#### **APPLICANT QUESTIONS #2**

Responses should be sent to DoN staff at DPH.DON@State.MA.US

While you may submit each answer as available, please

- List question number and question for each answer you provide
- Submit responses as a separate word document, using the above application title and number as a running header and page numbers in the footer
- When providing the answer to the final question, submit all questions and answers in one final document
- Submit responses in WORD or EXCEL; only use PDF's if absolutely necessary. If "cutting and pasting" charts, provide them in a PDF so they can be clearly seen
- Whenever possible, include a table with the response
- For HIPAA compliance Do not include numbers <11.

#### **Factor 1a: Patient Panel Need**

- 1. Responses to DoN Questions #1 states that the Applicant expects to achieve 100% utilization within the first year of the project. Thereafter, the Applicant expects to maintain utilization at 100% (pg.3).
  - a. How will the Applicant have the capacity to increase procedure volume in years two through five of project implementation, when the ASC will reach 100% utilization within the first year of the project?

The Applicant has a significant backlog of patients waiting for Procedures (this includes patients scheduled seven-eight months out, patients needing urgent Procedures, as well as additional patients waiting to be scheduled that the Applicant is tracking outside of its electronic system in a folder), which is why the Applicant anticipates reaching 100% utilization within the first year of the project. With the Proposed Project doubling the Applicant's capacity, the Applicant expects the backlog to be within an acceptable range by the end of the second year of the project and further managed in subsequent years. As to further increases in volume, as discussed in Question #4(b) below, it is unclear to what extent the reopening of Brockton Hospital's endoscopy center coupled with the recent closing of Carney Hospital may impact WE's volume, but the potential of increased volume exists.

As to mitigating factors which are expected to potentially reduce expected volume, the *US Multi-Society Task Force on Colorectal Cancer* has proposed changes in guidelines concerning the extension of recall times for certain types of pathologies which may reduce some of the Applicant's recall volumes.<sup>1</sup> Once the backlog is managed and to

<sup>&</sup>lt;sup>1</sup> See, Sameer Gupta et. al, *Recommendations for Follow-up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer*, GASTROINTESTINAL ENDOSCOPY 91(3), (Mar. 2020), available at <a href="https://www.giejournal.org/article/S0016-5107(20)30036-5/fulltext">https://www.giejournal.org/article/S0016-5107(20)30036-5/fulltext</a>

the extent the above factors decrease the Applicant's volume, the Applicant anticipates that the utilization rate will maintain at 100% because of its capacity to increase procedure volume.

- 2. The application states that currently scheduling delays are seven to eight months.
  - a. Is there a difference in wait time for upper and lower endoscopy?

The wait time, which we are referring to as scheduling delay, is the same for both upper and lower nonurgent Procedures, which is about seven to eight months.

With respect to urgent Procedures, while the wait times for each type of Procedures are not tracked separately, as compared between urgent upper endoscopy and urgent lower endoscopy, the wait time for upper endoscopy is generally shorter. This is because upper endoscopies can be scheduled on shorter notice when there is a cancellation due to a simpler procedure preparation process for patients.

Moreover, when there is a cancellation, patients needing upper endoscopy are prioritized according to their needs so the wait times for different types of upper endoscopy may vary depending on the urgency level. For example, the scheduling of upper endoscopies for dysphagia or other acute issues receives higher priority than the evaluation of Gastroesophageal Reflux Disease ("GERD ") or the surveillance of Barrette's Syndrome. When needed, the Applicant may also add acute endoscopy patients to an already full schedule resulting in physicians providing overtime care.

b. Is there a difference in wait time for screening endoscopy and diagnostic endoscopy?

The wait time for screening endoscopy and diagnostic endoscopy is the same but the Applicant prioritizes scheduling of diagnostic endoscopy over screening endoscopy when there is a cancellation. All screening endoscopies are scheduled in the order that they are received. The Applicant tries to schedule diagnostic endoscopy according to the level of acuity. The Applicant tries to save some spots for urgent patients, but they are filled quickly due to the rising volume of urgent and diagnostic cases. As noted in question 1 above, urgent diagnostic endoscopies are scheduled in a canceled spot or by physicians providing care overtime if necessary.

3. Given no current guidelines exist on optimal wait times for endoscopy procedures in the US, how did the Applicant determine that two months is the appropriate wait time for accessing endoscopy procedures?

While national recommendations are lacking in this regard, Applicant is familiar with guidelines set in other Western countries which suggest that two (2) months is the appropriate wait time for accessing endoscopy procedures. For example, according to the National Health Service England, patients should wait no more than six (6) weeks for endoscopy tests that can diagnose

bowel cancer. <sup>2</sup> Similarly, as Applicant noted in its response to DON Questions #1(Q #11(b)), the Canadian Association of Gastroenterology's maximal wait times for selected referral indications can be summarized as follows: two (2) months for diagnostic colonoscopy; six (6) months for screening colonoscopy.<sup>3</sup>

In the context of United States, a study published in the Journal of General Internal Medicine in 2020 regarding trends in wait times for outpatient colonoscopy in the veteran's health administration ("VA") from 2008-2015 found the mean wait times in days for outpatient coloscopy following positive fecal occult blood test (FOBT) ranged from 47 to 55 days. The study found this to be a clinically acceptable range because evidence suggest that delays of more than six (6) months after a positive FOBT are associated with worse clinical outcomes. However, the study also noted that while VA colonoscopy wait times were well within a clinically acceptable range based on available evidence, there was often a disconnect between delays in care that may be justifiable based on medical evidence and what patient or health system perceives as appropriate. According to the study, there is typically "a great deal of patient anxiety upon receipt of a positive cancer screening test, emotions that are often best addressed with prompt scheduling and completion of follow-up testing. In addition, evidence shows that longer wait times are associated with lower overall patient satisfaction with care, and also affect patient perceptions of their providers and quality of care.

- Within 24 hours: acute gastrointestinal bleeding, esophageal food bolus or foreign body obstruction, clinical features of ascending cholangitis, severe acute pancreatitis (endoscopic retrograde cholangiopancreatography within 72 hours, if indicated), severe decompensated liver disease, acute severe hepatitis
- Within two weeks: High likelihood of cancer based on exam or imaging, painless obstructive acute
  jaundice, severe and/or rapidly progressive dysphagia or odynophagia, clinical features suggestive of
  active inflammatory bowel disease
- Within two months: bright red rectal bleeding, documented iron deficiency anemia, one or more
  positive fecal occult blood tests, chronic viral hepatitis, stable dysphagia (not severe), poorly controlled
  reflux/dyspepsia, chronic constipation or chronic diarrhea, new onset change in bowel habit, chronic
  unexplained abdominal pain, confirmation of a diagnosis of celiac disease (antibody test)
- Within six months: Chronic gastroesophageal reflux disease for screening endoscopy, screening colonoscopy, persistent (more than six months) unexplained abnormal liver enzyme tests

<sup>&</sup>lt;sup>2</sup> BOWERCANCERUK, Bowel Cancer Testing Waiting Times Remain High, With Targets Missed for Thousands of People (Nov. 12, 2020), available at <u>Bowel cancer testing waiting times remain high, with targets missed for thousands of people | Bowel Cancer UK</u>

<sup>&</sup>lt;sup>3</sup> William G. Paterson et. al; *Canadian consensus on medically acceptable wait times for digestive health care*, CAN J GASTROENTEROL 20(6): 411–23. (June 2006), available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2659924/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2659924/</a>, Here is the overview of recommended maximal wait times by acuity category:

<sup>&</sup>lt;sup>4</sup> Megan A. Adams et. al, *Trends in Wait Time for Outpatient Colonoscopy in the Veterans Health Administration, 2008-2015,* J Gen Intern Med 35(6):1776-82 (Published Online March 24, 2020), available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7280466/#:~:text=At%20the%20facility%20with%20the,26%20days%2C%20respectively">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7280466/#:~:text=At%20the%20facility%20with%20the,26%20days%2C%20respectively</a>).

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> Id.

These study findings reflect the Applicant's experience in its own Patient Panel – patients tend to get very upset if they have to wait extended times once they decide to undergo the Procedures, especially when they have a positive Fecal Immunochemical Test (FIT) or positive Cologuard test, and as noted in Question #2(b) above, WE prioritizes scheduling for diagnostic colonoscopies over screening for these reasons.

- 4. The application and responses to DoN Questions #1 state that recent expected and unexpected temporary and permanent closures of hospitals in the South Shore area have caused a decrease in access to spaces in the region for performing endoscopy procedures and an increase in Applicant's volume. The responses named the closures of Brockton Hospital and Good Samaritan Medical Center.
  - a. Which service closures at Good Samaritan Medical Center have impacted WE's volume?
    - The closure of the endoscopic center at the Good Samaritan Medical Center has impacted WE's volume.
  - b. Will the previous closure of Brockton Hospital continue to impact WE's volume, now that the hospital has reopened?

The endoscopy center at Brockton Hospital has not reopened yet. It is hard to predict how the reopening of the center will impact WE's volume. Some patients may prefer to return to Brockton Hospital, while others may prefer to continue receiving care at WE.

There is also a new development since the date of our application that may impact volume. Two WE physicians practiced at Carney Hospital for years prior to joining WE, and with the Carney Hospital's permanent closure on August 31st, the Applicant has already received many calls from former patients looking to re-establish care at WE. Thus, Applicant anticipates that at least some volume it loses may be replaced by patients coming in from Carney Hospital. Still, it is unclear at this point what the combined effect of a Brockton Hospital's endoscopy center reopening coupled with the Carney Hospital's closure will be on WE's volume but there is some potential for a net increase, subject to mitigating factors discussed in the response to question 1, above.

#### Factor 1: b) Public Health Value, Improved Health Outcomes And Quality Of Life; Assurances Of Health Equity

- 5. The application attributes need for the Proposed Project to wait times for accessing endoscopy services. Please provide any data or sources demonstrating the negative impact of delaying endoscopy procedures.
  - The benefit of early detection of colon cancer is well-established. As discussed in the application, colorectal cancer ("CRC") is the second most common cause of death due to cancer

in the United States.<sup>8</sup> It is also highly curable if it is found and treated early.<sup>9</sup> According to the American Cancer Society, colorectal cancer is 90% survivable when found early or in the local stage before it has spread.<sup>10</sup> Esophageal carcinoma also benefits from early detection.<sup>11</sup>

From a practical standpoint, long wait times also lead to various difficulties for patients, primary care providers, and the Applicant's practice. When Procedures are booked out seven (7) months in advance, it becomes quite challenging to find a way to appropriately schedule more urgent procedures. Extended wait time for Procedures also often leads to significant stress for patients concerned that delay will contribute to an adverse outcome.

6. Describe any strategies/processes in place at WE to better understand and address disparities in access to and utilization of WE's service within the Applicant's Patient Panel and service area.

To address any disparities in access to and utilization of WE's service within the Patient Panel and service area, the Applicant plans on working with Manet Community Health Center ("Manet") to provide educational materials on the importance of colorectal screening, and the importance of upper endoscopy for people experiencing certain risk factors, such as GERD, stomach ulcers, swallowing disorders, heartburn etc. to underserved populations in its service area. The Applicant has already been working with Manet to identify any barriers to obtaining care in the past and has developed relationships to expedite medical care for Manet's patients. The Applicant plans on expanding those relationships and exploring ways to streamline colonoscopy referrals.

<sup>&</sup>lt;sup>8</sup> <u>Key Statistics for Colorectal Cancer</u>, Am. CANCER Soc. ("ACS") (last revised Jan. 29, 2024) (<a href="https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society's%20estimates,men%20and%2018%2C890%20in%20women).

<sup>&</sup>lt;sup>9</sup> <u>Data Report November 2020 on Colorectal Cancer in Massachusetts</u>, Mass. DEPT. OF PUBLIC HEALTH (Nov. 2020) (available at: <a href="https://www.mass.gov/doc/data-report-on-colorectal-cancer-in-massachusetts-november-2020/download">https://www.mass.gov/doc/data-report-on-colorectal-cancer-in-massachusetts-november-2020/download</a>);

David Opong-Wadee, *ASCA Continues to Advocate for Full Coverage of Colonoscopies*, THE ASCA JOURNAL, (Mar. 29, 2024) (available at: <a href="https://www.ascfocus.org/ascfocus/content/articles-content/articles/2024/digital-debut/ascacontinues-to-advocate-for-full-coverage-of-colonoscopies].; *See*, Djenaba A. Joseph, et al, *Vital Signs: Colorectal Cancer Screening Test Use — United States*, 2018, NAT'L LIB. OF MED. (Mar. 13, 2020) (<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7075255/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7075255/</a>).

<sup>&</sup>lt;sup>10</sup> Supra, note 9

<sup>&</sup>lt;sup>11</sup> See, Tae H. Ro, et al., Value of screening endoscopy in evaluation of esophageal, gastric and colon cancers, 21(33) World J. Gastroenterol. 9693 (Sep. 07, 2015) (Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4562953/).