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") for the relocation and expansion of the radiation oncology department at Lahey Hospital and Medical Center ("LHMC" or the "Hospital"), located at 41 Burlington Mall Road, Burlington, MA 01805. The new Radiation Oncology Department will accommodate the following: two (2) replacement LINAC units and one (1) replacement computed tomography ("CT") simulator; one (1) high dose radiation therapy ("HDR") procedure room with one (1) mobile CT unit for HDR; 11 exam rooms and space for complementary services; and shell space for a potential third LINAC in the future (the "Proposed Project").

The Applicant 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-Newham, 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 (collectively known as "BILH Hospitals").

LHMC is a world-renowned tertiary medical center known for its innovative technology, pioneering medical treatment, and leading-edge research. LHMC includes two campuses: Lahey Hospital & Medical Center, located in Burlington ("Lahey Burlington"), and Lahey Medical Center-Peabody; and two outpatient satellites. The Proposed Project will be located at Lahey Burlington which has 335 inpatient beds, an ambulatory care center, a 24-hour emergency department, and a Level I trauma center. Lahey Burlington also supports 50 medical and surgical specialties and various ancillary services, including onsite Pharmacy, Laboratory medicine, Anesthesiology, and Radiology.

To meet the needs of its patient panel, the Applicant requests DoN approval to re-locate and expand Lahey Burlington's radiation oncology department ("Department"). Currently, the Department is housed in the John G. Trump building, which is separate and detached from the main Hospital building. The existing Department consists of 8 examination rooms and two linear accelerators ("LINACs") and does not have any dedicated rooms for high-dose rate ("HDR") brachytherapy, nor does it have a dedicated mobile CT for HDR procedures. HDR therapy is currently performed in the Lahey Burlington operating rooms when space and time is available. Lahey Burlington's two LINACs are aging and require replacement, but the Department's current space is not compliant with DPH requirements for modern LINAC machines, and the Trump building's aging infrastructure cannot support renovation.

The Proposed Project will relocate the Department to the first floor of the east side of Lahey Burlington, in a central location that is proximal to the hematology oncology department. The new Department will have (2) vaults that will house the two (2) replacement LINACs. In addition, the Department will have a dedicated HDR procedure room with a mobile CT unit, family consult rooms, and rooms for alternative therapy and behavioral oncology. Finally, the Proposed Project will include shell space for a future 3rd LINAC as demand necessitates. The Proposed Project is necessary to ensure continued and expanded access to radiation therapy for the patient panel through modern facilities and technology, to co-locate and centralize cancer services, and to improve care coordination and patient satisfaction.

Finally, the Proposed Project will meaningfully contribute to Massachusetts' goals for cost containment by providing high-quality cancer care within the community. Accommodating replacement LINACs and

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.

providing dedicated space for HDR treatment will ensure that patients have access to timely services close to home. Further, by improving care coordination and co-locating services, the Proposed Project will improve the efficiency and effectiveness of care provided, thereby reducing costs.

In sum, the Proposed Project Proposed Project is necessary to ensure access to high-quality cancer care, without increasing health care costs. Through the centralization of services and facility improvements afforded by the new facility, the Applicant will improve care delivery as well as health outcomes and quality of life. Accordingly, the Proposed Project meets the factors of review for Determination of Need approval.

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

F1.a.i Patient Panel: 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. <u>Beth Israel Lahey Health Patient Panel</u>

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 Boston² 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 (collectively known as "BILH Hospitals"). BILH's vision is 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 true 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

An estimated five million people reside in the BILH service area.³ 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

² 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.

³ U.S. Census Bureau, *American Community Survey 1-year Estimates for Boston-Cambridge-Newton, MA-NH Metro Area*, CENSUS REPORTER (2021), https://censusreporter.org/profiles/31000US14460-boston-cambridge-newton-ma-nh-metro-area/.

2017 to 2022.⁴ As shown in the table below (Table 1), the BILH Patient Panel consisted of 1,633,109 patients in fiscal year 2022 (FY22)⁵, an increase of 34% from 2020.

Variables	FY2020	FY2020	FY2021	FY2021	FY 2021	FY 2021
Valiables	Count	Percent	Count	Percent	Count	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 ⁶	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%
Race - Other ⁷	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 ⁸ - 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%
Payor - Commercial	610,845	50.08%	687,224	48.13%	869,337	53.23%
Payor - Medicare	320,062	26.24%	363,058	25.43%	424,855	26.02%
Payor - Medicaid	143,168	11.74%	173,940	12.18%	165,605	10.14%
Payor - Multiple Payers	79,086	6.48%	85,629	6.00%	43,266	2.65%
Payor - Other ⁹	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%

B. Lahey Hospital & Medical Center Patient Population Data

LHMC is a world-renowned tertiary medical center known for its innovative technology, pioneering medical treatment, and leading-edge research. LHMC includes two separate hospitals – Lahey Hospital & Medical Center, located in Burlington, and Lahey Medical Center-Peabody – and two licensed facilities: Lahey Hospital & Medical Center- Outpatient Rehabilitation Services at Danvers, and Lahey Outpatient Center-

⁴ HENRY RENSKI ET AL., LONG-TERM POPULATION PROJECTIONS FOR MASSACHUSETTS REGIONS AND MUNICIPALITIES, (UMass Donahue Institute 2015).

⁵ For purposes of the Applicant's and the Hospital's patient panel, the fiscal year is defined as July 1 through June 30.

⁶ Patients for whom a gender is not specified or whose gender varies across visits over the time period are included in "Other."

⁷ 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. ⁸ 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 Includes self-pay, health safety net, and liability insurance coverage other than worker's compensation for an injury event.

Lexington MRI Suite. LHMC is a physician-led, nonprofit group practice with more than 500 physicians and 5,000 nurses, therapists, and other support staff working together.

When compared to the BILH Patient Panel, the Applicant offers the following observations about LHMC's Patient Population:

- **Age** The LHMC patient population has a higher proportion of patients aged 65 and older than the BILH Patient Panel (34.6% vs. 28.1%). Additionally, the BILH Patient Panel has a slightly higher percentage of patients aged 0 to 17 (11.1% compared to 5%).
- **Race** 83% of the LHMC patient population identify as White compared to 74% of the BILH Patient Panel. Approximately 5% of the LHMC patient population identifies as Asian compared to 6.5% of the BILH patient population.
- **Ethnicity** Similar percentages of patients identified as Hispanic, 5% of the LHMC patient population compared to 6% of the BILH Patient Panel.
- **Payer Mix** Commercial payers are the primary payer source for both BILH and LHMC patients (53% and 50% respectively), followed by Medicare (26% and 32.5% respectively).

Variables	FY2020	FY2020	FY2021	FY2021	FY2022	FY2022
Variables	Count	Percent	Count	Percent	Count	Percent
Total Unique Patients	227,129	100.00%	279,330	100.00%	270,649	100.00%
Age - 0 to 17	3,894	1.71%	9,843	3.52%	13,594	5.02%
Age - 18-64	142,940	62.93%	176,751	63.28%	163,465	60.40%
Age - 65+	80,295	35.35%	92,736	33.20%	93,590	34.58%
Gender - Male	104,097	45.83%	127,090	45.50%	121,461	44.88%
Gender - Female	122,923	54.12%	152,121	54.46%	149,051	55.07%
Gender - Other	109	0.05%	119	0.04%	137	0.05%
Race - White	185,684	81.75%	226,162	80.97%	225,560	83.34%
Race - Black or African American	5,294	2.33%	6,152	2.20%	6,843	2.53%
Race - American Indian or Alaska	206	0.09%	252	0.09%	227	0.08%
Native	200	0.0370	232	0.0370	227	0.0070
Race - Asian	10,019	4.41%	12,141	4.35%	13,160	4.86%
Race - Native Hawaiian or Other	64	0.03%	77	0.03%	91	0.03%
Pacific Islander	01	0.0370	,,,	0.0370	51	0.0370
Race - Other	23,980	10.56%	32,072	11.48%	20,648	7.63%
Race - Unknown	159	0.07%	139	0.05%	1,888	0.70%
Race - Patient Declined	1,723	0.76%	2,335	0.84%	2,232	0.82%
Ethnicity - Hispanic/Latino	9,684	4.26%	11,260	4.03%	13,959	5.16%
Ethnicity - Not Hispanic/Latino	210,912	92.86%	250,458	89.66%	247,048	91.28%
Ethnicity - Unknown	6,533	2.88%	17,612	6.31%	9,642	3.56%
Payor - Commercial	111,947	49.29%	142,482	51.01%	135,012	49.88%
Payor - Medicare	77,020	33.91%	87,298	31.25%	87,852	32.46%
Payor - Medicaid	23,456	10.33%	31,186	11.16%	7,973	2.95%
Payor - Multiple Payors	7,513	3.31%	8,599	3.08%	8,094	2.99%
Payor - Other	7,193	3.17%	9,765	3.50%	31,718	11.72%

TABLE 2: LHMC PATIENT PANEL DEMOGRAPHICS

The majority of LHMC's patients reside in northeast Massachusetts, in either Middlesex or Essex County. The table below shows the top 15 cities and towns from which LHMC's patients originated.

TABLE 3: LHMC PATIEN	T POPULATION	GEOGRAPHICS	5

Geographic Origin	FY2020	FY2020	FY2021	FY2021	FY2022	FY2022
	Count	Percent	Count	Percent	Count	Percent
Peabody	12,188	5.18%	14,393	6.11%	14,555	6.18%
Burlington	10,311	4.38%	12,449	5.29%	12,010	5.10%
Billerica	10,309	4.38%	12,455	5.29%	11,864	5.04%
Woburn	9,345	3.97%	13,773	5.85%	12,751	5.42%
Lexington	7,288	3.10%	9,252	3.93%	8,662	3.68%
Beverly	6,623	2.81%	9,242	3.93%	9,097	3.86%
Lynn	5,567	2.36%	6,724	2.86%	7,102	3.02%
Salem	5,360	2.28%	6,594	2.80%	6,595	2.80%
Danvers	5,200	2.21%	7,277	3.09%	7,377	3.13%
Lowell	5,079	2.16%	5,781	2.46%	4,963	2.11%
Wilmington	5,012	2.13%	7,955	3.38%	7,370	3.13%
Arlington	4,787	2.03%	6,971	2.96%	6,761	2.87%
Tewksbury	4,677	1.99%	6,895	2.93%	6,334	2.69%
Gloucester	3,956	1.68%	6,892	2.93%	6,422	2.73%
Bedford	3,853	1.64%	4,572	1.94%	4,318	1.83%

C. LHMC Radiation Oncology Patient Population Demographics

In FY22, 650 unique patients received care from Lahey Burlington's radiation oncology service, a 10% increase from the previous year. More than two-thirds of patients were over the age of 65, with less than 4% of patients under the age of 45.

Variables	FY2020	FY2020	FY2021	FY2021	FY2022	FY2022
	Count	Percent	Count	Percent	Count	Percent
Total Unique Patients	601	100%	588	100%	650	100%
Age - 0-17	0	0.0%	0	0.0%	0	0.0%
Age - 18-25	0	0.0%	0	0.0%	2	0.3%
Age - 26-45	21	3.5%	12	2.0%	24	3.7%
Age - 46-64	166	27.6%	193	32.8%	189	29.1%
Age - 65+	414	68.9%	383	65.1%	435	66.9%
Gender - Male	284	47.3%	278	47.3%	312	48.0%
Gender - Female	317	52.7%	310	52.7%	338	52.0%
Race/Ethnicity - White	543	90.3%	528	89.8%	588	90.5%
Race/Ethnicity - Black or African	15	2.5%	12	2.0%	19	2.9%
American	13	2.3%	12	2.0%	19	2.9%
Race/Ethnicity - Asian	19	3.2%	24	4.1%	21	3.2%
Race/Ethnicity - Other ¹⁰	24	3.99%	24	4.08%	22	3.38%

TABLE 4: LHMC RADIATION ONCOLOGY PATIENT DEMOGRAPHICS

The table below shows the top 20 cities and towns from which LHMC's radiation oncology patients originated.¹¹ More than 65% of patients live in Middlesex County, followed by Essex County (8%).

2020 Town 2020		2020 2020	2021 Town	2021	2021	2022 Tour	2022	2022
2020 Town	Count	Percent	2021 Iown	Count	Percent	2022 Town	Count	Percent
Billerica	56	9.32%	Billerica	66	11.22%	Burlington	56	8.62%
Burlington	38	6.32%	Woburn	44	7.48%	Billerica	55	8.46%
Woburn	38	6.32%	Burlington	30	5.10%	Woburn	53	8.15%
Wilmington	25	4.16%	Lexington	22	3.74%	Wilmington	32	4.92%
Arlington	20	3.33%	Wilmington	22	3.74%	Lexington	31	4.77%
N. Billerica	20	3.33%	Andover	16	2.72%	Tewksbury	27	4.15%
Tewksbury	20	3.33%	Bedford	16	2.72%	Bedford	19	2.92%
Lexington	19	3.16%	Haverhill	15	2.55%	Stoneham	18	2.77%
Chelmsford	17	2.83%	Reading	15	2.55%	Arlington	15	2.31%
Reading	15	2.50%	Tewksbury	14	2.38%	Chelmsford	15	2.31%
Stoneham	14	2.33%	Chelmsford	13	2.21%	Methuen	15	2.31%
Dracut	-	-	N. Billerica	-	-	Reading	-	-
Andover	-	-	Stoneham	-	-	N. Billerica	-	-
Bedford	-	-	Westford	-	-	Andover	-	-
N. Reading	-	-	Amherst	-	-	Winchester	-	-
Medford	-	-	N. Reading	-	-	Lowell	-	-
Tyngsborough	-	-	Winchester	-	-	N. Andover	-	-
Westford	-	-	Arlington	-	_	Malden	-	-
Littleton	-	-	Lawrence	-	-	Dracut	-	-
Methuen	-	-	Lowell	-	-	Hudson, NH	-	-

¹⁰ For confidentiality, "Other" includes all races/ethnicities not separately listed.

¹¹ The patient count is not provided for cities with fewer than 13 patients.

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 requests DoN approval to re-locate and expand LHMC's radiation oncology department. The new space will accommodate two (2) replacement LINAC units and one (1) replacement CT simulator; one (1) high dose radiation therapy ("HDR") procedure room with one (1) mobile CT unit for HDR; 11 exam rooms and space for complementary services; and shell space for a potential third LINAC in the future (the "Proposed Project"). Regarding the space for complementary services, the new department will include family consult rooms, alternative therapy rooms, social work, and behavioral oncology services. Through the Proposed Project, the Applicant seeks to ensure that the Hospital will be able to meet future demand in the community for high-quality, state-of-the-art radiation therapy services. The Proposed Project will offer an improved patient care experience close to home.

EXPANDED ACCESS AND IMPROVED PROVISION OF CARE THROUGH THE PROPOSED PROJECT

To ensure the continued provision of radiation oncology services at the Hospital and to meet the need for projected demand, the Proposed Project will address a number of physical plant limitations of the current radiation oncology department. Additionally, the Proposed Project will improve the patient care experience by facilitating care coordination and state-of-the-art treatment technologies.

The impetus for the Proposed Project is the Hospital's need to replace its existing LINACs. The two existing LINACs are both older units facing formal obsolescence, meaning that the vendor will no longer support maintenance or parts for the machines. The Hospital has already received notice of obsolescence from the vendor for one unit, with an obsolescence date of July 2023, and it anticipates that it will receive a notice of obsolescence for the other unit within the next three years. The age of the units has led to frequent and lengthy downtime, which impacts patient care. The Hospital faces a significant risk of more frequent and extended periods of downtime or complete failure once the LINACs can no longer be maintained, which would result in major disruptions to patient care and, eventually, eliminate the Hospital's ability to provide radiation oncology services altogether.

In order to ensure continuity of services at the Hospital, the Hospital plans to replace the older LINAC units. However, the current LINAC vaults in the existing radiation oncology department do not satisfy Facility Guidelines Institute ("FGI") and DPH requirements for the new machines. Specifically, the current vaults do not meet the modern equipment clearance requirements under FGI and DPH standards, and the building itself does not meet requirements for housing four or more patients incapable of self-preservation, nor the requirements to house inpatients. Further, the building infrastructure cannot support a major renovation. Therefore, the only option is to relocate the LINACs to a new location at the Hospital with space to accommodate compliant LINAC vaults. Not only will replacing the LINACs allow for the continued provision of radiation in the community, it will also improve the patient experience, as the newer machines will reduce treatment times. Reducing treatment times is particularly important for patients who benefit from breathhold techniques during radiation therapy, as they will have reduced breath-hold times and cycles.

In addition, the Proposed Project will add a dedicated operating room ("OR") space to perform high-dose rate ("HDR") brachytherapy, as well as a mobile CT unit dedicated to imaging *during* HDR procedures. Currently, Lahey Burlington does not have dedicated operating room space to perform HDR treatment, nor does it have a dedicated CT scanner for imaging during HDR procedures. Therefore, Lahey Burlington currently performs HDR operative insertions in a general operating room ("OR") when time is available, using the CT scanners in a separate non-operative space, requiring transport time and repositioning of the

patient. This arrangement significantly limits the number of HDR cases that can be performed at the Lahey Burlington, such that the Hospital cannot meet demand for this convenient, typically outpatient form of treatment, which can reduce the risk of damage to nearby healthy tissue, and in turn, fewer side effects for the patient.¹² Additionally, the current process adds to treatment length for HDR patients because the patient must wake up from anesthesia, recover in the Post-Anesthesia Care Unit, and then be transported to the CT simulator for imaging.

Accordingly, the Proposed Project will improve patient quality of life by expanding access to HDR services and by reducing transfers that patients need to make between the OR and the Department. Further, the duration of HDR procedures would be reduced under the Proposed Project by allowing for CT imaging *during* the procedure, which would eliminate intermediate transfer steps, allow for imaging and planning of the HDR treatment delivery while the patient is still under anesthesia in the OR, and decrease the possibility of applicator motion prior to the procedure.

The Proposed Project will also improve care coordination and overall access to services. The Hospital's existing Radiation Oncology department is located in a separate area of the Hospital from the hematology/oncology department. Outpatients must travel a lengthy distance from the radiation oncology suite to the hematology/oncology department if they have appointments for both services on the same day. The Proposed Project will bring the two departments closer together, reducing travel distance for patients and improving care coordination between the two departments.

Further impacting the efficiency of the existing services is the limited number of examination rooms and lack of space to provide wraparound services within the department. The existing department has 8 exam rooms, which are not adequate to accommodate patients of size. The Proposed Project will increase the number of exam rooms from 8 to 11 and expand the size of the rooms to improve patient comfort. Additionally, the Proposed Project will include space for wrap-around services and integrative wellness therapies that will allow the Hospital to support patients' physical and emotional well-being in a location that is co-located with treatment. There also will be family consult rooms for patients and their families to meet with their multi-disciplinary healthcare team. Finally, the new facility will include multiple elevators and entrances to provide easy access to the department for patients. Through the design of the new department, the Applicant will be able to provide greater access to radiation oncology services in the community and to centralize all outpatient oncology services to improve the patient experience.

HISTORICAL UTILIZATION AND PROJECTED DEMAND

The population in Lahey Burlington's service area is expected to grow significantly in the next 20 years, with particularly pronounced increases in the population aged 65 and over. Between 2020 and 2040, the UMass Donahue Institute estimates that the population in Lahey Burlington's primary service area will grow from 416,331 in 2020 to 445,057 in 2040, a growth of approximately 7%.¹³ Remarkably, the sub-population of adults aged 65 and over will grow by 43% during the same time period, reflecting a rapidly aging population.¹⁴ As the population grows and ages, the Applicant expects that there will be increased demand for radiation oncology services at Lahey Burlington.

The likelihood of being diagnosed with cancer increases with age. The CDC estimates that more than twothirds of all new cancers are diagnosed in patients aged 60 years and older.¹⁵ Moreover, the largest increase in new diagnoses is expected to impact adults ages 75 and over.¹⁶ These increases are believed to be attributed to the body's decreasing ability to repair DNA cells as adults age.¹⁷ As a result of increased life expectancy, the number of cancer cases is expected to increase among adults over the age of 65.¹⁸

¹² See infra notes 45-49.

¹³ UMASS DONAHUE INSTITUTE POPULATION ESTIMATES PROGRAM, Massachusetts Population Projections (2023),

http://www.pep.donahue-institute.org/

¹⁴ See id.

 ¹⁵ CTRS. FOR DISEASE CONTROL, DIV. CANCER PREVENTION & CONTROL, *Cancer Prevention During Older Adulthood* (Sept. 3, 2021), https://www.cdc.gov/cancer/dcpc/prevention/older-adulthood.htm.
¹⁶ Id.

¹⁷ Jaimin Patel et al., DNA Damage and Mitochondria in Cancer and Aging, 41 CARCINOGENESIS 1625, 1625–1634 (2020).

¹⁸ Id.

The need for access to radiation therapy for the Lahey Burlington patient population has already increased in recent years, despite interruptions caused by the pandemic. Between FY20 and FY22, the number of unique patients receiving care from LHMC Burlington's radiation oncology service increased by 8.2%. This includes a 53.0% increase in stereotactic radiation therapy treatments and a 3.5% increase in IMRT treatments. The following table details LHMC Burlington's historical radiation oncology utilization and patient volume.

Treatment type	FY2020	FY2021	FY2022
External Beam	3,888	3,582	3,567
Stereotactic	436	504	667
IMRT	4,723	4,484	4,886
All LINAC Treatments	9,047	8,571	9,120
HDR	164	144	105
Total Radiation Treatments	9,211	8,714	9,225
Total Radiation Patients	601	588	650

TABLE 6: HISTORICAL UTILIZATION

The Applicant anticipates that its Patient Panel will require continued access to radiation oncology services at Lahey Burlington. Specifically, the Applicant anticipates that radiation oncology volume at Lahey Burlington will increase by 5.5% between FY22 and FY27. This includes a 13% increase in stereotactic radiation therapy and a 138% increase in HDR treatment. The projections are based on historical utilization trends, operational efficiency and added capacity anticipated to result from the Proposed Project, and demand projections due to new technology and demographic changes. These projections are detailed in the following table.

TABLE 7: PROJECTED UTILIZATION

Treatment type	Year 1	Year 2	Year 3	Year 4	Year 5
External Beam Treatment	3,630	3,612	3,624	3,633	3,642
Stereotactic	713	745	747	749	751
IMRT	5,023	5,048	5,065	5,075	5,088
All LINAC Treatments	9,366	9,405	9,435	9,458	9,481
HDR	160	239	243	247	250
Total Radiation Patients	656	661	667	673	679
Total Radiation Treatments	9,526	9,644	9,679	9,704	9,731

In addition to the CDC's projection that the number of overall cancer diagnoses will increase, researchers also predict increases in certain types of cancer that are prevalent in the Lahey Burlington patient population. For example, between 2020 and 2030, researchers anticipate increases of 6,000-32,000 in the annual number of lung and breast cancer cases, which are two of the five most common diagnoses among historically treated by the radiation therapy department.¹⁹ Additionally, the Applicant anticipates that it will see increased demand for stereotactic radiation therapy. Stereotactic body radiation therapy ("SBRT") is a newer form of radiation therapy that provides a treatment option for patients who are not surgical candidates and who may otherwise receive no treatment.²⁰ SBRT is primarily used to treat early-stage lung cancer and pancreatic cancer, as well as cancers that have spread to the lung, liver, adrenal gland, and spine.²¹ This is notable, as lung cancer is among the five most common diagnoses in the Lahey Burlington patient population. The use of SBRT has increased rapidly in recent years and is expected to continue to increase

 ¹⁹ Lola Rahib et al., Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States, 74 CANCER RSCH. 2913, 2913-2921 (2014).
²⁰ Id.

²¹ Kavitha Prezzano et al., *Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer: A Review*, 10 WORLD J. CLINICAL ONCOLOGY 14, 14-27 (2019); Maged Ghaly et al., *New Potential Options for SBRT in Pancreatic Cancer*, 4 CANCER MEDICINE J. (Supplement 3) 41, 41-50 (2021); Chia-Lin Tseng et al, *Spine Stereotactic Body Radiotherapy: Indications, Outcomes, and Points of Caution*, 7 GLOBAL SPINE J. 179, 179-197 (2017).

as cancer incidence increases.²² Another form of stereotactic radiation therapy, stereotactic radiosurgery ("SRS") has been shown to be an effective and potentially lower risk treatment option for patients with brain and lung tumors, among others.²³ Brain cancer is also among the five most common diagnoses of the Lahey Burlington patient population. Finally, the Applicant expects to greatly expand capacity for HDR treatment through the Proposed Project.

CONCLUSION

For the reasons discussed above, the Proposed Project is necessary to ensure the Hospital's existing and future Patient Panel has continued access to radiation oncology services close to home and within their current system. Given the demand projections for the Patient Panel, the Proposed Project will ensure continued access to high-quality cancer and cardiac services close to home for the Hospital's Patient Panel. As a result of the Hospital's undersized radiation oncology unit and outdated LINAC vaults, the proposed new facility is needed to address the physical plant limitations that cannot be remedied through additional renovations. In addition to the significantly larger footprint that will be provided through the Proposed Project, the new facility will include elements that are necessary for a truly patient-centered, accessible, and coordinated care experience. To that end, the Proposed Project will facilitate the provision of high-quality, patient-centered care within the community with expanded access to radiation oncology services.

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 by creating a centralized environment for the continued provision of outpatient cancer services in the community. These improvements, including the expansion of services, are necessary to ensure access to high-quality cancer services remain available to Lahey Burlington's patients close to home.

First, the Proposed Project will allow the Applicant to ensure the continued provision of radiation oncology services in Burlington. Without the Proposed Project, Lahey Burlington will not be able to continue the majority of its radiation oncology services, including external beam radiation, intensity-modulated radiation therapy, and stereotactic treatment. As a result, current and future patients would need to seek services farther from home and potentially outside of the BILH network. Similarly, the Proposed Project seeks to expand capacity to HDR treatment, allowing more current and future patients to receive these services in their community.

Moreover, the Proposed Project will re-locate the radiation oncology service into an environment that meets or exceeds current design standards for hospital facilities, as well as a location much closer to the Hospital's hematology oncology department. As discussed in Section F1.a.ii., the Hospital currently provides radiation oncology services in an aging building that cannot be renovated to meet the size requirements needed for the replacement LINACs. However, in planning for the machines' future replacements, adequately-sized vaults were previously poured as part of a separate renovation project at the Hospital's Burlington campus, further contributing to the reasonableness of costs for the Proposed Project. Therefore, the Proposed Project will compete on the basis of price and health care spending by ensuring access to radiation treatment close to home and through cost-effective construction.

²² J.K. Jang et al., *Temporal Trends in the Utilization of Stereotactic Body Radiotherapy for Non-Small Cell Lung Cancer in the United States*, 105 INT'L J, RADIATION ONCOLOGY, BIOLOGY, PHYSICS (Supplement 2019) E511 (2019).

²³ J. Li et al., Stereotactic Radiosurgery Versus Whole-brain Radiation Therapy for Patients with 4-15 Brain Metastases: A Phase III Randomized Controlled Trial, 108 INT'L J, RADIATION ONCOLOGY, BIOLOGY, PHYSICS (Supplement) S21-S22 (2020).

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

Evidence-based literature supports the importance of access to radiation therapy for oncology patients and in turn, supports the need for the Proposed Project.

Α. Role of Linear Accelerators in Radiation Therapy

External Beam Radiation Therapy

The most common form of radiation therapy is external beam radiation therapy because of its ability to serve as the only form of treatment, in conjunction with surgery or chemotherapy, or as a palliative therapy to relieve a patient's symptoms.²⁴ External radiation is typically delivered using a linear accelerator, or LINAC. The machine produces high energy x-rays or electrons that are able to precisely target the tumor while leaving the surrounding healthy tissue intact.²⁵ During the treatment, patients are positioned on a moveable treatment couch that can be moved so that the patient does not move during the treatment.²⁶ Additionally, the LINAC's beam can be rotated around the patient, further ensuring radiation is delivered directly to the tumor.²⁷ Over the course of a patient's treatment, the cancer cells will be destroyed, in turn stopping the growth of the tumor and the disease.²⁸ Importantly, treatments using external radiation technology can be highly customized depending on the patient and their cancer. For example, patients whose tumors are located in close proximity to key organs may be eligible for Intensity-modulated radiation therapy ("IMRT").²⁹ Additional forms of external radiation include stereotactic radiosurgery ("SRS") and stereotactic body radiation therapy ("SBRT").³⁰ Both treatments deliver a high dose of radiation to the head or body, respectively, resulting in outcomes so precise, they're equated to surgery.³¹

Intensity-Modulated Radiation Therapy

As noted above, IMRT is a form of external beam radiation therapy that uses smaller beams of radiation to minimize damage to surrounding tissue.³² IMRT allows for a more precise radiation dose that conforms to the shape of the tumor by regulating the intensity of the radiation beam in multiple small volumes.³³ This requires that the treatment be carefully planned, including computerized dose calculations to determine the most appropriate dose intensity pattern.³⁴ During the treatment, combinations of multiple intensitymodulated fields coming from different beam directions provide the maximum radiation dose to the tumor determined during planning.³⁵ By providing a higher radiation dose on the tumor, IMRT is able to minimize exposure elsewhere.³⁶ Moreover, treatment toxicity may be lessened. However, given the additional time

³⁰ NAT'L CANCER INSTITUTE, External Beam Radiation Therapy for Cancer (May 1, 2018), https://www.cancer.gov/aboutcancer/treatment/types/radiation-therapy/external-beam [hereinafter NCI, External Beam]. ³¹ See, e.g., Zhen Liu et al., Comparison of Surgical Resection and Stereotactic Radiosurgery in the Initial Treatment of Brain

³² See AM. COLL. RADIOLOGY, ACR-ARS Practice Parameter for Intensity-Modulated Radiation Therapy (IMRT) (2021),

https://www.acr.org/-/media/ACR/Files/Practice-Parameters/imrt-ro.pdf. NCI. External Beam, supra note 30.

²⁴ NAT'L CANCER INSTITUTE, Radiation Therapy to Treat Cancer (updated Jan. 8, 2019), https://www.cancer.gov/aboutcancer/treatment/types/radiation-therapy [hereinafter NCI, Radiation Therapy]. ²⁵ Nat'L CANCER INSTITUTE, Types of Radiation Therapy, <u>https://training.seer.cancer.gov/treatment/radiation/types.html</u>.

²⁶ Sarah Hegarty et al., Please Place Your Seat in the Full Upright Position: A Technical Framework for Landing Upright Radiation Therapy in the 21st Century. 12 FRONTIERS ONCOLOGY (Article) 821887 (2022).

²⁷ Id.

²⁸ NCI, Radiation Therapy, supra note 24.

²⁹ A Taylor & MEB Powell, Intensity-Modulated Radiotherapy--What Is It? 4 CANCER IMAGING 68, 68-73 (2004).

Metastasis, 98 STEREOTACTIC & FUNCTIONAL NEUROSURGERY 404, 404-415 (2020); Joe Y Chang et al., Stereotactic Ablative Radiotherapy Versus Lobectomy for Operable Stage I Non-Small-Cell Lung Cancer: A Pooled Analysis of Two Randomised Trials. 16 LANCET ONCOLOGY 630, 630-7 (2015).

³³ Id. ³⁴ Id.

³⁵ Id.

³⁶ *Id*; Taylor & Powell, *supra* note 29.

needed for planning, overall treatment times are longer than with conventional radiation therapy, including time to start and daily treatments.³⁷

Stereotactic Treatment

SRS and SBRT are noninvasive methods of treating tumors in the brain (SRS) and throughout the body (SBRT) with very precise, high-dose radiation beams delivered in one to five outpatient procedures.³⁸ During treatment, patients lie comfortably while the advanced cancer treatment system targets their tumor and delivers numerous high-dose radiation beams directly to the tumor while sparing surrounding healthy tissue. SRS and SBRT do not require surgery or sedation, and patients typically experience minimal side effects due to the highly focused nature of treatment, which minimizes radiation exposure to normal tissue and organs.³⁹ Initial studies suggest that, despite its minimal side effects and shorter treatment times, SBRT and SRS are at least as effective as conventional radiation therapy,⁴⁰ and that SBRT is a seffective as surgery for certain patients.⁴¹ SBRT is a particularly useful treatment option for patients with small tumors and patients who are poor candidates for surgery,⁴² and it is primarily used to treat early-stage lung cancer and pancreatic cancer, as well as cancers that have spread to the lung, liver, adrenal gland, and spine.⁴³ SRS is commonly used to treat brain tumors, as well as cancers in the neck, lungs, liver, spine.⁴⁴

B. <u>High-Dose Rate Brachytherapy</u>

Another form of radiation therapy is brachytherapy, which is delivered internally through the placement of radiation source such as a seed, ribbon, or capsule in or near the patient's tumor.⁴⁵ Similar to external radiation, the internal radiation source works to destroy cancer cells only during the treatment procedure, in turn eliminating exposure for hospital staff and individuals physically close to the patient.⁴⁶

High-dose rate ("HDR") brachytherapy offers a convenient treatment option for patients because it involves a shortened treatment time as well as a reduced recovery time.⁴⁷ As a result, the procedure is typically performed on an outpatient basis.⁴⁸ Additional benefits include reduced risk of damage to nearby healthy tissue, and in turn, fewer side effects for the patient.⁴⁹ HDR is often used to treat cancers of the head and neck, breast, cervix, and prostate.⁵⁰ Breast and prostate cancer are among the most commonly treated cancers at Lahey Burlington.

Further adding to the convenience of the procedure, hospitals may use imaging, such as CT scanners, during the treatment procedure to help guide the devices into place and confirm accurate placement.⁵¹

⁴⁵ NAT'L CANCER INSTITUTE, *Brachytherapy to Treat Cancer* (updated Jan. 29, 2019), <u>https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/brachytherapy</u> [hereinafter NCI, *Brachytherapy*]. ⁴⁶ *Id*.

³⁷ WEILL CORNELL MEDICINE, RADIATION ONCOLOGY, *IMRT*, <u>https://radiationoncology.weillcornell.org/clinical-services-and-technologies/external-beam-radiation-therapy/imrt</u>.

³⁸ NCI, *External Beam*, *supra* note 30.

³⁹ JOHNS HOPKINS MEDICINE, *Stereotactic Radiosurgery*, <u>https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/stereotactic-radiosurgery</u>.

⁴⁰ Joseph Abi Jaoude, *Stereotactic Versus Conventional Radiation Therapy for Patients With Pancreatic Cancer in the Modern Era*, 6 ADVANCES RADIATION ONCOLOGY 100763 (2021);6(6); Li et al, *supra* note 23.

⁴¹ Ashwin Shinde et al., Stereotactic Body Radiation Therapy (SBRT) for Early-Stage Lung Cancer in the Elderly. 45 SEMINARS ONCOLOGY 210-219 (2018).

⁴² Jang et al., *supra* note 22.

⁴³ See supra note 21 and accompanying text.

⁴⁴ MAYO CLINIC, Stereotactic Radiosurgery, <u>https://www.mayoclinic.org/tests-procedures/stereotactic-radiosurgery/about/pac-20384526</u>.

⁴⁷ AM. BRACHYTHERAPY Soc'Y, *Brachytherapy Frequently Asked Questions*, <u>https://www.americanbrachytherapy.org/resources/for-</u>patients/brachytherapy-frequently-asked-questions/.

⁴⁸ NCI, *Brachytherapy, supra* note 45; Hideya Yamazaki et al., *High Dose Rate Brachytherapy for Oral Cancer*, 54 J. RADIATION RSCH. 1, 1-17 (2013).

 ⁴⁹ AM. COLL. RADIOLOGY, ACR-ABS-ASTRO Practice Parameter for the Performance of Radionuclide-Based High-Dose-Rate Brachytherapy (2020), <u>https://www.acr.org/-/media/ACR/Files/Practice-Parameters/hdr-brachyro.pdf</u>.
⁵⁰ Id.

⁵¹ AM. COLL. RADIOLOGY, ACR-ASTRO Practice Parameter for Image-Guided Radiation Therapy (IGRT) (2019), https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IGRT-RO.pdf.

Using imaging during brachytherapy allows providers to optimize the dose distribution, and using CT imaging in particular during brachytherapy has been shown to improve patient outcomes.⁵² Imaging during the procedure removes the following time-intensive steps that must be completed prior to radiation planning: waking up the patient from anesthesia, recovering them in the Post-Anesthesia Care Unit, and then transporting them to the CT simulator. Furthermore, the ability to plan and deliver the radiation treatment with the patient under general anesthesia ensures that the HDR catheters do not migrate, eliminating the need for time-intensive image reverification and potential repositioning of the catheters.

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 will report on the following measures of patient satisfaction and quality of care. The measures are discussed below and will be reported to DPH on an annual basis following implementation of the Proposed Project.

A. LINAC Project

1. **Patient Satisfaction**: Patients that are satisfied with their care are more likely to seek additional treatment when necessary.

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

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

Denominator = Total number of survey respondents

Baseline, Projections, and Monitoring: As the Proposed Project will not be implemented until construction is complete, the Applicant will provide baseline measures and three years of projections one year following implementation of the Proposed Project.

2. Treatment Duration: This measure will monitor the average length of SBRT and SRS treatments. As a result of the Proposed Project, the Applicant anticipates that treatment lengths will decrease, thereby improving the patient's experience and comfort.

Measure: SBRT/SRS treatment length will be used to determine the impact of the Proposed Project on quality of life and health outcomes.

Numerator = Total minutes of SBRT/SRS treatment time per month

Denominator = Total number of SBRT/SRS treatments per month

Baseline, Projections, and Monitoring: As the Proposed Project will not be implemented until construction is complete, the Applicant will provide baseline measures and three years of projections one year following implementation of the Proposed Project.

⁵² TP Hellebust, *Place of Modern Imaging in Brachytherapy Planning*. 22 CANCER RADIOTHERAPIE 326, 326-333 (2018).

B. HDR Project

3. Patient Satisfaction: Patients that are satisfied with their care are more likely to seek additional treatment when necessary. LHMC staff will review patient satisfaction scores from Press Ganey related to overall patient satisfaction.

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

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

Denominator = Total number of survey respondents

Baseline, Projections, and Monitoring: As the Proposed Project will not be implemented until construction is complete, the Applicant will provide baseline measures and three years of projections one year following implementation of the Proposed Project.

4. Treatment Duration: This measure will monitor the average length of HDR procedures. As a result of the Proposed Project, the Applicant anticipates that treatment lengths will decrease, thereby improving the patient's experience and comfort.

Measure: HDR treatment length will be used to determine the impact of the Proposed Project on quality of life and health outcomes.

Numerator = Total minutes of HDR treatment time per month

Denominator = Total number of HDR treatments per month

Baseline, Projections, and Monitoring: As the Proposed Project will not be implemented until construction is complete, the Applicant will provide baseline measures and three years of projections one year following implementation of the Proposed Project.

5. **Treatment Access:** This measure will monitor the total number of patients who receive HDR treatment at LHMC Burlington following implementation of the Proposed Project.

Measure: By tracking the number of patients treated using HDR, LHMC will be able to assess how the Proposed Project has improved access.

Baseline, Projections, and Monitoring: As the Proposed Project will not be implemented until construction is complete, the Applicant will provide baseline measures and three years of projections one year following implementation of the Proposed Project.

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.

The Proposed Project will work to reduce health inequity through increasing and improving access to radiation oncology therapies to all members of LHMC's community. LHMC welcomes all patients and does not discriminate on the basis of age, race, ethnicity, gender/gender-identity, physical ability, sensory or speech limitations, or religious, spiritual and cultural beliefs, nor a patient's ability to pay or payor source.

LHMC has implemented to following initiatives to facilitate equitable access to its services, including radiation oncology.

A. Ensuring Language Accessibility

LHMC is committed to ensuring doctors, nurses, and healthcare providers have the resources to be able to establish a direct relationship with their non-English or limited English-speaking patients through accurate and complete interpretation services which are available at no charge. LHMC offers multi-lingual services in person, by video, and by telephone. These services are available for 140 different languages and can be used 24-hours a day. Trained language service interpreters can assist during hospitalization and inform patients and their families about procedures, medications and other important information. LMHC's inperson staff interpreters provide interpreting in 12 different languages. Two remote interpreting services vendors offer interpreting in over 250+ languages, about 40 via video and 250+ via audio-only.

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 25% for FY22. LHMC currently employs 14 full time/part time staff and 1 full time/2 per diem staff (to be filled) within the department. In addition, LHMC has 106 video remote interpreting ("VRI") devices across in-patient/outpatient settings, which helps reduce waiting time and increase effectiveness and efficiency of interpreter services. If additional resources are needed, LHMC uses three agencies to meet the requests for in-person interpreters that cannot be filled by in-house staff. Additionally, LMHC has contracts with two vendors for remote interpreting (audio/video) needs.

Finally, LHMC has a full-time American Sign Language ("ASL") interpreter on staff. Additional in-person ASL interpreting needs are met through LMHC's collaboration with Massachusetts Commission for the Deaf and Hard of Hearing and through LMHC's other contracted interpreter vendor. Remote video interpreting devices are available across the system for encounters that can be effectively completed via video. LHMC has similar assistive listening devices available for all patients with hearing loss who would benefit from them. They are distributed across in-patient and out-patient settings. To communicate with patients at home, LHMC uses TTY and texting, and it is in the process of implementing a videophone device that either connects to other Deaf users directly or routes through an ASL relay interpreter.

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 in order to more consistent capture the data 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.

The Proposed Project will improve health outcomes and quality of life for LHMC's patient panel by maintaining and expanding access to radiation oncology treatments in Burlington and by continuing to ensure those services are accessible to all members of the community it serves. LHMC 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.

The Proposed Project will improve care continuity and coordination of care for radiation oncology patients by maintaining LINAC access and expanding access to HDR treatment at Lahey Burlington. Without these services, patients would be forced to seek care father from home, and potentially outside of the BILH system. The new radiation oncology department will be more centrally located and much closer to the hematology oncology department, facilitating improved coordination of care. This new location will also be closer to other key departments within the hospital, making it easier for patients to travel to other specialties. The new co-location of social work and behavioral oncology within the radiation oncology suite will also provide easier access to these services, while the dedicated alternative therapy room will provide greater access to massage therapy and acupuncture directly within the suite. The current department does not have the space to provide these wraparound services in one location. The Proposed Project, therefore, improves care coordination by physically co-locating various departments and services that cancer patients will need to access.

LHMC also promotes care coordination and effective communication with primary care providers and specialists through an integrated medical record system. With respect to the Proposed Project, LHMC's EMR serves as the primary linkage between the Hospital's radiology oncology department, affiliated specialists, and community primary care providers. In the first instance, the EMR allows LHMC'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 speciality physicians across the system and integrated into the patient's EMR. The EMR also allows authorized providers outside of the Applicant to view their patients' records and send progress notes back for improved continuity of care. This integration ensures that the LHMC patient panel benefits from care coordination through better outcomes and improved quality of life as discussed in F1.b.i and ii.

Furthermore, LHMC participates in the MassHealth ACO Program through BILH Performance Network ("BILHPN") and its clinically integrated network. In furtherance of the goals of the Program, BILHPN strives to increase access to high quality care for members who are more likely to have unmet Social Determinant of Health ("SDoH") needs than the commercially insured population. A significant portion of BILHPN's efforts to improve health care are accomplished through care coordination. Specifically, BILHPN's data analysis and risk management tools are provided to LHMC providers, including a Population Health Management Tool that helps primary care physicians monitor patients' health and manage chronic conditions. LHMC'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 LHMC 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 carried out a diverse consultative process with individuals at various regulatory agencies and departments regarding the Proposed Project. The following individuals and agencies are some of those consulted regarding this Project:

- Rebecca Rodman, Esq., General Counsel, Department of Public Health
- Dennis Renaud, Director, Determination of Need Program, Department of Public Health
- Jennica Allen, Manager of Community Engagement Practices, Bureau of Community Health and Prevention, Department of Public Health
- Elizabeth Maffei, Program Manager, Bureau of Community Health and Prevention, Department of Public Health
- Massachusetts Executive Office of Health and Human Services
- Health Policy Commission
- Center for Health Information and Analysis

• The Centers for Medicare & Medicaid Services

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.

As more fully described in Section F1.a.ii, the Applicant determined the need for the Proposed Project because of the pending obsolescence of the Hospital's existing LINACs and its Patient Panel's need for continued access to radiation therapy. In addition, the Applicant presented the Proposed Project to the Hospital's Patient and Family Advisory Committee, Community Benefits and Advisory Committee, and the public to inform the community of the Proposed Project and solicit their feedback in the development of the Proposed Project.

During each of the presentations described below, attendees were educated on the Applicant's proposed plans, including how the Proposed Project will benefit the Hospital's Patient Panel. Following the presentation, attendees were able to share feedback and ask the presenters questions.

First, the Proposed Project was presented to the Hospital's Community Benefit and Advisory Committee on December 13, 2022. The presentation was attended by 13 Committee members and led by Kevin Bennett, Interim Chief Operating Officer of LHMC.

Next, the Proposed Project was presented to the LHMC Community on December 20, 2022. The presentation was attended by six (6) community members and led by Keven Bennett.

Additionally, the Proposed Project was presented to the Hospital's Patient and Family Advisory Committee on February 7, 2023. The presentation was attended by sixteen (16) attendees and led by Kevin Bennett, Alan Bengzon, Christine Henley, and Michelle Snyder.

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".

As described in the previous section, the Proposed Project was presented to the Hospital's Community Benefit and Advisory Committee on December 13, 2022, the LHMC Community on December 20, 2022, and the Patient and Family Advisory Committee on February 7, 2023. In addition, the Applicant published a legal notice for the Proposed Project in the <u>Boston Herald</u> on May 2, 2023 and posted a copy of the legal notice prominently on LHMC's website.

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 The Commonwealth's goals for cost containment by maintaining and expanding access to radiation therapy close to home for Lahey Burlington patients. With the current LINAC machines slated for obsolescence due to their age and incompatibility with replacement parts and software updates, the equipment must be replaced. However, the replacement of both machines cannot be done in place due to current size requirements for LINAC vaults. Therefore, in order to maintain access within the community, the replacement machines must be sited elsewhere on campus. As part of the Hospital's strategic plan, it poured LINAC vaults during the construction of the Burlington campus's emergency department renovation project in 2017. To that end, the Proposed Project leverages existing campus infrastructure, ensuring the proposed location of the replacement equipment is the most-cost effective solution. Furthermore, the proposed re-location will enable LHMC to improve care delivery and care coordination through the co-location of radiation oncology, hematology oncology, and wraparound services. Lack of effective care coordination leads to waste and increased costs in the health care system,⁵³ while increased care coordination can reduce costs.⁵⁴ including among cancer patients.⁵⁵ Finally, the Proposed Project will allow the Applicant to provide expanded access to forms of radiation therapy, like HDR and SBRT, that have been shown to be more cost-effective than other treatment options.⁵⁶

Accordingly, the Proposed Project will reduce health care spending in furtherance of The Commonwealth's cost containment goals.

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

The Proposed Project will improve public health outcomes by providing the LHMC Patient Panel access to high-guality radiation oncology within their community. While patients currently have access, certain services are limited in capacity or will become severely impacted without the Proposed Project. First, due to the existing footprint of LHMC's Burlington radiation oncology service, HDR treatments are limited to two cases per week when an operating room can be booked one day per week. As a result, patients must either seek services in Boston or forego the improved local control benefit from boosting the radiation dose with prostate brachytherapy. External beam radiation therapy with androgen deprivation therapy is an option for patients with high-risk prostate cancers but local recurrence rates are improved with the addition of brachytherapy boost.⁵⁷ Additionally, the Hospital's existing LINAC machines are at the end of their useful life and must be replaced. Without their replacement, LINAC services will be reduced as the machines go offline due to lack of replacement parts and manufacturer support. Without the Proposed Project, patients will be forced to seek treatment outside of their community, which can result in access issues for patients requiring daily treatments.

These services ensure the Applicant's Patient Panel can access life-saving cancer treatment close to home. Many patients will receive radiation therapy once a day, five days a week, over a series of weeks personalized for their treatment plan. Without access to services close to home, patients may not be able to successfully complete their treatment plan due to access barriers, such as transportation or time spent getting to and from appointments. To that end, the Proposed Project is necessary to improving public health outcomes, patient satisfaction, and quality of life with respect to the availability of radiation oncology services to the Burlington community.

⁵³ William H Shrank et al., Waste in the US Health Care System: Estimated Costs and Potential for Savings, 322 JAMA 1501, 1501– 1509 (2019).

⁵⁴ Dhruv Khullar & Dave A. Chokshi, Can Better Care Coordination Lower Health Care Costs? 1 JAMA NETWORK OPEN e184295

^{(2018). &}lt;sup>55</sup> Sherri Sheinfeld Gorin et al., *Cancer Care Coordination: A Systematic Review and Meta-Analysis of Over 30 Years of Empirical* Studies. 51 ANNALS BEHAVIORAL MEDICINE 532, 532-546 (2017).

⁵⁶ David J. Sher et al., Cost-Effectiveness Analysis of SBRT Versus IMRT for Low-Risk Prostate Cancer. 37 AM. J. CLINICAL ONCOLOGY 215, 221 (2014); James B. Yu et al., Stereotactic Body Radiation Therapy Versus Intensity-Modulated Radiation Therapy for Prostate Cancer: Comparison of Toxicity, 32 J. CLINICAL ONCOLOGY 1195, 1195- 1200 (2014); Chirag Shah et al., Brachytherapy Provides Comparable Outcomes and Improved Cost-Effectiveness in the Treatment of Low/Intermediate Prostate Cancer, 11 BRACHYTHERAPY 441, 441-5 (2012).

⁵⁷ Aaron R Kent et al., Improved Survival for Patients with Prostate Cancer Receiving High-Dose-Rate Brachytherapy Boost to EBRT Compared with EBRT Alone. 18 BRACHYTHERAPY, 313, 313-321 (2019), https://www.brachyjournal.com/article/S1538-4721(18)30642-1/fulltext

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.

In addition to preserving access to radiation therapy services, the Proposed Project will enhance the Hospital's existing integrated care model through improved care coordination and integrative wellness offerings. Lahey Burlington currently offers cancer patients access to nutrition services, social work, physical therapy, as well as acupuncture, art therapy, and yoga. However, these services are currently provided in the Hematology Oncology suite which is located in a different building from the radiation oncology department. Through the Proposed Project's relocation of the radiation oncology department, patients will be able to experience these additional services in closer proximity to their radiation therapy treatments, both in terms of time and distance.

Additionally, as is the process today, the Applicant will work with patients and primary care providers to ensure patients are linked to social service organizations as needed. If concerns around social determinants of health are identified or suspected during pre-procedure screenings and appointments, staff will provide the patient with referral resources and notify the patient's primary care provider as appropriate to encourage necessary follow-up.

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.

Proposal: The Proposed Project seeks to replace existing LINAC equipment and relocate the service to a more convenient location on LHMC's Main Campus. Additionally, the Proposed Project will expand access to HDR treatment.

Quality: The Proposed Project is a superior option because of the significant impact it will have on patient outcomes, quality of life, and patient satisfaction. With continued and expanded access to radiation therapy, BID-P will improve its capacity to treat more patients close to home (including with newer, state-of-the-art treatment types), maintain the reliability of services, and improve care coordination by centralizing cancer care.

Efficiency: LHMC will relocate the replacement LINACs to LINAC vaults that the Hospital poured during previous construction, which creates efficiencies in terms of the construction process.

Capital Expense: \$30,182,667

Operating Costs: \$10,273,114

Alternative Proposal: An alternative the Applicant considered to the Proposed Project would be to not replace the existing LINAC equipment and to not expand access to HDR treatment.

Alternative Quality: Under this alternative, LHMC Burlington LINAC patients would lose access to LINAC treatment in their community. LHMC Peabody would not be able to absorb all patients so a significant portion of patients would be forced to seek care much farther from home. The same would be true for patients seeking HDR treatment.

Alternative Efficiency: This alternative is inefficient because it represents decreased access to care in the community.

Alternative Capital Expenses: None

Alternative Operating Costs: None