2. Project Description

Beth Israel Lahey Health, Inc. (the "Applicant" or "BILH"), with a principal place of business at 20 University Road, Suite 700, Cambridge, MA 02138, is filing a Notice of Determination of Need ("Application") with the Department of Public Health ("DPH") to acquire a computed tomography ("CT") unit for operation at Anna Jaques Hospital ("AJH" or "Hospital") located at 25 Highland Avenue, Newburyport, Massachusetts 01950. The Hospital currently has one CT unit. With the addition of the proposed unit, AJH will have two CT units to meet the needs of its patient population.

AJH is a 119-bed community hospital. AJH offers cancer care, emergency medicine, hyperbaric medicine, inpatient behavioral health, interventional pulmonology, orthopedics, pain management, radiation oncology, and Women's Health and OB/GYN care. Its service area includes cities and towns in the Merrimack Valley and North Shore, regions of Massachusetts, as well as Southern New Hampshire.

The Proposed Project seeks to meet the needs of the Hospital's patient population by expanding CT capacity to ensure timely access to CT imaging. AJH has experienced an increase in CT demand due to its clinical utility in diagnosing a number of conditions quickly. With only one CT unit at AJH, downtime due to maintenance or repair limits access to CT imaging as the Hospital has no back-up. With one CT to serve ED patients, inpatients, and outpatients, capacity for additional types of CT imaging is limited. Moreover, access to CT imaging often allows for timely diagnosis and treatment before health status worsens and requires more costly intervention.

In summary, the Proposed Project will meet an identified need for AJH's patients. Approval of Applicant's request for a second CT unit will increase CT capacity, improve public health outcomes, patient experience and meaningfully contribute to Massachusetts' goals for cost containment. Accordingly, the Proposed Project meets the Determination of Need factors of review.

Factor 1: Applicant Patient Panel Need, Public Health Values and Operational Objectives

F1.a.i <u>Patient Panel</u>:

Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measure, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status and other priority populations relevant to the Applicant's existing patient panel and payer mix.

A. Beth Israel Lahey Health

BILH is an integrated health care delivery system of teaching and community hospitals, physician groups, behavioral health providers, post-acute care providers and other caregivers serving patients in Greater Boston¹ and the surrounding communities in Eastern Massachusetts and Southeastern New Hampshire. Its member hospitals include Addison Gilbert Hospital; Anna Jaques Hospital; Beth Israel Deaconess Medical Center; Beth Israel Deaconess Hospital-Milton; Beth Israel Deaconess Hospital-Needham, Beth Israel Deaconess Hospital-Plymouth; Beverly Hospital; Lahey Hospital & Medical Center; Lahey Medical Center, Peabody; Mount Auburn Hospital; New England Baptist Hospital; and Winchester Hospital

¹ Greater Boston includes the following cities/towns: Acton, Arlington, Ashland, Bedford, Belmont, Boston, Boxborough, Braintree, Brighton, Brookline, Burlington, Cambridge, Canton, Carlisle, Chelsea, Cohasset, Concord, Dedham, Dorchester, Dover, Foxboro, Framingham, Hingham, Holbrook, Holliston, Hopkinton, Hudson, Hull, Lexington, Lincoln, Littleton, Marlborough, Maynard, Medfield, Millis, Milton, Natick, Needham, Newton, Norfolk, Northborough, Norwell, Norwood, Quincy, Randolph, Revere, Roslindale, Scituate, Sharon, Sherborn, Somerville, Southborough, Stow, Sudbury, Walpole, Waltham, Watertown, Wayland, Wellesley, Westborough, Weston, Westwood, Weymouth, Wilmington, Winchester, Winthrop, Woburn, and Wrentham.

(collectively known as "BILH Hospitals"). BILH aims to have a broader impact on the health care industry and patient populations in Massachusetts by sharing best practices, investing in foundational infrastructure to support population health management, and encouraging market competition based on value.

BILH also operates Beth Israel Lahey Health Performance Network, LLC ("BILHPN"), a clinically integrated network of physicians, clinicians, and hospitals. BILHPN is a Health Policy Commission ("HPC") certified Accountable Care Organization ("ACO") committed to providing high-quality, cost-effective care to the patients and communities they serve, while effectively managing medical expense. By leveraging best practices in population health management and data analytics, BILHPN seeks to improve care quality and patient health outcomes across the system through population health initiatives.

Patient Panel

It is estimated that five million people reside in the BILH service area.² This area has experienced 6.4% population growth since 2010 and is projected to increase at a faster rate (4.5%) than the state (3.5%) from 2017 to 2022.³ As demonstrated in Table 1, the BILH Patient Panel consisted of 1,633,109 patients in fiscal year⁴ ("FY") 2022, an increase of 34% from FY20. The following table illustrates the demographics of BILH's Patient Panel.

Demographic Measure	FY2020 Count	FY2020 Percent	FY2021 Count	FY2021 Percent	FY2022 Count	FY2022 Percent
Total	1,219,718	100%	1,427,711	100%	1,633,109	100%
Age - 0 to 17	82,569	6.77%	93,835	6.57%	180,927	11.08%
Age - 18 to 64	784,319	64.30%	924,797	64.77%	993,510	60.84%
Age - 65+	352,830	28.93%	409,080	28.65%	458,672	28.09%
Gender - Male	541,252	44.38%	630,371	44.15%	647,251	39.63%
Gender - Female	677,915	55.58%	796,777	55.81%	983,566	60.23%
Gender - Other ⁵	551	0.05%	563	0.04%	2,292	0.14%
Race - White	908,726	74.50%	1,022,257	71.60%	1,209,253	74.05%
Race - Black or African American	58,869	4.83%	69,537	4.87%	89,020	5.45%
Race - American Indian or Alaska Native	1,404	0.12%	1,610	0.11%	2,134	0.13%
Race - Asian	71,333	5.85%	79,440	5.56%	105,352	6.45%
Race - Native Hawaiian or Other Pacific Islander	778	0.06%	985	0.07%	1,139	0.07%

Table 1: BILH Patient Panel Demographics

² Census Reporter, Boston-Cambridge-Newton, MA-NH Metro Area,

https://censusreporter.org/profiles/31000US14460-boston-cambridge-newton-ma-nh-metro-area/.

³ UMass Donahue Institute, Long-term Population Projections for Massachusetts Regions and Municipalities, March 2015.

⁴ For purposes of the Applicant's and the Hospital's patient panel, the fiscal year is defined as July 1 through June 30.

⁵ Patients for whom a gender is not specified or whose gender varies across visits over the time period are included in "Other."

Race - Other ⁶	110,929	9.09%	127,248	8.91%	108,684	6.66%
Race - Unknown	59,190	4.85%	106,325	7.45%	93,208	5.71%
Race - Patient Declined	8,489	0.70%	20,309	1.42%	24,319	1.49%
Ethnicity ⁷ - Hispanic/Latino	51,758	5.05%	70,402	6.00%	82903	5.95%
Ethnicity - Not Hispanic/Latino	875,383	85.43%	959,434	81.75%	1120228	80.38%
Ethnicity - Patient Declined	28,549	2.79%	41,950	3.57%	40490	2.91%
Ethnicity - Unknown	54,010	5.27%	70,531	6.01%	102618	7.36%
Ethnicity - Other	14,974	1.46%	31,372	2.67%	47509	3.41%
Payer Mix - Commercial	610,845	50.08%	687,224	48.13%	869,337	53.23%
Payer Mix - Medicare	320,062	26.24%	363,058	25.43%	424,855	26.02%
Payer Mix - Medicaid	143,168	11.74%	173,940	12.18%	165,605	10.14%
Payer Mix - Multiple Payers	79,086	6.48%	85,629	6.00%	43,266	2.65%
Payer Mix - Other ⁸	57,565	4.72%	109,545	7.67%	130,033	7.96%
Payer Mix - Unknown	8,992	0.74%	8,315	0.58%	13	0.00%

Age – Data for FY20-FY22 show that the majority of BILH's Patient Panel is between 18 to 64, followed by 65+ and 0-17 age cohorts, respectively.

Gender – BILH's Patient Panel is approximately 57.20% female, 42.72% male, and 14.48% Other. These percentages remained largely unchanged between FY20 and FY22.

Race – Approximately 73.38% of the Patient Panel self-identify as White.

Ethnicity – Approximately 82.52% of the Patient Panel self-identify as Not-Hispanic/Latino.

Payer Mix – Commercial payers are the primary payer source (at approximately 50.48%), followed by Medicare (approximately 25.90%).

B. <u>Anna Jaques Hospital</u>

AJH is a community hospital serving the Merrimack Valley and North Shore, regions of Massachusetts as well as Southern New Hampshire. AJH is recognized for delivering high-quality community health care at a lower cost with an emphasis on patient satisfaction. AJH is a member of Beth Israel Lahey Health. AJH's primary service area includes Newburyport, Amesbury, Haverhill, Salisbury, Merrimac, West Newbury, Newbury, and Byfield.⁹ The following table illustrates the demographic profile of AJH's patient population.

⁸ Includes self-pay, health safety net, and liability is coverage other than worker's compensation for an injury event.

⁶ 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". "Other" is a choice for patients to select if they do not feel that their race/ethnicity is reflected in the list of choices.

⁷ Ethnicity information is not available at the system-level for three hospitals: BID-Milton, BID-Needham, and BID-Plymouth. For the remaining BILH hospitals, ethnicity information is self-reported. Patients for whom ethnicity is not specified are included in "Patient Declined," "Unknown," or "Other," per the local facility's data collection methodology. Patients for whom ethnicity varies across visits over the time period are included in "Other."

⁹ List of city and town populations that make up the primary service area is in descending order.

	opulation					
Domographic Moasuro	FY2020	FY2020	FY2021	FY2021	FY2022	FY2022
	Count	Percent	Count	Percent	Count	Percent
Age - 0 to 17	6,959	12.07%	6,030	9.10%	7,186	11.67%
Age - 18 to 64	34,821	60.38%	40,785	61.57%	36,187	58.79%
Age - 65+	15,894	27.56%	19,422	29.32%	18,182	29.54%
Total	57,674	100.00%	66,237	100.00%	61,555	100.00%
Gender -Female	35,642	61.80%	40,425	61.03%	38,433	62.44%
Gender - Male ¹⁰	22,032	38.20%	25,812	38.97%	23,122	37.57%
Total	57,674	100.00%	66,237	100.00%	61,555	100.00%
Race - White	53,694	93.10%	55,363	83.58%	55,363	92.42%
Race - African American	760	1.32%	769	1.16%	769	1.28%
Race - American Indian						
or Alaska Native	11	0.02%	13	0.02%	13	0.03%
Race - Asian	538	0.93%	564	0.85%	564	0.95%
Race - Native Hawaiian						
or Other Pacific Islander	17	0.03%	18	0.03%	18	0.02%
Race - Other	1075	1.86%	1165	1.76%	1165	2.21%
Race - Unknown	1009	1.75%	1069	1.61%	1069	1.77%
Race - Patient Declined	570	0.99%	7276	10.98%	7276	1.32%
Total	57,674	100.00%	66,237	100.00%	61,555	100.00%
Ethnicity -						
Hispanic/Latino	1,034	1.79%	1,099	1.66%	1,617	2.63%
Ethnicity - Not						
Hispanic/Latino	37,268	64.62%	38,617	58.30%	43,927	71.36%
Ethnicity - Patient						
Declined	19,372	33.59%	26,521	40.04%	16,011	26.01%
Ethnicity - Unknown	0	0.00%	0	0.00%	0	0.00%
Ethnicity - Other	0	0.00%	0	0.00%	0	0.00%
Total	57,674	100.00%	66,237	100.00%	61,555	100.00%
Payer - Commercial	31,425	54.49%	34,901	52.69%	31,929	51.87%
Payer - Medicare	16,414	28.46%	19,329	29.18%	18,623	30.25%
Payer - Medicaid	6,232	10.81%	6,909	10.43%	7,621	12.38%
Payer - Multiple Payors ¹¹	0	0.00%	0	0.00%	0	0.00%
Payer - Other ¹²	3,603	6.24%	5,098	7.69%	3,382	5.49%
Total	57,674	100.00%	66,237	100.00%	61,555	100.00%

Table 2: AJH's Patient Population

When compared to the BILH Patient Panel, the following observations about AJH's patient population are notable:

Age – Like BILH, data for FY20-FY22 show that the majority of AJH's patient population is between 18 to 64, followed by 65+ and 0-17 age cohorts, respectively.

Race – Approximately 89.7% of the AJH patient population self-identify as White compared to 73.38% of the BILH Patient Panel who self-identify as White.

¹⁰ Includes "Male" and "Other" for patient confidentiality.

¹¹ "Multiple Payors" is defined as patients whose primary payors within a given fiscal year fall into more than one

payor category. ¹² "Other" includes but is not limited to: self-pay, workers' compensation, other government payment, free care, health safety net, auto insurance, Commonwealth Care/ConnectorCare plans, Unknown (defined as patients whose primary payor is missing in the data) and dental plans.

Ethnicity – Similar to BILH, the majority of the AJH patient population self-identified as Not Hispanic/Latino (64.76%). However, on average, 33.21% of patients declined to disclose.

Payer Mix – Like BILH, Commercial payers are the primary payer source for AJH (53.02%), followed by Medicare (29.30%) and MassHealth (11.21%).

F1.a.ii <u>Need by Patient Panel:</u>

Provide supporting data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question F1.a.i that demonstrates the need that the Proposed Project is attempting to address. If an inequity or disparity is not identified as relating to the Proposed Project, provide information justifying the need. In your description of Need, consider the principles underlying Public Health Value (see instructions) and ensure that Need is addressed in that context as well.

The Applicant seeks to add a second CT unit at AJH to meet the needs of its patient population to ensure access to CT imaging, and to expand its interventional radiology and low-dose CT ("LDCT") programs. As reflected in the data below, there has been an increase in CT utilization. With one CT unit, urgent or emergency patients in need of CT delay access to CT for inpatients and disrupts the outpatient schedule. In addition, downtime to perform CT maintenance leaves the hospital without CT capability. As a result, patients are rescheduled, and stroke patients may be diverted to other facilities. Capacity constrains also hamper the Hospital's ability to expand access to interventional radiology procedures and LDCT lung cancer screening consistent with recommended screening guidelines. Moreover, the high demand for CT imaging by the Hospital's large geriatric population will only continue to grow as the patient population ages. Therefore, a second CT unit is needed to improve access to CT and health outcomes for the patient population.

A. <u>Historic Utilization</u>

As illustrated in Table 3 below, AJH experienced a 9.74% increase in CT scan volume between FY21 and FY22. Notably, patients in the 65+ age cohort represented over half (53.37%) of the patient population receiving a CT scan in FY22. In FY20 and FY21 this age cohort represented approximately 49% of patients who received a CT scan. This increase in utilization by an aging patient population is reflective of the growth in the Hospital's 65+ age cohort , which grew 14.40% between FY20 and FY22.

Historical CT Volume	FY20 ¹³	Percent Change	FY21 ¹⁴	Percent Change	FY22	FY23 through April
CT Volume	17,271	-2.21%	16,890	5.07%	16,890	10,547

TABLE 3: Historical CT Volume

¹³ Fiscal year is defined as October 1 through September 30 for all data aside from data in the Applicant and Hospital's patient panel.

¹⁴ CT scan volume likely decreased from FY20 to FY21 due to patient avoidance of hospitals during the COVID-19 Pandemic.

B. Limitations of One CT Unit

Currently, one CT unit at AJH serves the CT needs of the Hospital's inpatients, ED patients, and outpatients. Emergent and stroke patients must receive CT imaging quickly. As a result, these cases often disrupt access for inpatients and cause scheduled outpatients to be delayed or rescheduled. With only one CT, AJH is also limited in its ability to provide interventional radiology procedures without impeding access to CT imaging for stroke and other ED patients. In addition, expansion of the LDCT program is not possible with one CT unit. A second CT unit is needed to provide AJH's patient population with uninterrupted and increased access to CT imaging.

As demonstrated below, between FY20 and FY22, there was a 105% increase in downtime hours for the Hospital's CT unit. When the unit is not available, patients requiring CT imaging must wait, be transferred to another facility, or be rescheduled. For example, in FY22, 29 emergency patients were diverted by the EMS system from AJH to another facility because the CT was not available. Increased downtime and concerns that the existing unit will increasingly require routine and unanticipated downtime as it ages are indicators of the need for a second CT.

Downtime Type ¹⁵	FY20	FY21	FY22
CT Downtime for Interventional Radiology Procedures	125	128	141
CT Downtime (in use or maintenance)	36	81	190.3
Total Hours	161	209	331.3

TABLE 4: CT Downtime Hours

As the CT unit is taxed by high utilization, it is expected that downtime hours will increase and disrupt care. A second CT unit is necessary to mitigate downtime on the existing unit by allowing the Hospital to reduce the overutilization of the existing unit across two machines. With a second unit, the Hospital can extend the life of the current unit, delaying the need for replacement. In addition, the second unit will ensure redundancy if either unit requires repair or maintenance.

CT imaging also is widely used to diagnose stroke. As a designated Primary Stroke Services Hospital¹⁶, the Emergency Medical Services ("EMS") system sends patients experiencing symptoms of a stroke to the AJH ED. Clinical guidelines for stroke recommend that stroke patients receive CT imaging within 25 minutes of arrival at the ED.¹⁷ Acute stroke patients, and other patients requiring an emergent CT scan are prioritized over less urgent exams. In FY21 and FY22, nine to ten patients each year with stroke symptoms were transferred to another facility because the CT unit was not available. The number of other ED patients transferred because the CT unit was down or occupied increased from 23 patients in FY21 to 29 patients in FY22.

CT also is used for CT-guided interventional radiology procedures. Once an interventional CT procedure begins, it is not optimal for patient care to disrupt the procedure to accommodate emergent cases. As a

¹⁵ The term "downtime" indicates the CT unit is not available and emergent patients in need of CT imaging must be diverted elsewhere.

¹⁶ To be designated a PSS Hospital, a hospital must be equipped to readily provide timely acute stroke evaluation and treatment, and "must provide emergency diagnostic and therapeutic services 24 hours-a-day, seven days-a-week to patients presenting with symptoms of acute stroke." *Primary Stroke Service validation*, https://www.mass.gov/info-details/primary-stroke-service-pss-validation (last visited Feb. 24, 2022). *See also, Designated Primary Stroke Services* Hospitals, https://www.mass.gov/info-details/designated-primary-stroke-services-hospitals (last visited Feb. 24, 2022). ¹⁷*See Primary Stroke Services Time Target Recommendations* (6/2009), https://www.mass.gov/doc/pss-time-target-recommendations-0/download; *Get With the Guidelines – 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 (last visited Feb. 24).

^{24, 2020).}

result, AJH has limited interventional CT block times. The addition of a second CT unit will allow the Hospital to increase the number of time slots available for interventional radiology and thereby increase access for patients.

Further, AJH offers LDCT lung cancer screening. AJH does not currently market LDCT due to capacity constraints.

TABLE 5: Historical LDCT Volume

LDCT Screening	FY20	FY21	FY22
Annual Screening	287	379	440

Through the Proposed Project, AJH will have additional CT capacity to expand its LDCT screening program, which will increase screening rates and early identification of lung cancer. Early identification can lead to treatment when disease is more easily treated resulting in improved health outcomes and at lower costs. A second CT will provide improved capacity for LDCT patients and further adherence with the recommended guidelines for annual screenings.

C. Projected Growth and Future Demand

Based on historical volume trends, AJH expects CT volume will continue to increase as demonstrated in the table below. The population of AJH's primary service area is projected to increase by approximately 2.84% from 2020 to 2035.¹⁸ In particular, the age 65 and older cohort is expected to grow by approximately 43.30% from 2020 to 2035.¹⁹ As the patient population ages, patients will present with higher acuity and more frequently require advanced diagnostic imaging, including CT. Moreover, in contemplation of the expected increase in CT volume due to the expansion of interventional radiology and LDCT programs, AJH has hired an additional interventional radiologist and interventional cardiologist.

TABLE 6: Projected CT Volume

Projected CT Volume	Year 1 ²⁰	Percent Increase	Year 2	Percent Increase	Year 3	Percent Increase	Year 4	Percent Increase	Year 5
CT Volume	18,017	2.13%	18,400	1.63%	18,700	0%	18,700	0%	18,700

As discussed throughout this section, the Proposed Project will address current and future needs of AJH's patient population. Maintaining one CT unit at AJH will adversely impact access and outcomes as the existing unit ages and demand for CT continues to grow. A second unit will provide capacity to accommodate emergent patients without disrupting timely access to CT for inpatients and outpatients. Therefore, the Proposed Project will improve access to care, health outcomes and patient experience.

F1.a.iii Competition: Provide evidence that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending. When responding to this question, please consider Factor 4, Financial Feasibility and Reasonableness of Costs.

The Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending because the Proposed Project seeks to ensure timely access to CT services. To deliver quality care, improve health outcomes, meet patient expectations, and contain

¹⁸ Mass Donahue Institute MassDOT Vintage 2018 Population Projections, *Massachusetts Population Projections*, September 2018, http://www.pep.donahue-institute.org/.

¹⁹ *Id*.

²⁰ Calculated from the time the Proposed Project is implemented.

overall medical costs, hospitals must have the ability to provide access to CT. As discussed in the previous section, the increased instances of downtime interrupt and delay diagnosis and ultimately treatment leading to an increase in overall health care expenses. AJH anticipates it will need to hire two full time CT technologists, which will have a minimal impact on operating costs. Therefore, the Proposed Project is necessary to ensure access to care, provide timely diagnosis and treatment, and contain health care costs.

F1.b.i <u>Public Health Value /Evidence-Based:</u> Provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need that Applicant has identified.

The addition of a second CT unit at AJH will advance and support the needs of AJH's Patient Panel by providing timely access to CT imaging, avoiding delay in diagnosis and treatment, and expanding capacity for interventional CT procedures and LDCT screening for lung cancer. The use of diagnostic imaging, such as CT, has significantly increased over the last several decades because of technological advancements and the expansion of clinical applications.²¹ The Applicant relies on extensive evidence-based literature to demonstrate that routine and emergency CT imaging is an essential component of hospital care and improving public health.

Computed Tomography or CT is a computerized x-ray imaging tool that utilizes x-ray beams to generate cross-sectional images - or "slices" - of the bones, organs, blood vessels and soft tissue.²² As a result, CT scans produce more clear, detailed images than conventional x-rays, making CTs extremely useful in detecting, for example, tumors or lesions within the abdomen and lungs; detecting heart disease or abnormalities of the heart; head injuries; and blood clots and embolisms.²³ CT is also useful in diagnosing disease, trauma, and abnormality; planning and guiding procedures; and monitoring the effectiveness of therapy.²⁴ CT-guided interventional radiology is used to perform diagnostic and therapeutic medical procedures to treat neurological conditions, cancer, heart disease, spinal problems, and vascular disease, among others.²⁵ CT imaging can also be used for cardiac coronary computed tomography angiography to visualize coronary arteries and help aide in the diagnosis and need for intervention.²⁶ CT scans can generally be performed in minutes, which means providers can quickly detect and diagnose emergent conditions such as strokes and consequently, reduce the chances of brain damage and disability.²⁷

In addition to its general diagnostic utility, CT is the preferred diagnostic tool for patients presenting with symptoms of stroke. CT imaging is used to diagnose strokes and to determine the type of stroke a patient

Computed Tomography (CT), U.S. FOOD &

radiationem iltingproductsandprocedures/med icalimaging/medicalx-rays/ucm 115317. him (last updated Mar. 7, 2018).

²¹ See Recent Advances in CT Scan Technology, Neurologica, https://www.neurologica.com/blog/advances-ct-scantechnology (last visited Feb. 24, 2022).

²² See U.S. Department of Health & Human, https://www.nibib.nih.gov/science-education/science-topics/computed-tomography-ct (last visited Feb. 24, 2022); Mayo Clinic, https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675 (last visited Feb. 24, 2022).

²³ See How Does a CT or CAT scan work?, MedicalNewsToday,

https://www.medicalnewstoday.com/articles/153201#procedure (last modified June 23, 2017).

 ²⁴ Carlo Liguori et al., *Emerging clinical applications of computed tomography*, 8 MED. DEVICES 265 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmclarticles/PMC4467659/; *Computed Tomography*.

RADIOLOGYINFO.ORG, https://www.radiologyinfo.org/en/submenu.cfm?pg=ctscan (last visited Jun. 29, 2018);

DRUG ADMINISTRATION, https://www.fda.gov/radiationemittingproducts/

²⁵ Elizabeth Hanes, RN, What is Interventional Radiology?, DignityHealth, https://www.dignityhealth.org/articles/whatis-interventional-radiology (Aug. 26, 2017).

²⁶ Coronary CTA, RadiologiyInfo.org available at https://www.radiologyinfo.org/en/info/angiocoroct (last visited March 8, 2023).

²⁷ See How CT Scans and MRIs are Used to Diagnose Strokes, https://www.envrad.com/how-ct-scans-mris-used-todiagnose-strokes/ (last visited Feb. 24, 2022).

is experiencing.²⁸ Timely CT scanning and subsequent treatment will improve patient outcomes.²⁹ According to the Massachusetts Department of Health's Time Target Recommendations and the American Heart Association/American Stroke Association's "Get With the Guidelines – Stroke", CT imaging should be completed within 25 minutes of arrival to the hospital, and IV thrombolytic treatment should begin within one hour of patient arrival.³⁰

CT imaging also is used as a screening tool for lung cancer. In the United States, an estimated 127,070 people are expected to die from lung and bronchus cancer, making it the leading cause of cancer-related deaths.³¹ Approximately 8 million Americans qualify as high risk for lung cancer and are recommended to receive annual screening with low-dose CT scans.³² Screening with LDCT for those at high risk can decrease lung cancer mortality by 14% to 20%.³³ If half of the high risk individuals were screened, over 12,000 deaths from lung cancer could be prevented.³⁴

Finally, literature on patterns of CT use indicate that imaging rates tend to be higher among older adults.³⁵ According to a study published in 2013, average CT utilization rates were approximately 24, 72, 159, and 240 per 1,000 persons for ages <18, 18-44, 45-54 and 65+ years, respectively.³⁶ The high CT imaging rates among older adults are likely related to the modalities' abilities to diagnose and treat age-related conditions.

F.1.b.ii <u>Public Health Value /Outcome-Oriented:</u>

Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.

To assess the impact of the Proposed Project, the Applicant developed the following quality measures. The measures are discussed below and will be reported to DPH on an annual basis following implementation of the Proposed Project.

1. Access- Reduce Downtime: The Proposed Project seeks to reduce the downtime hours to increase access to CT services for ED, inpatients, and outpatients.

²⁸ Two main types of strokes are ischemic stroke (blocked artery) or hemorrhagic stroke (a blood vessel bursting or leaking). *See id.* Individuals may also experience a temporary disruption of blood flow to the brain, called a transient ischemic attack, but this does not tend to cause lasting symptoms. *Id.*

²⁹ "In a registry representing US clinical practice, earlier thrombolytic treatment was associated with reduced mortality and symptomatic intracranial hemorrhage, and higher rates of independent ambulation at discharge and discharge to home following acute ischemic stroke." Jeffrey L. Saver, M.D., Gregg C. Fonarow, M.D., Eric E. Smith, M.D., MPH, et al., *Time to Treatment With Intravenous Tissue Plasminogen Activator and Outcome From Acute Ischemic Stroke*, JAMA (June 19 2013), https://jamanetwork.com/journals/jama/fullarticle/1697967.

³⁰ See Primary Stroke Services Time Target Recommendations, supra note 15.

³¹ See Cancer Stat Facts: Common Cancer Sites, National Cancer Institute, https://seer.cancer.gov/statfacts/html/common.html#:~:text=Lung%20and%20bronchus%20cancer%20is%20responsi ble%20for%20the%20most%20deaths,deadliest%20cancer%2C%20causing%2050%2C550%20deaths (last visited May 4, 2023).

³² See Lung Cancer Fact Sheet, American Lung Association, https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet (last modified May 27, 2020).

³³ Id.

³⁴ Id.

³⁵ Rebecca Smith-Bindman et al., Rising Use Of Diagnostic Medical Imaging In A Large Integrated Health System, 27 HEALTH AFFAIRS 1491 (2008), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2765780/pdf/nihms-137739.pdf; Kathleen Lang et al., National trends in advanced outpatient diagnostic imaging utilization: an analysis of the medical expenditure panel survey, 2000-2009, 13 BMC MED. IMAGING 40 (2013), available at

https://pubmed.ncbi.nlm.nih.gov/24279724/

³⁶ Lang et al., *supra* note 36.

Measure: Downtime hours per year due to maintenance and interventional radiology procedures.

Baseline: Total Downtime hours: 331.3 hours

Projections: Year 1: 75 hours; Year 2: 50 hours; and Year 3: 25 hours

2. Access – Door to CT for Stroke Patients: Adding a second CT unit will likely decrease time from door to CT for stroke patients. As a result, stroke patients will receive a timely diagnosis that will direct subsequent medical treatment. Through the Proposed Project AJH seeks to maintain and improve average door to CT time.

Measure: Length of time between when patient reaches the Hospital to when a CT scan begins.

Baseline: Average door to CT scan time: 23 minutes

Projections: Year 1: 22 minutes; Year 2: 21 minutes; and Year 3: 20 minutes

F1.b.iii Public Health Value /Health Equity-Focused:

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's needbase, please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g. culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

AJH continually strives to ensure health equity to all populations, including vulnerable and underserved populations. The Proposed Project will increase access to hospital-based CT services and will ensure accessibility of AJH services for low income, medically indigent and/or Medicaid beneficiaries. AJH is committed to serving the community regardless of an individual's ability to pay and does not discriminate based on payor source.

The Proposed Project will increase access to high quality and cost-effective care for all clinically appropriate patients in the proposed service area. A vital component of such access is through the provision of culturally and linguistically competent care to all patients. Additionally, BILH is working to reduce health inequities through the collection of demographic data. By recognizing and responding to differences in cultures, BILH and AJH work to ensure patient understanding and promote a positive patient experience.

A. Ensuring Language Accessibility

AJH is committed to ensuring doctors, nurses, and healthcare providers have the resources to establish a direct relationship with their non-English or limited English-speaking patients through accurate and complete interpretation services which are available 24/7 at no charge. AJH has two language vendors with access to over 300 languages. Each vendor provides 24/7 phone interpretation and document translation as well as video interpretation for specific languages. AJH has a designated Spanish interpreter available on site as well as in-person interpretation through the vendor. AJH offers the use of iPads and web access to a third-party vendor to download the app and use it on any device. Trained language service interpreters assist during hospitalization and inform patients and their families about procedures, medications, and other relevant information.

As its Patient Panel grows in both size and diversity, the Hospital's Interpreter Services Department has expanded to meet its patients' needs. The number of requested and completed encounters increased more than 30% for FY22. AJH currently employs one per diem staff within the department. In addition, AJH has 6 video remote interpreting ("VRI") devices, and dual handled phones on the units which helps reduce waiting time and increase effectiveness and efficiency of interpreter services.

The Department also is staffed and equipped to facilitate communication for deaf and hard of hearing patients. A Certified Deaf Interpreter ("CDI") is available on-call when needed in-person. American Sign Language interpreters are available 24/7 on the VRIs. In addition, assistive devices such as Pocket Talkers, are also available to assist patients. Patients may also use the Hospital's Telecommunications Device for the Deaf ("TDD") to communicate with family or friends and is available for patient use 24 hours a day.

B. REAL Data Collection

BILH recently launched a new initiative to consistently request more detailed and complete demographic information from patients in furtherance of an organizational culture that embraces diversity, equity, and inclusion. Capturing patient diversity demographics, including gender and race, ethnicity, and language ("REAL Data") is foundational to understanding and addressing health disparities in the community. To that end, BILH created a multidisciplinary team of representatives from across the system including staff from patient access services, information services, nursing, social work, community benefits and community relations teams. Working with patient representatives, the multidisciplinary team established a standard set of data along with best practices and processes to capture the data more consistently in the electronic medical record ("EMR").

F1.b.iv Provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

As described throughout this Application, including the section above, the Proposed Project will improve health outcomes and quality of life for AJH's patient panel by expanding access to essential hospital-based imaging services and continuing to ensure those services are accessible to all members of the community it serves. AJH is committed to promoting health equity and to that end, will ensure patients can access the Hospital's services, can effectively communicate with their providers, and will be connected to services outside of the Hospital as required. As a result, the Applicant anticipates that the Proposed Project will result in improved patient care experiences and quality outcomes while promoting health equity.

F1.c Provide evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, how the Proposed Project will create or ensure appropriate linkages to patients' primary care services.

As a community hospital affiliated with primary care offices, specialists, and urgent care centers, integrated medical records are central to promoting quality of care and public health outcomes through effective coordination of care. With respect to the Proposed Project, AJH's EMR serves as the primary link between Radiology, AJH's specialists, and community primary care providers. In the first instance, the EMR allows AJH's radiologists real-time access to a patient's comprehensive medical information, including medical history, lab results, and clinical notes while they are protocoling or reading a study. Once the radiologist's report is complete, the EMR enables imaging results and information to be available to primary care and specialty physicians across the system and integrated into the patient's EMR. The EMR also allows authorized providers outside of the Applicant's system to view their patients' records and send progress notes back for improved continuity of care. This integration ensures that AJH's patient panel benefits from care coordination through better outcomes and improved quality of life.

Furthermore, AJH participates in the MassHealth ACO Program through BIDCO, part of BILHPN and its clinically integrated network. In furtherance of the goals of the Program, BIDCO 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 BIDCO's efforts to improve health care are accomplished through care coordination. Specifically, BIDCO's data analysis and risk management tools are provided to AJH providers, including a Population Health Management Tool that helps primary care physicians monitor patients' health and manage chronic conditions. AJH's links to primary care providers are vital to providing high-quality care and promoting coordination of care. These primary care linkages will continue to enhance care for AJH's patients, including timely access to radiology services that will be achieved through the Proposed Project.

F1.d Provide evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

The Applicant consulted with numerous individuals at multiple regulatory agencies regarding the Proposed Project. The following individuals were consulted with regards to the Proposed Project:

- Dennis Renaud, Director of Determination of Need Program, Massachusetts Department of Public Health;
- Jennica Allen, Manager of Community Engagement Practices, Massachusetts Department of Public Health;
- The Centers for Medicare & Medicaid Services; and
- MassHealth
- F1.e.i Process for Determining Need/Evidence of Community Engagement: For assistance in responding to this portion of the Application, Applicant is encouraged to review Community Engagement Standards for Community Health Planning Guideline. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the Proposed Project.

In addition to relying on the data described throughout this application that demonstrates the need for the Proposed Project, the Applicant also sought to engage the community to elicit feedback from patients and families regarding the Proposed Project. The presentations reviewed the purpose of the Proposed Project, what it would mean for patients and the community, and provided a general overview of the Proposed Project's process. The Proposed Project was presented to the following groups:

- The Hospital's Community Benefits Advisory Council ("CBAC");
- The Hospital's Patient Family Advisory Council ("PFAC");
- Community Meeting.
- F1.e.ii Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value".

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

- Presentation on the details of the proposed project to AJH's PFAC on February 7, 2023. Sixteen (16) individuals were in attendance.
- Presentation on the details of the proposed project to AJH's CBAC on March 21, 2023. Eleven (11) individuals were in attendance.
- Presentation at a Community Meeting on March 31, 2023. Eleven (11) individuals were in attendance.

At each of the presentations the feedback was resolute in the need for a second CT unit and unanimously recognized that lack of redundancy is leading to increased patient access concerns. There was also a significant concern about the overall perception of care that could be provided by AJH given the limitations of having one CT unit at AJH.

Factor 2: Health Priorities

Addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

F2.a. <u>Cost Containment:</u>

Using objective data, please describe, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment.

The Proposed Project will meaningfully contribute to and further the Commonwealth's goals for cost containment by ensuring high-quality CT imaging services are accessible and equitably available to every person. As discussed throughout the Application, the Proposed Project seeks to improve access to an essential component of hospital care. Timely access to CT imaging increases a patient's chance to receive timely treatment that can improve health outcomes and quality of life while avoiding more costly care resulting from later diagnosis and treatment. Moreover, there will be no change in AJH's contracted rates for CT services. In conclusion, the Proposed Project will contribute to the Commonwealth's goals of cost containment by having no impact on costs while ensuring timely access to care.

F2.b. <u>Public Health Outcomes:</u> Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

As discussed throughout this Application, the Applicant anticipates demand for CT imaging will continue to increase as the AJH patient population grows and ages. To serve the Patient Panel, it is necessary that AJH acquire an additional CT unit. An additional CT scan will not only improve access to care and health outcomes, but also decrease costs, contributing to overall public health.

F2.c. <u>Delivery System Transformation:</u> Because the integration of social services and community-based expertise is central to goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

The Applicant will continue to work with patients and primary care providers to ensure patients are connected to services as needed. First, the Applicant's Beth Israel Lahey Healthcare primary care practice locations in Amesbury, Haverhill, Newburyport and Seabrook, screen all patients for Social Determinants of Health 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"). The screener is filled out before the patient's visit on a tablet or paper. If a safety concern is flagged through the screener, the provider is notified immediately to address the issue during the visit.

AJH screens patients for the following needs during each encounter: Housing, Interpersonal Safety, Social Support (e.g., do you live alone), Health Behaviors (e.g., alcohol consumption, smoking, drug use, etc.), and Financial Stability. Employment and Transportation are also screened on a case-by-case basis as determined by the patient's care team. Additionally, certain patient characteristics, such as specific diseases (e.g., diabetes) and high intensity resource utilization may also prompt a needs screening. If a need is identified, a referral is made to a community-based organization or to a resource within the Hospital and/or BILH. Within the emergency department, direct referrals are made for behavioral health and substance use to embedded community partners, such as Recovery Coaches and LinkHouse. Through these approaches, the Applicant has implemented a robust screening and linkages process to identify and address the SDoH impacting its patients.

Factor 5: Relative Merit

F5.a.i Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant 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.

This Proposal: The Proposed Project is for the acquisition of a second CT unit.

Quality: The Proposed Project is the superior option because of the impact it will have on patient outcomes and quality of life. With a second CT unit, AJH will have increased capacity, providing patients with timely access to fundamental diagnostic imaging.

Efficiency: The acquisition of a second CT unit promotes redundancy which will minimize delays in access and care currently caused by unit downtime.

Capital Expense: The total capital expenditure for the CT unit is \$2,100,496.00 million dollars.

Operating Costs: The first-year incremental operating expense of the Proposed Project is \$591,634.00. By year five (5), operating costs are estimated at \$718,666.00.

Alternative Proposal: Do not acquire a second CT unit and continue to serve patients with a single CT unit.

Alternative Quality: This alternative does not address the need of AJH's patient population to have timely access to CT imaging. Delays in diagnosis result in delayed treatment, which can adversely impact patient outcomes and quality of life and increase costs.

Alternative Efficiency: AJH resources will continue to be strained under this alternative. As demand for CT continues to grow, outpatients will experience delayed access to CT imaging as wait times increase. When AJH experiences CT downtime, emergency patients, inpatients, and outpatients must wait or receive lesser imaging or be diverted to another facility. Finally, one CT unit reduces the ability to accommodate interventional CT procedures and expanded LDCT screening. A second unit will introduce flexibility in the schedule to expand these programs. On balance a second CT unit is the superior option for meeting the needs of the Patient Panel.

Alternative Capital Expenses: There are no capital expenses under this alternative.

Alternative Operating Costs: There are no additional operating costs under this option.