

September 26, 2019

Via Email and Hand Delivery – Return Receipt Requested

Margo I. Michaels, MPH, Program Director
Determination of Need Program
Department of Public Health
250 Washington Street
Boston, MA 02108

**BARRETT
& SINGAL**

Re: Application Number –PHS-19040915-HE - Partners HealthCare System, Inc.
Application for a Substantial Capital Expenditure and Substantial Change in
Service at The Massachusetts General Hospital

Dear Ms. Michaels:

We write on behalf of Partners HealthCare System, Inc. (“Applicant”) and The Massachusetts General Hospital (“MGH”) to thank the Department of Public Health (“Department”) for its diligence in reviewing the Applicant’s Determination of Need (“DoN”) application for a substantial capital expenditure and substantial change in service at MGH. Pursuant to 105 CMR 100.510(C), we write to submit written comments on behalf of the Applicant with respect to certain of the proposed conditions contained in the Department’s Staff Report to the Public Health Council (the “Report”). For the reasons explained in more detail below, the Applicant respectfully seeks to request revisions to certain of the proposed conditions, to provide additional information regarding the reporting requirements, and to clarify certain aspects of the community health initiative (“CHI”) analysis set forth in the Staff Report. Accordingly, we provide the following requests and comments.

1. With respect to Condition 3, the Applicant requests the Department change the requirement for when a Significant Change must be requested to increase clinical use of the PET/MR. Condition 3 suggests that a DoN amendment is required if the number of scans for clinical use appreciably increases from the projected volume. The Applicant requests that the measurement for when an amendment is required be changed as it is difficult to determine when utilization may exceed the projected scan volumes because actual utilization will be dependent upon a number of factors, including capacity management initiatives that may develop over time.

Historically, the Department has defined an approval for part-time clinical use of a DoN Required Technology based on days of operation and has not used the number of scans performed as a limit by which a Significant Change is measured. Accordingly, we request that the Department modify this condition to require that the Applicant seek a Significant Change prior to increasing the clinical utilization of the unit based on the total number of operating hours for the machine, the Applicant proposes utilizing the unit 70% of the time for clinical use and 30% of the time for research use. Should the Applicant

determine that it will exceed this allocation, it will seek a Significant Change from the Department before increasing clinical use.

2. With respect to Condition 4, the breakdown regarding CHI monies does not provide for administrative monies to MGH for implementation of the CHI. The retention of a portion of the CHI for administration of the entire process for distribution of CHI funds is permitted by CHI Guidelines and historically, the Department has consistently permitted the use of CHI funds for administrative use with other DoN approvals. Specifically, the Department has allowed Applicant's to retain 2% of the CHI funds for this purpose when implementing a Tier 3 CHI. Based on this precedent, we requested in the DoN application that the Department permit the Applicant to retain \$102,204.70 to assist in funding the work required to administer the Department's prescribed process for distribution of CHI funds.
3. In regard to the second Condition #4 (which may be listed as Condition #5) on page 34 of the Staff Report, the Applicant submitted a written response to the Department's request for explicit detail on how administrative funds would be used, which is not reflected in the Staff Report. As stated in those comments, the Hospital is not able to provide specific detail until the Community Advisory Board ("CAB") determines the process that it will follow to disburse CHI funding (e.g. solicitation process, alternative transparent process, pooling monies, or a combination of all three options). In its response, the Applicant proposed a DoN CHI Timeline that incorporated updates to the Department at regular intervals with the first update provided four to six months post-DoN approval and the second update provided one year post-DoN approval. This approach will provide the Applicant's CAB with time to determine the Health Priorities and Strategies for the DoN – CHI, as well as the disbursement mechanism(s) for funding, which are required prerequisites for determining how administrative monies will be used. Consequently, the Applicant requests that this alternative approach for providing documentation on administrative monies be utilized, rather than the language set forth in Condition #5.
4. The Applicant seeks to clarify language that is included in the analysis regarding Factor Six at page 32 of the Staff Report, which states that "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." The four areas that are noted in this section of the Staff Report are not requirements of the DoN – CHI Guidelines, and despite language in the Report indicating otherwise, Applicant previously provided clarification and specific detail to the Department as follows:
 - a. MGH's CAB has a specific charge: "1) To review and give input to MGH on its overall community health agenda; (2) To review and give input to MGH on its

annual Community Benefit filing to the Massachusetts Attorney General; and (3) To guide MGH on identifying priorities with appropriate community input and transparent processes for community health initiatives that are part of Determination of Need filings with the Department of Public Health. Based on this charge, the Applicant disclosed that a charter would be created and discussed at the next CAB meeting.

- b. Page 12 of the *Community Engagement Standards for Community Health Planning Guideline* outlines the required minimum constituencies required for an Advisory Committee and “resident” level representation is not a constituency that is listed. However, recognizing the importance of a “community voice” in CHI processes, the Applicant provided information to the Department that a survey tool had been developed to solicit relevant information from each CAB member.
- c. The Community Engagement Plan included in the DoN Application meets the community engagement standards outlined in the CHI Guidelines. Issue prioritization is occurring within the CHIP processes for each of the CHNAs in which MGH participates. Further prioritization will occur with the CAB and these processes, as well as plans for fund disbursement are documented in the CHI Narrative, as well as the Community Engagement Plan Form Supplement that was submitted with the DoN application.

As the issues raised in the Department’s analysis regarding these points are not explicit requirements of the CHI Guidelines and the Applicant provided clarification and specific detail to the Department within its Application and during the review process, the Applicant respectfully requests the Department remove from the Staff Report, the language to the contrary regarding these areas, along with the following language: “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.”

- 5. The Applicant has reviewed the Required Measures set forth at Attachment 1 and believes that it can provide the requested data. However, we offer the following clarifying information regarding the requested measures.
 - a. For many of the measures, the Department requires the Applicant to show improvement on each measure. We note that the Applicant will seek to improve outcomes; however, for some measures, MGH currently performs at a high level and as such, improvement may not be possible.
 - b. With respect to measures regarding the satisfaction of care provided, the Applicant seeks to clarify the following:

- i. Surveys are performed on a random sampling of patients and not sent to all patients. Accordingly, the response rates are often low and may not be statistically representative of the patient panel experience.
 - ii. Further, race and demographic data on surveys are self-reported and often patients choose not to provide responses to these questions.
 - c. For many of the measures, a sampling methodology is utilized due to the high volume of patients. The use of sampling is consistent with how other agencies, including the Centers for Medicare and Medicaid Services (“CMS”), have implemented reporting requirements.
 - d. With respect to Emergency Department, Measure 6: *Holder shall report on distribution of ED Visits by Professional Billing Levels as provided to DPH in Applicant response to Question 10.* The Applicant is concerned that administrative data changes over time, as well as billing and coding changes may not be reflective of acuity. This is because certain billing and coding regulations impact the distribution of coded data, and therefore, may not be indicative that the patient panel acuity is changing. However, the Applicant can report the requested data and provide an accompanying interpretation.
- 6. The Applicant also seeks to clarify certain statements made in the analysis portion of the Staff Report.
 - a. On page 15 of the Staff Report, the analysis states the following with respect to MRI wait times: “Applicant states that these waits will be diminished significantly with the use of the new equipment.” However, this is not an accurate interpretation of the impact that the part-time use of the PET/MR and MR will have on the current MRI wait times. The Hospital intends to primarily utilize the MRI portion of the unit to open up slots on its specialized MRI unit that can meet the unique needs of patients with a cardiac pacemaker and implantable device. As one of the few institutions in Greater Boston with the capability to scan these patients (nursing and electrophysiological support), wait times are substantially longer for this population of patients. With the new unit, the Applicant will be able to shift some of its lesser acute patients to the PET/MR for MRI imaging in order to preserve access on the specialized MRI unit. The Hospital believes that wait times for this patient population will decrease; however, the overall wait times for outpatient scans for non-complex patients will not be significantly diminished with the addition of the part-time MRI capacity provided on the PET/MR unit.
 - b. On page 16, staff analysis states that *[f]or 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*

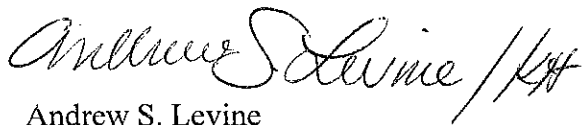
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week. The Applicant seeks to clarify that the addition of part-time MRI capacity will not significantly impact current wait times which are at 18 days for outpatient scans. One MRI exam takes approximately 60 minutes to complete. Additionally, as previously stated in the DoN Narrative, MGH has two hours of quality control and cleaning time built into each scanner's schedule per week. Given this information, 11 scans per MRI unit per day is an overestimation of the number of scans that will be provided at the Hospital.

The Applicant appreciates your consideration of our requested modifications to the conditions. Please contact Crystal Bloom, Esq. or me if you have any questions regarding this letter and our proposed changes. We would also make ourselves available to meet with you to discuss the proposed changes prior to the Public Health Council meeting on October 16, 2019.

Sincerely,



Andrew S. Levine

cc: R. Rodman, Esq.
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