STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED				
Applicant Name Beth Israel Lahey Health Surgery Center Plymouth, LLC				
Applicant Address	41 Resnik Road Plymouth, MA 02360			
Filing Date	March 14, 2024			
Type of DoN Application	Ambulatory Surgery			
Total Value	\$16,349,011.00			
Project Number	22062915-AS			
Ten Taxpayer Group (TTG)	None			
Community Health Initiative (CHI)	\$817,450.55			
Staff Recommendation	Approval			
Public Health Council	July 17, 2024			

Project Summary and Regulatory Review

Beth Israel Lahey Health Surgery Center Plymouth, LLC (Applicant) based at 41 Resnik Road, Plymouth, MA, submitted an Application for a Notice of Determination of Need (DoN) for the development of a freestanding ambulatory surgery center (ASC) to be located at 41 Resnik Road, Plymouth, MA (Proposed Project). The Applicant is a newly formed joint venture between BILH Surgery Center Plymouth Hospital Holdco, LLC, a subsidiary of Beth Israel Deaconess Hospital -Plymouth, Inc., and Pilgrim ASC LLC, a subsidiary of Plymouth Bay Orthopedic Associates, P.C., established for the purpose of developing a freestanding ASC. The Proposed Project is for a new construction of 19,091 gross square feet (GSF) to accommodate four operating rooms (ORs), sixteen pre/post operative bays, and associated administrative space. The capital expenditure for the Proposed Project is \$ \$16,349,011.00. The Community Health Initiatives (CHI) contribution is \$817,450.55.

This DoN Application falls within the definition of Ambulatory Surgery, which is 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.

Contents

Background and Application Overview
Patient Panel 4
Factor 1a: Patient Panel Need9
Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity
Factor 1: c) Efficiency, Continuity of Care, Coordination of Care
Factor 1: d) Consultation 17
Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel
Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending
Factor 1 Summary
Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation 19
Factor 2 Summary
Factor 3: Relevant Licensure/Oversight Compliance 21
Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis
Factor 5: Assessment of the Proposed Project's Relative Merit
Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application
Findings and Recommendations 25
Other Conditions
Appendix I: Required Measures for Annual Reporting
Appendix II: Literature Review
REFERENCES

Background and Application Overview

Beth Israel Lahey Health Surgery Center Plymouth (Applicant)

The Applicant is a newly formed joint venture between BILH Surgery Center Plymouth Hospital Holdco, LLC, a subsidiary of Beth Israel Deaconess Hospital - Plymouth, Inc. ("BID Plymouth" or "Hospital"), and Pilgrim ASC LLC, a subsidiary of Plymouth Bay Orthopedic Associates, P.C. ("PBOA"). The joint venture was created for the purpose of operating the ASC proposed in this Application. The proposed ASC will provide outpatient orthopedic surgery services for patients seeking treatment for musculoskeletal pain and conditions.

BID Plymouth

BID Plymouth is a 170-bed acute care hospital serving the communities of Plymouth, Carver, Kingston, Middleboro, Duxbury, Marshfield, Bourne, Pembroke, Sandwich, Halifax, and Plympton. The Hospital provides a full range of comprehensive community hospital services including primary and preventative care, emergency services, inpatient acute care, inpatient psychiatric services, and specialty services. The Hospital joined Beth Israel Deaconess in 2014 and is currently a member hospital of Beth Israel Lahey Health ("BILH").¹

PBOA

PBOA is a full-service musculoskeletal practice, including orthopedic surgeons trained in the management of the full spectrum of musculoskeletal diagnoses. PBOA also offers interventional pain management, occupational and physical therapy, surgical and non-surgical treatment options, as well as urgent orthopedic care services. PBOA has offices in Plymouth, Duxbury, and Sandwich, and its surgeons primarily perform surgery at BID Plymouth.

In compliance with 105 CMR 100.715(B)(2)(a)(3), the Applicant is affiliated with Beth Israel Lahey Health Performance Network, a Health Policy Commission (HPC) Certified Accountable Care Organization (ACO).²

Proposed Project

The Proposed ASC will be 19,091 Gross Square Feet (GSF) consisting of the following:

- 4 operating rooms (ORs), as well as related support and administrative areas
- 16 pre/post operative bays
- Lobby, waiting area, lounge, and lockers
- Sterile processing, including tank storage
- Loading dock, utility rooms/ storage

The proposed ASC will support surgical procedures currently performed at BID Plymouth. The Applicant anticipates that the majority of the procedures performed at the proposed ASC will be cases that are clinically appropriate to be shifted from the hospital setting to the ASC setting without

¹ BILH also includes Addison Gilbert Hospital; Anna Jaques Hospital; Beth Israel Deaconess Medical Center; Beth Israel Deaconess Hospital-Milton; Beth Israel Deaconess Hospital-Needham; Beverly Hospital; Lahey Hospital & Medical Center; Mount Auburn Hospital; New England Baptist Hospital; and Winchester Hospital.

² HPC-Certified ACOs - LEAP 2022-2023. <u>https://www.mass.gov/service-details/the-hpc-accountable-care-organization-aco-certification-program</u>

compromising quality or outcomes. Based on the orthopedic procedures most commonly performed on an outpatient basis at BID Plymouth, the Applicant expects the following procedures will comprise the majority of procedures at the proposed ASC:

- Total knee arthroplasty ("TKA")
- Knee arthroscopy
- Shoulder arthroscopy
- Carpal tunnel surgery
- Total hip arthroplasty

The Applicant asserts that the proposed ASC will provide the Patient Panel with an alternative to receiving services in the hospital setting or at other ASCs located further away, which can result in cost savings to insurers and patients.

Patient Panel³

The Proposed Project is for a new entity, which has no existing Patient Panel. The discussion of Patient Panel in this analysis refers to the patients of the health care facilities affiliated with the Applicant, as directed by the regulation. The Applicant relied on patient data from BID Plymouth and PBOA's Outpatient Orthopedic Surgery Panel as the population currently using the services proposed by the ASC to assess the need for the Proposed Project. Staff finds this is an acceptable way to define Patient Panel.

	2021	2022	2023
BID Plymouth ⁴	89,731	83,796	82,191
PBOA Surgical Panel ^{5,6}	1,700	2,644	2,892
BID Plymouth Orthopedic Surgical Population	2,309	2,417	2,542

Table 1: Overview of Unique Patients Served by Affiliated Health Care Facilities

Table 2 presents patient information for the BID Plymouth's overall patient population during fiscal year (FY)2023. Staff notes the following observations about these data below:

• Age: Patients aged 65+ were the largest cohort at 37%, follow closely by the 45-

³ 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.

⁴ Fiscal year October – September.

⁵ Fiscal year January – December.

⁶ The Applicant notes that PBOA surgeons most frequently perform surgery at BID Plymouth so the surgical patient panels of PBOA and BID Plymouth overlap significantly. The Applicant provided data showing that only 1% or less of all PBOA surgeries are performed outside of BID Plymouth, at South Shore Hospital.

64 age range at 29%

- **Race/Ethnicity:** majority of patients (88%) identified as White (non-Hispanic), which is slightly higher than the 2020 US Census for Plymouth County of 83% White.^a
- Patient Origin: Approximately 72% of patients are from Plymouth County.
- **Payer Mix:** Approximately 40% of patients were covered by a commercial insurance plan, 34% were insured through Medicare, 18% through Medicaid.

	Totals
Total Patients	82,191
Gender	
Male	42.2%
Female ⁷	57.8%
Total	100.0%
Age	
0-17	8.2%
18-25	5.9%
26-45	20.3%
46-64	28.8%
65+	36.9%
Total	100.0%
Race	
White	88.5%
Black or African American	2.3%
American Indian or Alaska Native	0.1%
Asian	0.6%
Native Hawaiian or Other Pacific	0.0%
Islander	
Other ⁸	1.7%
Patient Declined	6.7%
Total	100.0%
Ethnicity	
Hispanic/Latino	1.88%
Not Hispanic/Latino	87.10%
Unknown ⁹	11.02%
Total	100.0%
Patient Origin - Top 75% Cities/Towns	
Plymouth	36.7%

Table 2: Overview of BID-Pl	ymouth Patient Population	(FY2023)
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⁷ Due to the low numbers of patients identifying as "Other" or "Unknown", these categories have been combined with the "Female" category to protect confidentiality. Categories with <11 patients are typically added to the gender category with higher numbers.

⁸ "Other" is a choice for patients to select if they do not feel that their race/ethnicity is reflected in the list of choices.

⁹ Due to how Ethnicity data is pulled and the timing of when FY22 data was pulled, a discrepancy exists between the patient totals for Ethnicity and overall patients.

	Totals
Carver	5.7%
Kingston	5.5%
Middleboro	4.6%
Duxbury	3.9%
Marshfield	3.3%
Buzzard's Bay	2.5%
Pembroke	2.4%
Sandwich	1.7%
Halifax	1.6%
Sagamore Beach	1.4%
Mashpee	1.1%
Plympton	1.1%
Wareham	1.1%
East Falmouth	1.0%
East Sandwich	0.9%
Lakeville	0.8%
All other patient origins	24.6%
Total	100.0%
Payer Mix	
Commercial	40.3%
Medicaid	17.7%
Medicare	34.1%
Other ¹⁰	7.9%
Unknown	0.1%
Total	100.0%

The following table details PBOA's Orthopedic Surgery Panel details for Calendar Year (CY)2023.

- Age: Approximately 62% of patients are aged 65 and older.
- **Race:** The majority of patients (75%) identify as White. Staff notes that a significant portion of patients (24%) either declined or stated "Unknown" in collection of race data.
- Patient Origin: Approximately one third of patients originate from Plymouth, MA.
- **Payer Mix:** Approximately half of patients were covered by Commercial insurance, followed closely by 44% Medicare.

Table 3: PBOA	Orthopedic Surgery	Panel Overview CY2023
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	Totals
Total Patients	2,892
Gender	
Male	44.1%

¹⁰ Includes self-pay, health safety net, and liability is coverage other than worker's comp for an injury event.

	Totals
Female	55.9%
Total	100.0%
Age	
0-17	1.1%
18-64	36.8%
65+	62.1%
Total	100.0%
Race	
White	74.6%
Black or African American	0.4%
Other ¹¹	0.8%
Unknown/ Patient Declined	24.2%
Total	100.0%
Patient Origin - Top Ten Cities/Towns	
Plymouth	32.8%
Carver	6.5%
Kingston	4.7%
Middleborough	4.6%
Duxbury	4.4%
Bourne	4.3%
Barnstable	4.0%
Sandwich	3.4%
Wareham	2.7%
Marshfield	2.6%
Pembroke	2.3%
Falmouth	2.1%
Halifax	2.1%
All other patient origins	23.6%
Total	100.0%
Payer Mix ¹²	
Commercial	49.7%
Medicare	44.4%
Medicaid	1.3%
Multiple Payers	0.0%
Other	4.6%
Total ¹³	100.0%

The Applicant provided further detail on the BID Plymouth's Orthopedic Surgery population to

 ¹¹ For confidentiality, "Other" includes all races not separately listed.
 ¹² Payer mix is based on total patient encounters.
 ¹³ Payer mix is based on total patient encounters.

better illustrate the population most likely to benefit from the Proposed Project. Table 4 presents patient information for this patient population during FY2023. Staff notes the following observations about these data below:

- Age: Almost 60% of the patient population are aged 65 and older.
- Race/Ethnicity: The vast majority of patients (97%) identified as White, which is significantly greater than the 2020 US Census for Plymouth County of 83% White.^b
- **Patient Origin:** Approximately half (51.3%) of BID Plymouth's orthopedic surgery patients originated from Plymouth, Carver, Kingston, Duxbury, and Middleboro.
- **Payer Mix:** Approximately 67% of patients had Medicaid or Medicare coverage.

	lotals
Total Patients	2,542
Gender	
Male	43.6%
Female	56.3%
Total	100.0%
Age	
0-17	1.6%
18-25	1.8%
26-45	7.0%
26-64	30.5%
65+	59.0%
Total	100.00%
Race	
White	97.6%
Black or African American	0.9%
Other ¹⁴	1.5%
Total	100.0%
Patient Origin - Top Ten Cities/Towns	
Plymouth	32.3%
Carver	5.6%
Kingston	4.8%
Duxbury	4.2%
Middleboro	4.4%
Marshfield	2.2%
Buzzard's Bay	2.2%
Pembroke	2.4%
Sandwich	1.7%

Table 4: BID Plymouth Orthopedic Surgery Patient Population Overview FY2023

¹⁴ For confidentiality, "Other" includes all races not separately listed.

	Totals
Halifax	2.0%
All other patient origins	38.2%
Total	100.0%
Payer Mix	
All Other	33.1%
Medicaid	9.6%
Medicare	57.3%
Total	100.0%

Factor 1a: 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 hospital outpatient department (HOPD), the analysis of patient need focuses on historical and projected utilization of these particular services. The Applicant attributes Patient Panel need for an ASC to the following factors:

- 1. Historical and Projected Volume Increases
- 2. Growth In An Aging Population and Associated Conditions Requiring Surgery
- 3. Shift in the surgical procedures that can safely be performed in an outpatient environment

1. Historical and Projected Surgical Volume Increases

The Applicant states that the Primary Service Area has seen an increase in the volume of orthopedic surgeries, a trend which is predicted to continue. Table 5 shows a 65% growth in outpatient orthopedic surgeries performed at BID Plymouth from FY2019-FY2023. Growth in the outpatient orthopedic surgeries is attributed to both a shift in the surgical procedures that can safely be performed in an outpatient environment and the growth in an aging population experiencing conditions that require surgery.

	2019	2020	2021	2022	2023
Foot & Ankle	164	160	133	104	109
General/Other	71	56	88	83	103
Hand	730	624	750	753	744
Joint Replacement	28	220	493	644	846
Joint Arthroscopy	405	340	375	400	379
Spine	107	98	159	194	150
Trauma	41	60	54	41	43

Table 5: Outpatient Orthopedic Surgeries Performed at BID Plymouth¹⁵

¹⁵ PBOA and BID Plymouth do not share the same fiscal year. PBOA's fiscal year is January through December and BID Plymouth's fiscal year is October through September. As such, the unique patient totals in Tables 1-4 will not align with the totals in Table 5 due to the mismatch in months included.

Total	1546	1558	2052	2219	2265
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The Applicant determined that approximately 83% of orthopedic cases performed at BID Plymouth in FY2022 could have been performed at the ASC, and the Applicant projects that this volume will shift from the HOPD to the ASC once the ASC is operational.16 The Applicant anticipates that additional volume will be generated from within the BILH system, as the ASC will present a more geographically convenient location where patients in the service area historically had travelled for orthopedic surgery. In FY2023, patients of BILH Performance Network practices in the Plymouth region traveled out of the market for orthopedic surgery to the following: South Shore Health, New England Baptist Hospital, Good Samaritan Medical Center, Cape Cod Hospital, and Brigham and Women's Hospital. The Applicant states that in FY2023, 79 outpatient orthopedic cases from BILH Primary Care practices in the BID Plymouth area went to BILH hospitals other than BID Plymouth, primarily New England Baptist Hospital. These cases only represent outpatient surgical cases where the patient had a BILH primary care doctor and underrepresents the number of Plymouth County residents who left the service area for treatment. The Proposed ASC will not be limited to patients with a BILH affiliation, nor surgeons with a BILH affiliation, and therefore will improve access for all residents seeking outpatient orthopedic surgery in their community. The Applicant projects that the proposed ASC will perform 2,578 procedures in its first full year of operation, ramping up volume in subsequent four years of operation. The majority of cases at the proposed ASC will be outpatient orthopedic surgeries historically performed at BID Plymouth.

Table 6: Projected ASC Volume

PROJECTED ASC VOLUME	FY2025	FY2026	FY2027	FY2028	FY2029
Total Volume	2,578	2,871	3,064	3,197	3,330

To determine the number of operating rooms needed to support the Patient Panel's current and future need for an orthopedic ASC in Plymouth, the Applicant reviewed the average length of OR use for each of the subspecialities of the proposed ASC. The average procedure length time is 120 minutes, ranging from 65 minutes for average hand cases to 184 minutes for spine surgeries. These procedure times include surgical time, set-up, and turnover. In order to accommodate the growth projections, the Applicant determined four ORs would be required to meet demand based on available operating times of the Proposed ASC. Specifically, the ASC plans to be open 8 hours a day, 5 days a week, 50 weeks a year. This provides 120,000 minutes of operating time per OR. Based on the average times described above, four ORs will allow the ASC to operate at 64% capacity in Year One, ramping up to 86% capacity in Year Five.

¹⁶ FY22 actuals were not available at the time the Applicant determined projections for the Proposed Project and therefore annualized data was used. As a result, the Applicant projected only 76% of cases would shift. This figure was relied upon in the Applicant's proforma and financial feasibility study. However, FY22 actuals show a higher percentage of appropriate cases that can be shifted from BID Plymouth to the proposed ASC.

The Applicant anticipates that the new ASC will employ 12 orthopedic surgeons¹⁷, all of whom will accept MassHealth coverage. New surgeons will be added to the existing integrated orthopedic service developed between PBOA and BID-P. The anticipated surgeon roster includes the following specialties, noting that several current surgeons practice across multiple specialties:

- Two (2) Hand/Wrist/Elbow
- One (1) Shoulder
- Two (2) Sports
- Five (5) Joint Replacement
- Two (2) Spine

PBOA is actively recruiting surgeons from outside the market to increase access for the community and better meet the orthopedic needs of its members. The list above includes the current team of orthopedic surgeons as well as the immediately anticipated additions for 2024. PBOA anticipates eventually adding two joint replacement surgeons beyond the roster. In addition to PBOA and BID-P, any orthopedic surgeon also serving the Plymouth community is welcome to utilize the facility. At this time there are no prospective candidates, but it is an option available to the local surgical community.

2. Growth In An Aging Population and Associated Conditions Requiring Surgery

Based on the orthopedic procedures most commonly performed on an outpatient basis at BID Plymouth, the Applicant expects that total knee arthroplasty ("TKA"), knee arthroscopy, shoulder arthroscopy, carpal tunnel surgery, and total hip arthroplasty will comprise the majority of surgeries at the Proposed ASC. These procedures are most prevalent among older adults because age is a contributing risk factor to the underlying disease or condition. Adults ages 65 and older increasingly represent the largest share of ASC utilization based on age, in part driven by changes to Medicare's reimbursement policies.^c Patient need is also driven by disease prevalence contributing to joint damage. Arthritis is prevalent among older adults as a result of certain risk factors, including age, obesity, repetitive movements (e.g., repetitive knee bending), joint injury, and smoking.^d In 2012, nearly one in four adults in the US had arthritis, while almost 10% of all adults in the US reported at least one activity limitation in 2012. By 2040, 11.4% of all adults are projected to experience at least one arthritis-related activity limitation, representing 34.6 million adults.^e

Another prevalent disease linked to soft tissue damage and osteoarthritis is obesity. In Massachusetts, more than half of all adults are considered overweight, including 25% of all adults who are considered obese.^f Individuals carrying excessive weight are 20 times more likely to need knee replacement surgery than individuals who are not overweight due to the increased pressure placed on the body's joints.^g As obesity rates in the US climbed in recent decades, so too have the number of TKA procedures for overweight individuals.^h Based on current and projected incidence rates of arthritis and obesity, need for orthopedic surgical services necessary to treat joint-related issues is projected to increase over time. The majority of these surgeries are projected to be performed in the ASC setting, since Total Joint Replacements ("TJRs") were approved for

¹⁷ Ten of the surgeons are part of the existing integrated orthopedic service developed between PBOA and BID-P, with plans to add two joint replacement surgeons to the roster.

reimbursement by Medicare beginning in January 2021. As the populations ages, the Applicant anticipates more adults in the proposed service area will require orthopedic surgery to treat disease-related injuries, improve quality of life, and extend life expectancy.ⁱ

The majority of historical case volume at BID Plymouth and within PBOA's Surgical Panel arose out of the need to treat age-related conditions. More than half of patients who had outpatient orthopedic surgery at BID Plymouth were ages 65+. An additional one third of all outpatient orthopedic surgical patients were between the ages of 45 and 64. These age-based demand considerations are especially important for future planning for an orthopedic ASC. The population of adults over the age of 60 in Plymouth County is expected to increase over the coming decades. In the proposed service area, the 60+ age cohort is projected to grow 36% between 2015 and 2025 (UMDI Long Term Population Projections). Given that more than half of the patients who had outpatient orthopedic surgery at BID-Plymouth were ages 65+ and an additional one third were between the ages of 45 and 64, this anticipated growth in the Plymouth region will increase the number of older adults who are more susceptible to joint-related issues, further driving need for these procedures.

3. Shift in the surgical procedures that can safely be performed in an outpatient environment.

Insurance coverage is a significant driver of where a procedure is performed. Medicare recently removed several orthopedic surgeries from its inpatient-only list, allowing those procedures to be reimbursed by Medicare when provided in an ASC. Prior to this decision, those surgeries would only be eligible for Medicare reimbursement if performed on an inpatient basis. For example, BID Plymouth began performing clinically appropriate TJR as outpatient surgeries following a change in Medicare's reimbursement policy in June 2020. As a result, 63% of TJR cases in FY2021 were performed as outpatient surgeries compared to just 1% in FY2019. The decision to allow outpatient reimbursement for more orthopedic surgeries is prompting providers and patients to shift care to more cost-effective outpatient settings. Without local access to a freestanding ASC, the Patient Panel will face barriers to care as insurers increasingly promote the use of ASCs for certain surgeries.

Analysis

Staff finds that the Applicant has demonstrated increasing need for orthopedic surgery services at the ASC environment through data showing an increase in volume and projected increasing need for ASC services over the next five years within the Applicant's PSA. The Proposed Project will address growing need for high-quality, cost-effective, ambulatory surgical care. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1a.

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

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 Outcomes and Quality of Life

The Applicant anticipates the ASC will improve health outcomes, reduce wait times, reduce costs, and improve access to surgical procedures.

Health Outcomes: The Applicant provided research literature supporting the benefits of the surgeries that are expected to be performed in the proposed ASC, which can be found in Appendix II. The research covered total knee replacement, knee arthroscopy for meniscal tears, knee ACL repair, hand and wrist repair, shoulder arthroscopy, total hip replacement, and total knee replacement. A main theme among the research presented was improvement in the patient's quality of life following surgical intervention. Patients generally reported improved physical functioning, which ultimately lead to greater patient satisfaction post-surgery. Several studies showed continued positive outcomes several years after undergoing surgeries, across a variety of age demographics. The addition of the proposed ASC will provide the Patient Panel with the means to improve personal health outcomes at a convenient location. The Applicant proposed specific outcome measures to track the impact of the Proposed Project which staff has reviewed, and will become a part of the reporting requirements. These measures are shown in Appendix I.

Reduction in Wait Times: The current wait time at BID Plymouth to be scheduled for surgery (from the decision to move forward with surgery) is approximately 6 weeks.¹⁸ The long wait times are often due to the Hospital's need to prioritize urgent surgeries so that outpatient surgeries are delayed or rescheduled. Staff inquired about the historical wait times for surgical procedures and the Applicant stated that historical surgical wait time data was not tracked and could not be provided. Using the current 6 week wait as the foundational wait time, the Applicant predicts that the addition of the proposed ASC will reduce current wait times by approximately 50%. The Applicant notes that there are no industry standard/national benchmarks available for optimal surgical wait times, but a wait time of between 2 and 4 weeks would address patient pain in a timely fashion. For patients in need of treatment for painful, joint-related conditions or injuries, long delays can significantly impact a patient's quality of life and adversely impact outcomes.

Reduced Costs: ASCs are able to create significant savings due to more efficient use of time and resources that are not available in the hospital-based setting.^j For example, single-specialty ASC are able to streamline overhead expenses through the use of consistent staffing, laboratory, medication, and imaging equipment.^k Further, the narrow scope of services provided by a single-specialty ASC allows for efficiencies than cannot be created in hospitals. As a result, ASCs are able to create savings that are reflected in procedure costs.

The Applicant also notes that ASCs are reimbursed at rates nearly half of what the same procedure would be reimbursed at if performed by a hospital.¹ As a result of lower procedure costs, patients

¹⁸ Wait time is measured as the time between a consultation that results in mutual agreement between the surgeon and the patient that surgery is the next best course of action and the day the patient's surgery is scheduled.

with any form of financial responsibility will experience costs savings by opting to receive care in an ASC setting compared to a hospital outpatient department (HOPD). This includes patients with costsharing, as well as patients who self-pay for their care. Table 7 below demonstrates that Medicare beneficiaries realize an average cost savings of 45% through a reduced copay when performed in an ASC compared to having the same surgery in an HOPD.

Procedure Description	ASC Procedure Cost	<u>ASC</u> Medicare Pays	<u>ASC</u> Patient Copay	HOPD Procedure Cost	<u>HOPD</u> Medicare Pays	<u>HOPD</u> Patient Copay
Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)	\$1,999	\$1,599	\$399	\$3,531	\$2,824	\$705
Neuroplasty and/or transposition; median nerve at carpal tunnel	\$1,272	\$1,018	\$253	\$2,241	\$1,793	\$447
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

Table 7: Medicare Payment Comparison for Orthopedic Procedures by Setting^m

ASCs may also increase access to orthopedic surgery for patients who previously delayed or avoided care due to cost or convenience. Approximately one in eleven adults (9%) reported delaying or not receiving care due to cost.ⁿ The study also found that adults who are in worse health are twice as likely than those with better health to delay or go without care due to cost reasons.^o These figures demonstrate that the cost of care plays a significant role on the decision to receive or delay necessary medical care, and as a result, health outcomes.

Improved access to surgical procedures: Freestanding ASCs provide patients with a level of convenience that is difficult to replicate in a hospital. As with the proposed ASC, freestanding ASCs are often located independent from hospital campuses, making parking and wayfinding more accessible. The Applicant anticipates that the creation of a freestanding ASC in the community will improve access to outpatient orthopedic surgical services because the nearest freestanding orthopedic ASC for BID Plymouth's patients is located almost an hour away from the Hospital. Given that patients must have reliable transportation on the day of surgery and have an accompanying adult, this distance may present a significant barrier for patients seeking an ASC for their treatment. Affordability and convenient access to care greatly impacts the decision to receive care^p and may

play a large role in a patient's decision of not only whether or not to obtain care, but also where to obtain the care.

Analysis: Improved Outcomes and Quality of Life

Staff finds that increasing access to ambulatory surgery in the ASC setting has the potential to improve health outcomes and quality of life of the Patient Panel. The literature has reported on the numerous benefits of the surgeries that the ASC expects to perform, and the proposed ASC would provide the Patient Panel with an affordable and convenient option for care. As a result, Staff finds that the Applicant meets the requirements of Public Health Value: Health Outcomes as part of Factor 1b.

Public Health Value: Health Equity

The Applicant asserts that the proposed ASC will increase access to surgical services for all patients by offering a low-cost alternative for outpatient surgical procedures in the community setting. The proposed ASC will not discriminate based on age, race, ethnicity, gender/gender-identity, physical ability, sensory limitations, religious, spiritual, and cultural beliefs, nor a patient's ability to pay or payer source. The ASC will also be physically accessible to all patients. The ASC will follow non-discrimination and diversity, equity, and inclusion policies consistent with those of BID Plymouth Hospital relative to patient access to the ASC and employment policies. Employee recruitment practices will include strategies to ensure that staff are culturally and linguistically competent relative to market demographics. Staff and providers will participate in annual cultural competency training. Additionally, the ASC will have a Financial Assistance program to assist patients with applying for public assistance or other programs to help cover medical costs incurred at the ASC. The Applicant plans to implement the following initiatives to increase healthy equity for the Patient Panel.

- Interpreter Services. To address language barriers, the Applicant will have both translations and video interpreter services 24 hours a day, seven days a week. The ASC will use LanguageLine, which offers Deaf and Hard of Hearing (DHH) patients with access to an interpreter. the Applicant will employ a culturally competent staff to ensure each patient's experience meets their needs. Utilizing culturally competent staff recognizes the holistic needs of patients throughout their encounter at the ASC.
- **Transportation.** Prior to each scheduled surgery, the patient will be asked about their transportation arrangements to and from the facility for the day of surgery. Patients will be counseled on the need for an adult to accompany them home from surgery as they will not be able to drive after anesthesia. When needed, patients will be provided with referrals to potential community resources that may be able to assist with transportation, such as senior centers and houses of worship.

Staff inquired about planned efforts to reach underserved communities and improve access to the Medicaid population in the area. The Applicant noted that, in addition to the tools listed above, The ASC will collaborate with and serve as a resource to BID Plymouth's Community Health Implementation Strategy (IS), which identified Equitable Access to Care for racially, ethnically and linguistically diverse populations as an area of priority focus and investment. The ASC will broaden the reach of populations served through outreach and joint initiatives with identified IS partners,

such as Healthy Plymouth and the Quincy Asian Resources Inc.

Analysis: Health Equity

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

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

The Applicant states that the Proposed Project will improve care continuity and coordination of care for ASC patients through procedures and processes that effectively identify and address individual patient needs, described below:

- All patients will complete a pre-operative assessment with a Registered Nurse at the time of scheduling. During the assessment, the patient will be asked about potential discharge barriers, ability to afford postoperative medications, and access to transportation. All responses are recorded within the patient's electronic medical record.
- 2. If the assessment identifies specific barriers to care, ASC staff will work with the patient to identify appropriate community resources through the use of a community resource directory. Additionally, all responses will be included with the discharge summary and shared with the patient's primary care provider.
- 3. The ASC will ensure that each patient is screened by a registered nurse for post-operative complications and experience within 24 hours after surgery. Concerns raised during the call will be documented in the patient's medical record and the patient's primary care provider will be notified to maintain continuity of care.
- 4. As part of the ASC's quality improvement program, the ASC Administrator will review the ASC's quality data on a quarterly basis with the ASC governing board and quality oversight committee in compliance with Medicare reporting requirements.
- 5. The ASC will participate in the MassHealth ACO Program through BILHPN and its clinically integrated network. In furtherance of the goals of the Program, BILHPN strives to increase access to high quality care for members who are more likely to have unmet Social Determinant of Health ("SDoH") needs than the commercially insured population. A significant portion of BILHPN's efforts to improve health care are accomplished through care coordination. Specifically, BILHPN's data analysis and risk management tools help participating primary care physicians monitor patients' health and manage chronic conditions. Therefore, BILHPN patients who utilize the ASC's services will benefit from the coordination of care efforts made possible through BILHPN. The linkages available to BILHPN members through participating providers will continue to ensure their care is well-managed, organized, and facilitating improved health outcomes.

The Applicant notes that the ASC will be available to all patients in need of the surgeries provided. The surgeon will work directly with the patient to provide care coordination for post-surgical recovery/rehabilitation care (e.g., PT/OT). This care coordination begins before surgery and

continues after surgery until the patient is recovered. The ASC discharge nurse will review discharge orders with each patient, including all post-op care instructions and orders for follow-up care, and will provide written instructions. The ASC will ensure the surgeon and referring provider(s) have access to the operating and discharge summaries. The performing surgeon will have direct access to the full patient record including the operative note and discharge summary via the electronic medical record. With patient consent, the ASC will provide the patient's referring provider and/or primary care provider with access to the patient record.

Analysis

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

Factor 1: d) Consultation

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

As a result, Staff finds that the Proposed Project meets the requirements of Factor 1d.

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

The Department's Guideline¹⁹ 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."²⁰

To fulfill the community engagement requirement, the Applicant conducted information sessions/community forums to inform community members. During each of the presentations described below, attendees were educated on the Applicant's proposed plans for the ASC, including the types of surgeries to be performed, the number of ORs, plans for patient experience improvement, and how the Proposed Project will meet the community's current and future needs for orthopedic surgery. Following the presentation, attendees were able to share feedback and ask the presenters questions. Feedback in all meetings was positive with the perspective that the ASC would provide a lower-cost and more accessible option for outpatient orthopedic surgery, and that there would be no reduction of operating rooms at BID-Plymouth as a result.

• BID Plymouth's Community Benefits and Advisory Committee ("CBAC"): Presented on

¹⁹ Community Engagement Standards for Community Health Planning Guideline: Available at <u>https://www.mass.gov/doc/community-engagement-guidelines-for-community-health-planning-pdf/download</u>

²⁰ DoN Regulation 100.210 (A)(1)(e): Available at https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf

May 17, 2022. The presentation was attended by seven (7) members of the CBAC.

- <u>BID Plymouth's Patient and Family Advisory Council ("PFAC")</u>: Presented on June 8, 2022. The presentation was attended by seven (7) PFAC members.
- <u>BID Plymouth's Annual Public Meeting</u>: Presented on June 22, 2022, with 57 individuals from over 50 community organizations. The Proposed Project was widely publicized as an agenda item for the meeting through the Hospital's extensive network and email listserv.
- <u>BID-Plymouth's Quarterly Legislative Breakfast:</u> Presented on June 22, 2022. A State Senator and 4 State Representatives were in attendance.

Analysis

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

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

The Applicant asserts that the Proposed Project will meaningfully contribute to the Commonwealth's cost containment goals and compete on the basis of TME and provider costs by providing clinically appropriate patients with access to surgical services in a more cost-effective setting. The Applicant states that healthcare expenditures for elective and same day surgical procedures will decrease, reducing overall provider costs and directly impacting TME.

The Applicant cites research showing that the provision of clinically appropriate surgeries in freestanding ASCs saves the Medicare program and its beneficiaries more than \$4 Billion.^q Based largely on historical savings, it is projected that ASCs will reduce Medicare costs by \$73.4 Billion from 2019 to 2028.^r These savings are a result of lower reimbursement rates for procedures performed in an ASC compared to those performed in hospitals. Reimbursement rates for an ASC are on average just half of what Medicare would pay for the same procedure if performed in a hospital.^s These savings are especially valuable for ACOs that can better promote cost savings, care coordination, and health management of its covered lives when an ASC is available in its network.

The Applicant states that the growing availability of orthopedic ASCs has led more insurers, including Medicare, to incentivize the provision of additional types of surgeries in the outpatient setting and by increasing the types of surgeries approved for ASC reimbursement.²¹ Based on both cost savings and availability of ASC's, the Applicant expect that appropriate surgical cases will shift from hospitals to ASC's. Accordingly, it is expected that most orthopedic surgeries will be performed in an ASC within five years.^t Table 8 illustrates the shift in approved clinical settings for reimbursement by Medicare for total joint replacement procedures, beginning with hospital inpatient only ("IPO"),

²¹ For example, Empire BlueCross BlueShield in New York now requires medical necessity review for certain procedures if they're performed in a hospital outpatient setting instead of an ASC. Medicare indirectly incentivizes outpatient surgery through penalties for excessive hospital readmissions.

moving to hospital outpatient ("HOPD"), and ending with ASC.

CPT Code	Procedure	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

Table 8: Medicare Approved Clinical Setting for Reimbursement by Procedure

The Applicant asserts that the Proposed Project will ensure the Plymouth community has adequate access to outpatient orthopedic surgery in an ASC and therefore will compete on the basis of price, TME and provider costs.

Analysis

Staff finds the Proposed Project has the potential to reduce healthcare costs through providing a lower-cost site for outpatient surgeries. The Applicant cited research demonstrating costs savings that can results from surgeries performed in the ASC setting, versus the HOPD setting, and had further illustrated how such savings can occur for all payers. Staff finds that, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending and therefore, the requirements of Factor 1f have been met.

Factor 1 Summary

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

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

Cost Containment

The Proposed Project will meaningfully contribute to The Commonwealth's goals for cost containment by providing high-quality care in a lower cost setting than currently available in the community. The Proposed Project will meet these goals by establishing a freestanding ASC and shifting clinically appropriate cases from BID Plymouth and its affiliate hospitals to the ASC. As previously addressed in both the Patient Panel Need and Competition sections, reimbursement rates for procedures performed in ASCs are approximately 60% of the rate for the same outpatient procedures performed in a hospital setting.^u

Analysis: Cost Containment

Staff finds that the Applicant has adequately explained how it aligns with cost containment goals through the expansion of access to ambulatory surgery in a lower-cost setting. In their DataPoints series, the HPC examines ASC's and suggests that additional savings can be gained from expanding access to ASCs, and supporting greater shifts of care from HOPDs to ASCs.^v Therefore, DoN Staff can

conclude that the Proposed Project will likely meet the cost containment component of Factor 2.

Improved Public Health Outcomes

As noted in Factor 1b, the Proposed Project can improve patient health outcomes through increasing access to freestanding ASC care. The proposed ASC will provide capacity for more surgeries to be performed in the community. As a result, patients will experience improved convenience through local access to ASC care with shorter wait times for scheduling procedures in a non-hospital setting. Local, timely access will contribute to improved patient experience and satisfaction. Previous factors described in detail that the cost of surgery at the ASC will be significantly lower than if the same procedure were performed at the Hospital, which is currently the local access point for outpatient orthopedic surgery for patients in the Plymouth service area. As discussed previously, approximately 9% of adults delay or avoid care altogether because of the cost of care. By reducing costs through the provision of care in a freestanding ASC, the Proposed Project seeks to expand access to patients of all financial means, limiting the impact that cost of care plays in the patient's decision to receive necessary care.

Analysis: Public Health Outcomes

Staff finds that the Proposed Project will provide the Patient Panel with increased access to ambulatory surgery in the ASC setting, a need for which is growing due to population changes and the increasing prevalence of certain health conditions discussed earlier. Staff find that these procedures have the ability to improve health outcomes, quality of life, and functioning status. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the Public Health Outcomes component of Factor 2.

Delivery System Transformation

The Applicant asserts that patients will have assistance with social determinants of health (SDoH), needs and care management through a variety of processes, as outlined in detail in Factor 1c. The Applicant will work with patients and primary care providers to ensure patients are linked to social service organizations as needed. If concerns around social determinants of health are identified or suspected during pre-procedure screenings and appointments, staff will provide the patient with referral resources and notify the patient's primary care provider as appropriate to encourage necessary follow-up.

Analysis: Delivery System Transformation

The Applicant has demonstrated how the proposed ASC will support SDoH screening which has the potential to improve the continuity of care and health outcomes. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the Delivery System Transformation component of Factor 2.

Factor 2 Summary

As a result of information provided by the Applicant and additional analysis, staff finds that with the standard reporting conditions, the Applicant has demonstrated that the Proposed Project has met 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 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 a finding must be supported by an analysis conducted by an independent CPA. The Applicant submitted a report conducted by Meyers Brothers Kalicka, P.C. (CPA Report).

The CPA analysis included a review of numerous documents in order to form an opinion as to the reasonableness and feasibility of the projections regarding the Proposed Project including: historical volume and revenues for PBOA Orthopedics Surgery performed at BID Plymouth; projected volume of PBOA Orthopedics surgeries performed at BID Plymouth expected to shift to the ASC; and projected revenues, expenses, statements of cashflows and balance sheets for fiscal years 2025-2029. The CPA assessed the reasonableness²² of assumptions used in the preparation and feasibility²³ of the projections with regards to the Proposed Project.

Revenues: The CPA reviewed and analyzed the net operating revenues in the historical and projected financial information. The CPA analysis noted that it is likely that approximately 76% of approximately 2,230 cases currently performed at BID Plymouth could be shifted to the ASC during Year One of operations. In addition to the percentage of cases that are estimated to shift to the new ASC, the projections estimated additional volume based on the age of the population, convenience of the location, and Medicare now accepting TJR cases in an ASC setting. The estimated volume growth from Year one to Year Five ranges from 4% to 11 %. Gross charge per case is expected to increase approximately 3% each year. Estimates are based on a payer mix of Commercial (40%), Medicare (50%), and Medicaid (10%) reimbursement rates.

Expenses: The CPA analyzed Salary and Benefits, as well as Other Operating Expenses for reasonableness and feasibility as related to the Projections of the ASC. Salaries and benefits are projected to increase by 3% each year. Other expenses are projected to increase by approximately 4% per year. The CPA notes that the projected/pro-forma expenses for FY2025 through FY2029 are reasonable.

Lease agreement, Capital Expenses, and Cash Flows

²² Reasonableness is defined within the context of this report as supportable and proper, given the underlying information.

²³ Feasibility is defined as based on the assumptions used, the plan is not likely to result in insufficient funds available for capital and ongoing operating costs necessary to support the proposed project without negative impacts or consequences to existing Patient Panel.

The CPA reviewed the lease terms, projected capital expenditures, and future cash flows of the ASC. It is noted that the Applicant will finance project costs through debt over 120 months with a fixed interest rate of 7%, beginning in FY2025. The CPA stated that the capital needs and ongoing operating costs required to create, manage, and operate a freestanding ambulatory surgery center are not likely to result in a scenario where there is negative cash flow.

CPA's Conclusion of Feasibility

As a result of its analysis the CPA states that:

"We determined that the projections were not likely to result in insufficient funds available for ongoing operating costs necessary to support a freestanding ambulatory surgical center. Based upon our review of the projections and relevant supporting documentation, we determined the creation of a freestanding ambulatory surgery center by the Applicant is reasonable and based upon feasible financial assumptions."

Analysis

Staff is satisfied with the CPA's analysis of the Applicant's decision to proceed with the Proposed Project. As a result, staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

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

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

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

- 1. Continue outpatient orthopedic surgery at BID Plymouth There are no capital expenses and operating costs would remain the same under with this option. Under this alternative, operational efficiency cannot be maximized because BID Plymouth's operating rooms will continue to be used for outpatient, inpatient, and emergency surgeries, as well as for a range of specialties. Quality of care under this alternative is not inferior, but patient satisfaction may be lower in the hospital setting due to scheduling delays as well as higher costs.
- 2. Expand outpatient surgical capacity at the Hospital's Main Campus The Hospital considered expanding outpatient surgical capacity at the Hospital's Main Campus through the construction of an on-campus HOPD. However, this option would not reduce health care costs because it would be reimbursed as a hospital outpatient department and not a freestanding ASC. This option would not adequately address the cost concerns of the community.

Staff inquired whether the greater BILH system could assist with the outpatient surgical needs. The Applicant explained that, while the system could absorb these procedures, using the alternative sites would be more costly, time-consuming, and less convenient for patients; would have a negative impact on access to orthopedic care in the Plymouth region; and could potentially have a negative impact on continuity of care for patients in the Plymouth region. Using other BILH sites, only one of which is an outpatient ASC located in Dedham²⁴, would require that patients transition their care to surgeons outside the Plymouth region and travel outside the region for surgery. Or, assuming PBOA surgeons could secure surgical privileges at other BILH sites, use of these sites for surgery would require that PBOA surgeons travel long distances to perform surgery - which would reduce the time they were available to consult patients in their Plymouth office. This would extend appointment and surgical wait times, negatively impacting access for patients in the Plymouth region.

Analysis

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

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

This is a Proposed Project that will result in a Tier 2 CHI. To fulfill Factor 6 requirements, the Applicant submitted its 2022 Community Health Needs Assessment (CHNA) and 2023-2025 Implementation Strategy (IS), a Self-Assessment, Partner Assessments, and a CHI Narrative.

In the CHNA/IS, the Applicant highlights social determinants of health for priority cohorts and should focus CHI planning and implementation efforts in these key areas to ensure selection of strategies that meet the CHI and Health Priority Guideline principles. This will help the Applicant and their Community Benefits Advisory Committee (CBAC) focus on the priority areas that allow for implementation at the root cause level. In the existing CHNA, these areas are economic stability, education, food insecurity and nutrition, neighborhood and built environment, including housing and transportation. The Applicant will work with its CBAC to select priorities and approve implementation strategies. DPH staff have determined that if the Applicant agrees to address community conditions and root causes while engaging in ongoing work with their CBAC, CHI investment will align appropriately with the Health Priorities Guideline.

The Community Health Needs Assessment (CHNA) was released in 2022 and assessed the communities of Duxbury, Kingston, Carver, and Plymouth. Collectively, these cities and towns reflect

²⁴ The New England Baptist Outpatient Care Center, a joint venture by New England Baptist Hospital and Constitution Surgery Alliance, is 40 minutes/40 miles away from BID Plymouth.

diverse communities in terms of demographics (e.g., race, ethnicity, and age), socioeconomics (e.g., income, education, employment) and geography (e.g., suburban, and semi-rural), which influences community needs. Using a health equity framework, the CHNA focused on better understanding the needs of underserved communities, including individuals who speak a language other than English, those who are in substance use recovery and those who experience barriers and disparities due to their race, ethnicity, gender identity, age, disability status or other personal characteristics. With a focus on community engagement, the CHNA analyzed primary and secondary quantitative and qualitative data capturing key demographics and social determinants of health. This process included community listening sessions, a community health survey, focus groups and key informant interviews.

Guided by the CHNA findings, the Applicant's **2023-2025 Implementation Strategy** (IS) health priority needs include equitable access to care, social determinants of health, mental health and substance use and complex and chronic conditions across the priority populations of young people, low resourced populations, older adults, individuals with disabilities and racially, ethnically, and linguistically diverse populations.

Using the CHNA/IS, the Applicant will engage its CHI Community Benefits Advisory Committee (CBAC) to select priorities and identify strategies for implementation with the funds associated with this proposed project.

The Self-Assessment provided a summary of community engagement processes and sociodemographic information, data and highlights related to topics and themes of community needs related to the existing CHNA and IS. Through primary data collection such as community listening sessions, a community health survey, focus groups, key informant interviews and data analysis, the Applicant and participating community partners identified the key needs outlined in the CHNA/IS.

Partner Assessments (formally known as 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 CBAC, 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. With the administrative funds, the applicant's early plans are to develop and disseminate communication materials and support participation through meeting promotion and engagement barrier reduction activities. The timeline, RFP processes, and use of evaluation and administrative funds are all appropriate and in line with CHI planning guidelines.

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 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 \$817,450.55
 - a. \$198,231.76 will be directed to the CHI Statewide Initiative.
 - b. \$594,695.27 will be dedicated to local approaches to the DoN Health Priorities.
 - c. \$24,523.52 will be designated as the administrative fee.
- 2. To comply with the Holder's obligation to contribute to the CHI Statewide Initiative, the Holder must submit a check for \$198,231.76 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative) **within 30 days** from the date of the Notice of Approval.
 - a. Payments should be made out to:

Health Resources in Action, Inc. (HRiA) 2 Boylston Street, 4th Floor Boston, MA 02116 Attn: MACHHAF c/o Bora Toro DoN project #: 22062915-AS

b. Please send a PDF image of the check or **confirmation of payment** to <u>DONCHI@Mass.gov</u> and <u>dongrants@hria.org</u>

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

- In addition to BILH ASC's obligation to participate in MassHealth, pursuant to 105 CMR 100.310(11), the Holder must certify annually that all physicians and health professionals who practice at the facility are enrolled as participating providers of MassHealth to support equitable access to all clinicians at the facility regardless of payer.
- 4. In order to support equitable access to BILH's services, the Holder will report on annual efforts to promote health equity at BILH Surgery Center, including but not limited to efforts to identify and address disparities in access to BILH's services, and efforts to advance the provision of culturally and linguistically appropriate services at BILH.
- 5. The Holder shall report on BILH Surgery Center patients stratified by race and ethnicity, patient origin (zip code), and payer mix.
- 6. The Holder shall report on ongoing efforts to increase Medicaid in its payer mix, detailing the strategies being implemented to achieve this goal.

7. The Holder will report on Surgical Volume by Specialty for both the BILH Surgery Center and BID Plymouth based on the case type listed below. Annual reporting should demonstrate that the new ASC is reducing the volume of low acuity surgeries at BID Plymouth.

SURGICAL VOLUME BY CASE TYPE
Foot & Ankle
General/Other
Hand
Joint Replacement
Joint Arthroscopy
Spine
Trauma
Total

The DoN program shall review the data received in accordance with Condition 7 to determine whether one or more of the following Referral Indicators is present:

- a) A material increase in total volume of the targeted surgeries at the BID Plymouth
- b) A material decrease in total volume of targeted surgeries at BILH Surgery Center

If the DoN Program finds any one or more of the Referral Indicators, the matter shall be referred to the Public Health Council (PHC) for review to determine whether BILH Surgery Center is in violation of one or more of the conditions and thus out of compliance with the terms of this Notice of DoN.

Upon referral to the PHC based upon any one or more of the Referral Indicators, BILH Surgery Center shall have an opportunity to show cause why the PHC shall not find one or more of the Referral Indicators.

Appendix I: Required Measures for Annual Reporting

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

- **1.** The Holder shall report on progress in reduction of wait times for scheduling surgical procedures with a description of how wait time is calculated.
- **2.** Patient Satisfaction: Patients that are satisfied with their care are more likely to seek additional treatment when necessary.

Measure: Patient satisfaction scores will be used to determine the impact of the Proposed Project on patient experience.

Numerator = Number of top scores, such as "likely to recommend" or "highly satisfied".

Denominator = Total number of survey respondents

Projections: As the Proposed Project is to establish a new ASC, the Applicant will provide baseline measures and three years of projections following the first fiscal year of operation.

Monitoring: The ASC's Administrator or their designee will review survey scores monthly and report quarterly to the governing board of the Applicant.

3. Surgical Site Infection ("SSI"): This measure will monitor the rate at which the ASC's patients develop surgical site infections and aims to reduce or eliminate such incidences.

Measure: The percent of SSIs within 30 days of procedure.

Numerator = Number of SSIs

Denominator = Total number of procedures

Projections: As the Proposed Project is to establish a new ASC, the Applicant will provide baseline measures and three years of projections following the first fiscal year of operation.

Monitoring: The ASC's Administrator or their designee will review the incidence of SSIs monthly and report quarterly to the governing board of the Applicant.

4. Fall Prevention: This measure will monitor the number of patients who report a fall within 30 days of surgery and aims to reduce or eliminate such incidences.

Measure: The percentage of falls with injury 30 days of procedure.

Numerator = Number of falls with injury

Denominator = Total number of procedures

Projections: As the Proposed Project is to establish a new ASC, the Applicant will provide baseline measures and three years of projections following the first fiscal year of operation.

Monitoring: The ASC's Administrator or their designee will review fall reports monthly and report quarterly to the governing board of the Applicant.

5. **Pre-Operative Time-Out:** This measure will monitor compliance with the surgical team's performance of a time-out immediately prior to each procedure.

Measure: The percentage of time-outs completed each month.

Numerator = Number of time-outs completed

Denominator = Total number of procedures

Projections: As the Proposed Project is to establish a new ASC, the Applicant will provide baseline measures and three years of projections following the first fiscal year of operation.

Monitoring: The ASC's Administrator or their designee will review time-out compliance monthly and report quarterly to the governing board of the Applicant.

Appendix II: Literature Review

- Ayers DC, Yousef M, Yang W, Zheng H. Age-Related Differences in Pain, Function, and Quality of Life Following Primary Total Knee Arthroplasty: Results From a FORCE-TJR (Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement) Cohort. J Arthroplasty. 2023 07; 38(7 Suppl 2):S169-S176. PMID: <u>37121490</u>.
- Mark D. Porter, MD, DSc, FACSP, FRACS (Orth)and Bruce Shadbolt, PhD. Improved Outcome With Knee Arthroscopy Relative to Physiotherapy for Symptomatic Unstable Meniscal Tears: 2-Year Prospective Cohort Study <u>https://doi.org/10.1177/19417381231156378</u>
- Batuhan Çokyaşar M.D. ,Ozan Altun M.D. Uygar Daşar M.D. Anterior Cruciate Ligament Reconstruction Improves Functional Scores and Quality of Life in Patients Older Than 50 Years of Age <u>https://doi.org/10.1016/j.asmr.2023.100806</u>
- Cagle, Paul J. et al. An Outcomes Protocol for Carpal Tunnel Release: A Comparison of Outcomes in Patients With and Without Medical Comorbidities. Journal of Hand Surgery, 2014; Volume 39, Issue 11, 2175 – 2180
- Meyers, Abigail et al. A Systematic Review of the Outcomes of Carpal Ligament Release in Severe Carpal Tunnel Syndrome. Journal of Hand Surgery, 2023; Volume 48, Issue 4, 408.e1 - 408.e18
- Rivlin, Michael et al. Electrodiagnostic Grade and Carpal Tunnel Release Outcomes: A Prospective Analysis. Journal of Hand Surgery, 2018; Volume 43, Issue 5, 425 431
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