

STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	Emerson Endoscopy and Digestive Health Center, LLC
Applicant Address	310 Baker Avenue Concord, MA 01742
Filing Date	October 29, 2020
Type of DoN Application	Ambulatory Surgery
Total Value	\$4,636,588.00
Project Number	20090210-AS
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	\$231,829.00
Staff Recommendation	Approval with Conditions
Public Health Council	February, 2021
<p style="text-align: center;"><u>Project Summary and Regulatory Review</u></p> <p>Emerson Endoscopy and Digestive Health Center, LLC (Applicant) is a newly-formed joint venture between Emerson Hospital and Physicians Endoscopy, LCC located in Concord, MA. The Applicant submitted an application for a Proposed Substantial Change in Service to construct a free-standing, single-specialty ambulatory surgery center. The proposal is to renovate 8,185 gross square footage (GSF) in an existing building adjacent to the Emerson Hospital campus for two outpatient procedure rooms in order to provide routine endoscopy. The total value for the Proposed Project is 4,636,588.00. The Community Health Initiative (CHI) contribution is \$231,829.00.</p> <p>This DoN Application falls within the definition of Ambulatory Surgery, which are reviewed 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. For any Application for Notice of Determination of Need made pursuant to 105 CMR 100.715(B)(2)(a) 1. 2. or 3. which includes a Proposed Project within the Primary Service Area of an existing Hospital that is: 1. designated as an independent community disproportionate share or non-disproportionate share Hospital as defined by HPC's Massachusetts Hospital Cohort Designation and Affiliation Status, and 2. not an existing joint venture or Affiliate of the Applicant: a. The Proposed Project must constitute a joint venture with the independent community disproportionate share or non-disproportionate share Hospital; or b. The Applicant must obtain a letter of support signed by the independent community disproportionate share or non-disproportionate share Hospital's chief executive officer and board chair.</p>	

Table of Contents

Background: Emerson Endoscopy and Digestive Health Center, LLC and Application Overview.....	3
Patient Panel.....	5
Patient Information (2019)	5
Factor 1: a) Patient Panel Need.....	7
Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity	9
Factor 1: c) Efficiency, Continuity of Care, Coordination of Care	11
Factor 1: d) Consultation	12
Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel	12
Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending ..	12
Description of proposed measures, suggested Conditions, Factor 1.....	13
Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation.....	14
Description of proposed measures, suggested Conditions, Factor 2.....	15
Factor 3: Relevant Licensure/Oversight Compliance	15
Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis	16
Factor 5: Assessment of the Proposed Project's Relative Merit.....	17
Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application.....	17
Findings and Recommendations.....	19
Other Conditions.....	19
Attachment 1: Required Measures for Annual Reporting	21

Background: Emerson Endoscopy and Digestive Health Center, LLC and Application Overview

The Applicant is Emerson Endoscopy and Digestive Health Center, LLC, a newly formed joint venture between Emerson Hospital (Emerson or Hospital) and Physicians Endoscopy, LLC (PE). The newly formed joint venture was created for the purpose of establishing a free-standing, single-specialty ambulatory surgery center (ASC) to serve Emerson patients and the surrounding community. In compliance with 105 CMR 100.715(B)(2)(a)(3), the Applicant is an Affiliate of, or joint venture with an Entity that has or participates in, a Certified accountable care organization (ACO).^a

- **Emerson Hospital** is a 150-bed not-for-profit acute care, independent community hospital located in Concord, MA^{1,b} that is part of a full-service regional health system composed of multiple satellites, urgent care centers, and more than 300 primary care doctors and specialists providing inpatient, outpatient, and physician services, as well as home health, wellness, inpatient psychiatric and transitional care unit services. Emerson Hospital and Emerson Physician Organization (PHO) are part of Partners ACO network as participating providers and facilities.
- **Physicians Endoscopy, LLC** is a national development and management company for gastroenterology medicine ASCs. PE specializes in the development and management of freestanding, single-specialty endoscopic ASCs in partnership with practicing physicians and hospitals. PE is in partnership with 60 ASCs specializing in endoscopy.²

Application Overview

Emerson has a dedicated outpatient Endoscopy Department on its main hospital campus with four operating and procedure rooms. The Endoscopy Department provides routine, advanced, and urgent endoscopy services, on both an inpatient and an outpatient basis. The Applicant is proposing to renovate existing space located near the Emerson campus to construct a free-standing, single-specialty ASC with two procedures rooms in order to shift low-acuity endoscopy patients from the Emerson Hospital campus to a clinically appropriate, non-hospital setting that is convenient, cost-effective and patient-centered. Emerson will close two procedures rooms in its Endoscopy Department once the ASC is operational, leaving the remaining two rooms for emergency patients, inpatients, and advanced and complex endoscopy procedures that will not be available at the proposed ASC. The Applicant states that the Hospital has not determined how the space may be used and that it will follow DPH rules that apply when a plan is developed for the closed spaces. When Emerson closes the endoscopy procedure rooms, they can convert the rooms to shell space to be left unassigned to a particular function or convert them to another function; both would require plan review. Reactivating the two decommissioned endoscopy procedure rooms would constitute a Substantial Change in service requiring DoN approval, and plan approval.

¹ 150 licensed Beds: Medical/Surgical (70), Intensive Care Unit (7), Coronary Care Unit (7), Pediatric Service (11), Maternal Service (24), and Psychiatric Service (31). Well infant nursery (24 bassinets) and Special Care Nursery (5 bassinets).

² PE services include: Finance, Information Technology, Professional Guidance, Human Resources, Clinical Operations, and Marketing. PE Website: <https://www.endocenters.com/services/professional-management/>

OVERVIEW of PROPOSED PROJECT AND FACTOR REVIEW

Description	What's Needed to Meet Factor 1: Demonstration of need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending.	What's Needed to Meet Factor 2: Demonstration of cost containment, improved public health outcomes, and delivery system transformation	Factors 3, 4 & 5 ³	What's Needed to Meet Factor 6: Demonstration of plans for fulfilling ... responsibilities ... in the DPH Community-based Health Initiatives Guideline.
	<i>Staff Report finds</i>			
	MEETS w/ CONDITIONS	MEETS w/ CONDITIONS	MEETS	MEETS
The Applicant proposes to construct a free-standing ASC with two outpatient procedure rooms in order to provide routine endoscopy.	<ul style="list-style-type: none"> Reporting on the shift in routine endoscopy procedures, using endoscopy procedure volume at the proposed ASC and at the Emerson Hospital Endoscopy Department. Reporting on colorectal cancer education and outreach programs among Patient Panel to ensure appropriate screening rates/rescreening rates. Reporting on the measures outlined in Attachment 1. 	<ul style="list-style-type: none"> Reporting on colorectal cancer education and outreach programs in the community to reduce risk factors or increase screening rates/rescreening rates in the community 	✓	✓

³ 3: Sufficient evidence of compliance and good standing with federal, state, and local laws and regulations

4: Sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Project without negative impacts or consequences to the Applicant's existing Patient Panel 5: The ... Project, on balance, is superior to alternative and substitute methods for meeting ... Patient Panel needs.

Patient Panel⁴

The Applicant is a newly formed joint venture and does not have its own Patient Panel. Therefore, the Applicant relied on Patient Panel data from Emerson Hospital to determine need for the Proposed Project. The Applicant evaluated demographic and historical utilization data for Emerson Hospital and Emerson endoscopy patients. Staff finds this is an acceptable representation of the anticipated patients of the proposed ASC.

- Emerson served a large Patient Panel over the 36-month period covering fiscal year (FY) 17-19 with 96,786 unique patients in FY17, 97,153 unique patients in FY18, and 100,707 unique patients in FY19. The number of patients utilizing Emerson's services during this period increased by 4.0%. Preliminary data for FY20 indicate Emerson Hospital had 65,072 unique patients.^{5,6}
- Emerson endoscopy patients for the 36-month period covering FY17-19 included: 4,604 unique patients in FY17, 4,043 unique patients in FY18, and 3,474 unique patients in FY19.⁷ The Applicant states the number of patients and procedures declined due to physician attrition in the Endoscopy Department. However, the Hospital has since recruited new physicians and anticipates demand will return back to its historical utilization.

Patient Information (2019)

Table 1 presents patient information for the Hospital patient population and Emerson endoscopy patient population during FY19. This “snapshot” provides important comparison information. Staff notes the following observations about these data below:

- **Age** – The age 30-60 cohort comprises the majority (58.9%) of the Emerson Hospital Patient Panel.
 - **Age for Endoscopy** - Fifty-six percent of patients receiving endoscopy services are ages 50-69.
- **Race/Ethnicity** – The racial composition of Hospital patients and the Emerson endoscopy patients are very similar. The Applicant mentioned 46% of Hospital patients and 37% of Emerson endoscopy patients chose not to report their race/ethnicity. Race/ethnicity is a field in the Hospital's patient registration system MediTech and the information is requested during patient registration. Because the information is self-reported, and reporting is optional, patients may skip over the question resulting in a large number of patient non-responses. The Applicant affirms the ASC will continue to request race/ethnicity information during patient registration. The Applicant provided race/ethnicity data based on Sg2 Market Demographics used by Emerson in the preparation of its 2018 Community Health Needs Assessment (CHNA). Data show the following race/ethnicity information for

⁴ 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.

⁵ Fiscal Year is October 1 to September 30.

⁶ This represents 130,144 patients annualized. Annual comparisons are calculated using data for FY17-19 as the FY20 data is only for October 1, 2019 – March 30, 2020 and is subject to change over time.

⁷ Total cases: 4,929 in FY17, 4,346 in FY18, and 3,868 in FY19. Preliminary data for FY 20: 1,465 unique cases patients and 1,563 total cases.

the Emerson Hospital Service Area⁸: White, Non-Hispanic (82%), Asian (10%), Pacific Islanders Non-Hispanic (4%), and Black, Non-Hispanic (2%).^c

- **Patient Origin** – The majority of Hospital patients and Emerson endoscopy patients come from Middlesex County.
- **Payer Mix** – There is a higher percentage of Medicare payments among Emerson endoscopy patients (27.7%) than Hospital patients (16.9%).
- **ACO and Managed Care Contracts** – Emerson Hospital and Emerson Physician Organization (PHO) are part of Partners ACO network as participating providers and facilities. In FY, 5.1% of Hospital patients and 3.8% of Emerson endoscopy patients were covered under risk contracts.

Table 1: Overview of Emerson Hospital patient population and Emerson Endoscopy patient population (FY19)

	Emerson Hospital Patients	Emerson Endoscopy Patients
Total Unique Patients	100,707	3,474
Gender		
Male	38%	44.8%
Female	62%	55.2%
Age		Age
0-18	17%	
19-30	7.7%	0-49 (17.37%)
30-69	58.9%	50-69 (56.39%)
70+	16.4%	70+ (26.23%)
Race/Ethnicity^{9,10}		
White	56.5%	59.4%
Black/African American	0.6%	0.2%
Hispanic/Latino	0.5%	0.5%
Asian	2.17%	1.6%
Other	1.6%	1.3%
Unknown	46%	37%
Patient Origin	The majority of patients originate from Middlesex County. Approximately 70% of patients are from 20 communities. ¹¹	The majority of patients originate from Middlesex County. Approximately 78.4% of Emerson's endoscopy patients are from 20 communities. ¹²
Payer-Mix¹³		
Commercial	76.1%	73.3%
Medicaid	8.3%	7.4%
Medicare	16.9%	27.7%
Other ¹⁴	5.6%	2.8%

⁸ The Emerson Hospital Primary Service Area is made up by Acton, Bedford, Bolton, Boxborough, Carlisle, Concord, Harvard, Hudson, Lincoln, Littleton, Maynard, Stow, Sudbury and Westford. The Secondary West (SW) service area is made up by Ayer, Groton, Pepperell, Shirley, and Townsend. In aggregate, these towns represent 70% of Emerson Hospital discharges.

⁹ Based on self-reporting. The Applicant notes 46% of the Emerson Hospital Patient Panel chose not to report their ethnicity, and 37.4% of the Emerson endoscopy patient population did not report.

¹⁰ Totals over 100% due to multiple "responses" based on patients with more than one encounter during the year.

¹¹ 20 cities and towns in order of representation: Acton, Westford, Concord, Sudbury, Maynard, Littleton, Groton, Chelmsford, Stow, Bedford, Pepperell, Ayer, Hudson, Boxborough, Harvard, Carlisle, Leominster, Townsend, Lincoln, and Shirley.

¹² 20 cities and towns in order of representation: Concord, Acton, Westford, Sudbury, Maynard, Groton, Littleton, Chelmsford, Stow, Bedford, Ayer, Hudson, Pepperell, Harvard, Carlisle, Lincoln, Leominster, Shirley, Marlborough, and Bolton.

¹³ Emerson's patient payer mix data is compiled using unique patient visits. Patients who switch plan or payment type during the Hospital's fiscal year would be counted twice for purposes of payer mix data. This results in a payer mix total greater than 100% for all fiscal years presented.

¹⁴ The category Other represents self-pay and Worker's Compensation.

APM Contracts		
ACO and APM Contracts	5.1%	3.8%
Non-ACO and APM Contracts	94.9%	96.2%

Factor 1a: Patient Panel Need

In this section, we assess if the Applicant has sufficiently addressed Patient Panel need for the proposed ASC.

Patient Panel Need

The Applicant attributes Patient Panel need for routine endoscopy in the ASC setting to two factors:

1. **Clinically appropriate setting for care**
2. **Accommodate projected demand for routine endoscopy services**
 - a. An aging population
 - b. Clinical recommendations for routine CRC screening

1. **Clinically appropriate setting for care.** Emerson Hospital's outpatient Endoscopy Department has four licensed operating and procedure rooms, providing routine, advanced, and urgent endoscopy for procedures performed on an inpatient and outpatient basis.
 - a. Currently, routine procedures are performed in the same rooms as advanced endoscopy which require more time, space, and staff to perform. The Applicant provided a breakdown of the 4,077 endoscopy procedures for FY20: 15% of the total volume was performed on an inpatient basis and 85% was on an outpatient basis; 94% was routine, 4% was advanced, and 2% was urgent. The Applicant provided wait times for endoscopy procedures performed in the Endoscopy Department: wait times for routine procedures with one of the three gastroenterologists vary between two and six weeks depending upon appointment availability and patient preference; and wait times for advanced and complex procedures, which are time-sensitive, are usually one to two days, and no more than 10 days. The Applicant anticipates that as routine endoscopy cases shift from the Endoscopy Department to the proposed ASC focused on routine cases, wait times will improve because scheduling will not be impacted by inpatient and emergent cases.
 - b. The Applicant's review of Emerson's historical endoscopy volume showed a significant portion of endoscopy services currently performed at the Hospital could be shifted to the ASC setting, allowing the Endoscopy Department to focus on providing timely access to endoscopy services for patients requiring emergency, advanced and complex procedures. The proposed ASC will only perform routine endoscopy services limited to a narrow range of procedures including, colonoscopy, upper gastrointestinal endoscopy or esophagogastroduodenoscopy (EGD), and sigmoidoscopy.¹⁵ Clinically appropriate patients will be referred to the proposed ASC, based on type of service to be performed and their medical history.
 - c. Table 2 below shows projected endoscopy volume at Emerson's Endoscopy Department and at the proposed ASC. The Applicant projects that overall cases will increase, but those seen at the Hospital are expected to decrease over time as a percent of total cases. As projected, Hospital cases will make up 19% of Endoscopy procedures in FY22, 16% in FY23, 15% in both FY24 and FY25, and 14% in FY26.

¹⁵ Routine endoscopy is used for screening, diagnostic and treatment purposes. Routine endoscopy is most commonly used to help determine the cause of gastrointestinal symptoms, to biopsy tissue, and/or to guide doctors during surgery.

Table 2: Projected Endoscopy Procedures by Site

	FY2022	FY2023	FY2024	FY2025	FY2026
Cases at ASC	3,461	4,290	4,719	4,813	4,910
Cases at Hospital	816	819	822	825	828
Total	4,277	5,109	5,541	5,638	5,738

2. Increasing need for endoscopy services. The Applicant attributed the projected increase in endoscopy demand to two factors:

- a. *An aging population in the Proposed Project's service area.* The cities and towns comprising the ASC's proposed service area are expected to grow between 8.4% and 12.2% by 2035, and the age 65 and older population will comprise nearly 25% of the regional total population.^d Projected population increases will lead to a steady increase in routine endoscopy associated with colorectal cancer (CRC) screenings. CRC is the fourth most prevalent cancer type in the service area, and screening rates in the service area are below the state average.^e CRC screening data were provided by the regional Community Health Network Areas (CHNAs) of which 7 and 15 cover towns that are not part of Emerson's service area. Therefore, the CRC rates are not a complete representation of screening rates for the towns served by the Hospital. The Hospital does not track CRC screening rates or disparities in screening rates for Emerson Endoscopy patients due to the incompleteness of the data that are available.¹⁶
- b. *Recommendations for routine CRC screening.* In 2018, the American Cancer Society updated guidelines to lower the age to start CRC screening to age 45 instead of 50, and to continue CRC screening through the age of 75.^{f, g, 17} In October, 2020 the U.S. Preventive Services Task Force (USPSTF) also issued a draft recommendation statement to lower the recommended screening age for colon and rectal cancers to age 45 instead of 50.^{18, h} Colonoscopies and the removal of precancerous polyps has led to a reduction in the incidence of CRC. Organized colorectal cancer screening programs have been effective in increasing CRC screening and reducing cancer mortality.^{i, j, 19, 20} The Applicant asserts the Proposed Project is intended to improve CRC screening compliance by increasing access to affordable, community-based colorectal cancer screenings.

¹⁶ Emerson's endoscopy patients are generally referred by their primary care provider (PCP) or a GI specialist for endoscopy services. The PCP is responsible for recommending and referring patients for screening colonoscopies. The Applicant notes very few patients are seen without a referral for services. Emerson Hospital Patient Panel includes a large subset of patients who were referred from a PCP who is not a member of the Emerson Physician Hospital Organization (PHO), as a result Emerson is unable to track screening rates for patients that are referred to its endoscopy service from independent providers not affiliated with the Hospital.

¹⁷ The recommendation to begin screening at age 45 is a qualified recommendation. The recommendation for regular screening in adults ages 50 and older is a strong recommendation.

¹⁸ The draft recommendation proposes an "A" recommendation for colorectal cancer screening in all adults ages 50 to 75 but a "B" recommendation for screening adults ages 45 to 49. Grade A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Grade B: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

¹⁹ The replacement of an opportunistic colorectal cancer screening program based primarily on sigmoidoscopy and guaiac fecal occult blood test (gFOBT), with an organized screening program of annual fecal immunochemical testing (FIT) combined with opportunistic colonoscopy doubled the percentage of patients screening up-to-date, from almost 40% to over 80%.

²⁰ Opportunistic screening: office-based interaction between a healthcare provider and patient. Programmatic screening (sometimes called organized screening): a system-wide, organized approach to offering screening to a population or members of a healthcare plan.

Analysis

Colorectal cancer (CRC) is the third most common cancer diagnosed in men and women (excluding skin cancers) and is the third leading cause of cancer deaths in the United States.^{k,l} The U.S. Preventive Services Task Force estimates a quarter of people ages 50 to 75 have never been screened for CRC despite evidence of the effectiveness of screening.^m Delaying screening has been shown to result in more aggressive cancer, that is more difficult and expensive to treat.ⁿ Over the past 20 years CRC incidence and mortality has declined among people age 55 and older, due in part to early removal of colorectal polyps and finding cancers earlier when it is easier to treat. But, incidence and mortality has increased among younger individuals during the same period.^{o,p} Colonoscopies are the most thorough method of screening because they allow physicians to view the entire length of the colon and remove polyps as needed.^q With a focus on routine endoscopy, the proposed ASC will make care for CRC more efficient, and convenient,^r and thus has the potential to increase compliance with screening recommendations. In order to further demonstrate that the Proposed Project is addressing Patient Panel need through the appropriate shift of particular surgeries to a freestanding ASC setting, staff recommends the following Conditions:

- Reporting on the shift in routine endoscopy procedures, using endoscopy procedure volume at the proposed ASC and at the Emerson Hospital Endoscopy Department; and
- Reporting on colorectal cancer education and outreach programs among the Patient Panel to ensure appropriate screening rates/rescreening rates.

These are fully described under Conditions at the end of this report.

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

- **Contributing to improved outcomes.** Clinical evidence of the use of endoscopy to diagnose and treat digestive diseases and conditions is well-documented. Advancements in surgery and anesthesia has led to more surgeries, including minimally invasive and non-invasive procedures being performed in the outpatient setting.^s CRC screening allows for identification and removal of precancerous polyps leading to a reduction in the incidence of CRC. Early screening increases the chances of identifying CRC early when treatment is more effective, less invasive, and chance of recovery is high.
- **Physicians Endoscopy, LLC.** The Applicant will participate in ongoing quality improvement programs through PE, including review of quality of care outcomes, and identifying best practices and implementing performance initiatives. The Applicant asserts PE's expertise managing endoscopy ASCs will improve quality of care, efficiency, and outcomes at the proposed ASC.
- **Improved patient experience.** Provision of care in the ASC setting is associated with enhanced convenience and satisfaction for patients. The Applicant asserts the proposed ASC will create a more patient-centered experience through offering a convenient location that is easier to navigate than the hospital campus setting, allows for easier scheduling of procedures, and shorter wait times.^t The facility will offer dedicated parking and direct external access to the facility.

Analysis

Outpatient surgery is increasing in the ASC setting due to clinical and financial reasons and patient and physician preference.^{u,v,w} ASCs offer advantages as compared to hospital outpatient departments (HOPDs), leading to a gradual migration of surgical procedures from HOPDs to ASCs.^x

Advancements in gastrointestinal endoscopy have improved its diagnostic and therapeutic capabilities and utility.^y The proposed ASC will provide routine endoscopy to improve health outcomes and quality of life of the Patient Panel in a setting that will improve patient experience and satisfaction with care. The Applicant proposed specific outcome, process and balancing measures to track the impact of the Proposed Project. These measures are described fully in Attachment 1. Staff recommends that, in order to completely address Factor 1, all of these reporting measures be required as a Condition of Approval.

Health Equity and Social Determinants of Health (SDOH)

The Applicant asserts the ASC will not discriminate based on ability to pay or payer source, physical ability, sensory or speech limitations, or religious, spiritual and cultural beliefs. The Applicant asserts that it will implement measures to create an environment that is welcoming, understanding, and respectful of patients to support equitable access to the ASC's services

Interpretation and Translation Services

The proposed ASC will contract with Language Line Solutions to provide access to 24/7 telephonic and video interpretation services for all Limited English Proficient (LEP) and American Sign Language (ASL) interpretation, and the Application notes that this is offered at other PE centers. Language access services will be provided at no cost to patients. A registered nurse will screen patients prior to the procedure to assess patient barriers to care and to identify any level of assistance needed. Screening questions will be embedded into the electronic medical record and include: 1) Do you have any difficulty with reading or writing in the English language? and 2) Would you like to use an interpreter? If language access needs are identified on the day of the procedure, signage in the facility will be present to assist patients in identifying language or ASL needs and an interpreter will be made available immediately to assist through telephonic or video interpretation. Patients with visual impairments/limitations will be offered the option of having an individual read the document(s) to them in the patient's requested language, in a dedicated, private location. Printed and recorded material will be provided upon request.

Cultural Competence Training

The Applicant states that orientation processes are in place to inform staff and licensed independent practitioners of the proposed ASCs values, culture and procedures. The proposed ASC will require all staff to complete cultural competency training upon hire and annually thereafter through HealthStreams. Core Courses include: "Background and Benefits," and "Providing Culturally Competent Care." The Applicant will evaluate the completion of training on an ongoing basis and utilize a tool that is employed at PE centers, SPH Analytics, to conduct patient satisfaction surveys. Topics covered in the surveys include overall experience, and interactions with staff and their physicians. Results of surveys will be benchmarked against all PE centers and other single-specialty endoscopy centers across the country. Complaints and concerns identified in the surveys, or outside of the survey, will be immediately reviewed and investigated by PE staff.

Social Determinants of Health (SDoH) Screening

The Applicant states that as a provider of routine, non-urgent outpatient endoscopy services, staff of the proposed ASC will have limited interactions with patients due to the episodic nature of care that will be provided. A nurse will screen patients ahead of their procedures and screening questions will focus on transportation, escort availability, medication adherence, areas that are specific to endoscopy. These questions will, the Applicant asserts, allow staff to assess additional needs including financial capacity and personal safety. The screening tool is embedded in the proposed ASC's electronic medical record. Patient responses and any follow-up with the PCP or referring

physician are recorded in the patient's medical record. Patients with SDoH needs that are identified during the pre-procedure screening or on the day of the procedure will be immediately addressed by staff, and patients will be referred to appropriate local organizations when needed. A patient's SDoH referral information will be documented in the medical record and shared with the PCP or referring provider who will then follow up with the patient to facilitate further access to resources. The Applicant states that Emerson is restricted in its capability to follow-up with referral organizations about patients after referral because personal information about a patient cannot be provided without the patient's consent. Therefore, the Applicant proposes to follow-up with the patient and the patient's PCP as needed. The Applicant, through Emerson Hospital, will continue to build and strengthen existing relationships with local organizations where patients with positive SDoH screens will be referred, and will forge new partnerships to address and identified any deficiencies or limitations within its current network.

Analysis

Staff conducted a review of Emerson's CLAS initiatives, including language access, cultural competence training and SDoH screening and finds that the Applicant has sufficiently outlined, at a high level, a case for improved health outcomes and has provided reasonable assurances of health equity and access to care.

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

Efficiency - ASCs are tailored to a limited set of medical specialties and associated low-risk procedures, which create clinical and operational efficiencies and lead to more efficient use of resources.^{z,aa,21} ASCs do not accommodate emergency or inpatient needs, which allows greater control over scheduling leading to shorter appointment and wait times for appointments.^{bb,cc}

Care Coordination - In order to ensure that patients and providers are well-informed, prior to discharge, the patient, or an adult accompanying the patient, will receive prescriptions for any medications needing to be filled. Additionally, written instructions to promote recovery from the procedure, will be provided and will include warning signs of complications and information to contact the physician providing follow up care. Copies of each procedure and pathology report will be shared with the referring physician. Financial counseling will be offered to patients of the proposed ASC so that they are informed of the costs of care prior to their procedure. Patients will be contacted prior to their procedure to verify benefits, obtain prior authorization, if required, and notify patients of any out-of-pocket costs related to their procedure.

Analysis

The Applicant described how the proposed ASC will provide clinically appropriate care in a more efficient setting for patients and providers. In addition, the Applicant sufficiently described how the ASC's processes will support care coordination for patients across several providers.

²¹ Beneficiaries who are sicker may require more time to treat. On average, beneficiaries receiving surgical services in HOPDs are not as healthy as beneficiaries receiving those services in ASCs, as indicated by risk scores from the CMS hierarchical condition category risk adjustment model. Report to the Congress: Medicare Payment Policy. Chapter 5: Ambulatory surgical center services. Background.

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

- **Presentation to Emerson's Patient and Family Advisory Council – June 25, 2020** - The Applicant determined it was appropriate to engage Emerson Hospital's Patient Family Advisory Council (PFAC) because the Proposed Project will largely serve Emerson patients, and PFAC members best represent patients from the proposed service area. The PFAC is comprised of Hospital patients and their family members as well as Hospital staff. The Proposed Project was presented to the PFAC on June 25, 2020. Seven members were in attendance. The project's benefit to current and future patients was discussed and the Applicant reports receiving positive reactions to the project with no concerns raised.
- **Community Forum – July 30, 2020** - The Applicant held a community forum on July 30, 2020 using remote technology to engage residents and resident groups. Forty-four people were in attendance: six Emerson staff, four members of the Emerson Board of Directors, and 34 community members. Emerson leadership presented an overview of the Proposed Project and the benefits of establishing the ASC. The Applicant reports the discussion was thoughtful and community members asked questions and provided positive feedback.

Analysis

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the minimum required community engagement standard of *Consult* in the planning phase of the Proposed Project.

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

The Applicant asserts the Proposed Project will compete based on price, TME, costs and other measures of health care spending through providing the Patient Panel with a lower-cost alternative to endoscopy services. The Applicant cited several studies supporting the cost-effectiveness of ASCs for patients and insurers/payers.

1. Documented cost savings to the Medicare program for procedures performed at ASCs^{ff}
 - Medicare reimbursement for ASCs are on average 58% of the amount paid to HOPDs for the same procedures without compromising services or quality of care.
 - From 2008-2011, ASCs saved the Medicare program and its beneficiaries an estimated \$7.5 billion because surgical and diagnostic procedures were performed at ASCs instead of HOPDs; and it is estimated that the Medicare program and its beneficiaries could save over \$57.6 billion between 2013-2022 if additional procedures move from HOPDs to the ASC setting.
2. In general, ASC prices are significantly lower than HOPD prices for the same procedure in all markets, regardless of payer.^{gg}

- A review of commercial medical-claims data for calendar year 2014 found that U.S. healthcare costs are reduced by more than \$38 billion per year without compromising quality due to the availability of ASCs.²²
 - Only 48% of procedures eligible to be performed in ASCs are actually performed in ASCs and if the remaining 52% were done at ASC price points, an additional \$41 billion in healthcare costs could be saved annually.
3. Lower out of pocket costs may improve compliance with screening recommendations.^{hh}
- The Affordable Care Act made two change in cost sharing for colonoscopies under Section 4104: deductibles were waived for screening and therapeutic colonoscopies; and it removed coinsurance for screening colonoscopies, but not for therapeutic procedures. A study found a significant increase in screening rates among men following implementation of ACA section 4104 in 2011 demonstrating reductions in patient cost sharing can improve adherence to screening guidelines.²³ The study also stated that cost may still be an “important barrier” to CRC screening for socioeconomically disadvantaged men.
4. ASCs specializing in endoscopy are able to compete with HOPDs by providing equivalent or better clinical outcomes at a reduced cost.
- Care provided in ASCs is more efficient than hospitals. Single focus ASCs in particular can minimize staff, equipment and supplies required to provide care, keeping overhead costs low and maximizing efficiencies. Cost comparison between outpatient procedures and those performed in the hospital found lower laboratory, medication, and imaging costs for outpatient procedures.ⁱⁱ

Analysis

In 2018, CRC was the second largest expenditure for cancer care after breast cancer.^{jj} Early CRC detection and management improves health outcomes and minimizes healthcare spending.^{kk} It has been well documented that access to care and utilization is tied to cost.^{ll} Out of pocket expenses has been identified as a barrier to screening and reducing patient cost-sharing for procedures has been shown to increase compliance with screening recommendations. ASC patients’ out-of-pocket costs can be reduced through lower deductible and coinsurance payments and colorectal cancer detection at earlier stages could yield savings in treatment costs for payers.^{mm,nn}

Description of proposed measures, suggested Conditions, Factor 1

As a result of information provided by the Applicant and additional analysis, staff finds that, with the proposed conditions, the Proposed Project has met Factors 1(a-f). The Applicant proposed specific outcome, process and balancing measures to track the impact of the proposed transaction. Staff recommends that, in order to completely address Factor 1, all of these reporting measures be required as a Condition of Approval. Staff also suggests Conditions reporting on colorectal cancer education and outreach programs among the Patient Panel to ensure appropriate screening rates/rescreening rates and reporting on reporting on the shift in routine endoscopy procedures, using endoscopy procedure volume at the proposed ASC and at the Emerson Hospital Endoscopy Department. This is described fully under Conditions at the end of this report.

²² ASCs would not be the appropriate setting for a small percentage of patients (e.g., those with serious health issues) currently treated in HOPDs.

²³ Patients owe only coinsurance if a test is billed as screening, but they owe both coinsurance and deductibles for therapeutic colonoscopies.

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

Cost Containment

The Applicant states the Massachusetts Health Policy Commission's goal for cost containment is "better health and better care at a lower cost across the Commonwealth."^{oo} The Applicant asserts the Proposed Project meets the HPC's cost containment goal through providing high quality surgical services in an affordable setting. Expanding access to community-based CRC screenings can improve adherence to recommended screening guidelines. Furthermore, early screening for CRC leads to early detection and more effective treatment at a lower cost compared to when it is detected at advanced stages. The Applicant also reiterated care and cost efficiencies resulting from providing surgical services in the ASC setting. PE and Emerson will continue to engage the community in an effort to increase awareness for CRC and preventative measures, including colonoscopy.

Analysis: Cost Containment

Cost containment on a statewide level is impacted through pricing, which is a function of what providers charge payers and what payers agree to pay. While payment contracts between individual providers and commercial payers are confidential, those among providers and Medicare and Medicaid are relatively transparent. As a result, Staff cannot assess how the Applicant's contracts with payers, that may incentivize more or less utilization of services, are structured for the project components. Staff considered the Applicant's assertions around cost containment alongside reporting on the cost differentials between ASCs and HOPDs and the cost effectiveness of endoscopic screening. The Medicare Price Procedure Lookup for Outpatient Services, which compares national average prices for procedures done in both ASCs and HOPDs, indicates that procedures performed in the ASC setting can result in cost savings.^{pp} Reports from the Center for Health Information and Analysis (CHIA) show that Emerson, a community hospital (CH) with a statewide relative price (S-RP) of 0.87 (mean is 1.00) in 2019, is a lower cost provider.^{24,qq} While Staff cannot conclude that expanding access to ambulatory surgery services through the Proposed Project will not lead to higher prices and higher healthcare spending, Staff finds that increasing access to surgical services in the ASC setting has the potential to contribute to cost containment.

Improved Public Health Outcomes

The Applicant asserts that improving access to affordable and convenient services ultimately results in improved health outcomes. More convenient, lower cost access to CRC screening can help to increase screening compliance and improve health outcomes, and potentially, quality of life. The Applicant states that Emerson Hospital promotes CRC screening through increased awareness and education, including publication of Health Works Magazine, a Direct Mail Campaign, and a Podcast containing content colonoscopy screening.²⁵ The Applicant asserts that the proposed ASC will continue to promote CRC screening through patient marketing campaigns, as well as physician education.

Analysis: Public Health Outcomes

It is well established that endoscopy is an effective screening, diagnostic, and therapeutic tool for gastrointestinal conditions and cancers. Colonoscopy or sigmoidoscopy are used to screen for colon

²⁴ S-RP is a measure of the prices paid to a provider across multiple payers.

²⁵ Emerson Hospital Strategies to Improve CRC Screening: Emerson Hospital Health Works Magazine, reaching 140,000 household's in Emerson's total service area; Direct Mail Trigger campaign, reaching 25,000 individuals annually; and Podcast, *Colon Cancer Screenings: Latest Advances and Ways to Prepare Jennifer Naylor, MD*, shared via the Emerson website, social media, and available in app stores.

cancer. Screening at recommended intervals increases likelihood of either prevention, through removal of precancerous polyps, or early diagnoses at a curable stage. Among important public health outcomes are the reduction of risk factors for colorectal cancer and ensuring screening and rescreening rates at appropriate intervals. In 2018, 73% of adults aged 50-75 had a colonoscopy in the past 10 years.^{rr} Staff also notes however, that disparities in screening do exist.^{ss,tt,uu} In addition, studies show an association between patient race/ethnicity, socioeconomic status, and insurance status and location of outpatient surgery (ASC vs. HOPD) with patients of black race, lower socioeconomic status, and public insurance status, less likely to receive care in an ASC.^{vv,ww} Increasing timely access to endoscopy services is likely to improve health outcomes and quality of life for the Patient Panel. In order to ensure that public health outcomes are addressed, as a Condition of approval, staff suggests reporting of colorectal cancer education and outreach programs in the community to increase overall screening rates, and in particular among minority and low-income populations. This is described fully under Conditions at the end of this report.

Delivery System Transformation

The Applicant states that ACOs were created to improve care delivery, lower costs, and address population health. The Applicant argues ACOs are intended to improve these areas through, reducing fragmentation, improving accountability for quality and cost, and addressing the SDoH towards achieving population health.^{xx,yy} The Applicant argues that ASCs help ACOs achieve their aims through achieving cost savings, advancing care coordination, and improving care at the community level. The proposed ASC will work with patients and PCPs to ensure patients are referred for services as needed. Staff will provide referral resources to patients with SDoH concerns identified during pre-procedure screenings and appointments, and will also update the medical record so that the PCP is aware of the need for follow-up.

Analysis: Delivery System Transformation

ACOs are intended to improve health, the patient experience, and lower costs.^{zz} The Applicant has demonstrated how the proposed ASC will support these aims for its Patient Panel, and Emerson's ACO patients in particular through describing its status as a lower-cost setting for outpatient surgery, and its SDoH screening which has the potential to improve the continuity of care.

Description of proposed measures, suggested Conditions, Factor 2

As a result of information provided by the Applicant and additional analysis, staff finds that, with the condition below, the Applicant has sufficiently met the requirements of Factor 2. In order to ensure that public health outcomes are addressed, as a Condition of approval, staff suggests reporting of colorectal cancer education and outreach programs in the community to increase overall screening rates, and in particular among minority and low-income populations. This is described fully under Conditions at the end of this report.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and 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 Bernard L. Donohue, III, CPA (CPA Report).

The CPA analysis included a review of numerous documents in order to form an opinion as to the feasibility of the Proposed Project including:

- Emerson Endoscopy and Digestive Health Center, LLC's 5-year Projected Financial Statements, and Assumptions
- Documentation supporting calculations included in the projected financial statements
- DoN Application
- Websites (DoN, CMS, EOHHS, Becker's ASC, VMG Health Intellimarker Multi-Specialty ASC Study, Emerson Hospital, Physicians Endoscopy LLC).

In review of the reasonableness of assumptions used and feasibility of the Projections, the CPA report presented key metrics falling into three categories (liquidity, operating and solvency), comparing the operating results of the Projections for the first five years of operations.

The CPA analyzed the revenue identified by the Center in the Projections. Projected volume was based on a ramp-up schedule developed from an analysis of projected cases for the Center's service area and based on the hiring of additional physicians to service the ASC (The Center). The CPA compared the Center's benchmark data to an outside, independent survey of ASCs completed using 2017 data and found the Center's benchmarking to be reasonable. Payer mix was based on the current payer mix on Emerson Hospital's Endoscopy unit from where the ASC will derive most of its patients. Reimbursement rates were based on current Medicare ASC rates, Medicaid rates, and expected Commercial insurance contracted rates. The CPA compared the payer mix to the independent survey's payer mix for the Northeast United States and found them to be within the ranges published by the survey. The CPA report found the projected revenue projected is a reasonable estimation of future revenue of the Center.

The CPA analyzed salary and benefits, as well as other operating expenses for reasonableness and feasibility as related to the Projection of the Center. Projected increases per year include salary and benefits (3%), clinical expenses (3%), and most other expenses (3 or 4% after the baseline year). Staffing hours, wage rates for all clinical and administrative categories, medical surgical supplies, and other expenses were all compared to the independent survey and found to be consistent with survey results. The CPA report found operating expenses are reasonable.

The CPA reviewed the lease agreement, capital expenditures, and cash flows. The CPA report states 8,185 square feet of space at 310 Baker Avenue in Concord, MA will be leased by Emerson Endoscopy and Digestive Health Center, LLC. Rent expenses will be \$35 per square foot or \$286,475 per year. The lease will include a 2% increase every year. Total occupancy costs in the projections were compared to the survey and found to be within the range of the survey. The CPA determined pro-forma capital expenditures, facility lease, terms of equipment and working capital financing and the resulting impact on the cash flows of the Center are reasonable.

The CPA determined that the project and continued operating surplus are reasonable and based upon feasible financial assumptions. The CPA concluded that “the Projections are feasible and sustainable and not likely to have a negative impact on the Patient Panel or result in a liquidation of assets of Emerson Endoscopy and Digestive Health Center, LLC.”

As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 4.

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

The Applicant proposed the alternative of continuing with the status quo and serving patients through the existing Endoscopy Department at Emerson Hospital. This alternative was dismissed because continuing to perform low-acuity procedures in the Hospital’s Endoscopy Department will not address existing operational inefficiencies due to scheduling disruptions caused by the need to accommodate urgent or complex cases. In addition, in the alternative option would keep in place higher ongoing operating costs than the proposed ASC, due to the additional staff, equipment, and supplies required in the hospital setting.

The second alternative considered is constructing a new center at Emerson Hospital with other renovations the Hospital has planned for the next three years. This alternative was dismissed because the new rooms would not be operational for at least five years, and the Applicant asserts that during that time, the proposed ASC would not serve as a site for patients and providers choosing to move care to the ASC setting for routine endoscopy. The Applicant estimated costs to build a new endoscopy unit would be 5 million dollars and the new unit would result in higher operating costs due to the additional staff, equipment, and supplies needed in the hospital setting.

Staff agrees that the above alternatives will not adequately address Patient Panel need for high-quality and convenient access to outpatient surgical services. 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 DoN project is one of two current DoN applications under consideration and given that (subject to DoN project approval) CHI related activities would be implemented concurrently, the Applicant and DPH have agreed to one Factor 6 analysis for both DoN projects. Combined across DoN projects the CHI requirement is a Tier 1 CHI project. This analysis will appear in the staff report for both DoN projects and the required CHI contribution amount is the combined amount.

To fulfill Factor 6 for both DoN projects, the Applicant submitted its existing Community Health Needs Assessment (CHNA) for Emerson Hospital, a Self-Assessment (combined for streamlining purposes), Stakeholder Assessments, and a CHI Narrative.

The Community Health Needs Assessment was conducted in 2018 by Emerson Hospital, the entity that will implement CHI activities. The final CHNA utilized secondary data sources and primary data gathered from qualitative interviews with key informants. The CHNA describes quantitative and qualitative data collection methods and outlines key findings and themes from the service area and participating communities. These themes include barriers to positive outcomes,

populations of focus, and health conditions. The CHNA also shares the Hospital's Community Benefits Implementation Plan, based on the Key Finding Issues: Lack of Transportation, At-Risk Adolescents, Growing Aging Population, Cancer, and Mental Health and Domestic Violence.

The Self-Assessment provided a summary of community engagement processes and socio-demographic information, data and highlights related to topics and themes of community needs. Through data analysis, existing surveys, and key informant interviews, the participating community groups and residents identified the key concerns outlined in the 2018 CHNA.

Stakeholder Assessments submitted provided information on the individuals' engagement levels (e.g. their personal participation and role) and their analysis of how the Applicant engaged the community in community health improvement planning processes. The information provided in these forms were largely consistent with the self-assessment conducted by the Applicant.

The CHI Narrative provided background and overview information for the CHI processes. The narrative also outlines advisory duties for the advisory and allocation committees, and planned use of funding for evaluation and administrative activities. Additionally, the narrative outlines the CHI funds breakdown and the anticipated timeline for CHI activities.

The timeline, RFP processes, and use of evaluation and administrative funds are all appropriate and in line with CHI planning guidelines. There are, however, differences in approach and alignment between the Applicant's existing Community Benefits Implementation Plan and CHI principles. If used as a guide for choosing CHI strategies, the activities outlined in the Implementation Plan will not suffice in meeting Health Priority guideline principles around identifying needs and implementing activities at the root cause level. Based on strategies funded in the Applicant's Implementation Plan, staff have determined the Applicant agrees to additional activities to ensure ongoing work with the Community Benefits Advisory Committee (CBAC) will align with the Health Priorities Guideline. The Applicant will be recruiting for missing constituencies on the existing CBAC, and DPH will work with them to ensure the group's make up is sufficient to help them make decisions in line with Health Priority principles. The Applicant will also need additional touchpoints with DPH staff to establish processes for planning and implementation work moving forward. Specifically, DPH will work with the Applicant on community engagement in further needs assessing and outreach, decision making structure, outlining future CBAC meetings, and review of community engagement and RFP processes. Regarding the implementation of specific CHI strategies, DPH will work with the Applicant in moving upstream, and identifying needs at the root cause to support sustainable systems level solutions.

The anticipated timeline for CHI activities includes the first meeting of the Advisory Committee six weeks post approval, identifying the Health Priorities Strategies 3 months post approval, and releasing an RFP six months post approval, with funding awarded to successful RFP applicants 3-4 months thereafter.

With the administrative funds, the applicant's early plans are to support consultant time, external facilitation, communication, and reporting and dissemination of lessons learned and best practices.

Summary Analysis: As a result of information provided by the Applicant and additional analysis, staff finds that with the conditions outlined below, and the ongoing communication on items for

improvement outlined above, 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. Reporting of endoscopy procedure volume at Emerson Hospital Endoscopy Department and the proposed ASC, including a breakdown of endoscopy procedure volume by routine, advanced, and urgent cases, and inpatient and outpatient cases.
2. Provide a description of any programs or initiatives designed to increase CRC screening or rescreening behaviors according to appropriate intervals among the Patient Panel.
This shall include:
 - a. Program description and length (if applicable)
 - b. Description of program recruitment (if applicable) and number reached out to
 - c. Total number of participants
 - i. Percentage of participants from racial /ethnic minority groups to the extent possible based on follow up with existing patients
 - d. Any outcomes measured
3. Provide a description of any programs or initiatives designed to either reduce risk factors for CRCs and/or increase CRC screening or rescreening behaviors according to appropriate intervals in the broader community.
This shall include:
 - a. Program description and length (if applicable)
 - b. Description of program recruitment (if applicable) and number reached out to
 - c. Total number of participants
 - i. Percentage of participants from racial /ethnic minority groups to the extent possible
 - d. Any outcomes measured
4. Report on improvement of measures outlined in Attachment 1. Reporting will include a definition of the numerator and denominator of each measure.
5. Of the total required CHI contribution of \$231,829.40
 - a. \$22,255.62 will be directed to the CHI Statewide Initiative
 - b. \$200,300.60 will be dedicated to local approaches to the DoN Health Priorities
 - c. \$9,273.18 will be designated as the administrative fee.
6. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$22,255.62 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).

- i. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
- ii. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

Attachment 1: Required Measures for Annual Reporting

The Holder shall provide, in its annual report to the Department, the following outcome measures. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12). The following measures were suggested by the Applicant

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.

Projections: The benchmark for this measure is 6 minutes or greater.

Monitoring: Results will be benchmarked and reviewed quarterly by the quality committee and the Board of Managers.

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.

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

Projections: Overall ADR equal to or greater than 25% for the total patient panel; 30% for men and 20% for women.

Monitoring: Results will be benchmarked and reviewed quarterly by the quality committee and the Board of Managers.

Post-Procedure Infection – This measure evaluates the number of patients with post procedure infections and aims to reduce or eliminate such incidences.

Measure: The number of patients with post-procedure infections.

Projections: As the Proposed Project is to develop a new ASC, the Applicant will provide baseline measures and three years of projections following one full year of operation from the date of implementation of the Proposed Project.

Monitoring: Results will be reviewed on an on-going basis and reported to the quality committee monthly. Results are benchmarked and reviewed quarterly by the Board of Managers.

Patient Satisfaction: Patients that are satisfied with their care are more likely to seek additional treatment when needed. The Applicant will review patient satisfaction levels with the ASC's surgical services.

Measure: The Physicians Endoscopy Patient Satisfaction (PEPS) survey will be provided to all eligible patients. The PEPS survey focuses on the patient's experience in the following areas: 1) recovery; 2) discharge and follow-up; and 3) patient experience. The survey also asks for the patient's demographic information at the end.

Projections: As the Proposed Project is to develop a new ASC, the Applicant will provide baseline measures and three years of projections following one full year of operation from the date of implementation of the Proposed Project.

Monitoring: Results will be benchmarked and reviewed monthly by the quality committee and the Board of Managers.

REFERENCES

- ^a The HPC Accountable Care Organization (ACO) Certification Program. <https://www.mass.gov/service-details/the-hpc-accountable-care-organization-aco-certification-program>
- ^b Massachusetts Health Policy Commission. Bulletin on Independent Community Hospitals for Determination of Need Applicants. Available: <https://www.mass.gov/doc/bulletin-hpc-2020-01-independent-community-hospitals/download>
- ^c Emerson Hospital Community Health Needs Assessment. 2018. Available: <https://www.emersonhospital.org/EmersonHospital/media/PDF-files/2018-Community-Health-Needs-Assessment.pdf>
- ^d University of Massachusetts Donahue Institute, long-term population projections for Massachusetts regions and municipalities 11 (Mar. 2015). Available: http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf
- ^e Emerson Hospital Community Health Needs Assessment (2018). Available: <https://www.emersonhospital.org/EmersonHospital/media/PDF-files/2018-Community-Health-NeedsAssessment.pdf>
- ^f American Cancer Society Guideline for Colorectal Cancer Screening: A Summary for Clinicians. Available: <https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/summary-for-clinicians-acsguideline-for-colorectal-cancer-screening.pdf>
- ^g American Cancer Society. Colorectal Cancer Screening Guidelines. Available: <https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/colorectal-cancer-screening-guidelines.html>
- ^h U.S. Preventive Services Task Force Issues Draft Recommendation on Screening for Colorectal Cancer. Available: https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/colorectal-cancer-screening-draft-rs-bulletin-updated.pdf
- ⁱ Levin TR, Corley DA, Jensen CD, Schottinger JE, Quinn VP, Zauber AG, Lee JK, Zhao WK, Udaltsova N, Ghai NR, Lee AT, Quesenberry CP, Fireman BH, Doubeni CA. Effects of Organized Colorectal Cancer Screening on Cancer Incidence and Mortality in a Large Community-Based Population. *Gastroenterology*. 2018 Nov;155(5):1383-1391.e5.
- ^j Roselló S, Simón S, Cervantes A. Programmed colorectal cancer screening decreases incidence and mortality. *Transl Gastroenterol Hepatol* 2019;4:84. Available: <http://tgh.amegroups.com/article/view/5630/pdf>
- ^k American Cancer Society. Key Statistics for Colorectal Cancer. Available: <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html>
- ^l American Cancer Society. Colorectal Cancer Facts & Figures 2020-2022. Available: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf>
- ^m U.S. Preventive Services Task Force Issues Draft Recommendation on Screening for Colorectal Cancer. Available: https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/colorectal-cancer-screening-draft-rs-bulletin-updated.pdf
- ⁿ Am J Manag Care. A Path to Improve Colorectal Cancer Screening Outcomes: Faculty Roundtable Evaluation of Cost-Effectiveness and Utility. 2020;26:S123-S143. <https://doi.org/10.37765/ajmc.2020.43732>
- ^o Cancer screening in the United States, 2018: A review of current American Cancer Society guidelines and current issues in cancer screening. Available: <https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21446>
- ^p American Cancer Society. Key Statistics for Colorectal Cancer. Available: <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html>
- ^q Hamman MK, Kapinos KA. Affordable Care Act Provision Lowered Out-Of-Pocket Cost And Increased Colonoscopy Rates Among Men In Medicare. *Health Aff (Millwood)*. 2015 Dec;34(12):2069-76. doi: 10.1377/hlthaff.2015.0571. PMID: 26643627.
- ^r Ambulatory Surgery Center Association. Medicare Cost Savings Tied to Ambulatory Surgery Centers. Available: <https://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=7b33b916-f3f1-42e5-a646-35cc2f38fe4d&forceDialog=0>
- ^s Health Capital. Volume 3, Issue 5. May 2010. Outpatient Surgeries Show Dramatic Increase Available: https://www.healthcapital.com/hcc/newsletter/05_10/Outpatient.pdf
- ^t American Academy of Orthopaedic Surgeons. Ambulatory Surgical Centers Position Statement. Available: https://www5.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/1161%20Ambulatory%20Surgical%20Centers.pdf
- ^u Boodman SG. Popularity Of Outpatient Surgery Centers Leads To Questions About Safety | Kaiser Health News. Kaiser Health News. <https://khn.org/news/popularity-of-out-patient-surgery-centers-leads-to-questions-about-safety/>
- ^v Badlani N. Ambulatory surgery center ownership models. *J Spine Surg*. 2019;5(S2):S195-S203. doi:10.21037/jss.2019.04.20
- ^w Biesen T van, Johnson T. Ambulatory Surgery Center Growth Accelerates: Is Medtech Ready? | Bain & Company. Bain & Company.

- ^x Mackoul P, Danilyants N, Baxi R, van der Does L, Haworth L. Laparoscopic hysterectomy outcomes: Hospital vs ambulatory surgery center. *J Soc Laparoendosc Surg*. 2019;23(1). doi:10.4293/JLS.2018.00076
- ^y Ro TH, Mathew MA, Misra S. Value of screening endoscopy in evaluation of esophageal, gastric and colon cancers. *World J Gastroenterol*. 2015;21(33):9693-9706. doi:10.3748/wjg.v21.i33.9693. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4562953/>
- ^z American Academy of Orthopaedic Surgeons. Ambulatory Surgical Centers Position Statement. Available: https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/1161%20Ambulatory%20Surgical%20Centers.pdf
- ^{aa} Munnich EL, Parente ST. Procedures take less time at ambulatory surgery centers, keeping costs down and ability to meet demand up. *Health Aff (Millwood)*. 2014 May;33(5):764-9. doi: 10.1377/hlthaff.2013.1281. PMID: 24799572.
- ^{bb} Advancing Surgical Care. ASCs: A Positive Trend in Health Care. Available: <https://www.ascassociation.org/advancingsurgicalcare/aboutasc/industryoverview/apositivetrendinhealthcare>
- ^{cc} Report to the Congress: Medicare Payment Policy. March 2018. Available: http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf
- ^{dd} Community Engagement Standards for Community Health Planning Guideline. Available: <https://www.mass.gov/doc/community-engagement-guidelines-for-community-health-planning-pdf/download>
- ^{ee} DoN Regulation 100.210 (A)(1)(e). Available: <https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf>
- ^{ff} Ambulatory Surgery Center Association. Medicare Cost Savings Tied to Ambulatory Surgery Centers. Available: <https://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=7b33b916-f3f1-42e5-a646-35cc2f38fe4d&forceDialog=0>
- ^{gg} Healthcare Blue Book. Commercial Insurance Cost Savings in Ambulatory Surgery Centers. Available: <https://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=829b1dd6-0b5d-9686-e57c-3e2ed4ab42ca&forceDialog=0>
- ^{hh} Hamman MK, Kapinos KA. Affordable Care Act Provision Lowered Out-Of-Pocket Cost And Increased Colonoscopy Rates Among Men In Medicare. *Health Aff (Millwood)*. 2015 Dec;34(12):2069-76. doi: 10.1377/hlthaff.2015.0571. PMID: 26643627.
- ⁱⁱ Crawford DC, Li CS, Sprague S, Bhandari M. Clinical and Cost Implications of Inpatient Versus Outpatient Orthopedic Surgeries: A Systematic Review of the Published Literature. *Orthopedic Reviews*. 2015 Dec;7(4):6177. DOI: 10.4081/or.2015.6177. Available: <https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC4703913&blobtype=pdf>
- ^{jj} National Cancer Institute. Cancer Trends Progress Report. Financial Burden of Cancer Care. Available: https://progressreport.cancer.gov/after/economic_burden
- ^{kk} Am J Manag Care. A Path to Improve Colorectal Cancer Screening Outcomes: Faculty Roundtable Evaluation of Cost-Effectiveness and Utility. 2020;26:S123-S143. Available: <https://doi.org/10.37765/ajmc.2020.43732>
- ^{ll} Muthukrishnan M, Arnold LD, James AS. Patients' self-reported barriers to colon cancer screening in federally qualified health center settings. *Prev Med Rep*. 2019 May 15;15:100896. doi: 10.1016/j.pmedr.2019.100896. PMID: 31193550; PMCID: PMC6531912.
- ^{mm} Healthcare Blue Book. Commercial Insurance Cost Savings in Ambulatory Surgery Centers. Available: <https://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=829b1dd6-0b5d-9686-e57c-3e2ed4ab42ca&forceDialog=0>
- ⁿⁿ Hamman MK, Kapinos KA. Affordable Care Act Provision Lowered Out-Of-Pocket Cost And Increased Colonoscopy Rates Among Men In Medicare. *Health Aff (Millwood)*. 2015 Dec;34(12):2069-76. doi: 10.1377/hlthaff.2015.0571. PMID: 26643627.
- ^{oo} Massachusetts Health Policy Commission. 2019 Annual Health Care Cost Trends Report. February 2020. Available: <https://www.mass.gov/doc/2019-health-care-cost-trends-report/download>
- ^{pp} Medicare.gov Procedure Price Lookup. Available: <https://www.medicare.gov/procedure-price-lookup/>
- ^{qq} Center for Health Information and Analysis (CHIA). Relative Price and Provider Price Variation. Available: <https://www.chiamass.gov/relative-price-and-provider-price-variation/#relative-price-interactive>
- ^{rr} Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health. BRFSS Prevalence & Trends Data [online]. 2015. [accessed Dec 31, 2020]. URL: <https://www.cdc.gov/brfss/brfssprevalence/>
- ^{ss} May FP, Yang L, Corona E, Glenn BA, Bastani R. Disparities in Colorectal Cancer Screening in the United States Before and After Implementation of the Affordable Care Act. *Clin Gastroenterol Hepatol*. 2020 Jul;18(8):1796-1804.e2. doi: 10.1016/j.cgh.2019.09.008. Epub 2019 Sep 13. PMID: 31525514.
- ^{tt} Siegel RL, Miller KD, Goding Sauer A, Fedewa SA, Butterly LF, Anderson JC, Cercek A, Smith RA, Jemal A. Colorectal cancer statistics, 2020. *CA Cancer J Clin*. 2020 May;70(3):145-164. doi: 10.3322/caac.21601.

^{uu} Massachusetts Statewide 2017-2021 Cancer Plan. Available:

https://ftp.cdc.gov/pub/Publications/Cancer/ccc/massachusetts_ccc_plan-508.pdf

^{vv} Janeway MG, Sanchez SE, Chen Q, et al. Association of Race, Health Insurance Status, and Household Income With Location and Outcomes of Ambulatory Surgery Among Adult Patients in 2 US States. *JAMA Surg.* 2020;155(12):1123–1131. doi:10.1001/jamasurg.2020.3318

^{ww} Strobe SA, Sarma A, Ye Z, Wei JT, Hollenbeck BK. Disparities in the use of ambulatory surgical centers: a cross sectional study. *BMC Health Serv Res.* 2009 Jul 21;9:121. doi: 10.1186/1472-6963-9-121. PMID: 19622154; PMCID: PMC2725040.

^{xx} The Department of Healthcare Policy and Research. Accountable Care Organizations. Policy Brief. January, 2015. Available: https://hbp.vcu.edu/media/hbp-dev/pdfx27s/policy-briefs/virginia-health-policy-briefs/policyBrief0115_ACC.pdf

^{yy} Hacker K, Walker DK. Achieving population health in accountable care organizations. *Am J Public Health.* 2013 Jul;103(7):1163-7. doi: 10.2105/AJPH.2013.301254. Epub 2013 May 16. PMID: 23678910; PMCID: PMC3682617. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3682617/pdf/AJPH.2013.301254.pdf>

^{zz} Center for Health Care Strategies, Inc. Accountable Care Organizations: Looking Back and Moving Forward. January, 2016. Available: <https://www.chcs.org/media/ACOs-Looking-Back-and-Moving-Forward.pdf>