

Weymouth Endoscopy DON

1. Project Description

Weymouth Endoscopy, LLC (the “Applicant” or “WE”) is a freestanding single specialty ambulatory surgery center (“ASC”) established in 2004 located at 1085 Main St, South Weymouth, MA 02190 (“Main Site”). It is licensed by DPH as a clinic and certified by Medicare and MassHealth. WE provides the full spectrum of diagnostic and therapeutic upper and lower endoscopic services (“Procedures”) including routine diagnostic and therapeutic gastroscopy and colonoscopy at the ASC. WE is owned and operated by a group of six (6) physicians who are also the owners of an independent professional corporation, South Suburban Gastroenterology PC (“PC”), founded in 1990. PC’s medical practice is conveniently located in separate but adjacent space to the ASC.

The Applicant is filing a Notice of Determination of Need (“Application”) with the Massachusetts Department of Public Health (“Department”) for the expansion and relocation of the ASC to a larger facility located at 97 Libbey Industrial Parkway, Weymouth, Massachusetts 02189 (“Proposed Project”). The Applicant’s lease for the ASC at the Main Site expires in August 2025. Even if a renewal of the lease was an option, the current space is insufficient to meet the current needs of the Applicant’s patients, as demonstrated in this Application.

The Proposed Project consists of a newly renovated state-of-the-art freestanding ambulatory surgery center that will encompass approximately 9,466 gross square feet and will be able to accommodate the Applicant’s proposed expansion from its current three procedure rooms to six procedure rooms (the “New Center”). The procedure rooms in the New Center will be more spacious than the rooms in the ASC, which will better accommodate the clinical staff and equipment for improved collaborative teamwork and efficiency. There will be separate waiting rooms for the WE and PC patients. The Proposed Project is located only 2.3 miles away from its current location and is also conveniently accessible. It is located only 0.25 miles off of Route 3 and is about 0.2 miles from public transportation. As further discussed below in F1.e.i, the Applicant has received positive community feedback about the New Center’s location through its community engagement outreach.

The Proposed Project is necessary to meet the Applicant’s current demand for Procedures, but this Application also describes the ever-increasing demand for Procedures in Applicant’s Patient Panel and service area that will ensure that the New Center will be fully utilized. The expansion from 3 to 6 rooms will reduce but not eliminate the pent-up need for WE’s services. Both the Applicant and South Shore Hospital have a significant scheduling delay for Procedures (currently patients are waiting 7-8 months for an appointment as both locations are always fully booked). These significant scheduling delays coupled with the recent closures of hospitals on the South Shore have put further stress on the availability, and timely and convenient access to the Procedures. In addition, the prevalence of gastrointestinal disorders and related chronic conditions are on the rise which puts a higher demand on the Procedures. Colon cancer trends are

particularly concerning among people younger than 55 with the proportion of diagnoses increasing from 11% in 1995 to 20% in 2019.¹

The Applicant anticipates that the Proposed Project will provide patients with improved health outcomes and improved quality of life by creating additional access to high quality Procedures in a lower cost freestanding setting. The Applicant has sized the project to meet current need of the Applicant's Patient Panel who receive Procedures at either or both the Main Site and South Shore Hospital. The Applicant's goal is for patients to receive an appointment within two months of scheduling one. With more timely scheduling of procedures, there will be greater compliance by patients in obtaining necessary screenings and less stress due to reduced wait periods. Further, by improving access to screenings, patients will experience improved outcomes from earlier detection of cancers and precancerous lesions.

With the implementation of the Proposed Project, there will be no change in the complement of Procedures provided by WE at the New Center – only the reduction of scheduling delays through the concomitant increase in the quantity of procedures performed. Applicant expects to hire 2-3 additional physicians to reach full operating capacity at the New Center within the first year of operations. WE will continue to have the reserved block of time at the South Shore Hospital currently used for approximately 50% overflow patients and 50% for patients who have a medical necessity to have their Procedures in a hospital setting (including for patients of size the volume for which is increasing). WE's longest scheduling delays currently are for medically complex patients that require Procedures at the South Shore Hospital. Applicant anticipates that by shifting the overflow patients back to WE, there will be more availability at the South Shore Hospital to get these patients scheduled sooner.

Finally, the Applicant's physicians integrate their adjoining clinical consultative practice at the PC and their outpatient endoscopy practice at the Main Site for greater ease of access to seamlessly care for patients and coordinate all aspects of their patients care. Applicant's physicians are available for routine and urgent consultations at their PC offices and also provide 24 hour a day, seven days per week coverage for emergency consultations for inpatients at the South Shore Hospital and this will remain unchanged after the proposed relocation to the New Center. Notably, as further discussed below in F1.a.ii, the Application has received letters of support from the South Shore Health – which includes South Shore Hospital and South Shore Medical Center (South Shore affiliated primary care group) and from Healthcare South P.C.. Manet Community Health Center has also been supportive of the Proposed Project. In addition, WE physicians follow up with all patients primary care physicians as a matter of course. The Applicant has strong pre-existing relationships with area primary care providers including those noted above.

¹ One new physician has already been recruited from out of state contingent on the opening of the New Center, and Applicant is close to having commitments for additional physician staff.

F.1.a.i Patient Panel:

Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measure, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status and other priority populations relevant to the Applicant's existing patient panel and payer mix.

The Applicant's Patient Panel (the "Patient Panel")

The Applicant's Patient Panel is comprised of two sets of patients, with about 83% of its total patients being seen at the Main Site. As discussed above, the Applicant sees its remaining patients at the South Shore Hospital ("SSH Location") where it has a reserved block of time currently used for approximately 50% overflow patients and 50% for patients who have a medical necessity to have their Procedures in a hospital setting. For the purposes of transparency, the Applicant's Patient Panel is broken down by each site to describe the Patient Panel at the Main Site and the SSH Location. The current Patient Panel data used in this application is derived from patients who have received care at the Applicant's Main Site and SSH Location from 2021 to 2023.

I. Unique Patient Number

Table 1: Unique Patient Number

	FY17	FY18	FY19	FY20	FY21	FY22	FY23	Overall Growth Rate (FY21-FY23)
WE	4116	5466	6108	4604	6727	6870	7364	9.47%
SSH Location	593	756	1854	1264	1382	1314	1427	3.26%
Total	4709	6222	7962	5868	8109	8184	8791	8.4%

A. Main Site

The Patient Panel at the Main Site for the period 2021 and 2023 ranged from 6727 to 7365 unique patients. See Table 1. During this period, the Patient Panel grew approximately 9.47%. Except for reduction in 2020 due to the impact of COVID, the Applicant's Patient Panel at the Main Site has been consistently increasing over the last 5 years, with an approximately 20.57% increase when compared to its unique patients in 2019. The Applicant's patient mix consists of approximately 47% males and 53% females.

B. SSH Location

The Patient Panel at the SSH Location for the period 2021 and 2023 ranged from 1264 to 1427 unique patients. See Table 1. During this period, the Patient Panel grew approximately 3.26%. The growth at SSH Location is smaller than WE's location because South Shore Hospital has increasing need to use their endoscopy rooms for their inpatient population.² The Applicant's patient mix at the SSH Location is comparable to the Main Site, consisting of approximately 44% males and 56% females.

II. Multiple Procedures

The actual volume of Applicant's patients is always higher than the number of unique patients because a significant number of Applicant's Patient Panel also undergo multiple procedures (both upper and lower endoscopy). See Table 1b.

Table 2: Volume of Patients Undergoing Double Procedures

	Main Site						
	FY17	FY18	FY19	FY20	FY21	FY22	FY23
Multiple Procedures	262	288	338	412	619	603	719

	SSH Location						
	FY17	FY18	FY19	FY20	FY21	FY22	FY23
Multiple Procedures	185	162	98	89	122	132	152

² There is no guarantee that the current block at SSH will continue to be available to Applicant to the same extent that it is now.

III. Race

Table 3: Patients by Race

	Main Site			SSH Location		
	FY21	FY22	FY23	FY21	FY22	FY23
White	6599	6752	7236	1325	1252	1318
Asian	28	14	11	<11	12	16
Other/More than 1 race/Black/African American/Unreported/Refused/³	100	104	117	52	50	93
Total	6727	6870	7364	1382	1314	1427

The Patient Panel (self-identified) is a predominately white population. See Table 3.

IV. Age

Table 4: Patients by Age

	Main Site			SSH Location		
	FY21	FY22	FY23	FY21	FY22	FY23
0 to 44⁴	497	539	774	262	224	314
45-50	296	497	892	36	44	50
50-69	4201	4271	4360	599	557	566
69+	1733	1563	1338	485	489	497
Total	6727	6870	7364	1382	1314	1427

The majority of the Applicant's Patient Panel are between the ages of 50-69. The size of the Patient Panel has dramatically increased in the Main Location for the 19-69 age group from 2019 to 2023, with a decrease of patients in 69+ age group. The decrease in the oldest cohort is due to the shift in national guidelines that places less of an emphasis on colonoscopy in patients over the age of 75, increased focus on targeting younger population, and the recent and increasing use of home test kits for colorectal cancer screening such as Cologuard. The increase in the size of the Patient Panel does not appear as dramatic at the SSH Location because South Shore Hospital has increasing need for their endoscopy rooms for their inpatient population. The impact of the lowered recommended screening age recommendation from 50 to 45 is apparent in the Main Site's data, as demonstrated by 201% increase from year 2021 to year 2023 in this cohort.

³ In the category Other, More than 1 race, Black/African American and American Indian, the cell count was less than 11 so it was combined with the category Unreported/Refused to protect patient privacy.

⁴ In the category 0 to 18 the cell count was less than 11 so it was combined with the category 19-44 to protect patient privacy.

V. *Patient Panel by Service Area/Towns*

Table 5: Patients by Service Area/Towns and Cities or Zip Code

Main Site					SSH Location				
Zip code	town	FY21	FY22	FY23	Zip Code	Town	FY21	FY22	FY23
02043	Hingham	526	514	606	2043	Hingham	83	72	73
02050	Marshfield	440	443	420	2050	Marshfield	62	47	54
02066	Scituate	415	433	450	2066	Scituate	59	59	56
02339	Hanover	316	357	403	2339	Hanover	51	39	42
02360	Plymouth	330	325	342	2190	South Weymouth	68	51	52
02190	South Weymouth	302	312	343	2370	Rockland	70	55	45
02370	Rockland	269	291	283	2184	Braintree	63	51	64
02359	Pembroke	288	304	314	2169	Quincy	58	51	57
02361	Norwell	278	175	289	2045	Hull	55	36	48
02332	Duxbury	286	293	336	2189	Weymouth	55	39	40
02184	Braintree	264	321	330					

The Applicant's patients mainly reside in Plymouth and Norfolk country. Table 5 provides a breakdown of the FY21-FY23 patient origination from each of the primary cities and towns comprising the Applicant's service area for the Main Site and SSH Location respectively.

VI. *Patient Panel by Payer Mix*

Table 6: Patient Panel by Payer Mix⁵

	Main Site			SSH Location		
	FY21	FY22	FY23	FY21	FY22	FY23
Medicaid/Medicaid MCO⁶	304	285	776	114	130	49
Medicare	2391	2195	2072	569	497	550
Medicare MCO	21	51	114	137	59	132
Commercial/Other (self pay, workers'	4011	4339	4402	562	628	696

⁵ Prior to FY22, Applicant was only eligible to receive Medicaid reimbursement as an unenrolled provider where MassHealth was the secondary payer for dually eligible patients.

⁶ In the category Medicaid MCO, the cell count was less than 11 so it was combined with the category Medicaid to protect patient privacy.

comp, Health Safety Net (HSN)⁷						
Total	6727	6870	7364	1382	1314	1427

A significant portion of the Patient Panel is insured by commercial payers, with 40% and 45% government payors at the Main Site and SSH Location respectively. See Table 6.

VII. ACOs or Alternative Payment Models

The Applicant does not participate in any ACOs or other risk contract or alternative payment models.

F1.a.ii Need by Patient Panel:

Provide supporting data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question F1.a.i that demonstrates the need that the Proposed Project is attempting to address. If an inequity or disparity is not identified as relating to the Proposed Project, provide information justifying the need. In your description of Need, consider the principles underlying Public Health Value (see instructions) and ensure that Need is addressed in that context as well.

Through the Proposed Project the Applicant seeks to meet the existing and growing needs of its Patient Panel by expanding access to high quality Procedures in a clinically appropriate and cost-effective setting. Applicant evaluated its historical utilization and scheduling delays to determine that with the addition of 3 procedure rooms (and the assumed recruitment of 2-3 additional physicians), the Proposed Project would reach full operating capacity within the first year of operations. More specifically, the Proposed Project will address current capacity issues and help meet growing demand at both the Main Site and the SSH Location. It also will allow more flexibility for urgent Procedures at the Main Site, thereby increasing access to the SSH Location for patients who need to have their Procedures at the hospital due to medical necessity.

Historic Utilization

The demand for colorectal cancer (“CRC”) screening and other diagnostic endoscopic procedures has generally increased for a variety of reasons including expanding screening guidelines, increased awareness of the importance of CRC screening, and increasing indications for screening procedures based upon better understanding of the implications of a wide variety of

⁷ In the category Other, the cell count was less than 11 so it was combined with the category Commercial to protect patient privacy.

genetic abnormalities. The Applicant also has experienced a significant increase in demand in its large Patient Panel established over its 20+ years of operations. The Applicant currently has 3 procedure rooms at the Main Site and a reserved block of time at the SSH Location, but demand has created a significant scheduling delay (currently 7-8-month) at both the Main Site and SSH Location due to the confluence of factors further discussed below. Such a long scheduling delay is especially problematic because Applicant has established patients who develop symptoms that often require urgent evaluations. These patients cannot wait months or even weeks to be evaluated because without timely treatment they can develop gastrointestinal bleeding, colitis flares, or dysphagia and have difficulty eating. Similarly, many current patients who have an urgent need to have their Procedures done in a hospital setting because of their age or medical comorbidities are also having to wait weeks or months because the Applicant's SSH Location schedule is also full. Making patients wait long times for screening can lead to negative impacts on patient quality of life, treatment and outcomes. The Applicant uses best efforts to timely accommodate the urgent needs of its Patient Panel but the lack of flexibility in scheduling creates tremendous stress for all involved.

With additional procedures rooms to expand access to care, Applicant will be able to provide more timely diagnostic and therapeutic endoscopic evaluations thereby optimizing preventative health care, improving patient satisfaction, and improving patient quality of life. With additional spaces to perform endoscopic procedures, the Applicant will be able to employ additional gastroenterologists to address the overwhelming demand for endoscopic evaluation. The relocation of the ASC and addition of 3 procedure rooms is critical to meet the current Patient Panel demand for Procedures because the current lease for the Main Site is expiring, the option to renew was not offered, and expansion at the Main Site was not feasible anyway.

Current Need & Continuing Growth Due to Population Growth and Shifting Care Landscape

In addition to the current need not being met by Applicant at the Main Site, the projected volume of the Applicant's unique patients' and the number of total Procedures performed is expected to continue to grow over the next few years, as set forth in the table below:

Volume	Volume for the year ended December 31, 2023	Projected 2025 volume in the New Center	Projected 2026 volume in the New Center	Projected 2027 volume in the New Center	Projected 2028 volume in the New Center	Projected 2029 volume in the New Center
Total Procedures Performed	9934	10,805	11,886	13,074	14,382	15,820
Total Unique Patient Volume	7364	8,272	9,099	10,009	11,010	12,111

According to the South Shore Chamber of Commerce, there are also large multi-unit housing developments in progress in the area which are further expected to add to the population of the South Shore which will likely compound the existing demand.⁸

In addition, 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. South Shore Hospital has been operating at 110% to 120% capacity during the last 4-5 months, which may also contribute to more referrals to Applicant for Procedures. The Applicant has support for the Proposed Project from the hospital and local community providers including South Shore Medical Center, Manet Community Health Center, and Healthcare South, who each refer their patients to WE. See Exhibit A for letters of support from officials at the South Shore Health⁹ and Healthcare South, P.C. describing the unmet need for CRC and expressing enthusiasm for increased access to Procedures for their patients through the Applicant's proposed expansion.

Clinical Drivers of Patient Panel Need

The current backlog and anticipated rising need for Procedures is due to a confluence of factors:

1. Colorectal cancer trends nationally and in Massachusetts

Colorectal cancer is the second most common cause of death due to cancer in the United States¹⁰, In 2024, it is expected to cause approximately 53,010 deaths.¹¹ According to the American Cancer Society, about 106,590 new cases of colon cancer are projected to be diagnosed in 2024, and 46,220 new cases of rectal cancer.¹² According to the Department of Public Health November 2020 report on Colorectal Cancer, in Massachusetts, CRC is one of the most common cancers diagnosed and a leading cause of cancer-related deaths.¹³ According to the same report, many people in Massachusetts who have CRC are not being diagnosed early enough, and in fact, more than half do not have their cancer diagnosed until after it has spread beyond the colon or rectum. CRC is one of the most preventable forms of cancer if it is detected early enough. When early signs of CRC are identified, it can be averted and more effectively

⁸ Anecdotal information from the Applicant's architect.

⁹ The South Shore Hospital provides colorectal surgery at its Hingham ASC but there is no current or planned overlap of services.

¹⁰ Key Statistics for Colorectal Cancer, AM. CANCER SOC. ("ACS") (last revised Jan. 29, 2024) ([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\).](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).)

¹¹ *Id.*

¹² *Id.*

¹³ See, *Data Report November 2020 on Colorectal Cancer in Massachusetts*, MASS. DEPT. OF PUBLIC HEALTH (Nov. 2020) (available at: <https://www.mass.gov/doc/data-report-on-colorectal-cancer-in-massachusetts-november-2020/download>).

treated.¹⁴ According to the American Cancer Society, the 5-year relative survival rate when CRC is found at an early stage before it has spread is about 90%.¹⁵ As discussed below, colonoscopy is the ‘gold-standard’ for screening, detection, and treatment of CRC, so the need for Procedures is great.

2. Rising cases of colorectal cancer in younger adults and lowered screening age recommendation by U.S. Preventative Services Task Force

Cancer rates generally are rising among younger adults, and colon cancer trends among younger adults have been particularly disturbing with diagnoses and death rates on the rise in patients younger than 55.¹⁶ The proportion of CRC diagnoses among the 55 and younger group has increased substantially - from 11% in 1995 to 20% in 2019,¹⁷ with the rates increasing steadily by 1% to 2% a year since the mid-1990s.¹⁸ In older adults, the death rate from CRC has been dropping for several decades, in part because they screen for CRC regularly. In younger adults, death rates have been increasing by about 1% per year for about 2 decades,¹⁹ likely because the disease is diagnosed at a more advanced age due to lack of early detection.

Recognizing the need for screening in the younger population, the U.S. Preventative Services Task Force lowered the screening age recommendation for colorectal cancer from 50 to 45 in 2021.²⁰ For those with a family history of CRC, guidelines recommend screening starting at age 40 or 10 years before the age the immediate family member was diagnosed. With this lowered screening age recommendation, and insurance now covering screening of adults in the 45-50 age group, the demand for screening Procedures has increased nationally, and that demand is similarly reflected in Applicant’s Patient Panel and the South Shore population generally. In addition, we can expect that the demand will continue to increase as younger patients will also require repeat screenings. The Proposed Project is critical to meet the increasing demand from Applicant’s younger Patient Panel without further exacerbating Applicant’s scheduling delays.

3. Superiority of colonoscopy to alternative methods of testing

Primary Care Physicians (“PCPs”) sometimes recommend the use of home test kits such as Cologuard (stool DNA testing) and Hemoccults (fecal blood test) to patients who meet certain

¹⁴ *Id.*

¹⁵ *Can Colorectal Polyps and Cancer Be Found Early?*, ACS (last revised Jan. 29, 2024)

(<https://www.cancer.org/cancer/types/colon-rectal-cancer/detection-diagnosis-staging/detection.html>).

¹⁶ Erica Carbajal, *‘It doesn’t wow us anymore’: Experts on what healthcare needs more of as cancer strikes younger*, BECKER’S HOSPITAL REVIEW. (last updated Feb. 15, 2024)

(https://www.beckershospitalreview.com/oncology/it-doesnt-wow-us-anymore-experts-on-what-healthcare-needs-more-of-as-cancer-strikes-younger.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=2104E6464178D0W).

¹⁷ *Id.*

¹⁸ *Supra*, note 1.

¹⁹ *Id.*

²⁰ *See, Colorectal Cancer: Screening*, U.S. PREVENTATIVE SERVICES TASK FORCE (May 18, 2021)

(<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>).

criteria. While these tests are helpful particularly in encouraging anxious patients and in keeping them off procedures waitlists, they are not recommended as a replacement for a colonoscopy.²¹ Colonoscopy remains the “gold standard” of CRC prevention because it is a one-stop exam in which potential issues can be recognized, cancer can be ruled out or detected, and any suspicious polyps (abnormal growths that could become cancer) can be removed before they have time to grow and spread. In addition, Colonoscopies can detect 95% of large polyps while Cologuard can only detect 42% of large polyps, and while colonoscopy can detect cancer early before it develops and can also help prevent it, Cologuard tests are designed to detect cancer not prevent it. Moreover, Cologuard has a 12% false-positive rate,²² it does not detect a majority of large precancerous polyps, and the test is not indicated for high-risk patients or those with gastrointestinal symptoms.²³ Therefore, there is a higher need for colonoscopy procedures due to their clear superiority over other less alternative methods.

4. Increase in demand due to the increasing use of home test kits

The less invasive stool-based home test kits themselves have contributed to higher demand for colonoscopy procedures. Due to the convenience a home-test kit offers, people use them who might otherwise not have screened. However, when a positive result is captured, a diagnostic colonoscopy is required to confirm the results due to the high degree of false positives and to remove cancerous polyps.²⁴ Applicant has experienced an increase in demand for the Procedures in its Patient Panel from patients repeating home test kit results.

5. Increased volume due to higher Adenoma detection rates and other risk factors

While a healthy patient with no symptoms or family history of CRC does not need another colonoscopy for 10 years, people who are at high-risk (e.g. who have a family history of CRC, who have had certain types of polyps removed during a colonoscopy, who have had colon or rectal cancer, etc.) need to get colonoscopy more frequently.²⁵ Applicant’s Adenoma Detection Rate (“ADR”), which is the “gold standard” for quality measures in CRC screening,²⁶ is excellent due to the high quality examination it provides. Compared to the national benchmark for ADRs which is 25% overall²⁷, the Applicant’s ADR in the year 2023 ranged from 45-52%. Not only does this higher rate signify the high quality screening provided by the Applicant, but it also signifies that the need for Applicant’s Procedures at any given time is higher than the

²¹ *Is a Cologuard Test as Good as a Colonoscopy?*, GASTROENTEROLOGY CONSULTANTS OF SAN ANTONIO (Feb. 08, 2023) (<https://www.gastroconsa.com/is-cologuard-as-good-as-colonoscopy/>).

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *American Cancer Society Guideline for Colorectal Cancer Screening*, ACS (last revised Jan. 29, 2024) (<https://www.cancer.org/cancer/types/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>).

²⁶ Brian Liem and Neil Gupta, *Adenoma Detection Rate: the Perfect Colonoscopy Quality Measure or is There More?*, TRANSL GASTROENTEROL HEPATOL (March 21, 2018) (available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5897691/>).

²⁷ *Id.*

Applicant's current or projected unique patient volume as patients detected with adenoma need to get another colonoscopy more frequently - within 3-7 years.

6. Increasing rate of esophageal cancer in younger people

Esophageal cancer, which historically was rare in people aged 54 and below, has been increasing steadily between 1975 and 2015 by nearly 3% each year.²⁸ Some of the risk factors for esophageal cancer include but are not limited to increasing age, tobacco and alcohol use, Gastroesophageal reflux disease, developing Barrett's esophagus, physical inactivity, poor diet, obesity, etc.²⁹ With early detection, esophageal cancer can be treated more easily, more successfully and more cost effectively so regular screening is recommended for people with several risk factors.³⁰ Many of Applicant's patients also have multiple risk factors listed above, so Applicant anticipates an increasing need for esophageal endoscopy in its Patient Panel.

7. Recent MassHealth contract

As a single-specialty ASC, Applicant was not eligible to receive a provider contract with MassHealth until 2022. In just one year, the number of MassHealth patients seen at WE increased substantially (from 268 in 2022 to 454 in 2023). Applicant anticipates that its Medicaid caseload will continue to grow as availability is publicized. The expanded and convenient new location also will facilitate access to MassHealth recipients.

8. Increased demand due to patient choice.

When given a choice, patients prefer receiving care in ASCs closer to their homes than in hospitals because ASCs allow patients greater convenience and control over their care and because patients are able to receive high quality care at a lower cost setting with improved clinical outcomes.³¹ The New Center is located only 2.3 miles from its current location and is highly accessible. It has ample parking, it is only .25 miles from Route 3, and less than 5 minutes walking distance from an MBTA bus stop. Due to the amenities and accessibility the Proposed Project offers, the Applicant's existing Patient Panel will likely be interested in continuing to receive their care at WE. Additionally, with the Applicant's expansion and increased capacity, more people in the area may be interested in also receiving care at the WE.

²⁸ D.M. Pollock, *What is the Most Common Age for Esophageal Cancer?*, MED. NEWS. TODAY (Last updated Sep. 28, 2023) (<https://www.medicalnewstoday.com/articles/esophageal-cancer-age-range#risk-factors>).

²⁹ *Id.*

³⁰ *Id.*

³¹ *Health Policy Commission: Meeting of June 7, 2023* at 5, MASS HEALTH POL. COMM. (Jun. 07, 2023) ("They (ASC) provide comparable care to patients than an HOPD but at a lower price for patients, there is not a variation in quality as there is a variation in price").

F1.a.iii Competition:

Provide evidence that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending. When responding to this question, please consider Factor 4, Financial Feasibility and Reasonableness of Costs.

The Proposed Project is intended to expand access to the Applicant's services in the community to meet its current demand (which is also growing). The Proposed Project will compete on the basis of price, total medical expenses ("TME"), provider costs, and other recognized measures of healthcare spending by continuing to offer high quality Procedures in a lower cost setting to the Patient Panel but with improved clinical and operational efficiency. As also discussed below in Factor 2a, studies have found that ASCs have better clinical quality outcomes than a Hospital Outpatient Departments ("HOPD") as evidenced by their comparatively faster recovery time, lower infection, mortality, and morbidity rates, and lower rates of hospital revisits and readmissions post procedure as compared with patients treated in hospitals.³²

As also later discussed in Factor 2a, ASCs provide a lower-cost alternative to higher-cost HOPDs for the same surgical procedures.³³ ASCs specializing in endoscopy are able to compete with HOPDs by providing equivalent or better clinical outcomes at a reduced cost and much more efficiently. ASCs can achieve cost-savings by keeping overhead costs low and maximizing operational efficiencies.³⁴ This is especially true for single-specialty ASCs like the Applicant as it only needs to maintain the equipment, supplies, and staff needed for the specialty it offers. The cost savings are reflected in lower procedure costs for patients. Medicare reimbursement rates for ASCs are 58% of the amount paid to HOPDs on average for all eligible procedures, including endoscopy³⁵ which can translate into more than \$2.3 billion in savings for the Medicare program and its beneficiaries annually.³⁶ ASCs have the potential to save the Medicare program and its beneficiaries up to \$57.6 billion more over the next decade.³⁷

Similarly, as also discussed in the Application, there is an extended scheduling delay for Procedures in the Applicant's service area. The area's main hospital system, South Shore Hospital, has been operating at capacity for months, there is a significant unmet need in the area, and the providers in the area are supportive of the Applicant's Proposed Project. By expanding

³² Louis Levitt, M.D., *The Benefits of Outpatient Surgical Centers*, THE CENTERS FOR ADVANCED ORTHOPAEDICS (Jun. 15, 2017) (<https://www.cfaortho.com/media/news/2017/06/the-benefits-of-outpatient-surgical-centers>); and Mark A. Warner, et. al., *Major Morbidity and Mortality Within 1 Month of Ambulatory Surgery and Anesthesia*, 270(12) JAMA 1437 (Sep. 22, 1993) (available at: <https://jamanetwork.com/journals/jama/article-abstract/408575>).

³³ *Report to the Congress: Medicare Payment Policy Chapter 5: Ambulatory Surgical Center Service: Status Report*, MEDPAC (Mar. 15, 2022) ("evidence suggests that ASCs are a lower-cost setting than HOPDs. Studies that used data from the National Survey of Ambulatory Surgery found that the average length of time for ambulatory surgical visits for Medicare patients was 25 percent to 39 percent shorter in ASCs than in HOPDs, which likely contributes to lower costs in ASCs (citing Hair et al. 2012, Munnich and Parente 2014); HPC 2023 cost trends report (pg. 28).

³⁴ See, *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, AMBULATORY SURGICAL CENTERS ASSOCIATION (Sep. 2013) (available at <https://www.ascassociation.org/asca/about-ascs/savings/medicare-cost-savings/medicare-cost-savings-tied-to-ascs>).

³⁵ Id.

³⁶ Id.

³⁷ Id.

the services at Applicant's New Center, the demand for Procedures at the higher cost HOPDs and the scheduling delays will be alleviated. With timely scheduling, patients will be able to prevent, diagnose and/or treat their diseases or conditions earlier on when they are less serious and more treatable, which will also contribute to overall cost containment. Therefore, by expanding ASC capacity to provide existing, clinically appropriate patients with their Procedures, both patients and payers will realize cost savings from the Proposed Project.

F1.b.i Public Health Value /Evidence-Based:

Provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need that Applicant has identified.

The Applicant's Proposed Project seeks to expand its freestanding single specialty ambulatory surgery and to relocate within the same service area to the New Center in order to meet the unmet existing Patient Panel need (which continues to increase). The clinical value of endoscopy to diagnose and treat digestive health diseases and conditions, and the clinical value of ASCs as an alternative care delivery site to hospital-based surgery is supported by extensive literature, as described below. Moreover, by increasing the capacity to provide services in a cost-effective setting, and reducing the scheduling delays, all of which enhance the patient experience, the Applicant aims to improve patient compliance with screening and follow-up care thereby improving patient outcomes and further reducing health care expenditures.

Clinical Value of Endoscopy

As discussed in F.1.a.ii, there is a significant need for Applicant's services. CRC ranks as the second deadliest cancer in the US after lung cancer, and is a serious threat despite being the most preventable form of cancer if detected early.³⁸ Esophageal carcinoma, which also benefits from early detection, is the eighth most common cancer and sixth leading cause of cancer-related deaths.³⁹ Colonoscopy and upper endoscopy are each recognized as the "gold standard" for diagnosing colon cancer and esophageal cancer, respectively, due to the superiority of such procedures over the alternative methods.⁴⁰

Endoscopy is a nonsurgical procedure used to examine the digestive tract using an endoscope, a flexible tube with a light and camera.⁴¹ The more commonly known procedures are upper endoscopy and lower endoscopy, both of which are performed at Applicant's ASC. Upper endoscopy is a procedure in which an endoscope is passed through the mouth and throat into the esophagus to allow examination of the esophagus, stomach, and upper part of the small

³⁸ David Opong-Wadee, *ASCA Continues to Advocate for Full Coverage of Colonoscopies*, THE ASCA JOURNAL, (Mar. 29, 2024) (available at: <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2024/digital-debut/asca-continues-to-advocate-for-full-coverage-of-colonoscopies>).

³⁹ 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/>).

⁴⁰ Id.; and *Colorectal Cancer: What You Should Know About Screening*, FDA (Mar. 28, 2024) (<https://www.fda.gov/consumers/consumer-updates/colorectal-cancer-what-you-should-know-about-screening>).

⁴¹ *What is an Endoscopy*, HEALTHLINE (last reviewed Mar. 12, 2018) (last visited May 28, 2024) (<https://www.healthline.com/health/endoscopy>).

intestine.⁴² In lower endoscopy, endoscopes are passed into the large intestine through the rectum to examine the colon,⁴³ and depending on whether the whole colon is examined or only the lower part of colon and rectum, the procedures are called colonoscopy or sigmoidoscopy respectively.⁴⁴

The clinical value of endoscopy in evaluating, diagnosing, and treating digestive diseases and conditions including esophageal, gastric, and colon cancers is well-documented.⁴⁵ Endoscopy is a vital investigative and diagnostic tool that allows a trained doctor to get a clearer and more accurate picture of digestive system abnormalities and issues in a safe, minimally invasive and effective way. It enables gastroenterologists to evaluate internal organs, diagnose abnormalities and problems, and begin early treatment of certain conditions that may signal or result from cancer (e.g. removal of polyps and foreign object, dilation of strictures) while avoiding traditional surgery and large incisions.⁴⁶ Endoscopy is the most thorough method of screening for cancer detection in its early form when it is relatively less difficult to treat, while also helping to prevent further disease progression through the treatment accompanying the procedure.⁴⁷

Value of ASCs as an Alternative Care Delivery Site

ASCs provide high quality, specialized surgical services due in part to the inherent clinical and operational efficiencies that flow from focusing on a specific category or categories of lower acuity surgical cases, as further described below.⁴⁸ Studies show improved health outcomes for patients at all risk levels undergoing outpatient procedure at ASCs.⁴⁹ Studies also show lower surgical site infection rates in ASC patients compared to patients whose procedures were performed in a HOPD (4.84 in 1,000 patients and 8.95 per 1,000 patients respectively).⁵⁰ Surgeries performed in an ASC are generally of shorter duration and patient recovery time is

⁴² *Upper Endoscopy*, ACS (Jan. 14, 2019) (<https://www.cancer.org/cancer/diagnosis-staging/tests/endoscopy/upper-endoscopy.html>).

⁴³ Ro, *Supra*, note 34.

⁴⁴ *Id.*

⁴⁵ DPH EMERSON ENDOSCOPY AND DIGESTIVE HEALTH CENTER, LLC., STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED 9, 13 (Feb. 2021) (available at: <https://www.mass.gov/doc/emerson-endoscopy-and-digestive-health-center-staff-report/download>); See, Ro *supra*, note 34.

⁴⁶ *Supra*, note 34.

⁴⁷ *Id.*

⁴⁸ Elizabeth L. Munnich, Stephen T. Parente, *Returns to specialization: Evidence from the outpatient surgery market*, 57 J. Health Econ. 147 (Jan. 2018) (available at: <https://pubmed.ncbi.nlm.nih.gov/29274521/>); and Miho J. Tanaka, M.D., *Ambulatory Surgery Centers Versus Hospital-based Outpatient Departments: What's the Difference?*, AM. ACAD. OF ORTHOPAEDIC SURGEONS (Sep. 01, 2019) (<https://www.aaos.org/aaosnow/2019/sep/managing/managing02/>).

⁴⁹ *Id.* Munnich; and Sahely Mukerji, *Study Examines Patient Outcomes Across Settings*, THE ASCA JOURNAL (June 2018) (available at: <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2018/digital-debut/study-examines-patient-outcomes-across-settings>).

⁵⁰ Angie Stewart, *Half The Cost, Half The Risk' At ASCs Versus Hospitals — Dr. Shakeel Ahmed Makes The Case For Upheaving Referral Patterns*, BECKER'S ASC REVIEW (June 9, 2020) (<https://www.beckersasc.com/asc-coding-billing-and-collections/half-the-cost-half-the-risk-at-ascs-versus-hospitals-dr-shakeel-ahmed-makes-the-case-for-upheaving-referral-patterns.html>); *SSI Rates: Hospitals vs. ASCs, 2010*, BECKER'S CLINICAL LEADERSHIP (Feb. 14, 2014) (<https://www.beckershospitalreview.com/quality/ssi-rates-hospitals-vs-ascs-2010.html>).

faster than cases performed in a hospital.⁵¹ Surgical procedures performed in ASCs are associated with reduced morbidity and mortality rates.⁵² Patients who undergo outpatient procedures in ASC are also less likely to visit an ER or be admitted to the hospital than those treated in a HOPD.⁵³

As noted above, since ASCs focus on a more limited set of medical specialties compared to a HOPD, they allow for significant savings due to more efficient use of time and resources.⁵⁴ In the ASC setting, facilities are designed for the specialty services they provide and are tailored to the specific needs of their patients, thus enabling ASCs to maximize the use of space and staff for their needs. Single-specialty ASCs such as Applicant are particularly able to streamline overhead expenses through the use of consistent staffing, laboratory, medication, and imaging equipment.⁵⁵ In the ASC setting, procedures can be scheduled more timely and conveniently, specially trained and highly skilled staff can be assembled, and the equipment and supplies best suited to the specialty can be used.⁵⁶ The narrow scope of services provided by a single-specialty ASC allows for efficiencies that cannot be created in hospitals, and the resulting savings are reflected in lower procedure costs. In addition, ASCs allow intensified quality control processes, the ASC patients have the ability to bring concerns directly to the physician operator with direct knowledge about the patient's case and ASCs are also not impacted by the schedule disruptions that can occur in hospital settings.⁵⁷ Patients have reported a 92% satisfaction rate with both the care and service they receive from ASCs.⁵⁸

Evidence also shows that ASCs are a lower cost alternative to hospitals for outpatient surgical procedures.⁵⁹ The 2023 Massachusetts Health Policy Commission ("HPC") Cost Trends Report found that compared to the same services delivered in a HOPD setting, ASCs typically had lower commercial prices for their services.⁶⁰ In 2021, common surgeries at ASCs cost 27 to 57 percent less compared to services in a HOPD.⁶¹ Both Medicare and MassHealth pay lower rates for the

⁵¹ Levitt, *supra* note 25.

⁵² Warner, *supra* note 25.

⁵³ Munnich, *supra* note 41; Mukerji, *supra* note 42.

⁵⁴ Levitt, *supra* note 25; and Michael Barbella, *The ABCs of ASC Cost Savings*, ORTHOPEDIC DESIGN & TECHNOLOGY (Mar. 22, 2017), (https://www.odtmag.com/issues/2017-03-01/view_columns/the-abcs-of-asc-cost-savings/).

⁵⁵ Dennis C. Crawford, et al., *Clinical and Cost Implications of Inpatient Versus Outpatient Orthopedic Surgeries: A Systematic Review of the Published Literature*, 7 ORTHOPEDIC REV. 116 (Dec. 2015) (available at: <https://orthopedicreviews.openmedicalpublishing.org/article/23194-clinical-and-cost-implications-of-inpatient-versus-outpatient-orthopedic-surgeries-a-systematic-review-of-the-published-literature>).

⁵⁶ ASCs: A Positive Trend in Health Care, ADVANCING SURGICAL CARE (Last visited: May 31, 2024) (<https://www.ascassociation.org/advancingsurgicalcare/aboutasc/industryoverview/apositivetrendinhealthcare>).

⁵⁷ *Id.*

⁵⁸ *Id.* (citing Press-Ganey Associates, "Outpatient Pulse Report," 2008).

⁵⁹ *Supra*, note 24 ("They (ASC) provide comparable care to patients than an HOPD but at a lower price for patients, there is not a variation in quality as there is a variation in price").

⁶⁰ *Meeting of the Market Oversight and Transparency Committee* 6, MASS HEALTH POL. COMM. (Feb. 15, 2024) (<https://www.mass.gov/doc/presentation-2152024-moat-meeting/download>).

⁶¹ *Id.*

same services provided in an ASC compared to a HOPD setting.⁶² While lower prices at ASCs translate to lower patient cost sharing,⁶³ the quality of care is not compromised and in fact, patient quality and safety at the ASCs is comparable or sometimes better than the care delivered at a HOPD, as described above.⁶⁴ Lower cost of care also encourages patient compliance.

For all the reasons described above, there is a significant need for the Applicant's Proposed Project. Despite CRC being the second deadliest but largely preventable cancer in the US, nearly one-third of U.S. adults are not getting screened for colon cancer as recommended.⁶⁵ Expanding Applicant's capacity can help improve CRC screening compliance by increasing access to affordable, community-based CRC screenings. Additionally, as discussed throughout the Application, there is a significant scheduling delay (nearing 7-8 months) at both the ASC at the Main Site and SSH Location. Expanding capacity at the ASC will not only help mitigate the scheduling delay at the Main Site but it will also help reduce the current overflow scheduling at the SSH Location so that the Procedures performed by Applicant at the hospital can be primarily reserved for reasons of medical necessity.

F1.b.ii Public Health Value/Outcome-Oriented:

Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.

The Applicant anticipates that the Proposed Project will provide patients with improved health outcomes and quality of life by preserving and creating additional access to high quality endoscopy in a freestanding and conveniently accessible setting closer to their homes, with care that is delivered more timely and in a more efficient and effective facility contributing to improved care delivery and patient experience. As more fully discussed in the factors above, there is a significant need for Applicant's services in its current Patient Panel which has experienced continuous growth in the number of Procedures over the past several years (except during the COVID-19 Pandemic), and which growth is expected to continue. A key reason among the various reasons described in this application for such growth is the lowered screening age recommendation for CRC screening. In addition, Applicant has been able to enroll in the MassHealth program improving health equity in its Patient Panel as discussed in Factor 1.b.iii. Applicant's Proposed Project will help ensure that its Patient Panel has continued and expanded access to Procedures thus significantly mitigating the current seven to eight-month scheduling delay; the more timely a gastrointestinal disease/condition can be detected through endoscopy,

⁶² *Supra*, note 55

⁶³ Alison Kuznitz, *HPC: Non-Hospital surgical centers cheaper, but rare, in Mass.*, 22 NEWS WWLP (Feb. 15, 2024) (<https://www.wwlp.com/news/massachusetts/hpc-non-hospital-surgical-centers-cheaper-but-rare-in-mass/>).

⁶⁴ *Id.*

⁶⁵ See, Djenaba A. Joseph, et al, *Vital Signs: Colorectal Cancer Screening Test Use – United States, 2018*, NAT'L LIB. OF MED. (Mar. 13, 2020) (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7075255/>).

the more successfully it can be prevented/treated, resulting in an improved health outcomes and quality of life for patients. Through the Proposed Project, the Applicant will continue to offer an efficient, equitable, patient-centered experience at a lower cost setting while delivering clinical outcomes that are equivalent or better than outcomes at HOPDs.

To assess the impact of the proposed Project, the Applicant developed the following quality metrics and reporting schematic, as well as metric projections for quality indicators that will measure patient satisfaction and quality of care. The measures are discussed below:

- 1. Withdrawal Time:** Withdrawal time is the time in minutes that it takes a physician to withdraw the scope from the cecum during a screening colonoscopy when no biopsies are taken and no polyps are removed. Studies have shown that longer withdrawal rates correlate to higher adenoma detection rates.

Measure: Average withdrawal time of screening colonoscopy with no pathology. The national benchmark for this measure is 6 minutes or more.

Projection: The Applicant will continue to meet or exceed the benchmark for 100% of its patients each year.

Monitoring: Results will be benchmarked and reviewed quarterly by the Applicant.

- 2. Adenoma detection rate:** Adenoma detection rate (“ADR”) is the minimum target for adenomas detected in screening colonoscopy patients with no family history.

Measure: Average rate of adenomas detected in screening colonoscopy for patients 45 and older. The national benchmark for ADR is 25% overall, and 30% for men 20% for women.

Projection: The Applicant’s ADR for 2023 ranged from 45-52%, well above the national benchmark. The Applicant will continue to meet and exceed the ADR benchmark for 100% of its patients each year.

Monitoring: Results will be benchmarked and reviewed quarterly by the Applicant.

- 3. Patient Satisfaction:** The patient experience will be monitored as we strive to provide high quality care.

Measure: The Press Ganey patient satisfaction survey will be sent to all eligible patients.

Projection: The Applicant’s goal is to earn 100% good to excellent scores

Monitoring: Results will be reviewed quarterly by the Applicant.

F1.b.iii Public Health Value/Health Equity-Focused:

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need-base, please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g. culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

Through the Proposed Project, the Applicant seeks to continue its current efforts to foster health equity and to further equal access to cost-effective, convenient Procedures for its Patient Panel and service area. The Applicant became eligible to enroll in MassHealth in 2022 and experienced an immediate increase in its MassHealth patient population⁶⁶. As a MassHealth provider, Applicant has been able to expand its relationship with Manet Community Health Center, the local Federally Qualified Health Center, as well expand its existing relationships with South Shore Health and area primary care practices which serve MassHealth patients. These relationships in turn contribute to Applicant's ability to reach a greater diversity of patients. The Applicant does not discriminate based on race, color, ancestry, religion, sex (including pregnancy and childbirth), national origin, disability, age, genetic information, sexual orientation, gender identity, citizenship status, military service or the ability to pay or payer source. The Applicant has an environment that is welcoming, understanding, and respectful of patients to support equitable access to the Procedures.

As a threshold matter, the New Center will be physically accessible to all patients and staff will be trained to assist patients with mobility challenges to ensure their comfort and safety, and the new design for the facility will also assist with the sensory and emotional issues due to larger and quieter space with more privacy. Second, in order to ensure a welcoming and understanding environment for patients, the Applicant will continue to employ a culturally competent staff to ensure each patient's experience meets their needs, and to require all staff to complete cultural competency training upon hire and annually thereafter. These courses promote understanding of how clinical outcomes are associated with cultural competence, recognizing key terms, acknowledging common assumptions across cultures and best practices for improving the quality of interactions with patients and families.

Third, the Applicant strives to recognize and address the barriers relating to the social determinants of health of patients at the point of scheduling. For example, prior to each

⁶⁶ Prior to FY22, Applicant was only eligible to receive Medicaid reimbursement as an unenrolled provider where MassHealth was the secondary payer for dually eligible patients.

scheduled procedure, a patient is asked about their transportation arrangements to and from the facility for the day of the procedure and counseled on the need for an adult to accompany them home after the procedure. When needed, the Applicant works with patients to address their transportation needs after the procedure, including but not limited to providing them with referrals to potential community resources that may be able to assist with transportation.

Fourth, the Applicant is committed to continue to offer care that is respectful of each patient and that is delivered in a manner that they can comprehend and to that end offers tools to address language barriers. Patients will continue to be screened for language related services prior to the procedure to identify the level of assistance needed and will ensure services are always immediately available if an unanticipated need arises. Specifically, for all Limited English Proficient (LEP) translation and American Sign Language (ASL) interpretation, services will be provided through qualified language interpretation services. Additionally, in-person interpreter services will be available for individuals with hearing impairment. For patients who are visually impaired, someone will be available to read printed materials in a location that protects patient privacy. Printed or recorded materials can also be provided upon request. The Applicant anticipates that these policies will alleviate language differences, promote health equity, and further equal access to the Applicant's services.

Finally, the Applicant frequently provides and participates in community education programs to raise awareness about gastrointestinal diseases. For example, the Applicant's physicians have supported programs for the general public at SSH to raise awareness on these issues through education programs and brochures. The Applicant's physicians have supported the PCPs at SSMC through a grand round by educating them about the current standards of CRC screening. The physicians also have supported an information table at the Crohn's & Colitis Foundation Team Challenge Race. The Applicant plans future community education programs, (e.g., with Manet Community Health Center) including programs that will target underserved population in their service area.

F1.b.iv Provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

As described throughout this Application, the Proposed Project will improve health outcomes and quality of life for the Patient Panel by continuing and expanding local access to high quality Procedures in a lower cost setting and thus expanding timely access to the Procedures. Reducing patient scheduling delays and removing barriers to timely screening, diagnosis, and treatment ensures timely treatment and thus overall improved health outcomes with a reduced likelihood of disease-related complications and complications generally. Additionally, as also discussed in

F1.b.ii, the Applicant's quality measures including its withdrawal time and ADR are superior compared to national benchmarks, so through the Proposed Project, more patients will be able to get that high quality care more quickly.

The Applicant is committed to promoting health equity and will work to ensure the Procedures are accessible to all members of the community it serves. To that end, the Applicant's convenient location and set up will ensure patients can access the Procedures, and the Applicant's translation services, and care coordination will ensure patients can effectively communicate with their providers, and be connected to other needed services outside of the ASC. As discussed in F1.b.iii, the Applicant already strives to recognize and address the barriers relating to the social determinants of health of patients at the point of scheduling and will continue that practice at the New Center as well. Community awareness that the Applicant now treats Medicaid patients is growing, in part because of the collaborative relationship with Manet Community Health Center. As a result, the Applicant anticipates that the Proposed Project will result in improved patient access and experience increasing the likelihood of quality outcomes, all while promoting health equity.

F1.c Provide evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, how the Proposed Project will create or ensure appropriate linkages to patients' primary care services.

The Proposed Project will operate efficiently and effectively by furthering and improving the continuity and coordination of care for the Applicant's Patient Panel. At the New Center, the Applicant's physicians' clinical consultative practice will continue to adjoin the outpatient endoscopy practice at the Main Site for continued ease of access to seamless care for patients. This integration will continue to foster continuity of care and coordination of all aspects of their patients care.

As discussed in the Project Description, WE physicians follow up with all their patients' primary care physicians as a matter of course by sending pathology and procedure reports to them, and they will continue to ensure appropriate linkages to patients' primary care services at the New Center as well. Furthermore, as also discussed in the Project Description, the Applicant has strong pre-existing relationships with area primary care practices including South Shore Medical Center, Manet Community Health Center, and Healthcare South P.C. which would be expected to increase with the Proposed Project. The Applicant will continue to share electronic medical record ("EMR") with Healthcare South P.C. and South Shore Medical Center and can directly share results with these practices via the EMR which will facilitate care coordination and continuity of care. The close coordination with primary care practices will also encourage patient compliance with screening and follow up visits.

F1.d Evidence of Consultation

Provide evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

The Applicant has consulted with the following individuals at Government Agencies to further inform planning and provide feedback for the Proposed Project.

- Department of Public Health: Determination of Need Program; Dennis Renaud, Program Director; Rebecca Kaye, Senior Deputy General Counsel
- Department of Public Health: Health Care Facility Licensure and Certification, Daniel Gent, Director, Plan Review
- Department of Public Health: Office of Community Health Planning & Engagement: Katelyn Teague

F1.e.i Process for Determining Need/Evidence of Community Engagement: For assistance in responding to this portion of the Application, Applicant is encouraged to review Community Engagement Standards for Community Health Planning Guideline. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the Proposed Project.

In addition to relying on the data described throughout this application that demonstrates the need for the Proposed Project, the Applicant has also engaged the community to elicit feedback from patients and families regarding the Proposed Project.

The Applicant made the following public announcements about the Proposed Project:

- 1) A live zoom presentation regarding the project was held on May 16, 2024. The presentation was created by Mary Phillips, Practice Administrator and Nurse Manager at WE and Bradford Sampson, Managing Member at WE. The notice of the live presentation was posted on the Applicant's website with a copy of the presentation embedded a week in advance. A copy of notice and presentation were left at the Applicant's front desk. The notice of the presentation was also sent to the patients via a listserv a week in advance and the slides were mailed to the patients after the presentation. Approximately 7 people attended the meeting. The presentation reviewed the purpose of the Proposed Project, what it would mean for patients and the community and provided a general overview of the Proposed Project's process. See Exhibit B. After the presentation, one person emailed the Applicant with positive feedback saying that the

new location is great and easier to access, and it will be beneficial to reduce the scheduling delays.

- 2) In addition to the presentation, the Applicant sent a notification to its Patient Panel on Tuesday, June 18th, 2024 about the Proposed Project. In the notification, the Applicant offered to host another live presentation if there was an interest and provided a contact address for patients to ask any questions and to provide feedback. See Exhibit C.
- 3) The Applicant shared a copy of the May 16, 2024 presentation with its referral sources via email and requested that they share it with their respective patient panels.
- 4) A Notice of Intent regarding the Proposed Project was published in The Patriot Ledger on June 7, 2024.

F1.e.ii Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful Applicant will, at a minimum, describe the process whereby the “Public Health Value” of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to “Patient Panel” need; and Linking the Proposed Project to “Public Health Value”.

To ensure sound community engagement for the Proposed Project, the Applicant took the actions described above and engaged with the medical community and its referral sources in the area including with the South Shore Hospital, South Shore Medical Center, Manet Community Health Center, and Healthcare South P.C.

Factor 2: Health Priorities

F2.a. Cost Containment:

Using objective data, please describe, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment.

The Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment by increasing timely access to high quality, cost-effective, preventive and therapeutic care delivered in a lower cost ambulatory surgery center setting. Increasing the number of procedure rooms, coupled with care delivery and patient experience improvements from the state-of-the-art design, will facilitate more timely and efficient access to care leading to earlier detection rates and improved outcomes, thus further bending the cost curve⁶⁷. Moreover, Applicant is an

⁶⁷ STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED 9, 13, EMERSON ENDOSCOPY AND DIGESTIVE HEALTH CENTER, LLC (Feb. 2021) (available at: <https://www.mass.gov/doc/emerson-endoscopy-and-digestive-health-center-staff-report/download>) (“Delaying screening has been shown to result in more aggressive

experienced provider with excellent outcomes, so increasing Applicant's capacity and throughput will increase the availability of high quality, cost-effective services.

As discussed under Factor 1.a.ii, the prevalence of gastrointestinal disorders and related chronic conditions continues to rise leading to greater demand for Procedures. CRC is one of the leading causes of cancer-related death in the United States. CRC trends are particularly concerning among people younger than 55 with the proportion of diagnoses increasing from 11% in 1995 to 20% in 2019.⁶⁸ On the positive side, the 5-year relative survival rate when CRC is found at an early stage before it has spread is about 90%.⁶⁹ Similarly, esophageal cancer, which historically was rare in people aged 54 and below, has been increasing steadily between 1975 and 2015 by nearly 3% each year.⁷⁰ According to American Cancer Society, the 5-year relative survival rate for people diagnosed with localized esophageal cancer (cancer growing only in the esophagus) was 49% while the survival rate for people diagnosed with distant esophageal cancer (cancer spread to organs or lymph nodes away from the main tumor) was 6%.⁷¹ With early detection, CRC and esophageal cancer can be treated more easily, more successfully and more cost effectively.

By expanding access to services, Applicant will be able to detect adenomas in more of its patients at an earlier stage allowing for treatment that is more effective and at lower cost. Applicant's Adenoma Detection Rate ("ADR"), which is the "gold standard" for quality measures in screening colonoscopy, is already high due to its longer endoscope withdrawal time. On average for each 1% increase in ADR, there is a 3% reduction in the risk of CRC.⁷² Compared to the benchmark for ADR which is 25% overall⁷³, the Applicant's ADR in 2023 ranged from 45-52%.

By expanding the number of procedures performed in an ASC setting at the Main Site, the Proposed Project also will reduce unnecessary costs to the healthcare system. ASCs are able to create significant savings due to a combination of factors including the more efficient use of time and resources⁷⁴ and the ability to streamline overhead expenses.⁷⁵ These efficiencies lead to savings that are reflected in lower procedure costs, ultimately leading to overall reduced costs and total medical expenses. Studies undertaken by the Ambulatory Surgery Center Association (ASCA) provide that if half of the eligible surgical procedures were shifted from hospital-based outpatient departments to ASCs, Medicare would save an additional \$2.3 billion annually.⁷⁶

cancer, that is more difficult and expensive to treat," "Early CRC detection and management improves health outcomes and minimizes healthcare spending").

⁶⁸ One new physician has been recruited from out of state contingent on the opening of the New Center, with another two in process.

⁶⁹ *Supra*, note 8.

⁷⁰ *Supra*, note 21.

⁷¹ *Survival Rates for Esophageal Cancer*, ACS (Last Updated January 17, 2024)

(<https://www.cancer.org/cancer/types/esophagus-cancer/detection-diagnosis-staging/survival-rates.html>).

⁷² *Supra*, note 19.

⁷³ *Id.*

⁷⁴ Levitt, *supra* note 25; and Barbella, *supra* note 47.

⁷⁵ *Supra*, note 27.

⁷⁶ *Id.*

Similarly, Medicaid, other insurers and patients benefit from lower prices for services performed in the ASC setting due to lower levels of reimbursement and lower coinsurance payments.

This national data is consistent with the Massachusetts experience. As discussed above in Section F1.b.i, according to HPC 2023 Cost Trends Report, as compared to the same services delivered in a HOPD setting, ASCs typically had lower commercial prices for their services.⁷⁷ In 2021, common surgeries at ASCs were found to cost between 27 to 57 percent less compared to services in a HOPD.⁷⁸ Both Medicare and MassHealth pay lower rates for the same services provided in an ASC compared to a HOPD setting.⁷⁹

With respect to the Applicant in particular, an important consideration is that the Proposed Project will enable the bulk of Procedures for patients for whom a hospital-based procedure is not medically necessary to be provided in the ASC setting. Thus, the current overflow scheduling at SSH will be reduced and Procedures performed by Applicant at SSH will primarily be for reasons of medical necessity. Reimbursement rates for procedures performed in ASCs are approximately 60% of the rate for the same outpatient procedures performed in a hospital setting and patient coinsurance obligations are reduced.⁸⁰ Thus, Applicant receives lower reimbursement for Procedures performed at the Main Site than at the SSH Location, lowering industry costs, and providing patients with additional savings.

The goals for cost containment in Massachusetts centers around providing low-cost care alternatives without sacrificing high quality. The HPC set the following goal for cost containment: better health and better care – at a lower cost – for all residents across the Commonwealth).⁸¹ While lower prices at ASCs translate to lower patient cost sharing,⁸² the quality of care is not compromised and in fact, patient quality and safety at ASCs is comparable or better than the care delivered the HOPD.⁸³ Evidence shows ASC patients are able to experience better clinical outcomes as surgeries performed in this setting generally take a shorter amount of time, patients are able to benefit from a faster recovery time,⁸⁴ infection rates and readmission rates are significantly lower than,⁸⁵ and morbidity and mortality following ASC procedures is favorable.⁸⁶ Accordingly, the Proposed Project will reduce health care spending in furtherance of the Commonwealth's cost containment goals while maintaining or improving the quality of care

⁷⁷ *Supra*, note 53.

⁷⁸ *Supra*, note 56.

⁷⁹ *Supra*, note 11.

⁸⁰ Levitt, *supra* note 25.

⁸¹ Mass. Health Policy Commission, *About the Health Policy Commission (HPC)*, (last visited June 11, 2024), available at <https://www.mass.gov/about-the-health-policy-commission-hpc>

⁸² *Supra*, note 12.

⁸³ *Id.*

⁸⁴ Levitt, *supra* note 25.

⁸⁵ *Id.*

⁸⁶ Warner, *supra* note 25.

delivered, thus further improving public health outcomes further containing unnecessary health care expenditures.

F2.b. Public Health Outcomes: Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

The Applicant anticipates that by increasing access to Procedures, the Proposed Project will lead to more timely and increased CRC screening rates due to shorter appointment scheduling delays. By increasing access and thus screening rates, clinicians will be able to detect cancer earlier and provide more successful treatment options, leading to improved health outcomes and quality of life.⁸⁷ Similarly, by increasing its capacity to provide its existing high quality level of care through the Proposed Project, the Applicant can alleviate the significant unmet and rising need for Procedures within in its Patient Panel and service area, thereby further improving public health outcomes.

In addition, research has shown that improved physical settings contribute to reduced staff stress and fatigue, increased effectiveness in delivering care, improved patient safety, reduced patient stress and improved outcomes, and improved overall healthcare quality.⁸⁸ The Applicant anticipates that the New Center's modern facility design will similarly contribute to improved public health outcomes because of its reduced noise, improved lighting, better ventilation, better ergonomic designs, supportive workplaces and improved layout which will help reduce errors and stress.⁸⁹ The Applicant currently operates from a 20+ year old facility and will benefit from updated infrastructure and systems in many ways. The Proposed Project will allow increased clinical efficiency through expanded clinical space. The new procedure rooms will be spatially compliant with current codes and standards and provide more efficient treatment space with adequate in-room storage. Bigger space coupled with more daylight and modernized finishes will enhance both the patient and staff experiences. State-of-the-art infrastructure and the provision of multiple staff areas will improve collaboration between nursing and the medical staff. New pre/post-procedure bays will afford patients more privacy. Finally, new mechanical air conditioning and ventilation at the New Center will be able to support infection control protocols in a more efficient way. All of these improvements will help make the New Center a safer, more healing, and better place for patients to receive treatment and better place to work.⁹⁰

Similarly, the convenience and accessibility of the Proposed Project would logically contribute to greater patient compliance as patients will be more likely to adhere to their initial and repeat screening schedules. The New Center will be located in the same general area (2.3 miles from current location) in close proximity to major highway (0.25 miles off of Route 3) and walking distance from MBTA bus service (only 0.2 miles away) and will have ample parking and reduced

⁸⁷ *Supra*, note 1.

⁸⁸ See .Roger S. Ulrich, *The Role of the Physical Environment in the Hospital of the 21st Century: A Once-in-a-Lifetime Opportunity*, The Center for Health Design (September 2004) (p. 3) (can be accessed at: https://www.healthdesign.org/system/files/Ulrich_Role%20of%20Physical_2004.pdf.)

⁸⁹ *Id.*

⁹⁰ *Id.*

scheduling delays. Moreover, with the expansion of services at the New Center, Applicant's patients who previously may have received their Procedures at SSH due solely to overflow at the Main Site and not due to medical necessity will now have a greater assurance of an appointment at the New Center.

Further, through the Proposed Project, the Applicant seeks to continue to expand access to patients of all financial means, limiting the impact that cost plays in a patient's decision to receive necessary care. Being able to receive convenient care in a lower cost setting may encourage patients who otherwise might be unenthusiastic about having tests done in the hospital setting to get their Procedures when they need them.

Thus, the Proposed Project will improve access to care, the quality of care, the care experience and public health outcomes by providing more and timely access to the Procedures in an accessible, state of the art lower-cost setting.

F2.c. Delivery System Transformation: Because the integration of social services and community-based expertise is central to goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

As discussed in F1.c, the Applicant works with patients and primary care providers to ensure patients are linked to social services organizations as needed. Copies of patient pathology reports and procedure reports are always faxed to their primary care provider. If concerns around social determinants of health are identified or suspected during pre-procedure screenings and appointments, staff provide the patient with referral resources and notify the patient's primary care provider as appropriate to encourage necessary follow-up.

Factor 5: Relative Merit:

F5.a.i Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions

Proposal: The Proposed Project seeks to relocate the Applicant's ASC from its current location in South Weymouth to the New Center which is 2.3 miles away from its current location, and expand the ASC from three operating rooms to six operating rooms.

Quality: The Applicant anticipates that the Proposed Project will improve quality of care and patient satisfaction through greatly reduced scheduling delays due to increased access to the Procedures for the current Patient Panel which has continued to expand over the past several years. In addition, as described in F1.a.ii and F1.b.ii, Applicant's quality measures are high so the expanded access will increase access to already high quality care, and the new facilities will further improve the care delivery and patient experience environment yielding better outcomes.

Efficiency: As a single-specialty endoscopy ASC, the Applicant will continue to maximize clinical and operational efficiencies through the use of dedicated staff, streamlined overhead costs, and reduced scheduling disruptions when compared to HOPDs. The efficiency will also be improved by the modern infrastructure systems of the new state-of-the-art facility which will be spatially compliant with the latest codes and standards providing for treatment space and in-room storage. The New Center will be more energy efficient, allow for better infection control, enhance privacy and better sensory experience for patients, and enable better collaboration among care teams and between nursing and the medical staff due to larger procedure rooms, extensive daylight, modernized finish, more private patient pre/post-procedure bays, and the provision of multiple staff areas which will all add to efficiency. New mechanical air conditioning and ventilation at the New Center will be able to support infection control protocols in a more efficient way.

Capital Expense: \$5,346,983

Operating Costs (Incremental): \$1,177,851

Alternative Proposal 1: An alternative to the Proposed Project would be that the Applicant continues status quo or expand at the current location. However, the lease in the current location was not offered to the Applicant and even if it had been offered, due to restrictions on the Main

Site, the Main Site could not have accommodated the additional building footprint and associated parking to support an expansion

Alternative Quality: There would be no change in the quality of care under this alternative. However, it is not feasible to continue to provide care at the current location as the lease is expiring on August 2025, and the current space is not sufficient to accommodate the existing volume generated by the Patient Panel, let alone any continued growth, as described in the Application.

Alternative Efficiency: This alternative will result in continued clinical and operational inefficiencies due to the limitation in being able to meet the existing unmet need.

Alternative Capital Expenses: This alternative would not be associated with any new capital expenses. However, it would also not address the need to create capacity to meet demand for Procedures as described in Factor F1.a.ii, and the quality, operational and cost efficiencies gained through the Proposed Project would not be achieved.

Alternative Operating Costs: There would be no change to the operating costs under this alternative.

Alternative Proposal 2: Another alternative to the Proposed Project would be that the Applicant operates the Proposed Project at another location. As part of its due diligence for the Proposed Project, the Applicant worked with two real estate brokers for almost a year to evaluate a number of properties for the Main Site in its service area, primarily focusing on Weymouth. Ultimately, out of the three properties the Applicant considered, only the New Center was ideally located for the Patient Population and sized appropriately for an ASC with six (6) procedure rooms. In addition, there is no space equivalent to the space that Applicant has available at the South Shore Hospital to reserve for part-time Procedures.

Quality: It is hard to predict how the quality with this alternative would compare against the Proposed Project as the Applicant was not able to find an alternate property that met its needs.

Efficiency: It is hard to predict how the efficiency costs with this alternative would compare against the Proposed Project as the Applicant was not able to find an alternate property that met its needs.

Capital Expense: It is hard to predict how the capital expense with this alternative would compare against the Proposed Project as the Applicant was not able to find an alternate property that met its needs.

Operating Costs: It is hard to predict how the operating costs with this alternative would compare against the Proposed Project as the Applicant was not able to find an alternate property that met its needs.

Exhibit A
Letters of Support

See attached.

Exhibit B

PowerPoint Presentation Community Engagement

See attached.

Exhibit C

Notification to Patient Panel

Preview Bulletin

To

All patients connected to Gregory Bolduc, Bradford Sampson, Thomas Kenney, Christopher Kenney, Brian Gill, Jonathan Nass, Rachel Burbine, Ashley Van Lith

From

South Suburban Gastro

Subject

Weymouth Endoscopy Center growth

Message

Weymouth Endoscopy LLC will be applying to the department of public health for a determination of need. Our goal is to increase the availability of endoscopic services on the South Shore by moving from our current location at 1085 Main Street to 97 Libbey Industrial Parkway in Weymouth.

On May 16 we offered a zoom meeting presentation to explain our project. If you were unable to attend that presentation and would like to have more information please email me at: mary@weymouthendoscopy.com . I will arrange a time that is convenient for you to attend this presentaion

Thank you

Mary Phillips

Weymouth Endoscopy

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