

STAFF REPORT TO THE COMMISSIONER FOR A DETERMINATION OF NEED	
Applicant Name	Beth Israel Lahey Health, Inc.
Applicant Address	109 Brookline Avenue, Suite 300 Boston, MA 02215
Filing Date	June 17, 2022
Type of DoN Application	Substantial Change in Service, DoN-required Equipment
Total Value	\$1,589,750.00
Project Number	BILH-21120709-RE
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	\$79,487.50
Staff Recommendation	Approval
Delegated Review	Commissioner Approval
<u>Project Summary and Regulatory Review</u> Beth Israel Lahey Health, Inc. (Applicant) submitted a DoN Application for the acquisition of one, computed tomography (CT) imaging unit to be located on the main campus of Beth Israel Deaconess Hospital – Milton (BID-Milton) located at 199 Reedsdale Road, Milton, MA. The capital expenditure for the Proposed Project is \$1,589,750.00; the Community Health Initiatives (CHI) contribution is \$79,487.50. This DoN application falls within the definition of Substantial Change in Service, DoN-Required Equipment and Services, which are reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.	

Application Overview

Beth Israel Lahey Health (BILH or Applicant)

The Applicant, BILH, is a Massachusetts, non-profit, tax-exempt corporation that oversees an integrated health care delivery system comprised of teaching and community hospitals, physician groups, behavioral health providers, post-acute care providers and other caregivers serving patients in Greater Boston and the surrounding communities in Eastern Massachusetts and South Eastern New Hampshire.¹

Collectively known as “BILH Hospitals,” BILH’s member hospitals include:

Acute Hospital ²	Type (Per CHIA Category ^{a,b})
Anna Jaques Hospital	Community Hospital
Beth Israel Deaconess Hospital–Milton	Community Hospital
Beth Israel Deaconess Hospital–Needham	Community Hospital
Beth Israel Deaconess Hospital–Plymouth	Community-High Public Payer Hospital
Beth Israel Deaconess Medical Center	Academic Medical Center
Lahey Hospital & Medical Center	Teaching Hospital
Mount Auburn Hospital	Teaching Hospital
New England Baptist Hospital	Specialty Hospital
Northeast Hospital	Community-High Public Payer
Winchester Hospital	Community Hospital

BILH operates Beth Israel Lahey Health Performance Network, LLC (BILHPN), a Massachusetts Health Policy Commission (HPC) certified Accountable Care Organization (ACO), which the Applicant states is a value-based physician and hospital network whose goal is to partner with other community hospitals and providers throughout Eastern Massachusetts to improve quality of care while managing medical costs.

Beth Israel Deaconess Hospital – Milton (BID-Milton)

BID-Milton, the site of the Proposed Project, is a community hospital (CH) that is licensed to operate 100 acute care beds. BID-Milton provides inpatient and outpatient health services and 24-hour emergency services. BID-Milton services the towns of Milton, Randolph, Quincy, Braintree, Canton, Dorchester, Mattapan, Hyde Park, and the surrounding communities.³ The hospital is a DPH- designated Primary Stroke Service (PSS) Hospital providing 24/7 care to

¹ The Applicant states that an estimated five million people reside in the BILH service area.

² Beth Israel Lahey Health includes the following Hospitals: Addison Gilbert Hospital (Northeast), Anna Jaques Hospital, BayRidge Hospital (Northeast), Beth Israel Deaconess Hospital – Milton, Beth Israel Hospital – Needham, Beth Israel Hospital – Plymouth, Beth Israel Deaconess Medical Center, Beverly Hospital (Northeast), Lahey Hospital & Medical Center, Lahey Medical Center, Peabody, Mount Auburn Hospital, New England Baptist Hospital, and Winchester Hospital.

³ BID-Milton Demographics: Quincy (10.3%), Milton (10.2%), Randolph (8.5%), Braintree (6.1%), Squantum (3.4%), Quincy (3.3%), Hyde Park (3.1%), Canton (3.0%), Dorchester (3.0%), Stoughton (1.9%), Mattapan (1.7%), Brockton (1.71%), Dorchester (1.6%), Weymouth (1.5%), Weymouth (1.5%), Holbrook (1.3%), East Weymouth (1.2%), Plymouth (1.1%), Brockton (1.1%), Hingham (1.0%).

patients experiencing stroke and stroke symptoms.^{4,5} BID-Milton is contracted to participate in BILHPN and currently participates in its subsidiary ACO, Beth Israel Deaconess Physician Organization, LLC d/b/a Beth Israel Deaconess Care Organization (BIDCO).

Application Summary

BID-Milton currently has one CT unit in the Department of Radiology that provides CT services, including diagnostic exams and CT-guided procedures. The Applicant is proposing to add a second computer tomography (CT) unit at BID-Milton in order to meet Patient Panel need for timely access to CT imaging services. The current CT unit is used for inpatients, outpatients, and emergency patients, including patients experiencing stroke symptoms and patients undergoing low-dose CT for lung cancer screening.⁶ Having one CT unit to serve the imaging needs of emergency patients, inpatients, and outpatients has resulted in inefficiencies. The Applicant states BID-Milton has experienced an increase in CT utilization for inpatient, outpatients, and emergency patients, in addition to downtime on the current unit, resulting in increased wait times, delays for stroke patients, and limited ability to provide low-dose CT lung cancer screening. In addition, the Applicant anticipates Patient Panel need for CT services will increase due to an aging population with higher acuity and greater need for advanced imaging to diagnose and monitor conditions. The Applicant asserts that an additional CT unit is needed in order to address existing capacity constraints and provide the Patient Panel will access to high-quality CT services in the community.

⁴ Massachusetts Department of Public Health. Designated Primary Stroke Services Hospitals. <https://www.mass.gov/info-details/designated-primary-stroke-services-hospitals>

⁵ Primary Stroke Service (PSS) designation in Massachusetts indicates that a health care facility is ready to evaluate and treat acute stroke patients 24 hours a day. Massachusetts PSS facilities submit data to the Bureau of Health Care Safety and Quality (BHCSQ) as part of licensing.

⁶ Low-dose computed tomography is recommended as a screening test for adults who have a high risk of developing lung cancer based on their age and smoking history. Also called LDCT and low-dose CT scan. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/low-dose-computed-tomography>

Patient Panel⁷

The BILH Patient Panel consisted of 1,427,711 patients, in fiscal year 2021 (FY21).⁸ As shown in Table 1, the number of patients utilizing BILH's services increased by 11.5% between FY19 and FY21.

Table 1: BILH Patient Panel

FY19	FY20	FY21	% Change FY19-FY21
1,280,699	1,219,718	1,427,711	11.5%

The Applicant notes the following observations about the data below:

- **Age** - BID-Milton patient population has a higher proportion of patients aged 65 and older than the BILH patient population (35% vs. 28.65%). Additionally, the BILH patient population has a slightly higher percentage of patients aged 0 to 17 (6.57% compared to 2.31%).
- **Race** - Slightly over 70% of the BILH patient population identify as White compared to slightly less than 60% of the BID-Milton patient population. Approximately 14% of the BID-Milton patient population identifies as Black compared to ~ 5% of the BILH patient population.
- **Ethnicity** – A slightly larger percent of the BILH patient population identify as Hispanic (6%) than the BID-Milton patient population (2.42%).
- **Payer Mix** - Commercial payers are the primary payer source for BILH patients and BID-Milton patients, followed by Medicare.

Table 2: Overview of BILH and BID-Milton Patient Populations

	BILH patients	BID-Milton patients
Total Unique Patients (FY21)	1,427,711	84,130
Gender		
Male	44.15%	43.71%
Female	55.81%	56.29%
Other ⁹	0.04%	0.00%
Total	100%	100%
Age		
0 to 17	6.57%	2.31%
18 to 64	64.77%	62.69%

⁷ 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.

⁸ For purposes of the Applicant's Patient Panel and the Hospital's patient population, the fiscal year is defined as July 1 through June 30.

⁹ Patients for whom a gender is not specified or whose gender varies across visits over the time period are included in "Other."

65+	28.65%	35.00%
Total	100%	100%
Race¹⁰		
White	71.60%	59.29%
Black or African American	4.87%	14.38%
American Indian or Alaska Native	0.11%	0.17%
Asian	5.56%	5.27%
Native Hawaiian or Other Pacific Islander	0.07%	0.04%
Other ¹¹	8.91%	2.95%
Unknown	7.45%	18.10%
Patient Declined	1.42%	0.10%
Total	100%	100.3%
Ethnicity¹²		
Hispanic/Latino	6.00%	2.42%
Not Hispanic/Latino	81.75%	62.99%
Patient Declined	3.57%	
Unknown	6.01%	34.59%
Other	2.67%	
Total	100%	100%
Payer Mix		
Commercial	48.13%	46.85%
Medicare	25.43%	38.70%
Medicaid	12.18%	8.16%
Multiple Payers ¹³	6.00%	0.00%
Other ¹⁴	7.67%	6.30%
Unknown ¹⁵	0.58%	0.00%
Total	100%	100%

Factor 1: a) Patient Panel Need

The Applicant attributes Patient Panel need for expanded access to CT imaging to the following:

1. Historical Utilization
2. CT Scanning for Stroke
3. Loss of Capacity due to Downtime
4. Improved Access for Low-Dose Lung Cancer Screening

¹⁰ Self-reported.

¹¹ As a newly merged health system, BILH has not yet fully implemented a standardized data collection methodology for BILH Hospitals. As a result, "Other" may include patients whose race and/or ethnicity varied over time, as well as patients who did not report their race and/or ethnicity. Furthermore, patients who declined to report their race and/or ethnicity might also be captured in "Unknown" or "Patient Declined".

¹² Ethnicity information is not available at the system-level for three hospitals: BID-Milton, BID-Needham, and BID-Plymouth.

¹³ Patients whose primary payors within a given fiscal year fall into more than one payor category are included in "Multiple Payors."

¹⁴ "Other" includes the following payor categories: self-pay, worker's compensation, other government payment, free care, health safety net, auto insurance, Commonwealth Care/ConnectorCare plans, and dental plans.

¹⁵ Patients whose primary payor is missing in the data are included in "Unknown."

5. Projected Growth and Future Demand

- 1. Historical Utilization.** The Applicant asserts that BID-Milton is experiencing increasing demand on the existing CT unit, and this is leading to longer lengths of stay (LOS) and capacity constraints.

The BID-Milton patient population increased by ~40% between FY19 and FY21. This is shown in Table 3.

Table 3: BID-Milton Patient Population

FY19	FY20	FY21	% Change
Count	Count	Count	FY19-FY21
60,446	55,541	84,130	39%

The Applicant states that an increase in ED utilization drove the increase in BID-Milton's patient population: BID-Milton ED volume increased by ~17% during this same time period. LOS for ED patients increased during this same time period as well. An increase in wait time for CT scanning, which the Applicant attributes to capacity constraints, is cited as one reason for the longer LOS.

As shown in Table 4, BID-Milton's total CT scan volume increased by 12% between FY19 and FY21, with outpatient CT volume increasing by 17%.¹⁶

Table 4: BID-Milton CT Utilization by Patient Status¹⁷

	FY19	% of Total CT Volume	FY20	% of Total CT Volume	FY21	% of Total CT Volume	% Change (FY19-FY21)
Inpatient	4,399	26%	4,536	29%	4,805	26%	9%
Outpatient	4,970	30%	4,308	27%	5,806	31%	17%
Emergency	7,339	44%	6,993	44%	8,163	43%	11%
Total	16,708	100%	15,837	100%	18,774	100%	12%

The Applicant states that due to increasing demand, the existing CT's utilization in FY21 exceeds the CT unit's annual capacity of 17,520 scans.¹⁸ Because the CT unit operates 24/7, the Applicant is unable to extend hours of operation to accommodate increasing demand.

¹⁶ The Applicant states that the number of CT scans decreased slightly in FY20, likely due to patient avoidance during the COVID-19 pandemic, but demand increased in FY21, even beyond pre-pandemic levels.

¹⁷ Thirteen total CT-Guided Procedures are included in these numbers: FY19 (six procedures), FY20 (three procedures), and FY21(four procedures).

¹⁸ The Applicant states that annual CT capacity is based on an average scan time of 30 minutes and 24/7 operation.

Capacity constraints on the existing CT unit are resulting in longer wait times for patients, as shown in Table 5 below. The Applicant notes the following about wait times for CTs:

- CT scans for inpatients and outpatients are delayed in order to accommodate emergency patients.
- Current wait times for outpatients is five days.¹⁹
- A significant number of patients are referred outside of BILH due to longer wait times for outpatients CT scans, and due to prioritization of emergency patients disrupting scheduling for outpatients.

Table 5: Length of Time from Order to Exam

	FY19	FY20	FY21	% Change FY19-FY21
ED Patients	85 minutes	78 minutes	91 minutes	7%
Inpatients	216 minutes	228 minutes	298 minutes	38%

Current wait time for CT-guided procedures is one week. CT-guided procedures take approximately one hour to perform, which limits the Hospital's ability to accommodate additional volume.

- 2. CT Scanning for Stroke.** BID-Milton is designated by DPH as a Primary Stroke Service (PSS) hospital. This designation means that Emergency Medical Services (EMS) system sends patients experiencing symptoms of a stroke to the BID-Milton ED, and the facility is ready to evaluate and treat acute stroke patients 24 hours a day.

BID-Milton has difficulty meeting the guidelines for stroke imaging because of existing high utilization and only one CT unit. In accordance with clinical guidelines, patients should receive CT imaging within 25 minutes of arrival at the ED.^{c,d} The Applicant states that due to limited CT capacity, it is difficult for the Hospital to meet the guidelines for stroke CT imaging. Over the last 12 months, 21% of patients were scanned within 25 minutes of arriving at the BID-Milton ED. The average door-to-CT time for September 2021 was 62 minutes. In the event that a patient experiencing a stroke presents to the ED requiring a CT scan, it delays scans for other patients, including patients in the process of being scanned.²⁰

¹⁹ Based on third available appointment.

²⁰ The Applicant explained that certain outpatients and non-critical ED/inpatients may be removed prematurely from the scanner if there is a CODE Stroke or multi-trauma. However, patients receiving interventional CT would not be interrupted and therefore the scanner would remain unavailable for the remainder of the procedure. Similarly, patients receiving contrast would continue without being removed in order to prevent additional doses of iodinated contrast. Outside of these exceptions, non-emergency patients would be removed from the CT unit in order to allow for emergent imaging. Depending on where in the process the imaging was interrupted, the patient would be brought in after the stroke/trauma patient finished.

- 3. Loss of Capacity due to Downtime.** The existing CT unit experiences routine and unanticipated downtime for maintenance. The Applicant expects that the existing scanner will require increased routine and unanticipated downtime as it ages.

When the existing scanner experiences downtime, patients are rescheduled, wait for longer periods of time, or are directed to another facility.

Total downtime hours increased by 318% between FY19 and FY21. This is shown in Table 6. A second unit will help to provide uninterrupted access to CT imaging for patients in the event that one CT requires downtime and is unavailable, and the addition of a second CT unit will decrease the amount of downtime on the existing unit, which will in turn, prolong the useful life of both units.

Table 6: Downtime on Existing Unit

	FY19	FY20	FY21	FY22 ²¹
Scanner in use (%)	99.9	99.5	99.4	98
Downtime events (#)	1	5	3	1
Total downtime hours	11	46	46	48

- 4. Low-dose CT (LDCT) lung cancer screening.** BID-Milton started offering low-dose CT (LDCT) lung cancer screening in 2019, in partnership with Beth Israel Deaconess Medical Center.²² The Applicant asserts that early screening rates in Massachusetts remain low due in part to limited availability of CT in the community setting. When patients are identified as having lung cancer, it allows for treatment to begin earlier. The Applicant asserts that the screening program will be able to expand through the Proposed Project.

The number of patients participating in BID-Milton's LDCT screening program has been increasing every year to provide patients with ongoing screening and new patients access to the program. LDCT volume is displayed in Table 7. The addition of a second CT unit will allow BID-Milton to expand its screening program.

Table 7: Historical Lung Cancer Screening Volume

	FY19 ²³	FY20	FY21	% Change (FY19-FY21)
Annual Screening and Follow-up	167	311	508	204%

²¹ Includes dates of service 10/1/2021 – 12/31/2021.

²² LDCT screening is performed with the hospital's CT scanner which uses x-rays to create a three-dimensional view of the lungs. The enhanced clarity makes it easier to identify early cancers. The scan uses low doses of radiation, takes approximately 10 minutes and is covered by most health insurances with a physician referral. <https://www.bidmilton.org/events-and-education/new-lung-cancer-screening-program-now-at-bid-milton/>

²³ First year of implementation.

5. Projected Growth and Future Demand

The Applicant expects CT volume will continue to increase due to projected sustained growth in the Hospital's primary service area (PSA) in the coming years, leading to increases in outpatient CT volume; and an aging Patient Panel will increase the number of patients presenting with conditions that require advanced diagnostic imaging, including CT. Additionally, volume from the Hospital's low-dose CT lung cancer screening program and volume from patients currently receiving CT imaging outside of BID-Milton due to capacity constraints will contribute to volume increases. Table 8 displays projected CT volume after project implementation.

Table 8: Projected CT Volume

	Year 1	Year 2	Year 3	Year 4	Year 5	% Change (Year 1-Year 5)
Inpatient	4,800	4,944	5,092	5,245	5,402	13%
Emergency	9,052	9,052	9,052	9,052	9,052	0%
Outpatient	8,723	9,023	9,387	9,625	9,899	13%
Total CT Service Volume	22,575	23,019	23,531	23,922	24,353	8%

Analysis

Staff concurs that there is a clear need to alleviate current capacity constraints and improve access to critical CT services for all patients (inpatient, outpatient, and ED), especially those with stroke symptoms seeking care in the ED. For those patients in particular, the need for timely treatment is dependent on prompt imaging and interpretation, which is outlined in the AHA/ASA Get With the Guidelines – Stroke program measures. Additionally, freeing up capacity on the existing CT unit will address the CT imaging needs for inpatients and outpatients.

Staff concur that through the Proposed Project, BILH will be able to meet the current and near future needs of the Patient Panel for CT services at BID-Milton by providing increased access to timely CT services through the addition of a second CT unit. The proposed additional CT unit is expected to address existing capacity constraints and improve access to CT services for inpatients, emergency patients, and outpatients, as well as sustain local access to CT services in the community and reduce the need for patients to travel outside of BILH to obtain CT services. Based on the Applicant's Projections, BID-Milton will be able to better accommodate outpatients with the addition of a second CT unit and minimize scheduling delays and disruptions that occur due to the need to provide emergent and time-sensitive CT services to inpatients and outpatients.

Table 9: Projected Change in CT Volume by Patient Status

	FY21	Year 1	% Change (FY21 to Year 1)
Inpatient	4,805	4,800	-0.1%

Outpatient	5,806	9,052	55.9%
Emergency	8,163	8,723	6.9%
Total	18,774	22,575	20.2%

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

Public Health Value: Improved Outcomes and Quality of Life

The clinical benefits of CT have already been established and will not be discussed further. The Applicant cited evidence-based literature supporting the use of routine and emergency CT imaging as an essential component of Hospital care. The Applicant asserts that the Proposed Project will improve public health value through ensuring timely, appropriate access to CT services for inpatients, emergency patients, and outpatients, thereby improving both health outcomes and quality of life of the Patient Panel. In terms of the Proposed Project, the addition of a second CT unit will improve health outcomes and quality of life for specific patients requiring CT:

- Stroke:** Stroke is a leading cause of death in the United States and is a major cause of serious disability for adults.^e Non-contrast computed tomography (CT) remains the primary imaging modality for the initial evaluation of patients with suspected stroke.^f AHA/ASA Get With the Guidelines - Stroke program and PSS Time Target Recommendations recommend best practices for stroke care and outline the critical importance of patients receiving immediate medical treatment when experiencing a stroke due to the rapid decline in brain function as a stroke progresses. This includes receiving a CT within 25 minutes (door-to-CT time) and interpretation of the CT scan within 45 minutes. Rapid imaging is important for improving health outcomes; patients that present and receive a CT in a timely manner may be eligible for tPA (clot buster) to potentially prevent long-term cerebral damage. CT is used in diagnosis and to determine the type of stroke a patient is experiencing. CT scan can also rule out other brain abnormalities. Strokes can lead to permanent disability, brain damage, and death. Early diagnosis of stroke can reduce the likelihood of a patient living with a disability.
- Low-dose lung cancer screening:** Lung cancer is the leading cause of cancer death in the United States taking more lives than colon, breast and prostate cancer combined, and it is the second most diagnosed cancer in both men and women.^{g,h,i} Every year, 200,000 Americans are diagnosed with lung cancer and 160,000 die from it.^j Early detection of lung cancer using CT scanning can detect lung cancer in its earliest stage, which can result in a five-year survival rate of 90%. In Massachusetts, 18% of those at high risk were screened (compared to the national rate of 6%).^k The US Preventative Services Task Force (USPSTF) recommends yearly lung cancer screening with LDCT for people who have a 20 pack-year or more smoking history, and smoke now or have quit within the past 15 years, and are between 50 and 80 years old.^l

Analysis: Health Outcomes

- **Improved Outcomes** - CT can improve quality of life by providing more accurate information to facilitate appropriate treatment and reduce unnecessary treatment.
- **Reduced wait times for imaging** - Improved access to CT can allow for prompt scanning of more patients; reducing delays in diagnosis and treatment can improve health outcomes and quality of life.
- **Improved patient experience** - Reducing scan times can provide comfort to patients and improve patient experience and satisfaction. Earlier diagnosis and treatment can reduce time lost from work, family, and other activities, and as a result, patients may experience a greater sense of well-being.

The Applicant anticipates that the addition of one CT at this site will provide its patients with improved access to high quality CT services, which will improve health outcomes and thereby, quality of life. Research indicates that delayed access to quality health care negatively affects patient satisfaction as well as health outcomes due to delays in diagnosis and treatment. Quality of life includes aspects of physical health, and delayed access to care can also decrease one's quality of life. As a result, staff finds that through the Proposed Project, BID-Milton is likely to improve access to effective, high-quality imaging services, and thereby enhance patient satisfaction, health outcomes and quality of life for its patient population.

BID-Milton is in the process of implementing a clinical decision support tool in compliance with Medicare's Appropriate Use Criteria mandate. The Applicant has provided several measures, including wait times to appointments and access to screening, which may indicate improved outcomes. Staff reviewed the suggested measures that will become part of the annual reporting to DPH. To ensure that the Proposed Project will add measurable public health value in terms of improved health outcomes, quality of life, staff has suggested additional reporting measures. The revised measures are described in Appendix 1 below.

Health Equity

The Applicant provided the following examples of BID-Milton's efforts to achieve health equity across all populations.

- BID-Milton will ensure accessibility of its services for poor, medical indigent, and/or Medicaid eligible individuals or participation in the MassHealth ACO. BID-Milton is committed to serving the community regardless of an individual's ability to pay and does not discriminate based on ability to pay or payor source.
- BILH is working to reduce health inequities through the collection of demographic data (Race, Ethnicity and Language (REAL) data). BILH launched a new initiative to request more detailed and complete demographic information from patients and created a multidisciplinary team of representatives from across the System to develop best practices and processes to support consistent capture of data in the electronic medical record (EMR).

- Interpretation services are available at no charge.²⁴ Services are offered in person, by video, and by telephone, and are available for 140 different languages and can be used 24 hours a day. Trained interpreters assist during hospitalization and inform patients and their families about procedures, medication and other important information. Services are available to facilitate communication for deaf and hard of hearing patients. Certified Deaf Interpreter is available (10:00am -10pm, M-F; 11am-11pm on weekends). American Sign Language Interpreters are available 24/7 on the VRIs. Assistive Devices are available to assist patients. The Hospital's Telecommunications Device for the Deaf (TDD) is available for patients 24 hours a day.

Analysis: Health Equity

Staff finds that BID-Milton's language access services are appropriate for patients receiving CT scans. The Applicant has appropriately outlined at a high level a case for improved health outcomes and has provided reasonable assurances of health equity for CT patients.

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

The Applicant states that the Proposed Project supports coordination of care and linkages to primary care physicians (PCPs) through an integrated system. BID's electronic medical record (EMR) serves as the primary linkage between Radiology, BID-Milton's specialists, and community primary care providers. Further, the EMR allows BID-Milton radiologists real-time access to a patient's comprehensive medical information, enables imaging results and information available to primary care and specialty physicians across the system, and allows authorized providers outside of the Applicant's system to view patient record and send progress notes back.

Additionally, BID-Milton supports coordination of care and linkages through its MassHealth ACO Program participation, which increases access to high quality care for members who are more likely to have unmet social determinant of health (SDoH) needs, through its data management and risk management tools which are provided to BID-Milton providers, including a Population Health Management Tool, and through linkages to primary care providers.

Analysis

Staff concurs that when CT capacity is increased and the provision of CT services is more efficient, delays in diagnosis and treatment can be reduced and note that guidelines for managing stroke patients require efficient access to CT services. EMR systems enable access of imaging results and other patient information to primary care and specialty clinicians across a

²⁴ BID-Milton employs 1 full-time and 3 per diem staff within the department. BID-Milton has 10 video remote interpreting devices (one in each unit).

health system. EMRs improve efficiency for multi-faceted patient care. This helps to ensure that patients benefit from care coordination, better outcomes, and improved quality of life.

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 Guideline²⁵ 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."²⁶

To ensure sound community engagement throughout the development of the Proposed Project, the Applicant took the following actions:

- **Presentation at BID-Milton's Patient Family Advisory Committee (PFAC).** December 8, 2021. The PFAC is comprised of patients of BID-Milton and their family members, as well as BID-Milton staff. Nine individuals were in attendance, including three community members. The Applicant states the PFAC had positive reactions to the Proposed Project and did not voice any concerns.
- **Presentation to BID-Milton's Community Benefits Advisory Committee (CBAC).** December 10, 2021. Sixteen individuals were in attendance, including 11 community members and five representatives from BILH.

The Applicant provided the slides that were presented at the meetings.

Analysis

Staff finds that the Applicant 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 the Proposed Project will compete because it will improve access to CT services and provide timely diagnosis and treatment, which will help to contain healthcare costs. The Applicant seeks to improve timely access to CT services which will reduce long wait times which contribute to delayed diagnosis and treatment, can lead to longer LOS in the ED

²⁵ Community Engagement Standards for Community Health Planning Guideline

²⁶ DoN Regulation 100.210 (A)(1)(e). <https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf>

and inpatient units, and can contribute to poor patient experience. Longer wait times and rescheduled appointments experienced by outpatients increase likelihood that patients will forgo initial CT for diagnosis and for regular screening. The proposed second unit will be co-located with the Hospital's existing CT unit which will allow for leveraging of existing radiology staff to operate both CT units.²⁷

Analysis

A reduction in healthcare utilization and spending can occur with improved access to timely care. The Proposed Project will increase timely access to CT services and this will help to reduce the costs of care for patients. The benefits of an additional scanner include updated technology, a reduction in wait time for outpatients, more availability for outpatients, a reduction in equipment issues and faster diagnosis and treatment, all of which can reduce healthcare costs.

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 Project has met Factor 1(a-f). The Applicant proposed specific outcome, and process measures to track the impact of the Proposed Project which staff has reviewed, and which will become a part of the reporting requirements.

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

Cost Containment

As mentioned above in Factor 1, the Proposed Project will increase timely access to imaging services that will aid in early diagnosis and treatment, improved health outcomes, and reduced healthcare costs. In addition, the Applicant asserts that the Proposed Project is consistent with the Commonwealth's cost containment goals because BID-Milton is in the process of implementing a clinical decision support tool in compliance with Medicare's Appropriate Use Criteria mandate; and because the Proposed Project will not impact BID-Milton's contracted rates for CT services.

Analysis: Cost Containment

Staff finds that the Applicant has adequately explained how the Proposed Project aligns with the Commonwealth's cost containment goals through increasing access to high-quality, cost-effective imaging.

²⁷ The Hospital anticipates it will need to hire less than two (2) additional full-time employees for the additional unit. The Hospital anticipates the second scanner will require 1.65 full-time employees.

Improved Public Health Outcomes

The Applicant states that the Proposed Project will improve public health outcomes through improving access to CT services in the community, reducing travel times and wait times to access imaging, and reducing delays in diagnosis and treatment. BID-Milton's CT services support access to CT imaging for stroke patients, as well as enable increased access to lung cancer screening to aid in diagnosis and treatment.

Analysis: Public Health Outcomes

As detailed elsewhere in this Report, improvements in patient health outcomes result from efficient and timely access to CT services. Receiving immediate medical treatment can minimize long-term effects of a stroke and prevent death, and earlier diagnosis of lung cancer can allow for faster treatment and improved five-year survival rates.

Delivery System Transformation

The Applicant described its screening and linkages process for identifying and addressing social determinant of health (SDoH) needs impacting its patients. The Applicant's Beth Israel Deaconess Healthcare (BIDHC) primary care practices in Milton, Quincy, and Randolph screen patients for SDoH as part of their annual wellness exam. The screener form is modified from the Protocols for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE). BID-Milton screens for the following SDoH needs during each encounter: Housing, Interpersonal Safety, Social Support, Health Behaviors, and Financial Stability.²⁸ Patients complete the screener prior to the visit on a tablet or paper. When a need is identified through the screening, the patient is referred to a community health worker at the hospital, and providers are notified immediately when a safety concern is flagged in the screener in order to address the issue during the visit. Within the ED, direct referrals are made for behavioral health and substance use to embedded community partners such as Gosford Recovery Coaches and Aspire Health Alliance.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant has described how residents in the panel are assessed and how linkages to social services organizations are created.

²⁸ Employment and Transportation are screened on a case-by-case basis as determined by the patient's care team. In addition, certain patient characteristics (such as specific diagnoses) and high intensity resource utilization may prompt a needs screening.

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.

Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such finding must be supported by an analysis by an independent CPA. The CPA examined a range of documents and information in developing its report including five-year financial forecast (Projections) for fiscal years ending 2022 through 2026.²⁹ Additionally, it calculated key liquidity and operating metrics to assist in determining reasonableness of the Applicant's assumptions and feasibility of the Projections.^{30,31}

Revenues

The only revenue category that the proposed capital project would impact is net patient service revenue (NPSR). The CPA analyzed NPSR identified by BILH in both their historical and projected financial information and based on the analysis of the projected results from FY2022 to FY2026, the proposed capital project would represent ~0.010% (1 one-hundredths of 1%) of BILH operating revenues in FY2023, and ~ 0.014% (just over 1 one-hundredths of 1%) of BILH operating revenues in FY 2026. The CPA notes that the first year in which revenue is present for the Proposed Project is FY 2023. Thus, it is the CPA's opinion that the revenue growth projected

²⁹ 1. Projected income statements for the Project; 2. Income statements for the existing CT operations for fiscal years 2020 and 2021; 3. Determination of Need application instructions; 4. Determination of Need Factor 1 initial and final drafts; and 5. Audited Financial Statements of Beth Israel Lahey Health, Inc. and affiliates including consolidating balance sheets and statements of operations as of and for the years ended September 30, 2021 and 2020 and as of September 30, 2020 and 2019, and for the year ended September 30, 2020 and the seven-month period from March 1, 2019 to September 30, 2019. The information for BID-Milton is included in the consolidating financial statements for fiscal years 2021 and 2020. Separate financial statements for BID-Milton were provided for the year ended September 30, 2019.

³⁰ Liquidity metrics, measure quality and adequacy of assets to meet current obligations as they come due. Operating metrics, such as earnings before interest, taxes, depreciation and amortization ("Adjusted EBITDA") are used to assist in the evaluation of management performance in how efficiently resources are utilized. Solvency metrics, such as Debt to Equity, measure the company's ability to service debt obligations.

³¹ Reasonableness is defined with thin the context of the report as supportable and proper, given the underlying information. Feasibility is defined 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 BILH's existing Patient Panel".

by the revenue growth projected by Management reflects a reasonable estimation of future revenue of the Applicant based on BILH's historical operations.

Operating Expenses

The projections for operating expenses for the Proposed Project were reviewed in the context of actual operating results for BILH for the years ended 2020 and 2021 to determine the reasonableness of the expenses for Fiscal Years 2022 to 2026. The CPA determined from an analysis of the projected results from FY 2022 through 2026 that the Proposed Project would represent ~0.008% (less than 1 one-hundredths of 1%) of BILH operating expenses in FY2023, and ~0.009% (less than 1 one-hundredths of 1%) of BILH operating expenses in FY2026. Thus, it is the CPA's opinion that the projected operating expenses projected by Management reflects a reasonable estimation of future expenses of the Applicant based on BILH's historical operations.

Nonoperating Gains/Expenses and Other Changes in Net Assets

The CPA analyzed the nonoperating activity in aggregate and compared them to historical amounts. As a result of its analysis, the CPA determined that there were no non-operating expenses projected for the proposed capital project at BID-Milton. It is the CPA's opinion that the pro-forma nonoperating gains/expenses and other changes in net assets are reasonable.

Capital Expenditures and Cash Flows

The CPA reviewed BILH capital expenditures and cash flows in order to determine whether BILH anticipated reinvesting sufficient funds for technological upgrades and property, plant and equipment and whether the cash flow would be able to support that investment. As a result of its analysis, it is the CPA's opinion that the pro-forma capital expenditures and resulting impact on BILH cash flows are reasonable.

CPA's Conclusion of Feasibility

As a result of its analysis the CPA states that "because the impact of the proposed capital projects reflects a relatively insignificant component of projected operating revenues and expenses of BILH, although representing a positive contribution to operating results, I determined that the Projections are not likely to result in insufficient funds available for capital and ongoing operating costs necessary to support the Proposed Project." Accordingly, it determined that the Projections are reasonable and feasible, and not likely to have a negative impact on the Patient Panel or result in a liquidation of assets of BILH.

Analysis

Staff is satisfied with the CPA's analysis of Applicants 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 one alternative to the Proposed Project.

- 1. Maintain the status quo of the existing CT unit.** The Applicant rejected this option because access to care would continue to be reduced and wait times and delays would continue to increase for inpatients, outpatients, and emergency patients, as demand for quality CT services increases with patient volumes. Longer wait times would continue to adversely impact patient outcomes, quality of life, and patient satisfaction. In addition, this alternative would not eliminate the need to refer patients outside of BID-Milton for CT services.

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 relevant background and context for this application: This is a DoN project for an equipment project that will result in a Tier 1 CHI. Standard practice is to contribute the full CHI obligation to the statewide fund for DoN-regulated equipment. In this case, the Applicant has an existing Community Health Initiative project in the covered geography and will pool these funds with that existing investment. The Applicant and DPH have agreed to combined CHI funds for a transparent local CHI investment process, subject to DoN project approval.

In anticipation of this agreement, for this project, to fulfill Factor 6 requirements, the Applicant submitted its existing Community Health Needs Assessment (CHNA), a Self-Assessment and Supplement, Stakeholder Assessments, and a CHI Narrative.

The Community Health Needs Assessment was conducted in 2019 by the applicant, Beth Israel Deaconess Hospital *Milton* (BID-Milton). The Community Health Needs Assessment was implemented in three phases. The first phase utilized preliminary engagement strategies including key informant interviews and an internal evaluation of Community Benefits activities. The second phase included focus groups and a Community Health Survey. In the final phase, the Applicant engaged its Community Benefit Advisory Committee (CBAC) in internal meetings, conducted 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, Individuals with Chronic/Complex Conditions, and Racial/Ethnic Minorities and Non-English Speakers. The priority areas identified are Social Determinants of Health and Access to Care, Mental Health and Substance Use, and Chronic/Complex Conditions and Their Risk Factors. The Applicant will release a new Community Health Needs Assessment in 2022 and will employ similar strategies for engagement. The Applicant will engage its CBAC to select priorities and identify strategies for implementation.

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

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

The timeline, RFP processes, and use of evaluation and administrative funds are all appropriate and in line with CHI planning guidelines. In order to select strategies that meet Health Priority Guideline principles, the Applicant will need to focus on the priority areas in the upcoming final assessment that allow for implementation at the root cause level. The best aligned priority from the 2019 CHNA submitted is the Social Determinants of Health and if upstream, work across risk factors. The Applicant will work with its CBAC to select priorities and approve implementation strategies. Based on strategies in the Applicant'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 DoN Advisory Committee, CHI investment will align appropriately with the Health Priorities Guideline. The Applicant will also have additional touchpoints with DPH staff to share lessons learned and the final 2022 Community Health Needs Assessment to ensure sound processes for planning and implementation work moving forward.

The anticipated timeline for CHI activities includes a meeting of the Advisory Committee six weeks post approval, identifying the Health Priorities Strategies 3-4 months post approval, and deciding on best investment strategy five to six months post approval, with funding disbursement to begin 5-6 months thereafter.

With the administrative funds, the applicant's early plans are to encourage meeting participation through promotion and barrier reduction methods including interpreter services and stipends.

Summary Analysis: As a result of information provided by the Applicant and additional analysis, staff finds that with the conditions outlined below, and the ongoing communication on items outlined above, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project, and recommends that the Commissioner approve this Determination of Need, subject to all applicable standard and Other Conditions set out below.

Other Conditions

1. Of the total required CHI contribution of \$79,487.50
 - a. \$7,630.80 will be directed to the CHI Statewide Initiative
 - b. \$68,677.20 will be dedicated to local approaches to the DoN Health Priorities
 - c. \$3,179.50 will be designated as the administrative fee.
2. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for \$7,630.80 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
 - i. The Holder must submit the funds to HRIa within 30 days from the date of the Notice of Approval.
 - ii. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

Appendix 1

The Holder shall provide, in its annual report to the Department, the following outcome measures. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12). Reporting will include numerators and denominators where applicable.

1. **Access - Wait Times:** The Proposed Project seeks to ensure timely access to CT services for ED and inpatients. Accordingly, BID-Milton will track the median time from order placement to scan completion.
 - a. *Measure:* Average (median) time interval from when the CT was order to when the scan was completed.
 - i. *Emergency Baseline:* 91 minutes
 - ii. *Projections*³²: Year 1: 87 minutes; Year 2: 82 minutes; Year 3: 78 minutes
 - b. *Measure:* Average (median) time interval from when the CT was order to when the scan was completed.
 - i. *Inpatient Baseline:* 298 minutes
 - ii. *Projections*³³: Year 1: 283 minutes; Year 2: 269 minutes; Year 3: 255 minutes
2. **Access – Door to CT (Stroke):** The Proposed Project seeks to improve timely access to CT services for stroke patients. BID-Milton will continue to monitor the length of time between when a stroke patient reaches the Hospital to when a CT scan begins (i.e., door to CT).
 - i. *Baseline:* 136 minutes
 - ii. *Projections:* Years 1 – 3: Within 25 minutes
3. **Access – Lung Cancer Screening:** Increased access to screening services is likely to increase the number of patients who received lung cancer screening as recommended. BID-Milton will be able to offer additional lung cancer screening appointments upon implementation of the Proposed Project.
 - a. *Measure:* The number of low-dose CT scans provided at BID-Milton annually.
 - i. *Baseline:* 508 scans
 - ii. *Projections:* Year 1: 605 Year 2: 733; Year 3: 840
4. The Holder shall report on the percentage of BID-Milton stroke patients that had a CT scan within 25 minutes of arrival.
 - a. The rate should increase each year post-baseline. If the rate does not improve, Holder shall report on reasons why.

³² Based on projected utilization provided in Factor 1.

³³ Based on projected utilization provided in Factor 1.

REFERENCES

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- ^b Center for Health Information and Analysis (CHIA). Beth Israel Lahey Health. <https://www.chiamass.gov/assets/docs/r/hospital-profiles/2020/hospital-health-systems/Beth-Israel-Lahey.pdf>
- ^c Stroke Fact Sheet. https://www.heart.org/-/media/files/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke/stroke-fact-sheet_-_final_ucm_501842.pdf?la=en&hash=7FA33C71D753DF7AB1D4850451C95BBE25BEA622
- ^d Primary Stroke Services Time Target Recommendations. <https://www.mass.gov/doc/pss-time-target-recommendations-0/download>
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- ^f Birenbaum D, Bancroft LW, Felsberg GJ. Imaging in acute stroke. West J Emerg Med. 2011;12(1):67-76.
- ^g New Lung Cancer Screening Program Now At BID-Milton. <https://www.bidmilton.org/events-and-education/new-lung-cancer-screening-program-now-at-bid-milton/>
- ^h Centers for Disease Control and Prevention (CDC). Basic Information About Lung Cancer. https://www.cdc.gov/cancer/lung/basic_info/index.htm#:~:text=Lung%20cancer%20is%20the%20leading,as%20lung%20cancer%20treatments%20improve.
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- ^k American Lung Association. State of Lung Cancer. <https://www.lung.org/research/state-of-lung-cancer/states/massachusetts#:~:text=20%20Massachusetts%20%3A%2017.8%25-End%20of%20interactive%20chart.,it%20in%20the%20top%20tier>
- ^l U.S. Preventive Services- Task Force. Lung Cancer: Screening. <https://uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>