

**STAFF REPORT TO THE PUBLIC HEALTH COUNCIL
DETERMINATION OF NEED**

Applicant Name	New England Baptist Surgery Center, LLC
Applicant Address	40 Allied Drive, Suite #200, Dedham, MA
Filing Date	September 10, 2022
Type of DoN Application	Ambulatory Surgery (Transfer of Ownership)
Total Value	\$26,273,899.00
Project Number	NEBSC-22051121-TO
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	\$1,313,694.95
Staff Recommendation	Approval
Public Health Council	November 9, 2022

Project Summary and Regulatory Review

New England Baptist Surgery Center, LLC (Applicant, NEBSC) filed an application to establish a freestanding ambulatory surgery center (ASC) at 40 Allied Drive, Suite #200, Dedham, MA. The Applicant, NEBSC, is owned by NEBSC Hospital Holdings, LLC (Hospital HoldCo) and NEBSC Surgeon Holdings, LLC (Surgeon HoldCo). Through the Proposed Project, ownership of an existing surgery center will inure to NEBSC, which will then secure a new clinic license as a freestanding ASC. There are no changes in service, operating, or procedure rooms at the existing surgical center included in this Application. Currently, New England Baptist Hospital (NEBH) owns and operates the surgery center under its hospital license as a hospital outpatient department (HOPD).

Review of Applications for Ambulatory Surgery is under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

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Background and Application Overview

New England Baptist Surgery Center, LLC (NEBSC, Applicant) is a newly formed joint venture created for the purpose of creating the proposed freestanding ambulatory surgery center (ASC) from an existing hospital-based outpatient surgical satellite (HOPD¹). The Applicant, NEBSC, is owned by NEBSC Hospital Holdings, LLC (Hospital HoldCo), 51%, and NEBSC Surgeon Holdings, LLC (Surgeon HoldCo), 49%. Hospital HoldCo is majority owned by New England Baptist Hospital (NEBH) (85.6%) and Constitution Surgery Alliance (CSA),² (14.4%). CSA will manage the ASC. Both LLC's, Hospital HoldCo, and Surgeon HoldCo, were formed for the purpose of participating the NEBSC joint venture. The ownership relationships are illustrated in Table 1, below.

Table 1: Ownership Structure of New England Baptist Surgery Center

New England Baptist Surgery Center (NEBSC)	
NEBSC Hospital Holdings, LLC (Hospital HoldCo)	51%
New England Baptist Hospital (NEBH)	85.6%
Constitution Surgery Alliance (CSA)	14.4%
NEBSC Surgeon Holdings, LLC (Surgeon HoldCo)	49%

NEBH³ currently owns and operates the HOPD, which is located at the New England Baptist Outpatient Care Center. The Center also offers other services separate from the this Proposed Project, including physician consults, hand therapy, an interdisciplinary pain management program, imaging, osteopathic manipulative medicine, outpatient rehabilitation (physical, occupational and hand therapy), the Spine Center, and sports performance.

Surgeon HoldCo is composed of orthopedic surgeons who currently perform surgeries at the existing HOPD, and who will continue to perform surgeries there under the new NEBSC. The surgeon partners represent a variety of orthopedic sub-specialties, including: Total Joint Replacements (TJR, arthroplasty), hip preservation, and the Sports Medicine subspecialties of foot and ankle, hand, and general sports surgery. As of July 2022, membership of Surgeon HoldCo was not closed.

The Proposed Project

This Proposed Project is to convert an existing HOPD into a Freestanding ASC. Since the existing surgical site will no longer be licensed as a HOPD, but rather as a separate entity, a new ASC Clinic, it must be reviewed under Substantial Change in Service (105 CMR 100.715); it cannot be reviewed by DoN as a Transfer of Ownership (105 CMR 100.735).

¹ Staff uses "HOPD" to refer only to this HOPD surgical center. While NEBH has other HOPDs separate from the surgical site, these do not factor into this DoN.

² CSA currently manages 15 Ambulatory Surgery Centers and 2 Hospital Outpatient Departments; 4 centers in Massachusetts

³ NEBH is part of Beth Israel Lahey Health (BILH).

The site of this Proposed Project is approximately 33,000 gross square feet comprised of 8 operating suites, pre-operative and post-op/recovery areas, 2 procedure rooms located within the pre-op PACU suite, administrative offices, and a patient lobby and waiting area.⁴ There will be no change in the number of operating suites or procedure rooms, and NEBSC will continue so specialize in orthopedic surgery. While there is no substantial construction⁵ for the Proposed Project, the total value of the project of \$26,273,899 is based on the market rate for transferring ownership of the space from NEBH to NEBSC.

The Applicant states, while responding to market forces, the Proposed Project will serve existing and new patients in the service area more efficiently, cost effectively and with the same high quality and outcomes. As described further herein, the ASC will reduce costs for patients, commercial and government payers, and for the Commonwealth while maximizing operational efficiencies by utilizing a dedicated staff and an experienced management company, CSA.

Patient Panel⁶

Since the Applicant is a newly formed joint venture, it does not have its own patient panel. As such, the Applicant anticipates the Patient Panel for the proposed project will be that of NEBH's aforementioned HOPD surgery center in Dedham. Table 2 shows the Patient Panel demographic information for unique patients who had an orthopedic procedure over a 36-month period October 2019 – September 2021.

Table 2: Patient Panel Demographics Summary⁷ FY19-FY21

Demographic Characteristics	Unique Patients	Percent
Gender		
Male	4,176	47.1%
Female	4,692	52.9%
Total	8,868	100.0%

⁴It is located on the second floor of the New England Baptist Outpatient Care Center.

⁵ There are minor construction costs for code updates and "fit-out" \$617,441.

⁶ As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including patients seen at an emergency department (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.

⁷ - Patients who fall into multiple age categories in a given year are included in the younger category.

- Race information is self-reported. Patients for whom a race is not specified are included in "Unknown". Patients for whom race varies across visits over the time period are included in "Other." Under Race, "Other" includes American Indian or Alaska Native, Native Hawaiian, Hawaiian or Other Pacific Islander, and Patient Declined.

- Under ZIP Code Summary, "Other" includes CT, FL, and NY, which account for most of the cases among states not listed individually.

Age		
0 to 17	149	1.7%
18 to 64	7,011	79.1%
65+	1,708	19.2%
Total	8,868	100.0%
Race		
White	7,496	84.5%
Black or African American	644	7.3%
Asian	235	2.6%
Other	305	3.4%
Unknown	157	1.8%
Other	31	0.3%
Total	8,868	100.0%
Zip Codes Summary		
MA	8,342	94.1%
NH	209	2.4%
RI	146	1.6%
ME	42	0.5%
Other	129	1.5%
Total	8,868	100.0%

Highlights of the data during the reporting period include:

- **Gender:** Over the reporting period, the gender mix was 52.9 % females, and 47.1% males.
- **Age:** 1.7%, 79.1% and 19.2% were in the 1-17, 18-64, and 65 plus age cohorts respectively.
- **Race:** Based on self-reported data, 84.5% of the Patient Panel identified as white, 7.3% identified as Black or African American, 2.6% identified as Asian, and 2.0% identified as Hispanic/Latino.
- **Patient Origin:** Representing a broad geographic reach, the Applicant demonstrated that 75% of the Patient Panel resided in 97 Massachusetts towns during the three-year reporting period. The city of Boston contributed the largest percentage of patients 13.1% with the next largest percentage, 2.5% coming from Newton. (5.9% resided out of state or other.)

Table 3: Payor Mix FY 19- Quarter 1 FY 22

APM Contract Percentages					Non-ACO and Non- APM Contracts				
	FY 19	FY 20	FY 21	Q1 FY 22		FY 19	FY 20	FY 21	Q1 FY 22
ACO and APM Contract	5.20%	3.70%	3.60%	4.90%	Commercial PPO/Indemnity	9.80%	9.20%	8.00%	10.20%
					Commercial HMO/POS	60.60%	61.80%	61.90%	61.50%
					MassHealth	0.90%	1.10%	1.70%	0.90%
					Managed Medicaid	0.70%	1.50%	3.40%	2.00%
Non-ACO and Non-APM Contract	94.80%	96.30%	96.40%	95.10%	Commercial Medicare	5.00%	4.20%	4.50%	4.10%
					Medicare FFS	13.70%	13.90%	13.20%	13.40%
					All Other	9.20%	8.40%	7.20%	7.90%

- Payor Mix:** The share of patients covered by MassHealth and Managed Medicaid increased from 1.6% in FY19 to 5.1% in FY21 and decreased to 2.9% in the first quarter of FY 22. (see Table 3). The share of patients covered by an ACO/APM contract decreased from 5.2% in FY19 to 3.6% in FY21.

Factor 1: a) Patient Panel Need

In this section, staff assesses whether the Applicant has sufficiently addressed Patient Panel need for the Proposed Project. Because the Applicant anticipates that the proposed ASC will offer a similar set of orthopedic services as the HOPD, the analysis of patient need focuses on historical volume and projections based on demographic and technologic and reimbursement trends for ASC's.

The Applicant states that the main elements contributing to the patient panel need for this Proposed Project are:

- Increased demand for the facility's services
- Advances in technology leading the shift in the surgical procedures that can safely be performed in an outpatient environment,
 - the growth in demand from the aging population,
 - growth in demand from sports related injuries,
- Need to free-up NEBH's surgical suites to accommodate more complex procedures.

1. Increased Demand for the Facility's Services

The volume of outpatient orthopedic surgical services increased by 18.5% at the HOPD between FY 2019 and FY 2021, as shown in Table 4. Cumulatively accounting for 46.8% in 2019, to 44.3% in 2021 of the total, the most common procedures performed at the HOPD have been arthroscopy of the knee, hip and wrist endoscopy.

**Table 4: Orthopedic Surgical Procedure⁸ Volume by Service Line at NEBH Dedham Site
FY 2019 – FY 2021**

Service Line	FY 2019	FY 2020	FY 2021
Endoscopy/Arthroscopy Procedures on the Musculoskeletal System	1,499	1,150	1,680
Foot and Toes	492	405	563
Forearm and Wrist	283	239	356
Hand and Fingers	283	219	299
Leg (Tibia and Fibula) and Ankle Joint	143	158	242
General	205	175	174
Humerus (Upper Arm) and Elbow	100	87	146
Femur (Thigh Region) and Knee Joint	93	84	125
Shoulder	85	99	101
Other (including Pelvis and Hip Joint)	20	33	111
Total	3,203	2,649	3,797

2. Advances in technology leading the shift in the surgical procedures that can safely be performed in an outpatient environment.

As a result of advances in surgical techniques and anesthesia, the shift in procedures from the inpatient to the outpatient setting have been increasing for lower acuity patients. This has benefited all age cohorts including the aging population. Nationally, TJRs are expected to grow significantly, with most growth occurring in outpatient settings.^a Going forward, the Applicant anticipates an increase in TJRs at the ASC, given the national and local trends.

The Applicant notes that while COVID-19 and the associated suspensions of elective surgeries in Massachusetts temporarily depressed demand, in 2021, demand surpassed that of 2019. The Applicant cites research that in the next decade outpatient total hip and knee replacements are expected to see substantial growth, resulting in a corresponding inpatient decline.^b A similar shift is anticipated from inpatient to outpatient procedures for total shoulder replacements. Overall, outpatient shoulder replacements are projected to increase from 7% of surgeries in 2019 to 35% in 2029.^{c, 9}

⁸ Does not include pre- or post-op visits as those visits do not occur at the HOPD.

⁹ Sg2 projections are based on all hospital discharges for patients residing in the combined NEBH primary and secondary service areas.

a) Growth In Demand From The Aging Population

Analyses suggest that as the population ages and medical technology advances, there will be an exponential growth in demand for all orthopedic procedures.^d The share of the Massachusetts population aged 65 and older is projected to grow from 13.8% in 2010 to 21.2% in 2030.¹⁰ This is consistent with national trends, which indicate that adults aged 55 plus have experienced the greatest increase in surgical procedures in ASCs since 1990.^e In particular, arthritis and obesity are more prevalent among older adults and increase the likelihood of need for orthopedic surgery. Doctor-diagnosed arthritis is projected to affect 25.9% of all adults in the U.S. by 2040. Additionally, 24.4% of Massachusetts adults are obese and are therefore at enhanced risk of needing a knee replacement as they age.^f These trends suggest that demand will continue to increase for orthopedic surgery related to joint issues. Patients 65 and older represent approximately 19% of patients served at the HOPD.

b) Growth In Demand From Sports Related Injuries

The US demand for total joint replacement (TJR) in patients aged 45-64 is also increasing (188% for knee replacements and 123% for hip replacements from 2000-2009).^g Chronic conditions that have an impact on joints, such as obesity, and arthritis will also increase the need for TJRs and other orthopedic procedures.^h At the current site, approximately 79% of patients fall into this age cohort.

Another factor contributing to demand for outpatient surgery noted by the Applicant, is current patient anxiety about becoming infected with COVID-19 in the hospital setting. Because ASCs are designed to perform only a subset of procedures that require a shorter stay, the Applicant asserts they may be less likely to create widespread exposures for patients and staff in an ambulatory setting.

3. Need to free-up NEBH's surgical suites to accommodate more complex procedures.

The Applicant further states that currently, NEBH uses the sixteen operating rooms on the main campus at approximately 90% capacity, which is a highly utilized block schedule. The average wait time for elective surgery is about six weeks in the hospital; and for some surgeons it is up to six months. Further, NEBH has requests from spine surgeons who wish to perform surgery at NEBH but are unable to be accommodated due to space constraints. The shift of appropriate orthopedic procedures to the outpatient ASC will allow providers at NEBH to enhance capacity for more complex cases at the hospital (e.g., spine cases) – resulting in reduced wait times for those patients whose cases are complex. As more outpatient total knee and total hip replacement procedures move to NEBSC, the hospital will be able to provide more operating

¹⁰ Tufts Health Plan Foundation. (2014). Highlights from the Massachusetts Health Aging Data Report: Community Profiles 2014. Available at: <https://www.mass.gov/doc/mass-healthy-aging-data-report-community-profiles-commissioned-by-tufts-health-plan-0/download#:~:text=the%20percentage%20of%20the%20state,remarkable%20in%202030>

room time for surgeons performing more complex cases. Accordingly, the ASC will increase access for patients as wait times for certain procedures on NEBH's main campus decrease.

The Applicant's Projections

According to the Applicant, the proposed ASC will be able to handle more procedures than the HOPD, thus expanding access and reducing wait times for its own patient panel and patients seeking inpatient surgery at NEBH's main campus. Indeed, the Applicant projects a notable increase in throughput at the proposed ASC site, ramping up from 4,073 cases in projected year 1 to 5,531 cases in projected year 5 (see Table 5). The Applicant states that procedures performed in ASCs take 25% less time than procedures performed in inpatient settings, helping to facilitate increased throughput at the ASC.ⁱ

Table 5: NEBSC Projected ASC Volume for Five Years

	Year 1	Year 2	Year 3	Year 4	Year 5
Growth based from Existing Cases	2,930	2,988	3,048	3,109	3,171
Projected Additional Cases					
• Orthopedics	183	188	192	195	199
• Joint Arthroplasty	961	1,921	1,998	2,078	2,161
Total Additional Cases	1,143	2,109	2,189	2,273	2,360
Total Cases	4,073	5,097	5,237	5,382	5,531

The Applicant has projected volume at the ASC based on the following assumptions:

1. The existing orthopedic case volume at the HOPD stays at the newly formed ASC. Year 1 uses an adjusted case count for 2020 to present a conservative projection.
2. For participating total joint arthroplasty surgeons, an estimated 1/3 of their eligible cases will be performed at the ASC by Year 2.
3. For participating orthopedic surgeons who already perform more than 1/3 of their cases at the Dedham location, the Applicant assumes that volume will remain at the location, and be slightly augmented by moving their cases (if any) assumed to be performed at other locations, if HoldCo Physicians choose to do more of their cases at the ASC.
4. Year 1 includes a ramp up of additional orthopedics and joint arthroplasty cases.
5. The Applicant conservatively assumes that there is a 2% growth for orthopedics and 4% growth for arthroplasty cases.

Analysis

The Applicant outlined a need for converting the HOPD to an ASC and how this conversion will improve access to the Patient Panel as well as patients in the region for both outpatients and inpatients. The Applicant illustrates how in addition to current utilization of services, the growth of the aging population, and the shift of a growing number of less complex procedures deemed safe for performing in an ASC by payors, is improving access for patients needing more complex care at the NEBH main hospital. As a result of this analysis, Staff finds the Applicant has addressed the *Need* requirements of Factor 1 for the Proposed Project.

Factor 1: b) Public Health Value: Improved Health Outcomes and Quality of Life; Assurances of Health Equity

For this element of Factor 1, the Applicant must demonstrate that the Proposed Project adds public health value in terms of improved health outcomes and quality of life for the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

Public Health Value- Improved Quality and Outcomes

Public health value can be adversely impacted when access is limited for many reasons including affordability. The Applicant notes that about one in ten adults have delayed or forgone healthcare due to cost. Through the lower out-of-pocket costs generated by the conversion of the existing site to an ASC, the cost of recommended surgeries becomes more affordable, thereby improving access for those patients in the service area. Through reducing delays for lack of resources, and addressing patients' orthopedic needs, outcomes and quality of life may be improved.

The Applicant proposes to track the impact of the project using the following metrics:¹¹

- 1) Patient satisfaction (measured on a 0-10 scale)
- 2) Surgical site infection (the number of patients who develop a surgical-site infection within 30 days of surgery or within 90 days of surgery for arthroplasty implant procedures)
- 3) Fall prevention (the number of patients who report a fall at home within 24 hours of surgery)

Analysis

There is an extensive body of research supporting the public health value of ASCs that staff notes including the following.

- **Increasing access to high-quality surgical services.** Surgical procedures performed in ASCs are associated with reduced mortality, morbidity, and hospital admission rates as compared to outpatient surgery performed in the hospital setting, and patients experience shorter surgery and recovery times; these benefits appear to extend to vulnerable (highest-risk Medicare) patients.^{j, k, l}
- **Contributing to improved health outcomes.** Advances in medical devices and pharmaceuticals have contributed to reduced recovery times, which also enable the migration of surgical procedures from inpatient to outpatient care. As a result of these advances, it is now possible for patients who previously spent days in the hospital recovering from a surgical procedure to be discharged the same day as their surgery.^m Hand, wrist, knee and shoulder surgeries performed at ASCs are safe, cost-effective, and result in high quality outcomes.^{n, o, p}

¹¹ See Appendix I for more details.

- **Improved patient experience.** Provision of care in the ASC setting is associated with enhanced convenience and satisfaction for patients resulting from convenient locations that are closer to patients home, locations that are easier to navigate than hospital structures; they have easier scheduling of procedures, shorter wait times, improved accessibility to physicians, and high-quality care.^{q, r, s} These qualities may be particularly relevant for patients age 65 and over, who find the freestanding ASC experience less complicated and easier to access. Delays that can occur in the hospital setting when acute cases take precedence over elective procedures can lead to unnecessary expenses, anxiety and compromise plans for the care for patients upon discharge thereby diminishing the patient-centered experience.

Public Health Value: Health Equity

The Applicant asserts its commitment to promoting health equity and ensuring equal access to high quality care in several ways.

- 1) The Applicant shares the same commitment to diversity, equity, and inclusion as NEBH and BILH. The Proposed Project will not discriminate based on gender, race, religion, sexual orientation, or disability status or any other status protected by law.
- 2) NEBSC will not engage in discrimination based on a patient's insurer or ability to pay for services, and
- 3) At the Proposed Project, the Applicant will implement a financial assistance policy, modeled after NEBH's existing policy. This policy will offer patients assistance with applying for financial assistance programs including public assistance programs that may cover some or all of their medical bills.
- 4) The Proposed Project will provide language access through the same language line and interpreter services that are currently being used at NEBH. Cross Cultural Communication Systems currently provides NEBH with 24/7 access for language interpreter services – with the most commonly requested languages being Spanish, Russian, Portuguese, Italian and Greek.
- 5) Practitioners operating at the ASC will undergo the same annual cultural competency training as at NEBH. Every employee and licensed independent practitioner at NEBH is required to complete this learning management system training, which focuses on cultural and religious sensitivity, diversity, equity, and inclusion.

Analysis

Access to affordable health services is associated with improved outcomes and can reduce the need for additional care.^{t, u} Additionally, the literature suggests that surgeries performed in an ASC outpatient setting can result in fewer and lower infection rates than hospitals.^{v, w} ASCs are regulated to ensure the delivery of quality care, and NEBSC cited reporting processes that address quality of care, patient satisfaction, and outcomes. By presenting information on the projected increase in access to its services, its financial assistance services, and its extension of interpreter services, staff finds that the Applicant has sufficiently outlined, a case for improved

health outcomes, public health value, reasonable assurances of health equity, and access to care.

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

The Applicant described how coordination, continuity of care, and effective communication will be ensured in a number of ways:

- 1) NEBSC nursing staff aim to create a secure pathway to send the patient's operative report to the patient's PCP.
- 2) Each patient will be called the day after surgery by a NEBSC RN to inquire on the patient's condition. This evaluation reviews pain control, movement, ambulation, patient education deficits, general sense of well-being and any questions regarding prescriptions.
- 3) NEBSC will evaluate implementing an extensive Patient Reported Outcomes ("PRO") Program which could include the following elements, which will further improve care coordination and continuity.
 - Electronic patient follow-up at appropriate intervals. For example, TJA would be pre-operative and 30-, 90-, 180- and 365-days following surgery. Automated electronic patient follow-up encourages early intervention, if necessary.
 - Patient reported complications (e.g., infection, hospitalization) to be reported back to the surgeon's office.
 - Provision of tools for physician-patient shared decision-making, which will empower patients to make informed decisions about their care. These tools include Patient IQ and Force Therapeutics. Patient IQ is a patient engagement platform which allows for automated patient communication. Force Therapeutics is a platform which provides digital rehabilitation, virtual physical therapy, and virtual perioperative care.
 - Opportunities for patient education and digital care modules for all phases of surgical care.
 - Collection, organization, and benchmarking of clinical and cost data to understand and achieve better healthcare value and improve clinical processes and quality for patients. For example, data would be collected and merged into the CSA clinical quality registry, and then shared with national and international affiliates, such as the American Joint Replacement Registry and the International Consortium of Health Outcome Measures. All data collection and data sharing will be compliant with HIPAA and similar laws. Examples of data elements would include:
 - Patient Demographics
 - Surgical & Implant Information
 - Comorbidities
 - Adverse Events
 - Patient-Reported Outcome Measurements

- Integration of NEBSC data into shared risk stratification modeling to improve patient risk assessment for appropriateness of surgery and risk-based contract negotiations.
- Presentation of physician and facility level, risk-adjusted, benchmark dashboards for quality and outcomes analyses.

Analysis

The Applicant explained care coordination and information sharing across providers. Further, it detailed processes for post-surgical patient follow-up, screening, tracking and data collection to detect potential complications, (such as infections) and to determine potential processes for quality improvement. Integrated processes are of particular importance in the ASC setting for managing patient referral to different points of care.^x Staff finds NEBSC has adequate processes in place to facilitate care coordination and communication across providers, which will continue after its conversion to an ASC.

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 for community engagement^y 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."^z

The Applicant reports that NEBH held a meeting for members of its Patient and Family Advisory Council (PFAC) on June 21, 2022 at which 3 NEBH and 5 patient representatives attended. First David Passafaro, President of NEBH, presented on the Proposed Project and its impact, and then the floor was opened to PFAC for questions.

The Applicant reports that NEBH has a 10-year history of interaction with the HOPD's host communities of Dedham and Westwood (the town boundary bisects the ASC site). The President of NEBH has held briefings with several elected officials in the service area, including State Senator Michael Rush; State Representative Paul McMurtry; and Sarah MacDonald, then the Vice Chair of the Dedham Select Board.¹² In these discussions, NEBH reviewed the current HOPD site, its future state as a free-standing ASC, and how the conversion will address patient needs. On July 12, Mr. Passafaro wrote to the municipal leadership of Dedham and Westwood

¹² MacDonald left the board earlier this year.

providing details regarding the proposed project.¹³

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 that since the Proposed Project will convert an existing HOPD to a free-standing ASC where procedures are reimbursed by payers at lower rates in comparison to inpatient or HOPD settings, it will reduce the costs and therefore have a positive effect on TME and other measures of healthcare spending for both patients and payers. The Center for Medicare and Medicaid Services (CMS) reimburses ASCs for Medicare patients at an average of 58% of the HOPD rate (for ASC approved procedures), which translates to more than \$2 billion in savings for Medicare and its beneficiaries annually.^{aa}

Table 6 shows the dates of the progression of the CMS approved clinical setting for Total Joint Replacement procedures. It first approved reimbursement for the procedures performed on clinically appropriate patients *Inpatient only* (IPO), then in *HOPD* settings, and recently, in *ASCs* (see examples in Table 6).

Table 6: CMS Approved Clinical Setting for Reimbursement by Procedure

CPT Code	Procedure	Settings CMS will Reimburse				
		2017	2018	2019	2020	2021
27447	Total Knee	IPO	HOPD	HOPD	ASC	ASC
27130	Total Hip	IPO	IPO	IPO	HOPD	ASC
23472	Total Shoulder	IPO	IPO	IPO	IPO	HOPD
IPO = Inpatient Only						
HOPD = Hospital outpatient & Inpatient						
ASC = ASCs, Hospital Outpatient, Inpatient						

Similarly, ASCs reduce healthcare costs for patients who are commercially insured through lower deductible and coinsurance payments for insured patients.^{bb} Commercial insurance carriers are increasingly requiring procedures that formerly were only performed in hospital settings, to be performed in lower cost outpatient and ASC settings, unless the patient is expected to experience complications during or following surgery.

Both commercial and government payers including ACO's are expected to continue to shift reimbursement to incentivize the use of outpatient and ASC settings, where appropriate. In the

¹³ For Dedham: the town manager, assistant town manager, building inspector, and fire chief. For Westwood: fire chief, building inspector, and members of the select board.

next few years, it is anticipated that ASCs will perform over 60% of orthopedic surgeries thereby creating further savings for patients, private and public payers, and providers and driving down total medical expense.^{cc} From an integrated health system perspective, the option to perform these orthopedic surgeries in an ASC setting will allow ACOs to better manage total medical expense, in a clinically effective and efficient manner.

Analysis

Many studies detail the cost savings associated with performing surgeries in the an ASC.^{dd,ee, ff} ASCs focus on performing a narrow set of and surgical procedures for patients with lower acuity and risk of complications achieving savings through efficiencies and increased throughput.^{gg, hh} Staff compared total costs and copayments of select procedures using data from Medicare's Price Procedure Lookup tool that was provided by the Applicant that demonstrated that ASCs can be a cost-effective alternative for certain procedures.¹⁴ Table 7 below shows examples of costs-savings for select shoulder and knee procedures that are approved for an ASC setting.

Table 7: Comparison of Select Medicare Payments in an ASC vs HOPD

Procedure Description	ASC (US average)			HOPD (US average)		
	Total	Medicare Payment	Copay	Total	Medicare Payment	Copay
Arthroscopy, shoulder, surgical; distal claviclectomy including distal articular surface	\$2,025	\$1,620	\$404	\$3,527	\$2,822	\$705
Arthroscopy, shoulder, surgical; with rotator cuff repair	\$4,029	\$3,223	\$805	\$7,364	\$5,891	\$1,473
Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures	\$1,939	\$1,551	\$387	\$3,441	\$2,753	\$688
Arthroscopy, shoulder, surgical; biceps tenodesis	\$3,873	\$3,098	\$773	\$7,208	\$5,766	\$1,441
Arthroscopy, knee, surgical; with meniscus repair (medial or lateral)	\$2,040	\$1,631	\$407	\$3,542	\$2,833	\$708

¹⁴ It has been reported that data from the Price Procedure Lookup tool are limited because the prices are based on national averages and copayment estimates are only for patients with Original Medicare and no supplemental policy. In addition, Medicare costs and copayments are not always aligned; a patient copay may be less expensive at an HOPD, but the total cost of the procedure may be more expensive than an ASC.

The examples show that the average Medicare payment to the ASC's is less, and that there is approximately a \$300 copay cost saving for each of the procedures listed above.¹⁵

Factor 1 Summary

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the proposed ambulatory surgery project has met Factors 1(a-f).

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

Cost Containment

The Applicant explains that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment by providing efficient and high-quality care in a lower cost setting. As previously discussed in Factor 1 Competition, reimbursement rates for procedures performed in ASCs are, generally, reimbursed at 58% of the rate at HOPDs. Since the facility will be accessible to all patients in the service area, the lower cost setting will contribute to reducing the overall healthcare expenditures for the Commonwealth.

Analysis: Cost Containment

A review of the literature shows that the shift to outpatient surgery is increasing in the ASC setting. Studies show that payment differentials between ASCs and HOPDs are driving care to take place in the lower-cost ASC setting, where the provision of care may be more cost efficient.ⁱⁱ 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, contracts among providers and Medicare and Medicaid are more transparent. Since surgeries performed in the ASC setting have been shown to be efficient, cost-effective, and are of equal or higher quality than when they are performed in the HOPD, staff finds that expanding access to outpatient surgery in the ASC setting has the potential to contribute to the Commonwealth's cost containment goals.

Public Health Outcomes

The Applicant describes how, (as previously discussed in Factor 1b), the Proposed Project will improve public health outcomes by Increased access to care including through lower out-of-pocket costs, and reduced delays in care. As stated above, a substantial share of adults report deferring or skipping care due to cost,^{jj} which is associated with poorer outcomes.^{kk} The lower out-of-pocket costs occur as function of the site of care; and performing appropriate procedures at an ASC has been shown to lead to improved health outcomes and improved

¹⁵ Price data obtained using Procedure Price Lookup, Medicare.gov. <https://www.medicare.gov/procedure-price-lookup/>

quality of life for patients.^{ll} Further, delays in care are reduced at the NEBH main campus by reducing current wait times for orthopedic procedures without increasing the number of operating and procedure rooms, which not only may improve outcomes but also leads to cost savings.

Analysis: Public Health Outcomes

Surgical procedures performed in ASCs are associated with reduced mortality, morbidity, and hospital admission rates as compared to outpatient surgery performed in the hospital setting, and patients also experience shorter surgery and recovery times; these benefits appear to extend to vulnerable (highest-risk Medicare) patients.^{mm,nn,oo} Improving access to NEBSC's services has the potential to improve outcomes and quality of life for the Patient Panel.

Delivery System Transformation

The Applicant explains in Factor 1b) its commitment to providing patients with appropriate care planning resources, including linkages to social service organizations as necessary. As an affiliate of BILH, patients will have access to the full complement of social services support through NEBH or other BILH affiliates when these needs are identified. If during the pre-operative screening process, patients identify social determinants of health (SDOH) needs, staff at the ASC follow-up with the patient's primary care provider to notify them of the patient's needs. Further, the Applicant notes that its clinicians have training and experience at referring patients to other providers as needed, connect patients with resources to address SDOH concerns, and liaise with patients' PCPs as needed.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant described its social needs screening processes including how surgery patients are assessed and how referrals are made to the PCP and outside organizations.

Factor 2 Summary

As a result of information provided, staff finds that the Applicant has sufficiently met the requirements of Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

Factor 4: Financial Feasibility

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 a finding must be supported by an analysis conducted by an independent CPA. The Applicant submitted a report performed by Whittlesey Forward Advising. (CPA Report).

The CPA Report is limited to an analysis of the five-year financial projections provided by the Applicant. To assess the reasonableness of assumptions used in the preparation and feasibility of the projections for the proposed project, the CPA reviewed key standard financial metrics and numerous primary sources of information provided by the Applicant.¹⁶

A - Revenue

The CPA reviewed the underlying assumptions upon which Management relied. The projected volume was based on historical data at the existing HOPD and a gradual ramp-up schedule from 60% utilization in year 1 of operations to a sustained 70% utilization level for years 4 and 5 of the Projection.

The payer mix was based on that of the specialties practicing at the HOPD (orthopedic, joint replacement, hand, podiatry, spine and other services) and reimbursement rates were based upon current Medicare and Medicaid rates, and anticipated commercial insurance contracted rates based on historical information.

The CPA then compared the benchmark data to an outside, 2017 independent survey of ambulatory surgery centers and found that the benchmark data used was reasonable, and that the number of projected cases and procedures per operating room at full utilization were within the ranges of currently operating ambulatory surgery centers.

To determine the reasonableness of the payer mix in the projections, the CPA compared them to the aforementioned independent survey's payer mix for the Northeast United States and found them to be within the survey's ranges. The Medicare rates are standard rates, using the Medicare Outpatient Prospective Payment System (OPPS) rates as a guide, adjusted for inflation and by a wage index for the specific geographic location of the facility.

The CPA compared the Medicare rates used for year 1 of the Projections to the Medicare rates effective January 1, 2022.¹⁷ The Medicaid rates used in the projection are 70% of the Medicare rate. The CPA explained how it tested this assumption and found the average Medicaid rate to

¹⁶ New England Baptist Hospital – Dedham ASC – 5-Year Projected Financial Statements and Assumptions received from Management on February 28, 2022

2. Medicare rates and base rate calculations, received from Management on February 28, 2022

3. New England Baptist Hospital – Dedham ASC draft DoN Application as of May 2022

4. Determination of Need Application Instructions dated March 2017

5. CMS.gov (Medicare) Ambulatory Surgical Center Payment System website

6. Mass.gov Executive Office of Health and Human Services

7. Constitution's company website <https://www.csasurgery.com>

8. VMG Health Intellimarker Multi-Specialty ASC Study 2017

9. New England Baptist Hospital company website <https://www.nebh.org>

¹⁷ Adjusted by inflation and the wage index, included in the 2022 OPPS and ASC Proposed Final Rule, published by CMS effective January 1, 2022.

be approximately 76% of the applicable Medicare rate and concluded the assumption of Medicaid rates being equal to 70% of the Medicare rates is reasonable and deemed conservative. The Commercial Insurance and private pay rates were based on experience and are expected to be 180% of the Medicare rate 150% of the Medicare rate respectively and deemed to be reasonable. All of the rates were increased by 2.0% for each of the succeeding years. As a result, the CPA concluded the revenue projected by Management reflects a reasonable estimation of future revenues of the Dedham ASC.

B - Expenses

The CPA analyzed the Applicants Salaries and Benefits in terms of wage rates and staff hours provided as compared to the independent survey and were found to be consistent with the survey results for the Northeast United States and to Massachusetts median wages for 2022. Medical Surgical Supplies and Other Expenses included in the projections were also compared to the survey and found to be consistent with the ranges included in the survey and reasonable.

Salaries and benefits are projected to increase by 3% per year and Clinical expenses most Other Expenses are projected to increase by 2-3% per year after achieving full utilization. As a result, the CPA expressed that the operating expenses projected by Management are reasonable.

C - Lease Agreement, Capital Expenditures and Cash Flows

The CPA examined the cashflow and working capital projections to determine whether determine the ASCs ability to support payments of the Dedham ASC's lease, equipment and continued operations. Rent and common area maintenance are approximately \$68 per square foot and increase 1.5% annually. As a result the CPA determined that the pro-forma projections of working capital impact on the cash flows are reasonable.

The CPA completed an analysis of the Applicant's projections and assumptions including analysis of revenues, expenses cashflows, key financial metrics and compared these to a benchmark survey. Based upon review of the relevant documents and analysis of the projected financial statements, the CPA determined the project and continued operating surplus are reasonable and are based upon feasible financial assumptions.¹⁸

Accordingly, the CPA *"determined 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 the Dedham ASC."*

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

¹⁸ The Projections do not account for any changes in accounting standards which may have a material impact on individual future years, and are not anticipated to have a material impact on the aggregate Projections.

Factor 5: Relative Merit

To Evaluate Relative Merit, Factor 5, the Applicant is required to consider potential alternatives or substitutes to the Proposed Project in terms of the quality, efficiency, and capital and operating costs of the Proposed Project.

The Applicant considered and rejected one alternative to the Proposed Project- continue to operate it as a HOPD at the same location or maintain the status quo. Under this alternative it asserts the following for quality efficiency and costs:

Alternative Quality: Quality of care would not change under this alternative proposal (status quo). However, as noted under Factor 1b) procedures performed at ASCs can demonstrate the same or improved quality outcomes in comparison to HOPDs.

Alternative Efficiency: The status quo does not allow for the clinical and operational efficiencies that can be achieved through the Proposed Project through the use of highly trained staff performing a limited set of procedures, and through the use of an experienced management company (CSA).

Alternative Capital Expenses: Capital expenses would not change under this alternative.

Alternative Operating Costs: operating costs would exceed those projected under the Proposed Project. As noted earlier, procedures performed in an ASC setting are reimbursed by payers at lower rates in comparison to inpatient or HOPD settings which translates into savings for both the Commonwealth and patients.

Analysis

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

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

Summary and Background

The Applicant is engaged in a different process to fulfill their Community Health Initiative (CHI) requirements associated with this DoN project application. A DoN for an ASC would traditionally pay its entire CHI contribution to the Statewide Funds. However, for the Proposed Project, the Applicant will have a Local CHI, treated as a Tier 2 project, carried out by BID Needham.¹⁹ The Applicant and DPH have agreed that since the ASC will be in Dedham, within BID Needham's catchment area, BID Needham's community health planning materials and activities will serve as the basis for this analysis.

The Applicant submitted a CHI narrative, as well as BID Needham's 2019 Community Health Needs Assessment (CHNA), Self-Assessment and Stakeholder Assessments, all

¹⁹ Both BID Needham and NEBH are members of the Beth Israel Lahey Health System.

which cover the geography of the planned ASC. BID Needham's next CHNA will be released in Fall of 2022 and will further inform the BID Needham's investment strategies for the CHI funds associated with this application.

The Community Health Needs Assessment was conducted in 2019 by Beth Israel Deaconess Hospital Needham (BID-Needham). The Community Health Needs Assessment was implemented in three phases. The first phase utilized preliminary engagement strategies including key informant interviews and an internal assessment of Community Benefits activities. The second phase included focus groups, community meetings, and a Community Health Survey. In the final phase, the Applicant utilized internal meetings, a literature review, and developed an Implementation Strategy. The Needs Assessment identifies priority populations and describes key findings and themes from the service area and participating communities. The priority populations are Youth, Older Adults, Low-to-Moderate Income Individuals and Families, and Individuals with Chronic/Complex Conditions. The priority areas identified are SDOH, Substance Use and Mental Health, Behavioral Health Services, Chronic and Acute Physical Health Conditions, High Rates of Leading Risk Factors, and Challenges Navigating Systems and Coordinating Services. The Applicant will release a new CHNA in 2022 and will employ similar strategies for engagement. The Applicant will engage its Community Benefit Advisory Council (CBAC) to select priorities and identify strategies for implementation.

The Self-Assessment provided a summary of the community engagement processes and socio-demographic information, data and highlights related to topics and themes of community needs related to the current and ongoing assessment work (for the 2022 CHNA). Through primary data collection such as key informant interviews, focus groups, and community wide surveying, data analysis, and with guiding principles of equity, collaboration, engagement, and capacity building, the participating community groups and residents identified the key concerns to be outlined in the 2022 Community Health Needs Assessment.

Stakeholder Assessments are submitted to provide 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. In order to ensure a transparent and meaningful engagement process, DPH will be asking the Applicant to provide stakeholder input specific to this project.

The CHI Narrative provided background and overview information for the CHI processes that will be carried out by BID Needham. The narrative also outlines advisory duties for the advisory and allocation committees, and planned use of funding for evaluation and administrative activities as well as a breakdown of the CHI funds and an anticipated timeline for CHI activities.

DPH Staff notes, the timeline, RFP processes, and use of evaluation and administrative funds are all appropriate and in line with CHI planning guidelines. In order to select strategies that meet Health Priority Guideline principles, BID Needham will need to focus

on the priority areas in the upcoming final assessment that allow for implementation at the root cause level. Examples of this from the 2019 CHNA submitted include the SDOH and upstream work across the leading risk factors. BID Needham will work with its CBAC to select priorities and approve implementation strategies. Based on strategies in BID Needham's ongoing community benefit work, DPH staff have determined that if the Applicant agrees to address community conditions and root causes while engaging in ongoing work with the CBAC, CHI investment will align appropriately with the Health Priorities Guideline. The Applicant will also provide status updates and share the final 2022 Community Health Needs Assessment to DPH staff.

The anticipated timeline for BID Needham's CHI activities includes a meeting with its CBAC six-week post approval to review to 2022 CHNA to select Health Priorities for funding. Next, CBAC members will decide on the best investment strategy 2-4 months post-approval, followed by the creation of an Allocation Committee 5-6 months post-approval, with funding disbursed 9-12 months post-approval.

With the administration funds, BID Needham's preliminary plans are to develop and disseminate communication materials to encourage community participation in the process.

Analysis

As a result of the information provided by the Applicant and BID Needham, staff finds that with the conditions outlined below, and the Applicants commitment to ongoing Community Health Planning processes in the geography of the ASC, the Applicant has 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 Condition 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. Of the total required CHI contribution of \$1,313,694.95
 - a. \$318,571.03 will be directed to the CHI Statewide Initiative
 - b. \$955,713.08 will be dedicated to local approaches to the DoN Health Priorities
 - c. \$39,410.84 will be designated as the Administrative Allowance
2. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$318,571.03 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).

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

Payment should be sent to:

Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: Ms. Bora Toro

Appendix

Quality Reporting Measures

1. **Patient Fall Prevention:** This measure is the incidence of patient falls that occur within the ASC either before or after surgery. Fall prevention is critical to an interdisciplinary approach to care.
 - a. Measure: The number of patient falls. A fall is defined as a sudden, unintentional descent, with or without injury to the patient that results in the patient coming to rest on the floor, on or against another surface, on another person, or an object.
 - b. Projections: Since the Proposed Project is a new ASC and the Applicant is a newly created entity, the Applicant will provide baseline data and projections following the first full fiscal year once implementation of the Proposed Project is complete.
 - c. Monitoring: Monthly
2. **Surgical Site Infection:** Surgical Site Infections can be a significant setback to the patient's recovery. Effective surgical infection prevention encompasses systems and processes to reduce risk factors and optimize evidence-based processes of care.
 - a. Measure: The number of infections that were not present or incubating at the time of admission to the facility that occur within 90 days of surgery for hip replacement, knee replacement, laminectomy, and spinal fusions.
 - b. Projections: Since the Proposed Project is a new ASC and the Applicant is a newly created entity, the Applicant will provide baseline data and projections following the first full fiscal year once implementation of the Proposed Project is complete.
 - c. Monitoring: Monthly and quarterly
3. **Patient Satisfaction:** This self-reported metric measures the extent to which a patient is content with the care that they received from their health care provider. The results will drive performance improvement to enhance patient satisfaction.
 - a. Measure: CAHPS Patient Satisfaction Survey – Overall Rating 9/10 on Scale of 1-10.
 - b. Projections: Since the Proposed Project is a new ASC and the Applicant is a newly created entity, the Applicant will provide baseline data and projections following the first full fiscal year once implementation of the Proposed Project is complete.
 - c. Monitoring: Monthly

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