services – Capacity Constraints and Volume Growth

The Applicant states that the Endoscopy Suite is experiencing capacity constraints that are reducing access to certain endoscopy procedures[29] and reducing access to timely care. This is causing delays in endoscopy procedures and overcrowding in the pre- and post-procedure space. The Applicant asserts that increasing procedure and pre- and post-procedure space in the Endoscopy Suite will enable MGH to improve access to high-quality endoscopy services that will improve health outcomes and quality of life of the Patient Panel. The Applicant cites the need for additional capacity based on:

- **Physical plant constraints and access to care.** Current space constraints are leading to delays for patients and providers. When patients pre-and post-operative preparation and recovery[30] is longer than the hospital's median timeframes, "bottlenecks" are created in each part of the unit, causing delayed procedure start-times and leading to delayed processes throughout a patient's experience, including delayed discharge processes and longer lengths of stay.
- **Capacity constraints to meet patient need.** The Applicant notes that capacity constraints are causing overcrowding in the pre- and post-procedural space, which is negatively impacting patient privacy and the patient experience. The Applicant outlines historical volume trends for endoscopy services and anticipated future demand, projecting the volume to increase by 41% between 2017 and 2025.[31,32] In FY18, across MGH, 24% of procedures were for routine screening and 76% of procedures were diagnostics and/or treatment procedures.
- **An aging population at risk for particular conditions and diseases.** In Massachusetts, the age 65 and older population will represent a quarter of the population by 2035.[s] Further, patients age 65 and older make up a significant percentage of the Partners (26%), MGH (26%) and endoscopy (33%) Patient Panels.[33] Endoscopy procedures are commonly performed on older adults to diagnose and treat GI disorders.[t,u] New developments in endoscopy technique have also improved its utility as a screening tool.[v] They provided 2 key reasons for increasing demands for endoscopy services based on age:
  - **Risk for cancer.** Advancing age is a risk factor for cancer; 60% of new cancer cases and over 70% of cancer mortalities occur in elderly people.[w] The need for endoscopic procedures to identify and in some cases treat cancers will increase with the aging population.
  - **Risk for obesity.** Age is also a risk factor for obesity. Approximately 35% of older adults, age 65 and older were obese in 2007-2010.[x] Demand for endoscopy services will increase to address conditions associated with obesity such as nonalcoholic fatty liver disease, which is common among the elderly.[y]

Staff finds that the information provided by the Applicant demonstrates sufficient need by their Patient Panel through continuing growth in volume; an aging population; and capacity constraints that are limiting access to diagnostic and treatment services, and causing delays in pre-and post-operative preparation and recovery, and delays in procedure times. Moreover, the Proposed Project Component will allow MGH to accommodate projected growth in endoscopy services through increasing capacity within the Endoscopy suite.

[29] Procedures include Endoscopic retrograde Cholangiopancreatography (ERCP); Endoscopic ultrasound (EUS); Chromoendoscopy (CE); Capsule endoscopy; Enteroscopy; Esophageal manometry; Colonoscopy; and Sigmoidoscopy

[30] The median pre-operative preparation time is 18 minutes and median patient recovery time is 43 minutes.

[31] The Applicant is projecting a 17% increase in endoscopy volume between 2019 and 2020 due to the addition of new faculty.

[32] Volume from the three MGH sites was included (MGH's main campus, and MGH's hospital satellites – Charles River Plaza in Boston and the Mass General/North Shore Center for Outpatient Care in Danvers).

[33] FY18

Factor 1: a) Patient Panel Need: EP Lab

The Applicant reports a three-year (FY 2016-18) EP Lab Patient Panel of 7,241 patients that received EP Lab services at MGH. The number of EP Lab patients increased 59% from FY16 to FY18. The Applicant states that in FY18, the majority (62%) of the EP Lab Patient Panel was in the 65 and older age cohort.

Electrophysiology Services - Capacity Constraints and Volume Growth

The Applicant asserts that increasing procedure and pre- and post-procedure space in the EP Lab will enable MGH to meet current demand for EP Lab services in a timely manner and address operational inefficiencies. The Applicant cites the need for additional capacity based on:

- **Access to care – physical plant constraints.** Current capacity constraints are leading to operational inefficiencies. There is a single recovery bay, and this hampers throughput and causes delays, which is shown by overcrowding and inefficient transfers of patients to the inpatient setting for recovery. These inefficiencies lead to longer lengths of stay and negatively impact the patient experience. The Applicant described a negative cascading effect, whereby needed inpatient beds are no longer available for other highly acute patients, including those from the ED and for patient transfers needing quaternary care cardiac services. In FY18, 1,253 patients (35%) were transferred to the inpatient unit for recovery instead of to post-procedure recovery space within the EP Lab.
- **Current volume and projections.** MGH is also experiencing capacity constraints, citing a current six-week delay for elective outpatient invasive procedures. Wait times are also increasing, particularly for patients in need of complicated ablation surgeries.[34] EP Service volume increased by 27% between FY13 and FY17.
- **An aging population.** The age 65 and older population will represent a quarter of the Massachusetts population by 2035.[z] National data shows that due to the increasing age of the population, the number of individuals diagnosed with Atrial Fibrillation will increase from current estimates of 2.7-6.1 million individuals to between 5.6 and 12 million individuals by 2050.[aa,bb] The projected population growth of this age cohort will lead to increasing growth for the service.

Staff finds that the information provided by the Applicant demonstrates sufficient need by their Patient Panel through significant EP Lab volume growth, operational inefficiencies, and an aging population at risk for Cardiac Arrhythmias.[cc] Two-thirds of patients with Atrial Fibrillation are over age 75; comorbidities are frequent in the elderly with prognoses that may include poorer quality of life, increased number of hospitalizations and cardiovascular events.[dd,ee] The Proposed Project Component will address the capacity constraints and resulting operational inefficiencies that the Applicant has already begun to experience and accommodate the current and future demand for EP Lab services among its Patient Panel.

Factor 1: a) Patient Panel Need: PET/MR

Since this is the first proposed PET/MR for Partners and for MGH, there is no historic utilization data. The Applicant based projections on the incidence and mortality statistics for the disease categories where clinical applications have been demonstrated as discussed further herein. The Applicant states that the clinical benefits for combined PET/MR, while evolving, are now considered effective for diagnostic and staging of patients with certain cancers, cardiovascular, neurologic, musculoskeletal, and gastroenterological conditions, and also for pregnant, nursing and pediatric patients.

Cancer is the leading cause of death in Massachusetts with a mortality rate of 155.5/100,000 in 2014. Cancer incidence over the 2011-2015 time period was 459.4 per 100,000.[ff] The incidence rate for cancer in

[34] Applicant notes that MGH treats a subset of ablation cases that are considered medically complicated and must be performed at a tertiary medical facility.

Massachusetts is higher than the national average, and advancing age is the most important risk factor for cancer overall.[gg] Approximately 26% of the Applicant's and MGH's patient panels are aged 65 and over. The Applicant asserts that demand for diagnoses and treatments will continue to increase as the percentage of the population over age 65 increases. The Applicant states that PET/MRI appears to be better at evaluating certain lesions[hh] and as such, maintains that patients with these conditions will benefit with improved diagnosis, staging and monitoring.

Cardiovascular disease is the second leading cause of death in Massachusetts. From 2013-2015, adults diagnosed with myocardial infarction annually ranged from 5.2-5.7%, and those diagnosed with angina/coronary heart disease from 4.7-5.8%.[ii] The Applicant states that because of its sensitivity and specificity, PET imaging is the most frequently used modality for accurate prognosis of obstructive coronary artery disease, and that with contrast MRI, the images are further enhanced. MRI is preferred (the gold standard) for assessing many cardiac structural and functional conditions, and that further research may provide "valuable pathophysiologic data.[jj] The Applicant states that patient's enhanced access to PET/MR may assist clinicians in diagnosing and treating patients in a more timely fashion, thereby reducing complications from the disease.

The preliminary projections for the proposed combined PET/MR scans are low, (356-462 through years 1-5, ~1.3 scans per day) as shown in in Table 3. The ten MRI units at MGH are currently at capacity (growing ~5% from 2015-2017.[35] As Table 4 shows, the Applicant reports extended wait-times for access to their existing units; consequently, the Applicant proposes to allot 12 evening hours during the week and 16 hours per weekend day for MRI scans on the new unit, with a projected additional volume of 1,500 scans per year. This is based on a projected 1% annual growth rate for MRI scans. Applicant states these waits will be diminished significantly with the use of the new equipment.

Table 3 Applicant Volume Projections for PET-MR Unit

PET-MR Scans	Year 1	Year 2	Year 3	Year 4	Year 5
Clinical	356	416	462	462	462
Research	462	546	596	596	596
Total Projected PET/MR Volume	818	962	1058	1058	1058
Projected MRI only Scans using PET/MR Unit	1500	1500	1500	1500	1500

Table 4 Current MRI and PET Wait Times	
In-patient and ED	6 hours
Out-Patient Preferred times	up to 6 Weeks
Out-Patient non- Preferred times	18 days

[35] 37,804-39,577 from 2015-2017; ~11 scans per unit per day (if operating 365 days, with no down-time)

Analysis
Staff finds that the patient panel information provided by Applicant demonstrates sufficient need for additional MRI capacity resulting from volume growth within the Patient Panel. For the existing MRIs, Staff calculated ~11 scans per MRI unit per day, assuming no down-time, which demonstrates a need for additional clinical MRI scans that will be satisfied by adding 44 hours per week.

This unit combines the best of both technologies to enhance qualities of each and complement each other[36], thereby providing additional information that will improve diagnostic capability and ultimately patient outcomes. Moreover, patient burden is decreased by combining procedures in one timeslot[37]. Combining the two is particularly advantageous for diseases that progress between two separate scans times that are obtained at separate times with different patient positioning.[kk]

While it is clear there are many beneficial clinical uses for the combined PET-MR technologies across several specialties, particularly oncology and cardiology, the literature suggests that many other areas of clinical use should still be considered "promising." These include, but are not limited to, neurology, musculoskeletal conditions and hematologic cancers.[ll]

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

Improved Health Outcomes through Population Health Management

The Applicant states that MGH is in the midst of a ten-year Population Health Management (PHM) strategic plan aimed at improving the patient experience and clinical quality outcomes along with reducing the cost of care. The Applicant describes four PHM initiatives[38] designed to improve quality, efficiency and the patient experience throughout each department. In response to follow up questions on how PHMs operate in each of the Proposed Project Components, the Applicant explained that clinical indicators are used to identify patients for PHM enrollment/inclusion.

Health Equity and Social Determinants of Health (SDOH)

Health Equity

The Applicant states that Partners HealthCare, and specifically MGH, has adopted the Culturally and Linguistically Appropriate Service ("CLAS") standards for all practice sites. The Applicant listed the following strategies to demonstrate compliance with the standards:

- Diversity initiatives to address healthcare disparities, increase the percentage of employees from underrepresented groups, build trust among people of diverse backgrounds and evaluate the hospital's progress.
- Ongoing education and training in culturally and linguistically appropriate areas for staff at all levels and across all disciplines.
- Staff interpreters that speak eleven languages, including American Sign Language ("ASL").[39]
- In response to a follow up question, Applicant noted its Language Access and Assistive Services Plan that addresses all the CLAS Standards.[mm] These include staff training on linguistically and culturally appropriate care at MGH; staff within areas of each Proposed Project component have received training on language access assistance; Medical Interpreter Services ensure that appropriate

[36] MRI differentiates, with high definition, various soft tissues (such as nerves, muscle ligaments, fat) enabling clear visualization of different structures within for example, the brain and heart (which CT cannot do). PET shows metabolic function without the ability to visualize the tissue structure.
[37] Currently, patients must prepare for, travel to, and undergo two separate exams (a PET-CT and an MRI). This exposes them to unnecessary radiation (since PET is now performed with CT at most sites) in those circumstances where MRI is more appropriate for their condition.
[38] eConsult Program, Integrated Care Management program (iCMP); Patients Linked to Urgent Supports (PLUS) program, Partners Mobile Observation Unit (PMOU) and the MGH Home Hospital Program
[39] Interpretations for encounters that occur at MGH's main campus staff are documented in a centralized Interpreter Services Tracking System, which contains a reporting tool for year-end statistics of positive encounters. MGH staff review annual statistics and seek ways to improve these services.

infrastructure is in place so that all patients can access language assistance services; and the success of programs addressing CLAS standards are tracked.

- Participation 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.[40] In response to a follow up question, Applicant discussed overall progress over a long time frame.

Social Determinants of Health (SDOH)

The components of the Proposed Project will continue existing formal processes for linking patients to case management/social work support to ensure patients have access to resources around social determinant of health ("SDOH") issues. The Applicant asserts that these linkages help prevent unnecessary readmissions, ensure appropriate care management and provide the patient with additional resources that impact care. In response to follow up questions posed, Applicant stated that all of the 133 Partners primary care practices participating in the MassHealth Accountable Care Organization ("ACO") Program are screening patients for SDOH needs using similar screening tools. Partners is currently collecting data provided in Epic to better understand the SDOH needs of ACO patients, and will use the data to build a strategy to create more capacity for community-based partners. Partners is implementing a 2 to 3-year strategy to ensure that all patients are screened for SDOH needs, and MGH's long-term goal is to implement a universal SDOH screening program for all patients, regardless of payer. In support of this goal, the hospital is a member of the Boston Area Hospital Collaboration on the Social Determinants of Health, which is seeking to establish a consistent screening tool for evaluating individual and family SDOH needs.

In response to follow up questions, Applicant reiterates that while responsibility for SDOH screening lies with a patient's PCP, it outlined specific and extensive information as to how MassHealth ACO patients seeking services at the Emergency Department or within Specialty Services (EP Lab, Endoscopy or PET-MR) would have ongoing SDOH needs assessed and addressed, by an ED navigator in the Emergency Department, and by a social worker or community health worker for a patient seeking specialty services. All SDOH screens are tracked in a patient's EHR in the Epic system. Tracking includes whether a SDOH screen was conducted, if there were positive responses indicating the patient needs assistance, and if the patient was provided with written support materials ("Tip Sheets") or referred to a support person. Moreover, case managers and other staff assisting patients with SDOH needs may provide notes in the Epic system as to where the patient is in the process of accessing resources to address his/her SDOH needs.

Analysis

Staff finds that through their Language Access and Assistive Services Plan, #123Equity participation, and SDOH screening, the Applicant has sufficiently outlined, at a high level, a case for improved health outcomes and has provided reasonable assurances of health equity within the Partners system. The Applicant has described how "covered lives" patients in the panel are screened for SDOH and how linkages to social services organizations are created; staff notes that Applicant and MGH seek ongoing expansion of these efforts. Moreover, staff notes documented beneficial outcomes of the types of PHM programs described by Applicant[nn,oo,pp], and that each of the four Proposed Project Components take part or will take part in these programs.

Factor 1: b) Improved health outcomes and quality of life: Emergency Department

The Applicant asserts that having additional ED capacity will result in:

- **Improved outcomes** for APS Patients, as their ED experience will be less stressful and of shorter duration. There is evidence that longer stays for behavioral health patients worsen

[40] The campaign requires hospital leaders to accelerate progress in key areas

symptoms,[qq] and when psychiatric patients receive care in a timely manner in a discrete space, may even avoid a hospital admission.

- **Improved outcomes** for medical patients, including the elderly, as their will be new paths for various types/acuity of patients, better equipped for the patients' specific needs. This ensures patients receive the appropriate care in a timely manner with LOS reductions for less severe patients along with increased satisfaction.

Analysis

Staff concurs that for all ED patients, the efficient flow of patients and the additional secure behavioral health beds have the potential to improve overall ED care, reduce LOS and avoid hospital admissions; all of which have a positive impact on quality of life for patients and their families. Improved flow can reduce wait times, length of stay and costs for many urgent patients. Designated behavioral health areas are also associated with patient and staff satisfaction,[rr] greater cost savings, and reduced likelihood of a hospital admission.[ss] In order to ensure that the expansion helps address the overcrowding and patient needs outlined above, and thereby to ensure that the proposed component addresses Factor 1, staff recommends as a condition of approval, a revised set of reporting measures on these areas, as detailed in Attachment 1.

Factor 1: b) Improved health outcomes and quality of life: Endoscopy

The Applicant asserts that the Proposed Project Component will increase Patient Panel access to endoscopy treatment and services that are currently unavailable, and increase capacity to make the provision of endoscopy services more efficient. By increasing procedure and pre- and post-procedure space, the following outcomes will be improved:

- **Increased capacity to improving access** – Increasing procedural and peri-procedural space will ensure appropriate space for staff to utilize endoscopic equipment.[41] In addition, clinicians will be able to perform endoscopic procedures that are not currently provided in the unit.[42]
- **Improved health outcomes**. Endoscopy's use as a screening and diagnostic tool allows for early detection of disease and prevents further development of disease. Endoscopy is frequently used as a diagnostic tool to evaluate stomach pain, ulcers, gastritis, digestive tract bleeding, changes in bowel habits, and polyps and upon diagnosis is used as a treatment tool to remove polyps or stop bleeding. The Proposed Project Component will enhance quality of care for the Patient Panel because increasing capacity will ameliorate delays, and providing for earlier diagnosis and treatment may in turn, improve health outcomes. The Applicant asserts that timely treatment can result in fewer complications, which leads to reduced emergency department visits and hospitalizations. These improvements will, the Applicant asserts, enhance a patient's quality of life.
- **Improved patient experience**. Through reducing operational inefficiencies, the Proposed Project Component will increase patient throughput and reduce overcrowding which is likely to increase patient privacy and enhance patient satisfaction.

Analysis

Staff finds that convincing data was presented to demonstrate the value for the Proposed Project. A review of the literature shows that GI conditions and diseases contribute to significant healthcare utilization and spending.[tt,uu] It is well established that endoscopy is an effective screening, diagnostic, and therapeutic tool for gastrointestinal conditions and cancers. Colonoscopy/sigmoidoscopy are used to screen for colon cancer; screening and rescreening at recommended intervals can provide both diagnoses at an early, curable stage or prevention, through removal of precancerous polyps. Increasing timely access to endoscopy services is likely to

[41] such as endoscopic ultrasound, cryotherapy, and technology associated with radiofrequency ablations
[42] such as Peroral Endoscopic Myotomy (POEM), Gastric Peroral Endoscopic Myotomy (G-POEM), and Transoral Incisionless Fundoplication (TIF)

improve health outcomes and quality of life for the entire Patient Panel. Staff also notes however, that adherence to CRC screening guidelines among African Americans are lower than their white counterparts.[vv]

Finally, staff notes that routine colon cancer screening over age 75 is controversial, as it does not necessarily lead to improved health outcomes. While about 90% of new colon cancer cases occur in individuals age 50 and over,[ww,xx] the U.S. Preventive Task Force Services (USPSTF) states that screening for people aged 76 to 86 should be selectively offered.[yy] In order to ensure that the expansion helps address appropriate screening rates and rescreening rates for the entire Patient Panel, staff recommends annual reporting by age and by race in addition to revising the set of reporting measures proposed on these areas, detailed in Attachment 1.

Factor 1: b) Improved health outcomes and quality of life: EP Lab

The Applicant asserts that increasing capacity will enable MGH to meet growing need for EP Lab services, thereby increasing access for more patients. By increasing procedure and pre- and post-procedure space, the Applicant asserts that health outcomes will be addressed in a number of ways:

- **Improving access through the reduction of wait times.** The Proposed Project Component will increase the EP Lab's patient throughput capacity for both inpatient and outpatient volume by ~67% (from 3 to 5 procedure rooms) and increase pre- and post-procedure space by 900% (from 1 to 10 pre- and post-recovery bays) to increase recovery space for patients receiving EP Lab services and eliminate the need to transfer patients to the inpatient setting for recovery.[43] This increase in recovery space will in turn, reduce length of stay, and ensure timely discharge processes.
- **Improved outcomes.** Reducing wait times to access to EP Lab services will improve access to treatment options for arrhythmias. Atrial fibrillation, the most common arrhythmia, is a significant source of morbidity and mortality.[zz] Decreasing wait times for necessary interventions will reduce complications associated with delayed access to EP Lab services.
- **Improved quality of life.** Patients receiving outpatient treatment for arrhythmias show improved quality of life as demonstrated through a decrease in emergency room visits and hospitalizations, and improved psychological functioning and physical functioning.
- **Improved patient experience.** Increasing capacity in the EP Lab will improve the patient care experience and patient satisfaction.

Analysis

Staff found that convincing data was presented to demonstrate the need for the Proposed Project Component. AF is a frequent arrhythmia with increasing prevalence and the main aim of treatment is directed to improve the quality of life while reducing morbidity and mortality.[aaa] Moreover, AF is associated with an increase in morbidity and when left untreated, and it increases the risk and severity of stroke, heart failure and death.[bbb] The Proposed Project Component will increase capacity to improve access to EP Lab services and make the provision of care more efficient. This will increase patient throughput and enhance the patient experience. Increasing access to these services will improve health outcomes and quality of life for the Patient Panel. As noted above, for certain patients, population health management approaches will likely improve health outcomes and the patient care experience. Staff was able to locate outside information describing patient classes for risk reduction at the Cardiovascular Disease Prevention Center at the Heart Center.

In order to ensure that the expansion helps address the patient needs outlined above, and thereby to ensure that the proposed component addresses Factor 1, staff recommends as a condition of approval, a revised set of reporting measures on these areas, including on patient education, as detailed in Attachment 1.

[43] These bays are considered "flex" bays and may be used as pre- or post-procedure bays.

Factor 1: b) Improved health outcomes and quality of life: PET/MR

The Applicant asserts that the Proposed Project Component will increase Patient Panel access to MRI and to the new PET/MR technology, which in part will increase capacity to make the provision of MRI services more efficient. The Applicant describes several elements of the project that it asserts can improve health outcomes and quality of life, including

- **Improved Health Outcomes**
  - Delayed imaging lead to delays in diagnosis and treatment;[ccc] having more capacity for MRI reduces wait times, which can lead to earlier treatment leading to better sense of well-being and outcomes.[ddd]
  - The use of the combined technology will improve outcomes through rendering more precise information that may change the diagnoses and/or lead to altered clinical decision-making from initial evaluations or alternative testing such as PET-CT.[eee]
  - Zero to significantly less radiation exposure as a result of combined modalities- MRI alone does use radiation to obtain images. For PET and for some MRIs a radioactive contrast agent that exposes patients to small doses of radiation in employed. This is a significant benefit for pregnant women, children and for patients who need ongoing scans.[fff]
- **Improved Patient Experience** through faster scan times- the proposed MRI is a 3T (Tesla) MRI, which has a faster scan time than many MRIs, which are 1.5T and benefits patients who experience anxiety during long testing times and certainly relate to Quality of Life.

Analysis

Staff concurs that early and accurate diagnosis[ggg] for many health conditions through this technology has the potential to improve outcomes, providing patients with greater sense of well-being, since uncertainty from delays and potentially changing the course of treatment can lead to anxiety. The advantages of providing simultaneous scanning include decreased radiation dose, improved motion correction, and the convenience of a combined exam.[hhh] It also reduces time lost from work and other activities and for some rapidly changing conditions, provides valuable clinical information that may alter the course of treatment. Because the unique features of the MRI allow for more comprehensive imaging evaluation sequences than CT, the radiation dose from PET/MR is significantly lower than from other combination imaging PET/CT, making it preferable for patients needing ongoing scans, pregnant women and children.[iii]

While there appear to be "promising" potential benefits to PET/MR,[jjj] a number of authors have underscored the need for careful utilization outside the research setting. As one group concluded, "further clinical studies will have to prove an added value of PET/MRI over the current standards of care to justify [its use].[kkk]" Because of the potential for overuse of the combined PET-MR emerging technology, and thereby to ensure that the proposed component addresses Factor 1, staff recommends as a condition of approval, limits on volume of the new equipment (Research, PET/MR and MR alone) not to appreciably increase based on initial projections, as detailed below under Conditions.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care: Overall Emergency Department

The Applicant notes that improved work streams by acuity level results in a shorter LOS. Linkages to the Hospital's electronic health record (EHR) facilitates coordination of care and ensures continuity of services. As noted previously, implementation of the expanded ED with an expanded secure APS will increase throughput and more efficiently deliver care. Further, the benefits of consolidation of the APS can reduce costs since it has been shown to reduce length of stay and even reduce hospital admissions.[lll]

In response to follow up questions around potential overuse of ED services, the Applicant stated that ED visits of lower-moderate acuity is quite low, comprising only ~10% of visits according to its own analysis. Applicant noted MGH's ambulatory care practices are increasing same day access for urgent care visits, leading more patients to use urgent care instead of the ED. The Applicant also referred to the previously described PHM programs as successful models for reducing ED use. Additionally, the Applicant notes that it has a 3-day minimum stay waiver from Medicare,[44] which further reduces unnecessary ED visits and admissions.

Analysis

The Applicant provided data showing MGH's low percentage of "low acuity" ED visits and outlined its efforts to continue to address avoidable ED visits; staff notes such visits are an important contributor to ED overcrowding. There has been much attention and study paid to overuse of the ED in the Commonwealth, with its associated drivers and costs.[mmm] A recent HPC report noted that 42% of all ED visits in the state are considered avoidable.[nnn] While the treatment of lower-acuity conditions in EDs is declining, HPC has noted the issue remains problematic for the Commonwealth.[ooo]

Continuity of care and care coordination will also aid in ensuring linkages among community resources, primary care, and specialists, which can help prevent what many consider to be avoidable ED visits and readmissions.[ppp] Moreover, the use of EHRs achieve greater efficiencies, continuity of care and care coordination. These improvements have been well-documented in the literature.[qqq] For all patients, but especially the elderly and behavioral health patients, ensuring that patients receive coordination of care to appropriate outpatient treatment and community services prior to discharge from the ED is paramount to recovery and can reduce re-visits to the ED. Because older patients are frequent users of MGH's ED it is important that appropriate programs be in place to ensure continuity of care following an ED visit.[rrr] [sss]Success with the PHM programs described above and improvements in ED patient flow can lead to time-savings for patients and clinicians and improved quality of care with better outcomes.

Finally, staff also finds that the Applicant's proposal to expand behavioral health and medical ED care is likely to achieve improvements in the delivery of care. Greater efficiencies will be gained when patients are triaged into the appropriate track of care based on diagnosis and acuity. Efficiencies can be gained when "zones" are designated for a narrower focus in which they are appropriately equipped and stocked, and staff are familiar with and trained and work that more specialized area.

Endoscopy

The Applicant has suggested that renovating the clinical space will allow MGH to redesign patient throughput which will lead to the greater throughput and efficiencies in care processes, including creating more efficient discharge processes through reducing wait times for discharge and the length of stay. The Applicant asserts that patients are appropriately linked to care integration resources to support coordination and continuity of services. MGH PHM strategies also assist a subset of patients accessing these services.

Analysis

Staff finds that the Applicant's processes for follow-up care will serve to achieve greater efficiencies, continuity of care and care coordination. The expansion appears to make endoscopy services more efficient and enhance the patient experience, and it will improve continuity and coordination of care, which will address the particular needs of patients with complex care needs and significant healthcare utilization.

[44] Such a 3-Day Rule Waiver waives the requirement for a 3-day inpatient hospital stay prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries

PET/MR

The Applicant states that when the appropriate test is performed with minimal additional testing, arriving at a diagnosis is more efficient and less costly for patients and the treatment center. When wait-times for an MRI are reduced, continuity and coordination of care can be more efficient, particularly as a reduction in time related to diagnosis and staging can occur. Additionally, the MRI expansion will lead to greater through-put because there will be faster scan times with the 3T MRI.

The Applicant notes that with the existing aforementioned care integration resources and programs, EHR, communication of diagnoses, treatment plans among radiologists, referring specialists and primary care physicians, and live follow-up by care managers with patients following an ambulatory care procedure, better coordination of care can occur.

Analysis

Staff finds that the Applicant's plans to utilize the proposed unit for multiple purposes is an efficient way to extend the benefits of a proven technology, MRI that is not operating at capacity to more patients to ensure that care is delivered in a timely manner. For PET-MR, additional efficiencies related to the time-savings for patients who will now undergo just one exam and clinicians who might otherwise have the opportunity to treat additional patients are another benefit.

Further, utilizing existing staff and processes for case-management to perform individual needs assessment screenings for PET-MR patients would appear to improve continuity and coordination of care and address the complex individual care needs of those patients. As such, the Proposed Project Component appears to make screening services more efficient and enhance the patient experience.

EP Lab

The Applicant has suggested that renovating the clinical space will allow MGH to redesign the patient flow, which will lead to greater throughput and efficiencies in care processes, including creating more efficient discharge processes through reducing wait times for discharge and reducing the length of stay. The Applicant asserts that patients are appropriately linked to care integration resources to support coordination and continuity of services.

Analysis

Staff finds that the Applicant's processes for linking patients to PCPs and follow-up care will serve to achieve greater efficiencies, continuity of care, and coordination of care. Staff also recognizes the documented benefits of EHRs in achieving greater efficiencies, continuity and coordination of care for all 4 Project Components.

Factor 1: d) Consultation: Overall Application

The Applicant has provided evidence of consultation with government agencies that have licensure, certification or other regulatory oversight, which has been done and will not be addressed further in this report.

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

The Department's Guideline[45] 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. Regulations state that such consultation consist of a "community coalition statistically representative of the patient panel."[46]

[45] Community Engagement Standards for Community Health Planning Guideline
[46] DoN Regulation 100.210 (A)(1)(e). https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf

- **For ED expansion and Endoscopy**, the Proposed Project Component was presented at an Experience Design Workshop for the MGH Cambridge Street Patient and Family Advisory Council (PFAC). The Applicant provided an agenda for the meeting and a list of attendees. The workshop included a series of interactive activities. It appears that there was opportunity for participants to provide input on the Proposed Project Component.
- **For the EP Lab**, Surgical staff presented the Proposed Project Component to the Patient and Family Advisory Council ("PFAC") at MGH's Corrigan Minehan Heart Center ("Heart and Vascular PFAC"). The Applicant provided an agenda for the meeting, meeting minutes, and presentation slides. It appears that there was opportunity for questions, discussion, and feedback, and no opposition to the project was expressed.
- **For the PET/MR**, the Proposed Project Component was presented at a community forum at MGH in January 2019. Patients, providers, neighbors and other parties were encouraged to attend the presentation to provide feedback. The forum was advertised in clinical areas of the hospital and throughout areas at MGH to attract attendees. Twenty attended the forum, including patients, staff and providers.

Analysis

Staff finds that while the Applicant appears to have met the minimum required community engagement standard of *Consult* in the planning phase of the Proposed Project Component, of PFAC membership is unclear, as is how many patients attended the community forum.

Factor 1: f) Competition on price, Total Medical Expenses, costs and other measures of health care spending: Overall Application

The Applicant asserts that through the 4 Project Components, it will continue to compete based on price, TME, costs and other measures of health care spending through cost savings due to the expansion, leading to improved access in service, improvements in patient flow patterns, and enhanced diagnostic capabilities, all leading to more efficient delivery of service and care. Patients may be able to a) avoid the potential of undergoing more invasive, or less effective diagnostic or treatment therapies that are more expensive, as well as b) benefit from more targeted treatment plans, both of which are likely to result in reductions in healthcare spending. These improvements can result in lower provider and payer costs and out of pocket expenses, leading to a reduction in TME. When services can be delivered to patients in a timely, high quality manner, the Applicant will be able to ensure its competitive position.

Analysis

It has been well established that improving access to timely care is likely to reduce healthcare utilization and spending.[ttt,uuu] Moreover, numerous studies have detailed high costs for poorly controlled Atrial Fibrillation,[47] for GI diseases,[48] for high ED use[vvv,www] and for unnecessary repeat imaging[xxx] as may be ameliorated through appropriate use of PET-MR. For all Proposed Project Components, reducing operational inefficiencies will lead to lower operational overhead and lower healthcare spending, which will reduce TME.

Because the Applicant will be the sole provider of PET-MR technology in the state, use of PET-MR payment by CMS and other insurers is limited since much of its use is still considered investigational,[49,yyy] and that PET-MR is still considered "promising" for many conditions, staff suggests that, as a condition of approval, a)

[47] Atrial fibrillation (AF) is the most common arrhythmia with a substantial effect on individual morbidity and mortality as well as healthcare expenditure. Patients with AF are hospitalized twice as often as patients without AF and are three times more likely to have multiple admissions. (*Khaji A. 2017)*

[48] Costs of GI diseases totaled $135.9 billion in 2015 and in 2014, and the 3.0 million hospital admissions for GI diseases totaled more than 31 billion.(*January CT,. 2014)*

[49] CMS approves PET/MR use in limited cases. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=261 (see Background) & Medicare National Coverage Determinations Manual https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf (section 220.6) CMS allows MACs to determine coverage within their respective jurisdictions for oncologic imaging

volume on usage not appreciably exceed projections as noted above in Table 3, and b) protocols for informing patients about potential insurance denials for service each be reported over time, as detailed in the Conditions and in Attachment 1.

Staff finds that while difficult to measure on a service-specific level, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending have been met.

Description of proposed measures, suggested Conditions, FACTOR 1

As a result of information provided by the Applicant and additional analysis, staff finds that, with the conditions below, the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f).

The Applicant proposed specific outcome, process and balancing measures to track the impact of all 4 Proposed Project components. Staff reviewed the suggested measures and has provided a revised list of Annual Reporting measures, summarized below and described fully under Other Conditions and in Attachment 1. Staff recommends that, in order to completely address Factor 1, these reporting measures be required as a condition of approval.

Emergency Department

- Improvements in wait times, Boarding, LWOS, among other standard CMS measures, revised from Applicant's proposed list
- Reduction in lower acuity visits

Endoscopy

- A description of any programs to reduce patient risk factors for CRCs and/or increase CRC screening or rescreening behaviors according to appropriate intervals
- Reporting on asymptomatic patients receiving screening colonoscopy or sigmoidoscopy at regular intervals, by age and race, which shall not decrease
- Other improvements in standard outcome measures revised from Applicant proposed list

EP Lab

- A description of programs to either reduce risk factors for CVD and/or assist patients in managing their CVD
- Other improvements in standard outcome measures revised from Applicant proposed list

PET-MR

- The volume of procedures performed on the PET-MR equipment based on its three defined uses, to not appreciably exceed those defined in the projects; increases for clinical use to be subject to DON amendment
- Most frequent use of PET-MR
- Protocols on educating patients around insurance coverage of PET-MR

Factor 2: Cost containment, improved public health outcomes and Delivery System Transformation: Overall application

The Applicant has outlined why each of the Proposed Project Components will align with the Commonwealth's goal for cost containment (to provide better quality care at a lower cost), as well as contribute to improved public health outcomes.

Cost Containment

The Applicant describes its current difficulty in controlling expenses due to insufficient supply of care delivery spaces resulting in backlogs or bottlenecks in the delivery process. These add to unnecessary resource use due to extended stays in the ED, Endoscopy Suite and EP labs, as patients wait to be treated, wait in recovery, or wait to be either admitted or transferred. The PET- MR and MRI also will allow more appropriate imaging of patients and reduce wait times, which can also lead to faster, more accurate diagnosis and treatments.

The Applicant suggests the Proposed Project will address all of these shortcomings, thereby lowering the per-unit cost of care; much of this has already been discussed throughout Factor 1 above. In response to supplemental questions about potential MRI overuse, the Applicant described a new Prior Authorization Service Program and a Radiology Order System; these are showing that overall image ordering has recently decreased.

Improved Public Health Outcomes

The Applicant has discussed how more timely access to screening and diagnostic tools, as well as more efficient ED services, can lead to more appropriate, timely treatments that ultimately reduce morbidity and mortality rates for numerous diseases and conditions.

Delivery System Transformation

Overall, the Applicant **notes that Delivery System Transformation** will be addressed through linking patients to social service programs through its PHM programming and through SDOH screening and referral, both described above. In response to follow up questions, the Applicant also states that 57.9% of Partners primary care lives are covered in risk contracts.[50,51] The Applicant notes that this percentage is derived from the number of primary care lives within the Patient Panels of the Partner's primary care physicians (PCPs) that are covered under risk contracts (Partners bears risk); this percentage does not include referral patients.

Analysis: Cost Containment Overall

Generally, within a facility or system, cost containment can occur in two ways: a) by designing and implementing efficient processes that eliminate resources use including staff time and supplies thereby controlling per procedure/service operating expenses; and/or b) reducing unnecessary utilization that includes eliminating low value testing while ensuring timely access to the appropriate diagnostic and testing tools. Each of these approaches saves patients and providers time and money, and much of this has already been reviewed in Analysis of Factor 1f above. Staff believes the Proposed Project has the potential for the Applicant to lower certain operating costs through means described above.

Cost containment on a statewide level is impacted through pricing, which is a function of what providers charge payers and what payers agree to pay. While payment contracts between providers and Medicare and

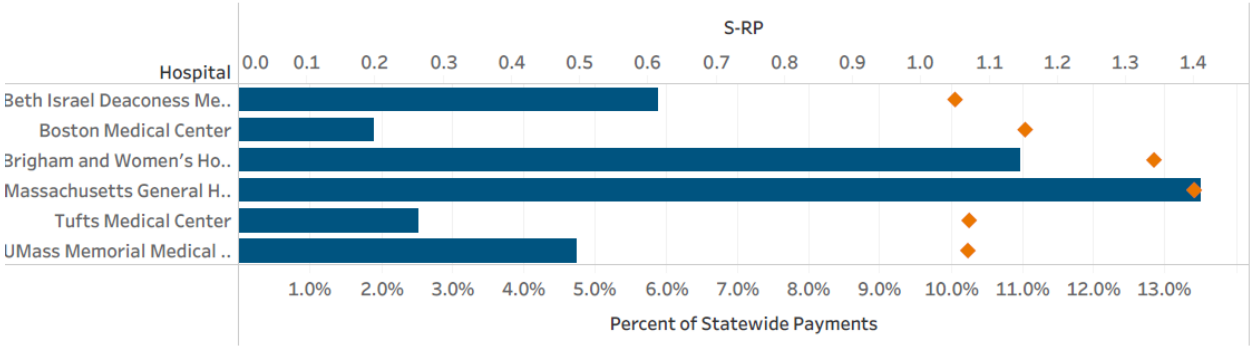
[50] The number of risk members is for CY2018 and includes members from the following risk contracts: MassHealth ACO, Medicare ACO - NextGen, BCBS AQC and BCBS PPO, HPHC, TAHP, AllWays Commercial. The total number of patients within a PCP's panel are for FY 2017 adult and pediatric patients.
[51] This percentage differs from the Partners' Patient Panel described the DoN Application.

Medicaid are relatively transparent, those between individual Providers and commercial payers are confidential. As a result, staff cannot assess how MGH's contracts with payers, that may incentivize more or less utilization of services, are structured.

Consequently, Staff reviewed recent reports from the Massachusetts Health Policy Commission and from the Center for Health Information and Analysis of health care cost and utilization trends in Massachusetts to evaluate the Proposed Project's alignment with the state's cost containment goals. Provider price variation and high academic medical center (AMC) costs are two issues of particular relevance to the Proposed Project.

To examine provider price variation in Massachusetts commercial market, the Center for Health Information and Analysis annually reports on the relative price, which takes into account differences in patient acuity, and the types of services delivered and groups providers into four categories. Two of Partner's hospitals, MGH and BWH fall into the Academic Medical Center cohort that includes four other hospitals.[52] The Statewide Relative price (S-RP) for CY17 for AMCs was 1.18. In addition, MGH and BWH had S-RP values of 1.40 and 1.38 respectively in 2017, as the orange diamonds in chart below shows.[zzz,53]

Share of Commercial Payments and S-RP by Hospital, 2017



The HPC states that total health care spending is a function of price and utilization.[aaaa,54, 55] and recommends focusing on reducing unnecessary utilization as a means of promoting an efficient, high-quality health care delivery system. Staff also notes that a recent report from Massachusetts Association of Health Plans (MAHP) and other business groups [bbbb] suggested that provider price remains the biggest health care cost driver in Massachusetts.

Staff concurs with the Applicant that the project is likely to impact healthcare expenditures through reducing healthcare unit costs, but notes that MGH is still the highest-cost AMC and cannot conclude how this will impact cost containment efforts. As described in the Overview section, the Applicant is a highly integrated, and as shown above, a high-cost provider. Several reports found that provider consolidation has resulted in increased leverage when negotiating provider contracts, leading to higher provider prices for large systems[cccc] like Partners.

Staff considered the Applicant's assertions around cost containment and documented strategies to reduce healthcare utilization alongside its position as a high-cost provider. While DoN staff cannot conclude that

[52] Beth Israel Deaconess, Tufts and UMass Memorial and Boston Medical Centers
[53] While MGH and BWH received the highest percent of commercial payments, 13.5% and 11% a respectively, relative size and volume analysis was not included in the analysis.
[54] Total Medical Expenses (TME) represents the full amount paid to providers for health care services delivered to a payer's member population, expressed on a per member per month (POMPOM) basis. TME includes the amounts paid by the payer and patient cost-sharing, and covers all categories of medical expenses and all non-claims related payments to providers, including provider performance payments.
[55] Total Health Care Expenditures (THE) is a measure that represents the total amount paid by or on behalf of Massachusetts residents for health care services covered by public and private health insurance.

expanding services through the Proposed Project will not lead to higher prices and higher healthcare spending, 105 CMR 100.310(A)(18) enables the Department to rely on the Health Policy Commission's oversight of increases in provider costs as a way to monitor provider spending.

Analysis: Cost and Public Health Outcomes for specific components

Costs and public health outcomes for Emergency Department

It is well established that appropriate care for behavioral health patients and the elderly are both likely to improve public health outcomes, however it is less known if and how such care can prevent (re)admissions and save costs. Staff recommends, as a condition of approval, reporting on readmission rates using standard CMS measures, outlined in Attachment 1.

Costs and public health outcomes for endoscopy

Increasing timely access to endoscopy services is likely to improve public health outcomes, as increases in colorectal screening, and ensuring rescreening is associated with a reduction in colorectal cancers and related sequalae; a recent study found that approximately 550,000 cases of colorectal cancer were prevented over the past 3 decades in the United States.[dddd]

Among important public health outcomes are the reduction of risk factors for colorectal cancer and ensuring screening and rescreening rates at appropriate intervals. Staff notes that while Massachusetts overall has high overall CRC screening rates[56,eeee], it is also clear that there are disparities in screening rates, based on SES, language, and ethnicity.[ffff] Adherence to CRC screening guidelines among African Americans are lower than their white counterparts.[gggg] MGH has also identified such disparities locally by race and ethnicity in a 2019 report[hhhh] and described several programs in use to increase screening rates. In order to ensure that public health outcomes are addressed, as a condition of approval, staff suggests reporting of colorectal cancer education and outreach programs in the community, and in particular to increase screening rates among minority and low income populations. Staff has already suggested other measures reporting on regular CRC screening for people over age 76, as this may not contribute to improved public health outcomes.

Costs and public health outcomes for EP Lab

Increasing timely access to EP services is critical for individuals with AF, leading to overall reductions in morbidity and mortality. An important public health outcome is the reduction of heart disease risk factors to reduce to need for EP services in the first place. There are clear health disparities in cardiovascular health.[iiii] While studies have shown a lower prevalence of AF in African-Americans than Whites, there is evidence that African Americans with AF have higher rates of stroke, heart failure, CHD, and mortality as compared with their white counterparts.[jjjj,kkkk] Moreover, a recent MGH study linked lower socioeconomic status (SES) to cardiovascular disease risk.[llll] In order to ensure that public health outcomes are addressed, as a condition of approval, staff suggests ongoing reporting of CVD risk reduction programs in the community, and in particular among minority and low income populations.

Costs and public health outcomes for MRI with the new PET/MR

Imaging overuse remains a cost concern in the Commonwealth. the Health Policy Commission describes in their 2018 Cost Trends Report that "Massachusetts ranks 4th in the nation in Medicare spending for imaging, reflecting both higher utilization and greater use of higher-priced hospital outpatient departments…. Common diagnostic imaging includes … MRIs. Many of these imaging services have been shown to have no diagnostic value for certain conditions.[mmmm]" While the Applicant noted the success of

[56] In 2016, ~75% of Massachusetts age-eligible residents had a current colorectal cancer (CRC) screening test (vs. ~67% of the eligible population screened in the United States) and ~78% over age 50 in Massachusetts have ever had a Sigmoidoscopy or Colonoscopy (vs. 70% of the US population (National Cancer Institute, State Cancer Profile)

the relatively new clinical decision support mechanism in use for MRIs, it should be noted that "clinical decision support strategies have demonstrated modest reductions in overall utilization of diagnostic imaging tests, but it is unknown if these interventions are lasting".[nnnn]

Concerns have already been noted about costs for PET-MR usage above.

Due to these concerns, staff has already suggested that, as a condition of approval, there be limits on volume of the use of new equipment for MR alone not to appreciably increase based on projections; increases for clinical use of PET/MR or MRI alone to be subject to DON amendment, as detailed in Other Conditions section.

Analysis: Delivery system transformation

Central to the goal of **delivery system transformation** is the integration of social services and community-based expertise. The Applicant has described, at a high level, how "covered lives" patients in the panel are assessed and how linkages to social services organizations are created. However, since the Applicant is a MassHealth ACO (Partners HealthCare Choice), a Medicare ACO (Next Generation ACO), and has 5 commercial risk contracts. As such, it has ongoing incentives to address population health needs and SDOH.

Description of proposed measures, suggested Conditions, FACTOR 2

As a result of information provided by the Applicant and additional analysis, staff finds that with the Conditions outlined below, the Applicant has demonstrated that the Proposed Project has met Factor 2. Staff recommends the following Conditions to be reported annually, noted here and described fully in Attachment 1:

Emergency Department

- Reduction in re-admission rates for all patients, by APS and patients over 65 (as noted in Factor 1)

Endoscopy

- Reporting on colorectal cancer education and outreach programs to reduce colon cancer risk factors in the community, as well as efforts to increase screening rates among minority and low income populations, with increased number of participants annually

EP Lab

- Information about CVD risk reduction and outreach programs in the community, and in particular among minority and low income populations, with increased number of participants annually

PET-MR

- Reporting on the volume of procedures performed on the PET-MR equipment based on its three defined uses, to not appreciably exceed projections; increases for clinical use to be subject to DON amendment

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: Overall Application

The CPA analysis included a review of multiple documents in order to form an opinion as to the feasibility of the Proposed Project including; FY 2018 audited financial statements for Partners Healthcare System, Inc.; a five year "Financial Framework" for PHS;[57] Finance Committee Reports and "Five Year Pro-Forma[58]" for all four components of the Project; and historic and projected metrics. Key metrics and ratios for profitability, liquidity, and solvency were compared against historic performance to measure Partners' overall financial health.[59] During its review of the Pro-Forma, it examined the underlying assumptions used for the development of revenues and expenses forecasts.

The CPA reports that Net Patient Service Revenue (NPSR) is the sole category that would be impacted by the Proposed Project. Consequently, it only analyzed NPSR and reports that the project represents a very small share of projected revenue of the Partners system ranging from 0.021% in 2019, the first year the ED revenue increase will be reflected, to 0.173% in 2023, the first year that the revenues for the endoscopy expansion will occur. Revenues from the EP Lab and PET MR projects will begin in 2020. The CPA reports that primarily based upon historic performance, the revenue growth projected by Management are a reasonable estimation.

The CPA's analysis reports that operating expenses will represent only about 0.027% in 2019 and 0.161% in FY 2023 of Partner's total operating expenses and relative to historic performance, determined that the Applicant's projections are reasonable. Capital Expenditures and cash flows were analyzed by the CPA to determine whether Partners allowed for sufficient reinvestment of funds for upgrades to property, plant, equipment and technology and whether Partners' cash flow would support necessary reinvestment. The analysis included current and projected loan financing obligations. As a result of the analysis, the CPA's opinion is that the pro-forma capital expenditures and cash flows are reasonable.

In conclusion, the CPA reports, "Because the impact of the proposed capital projects as listed above at MGH 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." The report continued with the following statement: "… I determined the projects and continued operating surplus are reasonable and based upon reasonable financial assumptions….The proposed capital projects … at MGH are financially feasible and within the financial capability of Partners."

Staff finds the CPA analysis to be acceptable, noting that MGH's favorable operating margin of 4.5-5.5%[oooo] is higher than the Academic Medical Center peer cohort range of 2.2-1.8% over the 2013-2017 timeframe based on reporting by CHIA.[60]

[57] Prepared as of December 6, 2018
[58] FY 2019-2023
[59] Incorporated in the overall financial projections, the CPA noted a balloon payment on long-term debt maturing in 2021.
[60] Staff relies on the CPA Analysis and CHIA reporting and does not perform its own financial analysis.

Factor 5: Assessment regarding Proposed Project Component's Relative Merit

Emergency Department Renovation and Behavioral Health Expansion

The Applicant compares the Proposed Project Component to the alternative of maintaining the status quo. This option would not allow for the timely and effective treatment of the rising number of APS patients which has a negative impact on quality of care for all patients. No efficiencies would be created for any patients with the current space constraints and infrastructure, and operating costs would rise because of longer lengths of stay, and for behavioral health, the aforementioned continued use of extra security.

Endoscopy Renovation and Expansion

The Applicant compares the Proposed Project Component to two alternatives: (1) expanding the unit across the Gray and Jackson building to create a larger multi-specialty procedural space for cardiology, pulmonary, and endoscopy, and (2) expanding the unit to an off-campus location. The capital expense for the first alternative was 98M, which is three times higher than the Proposed Project Component and this alternative would include disruption of services and interruptions to patient care, a phased construction lasting 6 years, and higher operating costs. The second alternative would have created two campuses with limited patient access, limited ability to meet the current and future Patient Panel need and an inability to maintain all services and acuity levels in one location. The Applicant dismissed the first and second alternatives because from a cost, efficiency, and quality perspective the Proposed Project Component represents a more cost-effective solution for expanding access to high quality Endoscopy services that sufficiently address Patient Panel need.

Electrophysiology Lab

The Applicant compares the Proposed Project Component to two alternatives: (1) expanding MGH's procedural services in the Gray, Jackson, and Black buildings, and (2) relocating the EP Lab to the 9th floor adjacent to the Cardiovascular Lab.

The capital expense for the first alternative was 95M for 54,540 GSF of renovated space, which was three times higher than the Proposed Project. The construction costs for the second alternative was $62.5M for 32,355 GSF of renovated space, and this alternative would result in a loss of inpatient capacity, disruptions to the lab during construction, and increased capital costs to upgrade infrastructure. The Applicant dismissed the first and second alternatives because from a cost, efficiency, and quality perspective, the Proposed Project Component provides the most cost-effective means of expanding access to high quality EP Lab services to meet Patient Panel need.

Addition of PET/MR and MRI Capacity

The Applicant compares the Proposed Project Component to the alternative of using the PET MRI for research use only. Not utilizing the MRI component of the unit for clinical purposes when it is not in use for research purposes would mean that wait times will continue to increase, and the effects of delayed diagnosis, staging and treatment could impact outcomes and patient satisfaction for ~4 patients per day.

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

As a result of information provided by the Applicant and additional analysis, staff finds the Applicant has reasonably met the standards of Factor 5.

Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application

Summary and relevant background and context: The Applicant is engaged in a new process to fulfill their requirements for a 2019 Community Health Needs Assessment (CHNA). They are participating in two separate and collaborative processes (with the Boston and North Suffolk CHNA/CHIPs). The Applicant has adopted a new advisory committee structure to facilitate these processes, with three committees with distinct roles, described below. In coordinating with the larger CHNA/CHIP processes for Boston and North Suffolk, the Applicant has utilized community-wide surveys, focus groups, and in person convenings to obtain community input, and will further engage the community across stages of the CHNA/CHIP process from assessment through prioritization and project planning. Given the timing of these larger processes and because these processes are distinct from the previous 2016 CHNA/CHIP cycle, the Applicant did not submit stakeholder assessments. Instead, staff requested further information on the Applicant's Committee Structures, Community Engagement, Commitment to Equity Framing, and use of Administrative Funds.

The Applicant submitted a CHNA/CHIP Self-Assessment, CHI Narrative, Community Engagement Plan, and Community Engagement Plan Addendum.

- **In the Self-Assessment**, the Applicant provided a summary of socio-demographic data and highlights of health outcome information related to these topics. Through surveys, focus groups, and in person meetings, the participating communities identified the lack of affordable housing as a key concern. Additionally, survey respondents believed that substance use disorders were the most important health concern. Given the timing of the application, this information was derived from the 2015-2016 Community Health Needs Assessment.
- **The CHI Narrative and Community Engagement Plan** provided background information for and explanation of current 2019 CHNA/CHIP planning processes, Community Benefit structure, advisory board duties, and administrative information. This document focused on the 2019 Community Health Needs Assessments for Boston and North Suffolk that were in process at the time. Each of these processes included multiple health systems, community based organizations, businesses, and residents in the communities represented.
- **The Community Engagement Plan Addendum, requested by staff,** included more specifics on the applicant's engagement plans for the CHI planning processes in coordination with the larger CHNA/CHIP processes for Boston and North Suffolk. These processes utilized community wide surveys, focus groups, and in person convenings to obtain input on community health needs. It also provided further detail on the plans to engage community across stages of the CHNA/CHIP process from assessment through prioritization and project planning.
- **Stakeholder assessments are normally required, but were, appropriately in this case, not submitted.** Based on discussions and current planning for the Boston and North Suffolk CHNA/CHIP, staff agreed with the Applicant that no stakeholder assessments or submission of the 2015-2016 Partners Healthcare CHNA would be required. In the absence of these materials, and in response to additional questions posed by staff upon review of the materials submitted, the Applicant provided additional narrative describing their plans and activities for the in-process 2019 Community Health Needs Assessment. This additional narrative provided supplementary information on:
    - **Committee structures** - There are three committees with distinct roles within the applicant's organization
        - Board Committee on Community Health – comprised of MGH Trustee Board members, and advises the hospital leadership on community health focus areas
        - Community Advisory Board – provides oversight and advises on the DoN processes pertaining to community engagement and community health planning. The Applicant

provided further description of the role and responsibility of this Board which includes both community benefits and CHI.
        - Executive Committee on Community Health – an internal committee convened to promote community health and health equity principles in all areas of hospital operation
    - **Community Engagement** - The applicant summarized in additional detail the extensive community activities undertaken as part of the Boston and North Suffolk CHNA/CHIP processes including detail on how identified needs are being prioritized through a multi-sector engagement process including subject matter experts, community members and hospital stakeholders.
    - **Commitment to equity framing** -Staff requested that the Applicant consider Department-provided framing questions (*Who benefits, who is harmed, who influences, who decides, what might be some unintended consequences*) throughout decision making processes; the Applicant provided examples of how these questions would be used with their Community Advisory Board.
    - **Use of Administrative Funds** - The Applicant stated that administrative funds will be used through a "to-be-determined" process of CHI implementation but with a focus on facilitating a transparent process that reduces barriers to public participation. However, while the Applicant committed to using administrative funds for CHI implementation and to reduce barriers to public participation, it is unclear how these funds will be specifically utilized. The Department requires applicants to be clear about what these funds will support. This is to ensure appropriate stewardship of funds that meets the goals of transparency and capacity building in the RFP process.

In order to help the Applicant meet Guideline requirements, Staff is continuing its work with MGH to strengthen particular elements of their community engagement processes around 4 areas:

- Community Advisory Board Decision Making Structure including the development of a charter for advisory committee members.
- Community Advisory Board Representation with a focus on resident level representation as the Board is expanded.
- Ongoing Community Engagement Processes beyond the CHNA including the development of a new community engagement plan to focused on issue prioritization processes and plans for CHI fund disbursement, and final plans for allocation of resources between the Boston and North Suffolk CHNA/CHIP processes.
- Completion of detailed plans for use of administrative funds. Staff recommends that this requirement be made a condition of approval, as outlined below.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended conditions summarized below and in Attachment 1, the Applicant has met each DoN factor for each component of the Proposed Project, and recommends that the Department approve this Determination of Need, subject to all applicable standard and Other Conditions.

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 improvement of the measures outlined in Attachment 1.
2. In order to demonstrate efficient, effective and appropriate use of the PET-MR, the Holder shall provide, in its annual report to the Department, report on its protocols to ensure that:
   a. the use of PET/MR is not duplicative of either PET-CT or MRI
   b. patients are informed of the cost if their scan is not covered by their insurance, and how such information is provided
   c. The volume of scans for each of the three specified uses for the PET-MR Unit (research, MRI, and combined PET-MR) to include:
      i. Overall volume
      ii. The number of research scans performed
      iii. The number of MRIs performed
      iv. The number of combined PET-MRs performed
      v. The top 10 clinical indications for PET-MR scans, and whether covered by patient's insurance
3. If the Holder wishes to transfer the use of research PET-MR to any clinical use, the Holder must notify the DoN program prior to such a change. At that time, if DoN program staff determine that the proposed increase in clinical use constitutes a Significant Change, the Holder must apply for an amendment to the Notice of Determination of Need.

Applicant Volume Projections for PET-MR Unit					
PET-MR Scans	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Clinical	356	416	462	462	462
Research	462	546	596	596	596
Total Projected PET/MR Volume	818	962	1058	1058	1058
Projected MRI only scans using PET/MR Unit	1500	1500	1500	1500	1500

CHI Conditions to the DoN

4. Of the total required CHI contribution of $5,110,234.80
    a. $1,277,558.70 will be directed to the CHI Statewide Initiative
    b. $3,832,676.10 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 $1,277,558.70 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
        i. The Holder must submit the funds to HRiA within 30 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.

4. The Holder shall provide DPH with a detailed plan for use of administrative funds that will focus on addressing barriers to public participation in the CHI process within three months of the Notice of Approval. This plan must demonstrate appropriate stewardship of the funds, support capacity building, and meet the grant making process requirements of transparency and reducing barriers to participation.

Attachment 1: Required Measures for Annual Reporting and Related Conditions

The Holder shall provide, in its annual report to the Department, the following outcome measures. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12).

I. Emergency Department Renovation and Behavioral Health Expansion
1. Overall satisfaction of care provided fair or lower only (from QDM survey vendor) Holder shall Report on the following: a) Satisfaction rate for all patients vs APS patients b) Patient response rate and provide a breakdown of respondents by race c) Policy changes[61] instituted as a result of Holder's evaluation of lower ratings In order to ensure Patient Outcomes are met, Holder shall report on progress in **making reductions in*:** 2. Percentage of patients who left the emergency department before being seen (OP-22 on CMS) Holder shall Report this measure for all patients and then for the subset of patients who are APS patients 3. Percentage of APS patients treated outside of the APS Area out of the total number of APS patients Holder shall Report on percentages 4. Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF 0496) Holder shall report NQF 0496 on all patients vs APS patients 5. Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF 0495) Holder shall report on NQF 0495 all patients vs APS patients To assess ongoing reduction in acuity levels among all ED patients: 6. Holder shall report on distribution of ED Visits by Professional Billing Levels as provided to DPH in Applicant Response to Question 10[62]. Holder shall also report on 7. Number of unique APS patients by quarter **(reported annually)** Holder shall Report on unique APS patients vs non-unique patients 8. Number of patients with more than 1 APS visit by quarter (**reported annually**) Holder shall Report on all APS patients vs those that have more than 1 visit per quarter, by # of visits

[61] Holder stated that low ratings will be " evaluated and policy changes instituted as deemed appropriate" and "evaluated on a quarterly basis by the ED operations team"

[62] https://www.mass.gov/files/documents/2019/07/23/partners-health-care-system-responses.pdf

*If improvement (e.g., decrease or increase from baseline) is not achieved, Holder shall report on reasons why and outline plans for improvement

Based on #7 and 8, Holder shall report on efforts to address the needs of frequent ED users, by APS and by all patients.

9. Percentage of ED Visits that return within 72-Hours
   Holder shall Report on unique APS patients vs non-unique patients
   Holder shall report on unique patients over age 65 vs non unique patients
   Based on #9, Holder shall report on efforts to address the needs of frequent return visits, by APS and by over age 65.

II. Endoscopy Renovation and Expansion
Holder shall Report on progress in making reductions* in

1. Median minutes from patient arrival to the unit to procedure start (scope induction).
   Holder shall Report on
   a) the median number of minutes between patient arrival on the unit and scope induction.
   b) Policy changes[63] instituted as a result of higher time intervals

2. Total patient time in the Endoscopy Unit measured from patient arrival to procedure
Holder shall Report on the median number of minutes between patient arrival on the unit and patient departure.

3. Median time between procedure end (patient to recovery) and procedure beginning for the next patient (scope induction)
   Holder shall Report on
   a) the median number of minutes between patient arrival in recovery and scope induction for the next patient.
   b) Policy changes[64] instituted as a result of higher time intervals

[63] Holder stated that data will be reviewed quarterly
[64] Holder stated that data will be reviewed quarterly
*If improvement (e.g., decrease or increase from baseline) is not achieved, Holder shall report on reasons why and outline plans for improvement

In order to ensure Patient Outcomes and Public Health Outcomes are met, report yearly on the following:

4. Rate of risk-standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare fee-for-service (FFS) patients aged 65 years and older. (NQF 2539)
   Holder shall report NQF 2539 on all patients
   Rate shall not increase* for any year

5. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (NQF measure 0658)
   Holder shall report the total number of patients receiving screening colonoscopy and the percentage with the appropriate follow up interval as specified in NQF 0658, by age, race/ethnicity
   Rates shall not decrease* for any year

In order to demonstrate improved health **and** public health outcomes for endoscopy are met, Holder shall

6. Provide a description of any programs or initiatives designed to either reduce risk factors for CRCs and/or increase CRC screening or rescreening behaviors according to appropriate intervals among the **Patient Panel**. This shall include:

   a. Program description and length (if applicable)
   b. Description of program recruitment (if applicable) and number reached out to
   c. Total number of participants
      i. Percentage of participants from racial /ethnic minority groups
   d. Any outcomes measured

Numbers of participants shall increase* each year.

7. Provide a description of any programs or initiatives designed to either reduce risk factors for CRCs and/or increase CRC screening or rescreening behaviors according to appropriate intervals in the **broader community**. This shall include:

   a. Program description and length (if applicable)
   b. Description of program recruitment (if applicable) and number reached out to
   c. Total number of participants
      i. Percentage of participants from racial /ethnic minority groups
   d. Any outcomes measured

Numbers of participants shall increase* each year.

*If improvement (e.g., decrease or increase from baseline) is not achieved, Holder shall report on reasons why and outline plans for improvement

III. Electrophysiology Renovation and Expansion
Measures initially suggested by Applicant and revised by staff: 1. Overall Rating of Care (Press Ganey Survey scores) Collapsed responses for Overall Rating of Care (collapse responses Fair, Poor and Very Poor) Holder shall report on the following: a) Any category receiving a less than "Fair" rating b) Overall patient response rate and a breakdown of respondent rate by race c) Policy changes[65] instituted as a result of Holder's evaluation of lower ratings
Holder shall also Report on progress in making reductions* in 2. Time interval from when the case was initiated for scheduling in EPIC to the date of the EP procedure. • Holder shall report average annual time intervals between scheduling and performance date by EP procedure category included and the urgency (acute, elective).
In order to demonstrate improved health outcomes **and** public health outcomes for the EP Lab, the Holder shall: 3. Report on programs or initiatives designed to either reduce risk factors for CVD and/or assist the **Patient Panel** in managing their CVD (and in particular, those related to arrhythmias). This shall include: a. Program description and length (if applicable) b. Program recruitment (if applicable) and number reached out to c. Total number of participants i. Percentage of participants from racial /ethnic minority groups d. Any outcomes measured Numbers of participants shall increase* each year. 4. Report on programs or initiatives designed to either reduce risk factors for CVD and/or assist the **broader community** in managing their CVD (and in particular, those related to arrhythmias). This shall include: a. Program description and length (if applicable) b. Program recruitment (if applicable) and number reached out to c. Total number of participants i. Percentage of participants from racial /ethnic minority groups d. Any outcomes measured Numbers of participants shall increase* each year. 5. Report on 30-90 day Risk-Standardized Complication Rate following Implantation of ICD. (NQF measure 694) Holder shall refer to NQF measure 694 for measure specification Complication rate shall not increase* for any year

[65] Holder stated that low ratings will be "evaluated and policy changes instituted as deemed appropriate"

*If improvement (e.g., decrease or increase from baseline) is not achieved, Holder shall report on reasons why and outline plans for improvement

IV. Addition of PET/MR and MRI Capacity
Measures initially suggested by Applicant and revised by DON staff: 1. Overall Rating of Care (Press Ganey Survey scores) Holder shall Report on the following: a) Collapsed responses (collapse all responses Fair, Poor and Very Poor) b) Patient response rate and provide a breakdown of respondents by race c) Policy changes[66] instituted as a result of Holder's evaluation of lower ratings **Holder shall also Report on progress in making reductions* in** 2. Time interval (in days) from when the case was initiated for scheduling in EPIC, to the next available outpatient appointment. Holder shall Report on the following: a) Median number of days between ordering elective MRI and imaging test performed. b) Median number of days between ordering elective CT and imaging test performed. c) Policy changes[67] instituted as a result of Holder's evaluation of increasing days 3. Reduction in percentage of PET/MR and MRI scans that triggered an IFA that the radiologist conducted a critical value report. Holder shall Report on the following: a) % of IFAs where critical value report indicated. b) % of critical value reports radiologists performed over the total number of IFAs c) Policy changes[68] instituted as a result of increasing critical value reporting

[66] Holder stated that low ratings will be " evaluated and policy changes instituted as deemed appropriate" for less than "good"
[67] Holder stated that "data will be reviewed quarterly by clinical staff."
[68] Holder stated that "PET/MR and MRI scans will be forwarded to the film library and follow-up will be conducted to the referring physician. The radiologist will be available to answer any questions."

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