DON APPLICATION: PHS-19040915-HE

Addendum to Staff Report

On September 13, 2019 and pursuant to 105 CMR 100.510, the Massachusetts Department of Public Health (DPH) Staff for the Determination of Need (DoN) Program forwarded to all Parties of Record its written Staff Report relative to DoN application PHS-19040915-HE filed on behalf of Partners HealthCare System, Inc. with regard to Massachusetts General Hospital. In accordance with the regulation, Parties of Record were authorized to submit written comments related to the Staff's recommendation and any other conditions recommended in the Staff report.

On September 26, 2019 the Applicant sent a letter to DPH outlining its concerns with some of the language used in the report and its accompanying conditions. Staff acknowledges receipt of this letter and its concerns. In particular,

- We understand that Applicant and DPH are of different opinion regarding around a number of issues regarding Community Health Improvement, and particularly around the Condition placed regarding the use of Administrative Costs. It has been the practice of DPH to ask Applicants to justify the use of these administrative costs, requiring why those costs are necessary and how they will be used to address activities that enhance community engagement related practices (such as barriers to public participation in RFP processes).
- DPH staff found the Applicant's description of the use of Administrative Costs to be inadequate. However, DPH acknowledges the Applicant's need to more fully understand how the Community Advisory Board will recommend implementing strategies and conducting ongoing community engagement activities. Upon DPH approval of the Applicant's plans for Administrative Costs, the Applicant will be allowed to use those resources for said plans. A revised condition appears below.
- We understand that Applicant would like to modify how it reports the clinical use of the PET-MR. A revised condition appears below.

We also understand there was an error on the bottom of page 3 of the Staff Report; it should read:

- 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

We copy pages 34-40 below, and we agree to make changes to 2 conditions as outlined in red on the pages that follow.

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~~.

3. **If over any 6 month period, the clinical PET-MR scan volume increases more than 15% over the Applicant-provided volume projections in the table below, the Holder must notify the DoN program.** At that time, if DoN program staff determines 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. Of the total required CHI contribution of $5,110,234.80
   a. CHI Funding for Statewide Initiative: $1,252,007.52 (25% of CHI contribution – less the Administrative Funds)
   b. CHI Local Funding: $3,756,022.58 (75% of CHI monies – less the Administrative Funds)

   To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $1,252,007.52 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.

~~2. 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.~~

5. The Holder may use up to 20% of the total allowed Administrative Funds of $102,204 upon DON approval in order to hire project staff and/or consultants for the purpose of assisting the Community Advisory Board's decisions related to developing strategies and funding priorities as well as mechanisms for a transparent implementation process.

6. In order to receive approval for use of the remaining Administrative Funds, the Holder shall provide DPH with a detailed Plan for use of these 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 public participation in the CHI process. Upon DPH approval of this Plan, the Holder will be able to use the remaining Administrative Funds (less the amount already spent for project staff and/or consultants).

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[1] 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[2]. 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

[1] 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"

[2] 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[3] 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[4] instituted as a result of higher time intervals

[3] Holder stated that data will be reviewed quarterly
[4] 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[5] 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

[5] 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[6] 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[7] 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[8] instituted as a result of increasing critical value reporting

[6] Holder stated that low ratings will be " evaluated and policy changes instituted as deemed appropriate" for less than "good"
[7] Holder stated that "data will be reviewed quarterly by clinical staff."
[8] 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."