

West Bridgewater MA Endoscopy ASC, LLC
CEC-24082115-AS

APPLICANT QUESTIONS #2

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

While you may submit each answer as available, please

- List question number and question for each answer you provide.
- Submit responses as a separate word document, using the above application title and number as a running header and page numbers in the footer.
- When providing the answer to the final question, submit all questions and answers in order in one final document.
- Submit responses in editable WORD or EXCEL format.
- Whenever possible, include a table with the response.
- **For HIPAA compliance Do not include numbers <11.**

staFactor 1a: Patient Panel and Need

- 1. What data base was used to report on Gender and Patient Origin? Please explain why the Press Ganey database was used to report on Age, Race and Ethnicity vs the database used for Gender and Patient Origin? If possible, provide the complete profile of Age, Race and Ethnicity.**

Response: In the initial application submission for CEC-24082115-AS (the “Initial Application”), the Applicant used its Allscripts EMR database, its source of patient data for billing, to report on Gender and Patient Origin. Unfortunately, the Applicant's Allscripts EMR does not allow the Applicant to create reports or data extracts that include patient Age, Race and Ethnicity data. The Applicant was able to extract limited Age, Race and Ethnicity data through its Press Ganey database, and used this data in the Initial Application, rather than not providing the requested data at all. The data provided was the most complete profile of Age, Race and Ethnicity that the Applicant was aware of at the time of submission. Upon receiving Applicant Questions #1 from the DON staff, the Applicant identified the Provation system used by the providers to record their operative notes at the ASC as an alternative source of data. The Provation data is more accurate and complete than the data reported from Press Ganey surveys because each patient case is reported, whereas the Press Ganey surveys include only data from patients who responded to the surveys.

Please see updated the Age, Race and Ethnicity patient panel data (unique patient counts, not procedures or cases) in the tables below using Provation data for Calendar Year 2020 through 2024 (2024 is based on January to September data annualized). Patient race categories with less than 11 patients in a year were grouped with other races to meet HIPAA requirements. Please note, patient race and ethnicity reporting is voluntary, and some patients choose not to report their race and/or ethnicity.

Patient Panel Age by Calendar Year:

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Patient Age	2020 # Patients	2020 % Patients	2021 # Patients	2021 % Patients	2022 # Patients	2022 % Patients	2023 # Patients	2023 % Patients	2024 Jan-Sept annualized# # Patients	2024 Jan-Sept annualized% Patients
0-44	585	15%	957	18%	788	15%	680	11%	695	11%
45-49	194	5%	355	6%	540	10%	931	16%	773	13%
50-69	2,501	64%	3,192	60%	3,019	58%	3,327	57%	3,448	57%
70+	605	16%	841	16%	851	17%	930	16%	1,167	19%
Grand Total	3,885	100%	5,345	100%	5,198	100%	5,868	100%	6,083	100%

Patient Race by Calendar Year:

Patient Race	2020 # Patients	2020 % Patients	2021 # Patients	2021 % Patients	2022 # Patients	2022 % Patients	2023 # Patients	2023 % Patients	2024 Jan-Sept annualized# # Patients	2024 Jan-Sept annualized% Patients
American Indian or Alaskan Native. Asian, Native Hawaiian or Pacific Islander, Other	27	2%	165	4%	162	3%	237	4%	213	4%
Black / African American	57	3%	207	4%	248	5%	446	8%	384	7%
White	1,553	95%	4,250	92%	4,475	92%	4,662	87%	5,031	89%
Grand Total	1,637	100%	4,622	100%	4,885	100%	5,345	100%	5,628	100%
Patient race not reported by patients	2,248		723		313		523		455	
Total Patients	3,885		5,345		5,198		5,868		6,083	

Patient Ethnicity by Calendar Year:

Patient Ethnicity	2020 # Patients	2020 % Patients	2021 # Patients	2021 % Patients	2022 # Patients	2022 % Patients	2023 # Patients	2023 % Patients	2024 Jan-Sept annualized# # Patients	2024 Jan-Sept annualized% Patients
Hispanic or Latino	46	4%	130	4%	133	4%	281	7%	192	4%
Not Hispanic or Latino	1,000	96%	3,366	96%	3,289	96%	3,866	93%	4,581	96%
Ethnicity Total	1,046	100.0%	3,496	100%	3,422	100%	4,147	100%	4,773	100%
Patient ethnicity not reported by patients	2,839		1,849		1,776		1,721		1,310	
Total Patients	3,885		5,345		5,198		5,868		6,083	

2. The application attributes need for the Proposed Project to wait times for accessing endoscopy services. Please provide

- a. any industry standard/ national benchmarks for acceptable wait times for the procedures performed.**

Response: The United States has not established any industry standards or national benchmarks for acceptable wait times for endoscopy services. While other western counties have established guidelines, they do not account for cultural and health system differences that impact patient outcomes and expectations around the availability of medically necessary services. For example, countries like Canada and England have

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notoriously long wait times for procedures, but greater access to physicians, which may indicate better access to preventative care overall.¹ Additionally, the United States has been shown to outperform other nations in terms of rates for screening for colorectal cancer.²

As noted in the Initial Application, the existing physicians and the New Physicians have reported increased wait times over the past several years, but the Applicant anticipates that expanded capacity in its ASC will help reduce wait times across the primary service area, including for higher acuity procedures performed in the HOPD setting.

b. data or sources demonstrating the negative impact of delaying endoscopy procedures.

Response: A study published in the Journal of General Internal Medicine in 2020 examined wait times for outpatient colonoscopy procedure in the veteran's health administration ("VA") and found the average wait times for scheduling an outpatient coloscopy following positive fecal occult blood test (FOBT) ranged from 47 to 55 days.³ Because evidence suggests that delays of more than six (6) months after a positive FOBT are associated with worse clinical outcomes, the study found the 47 to 55 day range to be clinically acceptable.⁴ However, although wait times were within a clinically acceptable range, the study found a disconnect between patient or health system expectations for scheduling procedures and clinically acceptable timelines.⁵ The study noted "a great deal of patient anxiety upon receipt of a positive cancer screening test, emotions that are often best addressed with prompt scheduling and completion of follow-up testing." Evidence also shows that longer wait times are associated with lower overall patient satisfaction and patient perceptions of their providers and quality of care.⁶

3. To better understand the utilization patterns for services, please provide the following:

a. Annual case and procedure volume at FY19 to FY24 broken down by age cohort below

¹ See The Commonwealth Fund, U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcome (January 31, 2023), available at <https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022>.

² *Id.*

³ Megan A. Adams et. al, *Trends in Wait Time for Outpatient Colonoscopy in the Veterans Health Administration, 2008-2015*, J Gen Intern Med 35(6):1776-82 (Published Online March 24, 2020), available at [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7280466/#:~:text=At%20the%20facility%20with%20the,26%20days%2C%20respectively\).](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7280466/#:~:text=At%20the%20facility%20with%20the,26%20days%2C%20respectively).)

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

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Response: As noted in response to question 1 above, the Applicant is not able to report on patient age in its Allscripts EMR, however the Applicant is able to report procedures by age in its Provation system. Unfortunately, the Provation reports procedures differently than the Allscripts EMR. Both are accurate for different purposes. The Provation system counts procedures as colonoscopies, flexible sigmoidoscopies and upper GI endoscopies, whereas the Allscripts EMR reports procedures using industry standard CPT coding. For example, a colonoscopy will be counted as one procedure in Provation, but may have multiple maneuvers, such as polyps, biopsies, submucosal injections which will be counted a multiple procedures with CPT codes in Allscripts. Upper endoscopies can also have multiple maneuvers, such as polyps, biopsies and dilatations. The Provation system is unable to report on case counts.

Please see the table below detailing procedures from the Provation system for 2019 through 2024 by age category. Flexible sigmoidoscopy and Upper GI endoscopy procedures have been combined to meet HIPAA requirements.

Age Range/ Procedure type	2019		2020		2021		2022		2023		2024 (Jan-Sept Annualized)	
	#	%	#	%	#	%	#	%	#	%	#	%
0-44 Total:	894	15%	688	16%	1,131	18%	955	16%	792	12%	835	12%
Colonoscopy	411	7%	335	8%	568	9%	495	8%	399	6%	455	7%
Flexible sigmoidoscopy and Upper GI endoscopy	485	8%	353	8%	563	9%	460	8%	393	6%	380	5%
45-49 Total:	383	6%	241	5%	423	7%	620	10%	1,031	16%	867	13%
Colonoscopy	232	4%	135	3%	283	5%	498	8%	906	14%	744	11%
Flexible sigmoidoscopy and Upper GI endoscopy	151	2%	133	2%	140	2%	122	2%	125	2%	123	2%
50-69 Total:	3,805	63%	2,795	63%	3,631	59%	3,440	57%	3,696	56%	3,813	56%
Colonoscopy	3,082	51%	2,241	52%	2,845	46%	2,690	45%	3,030	46%	3,129	46%
Flexible sigmoidoscopy and Upper GI endoscopy	723	12%	554	12%	786	13%	750	12%	666	10%	684	10%
70+ Total:	933	16%	690	16%	981	16%	1,005	17%	1,072	16%	1,352	20%
Colonoscopy	688	11%	503	11%	715	12%	704	12%	780	12%	992	14%
Flexible sigmoidoscopy and Upper GI endoscopy	245	5%	187	5%	266	4%	301	5%	292	4%	360	6%
Grand Total	6,015	100%	4,414	100%	6,166	100%	6,020	100%	6,591	100%	6,867	100%

b. An explanation for any increases or decreases in procedure volume from FY19 to FY24.

Response: Colonoscopy procedures have increased by 907 (21%) 2019 through 2024, while combined flexible sigmoidoscopies and upper GI endoscopies have decreased slightly by 55 (-3%). The increase in colonoscopies is attributed to changes in the recommended colon cancer screening age from 50 to 45, increased demand from patients and physicians

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for GI procedures in an ASC versus HOPD, the aging population in the primary service area, and disruptions in services available at local community hospitals.

- c. What has the utilization rate been at CEC over the past five years? What is the maximum number of procedures per room that you can perform annually? (What volume is considered 100% occupancy/utilization?)**

Response: The Applicant has calculated utilization over the past 5 years based on the following methodology using Provation data: total procedures divided by maximum booking slots. The Applicant books 30 minute time slots per patient plus 8 minutes for cleaning turnaround time, Monday through Friday, for 8 hours per day, excluding 10 holidays. Based on these assumptions, the maximum booking slots for each room is 3,183 in a year (6,366 for 2 rooms), resulting in the following utilization rate calculations for CY2019 through CY2024, as detailed in the table below. As noted below, the Applicant has been operating at very high utilization rates, exceeding 100% in 2023 and 2024. The increased utilization has been possible due to higher than average efficiency for some of the physicians and opening the ASC for occasional Saturday procedures to accommodate increased demand. The Applicant is unable to sustain year-round weekend hours based on staffing limitations.

Calendar Year	Procedures	Utilization (2 rooms)
CY2019 Actual	6,015	94%
CY2020 Actual	4,414	69%
CY2021 Actual	6,166	97%
CY2022 Actual	6,020	95%
CY2023 Actual	6,591	104%
CY2024 Jan-May annualized	6,867	108%

- d. Explain whether and how recent disruptions/closures of hospitals in the region have caused a decrease in access to endoscopy services in the region?**

Response: The physicians who perform procedures at the Applicant's ASC also perform procedures at local community hospitals that have been negatively impacted by disruptions and closures. These disruptions increased demand and wait times for scheduling outpatient GI procedures at the Applicant's ASC. Now that Brockton Hospital has resumed operations, and Morton and Good Samaritan Hospitals are transitioning to new ownership, the physicians continue to experience high demand for high quality outpatient GI procedures to be performed at a free standing ASC. Patients appreciate the ease of access and the lower out of pocket costs at a free standing ASC compared to an HOPD. The Applicant is currently the only free standing ASC offering GI procedures in the primary service area. Increasing access to GI procedures at a free standing ASC allows

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hospitals to prioritize procedure rooms for inpatient, complex outpatient and emergency GI procedures.

4. Describe the methodology used to determine that two (2) additional procedure rooms were needed to address Patient Panel need.

Response: The Applicant determined that two (2) additional procedure rooms were needed to address Patient Panel need based on input from the existing CEC physicians and New Physicians referenced in the Narrative. Even before the New Physicians began treating patients at the Applicant's ASC in early 2024, utilization was approaching or exceeding 100%. In the short term, the existing physicians have been sharing their block time to allow the New Physicians to start performing procedures at the Applicant's ASC and the ASC has opened up some Saturday hours, but these are not long-term solutions. As discussed in the Initial Application and above, need for the ASC's services is the result of changes in the recommended colon cancer screening age from 50 to 45, increased demand from patients and physicians for GI procedures in an ASC versus HOPD, the aging population in the primary service area, and disruptions in services available at local community hospitals.

5. The application provides five-year projections of ASC volume after project implementation
a. What is the first year of project implementation?

Response: The Applicant expects to begin providing services in November 2025, so the first year of implementation will be CY2026, based on timeline for DON approval and construction.

b. Where does the Applicant expect new volume will originate?

Response: The Applicant expects that the new volume will originate from patients of current CEC Physicians, the New Physicians referenced in the Narrative, and potentially other third-party referral services.

6. With the lowering of the screening age to 45 for colorectal cancers,
a. How many additional screenings were performed annually?

Response: In May 2021 the American College of Gastroenterology reduced the recommended age to start screening for colorectal cancer from 50 to 45. As noted in the response to question 1 above, the Applicant is not able to report CPT procedures by age, however, the Applicant did see a significant increase in year over year colorectal screenings since 2021, which the Applicant believes can be attributed, in part, to the change in screening recommendations.

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Colon CA screening Procedures (CPT codes)	CY20	CY21	CY22	CY23	CY24 (Jan- May annualized)	2021 to 2024 Increase #	2021 to 2024 Increase %
G00105 - Colon CA scrn; high risk	512	632	639	617	768	+256	+50%
G0121 - Colon CA scrn; not high risk	454	622	705	904	998	+544	+120%
TOTAL	966	1,254	1,344	7,308	1,766	+800	+83%

b. Calculate how many additional procedures are needed in the PSA?

Response: The Applicant does not have access to state-wide GI claims data to calculate use rates and project additional GI procedures needed in the PSA.

c. Can you correlate the regional incidence of colorectal cancers to the projected volume?

Response: The Applicant does not have access to state-wide GI claims data to correlate regional incidence of colorectal cancers to the projected volume.

d. What percentage of that volume is currently being met and will the project meet post implementation?

Response: Applicant does not have access to state-wide GI claims data to calculate what percentage of that volume is currently being met and will the project meet post implementation?

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

7. Describe strategies the Applicant plans to use to expand colonoscopy screenings for eligible populations in the service area and in particular those considered under-resourced populations. Describe plans to increase access for MassHealth Patients to screenings and diagnostic procedures.

Response: As a specialty provider, the Applicant's patients are primarily referred by primary care providers, who make referrals based on the patients' needs and circumstances. That said, the Applicant is committed to providing services, including colonoscopy services, to all eligible patients in the service area, including under-resourced populations and MassHealth patients. The Proposed Project will increase access to services generally and will therefore indirectly improve access for these populations. Additionally, the Applicant's physicians are currently working to develop and improve relationships with community health centers in the primary service area, which the Applicant believes will increase access to and awareness of the Applicant's services among more under-resourced populations.

8. Describe any strategies/processes in place to better understand and address disparities in access to and utilization of ASC service within the Applicant's Patient Panel and PSA.

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Response: As noted above, the Applicant's patients are generally referred by the patient's primary care providers, who make referrals based on the patients' needs and circumstances. However, the Applicant's physicians are strategically working with community health centers in the primary service area to increase access to and awareness of the Applicant's services among more under-resourced populations.

9. Describe any pre-procedural screenings that are utilized. Do you screen for SDOH. What protocols are in place to address any SDOH issues/concerns that may be identified?

Response: Conversations around SDOH for patients typically take place in the primary care setting. Because the patients are referred to the Applicant for screenings, the Applicant knows that the patients have an established primary care (and potentially additional specialty care physician relationships) and are able to access health care services. The Applicant's intake staff conducts screening relevant to the GI procedures being performed (for example, confirming that the patients have transportation to and from the procedure), but the Applicant appropriately relies on the patients' primary care relationships to address SDOH. The Applicant's staff will address any patient needs that arise during treatment and will appropriately coordinate with the Applicant's other providers.

10. Describe any cultural competency training for ASC staff and physicians?

- a. **Are these required for all staff, what percentage of staff undergone such training. If none are currently in place, explain what steps are being taken to implement such training.**

Response: The Applicant requires all staff and physicians to complete trainings on culturally competent care delivery and age-specific care delivery within 30 days of their start date and annually thereafter. The due date for the annual training is October 31, and all staff members have completed the trainings.

11. The application states for all Limited English Proficient (LEP) translation and American Sign Language (ASL) interpretation, services are provided through qualified language interpretation services.

- a. **What is the frequency of the need and what are the most frequently requested languages?**

Response: The Applicant does not track how frequently their language interpretation services are used.

- b. **How are arrangements made for an interpreter?**

Response: The Applicant uses a third-party platform, CyraCom, to provide interpreter services. The interpreter services are offered during appointment confirmation and again when the patient arrives at the ASC for their procedure.

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c. Are interpreters available in person or only telephonically?

Response: CyraCom provides remote interpreter services via video and telephonically.

12. Describe protocols in place in case of an emergency, including the plan for transferring patients who need emergency medical care from the ASC to a hospital.

Response: The Applicant currently has Transfer Agreements in place with Morton Hospital, Signature Healthcare Brockton Hospital, and Good Samaritan Hospital, as well as an Ambulance Agreement with the West Bridgewater Fire Department. The Applicant plans to execute Transfer Agreements with these three hospitals for the new site in Easton, as well as an Ambulance Agreement with the Easton Fire Department or another ambulance provider.

Factor 1: c) Efficiency and Care Coordination

13. The application states the Proposed Project will operate efficiently and effectively by furthering and improving the continuity and coordination of care for the Applicant's Patient Panel.

a. Will the consultative practice be located at the same site as the new ASC?

Response: Consistent with the ASC's current operations, the physicians have a number of consultative practice locations in the primary service area, including the following:

Brockton Location: 189 Quincy Street, Brockton, MA 02302

East Bridgewater Location: 1 Donalds Way, Ste. 203, E. Bridgewater, MA 02333

Taunton: 35 Summer Street, Taunton, MA

b. How will post procedural care and follow-up be implemented.

Response: Consistent with current operations, patients will be able to obtain follow-up care at any of the above practice locations. The Applicant's physicians will also continue to coordinate with the patients' primary care and other providers as necessary and appropriate.

Factor 1: Competition

14. The Application states reimbursement rates for procedures performed in ASCs are lower than for the same procedure at an HOPD.

a. If possible, provide data to demonstrate lower reimbursement for Procedures at CEC, such as Medicare costs in ambulatory surgical centers, hospital outpatient departments from Medical Procedure Price Lookup.

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Response: Please see the following table comparing Medicare costs at an ASC vs. HOPD for the top five (5) procedures performed at the Applicant's ASC according to the Medicare Procedure Price Lookup at <https://www.medicare.gov/procedure-price-lookup/>.

Procedure	Total Cost ASC	Patient Cost ASC	Total Cost HOPD	Patient Cost HOPD	Total Cost Variance	Patient Cost Variance
45385- Lesion Removal Colonoscopy	\$857.00	\$171.00	\$1,3690.00	\$273.00	\$12,833	\$102.00
43239- Upper GI Endoscopy, Biopsy	\$604.00	\$120.00	\$997.00	\$198.00	\$393.00	\$78.00
45380 - Coloscopy and Biopsy	\$805.00	\$160.00	\$1,317.00	\$262.00	\$512.00	\$102.00
G0121 - Colon Cancer Screening; not high risk	\$652.00	\$0.00	\$1,048.00	\$0.00	\$396.00	\$0.00
G0105 - Colon Cancer Screening; high risk individual	\$652.00	\$0.00	\$1,048.00	\$0.00	\$396.00	\$0.00

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