

STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	Weymouth Endoscopy, LLC
Applicant Address	1085 Main St Weymouth, MA 02190
Filing Date	July 31, 2024
Type of DoN Application	Substantial Change in Service – Ambulatory Surgery
Total Value	\$5,346,983.00
Project Number	WE-24062414-AS
Ten Taxpayer Groups	None
Community Health Initiative (CHI)	\$267,349.15
Staff Recommendation	Approval with Conditions
Public Health Council Meeting	November 13, 2024
<u>Project Summary and Regulatory Review</u> Weymouth Endoscopy, LLC (Applicant or WE) filed a Determination of Need (DoN) application to relocate and expand its existing ambulatory surgery center (ASC). The Applicant is proposing to relocate the ASC from its current location at 1085 Main Street, Weymouth, MA to 97 Libbey Industrial Parkway, Weymouth, MA, two miles from the current location. The Applicant is also proposing to increase the number of procedures rooms from three to six. The total value for the Proposed Project is \$5,346,983.00. The Community Health Initiative (CHI) contribution to the Statewide Initiative Fund is \$267,349.15. Review of Applications for Ambulatory Surgery is under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.	

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Background: Weymouth Endoscopy, LLC; and Application Overview

Weymouth Endoscopy, LLC (Applicant or WE) is a for-profit, freestanding, single specialty ambulatory surgery center (ASC) located at 1085 Main St, Weymouth, MA 02190. The ASC has been in operation since 2004, and 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. WE is owned and operated by a group of six physicians who are also the owners of an independent professional corporation, South Suburban Gastroenterology PC (PC), a single specialty practice founded in 1990. PC's medical practice is located in a separate but adjacent space to the current ASC. The Applicant is eligible to expand through the grandfathering provision of 105 CMR 100.715.¹

Application Overview

The Applicant has been operating its current ASC with three procedures rooms since 2004. The current ASC encompasses approximately 5,090 gross square feet. The Applicant's lease for the ASC at the current site expires in August 2025. The Applicant maintains that even if renewal of the lease was an option, it would still need to undertake the Proposed Project to relocate and expand the ASC because the current site is insufficient to address current and projected Patient Panel need for WE's services.

The Applicant asserts that the Proposed Project is needed to meet its Patient Panel's current need for Procedures, as well as the increasing need for Procedures in the Applicant's Patient Panel and service area. Under the current arrangement, the Applicant's Patient Panel receive Procedures at either or both the Applicant's current site in Weymouth and South Shore Hospital (SSH) in Weymouth. The Applicant states that SSH does not employ its own gastroenterologists. The physicians who own WE are credentialed at SSH and provide on-call coverage (7 days a week – 24 hours a day) for SSH's acute patients as part of their membership on the hospital's medical staff. The Applicant states further that SSH reserves a block of time for the Applicant's physicians for outpatient procedures from 7:30a.m. to 11:00a.m. Monday through Friday. The hospital also has set aside a block of time for inpatient procedures after 11:00a.m. daily. During off-hours, the Applicant's physicians perform emergency procedures in the operating room. The Applicant's physicians group bills for professional services rendered at the hospital and the hospital bills for the technical component. The Applicant affirms that its physicians follow hospital policy and procedures while practicing at the hospital.

The Applicant states that both the Applicant and SSH have significant scheduling delays for Procedures and that patients are waiting seven to eight months for an appointment for nonurgent procedures at both locations. In addition to these delays, the Applicant reports the recent closures of endoscopy services at hospitals on the South Shore has impacted access to Procedures. The

¹ An Expansion, Conversion, Transfer of Ownership, Transfer of Site, or change of designated Location for a Freestanding Ambulatory Surgery Center that received an Original License as a Clinic on or before January 1, 2017. 105 CMR 100.715(B)(2)(a)(iv).

Applicant states further that the prevalence of gastrointestinal disorders and related chronic conditions are increasing, which increases need for the Procedures provided by the Applicant.

The Applicant is proposing to relocate and expand WE in order to reduce scheduling delays and to address increasing need for its services among its Patient Panel and within its service area. Subject to DoN review and Department approval, the Applicant will relocate the ASC to a newly renovated state-of-the-art freestanding ASC two miles away from the current site that will encompass approximately 9,466 gross square feet, and include six procedure rooms. The Applicant states that there will be no change in the type of Procedures provided by WE at the proposed site. The procedure rooms at the proposed site will be more spacious than the procedure rooms in the current ASC, increasing in size by 40 to 48 square feet, allowing the procedure rooms to better accommodate the clinical staff and equipment for improved collaborative teamwork and efficiency. PC will be located adjacent to the relocated ASC at its new site, and there will be separate waiting rooms for WE and PC patients. Table 1 shows an overview of the Proposed Project.

Table 1: Overview of the Proposed Project

	Current Site 1085 Main Street	Proposed Site 97 Libbey Industrial Parkway	Proposed Change
Procedure Rooms	3	6	+3
Pre/Post Procedure Beds	11	17	+6

The Applicant's stated goal is for patients to receive an appointment within two months of requesting one after implementation of the Proposed Project. The Applicant asserts that the Proposed Project will (1) 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; (2) improve patient adherence to necessary screenings and reduce patient stress due to reduced wait periods; and (3) improve access to screenings, which can improve patient outcomes from earlier detection of cancers and precancerous lesions.

Patient Panel²

The Applicant provided Patient Panel data based on patients who have received care at the Applicant's current facility and patients seen at the SSH location from fiscal year (FY)21 to FY23. Patient Panel data are shown in Table 2.^{3,4} The Applicant attributes the reduction in patients seen in FY20 to the COVID-19 pandemic. The Applicant states that the growth in patients seen at the SSH

² As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder. Patient Panel also means: (1) If the Applicant or Holder has no Patient Panel itself, the Patient Panel includes the Patient Panel of the health care facilities affiliated with the Applicant; or (2) If the Proposed Project is for a new facility and there is no existing Patient Panel, Patient Panel means the anticipated patients; or (3) In the case of a Transfer of Ownership, Patient Panel also includes the Patient Panel of the Entity to be acquired.

³ The Applicant states that because a patient may have a Procedure at SSH and then require a follow-up at WE, it is possible that a patient could be counted twice in any given year. The Applicant estimates that approximately 10 such patients per year have a Procedure at SSH and then require a follow-up at WE.

⁴ The Applicant's fiscal year (FY) is calendar year January 1 to December 31.

location is smaller than WE because SSH has increasing need to use their endoscopy rooms for their inpatient population.

Table 2: Weymouth Endoscopy, LLC Patient Panel

	FY21	FY22	FY23	Patient Panel Growth Rate (FY21-FY23)
WE	6,727	6,870	7,364	9.47%
SSH Location	1,382	1,314	1,427	3.26%
Total	8,109	8,184	8,791	8.41%

The Applicant also provided data on patients seen at WE and SSH from FY17 to FY23. During this period, WE patients increased by 78.9%, SSH location patients increased by 140.6%, and the total (WE and SSH) increased by 86.7%. This is shown in Table 3. The Applicant states that a significant number of its Patient Panel undergo multiple procedures (both upper and lower endoscopy), so the actual volume of its patients is higher than the number of unique patients.

Table 3: Weymouth Endoscopy LLC Patients, FY17 to FY23

	FY17	FY18	FY19	FY20	FY21	FY22	FY23	Overall Growth Rate (FY17-FY23)
WE	4,116	5,466	6,108	4,604	6,727	6,870	7,364	78.91%
SSH Location	593	756	1,854	1,264	1,382	1,314	1,427	140.64%
Total	4,709	6,222	7,962	5,868	8,109	8,184	8,791	86.69%

Patient Information

The Applicant provided demographic data for the Patient Panel, which are presented in Table 4. Staff notes the following observations about these data below:

1. **Age:** The majority of the Applicant's Patient Panel are between the ages of 50 and 60, and over 75% of the Applicant's Patient Panel are aged 50 and older.
2. **Patient Origin:** The Applicant's patients mainly reside in Plymouth and Norfolk county.
3. **Race/Ethnicity:** Over 90% of the Patient Panel self-identified as White.
4. **Payer Mix:** At the current site, 60% of the Patient Panel is insured by commercial payers, and at the SSH site 50% are insured by commercial payers. With respect to government payers, 40% and 45% of the Patient Panel are insured by government payors at WE and SSH location, respectively. The Applicant does not participate in any ACOs or other risk contract or alternative payment models.

Table 4: Overview of Weymouth Endoscopy, LLC Patient Population

FY23	WE	SSH
Total Patients	7,364	1,427
Gender		
Male	47%	44%
Female	53%	56%
Total	100%	100%

FY23	WE		SSH	
Age				
0 to 44 ⁵	11%		22%	
45-50	12%		4%	
50-69	59%		40%	
69+	18%		35%	
Total	100%		100%	
Race/Ethnicity				
White	98.3%		92.4%	
Asian	0.1%		1.1%	
Other/More than 1 race/African American/ Unreported/refused/ ⁶	1.6%		6.5%	
Total	100%		100%	
Patient Origin⁷				
	Hingham	15%	Hingham	14%
	Marshfield	10%	Marshfield	10%
	Scituate	11%	Scituate	11%
	Hanover	10%	Hanover	8%
	Plymouth	8%	South Weymouth	10%
	South Weymouth	8%	Rockland	8%
	Rockland	7%	Braintree	12%
	Pembroke	8%	Quincy	11%
	Norwell	7%	Hull	9%
	Duxbury	8%	Weymouth	8%
	Braintree	8%		
Total	100%		100%	
Payer Mix				
Medicaid/Medicaid MCO ⁸	10.5%		3.4%	
Medicare	28.1%		38.5%	
Medicare MCO	1.5%		9.3%	
Commercial/ Other (self-pay, workers' comp, Health Safety Net (HSN)) ⁹	59.8%		48.8%	
Total	100%		100%	

⁵ In the category 0 to 18 the cell count was less than 11, so it was combined with the category 19 to 44 to protect patient privacy.

⁶ In the categories Other, More than 1 race, Black/African American and American Indian, the cell counts were less than 11 so they were combined with the category Unreported/Refused to protect patient privacy.

⁷ Represents patient origination from each of the primary cities and towns comprising the Applicant's service area for WE, the current, and SSH Location.

⁸ In the category Medicaid MCO, the cell count was less than 11 so it was combined with the category Medicaid to protect patient privacy.

⁹ In the category Other, the cell count was less than 11 so it was combined with the category Commercial to protect patient privacy.

Factor 1a: Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently demonstrated need for the Proposed Project components by the Applicant's Patient Panel.

Background

The Applicant's Patient Panel currently receive Procedures at either or both the Applicant's current ASC and at SSH in Weymouth. WE currently has three procedure rooms. SSH has two procedure rooms for endoscopy: PC uses one procedure room and Harbor Medical uses the other one. WE currently has reserved block time at SSH which is used for approximately 50% overflow patients and 50% for patients who have a medical necessity to have their Procedures in a hospital setting, which the Applicant states includes patients of size noting that the volume of procedure for these patients is increasing.^{10,11} The Applicant identifies a patient of size based on SSH's practices, as follows: Patients with a body mass index (BMI) over 40 are expected to have their procedures done at the hospital due to the increased risk of airway complications. Patients of Size with a BMI over 50 must have their procedures performed in the operating room per hospital policy. The Applicant states that both WE and SSH have significant scheduling delays for procedures, and that WE's longest scheduling delays currently are for medically complex patients that require Procedures at SSH.

The Applicant affirms that the Proposed Project is needed to reduce scheduling delays for procedures, and to address increasing need for WE's services due to increasing prevalence of gastrointestinal disorders and related chronic conditions. More specifically, the Proposed Project will address current capacity issues and help meet growing demand at both WE and the SSH location by allowing more flexibility for urgent Procedures at WE, thereby increasing access to the SSH location for patients who need to have their Procedures at the hospital due to medical necessity. After project implementation, WE will continue to have the reserved block of time at SSH currently used for approximately 50% overflow patients and 50% for patients who have a medical necessity to have their Procedures in a hospital setting. The Applicant maintains that by shifting the overflow patients back to WE, it anticipates more availability at SSH to schedule patients sooner for Procedures that must be performed in a hospital setting.

Historic Utilization and Scheduling Delays

The Applicant states that it has experienced a significant increase in need for its services by its large Patient Panel which has been established in its over 20 years of operation. Across WE and SSH, the Applicant has been experiencing wait times of seven to eight months for both upper and lower nonurgent endoscopy Procedures. The Applicant states that 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. In terms of urgent Procedures,

¹⁰ The Applicant states that the Department uses the term "patient of size" as part of its plan approval process. In addition, the Applicant provided the following link: <https://www.mass.gov/doc/op10-outpatient-surgery-facilities/download>

¹¹ Patient of size: A person whose height, body width, weight, and weight distribution throughout the body require increased space for care and mobilization as well as for use of expanded-capacity devices, equipment, furniture, technology, and supplies. Note: Such patients are not necessarily receiving bariatric care, thus, the term "patient of size" is often used in place of obese, morbidly obese, or bariatric. Per national Facilities Guidelines Institute (FGI) guidelines.

wait times for each type of Procedure are not tracked separately, but the wait time for upper endoscopy is generally shorter than the wait time for lower endoscopy

Scheduling delays negatively impact the Patient Panel because the Applicant's established patients develop symptoms that often require urgent evaluations, such as gastrointestinal bleeding, colitis flares, dysphagia, and difficulty eating. The Applicant notes that extended wait times can lead to stress and anxiety for patients concerned about adverse outcomes. The Applicant states that patients with an urgent need to have their Procedures performed in the hospital setting due to their age or medical co-morbidities are also experiencing wait times of weeks to months because the Applicant's SSH location schedule is full. As a result, patients experience long wait times for screening which can negatively impact early diagnosis, patient treatment, outcomes, and quality of life. The Applicant states that it is able to accommodate Procedures that need to be scheduled sooner due to medical necessity, allowing most medical necessity appointments to be scheduled within three months¹², and that the wait times for overflow WE patients is seven to eight months.

Over the past three years, the utilization rate at WE has averaged 103%. The Applicant states that utilization exceeds 100% because it includes physician overtime. WE's outpatient utilization rate at SSH over the past three years has been over 100%, and the Applicant explained that this is due to the fact that WE cannot book beyond the block of time that is available to them. The Applicant states that SSH has been operating at 110% to 120% capacity during the last four to five months, which may also contribute to more referrals to the Applicant for Procedures.

In response to staff inquiry, the Applicant maintains that there is limited information available on industry standard/national benchmarks for optimal wait times for the Procedures performed at WE. The Applicant states that it is familiar with guidelines set in other Western countries which suggest that two months is the maximum appropriate wait time for accessing lower endoscopy procedures. The Applicant cited a 2020 study referencing guidelines for maximal wait time for procedures based on the indication established by the Canadian Association of Gastroenterology, which recommend a maximal wait time of two months for diagnostic colonoscopy and six months for screening colonoscopy, with the study noting that "data regarding colonoscopy wait times in the United States are limited".^a The Applicant also points to the National Health Service (NHS) England, which states that "patients should wait no more than six weeks for endoscopy tests (colonoscopy or flexi-sigmoidoscopy) that can diagnose bowel cancer, and no more than two weeks to see a specialist if they've been referred urgently by their GP for suspected bowel cancer."^b

The Applicant provided annual volume of Procedures at WE and SSH. This is shown in Table 5. Between FY17 and FY23, volume at WE increased by 94% and volume at SSH increased by 165%. The Applicant states that 50% of annual volume at SSH is attributable to procedures that must be performed in a hospital setting due to medical necessity and 50% is attributable to overflow patients from the ASC location. The Applicant attributes the decrease in Procedures at both WE and SSH locations in FY20 to COVID-19 pandemic.

¹² The Applicant states that it attempts to accommodate a patient with active bleeding or anemia within two weeks, and that patients with bleeding, positive Cologuard tests, and positive Fecal Occult Blood Test (FOBT) are accommodated as soon as possible.

Table 5: Annual volume of Procedures at WE and SSH

	FY17	FY18	FY19	FY20	FY21	FY22	FY23	% Change
WE	4,733	5,739	7,085	5,479	8,072	8,450	9,205	94%
SSH	623	809	2,021	1,390	1,547	1,498	1,652	165%

The Applicant cited the following reasons for the increase in volume at WE and SSH, from FY18 to FY23:

- Rising colon cancer trends among younger adults,
- Changes to the Preventive Services Task Force screening guidelines for colorectal cancer (CRC) from 50 to 45,
- Increased awareness of the importance of CRC screening,
- Increased screening because of a better understanding of the implications of a wide variety of genetic abnormalities, the use of home test kits, higher Adenoma Detection Rate (ADR) by the Applicant which leads to more frequent recalls for repeat Procedures, and
- Recent expected and unexpected closures of endoscopy services at hospitals in the South Shore have caused a decrease in access to hospital space for endoscopy procedures, which has resulted in an increase in Applicant's volume.

The Applicant notes slower growth in procedures performed at SSH and attributes it to SSH's increasing need to use their endoscopy rooms for inpatients, which in turn limits the amount of time available to WE.

The Applicant also provided annual volume from FY23 at WE and SSH by age cohort. This is shown in Table 6. At WE and SSH, the age 50-69 age cohort comprised the most Procedure volume.

Table 6: FY23 Volume at WE and SSH, by age cohort

	WE	%	SSH	%
0-44	974	11%	376	23%
45-50	1,006	11%	62	4%
50-69	5,346	58%	647	39%
69+	1,879	20%	567	34%
Total	9,205	100%	1,652	100%

Colorectal cancer trends

The Applicant affirms that demand for colorectal cancer (CRC) screening and other diagnostic endoscopic procedures has generally increased due to 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 genetic abnormalities.

The Applicant points to national CRC statistics where CRC is the second most common cause of death due to cancer in the United States when numbers for men and women are combined.^c In 2024, CRC is expected to cause about 53,010 deaths.^d The American Cancer Society (ACS) expects about 106,590 new cases of colon cancer and about 46,220 new cases of rectal cancer in 2024.^e

Cancer normally arises in adults aged 50 and older, however, there has been an increase in the incidence of cancer of various organs in patients younger than 50 years old, also known as early-onset cancer.^f In recognition of increasing incidence of CRC in younger populations, the United States Preventive Services Task Force (USPSTF) and American Cancer Society (ACS) recommend to begin CRC screening at age 45. The USPSTF expanded the recommended ages for CRC screening to 45 to 75 years (previously, it was 50 to 75 years).^g High-risk patients are advised to begin screening before age 45.^{h,13} The USPSTF continues to recommend selectively screening adults aged 76 to 85 years for CRC.ⁱ

There are several test options available for CRC screening, however colonoscopy remains the gold standard method of screening for CRC because the exam offers a way in which potential issues can be recognized, cancer can be ruled out or detected, and polyps (abnormal growths that could become cancer) can be found and removed before they become cancerous. The Applicant states that it has experienced an increase in need for the Procedures in its Patient Panel from patients using at-home test kits results and attributes the increase in part to the convenience at-home test kits offers, and their use among people who might otherwise not have screened. The Applicant states that these at home test kits, are not, however, a replacement for a colonoscopy, and points to the differences in their effectiveness. The Applicant cites a reference stating 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.^{j,k}

Screening colonoscopy can help prevent cancer through finding and removing precancerous polyps, known as adenomas, before they turn into cancer.^l It can also reduce risk of death from cancer through detection of tumors at an earlier, more treatable stage.^m An endoscopist's adenoma detection rate (ADR), a reportable rate of the endoscopist's ability to find adenomas, is a quality indicator for endoscopy procedures.^{n,14} Per a reference provided by the Applicant, the ADR defines the quality of colonoscopy that an endoscopist performs and the endoscopist's ADR currently stands as the "gold standard" for quality measures in screening colonoscopy.^o The benchmark for ADRs is 25% overall, 30% in men, and 20% in women.^p One study cited by the Applicant found higher physician ADRs associated with lower risks of post-colonoscopy colorectal cancer (PCCRC).^q The Applicant states that its ADR, is indication of the high quality screening provided by the Applicant. The Applicant's ADR ranged from 45-52% in 2023, and was 46% in 2022 and 47% in 2021. The Applicant states further that it also demonstrates that need for the Applicant's Procedures at any given time is higher than the Applicant's current or projected unique patient volume as patients detected with adenoma need to get another colonoscopy more frequently – within three and seven years.^r

¹³ Patients who have a history of CRC or polyps; a first-degree family member with CRC or advanced polyps (those that would have gone on to become CRC if they had not been removed); a family history of certain genetic syndromes; or a history of inflammatory bowel disease (like Crohn's disease or ulcerative colitis) are some examples of high-risk factors.

¹⁴ The Applicant states that ADR is measured only within the following patient population: patients who are 45 years and older, have no family history of colon cancer, and have no clinical symptoms. It equals the number of patients that have at least one adenoma removed divided by the number of patients that present for their initial screening.

MassHealth contracting

The Applicant states that as a single-specialty ASC, it was not eligible to receive a provider contract with MassHealth until 2022, citing a July 2020 MassHealth Freestanding Ambulatory Surgery Center bulletin which allowed for MassHealth to begin allowing single-specialty ASCs to enroll as providers.⁵ In the one year since contracting with MassHealth, the number of MassHealth patients seen at WE increased substantially from 268 in 2022 to 454 in 2023. The Applicant anticipates that its Medicaid caseload will continue to grow as availability is publicized, and notes further that the proposed site with expanded and convenient access will facilitate access for MassHealth recipients.

Patient Choice

The Applicant cites reporting from the Massachusetts Health Policy Commission (HPC) which states that 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.^{t,u} The Applicant anticipates that the proposed site, with its convenient access from Route 3, accessibility by public transportation (MBTA bus stop is with 0.2 miles), ample parking, and amenities offered, will mean current patients will be interested in continuing to receive services from the Applicant, and more people in the Applicant's service area may be interested in receiving services from the Applicant.

The Applicant cited additional factors beyond those mentioned above that will contribute to increasing need for its services.

- Large, multi-unit housing developments are in progress in the area which are further expected to add to the population of the South Shore.¹⁵
- Closure of the endoscopic center at the Good Samaritan Medical Center, and the endoscopy center at Signature Healthcare-Brockton Hospital which has not reopened yet, have decreased access to spaces in the region for performing endoscopy procedures. The Applicant states that patients have been reaching out to WE independently and through the emergency room and this has resulted in an increase in the Applicant's volume. The Applicant states that it does not have exact data on the volume increase as a result of the closures, but that it has been fielding calls every day. The Applicant states that some patients may return to Signature-Healthcare Brockton Hospital when endoscopy services resume while others may prefer to continue receiving their care at WE. The Applicant notes that most recently, with Carney Hospital's permanent closure, the Applicant has received calls from patients looking to re-establish care at WE.

Projections

The Applicant determined that with the addition of three procedure rooms (and the assumed recruitment of two to three additional physicians), the Proposed Project would reach full operating capacity within the first year of operations and expects to maintain this utilization thereafter. Full operating capacity means that each of the six rooms will have an annual capacity of over 2,600

¹⁵ The Applicant states that this is according to the South Shore Chamber of Commerce and based on anecdotal information from the Applicant's architect.

Procedures annually. The Applicant explained that it expects to reach full capacity within the first year of project implementation because it currently has a significant backlog of patients waiting for Procedures, which includes patients scheduled seven to eight months out, patients needing urgent Procedures, and additional patients waiting to be scheduled that are being tracked by the Applicant. The Applicant states that the first year of project implementation is 2025. Table 7 shows the Applicant's projected case volume in the first five years after project implementation.

Table 7: Projected Volume

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	% Change Rate 2023-2029
Total Procedures Performed	9,934	10,805	11,886	13,074	14,382	15,820	59%
Total Unique Patient Volume	7,364	8,272	9,099	10,009	11,010	12,111	64%

The Applicant states that with the doubling of procedure room capacity, it expects the backlog to be within an acceptable range by the end of the second year, and managed further in subsequent years. The Applicant also stated that proposed guideline changes to Colorectal Cancer Screening Recommendations from the US Multi-Society Task Force on Colorectal Cancer concerning the extension of recall times for certain types of pathologies, may reduce the Applicant's expected volume, allowing the Applicant to increase procedure volume and maintain utilization at 100%.^v

In response to staff inquiry about new volume after project implementation, the Applicant states that it expects new volume to come from recall procedures because 60% of procedures performed by WE require a recall within five years. The Applicant also expects new volume to come from WE's referral partners, South Shore Medical Center, Health Care South, and Manet Community Health Center. WE is the preferred provider of endoscopy services for these providers, and the Applicant maintains that they all have growing primary care physician (PCP) panels therefore the Applicant can expect new volume to originate from them. The Applicant also states that it has been receiving four to five calls a day from patients receiving care at Carney Hospital.

The Applicant states that it will continue to work with the administration to ensure the availability of a sufficient block time at SSH for patients who need to have their Procedures at SSH due to medical necessity.

The Applicant cites the Massachusetts Department of Public Health's Data Report from 2020 which states that CRC was the third most commonly diagnosed cancer among men and women in Massachusetts during 2012 and 2016, and was also the third leading cause of cancer death for both men and women.^w The report states also that in Massachusetts, the highest overall CRC incidence rates for men and women from 2012 to 2016 were among Black non-Hispanic people, followed by white non-Hispanic people, Asian non-Hispanic people, and Hispanic people.^x The Data Report states

that CRC is one of the most preventable forms of cancer if it is detected early enough, and when early signs of CRC are identified, it can be averted and more effectively treated.^y According to the American Cancer Society (ACS), the five-year survival rate for localized colorectal cancer (cancer that is confined to the colon or rectum) is 91% while the five-year survival rate for distant colorectal cancer (cancer that has spread to distant areas of the body) is 13%.^{z,16} The Department's Data Report states that many people in Massachusetts who have CRC are not being diagnosed early enough, and more than half do not have their cancer diagnosed until after it has spread beyond the colon or rectum.^{aa}

Colorectal cancer (CRC), once the fourth leading cause of cancer death among men and women younger than 50 years old, is now the leading cause for men and second leading cause for women, due to increasing incidence of early-onset CRC.^{bb} From 1997 to 2016, incidence rates for CRC decreased by 4.0% for men and 3.1% for women each year in Massachusetts, however, incidence rates of CRC in those aged 49 years or less increased by an average of 2.2% each year between 1997 and 2016.^{cc} In addition to increasing incidence rates among those less than 50 years, CRCs were diagnosed more frequently at a regional (spread to some nearby areas) or distant (spread to other parts of the body) stage among those aged less than 50 years as compared to those aged 50 years or more.^{dd}

The Applicant anticipates an increasing need for esophageal endoscopy in its Patient Panel because many of its patients have multiple risk factors associated with esophageal cancer. While "young-onset" esophageal adenocarcinoma continues to constitute a small proportion of all esophageal adenocarcinomas (<10%), its incidence has increased by more than 200% over the last few decades, and young-onset esophageal adenocarcinoma patients present at more advanced stages when compared with older patients.^{ee} Additionally, while esophageal cancer in people aged 54 years and below is relatively rare, diagnoses of esophageal adenocarcinoma are increasing in people under 50 by nearly 3% each year between 1975 and 2015.^{ff} Risk factors for esophageal cancer include but are not limited to increasing age, gender, tobacco and alcohol use, diet, Gastroesophageal reflux disease, developing Barrett's esophagus, physical inactivity, and obesity.^{gg} Screening can be recommended for those with risk factors but no symptoms, and screening can allow for earlier detection which can lead to more effective treatment.^{hh}

The Applicant states that demand for screening Procedures has increased nationally, and in the Applicant's Patient Panel and the South Shore population, as a result of the lowered screening age recommendation, and insurance now covering screening of adults in the 45 to 50 age group. The Applicant states further that it expects the increase in demand for its services to continue as younger patients will also require repeat screenings.

Methodology

Table 8 below shows the Applicant's methodology for determining a need to increase procedure rooms by three in order to meet Patient Panel need for WE's services. The Applicant states that when determining Patient Panel need for procedure rooms, it evaluated its volume and wait time

¹⁶ Localized means there is no sign that the cancer has spread outside of the colon or rectum.

data, performing a simple calculation as to the number of Procedures per room.

Table 8: Methodology for Determining Need for Procedure Rooms

Current Capacity	- WE: 625 patients per month - SSH: 140 patients per month. Both are booked for the next seven to eight months
Waiting List	WE also has a waiting list on top of its six months wait for an appointment for the following: - 65 patients that should be seen within a two-week period ideally due to medical indications (rectal bleeding, positive Cologuard test, change in bowel habits, dysphagia) - 258 new patients waiting for the next schedule to be available
Recalls	- 350 per month
Additional patient needs	- Approximately 350 patients per month for whom a Procedure is newly recommended after an office visit for their presenting condition. - New patients who are referred from their PCPs for screening procedures.
Total monthly capacity	- 765 seen - 673 more waiting to be seen or recalled, plus approximately 350 patients per month whose office visit generates new Procedures and additional new patients. Equals more than double the number of patients currently served, supporting a doubling of procedure room capacity.

Staffing

The current ASC is owned and operated by six physicians who are also the owners of PC, an independent professional corporation. PC's medical practice will be located adjacent space to the new proposed ASC. The Applicant states that with additional spaces to perform endoscopic procedures, the Applicant will be able to employ additional gastroenterologists to address the demand for endoscopic evaluation. The Applicant expects to hire two to three additional physicians to reach full operating capacity at the proposed site within the first year of operations, which is scheduled for 2025. One new physician has already been recruited from out of state contingent on the opening of the proposed ASC, and the Applicant states that it is close to having commitments for additional physician staff.

The Applicant states that its physicians integrate their adjoining clinical consultative practice at PC and their outpatient endoscopy practice at the current site for greater ease of access to seamlessly care for patients and coordinate all aspects of their patients' care. The 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 SSH and this, the Applicant states, will remain unchanged after the proposed relocation to the proposed ASC.

Analysis

Staff find that by increasing WE's capacity to provide its existing high quality level of care through the Proposed Project, the Applicant can reduce wait times for Procedures within its Patient Panel and service area, thereby further improving health outcomes. While there is limited information on benchmarks for endoscopy procedure wait times, longer wait times for endoscopy can negatively impact patient functioning and quality of life. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1a.

Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity

Public Health Value: Improved Outcomes and Quality of Life

The Applicant's stated goal is for patients to receive an appointment within two months of scheduling one. Decreasing scheduling time will improve patient compliance with screening and follow-up care thereby optimizing preventative health care, improving patient outcomes, patient satisfaction, and quality of life. The Applicant affirms that increasing the number of procedure rooms from three to six rooms will expand access to care and provide timelier diagnostic and therapeutic endoscopic evaluations. The clinical value of endoscopy in evaluating, diagnosing, and treating digestive diseases and conditions including esophageal, gastric, and colon cancers is well-documented and will not be discussed further.

The Applicant cited studies which found that ASCs have better clinical quality outcomes than Hospital Outpatient Departments (HOPDs) such as 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.

- Studies show improved health outcomes for patients at all risk levels undergoing outpatient procedure at ASCs.ⁱⁱ
- 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).^{jj}
- Surgeries performed in an ASC are generally of shorter duration and patient recovery time is faster than cases performed in a hospital.^{kk}
- Patients who undergo outpatient procedures in an ASC are also less likely to visit an ER or be admitted to the hospital than those treated in a HOPD.^{ll,mm}

The ASC is accredited by the Accreditation Association for Ambulatory Health Care, Inc. and recognized by the American Society for Gastrointestinal Endoscopy. The Applicant states that it has a policy in place covering the transfer of a patient to a hospital facility when the patient requires services that exceed the scope of capabilities of WE. The policy includes notifying the transporting ambulance, maintaining all necessary care until the arrival of the ambulance, notifying the accepting facility, sending a copy of the patient's records with them, and the RN in charge calling the accepting facility and preparing the patient and family for transport.

To assess the impact of the Proposed Project, the Applicant developed quality metrics and a reporting schematic, as well as metric projections for quality indicators that will measure quality of care. The measures are presented in Appendix I and will be reported to DPH on an annual basis following implementation of the Proposed Project.

Analysis: Improved Outcomes and Quality of Life

Staff finds that increasing access to ambulatory surgery in the ASC setting has the potential to improve health outcomes and quality of life of the Patient Panel. Numerous benefits of surgeries performed in the ASC setting, including the quality of care provided, are well documented in the relevant literature. As a result, Staff finds that the Applicant meets the requirements of Public Health Value: Health Outcomes as part of Factor 1b.

Public Health Value: Health Equity

The Applicant affirms that it does not discriminate based on race, ethnicity, ancestry, religion, sex, national origin, disability, age, genetic information, sexual orientation, gender identity, citizenship status, military service or the ability to pay or payer source. The Applicant affirmed its commitment to promoting health equity and will work to ensure the Procedures are accessible to all members of the community it serves.

Interpreter Services: The Applicant provides language access services so that patients can effectively communicate with their providers. The Applicant provides interpreters in-person when possible, and uses telephonic interpreters in the event that in-person is not available. Patients will continue to be screened for language related services prior to the procedure to identify the level of assistance needed. The Applicant reports it 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.

Cultural Competency Training: The Applicant states that it will continue to employ a culturally competent staff and to require all staff to complete cultural competency training upon hire and annually thereafter. The Applicant states that cultural competency training 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. The Applicant states that it reviews the training annually.

Social Determinants of Health (SDoH) Screening: The Applicant states that it works to recognize and address barriers relating to the SDoH. Prior to each 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. These practices will continue at the proposed site.

Site Accessibility: The Applicant states that the proposed site's location will be convenient for patients and the setup will promote access for patients. The proposed site will be physically accessible to all patients, 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.

MassHealth Participation: The Applicant states that all physicians performing procedures at WE accept MassHealth and will continue to do so at the proposed facility. The Applicant states that prior to FY22, it was only eligible to receive Medicaid reimbursement as an unenrolled provider where MassHealth was the secondary payer for dually eligible patients. However, in 2020, MassHealth removed the Multi-Specialty Requirement from the freestanding ASC program regulation, allowing single-specialty freestanding ASCs to begin enrolling as MassHealth providers.ⁿⁿ The Applicant enrolled in MassHealth when it became eligible to enroll in 2022, and after enrolling in MassHealth, it experienced an immediate increase in its MassHealth patient population. The Applicant maintains that its MassHealth participation will result in improved patient access and experience. The Applicant states that as a MassHealth provider it has expanded its relationship with Manet Community Health Center, the local Federally Qualified Health Center, and its existing relationships with South Shore Health and area primary care practices which serve MassHealth patients, which has allowed it to reach a greater diversity of patients. The Applicant plans to organize community education programs with Manet Community Health Center and other community partners which will target underserved populations in their service area, and work with Manet Community Health Center to provide care to its patients that are in need of WE's services.

Community Programming: The Applicant provides and participates in community education programs to raise awareness about gastrointestinal diseases, which includes physician participation at programs for the general public at SSH, physician support of the PCPs at South Shore Medical Center through grand rounds by educating them about the current standards of CRC screening, and physician support of an information table at the Crohn's & Colitis Foundation Team Challenge Race. The Applicant states that it is planning for future community education programs, (e.g., with Manet Community Health Center) including programs that will target underserved populations in their service area.

Disparities in Access and Utilization: The Applicant states that it has been working with Manet Community Health Center to identify barriers to obtaining care in the past and has developed relationships to expedite medical care for Manet Community Health Center patients. The Applicant states further that it plans on expanding those relationships and exploring ways to streamline colonoscopy referrals. The Applicant asserts that it plans on working with Manet Community Health Center to address any disparities in access to and utilization of WE's services within the Applicant's Patient Panel and service area through providing education materials on the importance of colorectal screening and upper endoscopy for people experiencing certain risk factors (e.g.

Gastrointestinal Reflux Disease (GERD), stomach ulcers, swallowing disorders, heartburn, etc.) to underserved populations in its service area.

Analysis: Health Equity

Staff finds that with the “Other Conditions” listed below, the Applicant sufficiently demonstrated reasonable efforts to provide equitable access to WE’s services. As a result, Staff finds that the Applicant meets the requirements of the Public Health Value: Health Equity part of Factor 1b.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

The Applicant states that the Proposed Project will operate efficiently and effectively by furthering and improving the continuity and coordination of care for the Applicant’s Patient Panel. The Applicant states that its care coordination will ensure patients can effectively communicate with their providers and be connected to other needed services outside of the ASC.

Care Coordination: As noted above, the Applicant’s physicians integrate their adjoining clinical consultative practice at PC and their outpatient endoscopy practice at the current site to coordinate all aspects of their patients care. At the proposed site, the Applicant’s physicians’ clinical consultative practice will continue to adjoin the outpatient endoscopy practice. This integration will create ease of access to seamless care for patients and will continue to foster continuity of care and coordination of all aspects of their patients’ care. The 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 SSH. This will remain unchanged after the proposed relocation.

Electronic Medical Record (EMR): Currently, WE physicians follow up with all their patients’ PCPs by sending pathology and procedure reports to them. WE physicians will continue to ensure appropriate linkages to patients’ primary care services at the proposed site. The Applicant states that it has strong pre-existing relationships with area primary care practices including South Shore Medical Center, Manet Community Health Center, and Healthcare South P.C. and that these relationships are expected to increase through the Proposed Project. The Applicant affirms that the close coordination with primary care practices will also encourage patient compliance with screening and follow up visits. The Applicant will continue to share an 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 Applicant states that currently, Manet Community Health Center faxes patient information to WE, and once both the procedure and pathology report are completed by the Applicant, the two reports are faxed to Manet Community Health Center. The Applicant states that it is hopeful that there will be better interoperability of electronic health records between WE and Manet Community Health Center in the future.

Efficiency: ASCs’ focus on a specific category or categories of lower acuity surgical cases results in clinical and operational efficiencies, and this is reflected in the facility’s design, specialty services,

and tailoring to the needs of their patients, allowing ASCs to maximize use of their staff and their space.^{oo} The efficiencies of an ASC permit patients to spend less time in surgery and to move to recovering rooms sooner, allowing for more procedures to be performed in a day. ASC design accommodates specific surgical specialties. ORs and procedure rooms are sized to meet these needs, and the facility is equipped with equipment specific to the types of procedures being performed. Physicians operating in ASCs have more control over the surgical practice which allows physicians to schedule procedures more conveniently, assemble teams of specially trained and highly skilled staff, ensure that the equipment and supplies being used are best suited to their techniques, and design facilities tailored to their specialties and to the specific needs of their patients.^{pp} ASCs exercise better control over scheduling than in the hospital setting, reducing scheduling delays and rescheduled procedures.^{qq}

Analysis

Staff finds that the Applicant's care coordination will contribute positively to efficiency, continuity, and coordination of care. The Applicant demonstrated how it will maintain patient records, and facilitate communication with patients, pre- and post-operatively, and with other providers, to track patient progress and to promote better health outcomes. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1c.

Factor 1: d) Consultation

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

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

The Department's Guideline^{dd} for community engagement defines "community" as the Patient Panel, and requires that at minimum, the Applicant must "consult" with groups representative of t+

he Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."^{ee}

To fulfill the community engagement requirement, the Applicant took the actions described below and engaged with the medical community and its referral sources in the area including with SSH, South Shore Medical Center, Manet Community Health Center, and Healthcare South P.C.

The Applicant hosted a Zoom Presentation on May 16, 2024. The Applicant posted notice of the live presentation on its website with a copy of the presentation embedded a week in advance. The Applicant made a copy of the notice of the live presentation and the presentation available at the Applicant's front desk. The Applicant also sent a notice of the presentation to patients via a listserv a week in advance and the Applicant mailed slides to patients after the presentation. Seven people attended the Zoom Presentation. After the presentation, one person emailed the Applicant with

positive feedback saying that the new location is great and easier to access and that it will be beneficial to reduce the scheduling delays. The Applicant provided a copy of the slides that were presented at the sessions.

Additionally, the Applicant sent notification about the Proposed Project to its Patient Panel on June 18, 2024. 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, and a Notice of Intent regarding the Proposed Project was published in The Patriot Ledger on June 7, 2024.

The Applicant submitted letters of support for the Proposed Project from South Shore Health, which includes SSH and South Shore Medical Center (South Shore affiliated primary care group), and from Healthcare South P.C. In their letters, Health Care South P.C. and South Shore Health described working closely with WE to provide GI care for their patients and described an unmet need for colonoscopy and upper endoscopy in the region in particular for colonoscopy for colon cancer screening with wait times of four to five months. The Applicant states that Manet Community Health Center has also been supportive of the Proposed Project.

Analysis

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the required community engagement standard of Consult in the planning phase of the Proposed Project. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1e.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

The Applicant states that 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 with improved clinical and operational efficiency. The Applicant cites several studies reporting on the cost savings generated by ASCs.

- ASCs provide a lower-cost alternative to higher-cost HOPDs for the same surgical procedures.^{rr}
- 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.^{ss} 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.
- Medicare reimbursement rates for ASCs are 58% of the amount paid to HOPDs on average for all eligible procedures, including endoscopy.^{tt} ASCs saved the Medicare Program and its beneficiaries \$7.5 billion from 2008 to 2011.^{uu} Additionally, increasing the share of procedures performed in ASCs in the Medicare program has the potential to save the Medicare program an average of 5.76 billion each year.^{vv}

The Applicant states further that both patients and payers will realize cost savings from the Proposed Project because it will alleviate scheduling delays and demand for Procedures at higher cost HOPDs. 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. The Applicant cites the HPC's findings that compared to the same services delivered in a HOPD setting, ASCs typically had lower commercial prices for their services, and in 2021, common surgeries at ASCs cost 27% to 57% less compared to services in HOPDs. Both Medicare and MassHealth pay lower rates for the same services provided in an ASC compared to a HOPD setting.^{ww}

To further demonstrate the cost savings from shifting procedures performed in HOPDs to the ASC setting due to payment differences between the two sites of care, the Applicant cites reporting from the healthcare financial management association stating that as of May 2019, the allowable payment rate for a diagnostic colonoscopy in an HOPD was \$709.98, while the same procedure in an ASC was \$369.84^{xx}; and another recent study exploring site-related facility fee differences in the commercial market for colonoscopy procedures reported that facility fees for hospitals were approximately 55% higher than those at ASCs.^{yy}

Analysis

Staff finds the Proposed Project has the potential to reduce healthcare costs through providing a lower cost site for endoscopy procedures. The Applicant provided data demonstrating cost savings that can result from surgeries performed in the ASC setting, versus the HOPD setting, and has further illustrated how such savings can occur for all payers and for patients through the Proposed Project by increasing access to services in a cost-effective setting while simultaneously reducing scheduling delays. Staff finds that, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending and therefore, the requirements of Factor 1f have been met.

Factor 1 Summary

As a result of information provided by the Applicant and additional analysis, staff finds that with the "Other Conditions" outlined below and the standard reporting requirements, the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f).

Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation

Cost Containment

The Applicant states that 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 ASC setting. The Applicant states that the goals for cost containment in Massachusetts, established by the HPC, center around providing low-cost care

alternatives without sacrificing high quality. The Applicant maintains that 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 delivered, thus further improving public health outcomes while also further containing unnecessary health care expenditures.

As noted above, increasing access to the Applicant's ASC will reduce wait times for procedures which can lead to earlier detection rates resulting in earlier, more cost effective treatment which can contribute to a reduction in healthcare spending. The Applicant notes that increasing access to the facility with its excellent health outcomes as indicated through its ADR, will increase availability of high-quality, effective services.

As noted in Factor 1f, Medicare reimbursement rates for ASCs are 58% of the amount paid to HOPDs. Medicaid and commercial insurers also benefit from lower prices for services performed in the ASC setting. Increasing access to ASC capacity can contribute to lower spending for procedures. The additional access that will occur through the Proposed Project will reduce reliance on SSH for overflow patients and reserve more access at SSH for patients of medical necessity. Both more patients receiving their procedures at the proposed site, instead of SSH, and lower reimbursement for Procedures performed at the proposed site, than at the SSH Location, will contribute to further reductions in healthcare spending, including lower cost sharing for patients.

Analysis: Cost Containment

Staff finds that the Applicant demonstrated how the Proposed Project aligns with the Commonwealth's cost containment goals through the expansion of access to high-quality ambulatory surgery in a lower cost setting, and through reducing delays in access to endoscopy services. Therefore, DoN Staff conclude that the Proposed Project will likely meet the cost containment component of Factor 2.

Improved Public Health Outcomes

The Applicant states that by increasing access to WE's services and thus screening rates, clinicians will be able to detect cancer earlier and provide more successful treatment options thereby leading to improved health outcomes and quality of life. As noted above in Factor 1b, ASCs are reimbursed a lower amount than HOPDs without compromising quality of care. Patient quality and safety at ASCs is comparable or better than the care delivered at HOPDs including shorter procedure times, faster recovery times, and lower readmission and infection rates. The Applicant states that the proposed site's modern facility design will similarly contribute to improved public health outcomes because of its reduced noise, improved lighting, better ventilation, better ergonomic designs, more supportive workplaces, and improved layout which will help reduce errors and stress.

With early detection, CRC and esophageal cancer can be treated more easily, more successfully, and more cost effectively. According to the American Cancer Society (ACS), the five-year survival rate for localized colorectal cancer (cancer that is confined to the colon or rectum) is 91% while the five-year survival rate for distant colorectal cancer (cancer that has spread to distant areas of the body) is

13%.^{zz,17} Similarly, the 5-year relative survival rate for people diagnosed with localized esophageal cancer (cancer growing only in the esophagus) is 49% while the survival rate for people diagnosed with distant esophageal cancer (cancer spread to organs or lymph nodes away from the main tumor) is 6%.^{aaa} The Applicant states that it has demonstrated excellent outcomes, including the Applicant's ADR in 2023 which ranged from 45-52% compared to the benchmark for ADR, which is 25% overall.

The Applicant states that it 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 medical staff. New pre/post-procedure bays will afford patients more privacy and new mechanical air conditioning and ventilation at the proposed site will be able to support infection control protocols in a more efficient way.

Analysis: Public Health Outcomes

Staff finds that the Applicant demonstrated how the Proposed Project will improve health outcomes through increasing access to WE's services, which the Applicant has shown to be high-quality, and through reducing delays in diagnosis and treatment. Therefore, DoN Staff conclude that the Proposed Project will likely meet the Public Health Outcomes component of Factor 2.

Delivery System Transformation

The Applicant states that patients complete a health packet and demographic screening prior to procedures. The Applicant receives any SDoH concerns from the medical records, and works with patients and primary care providers to ensure patients are linked to social services organizations as needed. The Applicant affirms that they will continue to support appropriate linkages to patients' primary care services at the proposed ASC. As noted in Factor 1b, the Applicant screens patients prior to procedures to determine SDoH needs. If concerns around SDoH are identified or suspected during pre-procedure screenings and appointments, staff provide the patient with referral resources and notify the patient's PCP as appropriate to encourage necessary follow-up.

Analysis: Delivery System Transformation

The Applicant demonstrated how the proposed ASC will evaluate patients for health needs and track and communicate with patients post procedure, to improve continuity of care and health outcomes. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the Delivery System Transformation component of Factor 2.

Factor 2 Summary

As a result of information provided by the Applicant and additional analysis, staff finds that with the "Other Conditions" outlined below and the standard reporting conditions, the Applicant

¹⁷ Localized means there is no sign that the cancer has spread outside of the colon or rectum.

demonstrated that the Proposed Project has met Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant provided evidence of compliance and good standing with federal, state, and local laws and regulations. This will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such finding must be supported by an analysis conducted by an independent CPA. The Applicant submitted a report performed by Fopiano & Sullivan, LLC (CPA Report).

The CPA analysis included a review of numerous documents in order to form an opinion as to the reasonableness and feasibility of the projections regarding the Proposed Project. The projections are deemed reasonable, within the context of this report, if they are supportable and proper given the underlying information. The Proposed Project is feasible if, based on the assumptions used, the plan is not likely to result in insufficient funds available for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Company, its parties, or the Patient Panel.

To arrive at its conclusions, the scope of the CPA report is limited to an analysis of the five-year Projections for the fiscal years ending December 2025 through December 2029, prepared by Management of Weymouth Endoscopy, LLC (WELLC), and the supporting documentation. The Projections are delineated between five categories of revenue and six categories of operating expenses of WELLC as well as other nonoperative gains and losses for the Company.

Sources of information used and relied upon in the report:

- Operating revenue and expenses for existing results of WELLC for the 12 months ended December 31, 2023.
- WELLC internal financial statements as of and for the years ended December 31, 2020; 2021; 2022; and 2023.
- Projected pro-forma revenue and expenses for the five years ended December 31, 2025; 2026; 2027; 2028; and 2029.
- WELLC internal financial and statistical reporting procedures performed for the 12 months ended March 31, 2024.
- Historical volume of WELLC procedures performed by physicians for the years ended December 31, 2021; 2022; and 2023.

- WELLC's projected financial position when tenant improvements are complete.
- Determination of need application instructions dated March 2017
- Draft DoN provided June 5, 2024.

Revenues: The CPA reviewed and analyzed the net operating revenues in the historical and projected financial information. Based on discussions with Management and a review of the information, the CPA determined that there is an overall improvement in the net earnings of WELLC following the change in location. The CPA analyzed the projected/pro-forma revenue for fiscal years 2025 through 2029 in relation to the historical results for the 12 months ended March 31, 2024, in order to assess the reasonableness of the pro-forma statements of the Proposed Project, and based on their analysis, the CPA determined that the pro-forma operating revenues are reasonable. The CPA states that net patient service revenue is the only revenue category on which the proposed capital projects would have an impact. Therefore, the CPA analyzed net patient revenue identified by WELLC in both their historical and projected financial information. The CPA found the revenue growth projected by Management reflects a reasonable estimation based upon the company's historical operations.

Expenses: The CPA analyzed each of the categorized expenses for reasonableness and feasibility as it relates to the projected revenue. The CPA reviewed the historical actual results for the 12 months ended March 31, 2024. Expenses are based on average cost per procedure for the 12 months ended March 31, 2024. Management anticipates these expenditures to increase in congruence with anticipated procedures performed. The CPA reviewed the lease agreement and corresponding amendments and noted that the lease term is through February 28, 2035. The CPA analyzed the projected/pro-forma expenses for fiscal years 2025 through 2029 in relation to historical volume for the years ended December 31, 2023, 2022 and 2021, as well as the rolling 12 months ended March 31, 2024, to assess the reasonableness of the pro-forma statements.

Capital Contribution: Per the CPA's discussion with Management, it is anticipated there will be a build out loan of approximately \$1,960,000 and an equipment loan for the additional equipment of about \$1,250,000. This debt will be financed so there will be no capital contributions required by the members of WELLC. The Company will not require any capital contributions throughout the years of 2025 to 2029.

CPA's Conclusion of Feasibility

The CPA analyzed the projected operations, including volume of procedures, revenue, and expenses for WELLC. In performing their analysis, the CPA considered multiple sources of information including historical and projected financial information. The CPA determined that "the projections were not likely to result in insufficient funds available for ongoing operating costs necessary to support WELLC. Based upon our review of the projections and the relevant supporting documentation, we determined WELLC's continued operating income is reasonable and based upon feasible financial assumptions."

Analysis

Staff is satisfied with the CPA's analysis of the Applicant's decision to proceed with the Proposed

Project. As a result, staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

Factor 5: Assessment of the Proposed Project's Relative Merit

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) 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.

The Applicant considered and rejected two alternatives to the Proposed Project.

Alternative #1: continue status quo or expand at the current location. The Applicant states that the lease in the current location, which is set to expire in August 2025, was not offered to the Applicant and even if it had been offered, due to restrictions on the current site, the current site could not have accommodated the additional building footprint and associated parking to support an expansion. The Applicant states that the quality under this alternative would remain unchanged but that the facility would not be able to accommodate existing volume of the Patient Panel and any additional growth in volume. This alternative would result in continued operating inefficiencies due to the inability to meet the need for procedures. This alternative would not be associated with any capital expense nor would it result in any change in operating costs. Yet, it would still not be a feasible alternative to address Patient Panel need for the Applicant's services and earlier patient access to diagnostic and screening endoscopy.

Alternative #2: the Applicant operates the Proposed Project at another location. The Applicant states that it worked with two real estate brokers over the course of a year to evaluate a number of properties for the current ASC in its service area, primarily focusing on Weymouth, but that the proposed site was the only one that met the location and size requirements. The Applicant states that it was not able to explore the quality, efficiency, capital expense, and operating costs of this alternative because it ultimately did not find an alternative facility that met all of its requirements and needs.

Analysis

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives. As a result of information provided by the Applicant and additional analysis, staff finds the Applicant has reasonably met the standards of Factor 5.

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

Overall Application Summary and relevant background and context for this application:

This is a DoN project for a freestanding ASC that is not affiliated with a hospital. In turn, the

Proposed Project does not require the submission of CHI forms. Weymouth Endoscopy, LLC, will fulfill Factor 6 requirements by directing their full CHI contribution to the Statewide Community Health and Healthy Aging Funds (CHHAF).

With fulfillment of the below conditions, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended Conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project and recommends that the Department approve this Determination of Need, subject to all applicable Standard and Other Conditions.

Other Conditions

1. The total required CHI contribution of \$267,349.15 will be directed to the Massachusetts Statewide CHHAF and will be paid by Weymouth Endoscopy, LLC in **one installment** of \$267,349.15. Payments should be made out to:

Health Resources in Action, Inc. (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116 Attn: MACHHAF c/o Bora Toro
DoN project #: WE-24062414-AS

2. The payment of \$267,349.15 will be due to HRiA **within 30 days** from the date of the Notice of Approval. Please send a PDF image of the check or **confirmation of payment** to DONCHI@Mass.gov and dongrants@hria.org

If you should have any questions or concerns regarding the payment, please contact the CHI team at DONCHI@Mass.gov.

3. In addition to WE ASC's obligation to participate in MassHealth, pursuant to 105 CMR 100.310(11), the Holder must certify annually that all physicians and health professionals who practice at the facility are enrolled as participating providers of MassHealth to support equitable access to all clinicians at the facility regardless of payer.
4. In order to support equitable access to WE's services, the Holder will report on annual efforts to promote health equity at WE, including but not limited to efforts to identify and address disparities in access to WE's services, and efforts to advance the provision of culturally and linguistically appropriate services at WE. The annual report will discuss specific programs in place, efforts to improve linkages to referral partners, timeframe of implementation, patients served, and impact.

5. The Holder shall report on WE's screening and diagnostic endoscopy patients stratified by race and ethnicity, by patient origin (zip code), and by payer mix.
6. The Holder shall report on ongoing efforts to increase Medicaid in its payer mix, detailing the strategies being implemented to achieve this goal.
7. The Holder shall report on Procedure volume, and patient acuity at WE and SSH. Reporting will include the percentage of Procedures performed at SSH due to medical necessity, and overflow.
8. The Holder shall report annually on the Adenoma Detection Rate stratified by race/ethnicity, and by payer mix.
9. The Holder shall report on progress in reduction of wait times for scheduling surgical procedures. The Holder shall provide a description of how wait time is calculated.

Appendix I: Required Measures for Annual Reporting

The Holder shall, on an annual basis, commencing with approval of this DoN, and continuing annually for a period of five years after the Project is complete, report on the following data elements, pursuant to 105 CMR 100.310(A)(12). Reporting will include a description of numerators and denominators. If applicable, include baseline data for measures (a year prior to implementation of DoN-approved project).

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 the Applicant strives 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.

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