Dana-Farber Cancer Institute, Inc. DoN Application #: DFCI-23040915-HE Application for Determination of Need

Substantial Capital Expenditure Substantial Change in Service

October 24, 2023

Submitted By Dana-Farber Cancer Institute, Inc. 450 Brookline Avenue Boston, MA 02215-5450

Table of Contents

Introduction		1
Attachment 1: P	roject Description	3
Attachment 2: D	Determination of Need Narrative Responses	.4-51
Factor 1.a.i	Patient Panel	4
Factor 1.a.ii	Need by Patient Panel	15
Factor 1.a.iii	Competition	28
Factor 1.b.i	Public Health Value/Evidence-Based	29
Factor 1.b.ii	Public Health Value/Outcome-Oriented	30
Factor 1.b.iii	Public Health Value/Health Equity-Focused	31
Factor 1.b.iv	Public Health Value/Health Equity-Focused (Additional Info)	35
Factor 1.c	Furthering and Improving Continuity and Coordination of Care	37
Factor 1.d	Consultation with Government Agencies	39
Factor 1.e.i	Process for Determining Need/Evidence of Community Engagement	40
Factor 1.e.ii	Evidence of Community Engagement/Public Health Value	41
Factor 2.a	Cost Containment	42
Factor 2.b	Public Health Outcomes	44
Factor 2.c	Delivery System Transformation	45
Factor 5	Relative Merit	49
<u>Appendix A</u>	Projecting Demand for 2032 LINAC Sessions	A-1
Attachment 3: A	ffidavit of Truthfulness Form	
Attachment 4: A	pplication Filing Fee	
Attachment 5: A	ffiliated Parties Table	
Attachment 6: C	Change in Service Table	
Attachment 7: A	articles of Incorporation	
Attachment 8: C	Community Health Needs Assessment/Community Health Improvement Plan	
Attachment 9: E	vidence of Community Engagement	
Attachment 10:	CPA Certification	
Attachment 11:	Notice of Intent	

Introduction

Dana-Farber Cancer Institute, Inc. (the "Applicant") is an internationally renowned acute care cancer hospital and research institute in Boston, Massachusetts that has existed at the pinnacle of excellence in cancer care and at the forefront of cancer research innovation since its founding in 1947 by Dr. Sidney Farber, the father of modern chemotherapy. For over 75 years, the Applicant has focused exclusively on cancer care and related diseases and on developing world-renowned adult and pediatric cancer care programs that have consistently ranked among the best in the nation by *U.S. News & World Report*. It is the only hospital in the United States with adult and pediatric cancer care programs ranked by *U.S. News* in the top five. Based on year-to-date data collected by Press Ganey from the Applicant's patients, 98% reported the highest possible rating for overall care provided and similarly 98% gave the highest possible rating for likelihood to recommend the Applicant to others. In 2023, *Newsweek* ranked the Applicant fourth on its list of the best cancer hospitals in the world. Since 2005, the Applicant has been a Magnet®-designated hospital for nursing and health care excellence, a designation held by just 9% of hospitals in the United States.

The Applicant's research accomplishments are equally distinguished. In 1973, it became one of the first National Cancer Institute ("NCI")-designated comprehensive cancer centers and is one of only 56. Further, the Applicant's faculty have contributed to more than a third of all new cancer-related treatments approved by the United States Food and Drug Administration ("FDA") in the last five years. Physician-scientists affiliated with the Applicant also make groundbreaking discoveries, including the Applicant's former President Baruj Benacerraf, who won the 1980 Nobel Prize in Physiology or Medicine for his pioneering studies on the major histocompatibility complex; Dr. Gordon Freeman, who, by discovering the role of PD-L1 and PD-L2 proteins, helped launch immunotherapy; and Dr. William G. Kaelin Jr., whose discovery of an oxygen-sensing system in cells earned him a Nobel Prize in 2019.

Cancer treatment has grown significantly more sophisticated over the past few decades. As the population ages rapidly, the need for state-of-the-art inpatient cancer facilities that would help the Applicant provide life-saving care grows more pressing. Cancer incidence among patients over the age of 75 is expected to increase more than in any other age group, and older patients are more likely to experience side effects and complications from treatments that require an inpatient admission. The incidence of cancer in younger people is also increasing at an alarming rate. New cancer treatments, including many designed to target aggressive forms of cancer (*e.g.*, chimeric antigen receptor ("CAR") T-cell therapy), require inpatient care. These innovative and life-saving treatments are offered exclusively at comprehensive cancer centers like the Applicant or are offered at such comprehensive cancer care centers before they are offered anywhere else. The impact of these technological advances and demographic shifts on the Applicant is especially pronounced due to its provision of many new and experimental cancer treatments and its high-acuity patients.

The Applicant faces the same demands as many other similarly situated NCI-designated comprehensive cancer centers (*e.g.*, Memorial Sloan Kettering in New York City, Moffitt Cancer Center in Tampa, Florida, MD Anderson Cancer Center in Houston and Austin, Texas, City of Hope in Duarte and Irvine, California, and The James Cancer Hospital and Solove Research Institute in Columbus, Ohio). These national peer institutions are responding to these same trends

and needs by undertaking significant expansions of their inpatient capacity in new or renovated facilities that incorporate up-to-date technology and treatment tools. As of the date of this filing, MD Anderson Cancer Center has 757 inpatient beds, Memorial-Sloan Kettering has 514 inpatient beds, The James Cancer Hospital and Solove Research Institute has 356 inpatient beds, Moffitt Cancer Center has 218 inpatient beds, and City of Hope has 217 inpatient beds on its main campus in Duarte. These peer institutions also have plans to expand inpatient capacity significantly in the coming years.

Meanwhile, the Applicant, despite its preeminence in the provision of cancer care and the industrywide changes that necessitate provision of such care in an inpatient setting, has only 30 medical/surgical beds on its hospital license. The Applicant's beds sit in space leased to the Applicant by Brigham and Women's Hospital ("BWH"), situated among beds licensed to BWH, for which the Applicant provides professional medical oncology services through a more than 25year affiliation. In addition to its own licensed beds, the Applicant provides care to patients in certain BWH-licensed beds, which are dispersed across multiple locations within BWH (two separate buildings and at least seven different floors). While BWH and the Applicant have successfully collaborated to provide world-class cancer care for many years, the Applicant has determined that developments in cancer care require that operational and decision-making authority be vested in one entity for all medical oncology beds to best serve patients and ensure the best outcomes.

Increasingly, as the needs of the Applicant's patient panel grow more acute and the care it delivers more complex, there is a need for the Applicant to provide, or coordinate the provision of, sophisticated multidisciplinary care delivered by a number of different specialists, both within oncology and from other areas. Comprehensive cancer centers are, as a best practice, able to provide and coordinate the provision of such care most effectively through facilities that integrate inpatient and outpatient treatment areas with research, and through coordinated quality and safety practices and controls. Further, dedicated cancer centers have statistically significantly higher survival rates compared to other NCI-designated centers, academic medical centers, and other treatment centers that are not dedicated solely to cancer. As one example of innovation in better coordinated needs of cancer patients that has shown significantly reduced emergency department visits and hospitalizations. This program has reduced emergency department visits by approximately 20% and reduced subsequent hospitalizations for these patients by 80%, improving patient outcomes and limiting costly, unnecessary acute care.

To ensure that it is able to meet this growing need for sophisticated cancer care, the Applicant submits this application (the "Application") pursuant to the Determination of Need Regulations, 105 CMR 100 et seq. (the "Regulations"), to develop a freestanding, dedicated inpatient cancer hospital in Boston (the "Facility") with imaging and radiation oncology capabilities. Further, to ensure that the Applicant's patients have access to the full continuum of services and support services offered within the setting of a fully integrated, dedicated cancer center, the new Facility will be located adjacent to, Beth Israel Deaconess Medical Center ("BIDMC"), and will be physically connected to BIDMC by way of a bridge over Pilgrim Road.

Project Description

The Applicant has filed this Application in connection with the proposed acquisition of site by lease and construction, fit-out, and equipping of an approximately 688,100 square-foot inpatient hospital Facility to be located at 1 Joslin Place, Boston, Massachusetts 02215 and to include 300 adult inpatient beds and the addition of two magnetic resonance imaging ("MRI") machines, two computerized tomography ("CT") machines, one positron emission tomography machine ("PET-CT") (collectively, the "Inpatient Imaging Equipment"), two CT simulator machines, and three linear accelerators ("LINACs") (the "New Radiation Oncology Equipment") (collectively, the "Proposed Project"). Of the inpatient beds, 30 would be transferred from the Applicant's current bed complement at 75 Francis Street, Boston, Massachusetts 02115 and 270 would represent new beds on the Applicant's license dedicated to inpatient cancer care. The Applicant's existing three LINACs at 75 Francis Street, Boston, Massachusetts 02115 will also be transferred to the Facility. The Proposed Project will also include 20 observation beds. The Proposed Project will also include a tunnel under and a bridge over Brookline Avenue connecting the Facility to the Applicant's Dana Building at 440 Brookline Avenue.¹ The maximum capital expenditure for the Proposed Project is estimated to be \$1,675,700,000.

¹ It is anticipated that the bridge over Pilgrim Road connecting the Facility to BIDMC will be maintained and operated by BIDMC rather than the Applicant and, accordingly, is not included in this Proposed Project.

Factor 1ApplicantPatientPanelNeed,PublicHealthValuesandOperationalObjectives

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.

Patient Panel Demographics

Table 1 provides the demographic and geographic profile for the Applicant's patient panel. Table 2 sets out the same profile for inpatients admitted to beds on the Applicant's license, as well as inpatients admitted to BWH-licensed beds under the care of the Applicant's medical oncologists. Table 3 set out the same for the Applicant's outpatients. The source of data in this Application are the records of the Applicant's management unless otherwise noted. As the Proposed Project relates only to adult oncology care, and not to pediatric oncology care, all data presented includes only adult patients. The volume of patients seeking cancer care services from the Applicant has increased over the preceding three years by approximately 9% for patients requiring inpatient care, and approximately 16% for those patients that receive outpatient care. The vast majority of the Applicant's patients reside in Massachusetts and most patients are referred to the Applicant from across the Commonwealth, including from community providers and hospitals. The Applicant does not seek to retain patients in its system, instead it focuses on referring patients back to their community provider for ongoing care and supervision. Approximately 26.9% of inpatients in fiscal year ("FY") 2022 came from outside Massachusetts.² A significant plurality of the Applicant's patients—nearly 50%—are enrolled in Medicare, as shown in Table 10, and more than two-thirds of the Applicant's patients are over the age of 56.

Prevalence of Disease

Cancer is a leading cause of death in the Commonwealth and the United States³ and accounts for nearly one in six deaths worldwide.⁴ Cancer is a disease in which mutations to genes that control cell growth and function cause the body's cells to grow abnormally and uncontrollably.⁵ As these abnormal cells continue to grow, they spread throughout the body and crowd out the normal, functioning cells needed to stay alive.⁶ The genetic mutations and cell growth described above have a number of causes. The most frequently cited causes include genetics and family history, tobacco usage, poor diet, excessive alcohol consumption, excessive body weight, exposure to certain types of radiation (*e.g.*, ultraviolet radiation, radon, x-rays and gamma rays), and exposure to certain chemicals (*e.g.*, asbestos and diesel exhaust).⁷ According to the NCI, advancing age is

² Center for Health Information and Analysis All-Payer Claims Database, CHIA (2022) (sourced by Massachusetts Health Data Consortium). ³ Stats of the State of Mass., CTRS. FOR DISEASE CONTROL AND PREVENTION (last visited Oct. 1, 2023),

https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm; *Leading Causes of Death*, CTRS. FOR DISEASE CONTROL AND PREVENTION (last visited Oct. 1, 2023), https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm.

⁴ Cancer, WHO (Feb. 2, 2022), https://www.who.int/news-room/fact-sheets/detail/cancer.

⁵ What is Cancer, NAT'L. CANCER INST. (last updated Oct. 11, 2021), https://www.cancer.gov/about-cancer/understanding/what-is-⁶ What is Cancer, AM. CANCER SOC'Y (last revised Feb 14, 2022), https://www.cancer.org/treatment/understanding-your-diagnosis/what-is-

cancer.html. ⁷ *Chemicals and Cancer*, AM. CANCER SOC'Y. (last visited Oct. 1, 2023), https://www.cancer.org/cancer/risk-prevention/chemicals.html.

the most important risk factor for cancer overall and for many individual cancer types.⁸ Age is a recognized risk factor for cancer development as the normal aging process impacts important biological processes within the body causing proteins and DNA in cells to deteriorate and mutate over time, causing the formation and spread of cancer.⁹ "Beyond these intrinsic cellular changes, other bodily processes become less effective with age. The body's immune system, for example, becomes less protective and resilient, and is less efficient in detecting and fighting infection and diseases, including cancer."¹⁰

There are two main categories of cancer — hematologic cancers (*i.e.*, cancers affecting blood cells) and solid tumor cancers (*i.e.*, cancers of any other bodily organ or tissue, where the rapid cell growth described above causes tumors to grow). ¹¹ Within these broad categories are many different cancer types. The most common types of cancer worldwide are breast, lung, colorectal, prostate, skin (non-melanoma), and stomach cancers. ¹² The NCI estimates that, in 2023, lung cancer will be the deadliest form of cancer and that pancreatic cancer, liver and intrahepatic bile duct cancer, as well as lung cancer, will cause the most deaths as a proportion of new cases over the same time period. ¹³

Cancer incidence rates in Massachusetts are greater than the national incidence rates. Specifically, in Massachusetts the age-adjusted overall cancer incidence rate was 454.8 per 100,000 persons per year for years between 2015 and 2019, which is greater than the national incidence rate of 449.2 per 100,000 persons per year for years between 2015 and 2015 and 2019.¹⁴ The most commonly diagnosed types of cancer in Massachusetts for men during 2015 and 2019 were prostate cancer, followed by cancers of the bronchus and lung, colon/rectum, urinary bladder, and melanomas.¹⁵ Among women in Massachusetts, the most commonly diagnosed cancer types were cancers of the breast, bronchus and lung, colon/rectum, and uterus, and thyroid.¹⁶ Between 2015 and 2019, there were 63,589 cancer deaths in Massachusetts, an average of 12,718 deaths per year.¹⁷

Despite an increase in the incidence of cancer, statistics demonstrate that cancer mortality rates have decreased since 2013.¹⁸ These decreases in overall cancer mortality rates are evidence that treatment services, access to screening, early detection, and prevention, along with new technology and scientific discoveries, are leading to improved outcomes. However, according to the Applicant's Community Health Needs Assessment ("CHNA"), cancer remains pervasive in the Commonwealth, leading to more deaths in Massachusetts and Boston than any other disease, except for COVID-19. Additionally, the Applicant's CHNA found that Black residents in Boston continue to experience the highest rates of overall cancer mortality, statistically significantly higher than White residents. There are significant disparities in cancer screenings, with lower

⁸ Age and Cancer Risk, NAT'L CANCER INST (last updated March 5, 2021), https://www.cancer.gov/about-cancer/causes-prevention/risk/age.

⁹ Norman Sharpless, M.D, *The Challenging Landscape of Cancer and Aging: Charting a Way Forward*, NAT'L CANCER INST. (Jan. 24, 2018), https://www.cancer.gov/news-events/cancer-currents-blog/2018/sharpless-aging-cancer-research.

 $^{^{10}}$ *Id*.

¹¹ AM. CANCER SOC'Y, *supra* note 7.

¹² WHO, *supra* note 4.

¹³ Common Cancer Types, NAT'L. CANCER INST. (last visited Oct. 1, 2023), https://www.cancer.gov/types/common-cancers.

 ¹⁴ Age Adjusted Cancer Incidence Rates by Cancer Site (2015-2019), HD PULSE.(last visited Oct. 12, 2023), https://hdpulse.nimhd.nih.gov/data-portal/quick-profile/25/incidence.
 ¹⁵ Cancer Incidence Statewide Reports, 2015-2019, MASS.GOV, https://www.mass.gov/doc/cancer-incidence-and-mortality-in-massachusetts-

¹⁵ Cancer Incidence Statewide Reports, 2015-2019, MASS.GOV, https://www.mass.gov/doc/cancer-incidence-and-mortality-in-massachusetts-2015-2019-statewide-report/download (September 2023).

¹⁶ *Id*.

¹⁷ Id.

¹⁸ Id.

screening among certain subgroups, including Asian, Latino, Black, immigrant, low-income, and unemployed residents. See Factor 1.b.iii and Factor 2.c for a description of actions the Applicant has taken to address these disparities and improve equitable access to cancer care prevention, diagnostic, and treatment services, including to communities of color.

Many of the Commonwealth's sickest and most acute cancer patients receive treatment from the Applicant, including a high volume of patients with rare and orphan cancers who require subspeciality care. Consequently, the Applicant's Case Mix Index ("CMI") for medical oncology patients is higher than any other provider in the Commonwealth.¹⁹ In FY22, the Applicant saw a 9% increase in the average length of stay and an 18.1% increase in CMI, highlighting the higher acuity of patients seen by the Applicant.²⁰ This reflects that the Applicant's patient panel, on average, has higher acuity conditions than most other providers' panels and tends to require more prolonged inpatient management and intervention.

Patients seek cancer care services from the Applicant for numerous types of cancer, including rare cancers. <u>Table 4</u> provides the Applicant's inpatient utilization by disease center. In FY22, the most frequent diagnoses among the Applicant's inpatient patient panel were gastrointestinal, lymphoma, transplant, thoracic, and genitourinary cancers.

Inpatient bed need has increased between 2020 and 2022. Over 60% of the Applicant's inpatients were admitted through BWH's emergency department in FY22.²¹ The average length of stay in the BWH emergency department increased from 6.9 hours in 2018 to 8.6 hours in 2022, a 25% increase.²² Patients receive treatment in the emergency department to manage their symptoms, and some leave without being seen by a medical oncologist for cancer-specific care. The emergency department is not an optimal setting for patients with cancer, who are at risk for complications, including nosocomial infections.²³ See Factor 1.a.ii for further discussion regarding the impact of wait times on the Applicant's patient panel inpatient bed need.

Imaging Equipment

Imaging is an essential component of care for a cancer patient, utilized throughout the lifecycle of a cancer patient's treatment, including those treatments provided by the Applicant that require an inpatient stay. Imaging is also an essential diagnostic modality in the inpatient setting to detect and treat non-oncologic conditions such as infection, trauma, or other acute conditions. Imaging equipment assists physicians in the detection and diagnosis of cancers, the determination of a cancer's spread, the approach for delivering certain treatments, and the assessment of the efficacy of a particular treatment. <u>Table 6</u> provides Inpatient Imaging Equipment utilization in the Applicant's 30 licensed beds by the Applicant's patient panel. The percentage of oncology admissions requiring use of Inpatient Imaging Equipment increased substantially between 2020 and 2022—by approximately 40% for MRI scans, 25% for CT scans, and 43% for PET-CT scans. Additionally, <u>Table 7</u> provides utilization of imaging equipment such as MRI, CT, and PET-CT in

¹⁹ Center for Health Information and Analysis All-Payer Claims Database, CHIA (2022) (sourced by Massachusetts Health Data Consortium). ²⁰ Id.

²¹ Emergency Department Database (EDD) Reporting, CHIA (last updated May 25, 2023), https://www.chiamass.gov/emergency-departmentdatabase-edd-reporting/. ²² Id.

²³ See Erek S. Majka, MD & N. Seth Trueger, MD, MPH, *Emergency Department Visits Among Patients With Cancer in the US*, 6 JAMA OPEN NETWORK E2253797 (2023).

an outpatient setting (collectively "Outpatient Imaging Equipment"). The Applicant saw increased utilization of Outpatient Imaging Equipment on the Longwood medical campus, which includes the Applicant's main campus in Boston as well as its site in Chestnut Hill ("Longwood Medical Campus"), between 2021 and 2023. Specifically, there was an approximately 81% increase in MRI scans, 38% increase in CT scans, and 22% increase in PET-CT scans. This increase can be attributed partially to an increase in number of outpatients following the opening of the Applicant's site in Chestnut Hill in 2021, as shown in <u>Table 3</u>.

Radiation Therapy

Radiation therapy is an important component of curing and palliating cancer and is deployed across almost all cancer types.²⁴ Radiation can be used alone or with other modalities of treatment including chemotherapy, immunotherapy, or surgery. In high-income countries like the United States, radiation therapy is used in more than half of all cancer cases²⁵ and contributes towards 40% of curative treatment.²⁶

LINAC-based radiation therapy is the most commonly used technique to deliver radiation therapy to patients.²⁷ LINACs are machines used to deliver external beam radiation treatments to cancer patients to treat malignant tumors in a targeted fashion through the delivery of high doses of x-rays or electrons.²⁸ <u>Table 9</u> provides LINAC therapy utilization by the Applicant's patient panel. Patient panel utilization of LINAC therapy increased by approximately 18% between 2020 and 2022.

In addition, to prepare for radiation treatment, the majority of patients will undergo imaging with a CT simulator. CT simulator machines are equipped with much of the same technology as a CT machine, but they also include multi-image display and treatment planning technology that allow doctors to create custom treatment plans for patients and are also used to investigate causes of symptoms, complications of the disease, and its treatment.²⁹

<u>Table 8</u> provides radiation therapy patient volumes by disease center. The number of unique patients receiving radiation therapy increased by approximately 12% between 2020 and 2022. The Applicant provided the highest radiation therapy volume to patients with breast, head and neck, thoracic, and genitourinary cancers. Patients in the Applicant's patient panel receive radiation therapy treatment either in the Applicant's Radiation Oncology department or at BWH, based on the patient's disease center and/or need for specialized treatment.

Table 1³⁰

https://info.atlantisworldwide.com/blog/the-difference-between-a-ct-scanner-ct-simulator.

²⁴ Xin Liu et al., *Clinical application of MR-Linac in tumor radiotherapy: a systemic review*, 18 RADIATION ONCOLOGY 52 1153, 1186 (Mar. 14, 2023), https://ro-journal.biomedcentral.com/articles/10.1186/s13014-023-02221-8.

²⁵ Rifat Atun et al., *Expanding global access to radiotherapy*, 16 LANCET ONCOLOGY COMM'N 1153, 1153 (2015),

https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00222-3/fulltext.

²⁶ Rajamanickam Baskar et al., *Cancer and radiation therapy: current advances and future directions*. 9 INT. J. MED. SCIENCE 193, 193-199 (2012).

²⁷ PANKAJ K. AGARWALLA ET AL., APPLICATION OF CURRENT RADIATION DELIVERY SYSTEMS AND RADIOBIOLOGY, PRINCIPLES OF NEUROLOGICAL SURGERY (4th ed. 2018), https://www.sciencedirect.com/topics/nursing-and-health-professions/linear-accelerator.

²⁸ Treatment Techniques: Linear Accelerators, UFHEALTH (last visited Oct. 1, 2023), https://radonc.med.ufl.edu/patient-care/technologies-and-resources/treatment-techniques/.

²⁹ Vikki Harmonay, The Difference Between a CT Scanner & CT Stimulator, ATLANTIS WORLDWIDE (Aug. 24, 2022)

³⁰ This table is based on utilization data for the Applicant's current licensed beds, as well as an estimate of utilization for patients admitted to BWH-licensed beds under the care of the Applicant's oncologists derived from the Applicant's professional claim data. While precise utilization

	2020		2021		2022	
	Count	%	Count	%	Count	%
Total (unique patients)	60,203		66,241		69,891	
Gender						
Female	37,018	61.5 %	40,750	61.5 %	43,177	61.8 %
Male	23,167	38.5	25,229	38.1	26,691	38.2
Unknown	18	0.0	262	0.4	23	0.0
Race & Ethnicity						
Asian Non-Hispanic or						
Latino	1,807	3.0	2,063	3.1	2,376	3.4
Black or African American	2,483	4.1	2,845	4.3	3,108	4.4
Hispanic or Latino	2,424	4.0	2,729	4.1	3,085	4.4
Multiracial, non-Hispanic	467	0.8	607	0.9	895	1.3
Unknown & Other	6,699	11.1	6,931	10.5	6,924	9.9
White or Caucasian Non-						
Hispanic or Latino	46,323	76.9	51,066	77.1	53,503	76.6
Age ³¹						
0-18 ³²	72	0.1%	112	0.2%	70	0.1
19-35	3,903	6.5%	4,472	6.8%	4,693	6.7
36-55	15,400	25.6%	16,638	25.1%	17,564	25.1
56-75	33,349	55.4%	36,415	55.0%	38,211	54.7
>75	8,444	14.0%	9,627	14.5%	10,482	15.0
Geography ³³						
Massachusetts	41 145	68.3	15 737	69.0	49 504	70.8
New York	2 240	2.7	2 465	2.7	2 244	70.8
Outside MA	2,240	5.7	2,403	5.7	2,244	5.2
(New England) ³⁴	11,893	19.8	12,762	19.3	13,345	19.1
Outside MA					-	
(United States) ³⁵	18,414	30.6	19,852	30.0	19,558	28.0
Outside MA (International) $\frac{36}{36}$	659	1.1%	631	1.0%	871	1.2%

Total Unique Patients, Demographics, and Geography

Table 2³⁷

data for all such patients is available to the Applicant as part of its existing collaboration, portions of that data are proprietary to BWH, and the Applicant is restricted from disclosing it in this Application due to confidentiality restrictions.

³¹ Age categories may sum to more than 100%, as patients age into different categories during a fiscal year.

³² Includes only patients 18 or younger seen in adult clinical departments. Excludes patients seen in pediatrics departments.

 ³³ Given overlapping geographies, percentages will sum to be over 100%.
 ³⁴ As used herein, "New England" means Connecticut, Maine, New Hampshire, Rhode Island, Vermont, and unless otherwise noted,

Massachusetts.

³⁵ These patients include those from New England states, excluding Massachusetts.

³⁶ These patients include those with a permanent country of residence outside the United States.

³⁷ This table is based on utilization data for the Applicant's current licensed beds, as well as an estimate of utilization for patients admitted to

BWH-licensed beds under the care of the Applicant's oncologists derived from the Applicant's professional claim data. While precise utilization

	2020		2021		2022	
	Count	%	Count	%	Count	%
Total (unique patients)	4,501		4,783		4,887	
Gender						
Female	2,245	49.9 %	2,361	49.4 %	2,424	49.6 %
Male	2,239	49.7	2,368	49.5	2,443	50.0
Unknown	17	0.4	54	1.1	19	0.4
Race & Ethnicity						
Asian Non-Hispanic or Latino	173	3.8	172	3.7	181	3.8
Black or African American	266	5.9	294	6.6	318	7.2
Hispanic or Latino	186	4.1	252	5.3	240	4.9
Multiracial, non- Hispanic	26	0.6	38	0.4	55	0.6
Unknown & Other	206	4.6	212	4.1	236	4.7
White or Caucasian Non-Hispanic or Latino	3,644	81.0	3,815	80.1	3,857	79.0
Age						
0-18	18	0.4	56	1.2	19	0.4
19-35	186	4.2	196	4.2	218	4.5
36-55	794	17.7	836	17.7	879	18.1
56-75	2,575	57.4	2,668	56.4	2,848	58.5
>75	928	20.7	1,027	21.7	923	19.0
Geography						
Massachusetts	3,252	72.3	3,518	73.6	3,572	73.1
New York	121	2.7	114	2.4	109	2.2
Outside MA	833	18.5	818	17.1	932	19.1
(New England)	1 1 1 0	24.0	1 1 1 0	22.4	1 202	24.6
(United States)	1,119	24.9	1,119	23.4	1,202	24.6
Outside MA	133	3.0	147	3 1	115	2.4
(International)	155	5.0	17/	5.1	115	2.7

Total Unique Inpatient Patients, Demographics, and Geography

Table 3 Total Unique Outpatient Patients, Demographics, and Geography

data for all such patients is available to the Applicant as part of its existing collaboration, portions of that data are proprietary to BWH, and the Applicant is restricted from disclosing it in this Application due to confidentiality restrictions.

Outside MA

(International)

618

	2020		2021		2022	
	Count	%	Count	%	Count	%
Total (unique patients)	59,745		65,613		69,296	
Gender						
Female	36,783	61.6 %	40,672	62.0 %	42,909	61.9 %
Male	22,961	38.4	24,940	38.0	26,383	38.1
Other	< 11	<1.0	< 11	<1.0	< 11	<1.0
Age						
0-18	52	0.1	56	0.1	51	0.1
19-35	3,885	6.5	4425	6.7	4,647	6.7
36-55	15347	25.7	16571	25.3	17,498	25.3
56-75	33,125	55.4	36110	55.0	37,913	54.7
>75	8,300	13.9	9474	14.4	10,325	14.9
Race/Ethnicity						
Asian Non-Hispanic or	1,797	3.0	2,049	3.1	2,361	3.4
Latino						
Black or African	2,451	4.1	2,789	4.3	3,061	4.4
American	2.405	4.0	2 (00	4.1	2.056	4 4
Hispanic or Latino	2,405	4.0	2,680	4.1	3,056	4.4
Multiracial, non-	462	0.8	602	0.9	883	1.3
Null & Other	6 649	11.1	6 845	10.4	6.870	9.9
White or Caucasian	45 981	77.0	50 648	77.2	53.065	76.6
Non-Hispanic or Latino	45,901	//.0	50,040	11.2	55,005	70.0
1						
Geography						
Massachusetts	40,782	68.3	45,266	69.0	49,068	70.8
New York	2,236	3.7	2,458	3.7	2,236	3.2
Outside MA (New	11,841	19.8	12,700	19.4	13,236	19.1
England)			*			
Outside MA (United	18,345	30.7	19,760	30.1	19,424	28.0
States)						

Longwood Medical Campus

Table 438Inpatient Utilization by Disease Center

587

0.9

804

1.2

1.0

³⁸ The data provided in this table was gathered using a methodology that looks at the volume of outpatient encounters each patient had by disease center, within each FY, and attributes the disease center where the patient was seen most frequently for that year. As the Proposed Project relates only to adult oncology care, and not to pediatric oncology care, data presented includes only adult patients.

Dana-Farber Cancer Institute, Inc.

	2020		2021		2022	
	Count	%	Count	%	Count	%
Total (unique patients) ³⁹	4,501		4,783		4,887	
Breast Oncology Center	262	5.8 %	254	5.3 %	311	6.4 %
Cutaneous Oncology Center	22	0.5	24	0.5	24	0.5
Gastrointestinal Oncology	605	13.4	637	13.3	664	13.6
Genitourinary Oncology	249	5.5	303	6.3	311	6.4
Gynecology Oncology	217	4.8	239	5.0	279	5.7
Head and Neck Oncology	106	2.4	133	2.8	152	3.1
Hematologic Malignancies ⁴⁰	1,244	27.6	1,257	26.3	1,345	27.5
Melanoma Center	75	1.7	85	1.8	94	1.9
Neuro-Oncology Center	140	3.1	148	3.1	139	2.8
Sarcoma and Bone Oncology	79	1.8	115	2.4	130	2.7
Thoracic Oncology Program	351	7.8	383	8.0	409	8.4

³⁹ Due to limitations on the Applicant's ability to disclose BWH data, patients with only an inpatient stay (*i.e.*, no additional outpatient treatment provided) are included in the total patient count, but excluded from particular disease centers. Additionally, certain other patients included in the total but not specific disease centers are either (1) not assigned to a specific disease center or (2) assigned to a disease center with less than 11 unique patients. Total may not sum to disease center counts.

⁴⁰ "Hematologic Malignancies" is comprised of the following subgroups: Transplant Program, Leukemia, Lymphoma, Multiple Myeloma and Waldenstrom, Ungrouped Hematologic Malignancies.

	2020		2021		2022	
	Count	%	Count	%	Count	%
Total (unique patients) ⁴²	59,745		65,613		69,296	
Breast Oncology Center	12,178	20.4 %	13,569	20.7 %	13,950	20.1 %
Cutaneous Oncology Center	1,398	2.3	1,691	2.6	1,827	2.6
Gastrointestinal Oncology	5,734	9.6	6,321	9.6	6,714	9.7
Genitourinary Oncology	5,536	9.3	6,246	9.5	6,500	9.4
Gynecology Oncology	3,597	6.0	3,714	5.7	3,806	5.5
Head and Neck Oncology	2,369	4.0	2,675	4.1	2,759	4.0
Hematologic Malignancies ⁴³	13,231	22.1	14,355	21.9	15,186	21.9
Hematology Service	1,954	3.3	2,176	3.3	2,524	3.6
Melanoma Center	1,848	3.1	2,060	3.1	2,232	3.2
Neuro-Oncology Center	1,675	2.8	1,805	2.8	1,819	2.6
Sarcoma and Bone Oncology	2,022	3.4	2,064	3.1	2,013	2.9
Thoracic Oncology Program	3,105	5.2	3,245	4.9	3,298	4.8

Table 5⁴¹ **Outpatient Utilization by Disease Center** Longwood Medical Campus

⁴¹ The data provided in this table were gathered using a methodology that looks at the volume of outpatient encounters each patient had by disease center, within each FY, and attributes the disease center where patient was seen most frequently to them for that year. As the Proposed Project relates only to adult oncology care, and not to pediatric oncology care, data presented includes only adult patients. ⁴² Total may not sum to disease center counts because not all patients are assigned a specific disease center.

⁴³ "Hematologic Malignancies" is comprised of the following subgroups: Transplant Program, Leukemia, Lymphoma, Multiple Myeloma and Waldenstrom, Ungrouped Hematologic Malignancies.

Metric	2020	2021	2022
MRI			
Inpatient Scans	370	529	519
Percentage of Inpatients Requiring Scan	26%	38%	40%
СТ			
Inpatient Scans	705	907	884
Percentage of Inpatients Requiring Scan	50%	65%	69%
PET-CT			
Inpatient Scans	37	67	53
Percentage of Inpatients Requiring Scan	3%	5%	4%

Table 644Inpatient Imaging Equipment Utilization

Table 7
Outpatient Imaging Equipment Utilization
Longwood Medical Campus

Scans	2020	2021	2022
MRI	7,845	11,894	14,207
СТ	31,505	38,487	43,523
PET-CT	5,610	6,214	6,826

⁴⁴ Includes imaging equipment utilization for inpatient patients under the care of the Applicant's oncologists in the Applicant's licensed beds (derived in part using imaging order data due to contractual confidentiality restrictions).

	2020		2021		2022	
	Count	%	Count	%	Count	%
Total (unique patients) ⁴⁶	1,084		1,236		1,205	
Breast Oncology Center	350	32.3 %	455	36.8 %	455	37.8 %
Cutaneous Oncology Center	28	2.6	27	2.2	36	3.0
Gastrointestinal Oncology	29	2.7	38	3.1	37	3.1
Genitourinary Oncology	132	12.2	153	12.4	165	13.7
Gynecology Oncology	21	1.9	16	1.3	13	1.1
Head and Neck Oncology	200	18.5	237	19.2	234	19.4
Hematologic						
Malignancies ⁴⁷	13	1.2	20	1.6	25	2.1
Sarcoma and Bone						
Oncology	25	2.3	11	0.9	22	1.8
Thoracic Oncology Program	252	23.2	249	20.1	207	17.2
Other Oncology Patients ⁴⁸	41	3.8	50	4.0	24	2.0

Table 845Radiation Patient Volumes by Disease CenterLongwood Medical Campus

Table 9LINAC Therapy Utilization

Metric	2020	2021	2022
Total Radiation Oncology	21 567	25 450	25.256
Treatments	21,307	23,430	23,330

Table 10⁴⁹ Payor Mix (Gross Revenues) Longwood Medical Campus

	2020	2021	2022
Medicare	42.0 %	43.5 %	43.4 %
Medicaid	5.8	6.2	6.2
Blue Cross	23.8	23.3	23.3
HMO, Commercial, Other	28.1	26.8	26.9
Self-Pay	0.3	0.2	0.2

⁴⁵ Patient counts in table are attributed to the disease center where patients had the most outpatient encounters during the fiscal year. Estimates may not sum to 100%. Radiation oncology utilization for inpatients under the care of the Applicant's oncologists is derived from the number of unique patients scheduled for a radiation oncology treatment in the Applicant's Radiation Oncology department via the Applicant's electronic health record system.

⁴⁶ Total may not sum to disease center counts because not all patients are assigned a specific disease center.

⁴⁷ "Hematologic Malignancies" is comprised of the following subgroups: Transplant Program, Leukemia, Lymphoma, Multiple Myeloma and Waldenstrom, Ungrouped Hematologic Malignancies.

⁴⁸ Comprised of Melanoma Center and Neuro-Oncology Center.

⁴⁹ This table represents the data for the Longwood Medical Campus, inclusive of the Applicant's Chestnut Hill location.

F1.a.ii. Need by Patient Panel

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.

Conditions Driving Significant Increase in Need for Specialized Inpatient Cancer Care

The United States' population is getting older. According to the United States Census Bureau, the number of Americans aged 65 and older is projected to nearly double from 52 million in 2018 to 95 million by 2060.⁵⁰ Over the same timeframe, the share of the population aged 65 and older will increase by more than 40%.⁵¹ Massachusetts is projected to have an even larger demographic shift, as projections indicate that the impact of an aging population is likely to be even more pronounced in the Commonwealth than in the United States overall. For example, between 2010 and 2030 (only a 20-year projection, as compared to the national projection, which spans more than 40years) the share of the population aged 65 and older in Massachusetts is projected to increase by more than 50%. The national and state demographic changes are having an impact on the Applicant's patient panel, as well. As shown in Table 1, over the last three years, a higher percentage of the Applicant's patient panel is 56 years of age or older. As the national and state populations age rapidly in the coming decades, the prevalence of cancer will necessarily increase significantly because the primary risk factor for cancer is age.⁵² According to a study from the United States Centers for Disease Control and Prevention, the annual number of cancer cases is anticipated to increase 49% between the years 2015 and 2025.53 That same study finds that the largest percentage increase will occur among patients 75 years of age or older. Additionally, although much of the demand comes from the aging population, it is also important to recognize that there is also a large and concerning increase in young adult cancers.⁵⁴

The increase in cancer prevalence and an aging population means the number of cancer patients who will require hospitalization throughout the course of their cancer treatment will continue to grow. Hospitalization may be necessary as a result of symptoms or complications from the disease, such as intractable pain, or side effects or consequences of treatments, such as treatment of infection or need for nutrition support.⁵⁵ Hospitalization may also be required for patients who need palliative or hospice care.⁵⁶ Additionally, inpatient admission—and frequently admission with a long length of stay—is necessary to deliver innovative treatments for patients with complex diagnoses, for which the Applicant, as a comprehensive cancer center, is uniquely situated to

⁵⁶ Id.

⁵⁰ Mark Mather et al., *Aging in the United States*, 70 POPULATION BULLETIN, no. 2, at 3 (2015), https://www.prb.org/resources/fact-sheet-aging-in-the-united-states/.

⁵¹ Id.

⁵² NAT'L CANCER INST., *supra* note 9.

⁵³ Hannah K. Weir et al., *Cancer Incidence Projections in the United States Between 2015 and 2050*, 18 PREVENTING CHRONIC DISEASE (2021), https://www.cdc.gov/pcd/issues/2021/21_0006.htm.

⁵⁴ Annika Neklason, *Cancer rates are climbing among young people*, THE HILL (June 15, 2023), https://thehill.com/policy/healthcare/4041032-cancer-rates-are-climbing-among-young-people-its-not-clear-why.

⁵⁵ MOHAMED A. KHARFAN-DABAJA, THE INPATIENT UNIT IN A CANCER CENTER, THE COMPREHENSIVE CANCER CENTER 16 (Mahmoud Aljurf et al., 2021), https://link.springer.com/chapter/10.1007/978-3-030-82052-7_3.

provide. For example, patients with acute leukemia (a type of cancer that forms in white blood cells) often undergo induction therapy (a type of chemotherapy) as a first phase of treatment.⁵⁷ Typically, patients undergoing induction therapy can remain in the hospital as an inpatient for four to six weeks with frequent needs for subsequent admissions during the course of treatment.⁵⁸ Similarly, CAR T-cell therapy is a new, extraordinarily effective cancer treatment used to treat an increasing number of different and previously fatal blood cancers by altering genes inside T-cells (a type of white blood cell) to make them more effective at fighting the cancer.⁵⁹ This treatment modality is expanding within hematologic malignancies and actively being investigated in solid tumors. There are now several commercial products approved for acute lymphoblastic leukemia, non-Hodgkin lymphoma and multiple myeloma. In addition, use of bi-specific T-cell engager therapy, a novel pharmaceutical version of immune cell therapy, is also expanding, including in solid cancers.⁶⁰

CAR T-cell therapy usually involves an inpatient stay with frequent subsequent urgent admissions to treat potentially serious side effects of the therapy.⁶¹ As stated below, these treatments can lead to the development of cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome, known potential complications of these treatment modalities which can be fatal if not promptly recognized and treated. Some, but not all of these treatments are administered on an outpatient basis; however, even when administered outpatient the inpatient hospitalization rate can be 30-70%.⁶² In FY 2023, based on the Applicant's internal data, the ALOS for CAR T-cell patients admitted to the Applicant's 30-bed inpatient hospital was 12 days, but this represents only a small percentage of the overall CAR T-cell patient population of the Applicant (with the remainder completing their inpatient stays at BWH), which has varying levels of acuity. The Applicant's data on CAR T-cell ALOS, therefore, may underrepresent the true ALOS for such patients.

Stem cell transplantation is another treatment that can involve lengthy inpatient stays. The Applicant's Adult Stem Cell Transplant Program, founded in 1972, is the second largest transplant program in the country, performing approximately 600 transplants per year and is in the top 6% of centers for outcomes (*i.e.*, survival) for allogeneic transplants. ⁶³ The Applicant's limited inpatient bed capacity is a constraint on use of these innovative and effective procedures, and this contributes to access issues for the Applicant's most vulnerable patients (including, but not limited to, patients of color and low-income patients). During FY 2023, the ALOS in the Applicant's 30-bed inpatient hospital for autologous and allogeneic stem cell transplantations was 19 and 21 days, respectively. Like with CAR T-cell therapy, this represents only a small percentage of the overall stem cell patient population of the Applicant (with the remainder completing their inpatient stays at BWH),

⁵⁷ *Chemotherapy*, LEUKEMIA & LYMPHOMA SOC'Y (last visited Oct. 1, 2023), https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/treatment/chemotherapy.

⁵⁸ Id.

⁵⁹ CAR T-Cell Therapy and Its Side Effects, AM. CANCER SOC'Y (last revised Mar. 1, 2022), https://www.cancer.org/treatment/treatments-andside-effects/treatment-types/immunotherapy/car-t-cell1.html.

⁶⁰ Mohamed Shanshal, *T-Cell Engagers in Solid Cancers—Current Landscape and Future Directions*, 15 CANCERS (BASEL) 2824 (2023).
⁶¹ CAR T-Cell Therapy, CLEVELAND CLINIC (last revised Jan. 19, 2022), https://my.clevelandclinic.org/health/treatments/17726-car-t-cell-therapy.

⁶² Azra Borogovac et al., Safety and feasibility of outpatient chimeric antigen receptor (CAR) T-cell therapy: experience from a tertiary care center, 57 BONE MARROW TRANSPLANT 1025 (2022); Maurice Alexander et al., Chimeric Antigen Receptor T Cell Therapy: A Comprehensive Review of Clinical Efficacy, Toxicity, and Best Practice for Outpatient Administration, 27 TRANSPLANT CELL THER. 558 (2021).

which has varying levels of acuity. The Applicant's data on stem cell ALOS, therefore, may underrepresent the true ALOS for such patients.

Limited inpatient capacity means that cancer patients often receive acute symptom management in the emergency department due to long wait times for inpatient beds. Further, wait times in the emergency department have risen in Massachusetts. The average length of stay for emergency department patients has increased by approximately two hours across the Commonwealth from 2018 through 2022, a 38% increase.⁶⁴ Massachusetts is tied for the second longest emergency department wait time in the United States.⁶⁵ For this reason, the Applicant has been piloting an innovative oncology-focused acute care clinic that has successfully reduced emergency department visits and helped ensure cancer patients are treated in the most appropriate setting for their care.⁶⁶ However, even with alternative strategies in place, the need for inpatient admission for many patients will remain. Providing more inpatient access should minimize barriers for patients waiting for inpatient beds in the emergency department, move patients more efficiently between care settings, and reduce emergency department wait times.

The Applicant in particular is experiencing an increasing demand for inpatient beds. In FY22, the number of oncology discharges grew by 2.6%. In that same time period, the Applicant's CMI grew by 18.1%, indicating that the Applicant cares for an increasingly sicker population that requires higher acuity care. Over 60% of the Applicant's admissions came through BWH's emergency department in 2022. Further, there are patients currently waiting for beds for days and patients who have spent their entire inpatient cancer admission in the emergency room due to the long wait times. The Applicant estimates the average daily census (or "ADC") in FY23⁶⁷ was approximately 116% of oncology beds it manages in partnership with BWH.

In addition, the Applicant estimates that seven patients per day are unable to be transferred into the Applicant's facility because the Applicant is able to offer transfer for only one patient per day. The seven patients include established patients who have been receiving their ambulatory care with the Applicant and newly diagnosed patients, seeking transfers from outside emergency rooms or inpatient settings, and clinically accepted for transfer. This population represents additional demand for the Applicant's inpatient services who currently have their care disrupted due to lack of access and capacity. The inability to transfer these patients into the Applicant's facility due to bed capacity constraints fragments care and results in increased medical costs and poorer outcomes.

The Applicant's need for additional beds is anchored in both increasing patient volume and increasing acuity. As with many other hospitals across the Commonwealth,⁶⁸ the Applicant is facing post-acute care challenges. Notably, approximately 7% of the Applicant's discharges are to skilled nursing facilities versus 13% statewide. This is due in large part to a difference in post-

⁶⁷ This time period includes October 2022 through August 2023.

https://mhalink.informz.net/mhalink/data/images/ACloggedSystemMHAReport.pdf.

⁶⁴ Emergency Department Database (EDD) Reporting, CHIA (last updated May 25, 2023), https://www.chiamass.gov/emergency-department-database-edd-reporting/.

⁶⁵ Tom Marino, *Study: Over 3 Hours Average Wait Time for ER in Mass.*, THIS WEEK IN WORCESTER (Aug. 9, 2023). https://thisweekinworcester.com/over-3-hours-wait-time-er-mass.

⁶⁶ Anamika Chaudhuri et al., Impact of an oncology acute care clinic (ACC) in a comprehensive cancer care setting to reduce emergency visits and subsequent hospitalizations: A pilot study, 37 J. OF CLINICAL ONCOLOGY 110 (2019).

⁶⁸ Mass. Health & Hosp. Assoc., A Clogged System: Keeping Patients Moving Through their Care Journey (June 2023),

discharge care plans for cancer patients as opposed to other medical and surgical patients with other conditions seen in standard general acute care hospitals.⁶⁹ Strategies related to bed capacity must be tailored to the oncology population due to the difference in distribution in discharge disposition for the Applicant's inpatient panel versus the statewide distribution. Solutions such as the Commonwealth's Skilled Nursing Facility Short Term Rehab Capacity Program will inherently have a lower impact for the Applicant because the Applicant discharges fewer patients to a post-acute sites. The inefficiencies and delays patients are currently facing are best resolved by increased coordination and facilitation of hospital-based services which the Applicant seeks through the Proposed Project.

Estimation of Projected Inpatient Bed Demand

The Applicant projects that by 2032, there will be a need by its patient panel for approximately 384 inpatient beds dedicated to the advanced cancer care provided by the Applicant, as shown in Table 11.

The Applicant intends to provide that advanced cancer care within a dedicated cancer center setting. Dedicated cancer centers have statistically significantly higher survival rates compared to other NCI-designated centers, academic medical centers, and other treatment centers that are not dedicated solely to cancer.⁷⁰ The Applicant provides high-quality, subspecialized services to a highly acute and medically complex patient panel that increasingly requires multi-day inpatient treatment with access to specialized equipment, tools, and support services. For example, patients undergoing myeloablative conditioning as part of stem cell transplantation have historically required lengthy inpatient hospitalization, not only for the administration of intensive chemotherapy, but also for intensive supportive care, including the frequent administration of blood products and intravenous antibiotics, in a setting of strict infection control practices following intensive therapy, and to manage the debilitating side effects from such treatments.⁷¹

When the Facility is operational, the Applicant expects its patient panel will include the cancer patients it has historically cared for, as well as cancer patients previously admitted to BIDMC but who require the sort of advanced cancer care the Applicant will provide at the Facility. To project the need by that patient panel in 2032, the Applicant applied national industry average 10-year growth rates to the 2022 average daily census. It then calculated the minimum number of beds needed to accommodate that projected 2032 average daily census using an industry standard statistical analysis.

a) <u>Calculating 2022 Average Daily Census</u>

⁶⁹ Center for Health Information and Analysis All-Payer Claims Database, CHIA (2022) (sourced by Massachusetts Health Data Consortium).
⁷⁰ Patients treated at dedicated cancer centers have higher survival rates at five years and a reduced risk of mortality than those treated at NCIdesignated centers, academic medical centers, and other treatment centers. See David Pfister, et al., Risk Adjusting Survival Outcomes in Hospitals That Treat Patients With Cancer Without Information on Cancer Stage, 9 JAMA ONCOLOGY 1303, 1303-1310 (2015).

⁷¹ Laura X. Wang et al., *Health care utilization and steroid-refractory toxicities from immune checkpoint inhibitors*, 126 CANCER 322, 322-328 (2019); Saby George et al., *The Impact of Adverse Events on Health Care Resource Utilization, Costs, and Mortality Among Patients Treated with Immune Checkpoint Inhibitors*, 26 THE ONCOLOGISTS 1205, 1205-1215 (2021); Mark Kalinch et al., *Prediction of severe immune-related adverse events requiring hospital admission in patients on immune checkpoint inhibitors: study of a population level insurance claims database from the USA*, 9 J. FOR IMMUNOTHERAPY OF CANCER (2021).

To measure the historical average daily census for inpatient cancer beds under its management, in light of confidentiality restrictions on disclosing proprietary BWH information, the Applicant analyzed Center for Health Information Analysis ("CHIA") inpatient case mix data, which includes information on patient discharges, obtained from the Massachusetts Health Data Consortium ("MHDC"). It identified applicable cancer discharges attributable to the Applicant's oncologists and to BIDMC based on the following discharge-level ICD-10 diagnoses codes:

ICD-10 Code	Description
C00-C96	Includes malignant neoplasm, malignant melanoma, lymphoma, leukemia, basal and squamous cell carcinoma, mesothelioma, Kaposi's sarcoma, gastrointestinal stromal tumor, Merkel cell carcinoma, malignant carcinoid tumor, mycosis fungoides, Sezary Disease
D00-D09	Includes carcinoma in situ and melanoma in situ
D37-D49	Includes neoplasm of uncertain behavior, benign carcinoid tumors, refractory anemia, desmoid tumor
Z19	Includes hormone sensitivity malignancy status
Z51.0	Includes antineoplastic radiation therapy
Z51.1	Includes chemotherapy for neoplasm
Z51.11	Includes antineoplastic chemotherapy
Z51.12	Includes antineoplastic immunotherapy

However, not all patients with these diagnosis codes represent the sort of patients attributable to Dana-Farber oncologists and who would require the sort of inpatient cancer care that will be provided in the Applicant's new Facility. To further refine these data to include only those discharges with characteristics congruent with the new Facility's intended use, the Applicant's clinical leadership team assessed patient age, ICD-10 procedure codes, diagnosis-related groups ("DRGs"), and all patient-DRGs included within the CHIA data on a discharge-by-discharge basis. Discharges excluded from the initial data set based on ICD-10 diagnosis codes included those for: (1) patients under the age of 18 (as the new Facility will not treat pediatric patients), (2) surgical-only patients (as the new Facility will not have surgical capabilities),⁷² and (3) patients with an admission unrelated to cancer (*e.g.*, if the patient was receiving treatment for a stroke, myocardial infarction, or other non-cancer-related matter). The result of this process was a total 2022 discharges number, as reported in Table 11, that included only those cases of the type that the Applicant to sort the 2022 discharges estimate into the six medical oncology bed type categories provided in Table 11.

Once an estimate of total 2022 discharges had been derived, the Applicant estimated the total 2022 average daily census (or "ADC") by multiplying 2022 discharges by the Applicant's historical

⁷² There are instances under the Applicant's current operations where patients receive surgeries at BWH and have their inpatient stays managed by the Applicant's medical oncologist with surgical consultation provided by BWH surgeons. However, the Applicant cannot disclose data relating to these instances due to confidentiality restrictions. Instead, it has elected to remove all surgical-only cases from its CHIA data-derived data set. The resulting calculations may ultimately underestimate the Applicant's overall inpatient bed need.

average length of stay (or "ALOS"), based on CHIA data sourced from the MHDC, as shown in <u>Table 11</u>, and dividing by 365.⁷³ Approximately 30-35% of the historic average daily census shown in the fourth column of <u>Table 11</u> is attributable to cancer patients discharged from BIDMC, which resulted in an average daily census of 272.9 in FY22, with 186.4 patients attributable to the Applicant and 86.7 BIDMC-managed patients. Additionally, the calculated historical average daily census does not include, due to lack of information and difficulty in calculation, all of the patients who were clinically accepted to be transferred to the Applicant or BWH's beds for cancer treatment or management and were unable to transfer due to capacity constraints. Based on internal data, however, the Applicant estimates that it is unable to accept transfer of approximately seven patients per day due to capacity constraints.

b) Calculating ICU Bed Allocation

A portion of patients admitted will require intensive care, necessitating intensive care unit ("ICU") beds. To determine the number of oncology ICU beds needed, the Applicant reviewed Medicare cost report data for certain of its peer comprehensive cancer centers, namely Memorial Sloan Kettering Cancer Center in New York City; Moffitt Cancer Center in Tampa, Florida; MD Anderson Cancer Center in Houston, Texas; and City of Hope in Duarte and Irvine, California. The Applicant found that the ICU census of those hospitals ranged from 7%-14% of total ADC. Unlike the Applicant, a number of those peer hospitals perform surgeries within their inpatient facilities, requiring somewhat greater ICU capacity. As such, when deriving the portion of ADC attributable to ICU beds, the Applicant assumed a percentage—7.5%—on the lower end of its peer hospitals and consistent with the Applicant's own experience. In addition, when making such calculation, the Applicant anticipates that those patients would not require a transfer to a separate ICU bed, given the nature of those patients and the capabilities of the beds associated with those service lines.⁷⁴

c) Projecting Average Daily Census for 2023

The Applicant then used the 2022 ADC to project the 2032 ADC using 10-year national organic growth projections sourced from Sg2 and The Advisory Board Company. To forecast 2032 bed need, a Poisson distribution model analysis was performed, using a 90% confidence interval. A Poisson distribution is a common approach to bed need calculation, especially when many admissions are unplanned, as in the case for the Applicant, where many admissions come from BWH's emergency department and via transfer from another facility.⁷⁵

⁷³ The level of patient discharges and the ADC derived from these calculations are consistent with the Applicant's internal data, which cannot be disclosed due to confidentiality restrictions.

⁷⁴ For example, cell therapies inpatients are admitted to beds with positive pressure and that have the ability to conduct continuous

electroencephalogram monitoring. So long as the appropriate physicians were consulting with respect to such patients care (e.g., a neurologist for patients who require neurological intensive care) such patient could receive sufficiently intensive care without requiring transfer to the intensive care unit.

⁷⁵ Timo Latruwe, et al., *A long-term forecasting and simulation model for strategic planning of hospital bed capacity*, 36 OPERATIONS RSCH. FOR HEALTH CARE 100375 (2023); David R. Sinclair, MD, *Poisson probability function can help optimize trauma operating room availability*, 58 CAN. J. ANESTH. 342 (2010); Linda V. Green, *How many beds*?, 39 INQUIRY 400 (2002).

The Poisson model takes both projected 2032 ADC and ALOS into account in order to project bed demand.⁷⁶ This 90% confidence interval means that there is a 90% likelihood that a bed will be available for each patient that needs one. As a means of comparison, the Poisson distribution-based need calculation in the eighth column of <u>Table 11</u> is shown next to another calculation commonly used to evidence need (final column in <u>Table 11</u>), derived using the projected 2032 average daily census, assuming an 85% occupancy rate.

<u>Bed Types</u>	2022 Discharges ⁷⁹	ALOS	<u>2022</u> <u>ADC</u>	<u>10-year</u> growth rate	<u>Projected</u> <u>2032</u> <u>Discharges</u>	Projected 2032 ADC	Projected 2032 bed <u>need</u>	<u>85%</u> <u>Occ</u>
Medical Oncology Beds								
Cell Therapies (BMT & CAR)	464	23.9	30.4	46.0%*	678	44.4	53	52.2
Neuro Oncology	828	7.1	16.0	10.8%**	917	17.7	23	20.8
Palliative Care	953	10.0	26.1	10.8%**	1,055	28.9	36	34.0
Young Adult Oncology	875	8.4	20.2	18.5%**	1,041	23.9	30	28.2
Geriatric Oncology	1,371	7.9	29.7	34.8%**	1,848	40.0	48	47.1
Medical Oncology	7,085	6.9	134.2	10.8%**	7,861	148.7	169	174.9
Intensive Care Beds								
Oncology ICU ⁸⁰		4.1	16.2	10.8%**		18.0	25	21.1
TOTAL/AVERAGE	11,576	8.6	272.9	17.9%	13,400	321.6	384	378.4

Table 11	
Projected Inpatient Bed Demand ^{77,78}	Proj

* Source: Sg2

**Source: The Advisory Board Company, adjusted for certain factors included in The Advisory Board Company growth rates applicable only to community hospital providers.

d) National Need as Demonstrated by Other Cancer Centers

Further, as evidenced from the patient panel, the Applicant has a significant patient base outside of the Commonwealth, with patients traveling from around the country and the world to receive care from the Applicant. Because the Applicant draws patients from across and outside of the United States, its most comparable peers exist beyond the greater Boston area and include Memorial Sloan Kettering Cancer Center; Moffitt Cancer Center; MD Anderson Cancer Center; City of Hope; and The James Cancer Hospital and Solove Research Institute in Columbus, Ohio.

⁷⁶ For a discussion of the appropriateness of using Poisson distribution to project bed need and for additional detail on the methodology for deriving such a projection, *see* Timo Latruwe, et al., *A long-term forecasting and simulation model for strategic planning of hospital bed capacity*, 36 OPERATIONS RSCH. FOR HEALTH CARE 100375 (2023); David R. Sinclair, MD, *Poisson probability function can help optimize trauma operating room availability*, 58 CAN. J. ANESTH. 342 (2010); Linda V. Green, *How many beds*?, 39 INQUIRY 400 (2002).

⁷⁷ This table does not include data for 2020 due to COVID-19. Analysis completed using data obtained from the Massachusetts Health Data Consortium based on CHIA Inpatient Case Mix data and includes patient volumes and days from cancer patients within the Applicant's beds and BWH beds as well as BIDMC cancer patients. Projections through 2032 based on Advisory Board projections for oncology patients in Massachusetts, filtered for Geriatric ages and Young adult age cohort.

⁷⁸ Numbers may not total due to rounding.

⁷⁹ While precise discharge data for all such patients is available to the Applicant as part of its existing collaboration, portions of that data are proprietary to BWH, and the Applicant is restricted from disclosing it in this Application due to confidentiality restrictions.

⁸⁰ ICU ADC was calculated using total 2022 ADC less the portion of ADC attributable to cell therapy and palliative care, as explained above.

A number of these comprehensive cancer centers have in recent years or are currently undergoing significant inpatient expansion.⁸¹ For example, MD Anderson Cancer Center recently announced a new cancer center in Austin, Texas with 150 inpatient beds, to add to their existing 757 beds, and an outpatient facility.⁸² The Applicant looks at quality and outcomes at these comparators as a driver, and seeks to expand to ensure that it can continue to provide innovative, high quality, and life-saving care to its patients both within the Commonwealth and those who travel to Boston for the sole purpose of receiving care at the Applicant's facility. The table below shows the investments that other dedicated cancer centers across the country are making in additional inpatient capacity.

co	Dedicated NCI- designated omprehensive cancer	Current Inpatient Beds	Planned Projects
1.	centers Dana-Farber Cancer Institute	30	Proposed Project, which contemplates adding 270 net new dedicated oncology beds.
2.	MD Anderson Cancer Center	757 ⁸³	Announced August 2023, a new cancer center in Austin, Texas with 150 inpatient beds and an outpatient facility.
3.	Memorial Sloan Kettering Cancer Center	514 ⁸⁴	31-story cancer care pavilion on main campus, estimated to be completed in 2030, will add 200 inpatient oncology beds.
4.	The James Cancer Hospital and Solove Research Institute	356 ⁸⁵	In 2014, opened new 1.1-million-square-foot, 21-level, 306-bed dedicated cancer hospital, including 36-bed BMT unit.
5.	Moffitt Cancer Center	218 ⁸⁶	Opened on July 31, 2023, 10-story, 498,000 sq. ft facility adds 128 inpatient oncology beds, with capacity for up to 400 in total as well as one MRI scanner, a diagnostic CT scanner, and two nuclear cameras
6.	City of Hope	217 ⁸⁷	Building a new \$1 billion cancer center in Orange County, with a 190,000 sq. ft. outpatient building already opened on the site. Additionally, adding 73 dedicated inpatient oncology beds at Orange County's only stand-alone cancer hospital, planned to open in 2025.

e) Inpatient Need on the Longwood Medical Campus

⁸¹ The City of Hope Orange County Lennar Foundation Cancer Center, CITY OF HOPE (last visited Oct. 1, 2023),

https://www.cityofhope.org/lennar; see Press Release, Memorial Sloan Kettering Cancer Center, Memorial Sloan Kettering Plans New Pavilion to Ensure Greater Access to Care for All People in New York and Beyond (Mar. 15, 2022), https://www.mskcc.org/news-releases/msk-plans-new-pavilion-ensure-greater-access-care-all-people-new-york-and-beyond; see also, Press Release, Moffitt Cancer Center, Moffitt Cancer Center Celebrates Grand Opening of Moffitt McKinley Hospital (July 21, 2023), https://moffitt.org/give/mckinley-expansion/; Ford Sanders & Jeff Bell, UT Austin partners with cancer center MD Anderson to build new campus hospital, KVUE (Aug. 17, 2023),

https://www.kvue.com/article/news/education/university-of-texas/ut-austin-md-anderson-dell-medical-school-hospital/269-b58cc457-1a0e-47b4-8b1c-4e87a202ce67.

⁸² See Sanders, supra note 81.

⁸³ FY22 Quick Facts, MD ANDERSON (last visited Oct. 11, 2023), https://www.mdanderson.org/documents/about-md-anderson/about-us/facts-and-history/quick-facts.pdf.

⁸⁴ History and Milestones, MEMORIAL SLOAN KETTERING CANCER CENTER (last visited Oct. 11, 2023), https://www.mskcc.org/about/historymilestones.

⁸⁵ The James Cancer Hospital and Solove Research Institute, THE JAMES (last visited Oct. 11, 2023), https://cancer.osu.edu/locations/the-jamescancer-hospital-and-solove-research-institute.

⁸⁶ 2022 Annual Report, MOFFITT CANCER CENTER (last visited Oct. 11, 2023),

https://www.moffitt.org/contentassets/d49ae52b00f944f589bc060e91c0ce73/annual-report-2022.pdf.

⁸⁷2021–2023 Implementation Strategy, CITY OF HOPE (last visited Oct. 11, 2023), https://www.cityofhope.org/sites/www/files/2022-05/implementation-strategy-2021-2023.pdf.

For a variety of reasons, it is imperative that this inpatient Facility be located on the Longwood Medical Campus. Most inpatients managed by the Applicant begin their journey through the Applicant's ambulatory practices on the Longwood Medical Campus, underscoring the need for a proximate Facility that can facilitate seamless transitions of care and provide an integrated patient experience. Oncology clinicians frequently move between clinics and the hospital, thereby requiring close proximity to optimize efficiency and seamless coordination of patient care. Moreover, the Applicant's inpatient cancer population is highly acute and medically complex, requiring immediate and sophisticated intervention, sometimes through the provision of intensive care like emergency intubation and continuous electroencephalogram monitoring, only feasible through direct access to a quaternary care center. Proximity is also integral to fostering institutional objectives in research and teaching, as proximity catalyzes interdisciplinary collaboration, hastens the translational process from research to bedside care, and enriches the educational milieu for future healthcare professionals.

For all the foregoing reasons, and as the Applicant's current arrangement with BWH is coming to an end, a freestanding Facility, with a sufficient complement of licensed beds, is necessary to ensure the Applicant is able to continue providing world-class cancer care and engage in innovative research. The identified need cannot be met by other hospitals within the Commonwealth because of the highly specialized nature of inpatient oncology care required by the Applicant's patient panel and the growing demand for such care.

Need for Inpatient Imaging Equipment

MRI scans are used to detect cancer and to determine how significantly a particular cancer may have metastasized within the body.⁸⁸ CT scans are used to indicate the shape, size, and location of tumors. Successive CT scans help doctors determine how well cancer patients are responding to treatment.⁸⁹ Unlike MRIs or CT scans, which show anatomic detail, PET-CT images biochemical or physiologic irregularities. Therefore, PET-CT offers substantial advantages over anatomic imaging modalities in oncologic imaging and can often distinguish between benign and malignant lesions when CT and MRI cannot.⁹⁰

The number of machines needed for each modality, as set forth in <u>Tables 14-16</u>, was calculated by dividing the projected 2032 annual demand for scans for such modality by the estimated number of scans that can be performed per machine in one year (collectively known as "throughput"). The projected 2032 demand for scans was estimated by first multiplying projected 2032 discharges (as shown in <u>Table 11</u>) by the average number of scans per discharge for each modality based on historical data of the Applicant. Second, the Applicant included projected 2032 outpatient scan volume. 2032 outpatient scan volume was estimated by taking the number of CT and PET-CT scans in 2022 that the Applicant referred to other hospital facilities due to lack of capacity at its sites (namely, 7,155 CT scans and 1,722 PET-CT scans) and projecting that volume using the Sg2 growth rate of 4%, which is consistent with the Applicant's own historical growth rate. Because

⁸⁸ MRI for Cancer, AM. CANCER SOC'Y (last revised May 16, 2019), https://www.cancer.org/cancer/diagnosis-staging/tests/imaging-tests/mri-forcancer.html.
⁸⁹ Id.

⁹⁰ Landis K. Griffeth, *Use of PET/CT scanning in cancer patients: technical and practical considerations*, 18 PROCEEDINGS (BAYLOR UNI. MED. CENTR) 321, 321-330 (2005).

the Applicant anticipates using the entirety of the new MRI machines to service inpatients, outpatient volume projections were not incorporated into the demand calculations in <u>Table 15</u>.

Throughput, or annual scan capacity of one machine for each modality, was estimated based on the Applicant's historical throughput experience for each imaging modality, on both an inpatient and outpatient basis. These estimates, shown in <u>Tables 12 and 13</u>, were based on such machine's number of operational days per year (365 for inpatient CT and MRI, 312 for inpatient PET-CT, and 250 for Yes CT and PET-CT), an assumed ten operational hours per day, and the average amount time required per scan based on historical data, with an 85% efficiency adjustment.⁹¹ Because the CT machines and the PET-CT machine will be used on an inpatient and outpatient basis, the Applicant used a weighted average throughput (based on the throughput estimates used in <u>Tables 12 and 13</u>) for purposes of calculating need.

Table 12Inpatient Imaging Equipment Throughput Assumptions

Equipment	Days/Year	Hours/Day	Patient Time (hr)	Efficiency	Throughput
СТ	365	10	0.5	85%	9,928 ⁹²
MRI	365	10	1.00	85%	3,103
PET-CT	312	10	0.75	85%	3,536

Table 13Outpatient Imaging Equipment Throughput Assumptions

Equipment	Days/Year	Hours/Day	Patient Time (hr)	Efficiency	Throughput
CT	250	10	0.33	85%	10,200
PET-CT	250	10	0.50	85%	4,118

To conduct this calculation, the Applicant first examined historical utilization patterns for its inpatient encounters across the various inpatient imaging treatment modalities. The historical utilization data reviewed included discharges for FY21 and FY22, which were 1,440 and 1,463 patients respectively, and the historical Inpatient Imaging Equipment numbers shown in <u>Table 6</u> above for FY21 and FY22. The Applicant divided the historical imaging volume by the discharges to calculate the imaging-to-discharge or "applied scan" ratio. The applied scan ratio is 0.62 for CT, 0.36 for MRI, and 0.04 for PET-CT. Such ratio was multiplied by projected 2032 discharges to derive future projected scans.

⁹¹ Inpatient throughput assumptions reflect estimates of operational days and hours where the imaging equipment in question is expected to be routinely productive. Applicant understands that, in the inpatient setting, imaging will need to be available outside of normal operating hours.
⁹² Initial Applicant data on CT scans was produced on an appointment-level basis. The Applicant estimates, based on internal data, that, on average during an appointment, a patient receives approximately 1.6 scans. As such, initial CT appointment-level data was multiplied by 1.6 to produce scan-level data.

Table 14	
Projected Demand for CT with Proposed Project	t

Metric	2032
CT Applied Scan Ratio	0.62
Projected Inpatient CT Scans	8,269
Projected Unmet Outpatient CT Scans	10,131
Total Projected CT Scans	18,400
CT Weighted Average Throughput	10,078
Total CT Need	2

Given how critical CT scans are to inpatient medical oncology care, it is important that there be more than one CT scanner both to accommodate surge capacity and to ensure redundancy.

Table 15Projected Demand for MRI with Proposed Project

Metric	2032
MRI Applied Scan Ratio	0.36
Projected Inpatient MRI Scans	4,839
Projected Unmet Outpatient MRI Scans	N/A
Total Projected MRI Scans	4,928
Inpatient MRI Throughput	3,103
Total MRI Need	2

Table 16Projected Demand for PET-CT with Proposed Project

Metric	2032
PET-CT Applied Scan Ratio	0.04
Projected Inpatient PET-CT Scans	555
Projected Unmet Outpatient PET-CT Scans	2,455
Total Projected PET-CT Scans	3,010
PET-CT Weighted Average Throughput	4,118
Total PET-CT Need	1

Need for New Radiation Oncology Equipment

The data in <u>Table 18</u> below set forth projected demand for LINACs⁹³ in 2032. The number of LINAC machines needed was calculated by dividing the projected 2032 annual demand for LINAC sessions by a LINAC machine's throughput. Throughput, or annual session capacity, of

⁹³ For purposes of calculating need, "LINAC" refers only to standard linear accelerator machines and does not refer to any type of specialty or modified LINAC (*e.g.*, MRI-guided LINAC or full body LINACs). The Applicant excluded such specialty or modified LINACs from the need calculations in light of confidentiality restrictions on disclosing proprietary BWH information. As such, its overall estimate of LINAC need is likely underestimated.

one LINAC was estimated, based on the Applicant's historical experience, using the information shown in <u>Table 17</u>. The projected 2032 annual demand for LINAC sessions was derived as described in <u>Appendix A</u> attached hereto.

Equipment	Days/Year	Hours/Day	Patient Time (hr)	Efficiency	Throughput
LINAC	250	10	0.3	85%	7,000

Table 17LINAC Throughput Assumptions

Table 18	
Projected Demand for LINAC Sessions	(w/ Proposed Project)

Metric	Total	
Applicant		
Projected 2032 LINAC Sessions	47,456	
BIDMC		
Projected 2032 LINAC Sessions	18,080	
Total Projected 2032 LINAC Sessions	65,536	
Throughput	7,000	
Total LINAC Need	10	

Radiation therapy services are an essential component of a designated cancer hospital and critical to the Applicant's desire to defragment the delivery of cancer care to cancer patients. The Applicant currently operates three LINACs in its existing facilities. The Applicant proposes adding three additional LINACs as part of the Proposed Project, for a total of six LINACs. In the future, the Applicant anticipates further expanding its LINAC capacity through the acquisition by lease of three LINACs currently licensed to BIDMC, for a total of nine LINACs, still shy of the total demonstrated need of 10. The Applicant expects any future addition of the BIDMC LINACs would be the subject of a separate Determination of Need application.

The data in <u>Table 21</u> below set forth projected demand for CT simulators in 2032. The number of CT simulators needed was calculated by dividing the projected 2032 annual demand for CT simulations by each CT simulator's throughput. Throughput, or annual session capacity of one CT simulator, was estimated based on the Applicant's historical experience, using the information shown in <u>Table 19</u>.

Equipment	Days/Year	Hours/Day	Patient Time (hr)	Efficiency	Throughput
CT Simulator	250	10	1.0	85%	2,125

Table 19CT Simulator Throughput Assumptions

The projected 2032 demand started with the projected 2032 LINAC sessions described in <u>Table 18</u> above and, using historical data of the Applicant and BIDMC, estimated the projected number of unique patients that would undergo treatment with LINACs in 2032 at each of the Applicant and BIDMC, as shown in <u>Table 20</u> below. This calculation was derived by dividing the number of unique patients by total LINAC therapy scans. Because CT simulators are used for diagnostic purposes for all patients undergoing treatment with LINACs, the Applicant assumed that each unique patient undergoing LINAC treatment also had one CT simulator treatment prior to receiving LINAC treatment.

The ratio was applied to estimate total CT simulation scans based on the premise that each unique patient represents a "new start" and would require a CT simulation appointment, resulting in the estimated number of CT simulation scans.

 Table 20

 Total CT Simulator Appointments per Unique Patient (Applicant & BIDMC Combined)

Metric	2032
Unadjusted LINAC Sessions	65,536
Weighted Average Treatments/Unique Patient	11.0
Total Projected CT Simulator Treatments	5,958

 Table 21

 Projected Demand for CT Simulator (w/ Proposed Project)

Metric	2032
Projected 2032 CT Simulator Treatments	5,958
Throughput	2,125
Total CT Simulator Need	3

CT simulator need was determined using throughput assumptions outlined above in <u>Table 21</u>. Based on this analysis, there is a need for three CT simulators. The Applicant proposes to add two CT stimulators as part of the Proposed Project. In addition, BIDMC has one CT simulator, which it will continue to operate as part of the collaboration with the Applicant.

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 Applicant anticipates that the Proposed Project will have a pro-competitive impact on the health care market in the Commonwealth. Massachusetts General Hospital ("MGH"), a sister hospital to BWH and part of the Mass General Brigham ("MGB") system, also provides subspeciality-level inpatient cancer care in Boston. The Proposed Project, along with the Applicant's collaboration with BIDMC, would establish the Applicant as independent from any MGH affiliate, serving to promote competition in the market.

Additionally, the Applicant does not compete with community hospitals for patients. As previously mentioned, it refers many patients back to their community physicians once the specialized care they need is complete. The Proposed Project also increases the efficiency of care, as patients will not have to rely so heavily on admittance to the emergency department in order to receive medical oncology care, as discussed in Factor 1.a.ii.

In connection with the Proposed Project, the Applicant anticipates that a significant volume of cancer care will shift from higher-priced health sites of care to relatively lower-priced ones. A significant percentage of patients currently receiving medical oncology services at BIDMC or BWH (and some receiving medical oncology services at MGH) will begin receiving such services from the Applicant. Similarly, the Applicant anticipates that a significant percentage of patients currently receiving surgical oncology services at BWH (and some receiving surgical oncology services at BWH (and some receiving surgical oncology services at BWH (and some receiving surgical oncology services at MGH) will begin receiving surgical oncology services from BIDMC. As both the Applicant and BIDMC provide care at lower rates than BWH and MGH, the Applicant anticipates a decrease in total medical expenses associated with such shifts. A plurality of the Applicant's patients are Medicare beneficiaries. The new Facility established through the Proposed Project is expected to be exempt from the Medicare Prospective Payment System ("PPS"). Nonetheless, once the Proposed Project is operational, the Applicant expects that its inpatient cost-based Medicare rates will not be materially greater than those received by BIDMC and BWH under PPS reimbursement.

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.

The Proposed Project will establish the dedicated inpatient cancer beds in a specialty hospital setting that will provide the most appropriate level of care, at the highest quality for the growing number of Massachusetts residents who will require advanced cancer care. Further, the Proposed Project would allow the Applicant to meet the need for equipment to provide this needed treatment, as noted in Factor 1.a.ii. The Applicant's proposed expansion of oncology services is supported by extensive literature related to evidence-based strategies on effective cancer care, as further discussed in Factor 1.b.iv.

Additionally, over the past decade the number of innovative, complex treatments that require inpatient hospitalization for either the administration or monitoring of the therapy has increased. For example, the number of FDA-approved CAR-T products and bi-specific antibody therapies is expanding. There are now six FDA-approved CAR T-cell products and several more in development.⁹⁴ Bi-specific antibody therapy or T-cell engager therapy is also an expanding therapeutic class, several of which are now widely available.⁹⁵ Currently, the majority of the bispecific treatments and several CAR-T products require hospitalization following administration to manage potential cytokine release syndrome, a known toxicity that can result from a high-level of immune activation that can be life-threatening if not promptly recognized and treated.⁹⁶

Through the Proposed Project, the Applicant will make these services more accessible to those who need inpatient cancer care in order to meet the need discussed at length in Factor 1.a.ii.

⁹⁴ Yi-Ju Chen et al., CAR-TL What Is Next?, 15 CANCERS 663 (2023).

⁹⁵ James E. Frampton, Epcoritamab: First Approval, DRUGS (2023); Michael J. Dickinson et al., Glofitamab for Relapsed or Refractory Diffuse Large B-Cell Lymphoma 387 NEW ENG. J. MED. 2220, 2220-2231 (2022); Philippe Moreau, Teclistamab in Relapsed or Refractory Multiple Myeloma, 387 NEW ENG. J. MED. 495, 495-505 (2022); Hagop Kantarjian et al., Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia, 376 NEW ENG. J. MED. (2017). ⁹⁶ Dustin A. Cobb & Daniel W. Lee, Cytokine Release Syndrome Biology and Management, 27 CANCER J. 119, 119-125 (2021).

F1.b.ii. Public Health Value/Outcome-Oriented

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.

The Proposed Project will provide patients with improved health outcomes, quality of life and access to cancer care services as more fully discussed in Factor 1.a.ii. To assess the impact of the Proposed Project, the Applicant will track the following metrics:

- 1. The proportion (per 1,000 patients) of patients travelling from the New England region that are able to obtain the Applicant's inpatient cancer care services.
- 2. <u>Patient Satisfaction</u>: Patients who are satisfied with care are more likely to seek additional treatment when necessary and tend to have better quality outcomes. The Applicant will review ratings of satisfaction with the care coordination of all inpatient medical oncology services via Press Ganey or an equivalent third-party firm.
 - a. <u>Measure</u>: To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients at the Facility with specific questions addressing (a) care coordination among doctors and caregivers; (b) satisfaction with care services; and (c) the likelihood of recommending services.
 - b. <u>Projections</u>: The Proposed Project will not be implemented for several years. Therefore, the Applicant will provide baseline measures and three years of projections at least one year prior to implementation of the Proposed Project.
 - c. <u>Monitoring</u>: Any category receiving a less than exceptional rating (satisfactory level) will be evaluated and policy changes considered. These data will be evaluated on an annual basis by the Applicant's performance improvement and quality staff.
- 3. The number of patients who obtain radiation therapy at the new Facility.

F1.b.iii. Public Health Value/Health Equity-Focused (Reducing Health Inequity)

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need-base, 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 Applicant is committed to promoting equal and equitable access to cancer care and to reducing barriers to high-quality cancer care for medically underserved patients. Cancer imposes a profound burden on residents in Boston and its surrounding neighborhoods, especially among communities of color. The Applicant's efforts to lessen this burden include a broad range of public health programs designed to reduce cancer incidence and mortality, support community development, and ensure every patient receives equitable and culturally appropriate care, as further described in Factor 2.c below.

The Joint Commission Commended the Applicant for Making Health Equity a Central Focus

The Applicant was the first hospital in the country and the Commonwealth to undergo The Joint Commission's newest National Patient Safety Goal, which, effective January 2023, assesses compliance with new health equity requirements. The Joint Commission commended the Applicant for making health equity a central focus of its core values, strategic plan, and day-today operations and emphasized that the Applicant's outreach efforts were industry-leading as many of the Applicant's initiatives pre-dated regulatory requirements. The Applicant met all six elements of performance by designating leaders to reduce health disparities for patients, assessing health related social needs, providing resource information and meeting identified patient needs with resources, stratifying quality and safety data by socio-demographic characteristics, developing a written action plan to address at least one health disparity, evaluating the action plan and taking action to achieve those goals, and informing leaders, practitioners, and staff about progress to reduce identified disparities. Among other initiatives and in accordance with The Joint Commission's standards, the Applicant included a social determinants of health screening via its new patient intake questionnaire, developed a written action plan to improve access to transportation for patients in the patient navigation program (discussed below) and embedded health equity initiatives and progress reporting within Quality Assurance and Performance Improvement goals and structure, the Applicant's operating goals, as well as via other reporting structures.

Access

The Applicant participates in outreach activities aimed at the reduction of cancer incidence, morbidity, and mortality, supports community-based programs, and conducts community-based research. These activities are informed by the Applicant's CHNA, conducted every three years to gain a better understanding of the health issues patients face in the community. Further, the Applicant's community outreach mission, which was formally adopted by Applicant's Board of

Trustees in 1995 and revised in 2022 seeks to: (1) expand access to the Applicant's measurable, evidence-based programs in early detection, screening, and cancer prevention and education to reach at-risk, historically marginalized, and diverse populations, and (2) partner with community health centers, community-based organizations, and government entities to assess, enhance, and improve the overall health and well-being of the members of the Applicant's communities. The Applicant was the first hospital to establish a Patient and Family Advisory Council ("PFAC"), integrating patient and family voices in the development and shaping of programs, services, and initiatives, and was instrumental in passing legislation mandating that all Massachusetts hospitals have similar councils.

Commitment to Clinical Access and Equity

The Applicant launched its Cancer Care Equity Program (the "CCEP") in 2010, and has since expanded its outreach programming to two Federally Qualified Health Clinics ("FQHC"), Harvard Street Neighborhood Health Center ("Harvard Street") in Dorchester and The Dimock Health Center in Roxbury.⁹⁷ The goal of the CCEP is to reduce disparities in cancer outcomes for historically marginalized groups locally, as well as become a national model for translating cancer equity research into interventions that have demonstrable impact. Current CCEP outreach programs provide on-site evaluation services by the Applicant's providers (oncologists and other clinicians) to patients at Harvard Street and The Dimock Center based on a co-location model. In coordination with their primary care provider, patients are referred to the CCEP for diagnostic evaluation of suspected cancers and abnormal screening, cancer genetic counseling and testing, lung cancer screening and smoking cessation counseling, selected long-term follow-up or, for those with previous cancer histories, to re-establish connections with oncology. The Applicant's clinicians provide care under the license of the FQHCs, which allows for continuity of care and reduced administrative burdens for patients. When patients who participate in these clinics present with cancer-related issues, the CCEP navigates the patient to a cancer facility of their choosing, including, if appropriate, the Applicant, for further care. If a patient does not present with a cancerrelated issue, the CCEP helps navigate those patients to other, non-cancer specialty care according to the wishes of the patient. A study conducted of the CCEP model indicates that the model improves access to care for historically marginalized populations.⁹⁸

Community Focused Patient Navigation

To reduce gaps in timely cancer screening, diagnosis, and treatment for patients from historically marginalized and vulnerable groups who are most at risk to loss at follow up, the Applicant created a patient navigation program in 2005 with the aim of guiding medically underserved patients and their families through the complexities of both cancer screening and cancer care in a culturally sensitive way. Patient navigation, a concept pioneered in the 1990s by Harold Freeman, MD, is an evidence-based, community-based intervention designed to promote timely access to cancer

⁹⁷ Laura Tesler Waldman et al., A novel community-based delivery model to combat cancer disparities, 1 HEALTHCARE (AMST) 123, 123-129

^{(2013).} ⁹⁸ Laura Tesler Waldman et al., Using FastTrack to Implement an Academic Medical Center and Community Health Center Collaborative for Cancer Care Delivery, HEALTHCARE (AMST) 130, 130-135 (2013); Huma O. Rana et al., A comparison of cancer risk assessment and testing outcomes in patients from underserved vs. tertiary care settings 9 J. COMM. GENETICS 233, 233-241 (2018); Leah S. Stockman, The Colocation Model in Community Cancer Care: A Description of Patient Clinical and Demographic Attributes and Referral Pathways, 19 JCO ONCOLOGY PRACTICE e916, e916-926 (2023); DF/HCC Community Outreach Supplement, Cancer Center Support Grant NIH/NCI P30 CA006516-51S3. 2017-2020.

diagnosis and treatment by eliminating barriers to care from point of cancer detection to survivorship or end of life, such as: financial and economic disparities, health care system complexity, language and cultural differences, communication and information breakdown, and fear and distrust of health care providers/system.⁹⁹ Though anchored at the Applicant, the Applicant's patient navigators have established visible relationships with community level providers such as community health centers, primary care practices, community hospitals and other social service organizations. A patient navigator is an individual trained to help identify and resolve real and perceived barriers to care, enabling cancer patients to adhere to treatment recommendations, and thereby improving their cancer outcomes.¹⁰⁰ Patient navigators are tasked with identifying high-risk patients, conducting outreach to marginalized communities, and assisting patients in accessing the Applicant's cancer care and supportive services. Further, the Applicant's patient navigators proactively engage with adult patients from historically marginalized communities, eliminate barriers to timely care, and help patients navigate health care system complexities and logistics throughout the cancer continuum. Studies have found that cancer patient navigation programs result in increased access to and utilization of cancer care for poor and underserved individuals.¹⁰¹ Research shows that patients who face the greatest barriers in accessing care are at risk of foregoing diagnostic testing and/or treatment until later stages of cancer without the involvement of a navigator to provide support, encouragement, and linkages to resources to facilitate completion of treatment, making this a critical resource for patients.

In October 2021, as an operational priority, this program was expanded with a focus on increasing access and equity for the Applicant's priority community neighborhoods and integrating the navigation with the clinical operations under the CCEP in collaboration with the Applicant's Community Benefits Office. The Applicant's CHNA identified priority neighborhoods for community health work including, Roxbury, Dorchester, Mattapan, and Jamaica Plain, which are some of Boston's most diverse areas. Currently in the pilot phase, the Applicant's community focused patient navigation is integrating into the clinical operational space, with plans to expand to all areas of the clinical enterprise. The Proposed Project will allow the Applicant to consolidate outreach efforts to a standalone inpatient hospital for its community prevention and diagnostic services and provide a sole focus on cancer to its priority neighborhoods, as well as expand the capacity to impact marginalized communities throughout the greater Boston area.

To further these efforts, the Applicant maintains a strategic alliance with Boston Medical Center ("BMC"), which allows BMC patients and physicians to access Applicant's clinical trials, thereby promoting access to innovative studies and investigational products.

The Applicant employs financial counselors who work closely with patients to remove access barriers by ensuring patients fully understand their available insurance coverage and any sources of potential financial assistance. Through its recent contract with Wellsense, formally the Boston Medical Center HealthNet Plan, the second largest MassHealth managed care plan in the Commonwealth, the Applicant expanded access to thousands of MassHealth patients, which raised

⁹⁹ Harold P. Freeman & Rian L Rodriguez, *The History and Principles of Patient Navigation*, 117 CANCER 3539, 3539-3542 (2011). ¹⁰⁰ *Id.*

¹⁰¹ Kathryn L. Braun et al., *Cancer Patient Navigator Tasks across the Cancer Care Continuum*, 23 J. OF HEALTH CARE FOR THE POOR AND UNDESERVED 398, 398-413 (2012).

the percentage of MassHealth members in Massachusetts who were enrolled in a health plan that offered access to the Applicant from 67% to 88%.¹⁰²

Further, the Applicant is making significant progress in curbing youth access to tobacco, providing breast cancer screenings, increasing vaccination rates for human papillomavirus ("HPV"), and educating residents about their risk for cancer. The Applicant's Community Benefits Office partnered with Union Capital Boston and Dana-Farber/Harvard Cancer Center for Cancer Equity & Engagement ("DF/HCC") to host four Cancer Awareness Resource Nights focused on breast cancer screening, tobacco cessation, HPV vaccination, and cancer survivorship, engaging over 500 residents virtually. The impact of these programs is greatly strengthened by embedding these initiatives and services in the fabric of the communities that the Applicant serves and through comprehensive partnerships with community-based organizations and across the Commonwealth.

Aside from the patient navigation program discussed above, the Applicant offers a comprehensive array of supportive resources and services, including resource specialists, social workers, clinical nurse navigators, among others to help address cultural, language, transportation, financial, and other barriers to care for patients, as discussed in Factor 1.c.

Site Accessibility

Although cancer affects all racial and ethnic groups in Massachusetts, some groups are disproportionally impacted. The Applicant's CHNA findings indicate that Black men in Boston continue to experience the highest rates of overall cancer mortality and premature cancer mortality. Barriers to accessing cancer services include, among other things, access to transportation. Of the unique patients identified by the Applicant's patient navigators, 15% reported transportation as a barrier to their cancer care. Of these patients, the majority self-identify as Black or African American (58%) and have Medicare or Medicaid (76%). The Applicant has been working to address the transportation needs of its patient panel and has been successful in securing grant funding to continue to address these needs and reduce patient no-shows. For example, patient navigators helped coordinate ride-sharing resources such as Uber, PT-1, and the Massachusetts Bay Transportation Authority's The RIDE service, to help prevent patient no-shows and delays in cancer treatment. Further, the Proposed Project would preserve and increase the number of much needed inpatient cancer care beds on the Longwood Medical Campus, which is accessible by both car and public transportation, allowing for greater flexibility for those who may not have reliable access to a car. The Proposed Project site's location and design will ensure accessibility for disabled and mobility-impaired patients.

The building of the new Facility as part of the Proposed Project gives the Applicant the opportunity to take lessons learned from ongoing work to address health equity and cancer health disparities and apply those lessons in the fabric of the design of the Applicant's Facility, its clinical programming, and its ability to reach historically underserved communities.

¹⁰² Dana-Farber Becomes In-Network Provider for BMC HealthNet Plan, DANA-FARBER CANCER INST. (last updated Mar. 9, 2022), https://blog.dana-farber.org/insight/2022/01/dana-farber-becomes-in-network-provider-for-bmc-heathnet-plan/.

F1.b.iv. Public Health Value/Health Equity-Focused (Additional Information)

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 Applicant provides, and through the Proposed Project will expand its ability to provide, a continuum of cancer care, including risk assessment, primary prevention, screening, detection, diagnosis, treatment, palliative and psychosocial care, survivorship, and end-of-life care. Each of these services includes a number of departments, and the inclusion of a multidisciplinary team of providers and departments, which can improve care outcomes.¹⁰³ The Applicant continues to advance the mission of Dr. Sidney Farber's groundbreaking core philosophy of "Total Patient Care," in which all patient services are provided in one place and decisions are made as a team in collaboration with the patient. The Applicant's approach is to bring together multidisciplinary teams with expertise in cancer care whose focus is to achieve superior outcomes for patients while delivering care which meets rigorous clinical quality and safety standards. These multidisciplinary teams include medical oncologists, hematologists, medical subspecialists, surgical oncologists, radiation oncologists, advanced practice providers, specialized oncology nurses, nurse navigators, clinical social workers, and patient navigators. Specialists work closely together to offer patients the latest therapies, specialty programs, and clinical services, including access to innovative clinical trials.

Inpatient Clinical Centers

Further, the Applicant's inpatient structure in its existing unit and across the inpatient care it manages at BWH has been developed to continue this model of integrated, specialized, and subspecialized care across the care continuum from the outpatient setting into the acute care inpatient setting. Patients are assigned to an inpatient team based upon their disease type or modality of treatment with attending physicians who are expert in their specific disease. The Applicant has dedicated teams of oncology nurses, advanced practice providers and physicians specialized in solid tumor malignancies, hematologic malignancies, and bone marrow transplants, immune effector cell therapies, as well as palliative care. Inpatient teams are led by the Applicant's faculty, staffed by highly trained physician assistants and internal medicine residents, and regionalized to units with dedicated and highly specialized oncology nurses. Additionally, the Applicant's solid tumor teams are predominantly disease-center based with dedicated services for breast cancer, gynecological cancers, gastrointestinal cancers, thoracic cancers, etc., as well as the treatment of immunotherapy toxicity. Within its hematologic malignancy teams, the Applicant has teams dedicated to bone marrow transplantation, immune effector cell therapies (including CAR-T), leukemia and the treatment of lymphoma and multiple myeloma.

The Applicant provides all aspects of oncologic care including chemotherapy, palliative care, and treatment to mitigate the toxicities and side effects of cancer diseases and their treatments. Further, the Applicant's inpatient palliative care team operates a unit of specialized palliative care physicians and nurses. This unit is dedicated to intensive palliative care and care focused on the needs of cancer patients experiencing symptoms related to their cancer or its treatment or whose

¹⁰³ Jane Zapka et al., *Multilevel Factors Affecting Quality: Examples from the Cancer Care Continuum*, 2012 JNCI MONOGRAPHS 11, 11-19 (2012).

hospitalization is devoted to symptom control and/or end of life care. In addition, the Applicant has dedicated and specialized medical and surgical subspecialty care including infectious disease, nephrology, cardiology pulmonary medicine and other medical subspecialties, intensive care, and state of the art radiation oncology therapy and radiology services (including nuclear medicine), MRI and CT, and interventional radiology. Further, ancillary services including clinical social work, medical nutrition therapy, respiratory care, physical and occupational therapy, and spiritual care are central to the Applicant's inpatient multidisciplinary teams. Consistent with Dr. Farber's "Total Patient Care" philosophy, all care is supported by the availability of medical interpreters for patients for whom English is not their first language, as detailed in Factor 1.c.

Other Adult Clinical Services and Adult Specialty Centers

The Applicant's patients also benefit from other clinical services and specialty programs, including systemic infusion therapy (*e.g.*, chemotherapy, biologic, endocrine and immunotherapies), imaging services (radiology/nuclear medicine), oncology hospital medicine (inpatient care), oral medicine and oral oncology, pathology, the adult survivorship program, the adult fertility preservation (oncofertility) program, adult psychosocial oncology, the Zakim Center for Integrative Therapies and Healthy Living, the Center for Cancer Therapeutic Innovation, the Adolescent and Young Adult Program, the Center for Immuno-Oncology, and the stem cell transplantation and cellular therapies division, including The Connell and O'Reilly Families Cell Manipulation Core Facility, where the Applicant processes cells for more than 600 adult and pediatric stem cell transplants and supports more than 40 diverse active clinical research protocols. Further, the Applicant also manages a comprehensive immunotoxicity service for rapidly evolving care, with intense care coordination between the inpatient and outpatient settings for patients who have received immunotherapy in the last several months, even if the patient is no longer being treated with immunotherapy (because these toxicities may occur even months after discontinuation of this therapy).

The Applicant's differentiated care is supported in part by its oncology research infrastructure, including specialized research nurses, pharmacists, research coordinators, and data managers in addition to the Applicant's oncology pharmacy which provides specialized coordination between ambulatory and inpatient care settings. The Applicant has oncology-trained staff including resource specialists, nurse navigators, patient navigators, spiritual care providers, and nutritionists, as well as oncology-trained staff that are subspecialized in specific cancer types, such as oncology nurses trained in each specific cancer type, clinical social work, psychiatry, palliative care, infection control, and infectious diseases.

The ability to consolidate oncologic subspecialized care in the inpatient setting will allow for implementation of a more equitable, integrated, cancer-focused health care delivery infrastructure as described above. In addition, the Proposed Project will also facilitate enhanced coordination of cancer prevention, outreach, and screening and diagnostic services for communities.

Through the Proposed Project, the Applicant will continue to facilitate expedited access to fully integrated cancer care services, assisting patients and families in navigating the complex clinical system and providing essential supportive services that positively impact overall health outcomes and patient experience.

F1.c. Furthering and Improving Continuity and Coordination of Care

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.

To ensure continuity of care, improved health outcomes, and enhanced quality of life through the Proposed Project, the Applicant's staff will continue existing formal processes for linking cancer patients with referring physicians (often primary care physicians) and other specialists for follow-up care. Currently, the Applicant works with physicians' groups and community medical groups throughout the Commonwealth, including, but not limited to, MGB-affiliated physician's offices and community medical groups, Beth Israel Lahey Health ("BILH")-affiliated physician's offices and community medical groups, South Shore Health Medical Group, Steward Medical Group, Berkshire Health System Medical Group, Harvard Street Health Center, and Cape Cod Healthcare Physician Groups, to ensure that patients are receiving the appropriate follow-up care across the care continuum. The Applicant will also continue its efforts to ensure patients receive the right care in the right setting, including through its provision of second opinion services to community hospitals and its practice of returning patients to community hospitals when they do not require the Applicant's specialized cancer expertise.

The Applicant provides care coordination services in numerous ways. As discussed in Factor 1.b.iii, the Applicant has an array of supportive services that coordinate care, such as patient navigators and resource specialists who help to decrease barriers to care, in addition to nurse navigators who follow the patients throughout their cancer journeys and provide symptom management and coordination of their medical care across the cancer service continuum. Further, as also discussed in Factor 2.c, the Applicant partners with community organizations to assess, enhance, and improve the overall health and well-being of the members of the Applicant's communities.

In addition to patient navigation services, the Applicant provides linkages to its adult social work program, resource specialists, financial counseling assistance program, pro-bono legal services as well as interpreter services. Social workers provide assistance to patients and families on a number of issues, such as dealing with depression and anxiety, concerns about drug and alcohol use, coping with advanced cancer, and finding supportive local resources. Financial counselors aid patients who are unable to pay for care in understanding sources of potential financial assistance. Consistent with all applicable laws, resource specialists assist patients in obtaining local transportation, short-term accommodations during treatment, and other special needs (such as, pro bono legal services, fuel and food pantry assistance, and other financial assistance). Between FY21 and FY23, the Applicant's Adult Resource Office has assisted 18,173 unique patients in accessing these resources.

With regard to interpreter services, the Applicant has adopted the Culturally and Linguistically Appropriate Service standards (specifically the Communication and Language Assistance Standards) set forth by the United States Department of Health and Human Services Office of Minority Health. The Applicant provides effective, understandable, and respectful care with an understanding of patients' cultural health beliefs and practices and preferred languages. Accordingly, the Applicant provides medical interpreters at no charge to patients and families who speak a language other than English. The Applicant's medical interpreters are trained professionals who speak a patient's language, share a patient's culture, have knowledge of medical terminology, and support a patient and their care team. Further, in addition to translating important clinical conversations, interpreters meet patients who are identified as having a primary language other than English and escort them through registration. Additionally, ambassadors accompany patients to their appointments, help with referrals and pharmacy pick up, and inform them of the many supportive programs and resources at the Applicant. To foster trust in the ambassador, the Applicant's interpreter services program aims to pair an interpreter with a specific patient and their family regularly. Ambassadors often meet the same patients up to four times as they get accustomed to the Applicant and continue to provide support for a patient through their experience with the Applicant. Through all of these efforts, the Applicant ensures that all patients have access to high quality oncology services and exceptional patient experience.

F1.d. Consultation with Government Agencies

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 following is a list of the Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant and/or the Proposed Project. The Applicant has consulted, or will consult with each of the following Government Agencies prior to or after the Filing Date.

- United States Department of Health and Human Services, Centers for Medicare and Medicaid Services;
- Massachusetts Executive Office of Health and Human Services;
- Massachusetts Office of the Attorney General;
- Massachusetts Health Policy Commission;
- Massachusetts Department of Public Health: Office of the Commissioner, Office of Legal Counsel, Determination of Need Program, Office of Health Equity;
- Massachusetts Center for Health Information and Analysis;
- Massachusetts Medicaid (MassHealth);
- Boston Planning & Development Agency, Zoning Board of Appeal; and
- Massachusetts Environmental Policy Act Office.

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.

To ensure appropriate patient and family engagement, the Applicant's staff first presented the Proposed Project to the Applicant's Adult PFAC. This is one of two PFACs at the hospital (there is a separate Pediatric PFAC) comprised of patients, family, and staff members that seek to ensure that the Applicant provides patient- and family-centered care with a commitment to dignity and respect, information sharing, participation, and collaboration. The PFACs' mission is: (1) to help disseminate information and implement services that affect the Applicant's patients and their families; (2) to support patients and their families becoming informed advocates for their own care; (3) to offer a patient and family voice; (4) to initiate ideas for policies, programs, projects, and services within the patient care environment; and (5) to provide ongoing opportunities to hear the voices, experiences, and perspectives of patients and their families.

On September 14, the Applicant's clinical leadership met with the PFAC staff management to initially inform them of the public announcement of the Proposed Project. The Applicant sought feedback from its PFAC about the Proposed Project and members of the PFAC informed leadership and staff of its view of need for increased inpatient capacity, patient experience and satisfaction, wait times, and inability to access care. Further, on October 3, 2023, the Applicant's Chief Medical Officer and Senior Vice President, Patient Care Services, in collaboration with the PFAC Co-Chairs, presented on the Proposed Project at a special PFAC meeting, providing the PFAC with background, a high-level timeline for progression, and an opportunity to ask questions. A discussion took place regarding the impact of the Proposed Project on patients, patient care and the overall patient experience during the next five years, as well as the benefits of a dedicated cancer hospital and vision for the future of cancer care. The materials from these meetings are attached in Attachment 9.

Separately, the PFAC was informed that patients would have an opportunity to provide feedback at patient open forums, which took place on the 16th, 17th, and 18th of October 2023. These virtual forums offered patients and families the opportunity to learn more about the Proposed Project and the Applicant's vision for the future of cancer care. An invitation was sent to all of the Applicant's current patients for each of the three forums. Patients and families could choose to attend whichever forum was convenient for them. Participants were able to submit questions in advance of the forums as well as anonymously submit questions during the event. The presentation slides used for the patient forums are also attached in Attachment 9.

The Applicant will also meet with government stakeholders prior to and after the filing of this Application, including individuals in the Governor's Office, Lieutenant Governor's Office, Attorney General's Office, Executive Office of Health and Human Services, Department of Public Health, Health Policy Commission, and elected individuals representing the City of Boston and the Commonwealth, as well as individuals at the Department of Health and Human Services, Centers for Medicare and Medicaid Services.

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".

The Applicant has engaged in a robust community engagement process including, without limitation presenting the Proposed Project to its PFAC members, Community Benefits/DoN External Advisory Committee, and the public to inform the community of the Proposed Project and solicit feedback in the development of the Proposed Project. Further, when engaging with stakeholders, the Applicant discussed and sought feedback on the Public Health Value of the Proposed Project, as outlined in Factor 1.b, and addressed concerns as appropriate. The Applicant considered this feedback when identifying its patient panel need, described in Factor 1.a.ii, and designing the Proposed Project to address the patient panel need and to ensure the Proposed Project had a positive Public Health Value on its community.

Factor 2 Health Priorities

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

F2.a. Cost Containment

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.

As discussed above in Factor 1.a.i and Factor 1.a.iii, as the only freestanding, NCI-designated comprehensive cancer center in New England, the Applicant's patient panel includes all residents of Massachusetts that may receive a cancer diagnosis. The Applicant is pursuing this Proposed Project because it recognizes that there is a growing need for both inpatient medical oncology services and radiation therapy services in the Commonwealth. Through the Proposed Project, the Applicant further seeks to expand access to world-class, potentially life-saving cancer care without a meaningful increase in cost, and without a meaningful impact on cost growth as noted above in Factor 1.a.iii. As discussed above, because the Proposed Project results in the transition of care of the sickest patients from one of the highest cost centers to more cost-effective cost centers, the Applicant anticipates a decrease in total medical expenses in the Commonwealth.

The Applicant plans to continue its preexisting efforts at containing health care costs in the Commonwealth. By way of example of these efforts, the Applicant has developed an alternative to emergency care. The Applicant has no emergency department. Emergency departments of general acute care hospitals generally do not have oncology subspecialty capabilities. Further, oncology patients unnecessary visiting emergency departments puts said patients at a greater risk of complications, given cancer patients' susceptibility to communicable diseases.¹⁰⁴ In addition. emergency department visits are a major source of health care resource utilization and costs, including because emergency department visits often yield inpatient admissions that could have been avoided had the appropriate treatment been provided initially in the outpatient setting.¹⁰⁵As such, the Applicant recognized that providing patients with an alternative to the emergency department could both increase the quality of care provided to cancer patients, while also reducing the cost. The Applicant, therefore, developed an oncology-specific acute care clinic that caters to urgent medical needs of cancer patients. A published study assessing the impact of the clinic was completed using a retrospective analysis of four months pre- and post-opening of the clinic, looking at patient emergency department visits and subsequent hospitalizations for patients.¹⁰⁶ The study found that the impact of the acute care clinic found that it resulted in an approximately 20% reduction in emergency department visits and less care in acute care settings, including double the proportion of patients discharged to home and approximately one-fifth the proportion of patients admitted to an inpatient bed.¹⁰⁷

 ¹⁰⁴ Amir Alishahi Tabriz, MD, PhD, MPH, et al., *Trends and Characteristics of Potentially Preventable Emergency Department Visits Among Patients with Cancer in the US*, 6 JAMA NETW OPEN 1 (2023).
 ¹⁰⁵ Id

¹⁰⁶ Chaudhuri et al., *supra* note 66.

¹⁰⁷ Id.

As a further example of the Applicant's efforts to extend care beyond inpatient academic hospitals, the Applicant has instituted a "Shared Care" model, which allows patients to be seen locally in their communities for follow-up care after receiving allogenic hematopoietic cell transplantation from the Applicant. This program has the opportunity to help reduce reliance on academic hospitals in Boston and promotes the provision of cost-effective care within local community hospitals. Similarly, the Applicant's efforts to bring cancer screening into underserved communities (including through the initiatives discussed in more detail in Section <u>F2.c.</u>) can provide additional cost savings through earlier diagnosis and intervention and decreased variation in acute care utilization. Acute care utilization is the single largest driver of regional spending variation in oncology care, accounting for 48% of spending and 67% of variation.¹⁰⁸ Further, in a study reviewing cost of care for breast cancer, which included two years of post-diagnosis claims data analyzed by stage at diagnosis, researchers found that the average cost per patient at disease stages III and IV were between 64% and 154% higher than the cost of those patients treated at Stage 0, I and II.¹⁰⁹

¹⁰⁸ Gabriel A. Brooks et al., Acute hospital care is the chief driver of regional spending variation in Medicare patients with advanced cancer, 30 HEALTH AFF. 1793, 1793-1800 (2014).

¹⁰⁹ Helen Blumen, MD, et al., *Comparison of Treatment Costs for Breast Cancer, by Tumor Stage and Type of Service*, 9 AM. HEALTH DRUG BENEFITS 23, 23-32 (2016).

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 increase the accessibility of inpatient medical oncology services and radiation therapy services for Massachusetts residents, especially for the highest acuity patients with the most complex diagnoses. As a result of such increased accessibility, the Proposed Project will improve quality of life and save patient lives.

Specifically, the Proposed Project will enhance oncology services in Massachusetts, offering residents greater access to the high quality, cutting-edge inpatient medical oncology, and radiation therapy services by expanding the number of beds and equipment available to the Applicant to meet the needs for these services and keep patients out of the emergency room, as further outlined in Factor 1.b.ii and Factor 1.b.iii.

The Applicant is focused on providing care across the entire cancer care continuum. This perspective allows the Applicant to focus on opportunities for innovation, improve delivery and efficiency of care, and disseminate this knowledge to the broader oncology community to improve outcomes for cancer patients world-wide. The Proposed Project will have a direct impact upon public health outcomes by expanding the availability and access to this type of highly specialized and focused care, as well as improving access to clinical trials. Furthermore, data support that risk-adjusted outcomes for patients with cancer treated at dedicated cancer hospitals (including of the type the Applicant is proposing as the Project) are superior to the outcomes of patients treated at other facilities, including NCI-designated cancer hospitals and academic medical centers.¹¹⁰

Furthermore, the Proposed Project will have the downstream effect of increasing the likelihood of patients getting to the right treatment, in the appropriate setting, at the optimal time. Increased inpatient capacity will mean more timely care. Delays in cancer care have been associated with poor outcomes and increased mortality.¹¹¹ As a result of the Proposed Project, fewer people will be awaiting tertiary-level care. The proposed number of LINACs also will ensure fewer people are waiting for radiation oncology services. Furthermore, the Applicant anticipates that the downstream effect of more inpatient bed availability will translate into fewer patients boarding in the emergency department. Emergency department boarding is associated with negative patient-related outcomes including, lower patient satisfaction, delayed time to medication and treatment, higher complication rates, and higher inpatient mortality rates.¹¹² The Proposed Project will increase inpatient adult cancer care bed capacity and alleviate boarding in the emergency department will increase the availability of emergency department resources for the appropriate and timely delivery of emergency care services for patients seeking care for myocardial infarction, stroke, trauma, and other life-threatening emergencies.

¹¹⁰ David Pfister, et al., *supra* note 70.

¹¹¹ Timothy P Hanna, et al., Mortality due to cancer treatment delay: systematic review and meta-analysis, 371 BRIT. MED. J. m4087 (2020)

¹¹² Adam Singer, et al., *The Association Between Length of Emergency Department Boarding and Mortality*, ACAD. EMERGENCY MED. 1553, 1324, 1324 – 1329 (2011)

F2.c. Delivery System Transformation

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.

Linkages to Social Services Organizations

The Applicant recognizes that efforts to reduce the cancer burden must go beyond cancer care and treatment, and so it partners with social services and community-based organizations to link its patient panel to resources that help address health disparities. These partnerships include:

- **Boston Breast Cancer Equity Coalition:** Launched in 2014 by the Applicant, this crosssector coalition seeks to eliminate the differences in breast cancer care and outcomes by promoting equity and excellence in care among women of all racial/ethnic groups in the City of Boston. The Applicant continues to be an engaged member of the coalition.
- **Boston CHNA/CHIP Collaborative**: The Applicant is a founding member of the Boston CHNA/CHIP Collaborative, a large multi-sector effort launched in September 2018 to conduct the first citywide Community Health Needs Assessment and Implementation Plan ("CHNA/CHIP"). The Applicant also serves as the co-chair of the Collaborative and previously co-chaired the Community Engagement Work Group in collaboration with BPHC.
- **Boston Public Health Commission ("BPHC"):** The Applicant works closely with the BPHC to implement and sustain initiatives that address the need for cancer prevention education, screening services, and survivorship education. BPHC is also an active member of the Applicant's Community Benefits External Advisory Committee.
- **CHNA Partners**: The Applicant worked closely with Enhance Asian Community on Health, Roxbury Tenants of Harvard, Union Capital Boston and BPHC to implement community engagement efforts for Dana-Farber's 2022 Cancer CHNA Report.
- Dana-Farber/Harvard Cancer Center for Cancer Equity & Engagement ("DF/HCC CCEE"): The Applicant and the DF/HCC CCEE continue to collaborate and develop programming in a variety of areas aimed at reducing the unequal burden of cancer in partnership with the Faith-based Cancer Disparities Network and other community-based organizations. Early in its history, the consortium created the Initiative to Eliminate Cancer Disparities ("IECD") to maximize the acceptance and desirability of cancer research in communities that have traditionally experienced significant disparities in cancer care. The DF/HCC IECD is also the convener of the Patient Navigator Network.
- Dana-Farber's Center for Community-Based Research ("CCBR"): CCBR conducts cancer prevention research with the goal of developing effective intervention strategies to reduce the risk of cancer. CCBR works extensively with neighborhood health centers, low-income housing, faith-based organizations, health departments and community-based

organizations.

- **Massachusetts Coalition for HPV:** The Applicant continues to partner with Team Maureen to lead the statewide HPV Coalition and identify opportunities for greatest impact in increasing statewide vaccination rates and knowledge around HPV-related cancers. The Applicant also continues to play an active role in supporting the annual HPV-Related Cancer Summit.
- **Massachusetts Department of Public Health:** Through ongoing partnerships with DPH's Chronic Disease Prevention and Control Unit, programs in colorectal, prostate, skin and women's cancers have been established with DPH and other community agencies across the Commonwealth.
- **Prostate Cancer Foundation ("PCF"):** In 2020, the Applicant, PCF, and VA Boston Healthcare System partnered to launch the first PCF-Veterans Affairs Center of Excellence in New England to advance prostate cancer treatment for veterans.
- **Prostate Health Education Network ("PHEN"):** The Applicant and PHEN partner on education, outreach and advocacy efforts and together sustain a prostate cancer support group for men of color that meets monthly at the Applicant's facility.
- **Tobacco Free Mass Coalition:** As a member of the Tobacco Free Mass Coalition, the Applicant supports the development of policies that aim to reduce youth access to tobacco, prevent nicotine addiction, and increase tobacco control funding.
- Union Capital Boston ("UCB"): The Applicant is actively involved in a partnership initiative with UCB focused on promoting cancer prevention and survivorship and strengthening the work of the Applicant's Community Benefits Office. The Applicant also worked closely with UCB to carry out focus groups with cancer patients, survivors, and caregivers for the Applicant's 2022 Cancer CHNA.
- Rian Immigrant Center ("Rian") and Health Law Advocates ("HLA"): The Applicant has established an immigrant-focused medical-legal partnership with two respected Boston-based community organizations, Rian and HLA. The partnership established a comprehensive pro bono legal services program for low-income patients and their families with a focus on improving access to care and offering legal services directly to patients who could not otherwise afford an attorney and who need legal representation to remove barriers to health care.

Applicant Social Linkage Programs and Social Determinants of Health

As previously discussed in Factor 1.b.iii, the Applicant maintains programs in place to address the needs of its patient panel and ensure appropriate linkages to social services. These include, but are not limited to, the services described below.

To address the social determinants of health that might prevent a patient from completing treatment, patient navigation and social work services provide patients with timely, compassionate support and connect patients to essential resources, including transportation and interpreter services.

The Applicant also provides patients with resource specialists who seek to address patients' social determinants of health needs. These resource specialists focus on alleviating the financial burden that cancer places on individuals and their families by securing concrete supportive assistance, including short-term lodging/housing accommodation, such as the Hope Lodge operated by the American Cancer Society, and financial supports from foundations and other local resources. Additionally, Pharmacy Resource Specialists assist with the frequently high co-pays for cancer-related medications (*e.g.*, by assisting patients with navigating insurance coverage). Providing patients with these services ensures patients have reduced barriers to care through the provision of the necessary support and tools to complete their treatment regimens, thereby reducing unnecessary readmissions and visits.

Additionally, the Applicant also launched a state-of-the-art mobile mammography van equipped with new tomosynthesis imaging technology. By bringing the most efficient and innovative technologies to underserved neighborhoods, the mammography van provides vital early detection services for populations that statistically receive later diagnoses and experience worse outcomes. This mobile van has increased access to early detection, screening, and cancer prevention services to at-risk, historically marginalized, and diverse populations. For example, since program inception in April 2002, the mammography van has provided more than 52,000 mammograms to more than 23,000 unique patients. Further, since program inception in October 2013, the mammography suite at the Whittier Street Health Center has provided more than 5,900 mammograms to more than 3,000 unique patients.

The mammography van program also provides community outreach events (*e.g.*, health fairs and workshops) annually to reduce barriers to access by delivering information pertaining to health insurance and breast health education and to ensure that underserved communities are able to obtain access to subspecialty oncology care when needed. The services provided by the Applicant's mammography van and the mammography suite at Whittier Street Health Center are linked to increased access to care at the Applicant's facility through the Applicant's patient navigation program (previously described in Section F1.b.iii). Patients that use the mammography van and suite at Whittier Street Health Center who need additional health care services choose where they would like to receive follow-up care. If those patients choose to receive care at the Applicant's facility, the Applicant's team immediately connects them to a new patient coordinator, who assists with ensuring access to an initial appointment with the Applicant's breast oncology team and informs the breast cancer patient navigator to ensure continuity of care. Information from FY2023 regarding the number of patients receiving screenings through either the mammography van or the mammography suite at Whittier Street Health Center and follow-up care at the Applicant in 2023 is shown in the table below.

Mammography Van		Whittier Mammography Suite	
Patient Screenings 1,516		712	
Patients Requiring	206 (13.6% of patient	102(14.20) of notions concernings)	
Diagnostic Treatment screenings)		102 (14.3% of patient screenings)	
Patients Receiving	54 (26.2% of patients	50 (57.20) of notion to nonvining	
Diagnostic Treatment requiring diagnostic		diagnostic treatment)	
w/Applicant	treatment)	diagnostic treatment)	

The patient navigator program, which supports patients who receive abnormal findings, enables the Applicant to reduce access barriers by supporting patients through their cancer journey. The program provides additional support to its patients by identifying individual needs and providing the appropriate assistance, eliminating barriers to timely diagnosis and treatment, and helping to navigate health care system complexities and logistics throughout the cancer continuum.

Factor 5 Relative Merit

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.

The Applicant has engaged in a multi-year strategic planning process to assess how best to expand access, address the unmet need of its patient panel, ensure continuity of care, and further its clinical and academic mission in light of the limited remaining term of its arrangement with BWH, and decided that a new Facility with expanded inpatient capacity was necessary for patient care. Through that process, several key criteria were identified. The new Facility must be contiguous to the Applicant's existing care locations to ensure seamless integration of services and to foster interdisciplinary collaboration among healthcare professionals. The center must be dedicated exclusively to cancer care, consistent with the Applicant's commitment to specialized treatment and research in oncology. The layout and operations must be designed to significantly reduce the fragmentation of care, enhancing both the quality and continuity of patient services and ability to care for non-cancer care needs of medically complex and highly acute patients. Finally, the new Facility must be equipped with state-of-the-art research capabilities to advance the Applicant's institutional mission in the domain of cancer research.

As part of that process, the Applicant evaluated a wide variety of options. The Applicant also engaged in extensive discussions with MGB regarding a new affiliation to replace the existing arrangement, including the potential to add increased inpatient cancer capacity. Ultimately, those discussions were not successful, and as a result, the current affiliation will be coming to an end.

Following this process, the two options that remained were for the Applicant to build an independent cancer care center ("Alternative Option"), or to collaborate with BIDMC to enter into the Proposed Project.

Below is a summary comparison of the Proposed Project and Alternative Option, with respect to quality, efficiency, capital expense, and operating cost, along with a more detailed discussion of the Proposed Project and each option against the same characteristics.

Quality: The Proposed Project provides the Applicant with the facility upgrades and clinical control it needs to provide care of the quality and complexity required of a world-class cancer center. Through a clinical collaboration with BIDMC, the Applicant can better manage continuity of care with a consistent clinical partner for surgical oncology services and other cancer-adjacent services. Care continuity is more challenging under the Alternative Option, where the Applicant would have no consistent clinical partner with which to coordinate care. As such, the Proposed Project is the superior option on quality.

Efficiency: The Proposed Project vests the Applicant with full control over the full continuum of medical oncology services provided to its patients in the new Facility, while leveraging the

expertise and facilities of its clinical partner, BIDMC, to provide surgical oncology services to its patients. The Applicant and BIDMC have also committed to a long-term relationship that provides the Applicant with greater certainty over its future operations and greater comfort in committing to making long-term investments in the new Facility and in care coordination with BIDMC, improving the efficiency and quality of patient care overall. If the Applicant were to pursue the Alternative Option, it would be required to establish a new surgical oncology service line in order to offer its patients the full continuum of cancer care. The Applicant does not currently operate surgical suites and doing so may result, at least initially, in some operational and administrative inefficiencies and challenges. By avoiding the addition of surgical oncology facilities in the new Facility, the Applicant is able to avoid significant construction and equipment expenditures. As such, the Proposed Project is can achieve greater efficiency.

Capital Expense: The capital expenditures incurred by the Proposed Project are significantly less (approximately 62% lower) than the capital expenditures that would be required to be incurred under the Alternative Option.

Operating Costs: The annual operating costs of the Proposed Project are significantly less (approximately 49% lower) than the operating expenses that would be required for the Alternative Option. Currently, the Applicant does not have surgeons or other non-oncology physicians on its faculty. Under the Alternative Option, the Applicant's operating costs would include the costs associated with hiring surgeons and other physician specialties, the administrative support staff for those functions, as well as the facility costs, maintenance, and staff to support the operating costs associated with operating an inpatient medical oncology Facility, as contemplated under the Proposed Project.

	Proposed Project	Alternative Option
Description	See Project Description	The Applicant constructs and operates a completely independent comprehensive cancer center.
Quality	 Improves and updates the facilities in which inpatient medical oncology services are delivered to the Applicant's patients. Collaborates with BIDMC, a renowned academic medical center, to provide the Applicant's patients with coordinated access to high quality care across the care continuum. 	Lack of a primary clinical partner may reduce care coordination for essential cancer-adjacent services (<i>e.g.</i> , dermatology, psychiatry, etc.).
Efficiency	Requires collaboration with BIDMC, an experienced provider of surgical oncology services. Requires that BIDMC use its existing surgical oncology	Requires the Applicant to establish its own operating surgical suites, which may result in initial operating inefficiency due to the Applicant's lack of experience and cost inefficiencies

	facilities and equipment to provide surgical oncology services to patients. Vests the Applicant with control over medical oncology services provided to patients.	associated with having duplicate services. Requires the new construction and equipping of expensive operating surgical suites as well as emergency department and surgical ICU.
	Establishes long-term relationship with BIDMC, providing the Applicant with more operational certainty into the future.	
Capital Expense	Requires the construction of a new Facility. Requires an estimated \$1,675,700,000 in initial capital expenditures.	Requires the construction of a new facility with medical oncology and surgical oncology capacities. Requires an estimated \$3.4 billion in initial capital expenditures.
Operating Costs	Requires an estimated increase of \$360 million in annual operating expenses.	Requires an estimated increase of \$700 million in annual operating expenses.

Appendix A – Projecting Demand for 2032 LINAC Sessions

To determine annual demand for LINAC sessions, the Applicant utilized its 2022 patient panel data to estimate the percentage of its patients that require LINAC therapy (the "LINAC Conversion Ratio"). Under its current arrangement with BWH, the Applicant's patients receiving LINAC therapy on the Longwood Medical Campus do so at facilities operated by the Applicant or facilities operated by BWH, depending on the particular patient's disease center.¹ In light of confidentiality restrictions on disclosing information regarding patients treated in collaboration with BWH, the Applicant first utilized data for the three disease centers (breast, head and neck, and thoracic) for which it administers LINAC therapy in its own facilities most frequently.

To determine the LINAC Conversion Ratio for the other disease centers, the Applicant utilized data from its site at South Shore Hospital in Weymouth, Massachusetts ("SSH"), at which it provides LINAC therapy for the other disease centers. The percentage of patients receiving LINAC therapy for all applicable disease centers is shown in the first column of <u>Table A-2</u>, below. An adjustment is necessary, however, as a greater proportion of patients receive LINAC therapy at community sites than at urban academic medical centers.² To calculate the adjustment factor, the Applicant compared the proportion of patients that received LINAC therapy on the Longwood Medical Campus to the proportion that received LINAC therapy at SSH for the breast, head and neck, and thoracic cancer disease centers. A weighted average adjustment factor was calculated, as shown in <u>Table A-1</u>—namely, 3.33x. The percentages of patients receiving LINAC therapy for those other disease centers at SSH were divided by the adjustment factor to arrive at estimated percentages of patients receiving LINAC therapy for those disease centers at the Longwood Medical Campus—*i.e.*, the LINAC Conversion Ratio.

The Applicant then multiplied the LINAC Conversion Ratio by the number of Longwood Medical Campus outpatients in each disease center (as shown in <u>Table 5</u> and in <u>Table A-2</u>). This results in an estimate of the Longwood Medical Campus patients that required LINAC therapy in 2022. The Applicant estimates, based on internal data, that each patient requires, on average, 21.3 LINAC sessions. The Applicant then multiplied the total number of LINAC patients by the average number of sessions per patient to derive the total number of LINAC sessions required in 2022, as shown in <u>Table A-3</u>.

To calculate the combined LINAC need at the new Facility and at BIDMC, the Applicant combined its estimated 2022 sessions with 2022 LINAC session data from BIDMC (18,080), as shown in <u>Table 18</u>. Consistent with Sg2 and The Advisory Board Company's projections regarding radiation therapy, the Applicant assumed flat growth to project 2022 numbers to 2032. Thereafter, LINAC need was derived as shown in <u>Table 18</u> and as described in the narrative accompanying it.

¹ Because a portion of the Applicant's patients receive LINAC therapy at BWH, the data included in <u>Table 8</u> does not capture the total amount of LINAC therapy provided to the Applicant's patients and instead shows only the LINAC therapy services provided by the Applicant in its own facilities. As such, <u>Table 8</u> does not adequately capture the need for LINAC therapy amongst the Applicant's patient panel and cannot be relied upon to complete the LINAC need analysis described herein.

² This is due to a number of factors, including that urban academic medical centers provide a significant number of second opinions.

 Table A-1

 Calculation of SSH to Longwood Medical Campus Conversion Factor

Disease Center	Total Outpatients (SSH and Longwood Medical Campus)	Share of Patients Receiving LINAC Therapy - SSH	Share of Patients Receiving LINAC Therapy – Longwood Medical Campus	Conversion Factor
Breast Oncology Center	17,616	11.16%	3.26%	3.42x
Head and Neck Oncology	2,983	24.55%	8.48%	2.95x
Thoracic Oncology Program	3,928	20.48%	6.28%	3.19x
Weighted Average Conversion Factor				3.33x

 Table A-2

 Estimate of Longwood Medical Campus LINAC Therapy Patients

Disease Center	Percent of Patients Receiving LINAC Therapy at SSH	Estimated Percent Patients at Longwood Medical Campus Receiving LINAC Therapy	Total Outpatients on the Longwood Medical Campus	Estimated LINAC Therapy Patients - - Longwood Medical Campus
Breast Oncology Center	11.16%	3.35%	13,950	467
Cutaneous Oncology Center	20.87%	6.26%	1,827	114
Gastrointestinal Oncology	7.75%	2.33%	6,714	156
Genitourinary	17.55%	5.27%	6,500	342
Oncology				
Gynecology Oncology	9.02%	2.71%	3,806	103
Head and Neck Oncology	24.55%	7.37%	2,759	203
Hematologic Malignancies	2.89%	0.87%	15,186	132
Hematology Service	0.34%	0.10%	2,524	3
Melanoma Center	5.05%	1.52%	2,232	34
Neuro-Oncology Center	30.63%	9.19%	1,819	167
Sarcoma and Bone Oncology	16.67%	5.00%	2,013	101
Thoracic Oncology Program	20.48%	6.15%	3,298	203
Other ³	10.13%	3.04%	6,668	203
Total			69,296	2,228

Table A-3LINAC Treatments (Applicant)

Metric	2022
Total Patients with LINAC Treatment	2,228
Sessions per Unique Patient	21.3
Total LINAC Sessions	47,456

³ In addition to the disease centers included in <u>Table 5</u>, <u>Table A-2</u> includes an "other" category equal to those 2022 outpatients at SSH and on the Longwood Medical Campus not classified into a particular diseases center. For the Longwood Medical Campus, this number is derived by subtracting the total number of unique outpatients with a disease center classification (as shown in <u>Table 5</u>) from the total number of unique outpatients overall (as shown in <u>Table 5</u>). The "other" category includes patients seen in the survivorship and palliative care programs, as well as multiple other smaller disease centers.