2. Project Description

Colorectal cancer is the second leading cause of cancer deaths in the United States, resulting in an estimated 53,000 deaths in 2025. Unlike most cancer screening tools, colonoscopy not only detects cancerous polyps, but allows for the removal of precancerous polyps during the same procedure before they turn into cancer. Massachusetts currently has one of the highest colorectal cancer screening rates in the United States at 70% across all populations, but is still well below the national goal of 80%. Increasing colorectal cancer screening prevalence to 80% could reduce deaths from colorectal cancer by 33% by 2030.

One of the biggest limiting factors to increasing screening prevalence is access to colonoscopy. Per capita, Massachusetts has the fourth fewest ambulatory surgery centers (ASC) in the United States, ⁵ resulting in the majority (73%) of ASC-eligible outpatient gastrointestinal/endoscopy procedures being performed in hospital-based outpatient departments (HOPD). ⁶ Even more concerning is the growing wait list for colonoscopy in Massachusetts. ⁷ As of this Application, Mass General Brigham's two academic medical centers (AMC), Massachusetts General Hospital (MGH) and Brigham and Women's Hospital (BWH) (collectively, the "MGB AMCs") have more than 25,000 patients waiting for their endoscopy procedures to be scheduled. The majority of these cases could be performed in an ASC, but due to the limited number of ASCs in the Greater Boston area, patients must obtain care at the main campuses of both MGH and BWH. As a result, the backlog of screening endoscopy cases continues to grow, impacting access for inpatient and emergency cases at the AMCs. Not only are wait times for screening colonoscopies increasing, but inpatients are requiring longer lengths of stay because of wait times to receive endoscopy required for discharge. With the current available capacity for endoscopy, MGB is unable to provide timely colorectal cancer screening and intervention for its patient panel. Additional endoscopy capacity is critical to improving health outcomes for MGB's patient panel.

To that end, Mass General Brigham Ambulatory Surgery – Cambridge, LLC (the "Applicant") is filing this Notice of Determination of Need ("Application") to establish a freestanding single-specialty ASC to be located at 799 Concord Ave, Cambridge, MA 02138 (the "Proposed Project"). The Applicant is owned by New England Surgery Center Holdings, LLC, a joint venture between Mass General Brigham Incorporated (MGB) and Regent Surgical Health, L.L.C. (collectively, the "Applicant Parties").

The Proposed Project will allow MGB to decrease wait times for patients needing routine screenings and to shift routine screenings that are currently performed at MGH and BWH to a more convenient, cost-effective setting improving access and throughput for cases that must be performed in the hospital setting. The proposed ASC will operate three procedure rooms and ten pre/post-operative bays in 6,095 square feet of leased space. The Maximum Capital Expenditure is \$7,349,450. Upon opening, the proposed ASC will alleviate some of the growing backlog of patients who are overdue for screening colonoscopies and achieve significant cost savings for the payers, including patients, of endoscopy procedures compared to the AMC setting. Simultaneously, the shift of cases to the proposed ASC will

¹ Key Statistics for Colorectal Cancer, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html (last revised Apr. 28, 2025).

² Colorectal Cancer Screening, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/colorectal-cancer/screening/index.html (Feb. 26, 2025).

³ Meester RG, Doubeni CA, Zauber AG, et al. Public Health Impact Of Achieving 80% Colorectal Cancer Screening Rates In The United States By 2018. *Cancer*. 2015;121(13):2281–2285, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21772.

⁴ Colorectal Cancer, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nccdphp/priorities/colorectal-cancer.html (Oct. 16, 2024).

⁵ Claire Wallace, ASCs Per Capita In All 50 States, BECKER's ASC REVIEW (Nov. 6, 2023), https://www.beckersasc.com/asc-news/ascs-percapita-in-all-50-states-2023/.

⁶ HPC DataPoints, Issue 26: Trends in Ambulatory Surgical Centers in Massachusetts, MASSACHUSETTS HEALTH POLICY COMMISSION, https://www.mass.gov/doc/datapoints-issue-26-printable-version/download (last visited June 18, 2025).

⁷ See Weymouth Endoscopy, LLC Determination of Need Application. See also West Bridgewater MA Endoscopy ASC Determination of Need Application.

create capacity at MGH and BWH to address emergency and inpatient needs in a timely manner. The proposed ASC will contribute to and promote adherence to MGB's, the Commonwealth's, and national cancer screening recommendations by creating improved access to endoscopy.

As detailed throughout this Application, there is a need for dedicated outpatient procedure rooms to address a growing backlog of endoscopy that will continue to increase as screening guidelines evolve based on cancer incidence rates. Further, the Proposed Project offers a more cost-effective option because the cost of procedures performed in an ASC are significantly lower compared to a hospital setting. Not only will the Proposed Project provide cost savings per procedure, but it will contribute to overall cost containment through timely diagnosis and treatment, often within the same endoscopy case. The proposed ASC will deliver equally high-quality care in a lower cost setting as the MGB AMCs, therefore the Proposed Project provides the best option to improve access to outpatient endoscopy for the Patient Panel.

In summary, the Proposed Project will meet an identified need for the Patient Panel by expanding access to routine endoscopy in an ASC. The proposed ASC will provide patients with more timely access to high-quality endoscopy, improving their ability to receive screening colonoscopy which contributes to not only the timely diagnosis of colorectal cancer, but also the successful treatment of such cancers. Moreover, the provision of screening colonoscopies at the proposed ASC will reduce endoscopy volume at the MGB AMCs, in turn, allowing endoscopy cases that must be performed in the hospital to be done more quickly, not only improving treatment time and throughput but reducing inpatient lengths of stay and overall costs as a result. The Applicant respectfully requests the Department find that each factor of review is met and recommend approval of this Application for Determination of Need.

Factor 1: Applicant Patient Panel Need, Public Health Values and Operational Objectives

F1.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.

A. Overview of Patient Panel Selection

The Applicant is owned by New England Surgery Center Holdings, LLC, a joint venture between MGB and Regent Surgical Health, L.L.C. As the Applicant is newly formed and does not have its own patient panel, the Applicant relied on certain historical data from MGH and BWH to determine the need for the Proposed Project.

Specifically, the Applicant reviewed historical outpatient endoscopy volume that would have been appropriate for treatment in an ASC. This data was further narrowed by patient zip codes to better illustrate the need for endoscopy by the MGB AMC's patients. Towns with the highest need for outpatient endoscopy currently receiving care at the MGB AMCs include Arlington, Belmont, Boston, Brookline, Cambridge, Chelsea, Everett, Malden, Medford, Newton, Revere, Somerville, Watertown, and Winthrop (collectively, the "Proposed Service Area"). A detailed breakdown of zip codes is provided in Table 2.

Using this proposed service area, the Applicant notes the following of its Patient Panel:

• Age: More than 75% of the Patient Panel was between the ages of 40 and 80 in FY2024, with 37% of the Patient Panel between the ages of 40 and 60.

- Race/ Ethnicity: The majority of patients (67%) self-identified as White, 16% of patients identified as Hispanic/ Latino, 10% of patients identified as African American, and 7% identified as Asian.
- Payer Mix: Public payers represent roughly 40% of the Patient Panel payer mix, with almost 30% Medicare (Medicare Fee for Service and Managed Medicare) and 10% Medicaid (MassHealth primary and Managed Medicaid).
- <u>Geographic Origin</u>: 75% of the Patient Panel reside in Boston, Cambridge, Revere, Chelsea, Somerville, and Brookline.

The tables below reflect historical BWH and MGH patients who would have been eligible to have their endoscopy procedures⁸ performed in an ASC.

⁸ Colonoscopy - Diagnostic/Screening; Colonoscopy - Procedural; EGD - Diagnostic; EGD - Procedural; Anoscopy - Procedural; Enteroscopy - Diagnostic; Enteroscopy - Diagnostic; Enteroscopy - Procedural; Esophagoscopy - Diagnostic; Esophagoscopy - Procedural; Other GI Procedures - Dilation - Esophagus; Other GI Procedures - GI Tube Insertion/Replacement/Service - Percutaneous; Other GI Procedures - Other Tube Placement; Proctosigmoidoscopy - Diagnostic; Proctosigmoidoscopy - Procedural; Sigmoidoscopy - Diagnostic/Screening; Sigmoidoscopy - Procedural

Table 1: Patient Panel Demographics Data	FY22 Count	FY22 %	FY23 Count	FY23 %	FY24 Count	FY24 %
Total Unique Outpatient Endoscopy Patients	8,184	100%	8,422	100%	7,716	100%
Gender: Female	4,529	55%	4,625	55%	4,299	56%
Gender: Male & Other/Unknown	3,655	45%	3,797	45%	3,417	44%
Age: 0-20	160	2%	187	2%	190	2%
Age: 20-40	1,096	13%	1,100	13%	1,133	15%
Age: 40-60	3,264	40%	3,349	40%	2,820	37%
Age: 60-80	3,168	39%	3,388	40%	3,186	41%
Age: 80-100	496	6%	398	5%	387	5%
Race: White	5,281	65%	5,585	66%	5,132	67%
Race: Black or African American	962	12%	860	10%	779	10%
Race: Asian	596	7%	677	8%	555	7%
Race: Other/Unknown ⁹	1,335	16%	1,300	15%	1,250	16%
Ethnicity: Hispanic	1,365	17%	1,281	15%	1,210	16%
Ethnicity: Not Hispanic	6,353	78%	6,674	79%	6,008	78%
Ethnicity: Other	466	6%	467	6%	498	6%

Table 2: Patient Panel Payer Data	FY22 %	FY23 %	FY24 %
Payer: Commercial	59%	61%	60%
Payer: Medicare	21%	20%	19%
Payer: Medicare Managed	7%	8%	9%
Payer: Medicaid	12%	6%	3%
Payer: Medicaid Managed	1%	4%	7%
Payer: Other	1%	1%	2%
Total	100%	100%	100%

 $^{^{9}}$ Includes Native Hawaiian, Race Not Listed, Unavailable, and Declined.

able 3: Patient Panel Geographic Origin		FY2022	FY2022	FY23	FY23	FY24	FY24
Zip Code(s)	Town	Count	Percent	Count	Percent	Count	Percent
02108, 02109, 02110, 02111, 02113, 02114, 02115, 02118, 02199, 02210,							
02215, 02130, 02131, 02124, 02127, 02136, 02125, 02119, 02121, 02126,							
02122, 02134, 02135, 02129	Boston	3,574	44%	3,448	41%	3,286	43%
02138, 02139, 02140, 02141, 02142	Cambridge	687	8%	763	9%	691	9%
02151	Revere	612	7%	708	8%	628	8%
02150	Chelsea	435	5%	462	5%	413	5%
02144, 02143, 02145	Somerville	397	5%	454	5%	408	5%
02445, 02446	Brookline	404	5%	389	5%	389	5%
02155	Medford	373	5%	389	5%	350	5%
02149	Everett	320	4%	331	4%	321	4%
02152	Winthrop	314	4%	298	4%	314	4%
02148	Malden	348	4%	324	4%	272	4%
02474, 02476	Arlington	254	3%	286	3%	233	3%
02478	Belmont	169	2%	253	3%	168	2%
02464	Newton	152	2%	150	2%	130	2%
02472	Watertown	145	2%	167	2%	113	1%
	Total	8,184	100%	8,422	100%	7,716	100%

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.

In 2025, an estimated 154,270 adults will be diagnosed with colorectal cancer and more than 50,000 people will die from the disease. Fortunately, colonoscopy is not only a highly effective screening tool but is associated with as much as a 69% decrease in new cases of colorectal cancer and an 88% decrease in the risk of death from it. He start of the COVID-19 pandemic, the colorectal cancer screening rate in and around Boston was 72%. By 2023, the rate dropped to 67% due in large part to the restrictions placed on non-essential surgeries during the pandemic, ongoing staffing challenges, and IV shortages. As colonoscopies were cancelled, the backlog of cases at MGH and BWH continued to grow as more adults became eligible by virtue of turning 45, the age at which average-risk adults should start having screening colonoscopies. However, while cancer rates typically increase with age, colorectal cancer rates have increased 2% annually since the 1990s among younger adults 20-39, contributing further to the need for colonoscopy across ages. By July 2025, the number of adults waiting to be scheduled for a routine endoscopy procedure at the MGH and BWH alone had grown to more than 25,000 while the wait list across all sites includes more than 45,000 MGB patients.

To address the need for endoscopy by the Patient Panel, the Applicant seeks to establish a new, freestanding ASC in Cambridge to improve access to outpatient endoscopy, in turn reducing wait times while also offering cost savings and a more convenient setting. Improving access to endoscopy is necessary for improving colorectal screening adherence. Without improved access through the expansion of ASC operating capacity, Massachusetts cannot meaningfully improve screening adherence which directly impacts health outcomes. Moreover, the availability of a dedicated endoscopy ASC for MGB patients in the community will decrease outpatient cases at the MGB AMCs, freeing up endoscopy rooms for higher acuity patients and procedures. Independently and collectively, these objectives are imperative for better public health outcomes and cost containment.

In FY2024, the MGB AMCs performed 35,195 endoscopy procedures, including 29,723 outpatient procedures. Of those, 99% were eligible to be performed in an ASC. At the time of this Application, there

¹⁰ Cancer Stat Facts: Colorectal Cancer, NATIONAL CANCER INSTITUTE, https://seer.cancer.gov/statfacts/html/colorect.html (last visited July 11, 2025).

¹¹ How Well Do Colonoscopies Prevent Colorectal Cancer? What You Need To Know, HARVARD MEDICAL SCHOOL, https://www.health.harvard.edu/blog/how-well-do-colonoscopies-prevent-colorectal-cancer-what-you-need-to-know-202210182834 (last visited July 11, 2025).

¹² Siyu Wang et al., *Colorectal Cancer: Epidemiology, Risk Factors, and Prevention*, PREVENTIVE MEDICINE REPORTS (Jan. 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC10788250/.

¹³ Archive of COVID-19 Public Health Guidance and Directives, MASS. DEP'T PUB. HEALTH, https://www.mass.gov/info-details/archive-of-covid-19-public-health-guidance-and-directives (last visited July 11, 2025).

¹⁴ Robert King, Massachusetts Calls on Hospitals to Reduce Elective Procedures Amid Staffing Shortages, FIERCE HEALTHCARE (Nov. 27, 2021), https://www.fiercehealthcare.com/hospitals/mass-calls-hospitals-to-reduce-elective-procedures-amid-staffing-shortages.

¹⁵ Jackie Fortier, *Nationwide IV Fluid Shortage Changing How Hospitals Manage Patient Hydration*, NPR (Nov. 19, 2024), https://www.npr.org/sections/shots-health-news/2024/11/19/nx-s1-5193027/nationwide-iv-fluid-shortage-intravenous-drugs-hospitals-patient-hydration-helene-hurricane-baxter.

¹⁶ American Cancer Society Guideline for Colorectal Cancer Screening, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/types/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html (last visited June 12, 2025).

¹⁷ Colorectal Cancer Rates Are Skyrocketing in Young Adults – Is Your Lifestyle Putting you at Risk?, CANCER RESEARCH INSTITUTE, https://www.cancerresearch.org/blog/colorectal-cancer-awareness-month (last visited July 11, 2025).

is only one dedicated endoscopy ASC in Boston. As a result, MGB's metro-Boston patients do not have non-hospital options for endoscopy at a time when routine and diagnostic colonoscopy is more needed than any previous time period due to rising colorectal cancer rates in younger adults and changes to screening guidelines.

Specifically, the Proposed Project is needed to address four objectives. As of July 30, 2025, 26,586 MGB patients are waiting for their endoscopy procedure to be scheduled at MGH and BWH. Additional capacity is needed to (1) address this growing backlog of MGB's outpatient endoscopy cases and (2) simultaneously alleviate capacity constraints that will allow emergent and inpatient cases at the MGB AMCs to be performed sooner. Third, the proposed ASC will significantly reduce costs for patients and payers compared to endoscopy at the MGB AMCs. Lastly, improving access to endoscopy is crucial in light of rising colorectal cancer rates and the importance of timely screening adherence. As supported by the data provided below, the proposed ASC will offer additional capacity and timelier access to high-quality endoscopy at a lower cost while simultaneously creating more capacity at the MGB AMCs for inpatient and emergency cases.

A. Historical Utilization

In FY2024, MGB and BWH performed 20,117 endoscopy procedures which could have been performed in an ASC. Of those ASC-eligible procedures at the MGB AMCs, 9,879 procedures were for patients residing in the Proposed Service Area. To that end, providing endoscopy at the Proposed ASC will reduce the unnecessary reliance on MGB and BWH for the Patient Panel. The table below breaks down the Patient Panel's outpatient endoscopy utilization by facility, category, and type.

Table 4: Historical Utilization	FY22	FY22 %	FY23	FY23 %	FY24	FY24 %
Outpatient Endoscopy Volume Total	9,879	100%	10,237	100%	9,449	100%
Facility: BWH	2,496	25%	2,007	20%	2,055	22%
Facility: MGH	7,383	75%	8,230	80%	7,394	78%
Category: Diagnostic	4,232	43%	4,241	41%	3,988	42%
Category: Procedural/Screening	5,077	51%	5,503	54%	4,916	52%
Category: Other ¹⁸	570	6%	493	5%	545	6%
Type: Upper	2,832	29%	2,660	26%	2,329	25%
Type: Lower + Other	7,047	71%	7,577	74%	7,120	75%

Outpatient procedures account for approximately 85% of all endoscopy performed at the AMCs. This is consistent FY2022 – FY2024, with a small shift in FY2025 due to an increase in inpatient procedures. In FY2024, the AMCs performed 5,435 inpatient procedures and are on track to perform 6,902 inpatient procedures in FY2025, a 27% increase. As a result of the increased inpatient volume, the average utilization rate of BWH's endoscopy rooms is 89% and MGH's is 75% ¹⁹ (July 2025). Moreover, inpatients are waiting longer for endoscopy procedures. Inpatients at MGH are waiting on average almost a full day for endoscopy (22 hours), while inpatients at BWH are waiting 18 hours. These delays result in longer stays for the patient with associated higher risks of negative outcomes, including physical and function decline and hospital-acquired infections ²⁰, as well as higher costs for payers. Moreover, longer than necessary inpatient stays prevent new patients from being admitted to an inpatient bed from the

¹⁸ Includes follow-up for positive FIT/Cologuard and surveillance for history of polyps.

¹⁹ MGH's current endoscopy room utilization is down 10 percentage points from FY24 (85%) due to the opening of a second inpatient room in the afternoon to accommodate the growing number of inpatient endoscopy cases.

²⁰ David W. Bates et al, *The Safety of Inpatient Health Care*, NEW ENGLAND JOURNAL OF MEDICINE, available at https://www.nejm.org/doi/full/10.1056/NEJMsa2206117.

emergency department or a community hospital, contributing to throughput challenges across the MGB AMCs and region.

B. Proposed Project

In order to provide the Patient Panel with adequate access to outpatient endoscopy, the Applicant proposes a freestanding, single-specialty ASC in Cambridge. The proposed ASC will have three (3) procedure rooms and 10 pre/post-operative care bays. Each procedure room will have a maximum procedural capacity of 12 cases per day. The ASC will be open five days per week (Monday – Friday), with closures for 11 holidays, resulting in an annual maximum capacity for the ASC of 9,000 once the ASC is fully operational. The ASC's proposed utilization is set for in Table 5 below.

Table 5: Proposed Utilization	Year 1	Year 2	Year 3	Year 4	Year 5
Volume	4,752	7,350	7,460	7,572	7,686
Operating Capacity	53%	82%	83%	84%	85%

As noted earlier, the immediate effect of the proposed ASC will be to reduce wait times for outpatient endoscopy for the Patient Panel. This will create more timely access to colonoscopy for patients due for their routine screening and reduce wait times for inpatients at the MGB AMCs. Creating additional procedural capacity is necessary for promoting screening adherence and follow-up care, both of which will continue to be crucial for health outcomes as colorectal cancer rates rise and the population ages. Each of the top towns in the Proposed Service Area are expected to grow in the coming years, resulting in almost 8,000 more residents between the ages of 45 and 75 by 2040.²¹ Of note, Cambridge, Revere, and Somerville are projected to experience significant growth by 2035 including 20% growth of Cambridge residents ages 50-59, 33% growth of Revere residents 45-54, 23% growth of Somerville residents ages 45-54.²² To that end, timely access to outpatient endoscopy must be available to the Applicant's Patient Panel.

The Proposed Project will provide capacity for thousands of additional MGB patients to be screened for colorectal cancer and receive diagnostic endoscopy care each year. Through the Proposed Project, MGB will have capacity to meaningfully address the backlog of endoscopy cases that have accumulated since the COVID-19 pandemic, disrupting endoscopy care for all patient classes. The additional capacity created through the Proposed Project will also address the projected population increase among colonoscopy screening eligible individuals within its Patient Panel. With additional colorectal screening slots available, more patients will receive screenings timely, initiating treatment sooner and achieving improved health outcomes.

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

The Proposed Project will compete on the basis of price, total medical expenses (TME), provider costs, and other health spending factors by expanding access to lower-cost endoscopy at the proposed ASC. The Applicant's provision of endoscopy services will generate significant cost savings for both payors and patients, as ASCs offer these procedures at significantly lower costs than hospital-based outpatient departments (HOPD). ASCs compete effectively with HOPDs by delivering high-quality care at

²¹ UMDI-V2024 Massachusetts Population Projections, UMASS DONAHUE INSTITUTE, https://donahue.umass.edu/documents/UMDI_V2024_Long-

Term Population Projections MCD%2C County%2C RPA%2C State Age Sex detail 2010-2050.xlsx (last visited July 11, 2025). 22 Id.

significantly lower costs. ASCs achieve cost-efficiency through various operational efficiencies, including utilizing only the staff, equipment, and supplies necessary to meet patient needs. A recent study analyzing 220 procedures performed in ASCs and HOPDs found that ASCs outperformed HOPDs in ancillary time, procedure time, exit time, turnover time, and nonoperative time. ²³ As a result, ASC facility fees are considerably lower than those of HOPDs, directly translating into savings for both patients and payers. ²⁴ Consequently, the Proposed Project will further the Commonwealth's goal of reducing overall healthcare spending by achieving cost and operational efficiencies available through ASCs.

By expanding access to ASC endoscopy services, the Proposed Project will facilitate earlier detection of colorectal cancer, ultimately reducing TME. Timely detection is strongly correlated with improved patient outcomes. Notably, the five-year survival rate exceeds 90% when colorectal cancer is diagnosed at a localized stage but drops below 20% for late-stage diagnoses. Moreover, the stage at which colorectal cancer is detected also significantly influences treatment costs, averaging \$36,000 for patients with stage 1 colorectal cancer and rising to \$74,000 for patients with stage 4 within the first year post-diagnosis. This means earlier detection of colorectal cancer through adherence to screening guidelines can result in thousands of dollars of treatment cost savings within the first year after a patient's diagnosis. However, many Americans have not satisfied the colonoscopy screening by the time they are Medicare-eligible at age 65. One study projected that if 60–70% of Americans were up to date with colorectal cancer screenings, Medicare could save between \$2.7 billion and \$4 billion in treatment costs by 2060. Moreover, while increased screening participation may lead to short-term cost increases, long-term savings are substantial, ranging from 60% to 89% in Medicare treatment costs over a 50-year period. Property of the property of the strong participation of the substantial of the property of

Furthermore, the Proposed Project will improve patient throughput and reduce the average length of stay at the MGB AMCs, ultimately lowering healthcare costs for inpatients. Between 2022 and 2024, inpatient endoscopy procedures at the AMCs increased 27%, resulting in higher-than-expected utilization. This translates into current inpatient wait times between 17 and 22 hours at the MGB AMCS, extending hospital stays by at least one day. Not only do discharge delays due to endoscopy procedures increase admission costs, but they prevent inpatient beds from becoming available to patients waiting in the ED or in community hospitals who require tertiary and quaternary care only available at an AMC. To that end, the Proposed Project will improve inpatient throughput and reduce medical costs by reducing endoscopy utilization at and reliance on the AMCs.

Next, ASCs present a compelling cost-saving opportunity for payers through lower overall prices and TME. On average, Medicare reimburses ASCs at just 58% of the rates paid to HOPDs for the same procedures.³⁰ This pricing differential results in more than \$4.2 billion in annual Medicare savings when low-acuity procedures are performed in ASCs rather than HOPDs.³¹ ASCs are projected to generate approximately

https://www.americanjournalofsurgery.com/article/S0002-9610(18)31528-9/abstract.

²³ Johnathan B. Imran et al, Analysis of Operating Room Efficiency Between a Hospital-Owned Ambulatory Surgical Center and Hospital Outpatient Department, AMERICAN JOURNAL OF SURGERY (2019), available at

 $^{^{24} \}textit{Procedure Price Lookup}, \texttt{MEDICARE.GOV}, \underline{\texttt{https://www.medicare.gov/procedure-price-lookup/}} (last \textit{visited July 1, 2025}).$

²⁵ Beverly B. Green MD, MPH, Richard T. Meenan PhD, MPH, Colorectal Cancer Screening: The Costs and Benefits of Getting to 80% in Every Community, CANCER (July 20, 2020), https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.32990.

²⁷ Goede SL, Kuntz KM, van Ballegooijen M, et al. Cost-savings to Medicare from pre-Medicare colorectal cancer screening. *Medical Care*. 2015;53(7):630–638.

²⁸ Id.

²⁹ Id.

³⁰ Medicare Cost Savings Tied to ASCs, AMBULATORY SURGERY CENTER ASSOCIATION, https://www.ascassociation.org/asca/about-ascs/savings/medicare-cost-savings/medicare-cost-savings-tied-to-ascs (last visited June 18, 2025).

³¹ Medicare Cost Savings: An Overview, AMBULATORY SURGERY CENTER ASSOCIATION, https://www.ascassociation.org/asca/aboutascs/savings/overview (last visited June 18, 2025).

\$73.4 billion in Medicare savings between 2019 and 2028.³² The potential for a high rate of savings extends beyond Medicare, and can benefit Medicaid and commercial payers as well.

Table 6 below presents 2025 Medicare cost comparisons for common endoscopy services performed in ASCs and HOPDs. The data highlights the substantial cost advantages associated with shifting eligible procedures to ASCs. The total procedure price for endoscopy services performed in ASCs ranges from \$291 to \$1,016, significantly lower than the \$1,021 to \$2,049 range in HOPDs. By increasing the proportion of low-acuity endoscopy services performed in ASCs, Medicare can achieve meaningful cost reductions without any effect on the quality of care. Accordingly, the Proposed Project represents a strategic opportunity for Massachusetts to advance its cost containment goals while preserving access to high-quality, efficient services.

Table 6: 2025 Medicare Endoscopy Services Cost by Setting³³

Procedure	ASC Cost	HOPD Cost	Cost Savings of ASC (\$)	Cost Savings of ASC (%)
Enteroscopy - Diagnostic	\$1,001	\$2,033	\$1,032	51%
Enteroscopy - Procedural	\$1,016	\$2,048	\$1,032	50%
Esophagoscopy - Procedural	\$962	\$1,994	\$1,032	52%
Anoscopy - Procedural	\$291	\$1,252	\$961	77%
Colonoscopy - Procedural	\$824	\$1,371	\$547	40%
EGD - Diagnostic	\$621	\$1,055	\$434	41%
EGD - Procedural	\$635	\$1,069	\$434	41%
Esophagoscopy - Diagnostic	\$587	\$1,021	\$434	43%
Colonoscopy - Screening	\$666	\$1,088	\$422	39%

In Massachusetts, the Health Policy Commission (HPC), an independent state agency that monitors healthcare spending growth, recently reported that in 2021, total prices for the most common outpatient surgeries were 27% to 57% lower in ASCs than in HOPDs for commercially insured patients. ³⁴ Similarly, for MassHealth patients, the price differential ranged from 26% to 67% for the same procedures. ³⁵ Despite these savings, the HPC also found that ASC utilization for endoscopy procedures remains disproportionately low as compared to HOPDs. ³⁶ Among all commercially insured patients, annually only 27% of ASC-eligible gastrointestinal/endoscopy procedures are performed in ASCs. ³⁷ For MassHealth patients, the figure is even lower at just 10% of ASC-eligible procedures being performed in an ASC. ³⁸ The HPC also found that colonoscopies with polyp removal were 32% less expensive in ASCs than in HOPDs for commercially insured patients, and 61% less expensive for MassHealth patients. ³⁹

Freestanding ASCs are ideal for routine procedures because they deliver high-quality care at lower costs than HOPDs. By increasing the number of ASCs in Massachusetts, the Commonwealth can expand access to high-value healthcare services which will contribute to earlier detection of colorectal cancer and reduce TME. Moreover, shifting low-acuity endoscopy procedures to the proposed ASC will reduce

³² Reducing Medicare Costs, AMBULATORY SURGERY CENTER ASSOCIATION, https://www.ascassociation.org/asca/about-ascs/savings/medicare-cost-savings/reducing-medicare-costs (last visited June 18, 2025).

³³ Please note, the endoscopy services costs are based on Medicare's 2025 payments and copayments rates, as reviewed on July 1, 2025 and are available at https://www.medicare.gov/procedure-price-lookup/.

³⁴ HPC DataPoints, Issue 26, supra note 6.

³⁵ HPC DataPoints, Issue 26, supra note 6.

³⁶ HPC DataPoints, Issue 26, supra note 6.

³⁷ HPC DataPoints, Issue 26, supra note 6.

³⁸ HPC DataPoints, Issue 26, supra note 6.

³⁹ HPC DataPoints, Issue 26, supra note 6.

capacity constraints at the AMCs, further contributing to cost savings by reducing the length of stay for inpatients with endoscopy needs. By expanding access to outpatient endoscopy, the Proposed Project will compete on healthcare spending metrics, including prices, TME, and provider costs, while supporting broader efforts to contain healthcare expenditures.

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.

As demonstrated throughout this Application, there is clear and compelling evidence that expanding access to outpatient endoscopy services provides significant public health benefits. The Proposed Project will increase the availability of ASC procedure rooms for endoscopy, thereby improving timely access to essential screening, diagnostic, and treatment services. This conclusion is supported by robust, evidence-based research linking endoscopy to early detection, diagnosis, and treatment of a range of conditions. By expanding ASC capacity, the Proposed Project will reduce healthcare costs and improve patient outcomes for the Applicant's Patient Panel.

A. <u>Clinical Overview of Routine Endoscopy</u>

Endoscopy is a minimally invasive procedure that uses a thin, flexible tube with a camera, an endoscope, to examine a patient's organs. 40 Unlike traditional surgery, endoscopy does not require large incisions, making it a safer and more efficient diagnostic and therapeutic tool. As a result, routine endoscopies, such as colonoscopies, and esophagogastroduodenoscopies (EGD), are widely used to screen, diagnose, and treat conditions including cancer, gastrointestinal disorders, and inflammatory diseases. 41 These procedures often include biopsies, where abnormal tissue is removed for further analysis as part of the diagnosis process. 42 Studies show that a patient's single endoscopy with biopsy can detect cancer in approximately 70% of cases, increasing to 98% if a patient has seven biopsies. 43 Thus, endoscopy is a clinically powerful and highly reliable tool. Endoscopy also plays a therapeutic role, allowing physicians to seal wounds, inject medication, drain fluid, stop internal bleeding, and remove tumors or damaged tissues. 44

A brief overview of the clinical application of the most common forms of endoscopy are as follows:

- **EGD:** Evaluates the esophagus, stomach, and duodenum to diagnose ulcers, gastrointestinal disorders, and tumors. ⁴⁵ Physicians also use EGD to treat patients by draining abscesses, inserting medical devices, and removing polyps. ⁴⁶
- Colonoscopy: Examines the colon and rectum as a method for routine colorectal cancer screening and to investigate symptoms, including rectal bleeding or changes in bowel habits.⁴⁷

⁴⁰ Endoscopy, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/diagnostics/25126-endoscopy (last visited June 4, 2025).

⁴¹ Upper Endoscopy, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/endoscopy/about/pac-20395197 (last visited June 4, 2025).

⁴² Id.

⁴³ Johnathan Y Xia and Aziz Aadam, *Advances in Screening and Detection of Gastric Cancer*, J Surg Oncol. 125(7) (2022), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC9322671/.

⁴⁴ Endoscopy, supra note 40.

⁴⁵ Upper Endoscopy, American Cancer Society, https://www.cancer.org/cancer/diagnosis-staging/tests/endoscopy/upper-endoscopy.html (last visited June 4, 2025).

⁴⁶ EGD Procedure (Upper Endoscopy), CLEVELAND CLINIC, https://my.clevelandclinic.org/health/procedures/22549-egd-procedure-upper-endoscopy (last visited June 4, 2025).

⁴⁷ Colonoscopy, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/diagnosis-staging/tests/endoscopy/colonoscopy.html (last visited June 4, 2025).

B. Cancer Rates and Endoscopy Screening Guidelines

Rising cancer rates across the United States highlight the urgent need to expand access to endoscopy services. The American Cancer Society projects 2,041,910 new cancer cases in 2025, including 154,270 cases of colorectal cancer.⁴⁸ This represents a 4.3% increase in annual cancer cases from 2020, when 147,950 individuals were diagnosed.⁴⁹ In Massachusetts alone, 2,770 new colorectal cancer cases and 820 related deaths are expected this year.⁵⁰ To respond to the growing incidence of cancer throughout the country, it is imperative to expand access to lifesaving screening, diagnostic, and treatment tools.

Cancer rates are also rising among younger adults. Each year, 800,000 individuals aged 20-39 are diagnosed with cancer, accounting for 4% of all cancer cases annually. ⁵¹ Colorectal cancer is among the most common form of cancer diagnosed in this age group, yet diagnosis and treatment is often delayed due to the absence of routine screening recommendations. ⁵² This delay contributes to stagnant survival rates in younger populations, as compared to the improved outcomes seen among other age groups for various types of cancer. ⁵³ Despite the prevalence of colorectal cancer diagnoses among individuals aged 20-39 and 45-75, most Americans do not receive their recommended screening.

Colorectal cancer is the second leading cause of cancer-related deaths in the United States.⁵⁴ This year, the American Cancer Society estimates that 52,900 individuals will die from colorectal cancer.⁵⁵ Early detection through routine endoscopy screening is key to reducing mortality and improving patient outcomes.⁵⁶ Currently, screening guidelines recommend that adults without a family history of colorectal cancer begin routine screenings at age 45, continuing every 10 years through age 75.⁵⁷ However, routine screening recommendations have not been amended to account for the growing prevalence of colorectal cancer among individuals aged 20-39. As a result, young adults rely on endoscopies as diagnostic and treatment tools.⁵⁸ Given the varying reasons for seeking endoscopies between adults aged 20-75, it is important to increase endoscopy capacity to ensure that the needs of all individuals are met.

Despite routine screening guidelines, screening rates remain low throughout the United States. In 2023, only 41% of adults aged 45-75 were up to date on their colorectal cancer screenings. ⁵⁹ However, the number of annual screenings continues to increase, with over 3.3 million performed in 2023, up from 2.7 million in 2022. ⁶⁰ This 22% increase in the number of screenings indicates a growing understanding among Americans of the dangers of colorectal cancer and a desire to benefit from earlier diagnosis and treatment. ⁶¹ As the number of individuals who are eligible for screening colonoscopy continues to grow each year, it is necessary to expand access to these services to match the demand.

⁴⁸ Key Statistics for Colorectal Cancer, supra note 1.

⁴⁹ Rebecca L Siegel et al, *Colorectal Cancer Statistics*, 2020, CA CANCER J CLIN. (2020), available at https://pubmed.ncbi.nlm.nih.gov/32133645/.

⁵⁰ Key Statistics for Colorectal Cancer, supra note 1.

⁵¹ Key Statistics for Cancers in Young Adults, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/types/cancer-in-young-adults/key-statistics.html (last visited June 9, 2025).

⁵² Can Cancers in Young Adults Be Prevented?, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/types/cancer-in-young-adults/prevention.html (last visited June 9, 2025).

⁵³ Key Statistics for Cancers in Young Adults, supra note 51.

⁵⁴ Kev Statistics for Colorectal Cancer, supra note 1.

⁵⁵ Key Statistics for Colorectal Cancer, supra note 1.

⁵⁶ Michael Bretthauer et al, Effect of Colonoscopy Screening on Risks of Colorectal Cancer and Related Death, THE NEW ENGLAND JOURNAL OF MEDICINE (2022), available at https://www.nejm.org/doi/full/10.1056/NEJMoa2208375.

⁵⁷ American Cancer Society Guideline for Colorectal Cancer Screening, supra note 16.

⁵⁸ Key Statistics for Cancers in Young Adults, supra note 51.

⁵⁹ Colorectal Cancer Is a Major Public Health Problem, AMERICAN CANCER SOCIETY, https://nccrt.org/our-impact/data-and-progress/ (last visited June 4, 2025).
⁶⁰ Id.

⁶¹ Key Statistics for Colorectal Cancer, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html (last visited August 8, 2025) (discussing how the rate of individuals diagnosed with colorectal cancer has dropped overall since the 1980s mostly because of increased colonoscopy screenings and changes in lifestyle-related risk factors).

C. Value of Ambulatory Surgery Centers

Both single and multi-specialty ASCs demonstrate greater clinical and operational efficiency compared to HOPDs. ⁶² By focusing on a limited range of procedures, ASCs can deliver more personalized care through dedicated surgical and/or procedural teams. ⁶³ Moreover, studies have shown that procedures performed in ASCs are associated with better clinical outcomes. One study found that complication rates for colonoscopies were higher in HOPDs than in ASCs over a 90-day period. ⁶⁴ Consequently, ASCs are a better option for patients compared to HOPDs because of the tailored patient-care approach and lower complication risk.

In addition to clinical benefits, ASCs offer significant cost savings. The HPC's February 2024 Datapoints report found that services provided in ASCs are substantially less expensive than those in HOPDs across both public and private insurers. 65 This cost differential is primarily due to lower facility fees as ASCs. For example, a colonoscopy with polyp removal costs 32% less in an ASC than in a HOPD for commercially insured patients. 66 For MassHealth, the same procedure is 61% less expensive in an ASC. 67 The increased capacity constraints and high utilization of the AMCs discussed throughout this Application result in unnecessarily higher costs for endoscopy procedures for public and private insurers. Transitioning even a small amount of endoscopy procedures performed at the AMCs will create immense cost savings in Massachusetts. Expanding access to ASC endoscopy services will support earlier detection of colorectal cancer, and thus, improve patient outcomes and reduce treatment costs.⁶⁸ Early-stage diagnosis significantly increases survival rates and lowers healthcare expenses, while delayed screenings, common among Medicare-eligible individuals, lead to later stage diagnosis resulting in higher medical expenses within the first year after diagnosis. 69 One study projected that if 60–70% of Americans were up to date with colorectal cancer screenings, Medicare could save between \$2.7 billion and \$4 billion in treatment costs by 2060. ⁷⁰ Moreover, while increased screening participation may lead to short-term cost increases, long-term savings are substantial, ranging from 60% to 89% in Medicare treatment costs over a 50-year period.⁷¹

Despite these advantages, ASCs remain underutilized. Massachusetts has one of the lowest per capita ASC capacities in the country and ranks fourth lowest nationally. As of February 2024, Massachusetts had only 23 ASC operating rooms per one million residents – far below the national average of 56. To meet the national average, Massachusetts needs to more than double its current number of ASC procedure rooms. Per Specifically for endoscopy, Massachusetts has only 12 single-specialty endoscopy ASCs and six multi-specialty ASCs that offer endoscopy. Expanding the number of procedure rooms dedicated to endoscopy through the Proposed Project will support both increased access to endoscopy for the Patient Panel and an overall reduction in TME.

⁶² Ambulatory Surgery Centers Versus Hospital-Based Outpatient Departments: What's the Difference?, AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS, https://www.aaos.org/aaosnow/2019/sep/managing/managing02/ (last visited June 4, 2025).

⁶⁴ James C. Robinson and Christoper M. Whaley, *Prices and Complications in Hospital-Based and Freestanding Surgery Centers*, AMERICAN JOURNAL OF MANAGED CARE, (2024) https://www.ajmc.com/view/prices-and-complications-in-hospital-based-and-freestanding-surgery-centers.

⁶⁵ HPC DataPoints, Issue 26, supra note 6.

⁶⁶ HPC DataPoints, Issue 26, supra note 6.

⁶⁷ HPC DataPoints, Issue 26, supra note 6.

⁶⁸ Goede et al, supra note 27.

⁶⁹ Id.

⁷⁰ *Id*.

⁷¹ *Id*.

⁷² HPC DataPoints, Issue 26, supra note 6.

⁷³ This information is based on the HPC *Datapoints* released in February 2024 before the approval of any subsequent ASC DoN applications.

⁷⁴ This information is based on the HPC *Datapoints* released in February 2024 before the approval of any subsequent ASC DoN applications.

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 Proposed Project will provide public health value by improving access to high-quality outpatient endoscopy in Cambridge, thereby improving health outcomes and patient satisfaction. To assess the impact of the Proposed Project, the Applicant will monitor and report the following quality metrics.

1. Withdrawal Time: Withdrawal time is based on the average number of minutes a physician took to withdraw the scope from the cecum during a screening colonoscopy when no maneuvers were performed. Longer withdrawal times during screening colonoscopies are associated with increased adenoma (polyp) detection rates, which is essential to making safe recommendations for intervals between screening and surveillance examinations.

Measure: Average withdrawal time in normal-result colonoscopies performed for colorectal cancer screening in average-risk patients with intact colons.

Numerator: Total number of withdrawal minutes for all patients.

Denominator: Total number of patients.

2. Adenoma Detection Rate: The Adenoma Detection Rate (ADR) is the minimum target for adenomas detected among an individual provider's patient panel. An increased ADR is associated with a reduction in CRC incidence and a reduction of cancer mortality.⁷⁵

Measure: Average rate of adenoma detection among an endoscopist's patient panel ages 50 years or older.

Numerator: The number of procedures for patients over 50 years of age where at least one adenoma was detected.

Denominator: Total number of procedures for patients over 50 years of age.

3. **Patient Satisfaction:** Patients that are satisfied with their care are more likely to seek additional treatment when needed. The Applicant will continue to review patient satisfaction levels with the ASC's surgical services and compare across like-facilities and regional benchmarks.

Measure: A Press Ganey Patient Satisfaction survey is provided to all eligible patients following their procedure. This survey focuses on the patient's experience in multiple areas, including, net promoter score (NPS), wait times, facility operations, care communication, nurse/physician treatment, and discharge. The survey also allows for anonymous comments from patients to further provide insight into areas of improvements and praises or concerns.

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 needbase, 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.

⁷⁵ Quality Indicators for GI Endoscopic Procedures, AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY, https://www.asge.org/docs/default-source/default-document-library/quality-indicators-for-gi-endoscopic-procedures.pdf?sfvrsn=e0d2ea51_0 (last visited July 11, 2025).

Acknowledging the rising variations in colorectal cancer screening across neighborhoods, MGB implemented a system-wide community health strategy to improve screening for all. As part of MGB's Community Health strategy, MGB launched a Colorectal Cancer Screening Campaign in June 2025. This campaign aims to eliminate variations in colorectal cancer outcomes by increasing colorectal cancer screening for residents in Chelsea, Revere, Mission Hill, Lynn, Salem, Dorchester, Hyde Park, Mattapan, Jamaica Plain, and Chinatown. This public health education campaign includes targeted primary care and community health initiatives, as well as a multi-channel, multilingual communications campaign.

Within primary care, MGB is reducing barriers by standardizing colonoscopy prep instructions and translating materials into the top six patient languages spoken across MGB: Spanish, Portuguese, Haitian-Creole, Mandarin, Arabic, and Russian. Additionally, MGB identified four primary care clinics with higher variations in colorectal cancer screening to receive targeted support from three bilingual navigators. These navigators provide support to help patients overcome barriers that have historically prevented patients from completing their recommended colorectal cancer screening, including outreach to patients who are overdue, direct education with translated materials, assistance with scheduling, reminders, transportation, and preparation instructions.

The campaign is also creating more access to colorectal cancer screenings through MGB's three Community Care Vans. Patients and community members are able to speak with a Cancer Patient Navigator to learn more about colorectal cancer screening and the screening options available which empowers patients to make the best decision for themselves. Patients can either complete a stool-based test on the van or can schedule a colonoscopy. The Cancer Patient Navigator and care team will follow up with the patient with results and next steps, regardless of whether the patient was an existing MGB patient or is a new patient.

With respect to the proposed ASC, patients will not be discriminated against or scheduled differently based on ability to pay or payer source. Further, medical interpreter services will be available to all patients at no cost. The ASC will use LanguageLine for all translation services which will cover all languages, including ASC. Furthermore, the Applicant is working towards implementing a communication board to assist/enable communication with patients who are non-verbal.

As the Applicant's Patient Panel is based on existing MGB patients, it expects the majority of patients will be referred to the proposed ASC from an MGB provider. As a result, the Applicant expects most of its patients will be screened for social determinants of health by their MGB primary care provider. At this time, it is MGB's policy to screen all Medicaid ACO patients annually, while many MGB primary care practices are screening all patients regardless of payer. In addition, every inpatient admission and emergency department encounter initiates a screening.

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.

The Proposed Project will facilitate improved health outcomes and quality of life for the Applicant's Patient Panel by providing timely access to routine and diagnostic endoscopy in a non-hospital setting. Given the long wait times that currently exist for patients in the Boston area, the ASC will significantly improve access, in turn promoting better screening adherence. Specifically, the Applicant anticipates that patients will be more likely to comply with screening recommendations if services are provided in a more convenient location outside of a hospital and at a lower cost. By improving colorectal cancer screening rates regardless of financial status, more cancers will be detected earlier, ultimately leading to improved health outcomes and quality of life.

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 contribute to improved continuity and coordination of care through the secure, frequent exchange of electronic health information. The proposed ASC will implement an electronic medical record system and an endoscopy documentation platform to support comprehensive physician documentation and the seamless sharing of patient data. These systems will enable bidirectional data exchange and robust reporting capabilities. As the patient is part of the MGB health system, integration with these platforms will ensure clinical documentation flows directly into the broader health system. This will support timely review by care teams, enhance communication among stakeholders, and provide patients with access to relevant health information.

In the event of a medical emergency, the proposed ASC will immediately initiate a 911 call to request emergency medical services. A designated staff member will provide essential information about the patient's condition to ensure a timely and appropriate response. Additionally, the proposed ASC will maintain a transfer agreement with a nearby hospital in compliance with the Department's clinic licensure regulations. While emergency transport will be coordinated through 911, the proposed ASC may also establish agreements for inter-facility transport in non-emergency situations to support continuity of care. When a patient is referred to another facility, agency, or healthcare provider, the proposed ASC will send relevant portions of the patient's medical record to the receiving party, unless the patient objects. These procedures will be documented in the proposed ASC's written emergency and referral policies. All proposed ASC staff will be trained on these protocols to ensure compliance with regulatory requirements and to promote patient safety.

F1.d 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 consulted with the following individuals and agencies regarding the Proposed Project:

- Massachusetts Department of Public Health, including but not limited to: Dennis Renaud, Director, Determination of Need Program; Jennica Allen, Manager of Community Engagement Practices, Bureau of Community Health, and Prevention; Katelyn Teague, Community Health Planning + Engagement Specialist, Bureau of Community Health, and Prevention
- Massachusetts Executive Office of Health and Human Services
- Health Policy Commission
- Center for Health Information and Analysis
- The Centers for Medicare & Medicaid Services

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 also sought to engage the community to elicit feedback from patients and families regarding the Proposed Project. On July 29, 2025, MGB's Chief Medical Officer Dr. Tom

Sequist, presented the Proposed Project to the community though a virtual public meeting that was advertised on the AMCs' websites and on TV screens within the hospitals leading up to the event. Dr. Sequist spoke to attendees about the importance of colorectal cancer screening and the need for additional capacity in order for MGB to provide improved access to endoscopy to its patients. Five (5) community members attended the meeting.⁷⁶

Additionally, email communications regarding the Proposed Project were sent to the AMCs' Patient and Family Advisory Council (PFAC) ahead of in-person presentations that were held in August 2025. During the PFAC presentations, council members were informed about the current backlog of screenings impacting MGH and BWH patients and the need to prioritize timely screenings based on screening guidelines. The presentation also included specifics about the proposed ASC and how it will provide improved access to outpatient endoscopy as well as improve capacity at the MGB AMCs for emergent, inpatient, and higher acuity outpatient cases. As of this Application, the Applicant has received several positive comments regarding the Proposed Project generally.

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 throughout the development of the Proposed Project, the Applicant took the actions detailed in Factor F1.e.i. In addition, the Applicant published two legal notices announcing the Proposed Project in the *Boston Herald* on July 16, 2025. Please refer to Appendix 7 for copies of the legal notices.

Factor 2: Health Priorities

Addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

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 expanding access to high-quality endoscopy in a lower cost setting than existing options for the Patient Panel. ASCs offer high-quality services to patients while maximizing operational efficiencies, which translate into lower healthcare costs. Furthermore, the proposed ASC will improve access to timely screening and diagnostic endoscopy procedures, ultimately improving public health outcomes and reducing treatment costs.

Table 7 below details the out-of-pocket costs that Medicare patients incur for common endoscopy procedures, highlighting the cost disparity based on the setting in which services are received. The data emphasizes the importance of expanding access to high-quality, lower-cost endoscopy services in ASCs

⁷⁶ At the time of this Application, the Applicant has not received feedback from the community regarding the Proposed Project.

to help reduce the financial burden on patients. By receiving endoscopy services in ASCs rather than HOPDs, patients can significantly lower their out-of-pocket expenses and may be more likely to comply with recommendations for endoscopy. Therefore, even modest shifts of ASC-eligible procedures from HOPDs to ASCs have the potential to generate meaningful cost savings for patients and contribute to broader healthcare affordability for Massachusetts residents.

Table 7: 2025 Medicare Procedural Out-of-Pocket Costs for Patients77

Procedure	ASC Out-of-Pocket Costs	HOPD Out-of-Pocket Costs	ASC Patient Out-of-Pocket Savings
Colonoscopy	\$164	\$273	\$109
EGD	\$126	\$213	\$87
Enteroscopy	\$202	\$409	\$207
Esophagoscopy	\$191	\$398	\$208

Massachusetts aims to reduce healthcare costs by expanding access to high-quality, affordable services. The HPC emphasizes that achieving this goal requires making *health care more affordable*, *transparent*, *and equitable*. However, the HPC recently reported that the Commonwealth ranks fourth lowest in the nation for ASCs per capita. He ASCs operating in the Commonwealth, there are only 18 offering endoscopy services (12 single-specialty and 6 multi-specialty). As a result, there is insufficient ASC availability and capacity to meet the needs of the Massachusetts population and patients must rely on HOPD services to receive low-acuity procedures, thereby increasing total healthcare costs. To address this problem, the Proposed Project will create an additional ASC, thereby improving the rate of ASCs per capita in the Commonwealth.

The existing ASCs in Massachusetts lack enough procedure rooms to ensure timely access to care for all patients seeking low-acuity outpatient care. According to the HPC, in 2023 Massachusetts had only 23 ASC operating rooms per one million residents, compared to the national average of 56.81 To meet this benchmark and promote cost containment, Massachusetts must more than double the total number of ASC procedure rooms.82 Since the HPC's report, the Department has approved only two (2) endoscopy ASC DoN applications, adding just five (5) new operating rooms across the Commonwealth, an increase that falls far short of what is needed to align with national standards and meet growing patient demand.83 Thus, Massachusetts residents remain overwhelmingly dependent on HOPDs to provide screening and diagnostic endoscopy services, which stunts the Commonwealth's goal of cost containment. Accordingly, the Proposed Project will assist the Commonwealth in working toward matching the national average of ASC operating rooms per one million residents.

Increasing the number of ASCs offering endoscopy services will further the Commonwealth's goal of cost containment by reducing overall reliance on HOPDs to provide low-acuity procedures, which result in significantly higher TME and provider costs compared to ASCs.

⁷⁷ Please note, the out-of-pocket costs for patients is based on Medicare's 2025 payments and copayments rates, as reviewed on July 10, 2025 and are available at https://www.medicare.gov/procedure-price-lookup/.

⁷⁸ About the HPC, MASSACHUSETTS HEALTH POLICY COMMISSION,

https://masshpc.gov/about#:~:text=Through%20market%20oversight%2C%20data%2Ddriven,affordable%2C%20transparent%2C%20and%20equitable. (last visited June 18, 2025).

⁷⁹ HPC DataPoints, Issue 26, supra note 6.

⁸⁰ HPC DataPoints, Issue 26, supra note 6.

⁸¹ HPC DataPoints, Issue 26, supra note 6.

⁸² HPC DataPoints, Issue 26, supra note 6.

⁸³ While the recent approval of two endoscopy DoN applications has slightly increased the availability of ASC procedure rooms per one million residents in the Commonwealth, the addition of five procedure rooms is insufficient to meet the national average of operating rooms per one million residents. As a result, the information from the February 2024 HPC Datapoints remains relevant in contextualizing the importance of increasing ASC capacity in Massachusetts and the need for approval of this Application.

Moreover, the cost savings derived from more accessible ASC services extend beyond the services themselves. Increasing the availability of colonoscopies through additional procedural capacity also impacts TME through the overall reduction of colorectal cancers that require treatment. In 2020, the cost of colorectal cancer care was \$24.3 billion and accounted for 11.6% of all cancer treatment costs. ⁸⁴ The average per-patient costs for medical services during the first year after diagnosis is \$66,500. ⁸⁵ Increasing screening prevalence to 70% among adults age 50 to 64 could reduce Medicare spending by \$14 billion (in 2010 dollars) by 2050. ⁸⁶ Increasing the availability of colonoscopy has a direct impact on patient outcomes and health care spending.

For these reasons, the Proposed Project will meaningfully and significantly contribute to the Commonwealth's cost containment goals.

F2.b. Public Health Outcomes

Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

The Proposed Project will advance public health outcomes by increasing access to high-quality endoscopy for the Patient Panel in a lower-cost, more convenient setting. ASCs offer a convenient, accessible, and cost-effective alternative to HOPDs, which can significantly improve the patient experience and increase adherence to recommended colorectal cancer screening guidelines, particularly among individuals aged 45–75. As discussed throughout this application, timely access to screenings and treatment not only improves health outcomes but also minimizes avoidable costs patients incur as a result of delays in treatment. When services are more affordable and easier to access, patients are more likely to undergo timely screenings, leading to earlier detection of colorectal cancer and more effective treatment. The Applicant also anticipates that individuals aged 20–39 will benefit from improved outcomes through more timely access to diagnostic and therapeutic endoscopy services. By promoting earlier diagnostic and treatment opportunities, the Proposed Project will improve health outcomes for the Applicant's Patient Panel.

The Proposed Project will expand access to endoscopy services for the Applicant's Patient Panel in support of adherence to the updated colorectal cancer screening guidelines, contributing to earlier detection and improved outcomes. Since the recommended colonoscopy screening age was lowered from 50 to 45 in 2018, screening rates among adults ages 45-49 increased by 62% between 2019 to 2023. This rise in screenings has led to a notable increase in diagnosed cases, from an annual rate of 1.1% between 2004 to 2019 to 12% between 2019 to 2022, primarily due to first-time screenings rather than a true surge in colorectal cancer prevalence. Earlier detection allows for timely intervention, which is critical given the significantly higher survival rates and lower treatment costs associated with early-stage diagnoses. These trends underscore the importance of expanding access to endoscopy screening services, particularly through approval of the Proposed Project, to ensure that individuals can maintain adherence to guidelines to continue improving cancer outcomes and reduce long-term healthcare burdens.

The Applicant's owners are committed to improving public health outcomes and employ a range of strategies to promote colorectal cancer screening across its service area. In addition to the initiatives discussed in Section F1.b.iii, MGB conducts public outreach through advertisements in MBTA stations and other high-traffic locations, emphasizing the importance of adhering to screening guidelines. At the

⁸⁴ Health and Economic Benefits of Colorectal Cancer Interventions, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 16, 2024), https://www.cdc.gov/nccdphp/priorities/colorectal-cancer.html.

⁸⁶ Goede et al, supra note 27.

⁸⁷ Jessica Star, MA, MPH, et al., *Trends in Colorectal Cancer Screening in US Adults Aged 45 to 49 Years*, JAMA (Aug 4, 2025), https://jamanetwork.com/journals/jama/article-abstract/2837231.

⁸⁸ Colorectal Cancer Statistics, supra note 49.

patient level, MGB uses its online Patient Gateway to send screening reminders and follow-up messages directly to patients. This platform also enables population health coordinators to engage with individuals, particularly those affected by social determinants of health barriers, to encourage them to receive colorectal cancer screenings. In clinical settings, when care gaps are identified, MGB notifies the patient's provider to reinforce the need for timely endoscopy screenings and adherence to follow-up and treatment protocols. Through its Ambulatory Safety Net outreach and navigation efforts, MGB ensures that patients with abnormal results receive appropriate and timely follow-up care, including adherence to recommended endoscopy intervals of 6 months, 1 year, or 2 years for high-risk individuals. Approval of this Proposed Project will expand MGB's capacity to serve its Patient Panel, increasing access to education and services that support timely colorectal cancer screening and follow-up care.

Lastly, the Proposed Project will contribute to public health outcomes by reducing volume at the MGB AMCs, in turn improving access to endoscopy for emergency and inpatient endoscopy. The MGB AMC endoscopy procedure rooms are operating near or above target utilization (78%) which delays inpatients procedures and extends their hospital stay. Many of these patients are ready to be discharged but cannot be until they receive the endoscopy ordered by the treating physician. The delays caused by insufficient operating capacity unnecessarily extends inpatient stays, not only leading to higher costs, but may also contribute to an increased risk of hospital-acquired infections, functional decline, and negative patient experience. Moreover, these extended stays due to endoscopy delays prevent better throughput for patients boarding in the ED or waiting in a community hospital bed for an inpatient bed at the MGB AMCs to become available. Reducing endoscopy volume at the MGB AMCs is imperative to improving procedure room throughput, timely discharge, and in turn health outcomes.

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.

a. Commitment to Health Equity and Community Partnerships

The Applicant will contribute to delivery system transformation through the integration of social services and community-based expertise to address the needs of its Patient Panel. To achieve this goal, the Applicant will connect the medical services it provides with social support by working closely with local communities. The Applicant will review opportunities for partnering with diverse groups and will provide high-quality care while addressing social determinants of health such as housing, food security, and education. The Applicant is also exploring opportunities for MGB to collaborate with community organizations to address barriers that can limit access to healthcare services for groups within its Patient Panel. Therefore, the Proposed Project will contribute to the Commonwealth's goal of delivery system transformation by providing comprehensive care planning and holistic care delivery to a greater number of Massachusetts residents.

The Proposed Project supports the Commonwealth's goal of expanding access to community-based care by increasing overall ASC endoscopy procedural capacity. Creating outpatient endoscopy services at the proposed ASC will directly benefit the Applicant's Patient Panel by promoting timely access to routine screenings and diagnostic procedures, particularly for colorectal cancer. The proposed ASC will meet growing demand, reduce wait times, and improve adherence to screening guidelines, all of which are critical for early detection and treatment. As a result, the Applicant's commitment to ensuring timely

⁸⁹ David W. Bates et al, *The Safety of Inpatient Health Care*, NEW ENGLAND JOURNAL OF MEDICINE, available at https://www.nejm.org/doi/full/10.1056/NEJMsa2206117.

access to preventative care and treatment will enhance patient satisfaction and contribute to better health outcomes for its Patient Panel. Thus, the Proposed Project will directly support long-term improvements in the overall population health of Massachusetts.

b. Addressing Socioeconomic Barriers to Cancer Care

As demonstrated throughout this Application, timely access to cancer screening and treatment is closely linked to improved outcomes. However, research consistently demonstrates that socioeconomic status significantly affects a patient's ability to access and complete necessary cancer care. ⁹⁰ Barriers such as poverty, housing instability, and transportation challenges often prevent individuals from adhering to routine screening guidelines. ⁹¹ These same factors are associated with delays in treatment initiation, lower quality of care, and higher rates of treatment non-adherence or early discontinuation, all of which negatively affect a patient's overall outcome. ⁹² By expanding access to affordable, high-quality endoscopy services, the Applicant aims to mitigate the negative effects of socioeconomic barriers on healthcare access, diagnosis, and treatment. As a result, the Proposed Project will promote health outcomes in alignment with the Commonwealth's broader efforts to improve outcomes for all residents.

Factor 5: Relative Merit

P5.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.

Alternative Proposal 1: Use the existing procedure rooms in the HOPDs at BWH and MGH to continue to provide endoscopy procedures.

Alternative Quality: This alternative option fails to leverage the high-quality of patient care ASCs provide. Compared to HOPDs, ASCs have higher patient satisfaction rates and lower incidences of post-procedure hospitalization. Moreover, the Proposed Project will increase capacity and expand access which cannot be achieved by this Alternative.

Alternative Efficiency: Continuing to rely on the AMC procedure rooms will further strain an already inefficient system, leading to longer wait times for endoscopy access. These delays, often exceeding six months, can significantly impact timely diagnosis and treatment, ultimately affecting patient outcomes. Extended wait times also increase the risk that patients will forgo their appointments altogether, perceiving the service as non-essential. Moreover, inefficient throughput in the AMC setting contributes to longer inpatient lengths of stay as patients awaiting procedures occupy beds that could otherwise be used for admissions from the ED or for patients who need a higher level of care than available in the community. This bottleneck affects the entire hospital system, delaying care for all patients waiting for a bed. Expanding access to timely endoscopy screenings is essential to addressing the rising incidence of cancer and improving overall

⁹⁰ Shen Li et al, An Umbrella Review of Socioeconomic Status and Cancer, NATURE COMMUNICATIONS (2024), available at https://www.nature.com/articles/s41467-024-54444-2.
⁹¹ Id

⁹² Amber Bourgeois et al, *Barriers to Cancer Treatment for People Experiencing Socioeconomic Disadvantage in High-Income Countries: A Scoping Review*, BMC HEALTH SERV RES, (2024), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11134650/.

patient care. Without improvements in procedural access, these goals remain out of reach.

Alternative Capital Expenses: There are no capital expenses under this alternative.

Alternative Operating Costs: The HOPDs at BWH and MGH have higher operating expenses than the Proposed Project due to the overhead costs required of a hospital, including clinical and administrative workforces, capital investments, utility expenses, and equipment costs. Operating costs will remain the same under this alternative.

Alternative Proposal 2: Construct and license additional endoscopy procedures rooms at BWH and MGH.

Alternative Quality: As stated above, this alternative option fails to leverage the high-quality of patient care ASCs provide. Compared to HOPDs, ASCs have higher patient satisfaction rates and lower incidences of post-procedure hospitalization. Moreover, the Proposed Project will increase capacity and expand access which cannot be achieved by this Alternative.

Alternative Efficiency: Expanding endoscopy services at BWH's and MGH's HOPDs fails to leverage the operational efficiencies and financial benefits that the Proposed Project offers patients and payers. Further, the construction projects necessary to complete this alternative option will impact patient care, potentially increasing wait times above what they are now.

Alternative Capital Expenses: The capital expenses under this alternative would be significant as there is not currently available space at the AMCs to add more procedure rooms.

Alternative Operating Costs: The endoscopy rooms at the MGB AMCs require higher operating costs compared to the Proposed Project due to the associated overhead expenses of a hospital, including clinical and administrative workforces, capital investments, utility expenses, and equipment costs. As with the first alternative, operating costs are expected to remain stable, without any financial benefit compared to the Proposed Project.