Dana-Farber Cancer Institute

DoN Application #: DFCI-25090516-RS

Application for Determination of Need

Substantial Change in Service

Dana-Farber Cancer Institute

October 17, 2025

Submitted By

Dana-Farber Cancer Institute

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Narrative

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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 been committed to reducing the burden of cancer for adults and children through scientific inquiry, clinical care, education, community engagement, and advocacy. The Applicant has consistently ranked among the best in the nation by U.S. News & World Report for cancer care and related diseases and is the only hospital in the United States with adult and pediatric cancer care programs among the top five ranked programs. Based on year-to-date data collected by Press Ganey from the Applicant's patients, 98% gave 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 2025, Newsweek ranked the Applicant sixth on its list of the best cancer hospitals in the world. Since 2005, the Applicant received a Magnet®-designation for nursing and health care excellence, a designation held by just 9% of hospitals in the United States.

The Applicant is renowned for its treatment of children and adolescents with cancer, offering the combined expertise of both a world-class cancer center and a preeminent children's hospital, Boston Children's Hospital ("BCH"). Together, the Applicant and BCH have provided comprehensive, dedicated care for pediatric oncology and hematology patients since 1947. In concert with BCH, the Applicant provides pediatric oncology care across the cancer care continuum, employs over 250 oncology and hematology physicians and fellows, including pediatric oncology advanced practice providers, and nurses; further meeting all pediatric patients and their family's needs, including through the provision of mental health and social work resources. The Applicant's clinicians work alongside BCH clinicians to treat patients in BCH beds and operate a cohesive, integrated service.

Radiation therapy is vital to cancer treatment. Traditional photon-based radiation therapy is significantly riskier for children due to their developing bodies and long-life expectancy. Proton beam therapy uses protons as the delivery mechanism for the radiation therapy used to treat certain kinds of cancer. Using protons allows for the delivery of a sharp and precise dosage of radiation to cancerous tumors, while significantly reducing exposure of healthy tissue to radiation. The more commonly used photon-based radiation therapy cannot deliver radiation dosages in as exacting a manner as protons. Children who cannot access proton beam therapy and receive traditional radiation therapy are at a higher risk for life-altering toxicities of radiation, secondary tumors, neurocognitive decline, hearing loss, the need for lifelong hormone replacement, infertility, and growth abnormalities. For this reason, proton beam therapy is preferred for most pediatric patients. Currently, many pediatric patients cannot access proton beam therapy in the Commonwealth. Capacity in the Commonwealth is not sufficient. Some patients travel out of state to access proton therapy, while others forgo treatment to maintain continuity of care and access to necessary specialized services at BCH. The availability of proton beam therapy would be a transformative advancement for the Applicant's patients. The Applicant seeks to provide patients, especially those with complex or sensitive cases, such as pediatric patients, with the most effective treatment options, improved health outcomes, and enhanced quality of life, while also contributing to cost-

effective, high-value cancer care. Therefore, the Applicant proposes to construct and operate a new proton beam therapy center (the "Center") on the Applicant's campus in Boston.

Adult patients receiving photon-based radiation therapy can also experience damage to healthy tissues, increasing the likelihood of secondary conditions that require additional medical interventions, such as organ dysfunction, secondary malignancies, infertility, or prolonged supportive care. These complications contribute to substantial financial strain on both healthcare systems and patients, reinforcing the urgent need for a treatment option that minimizes avoidable expenditures. Use of proton-based radiation leads to better outcomes for pediatric patients and adult patients with tumors located near vital organs or with certain kinds of recurrent cancers. There is significant need in the Applicant's pediatric patient panel for proton therapy. Further, taking into account adult patients with diagnoses and conditions for which the Centers of Medicare & Medicaid Services ("CMS") has identified proton therapy as the preferred treatment, the need for these services is tenfold compared to just the Applicant's pediatric need.

In developing its plan for the Center, the Applicant considered the needs of its patient panel that stands to benefit most significantly from proton-based radiation. The Center would be the first proton therapy center in the Commonwealth with upright patient rotation. This innovative design means that the Center is small enough to be housed on the Applicant's Boston campus, in a facility where the Applicant's pediatric cancer patients often receive treatment, and which is physically connected to BCH. The location also provides convenient access for adult patients from across the socioeconomic spectrum.

The Center's small footprint and innovative design will allow the Applicant to construct the center with significantly less capital investment than is typically required for traditional gantry style proton therapy. Therefore, the Center can be made accessible in an existing space without costly and time-consuming renovations. The Applicant specifically seeks to pursue this proposed project because it will deliver maximum benefits to its patient panel that requires this level of treatment with the least upfront cost. Although the Applicant cannot address the needs of all patients, the Center is the best option from a cost and space perspective and its most consistent with the Commonwealth's cost containment goals.

There is a strong need for additional proton therapy capacity in the Commonwealth. Given its significant, long-standing expertise treating the patient population mostly likely to benefit from proton-based radiation, the Applicant is best equipped to fill that need, and will do so most effectively in the thoughtfully and cost-consciously designed Center that is the subject of this Determination of Need ("DoN") Application (the "Application"). To that end, the Applicant is pleased to submit this Application pursuant to the DoN Regulations, 105 CMR 100 et seq. (the "Regulations")—to develop a proton beam therapy center. The DoN-Required Equipment and Services Guidelines categorize proton beam therapy as megavoltage radiation therapy, a DoN-Required Service. In addition, in order to provide complete proton therapy services at the Center, the Applicant will also purchase a Computed Tomography ("CT") scanner that will be used for prerequisite treatment planning. The Guidelines list CT scanners as DoN-Required Equipment.

Project Description

The Applicant has filed this Application in connection with a phased project plan to renovate, fit out, and equip approximately 4,500 gross square feet of ambulatory health care-zoned Center at 35 Binney Street in Boston (the "Proposed Project"). The maximum capital expenditure for the Proposed Project is estimated to be $50,500,663. The Proposed Project will include interior demolition as needed, construction of radiation-shielded treatment and clinical support rooms, installation of a state-of-the-art upright single-gantry proton therapy system with a dedicated accelerator, which includes a CT scanner for daily treatment image-guidance, and a separate vertical CT for simulation and treatment planning. Additional spaces for clinical staff, patient intake, anesthesia support, and administrative operations will be integrated into the design to ensure seamless patient flow and multidisciplinary care.

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

F1.a.i. Patient Panel

Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measures, 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 Overview

The Applicant manages a complex and diverse patient population, mirroring the cancer landscape in Massachusetts and throughout New England. The volume of patients seeking cancer care services from the Applicant continues to increase, most recently by nearly 8% from the preceding year. In FY 2024, the Applicant served a total of 118,830 patients, comprising adult and pediatric patients. This patient group is characterized by a wide spectrum of demographics and clinical presentations, influenced by varying disease incidence, behavioral risk factors, and significant health disparities. Disease acuity among the Applicant's patients comprises the entire spectrum, ranging from early-stage, lower-acuity diagnoses to intricate, high-acuity presentations that demand multidisciplinary interventions. Socioeconomic disparities frequently intersect with acuity, affecting both access to timely diagnosis and the intensity of care needed.

Table 1 provides the demographic and geographic profile for the Applicant's total patient panel. Patient demographics for the Applicant's Massachusetts patient panel are reflected in Table 2. According to self-reported data from the Applicant's FY 2024 patients, approximately 73.3% of patients identified as White, 7.3% as Hispanic or Latino, 4.5% as Black/African American, and 3.2% as Asian.

The Applicant's patient panel spans an extensive geographic area, with a concentration of patients from Boston and its surrounding zip codes, alongside referrals from across New England. The majority of the Applicant's patients in FY 2024 were from the Commonwealth at 75.3%; however, over 22,000 patients were from the other New England states making up approximately 19.1% of the patient panel.

Table 1
Total Unique Patients, Demographics, and Geography[1]

	FY22		FY23		FY24	
	Count	%	Count	%	Count	%
Total Unique Patients	103,795	100%	110,560	100%	118,830	100%
Gender						
Female	64,810	62.4%	68,846	62.3%	74,012	62.3%
Male	38,979	37.6%	41,712	37.7%	44,810	37.7%
Unknown	*Masked*[2]	*Masked*	*Masked*	*Masked*	*Masked*	*Masked*
Age						
21 & Under	3,415	3.3%	3,689	3.3%	3,671	3.1%
22-35	6,500	6.3%	7,030	6.4%	7,504	6.3%
36-55	24,024	23.1%	25,387	23.0%	27,103	22.8%
56+	70,812	68.2%	75,424	68.2%	81,602	68.7%
Race/Ethnicity[3]						
Asian Non-Hispanic or Latino	3,110	3.0%	3,471	3.1%	3,762	3.2%
Black or African American	4,423	4.3%	4,654	4.2%	5,288	4.5%
Hispanic or Latino	7,027	6.8%	7,810	7.1%	8,687	7.3%
White or Caucasian Non-Hispanic or Latino	76,945	74.1%	81,621	73.8%	87,136	73.3%
Other	12,290	11.8%	13,004	11.8%	13,957	11.7%
Geography[4]						
Massachusetts	77,996	75.1%	82,885	75.0%	89,515	75.3%
New Hampshire	7,239	7.0%	7,659	6.9%	8,193	6.9%
Rhode Island	3,603	3.5%	3,829	3.5%	4,174	3.5%
Maine	3,120	3.0%	3,562	3.2%	3,814	3.2%
New York	2,498	2.4%	2,594	2.3%	2,749	2.3%
Connecticut	2,406	2.3%	2,596	2.3%	2,741	2.3%
Florida	1,671	1.6%	1,747	1.6%	1,788	1.5%
Vermont	896	0.9%	950	0.9%	1,058	0.9%

[1] The patient demographics set forth in Table 1 differ from the patient demographics provided in response to Questions #1 to the DoN filed for the Applicant's future cancer hospital ("FCH DoN") because the patient populations considered are different. The patient panel for this Application includes pediatric patients scheduled in pediatric departments. The FCH DoN table included pediatric patients only if scheduled in adult departments. This Application also includes patient encounters from the Applicant's Longwood Medical Area location, Chestnut Hill, and other satellite locations.

[2] For HIPAA compliance, numbers below 11 are not included.

[3] Race/Ethnicity/Other includes NULL, Unknown, Multiracial, Non-Hispanic

[4] Represents only certain states, and therefore will not add to 100%.

Table 2
Total Unique Patients, Demographics, and Geography – Massachusetts

	FY 2022		FY 2023		FY 2024	
	Count	%	Count	%	Count	%
Total Unique Patients	77,996	100%	82,885	100%	89,515	100%
Gender						
Female	50,039	64.2%	53,092	64.1%	57,444	64.2%
Male	27,954	35.8%	29,791	35.9%	32,067	35.8%
Unknown	*Masked*[5]	*Masked*	*Masked*	*Masked*	*Masked*	*Masked*
Age						
21 & Under[6]	2,329	3.0%	2,541	3.1%	2,560	2.9%
22-35	4,917	6.3%	5,336	6.4%	5,783	6.5%
36-55	18,117	23.2%	19,151	23.1%	20,558	23.0%
56+	53,357	68.4%	56,595	68.3%	61,405	68.6%
Race/Ethnicity[7]						
Asian Non-Hispanic or Latino	2,511	3.2%	2,784	3.4%	3,053	3.4%
Black or African American	3,944	5.1%	4,156	5.0%	4,757	5.3%
Hispanic or Latino	6,322	8.1%	7,041	8.5%	7,887	8.8%
White or Caucasian Non-Hispanic or Latino	56,423	72.3%	59,610	71.9%	63,846	71.3%
Other	8,796	11.3%	9,294	11.2%	9,972	11.1%

[5] For HIPAA compliance, numbers below 11 are not included.
[6] The patient demographics set forth in Table 2 differ from the patient demographics provided in response to Questions #1 to the FCH DoN because the patient populations considered are different. The patient panel for this Application includes pediatric patients scheduled in pediatric departments. The FCH DoN table included pediatric patients only if scheduled in adult departments. This Application also includes patient encounters from the Applicant's Longwood Medical Area location, Chestnut Hill, and other satellite locations.
[7] Race/Ethnicity/Other includes NULL, Unknown, Multiracial, Non-Hispanic.

Prevalence of Disease

Cancer is the leading cause of death among Massachusetts residents.[8] Specifically, in Massachusetts the age-adjusted overall cancer incidence rate was 437.2 per 100,000 persons per year for years between 2017 and 2021, aligning with the national incidence rate of 444.4 per 100,000 persons per year for years between 2017 and 2021.[9] The cancer incidence for pediatric patients in the Northeast is consistently the highest in the United States, at approximately 188 per 1,000,000 persons aged less than 20 years per year. The most common cancers are leukemia, central nervous system tumors, and lymphomas. Pediatric cancers are highly curable, with an approximately 85% cure rate, but these patients are at a much higher risk of developing late toxicity from radiation therapy.[10]

There were 196,399 new cancer cases in Massachusetts between 2016 and 2020, an average of 39,280 cases per year.[11] The most common cancers in Massachusetts for men during this time period were prostate, lung and bronchus, colon and rectum, urinary and bladder, and melanoma.[12] The most common cancers in Massachusetts for women during this time were breast, lung and bronchus, uterine, colon and rectum, and thyroid.[13] Between 2016 and 2020, there were 63,231 cancer deaths in Massachusetts with an average of 12,646 deaths per year.[14]

Table 3 outlines the historical data for new patient consults by disease area for the Applicant's patient panel.

[8] CDC, *Stats of the States: Massachusetts, https://www.cdc.gov/nchs/pressroom/sosmap/cancer_mortality/cancer.htm* (last visited Sept. 3, 2025).
[9] NIH, *Quick Profiles: Massachusetts (2017-2021)*, State Cancer Profiles: Quick Profiles, https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statename=massachusetts#t=2 (last visited Sept. 3, 2025),
[10] David A. Siegel et al., *Counts, Incidence Rates, and Trends in Pediatric Cancer in the United States, 2003-2019,* 115 J. NAT'L CANCER INST. 1337-54 (2023).
[11] Mass. Dep't Pub. Health, *Cancer Incidence and Mortality in Massachusetts 2016-2020, Statewide Reports,* MASS.GOV, https://www.mass.gov/doc/cancer-incidence-and-mortality-in-massachusetts-2016-2020-statewide-report (June 26, 2024).
[12] *Id.*
[13] *Id.*
[14] *Id.*

Table 3
New Patient Consult Volume[15]

Metrics	FY 2022	FY 2023	FY 2024
Total (unique patients)	37,440	39,201	40,336
Breast Oncology Center	4,821	4,840	5,003
Cutaneous Oncology Center	691	766	709
Gastrointestinal Oncology	3,789	3,763	4,013
Genitourinary Oncology	3,033	3,568	3,901
Gynecological Oncology	1,911	2,075	2,117
Head and Neck Oncology	1,153	1,280	1,276
Hematology Services	1,052	1,035	830
Leukemia	879	982	1,159
Lymphoma	1,774	1,644	1,688
Medical Oncology Regional Sites	10,795	11,224	11,178
Melanoma	843	901	978
Multiple Myeloma	1,357	1,514	1,547
Neuro-Oncology Center	835	897	950
Pediatric Oncology	1,012	1,023	974
Sarcoma and Bone Oncology	794	808	1,007
Thoracic Oncology Program	2,111	2,225	2,297
Transplant	590	656	709

Payor Mix

Table 4 demonstrates the Applicant's payor mix by gross revenue for pediatric patients 21 and younger, including all of the Applicant's sites, derived based on hospital billing excluding clinical trials and retail pharmacy.

Table 5 demonstrates the Applicant's payor mix by gross revenue for adult patients, including all of the Applicant's sites, derived based on hospital billing excluding clinical trials and retail pharmacy.

[15] If a patient had most of their encounters in a fiscal year in an excluded 'department', they are omitted from this analysis (i.e., Other, Inpatient Service, Imaging, etc.)

Table 4
Payor Mix - Pediatric
(Percentage of Gross Revenues)

	FY 2022	FY 2023	FY 2024
Medicare	0.0%	0.0%	0.0%
Medicaid	26.3%	27.4%	36.2%[16]
Blue Cross	40.4%	23.2%	24.4%
HMO, Commercial, Other	33.2%	48.5%	38.8%
Self-Pay	0.1%	1.0%	0.6%

Table 5
Payor Mix – Adult
(Percentage of Gross Revenues)

	FY 2022	FY 2023	FY 2024
Medicare	48.4%	50.4%	50.9%
Medicaid	6.2%	6.6%	6.4%
Blue Cross	21.4%	20.5%	20.0%
HMO, Commercial, Other	23.9%	22.4%	22.6%
Self-Pay	0.2%	0.1%	0.2%

Proton Beam Therapy

Proton beam therapy is the preferred radiation treatment for most pediatric patients. CMS categorizes cancer patients into two groups. Patients in "Group 1" have cancer diagnoses and conditions for which CMS has identified proton therapy as necessary and clearly superior to other radiation oncology treatments. Group 1 includes *all* pediatric patients with solid tumors.[17] Patients in "Group 2" have cancer diagnoses and conditions for which CMS has identified proton therapy as medically reasonable, but requires demonstration of clinical benefit over other radiation oncology techniques.[18] Using the Applicant's internal new patient consult data (see Table 3 herein), the Applicant grouped patients into Group 1 or Group 2 using patients' top three diagnosis

[16] The 8.8% shift in patient's who are covered by Medicaid is attributable to change in the Wellsense ACO shifting networks from commercial plans to Medicaid, which has a more significant impact on pediatric payor mix because of the higher percentage of pediatric patients that are enrolled in Medicaid.

[17] Group 1 conditions include (1) benign or malignant conditions otherwise not suitable for intensity modulated radiation therapy or 3-dimensional conformal therapy involving the base of the skull or axial skeleton, including but not limited to chordomas and chondrosarcomas; (2) solid tumors in children; (3) benign or malignant CNS tumors to include primary and variant forms of medulloblastoma, astrocytoma, glioblastoma, arteriovenous malformations, acoustic neuroma craniopharyngioma, benign and atypical meningiomas, and pineal gland tumors; and (4) intraocular melanomas. *See* Ctrs. Medicare & Medicaid Servs., *Local Coverage Determination: Proton Beam Radiotherapy* (Oct. 25, 2019), https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33937.

[18] Group 2 conditions include (1) malignant lesions of the head and neck when the intent of the treatment is to be curative; (2) malignant lesions of the Para nasal sinus; (3) malignant lesions of the prostate; (4) malignant advanced stage, non-metastatic tumors of the bladder; (5) advanced pelvic tumors including malignant lesions of the cervix; (6) left breast tumors; (7) pancreatic and adrenal tumors; (8) skin cancer with perineural/cranial nerve invasion; (9) unresectable retroperitoneal sarcoma and extremity sarcoma; (10) cancers of the lung and upper abdominal/per-diaphragmatic cancers; and (11) malignant lesions of the liver, biliary tract, anal canal and rectum. *See id*.

codes from the tenth revision of the International Classification of Diseases ("ICD-10"), matching them with diagnosis codes CMS's classification of Group 1 or Group 2. Table 6 categorizes the new patient consults (from Table 3) into Group 1 or Group 2 based on each patient's top three diagnoses codes and the CMS classification. The table further breaks these consults down into pediatric and adult based on the department that scheduled such patient.

Table 6[19]
Proton Therapy Eligibility

Patient Population	CMS Group	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Adult	Group 1	2,381	2,893	2,848	3,012	3,190
	Group 2	11,109	14,004	13,964	14,201	15,116
Adult Total		**13,490**	**16,897**	**16,812**	**17,213**	**18,306**
Pediatric	Group 1	192	381	256	269	276
	Group 2	92	96	145	150	147
Pediatric Total		**284**	**477**	**401**	**419**	**423**
Grand Total		**13,774**	**17,374**	**17,213**	**17,632**	**18,729**

Imaging Equipment

Imaging is an essential component of radiation treatment planning. CT scans are the most common form of imaging used for radiation treatment planning and the tissue density determined by CT necessary for proton treatment planning. Separately, the proton therapy system has an integrated CT that is used to guide the radiation oncologist during a proton beam therapy session.

[19] Some portion of new patients that had a clinical consult visit with one of the Applicant's medical oncologists may ultimately elect not to continue medical oncology treatment with the Applicant for any number of reasons. While difficult to estimate that proportion with precision, it is reasonable to assume that the proportion would be higher among adult patients than pediatric patients. Regardless, each of the patients still represent need within the patient panel for proton beam radiation therapy based on their Group 1 diagnoses. Further, patient panel need for the Proposed Project would be sufficiently demonstrated even if considering only the pediatric Group 1 patients. Patient panel need may be understated as new patient consults do not reflect those patients who elected not to seek treatment from the Applicant because proton therapy was not offered, and does not reflect existing patients who would be eligible for proton therapy.

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.

Proton Beam Therapy

Background

Proton therapy is a form of radiation therapy that uses protons instead of photons to deliver radiation to tumors. Its primary advantage is its ability to precisely target tumors while minimizing radiation exposure to surrounding healthy tissues, due to the unique physical properties of protons, which deposit most of their energy at a specific depth and have minimal entry and exit dose. By contrast, photons cannot deliver radiation therapy to patients in as precise a manner. As a result, patients receiving photon-based radiation therapy experience unintended damage to healthy tissues, increasing the likelihood of secondary conditions that require additional medical interventions, such as organ dysfunction, secondary malignancies, or prolonged supportive care.

Proton therapy is widely accepted as the most appropriate radiation modality for most pediatric patients.[20] Pediatric patients have healthy tissues and organs that are more sensitive than adult patients because they are not yet fully developed. Children have higher rates of life altering toxicities of radiation,[21] and can experience secondary tumors,[22] growth impediments,[23]

[20] Benjamin A. Greenberger & Torunn I. Yock, The Role of Proton Therapy in Pediatric Malignancies: Recent Advances and Future Directions, 47 SEMIN. ONCOL. 8 (2020).

[21] Proton therapy's ability to avoid healthy tissue reduces acute toxicities (e.g., nausea, fatigue) and late effects (e.g., endocrinopathies, cardiovascular disease). A review of proton therapy for pediatric CNS tumors reported lower rates of acute toxicity compared to photon therapy, with fewer hospitalizations. Gita Suneja et al., *Acute Toxicity of Proton Beam Radiation for Pediatric Central Nervous System Malignancies*, 60(9) PEDIATR. BLOOD CANCER 1431 (2013). For non-CNS tumors like rhabdomyosarcoma, proton therapy achieved comparable local control (94% at 2 years) with reduced toxicity to surrounding organs. Matthew M. Ladra et al., *Preliminary Results of A Phase II Trial of Proton Radiotherapy for Pediatric Rhabdomyosarcoma*, 32 J. CLIN. ONCOL. 3762 (2014), *Erratum* in: 33(2) J. CLIN. ONCOL. 228 (2015). Proton therapy is particularly effective for tumors requiring high doses near critical structures, such as ependymoma, rhabdomyosarcoma, and neuroblastoma. A study of proton therapy for high-risk neuroblastoma reported 2-year and 5-year local control rates of 94% and 87%, respectively, with minimal toxicity to surrounding organs. Christine Hill-Kayser & Maura Kirk, *Brainstem-Sparing Craniospinal Irradiation Delivered with Pencil Beam Scanning Proton Therapy,* 62(4) PEDIATR. BLOOD CANCER 718 (2015). For retinoblastoma, proton therapy achieved excellent tumor control while sparing orbital bones and reducing cosmetic side effects. Angela Sardaro et al. *Proton Therapy in the Most Common Pediatric Non-Central Nervous System Malignancies: An Overview of Clinical and Dosimetric Outcomes,* 45 (1) ITAL. J. PEDIATR.170 (2019) These outcomes highlight proton therapy's role as a standard of care for many pediatric tumors.

[22] A study comparing proton and photon therapy for pediatric medulloblastoma found that proton therapy reduced the risk of second malignancies by approximately 50% due to lower doses to normal tissues. Rui Zhang et al., *A Comparative Study on the Risks of Radiogenic Second Cancers and Cardiac Mortality in a Set of Pediatric Medulloblastoma Patients Treated with Photon or Proton Craniospinal Irradiation,* 113 RADIOTHER ONCOL. 84-88 (2014).

[23] Proton therapy minimizes radiation exposure to growth plates, bones, and vital organs, preserving physical development. For example, in spinal tumors, proton therapy reduces dose to vertebral growth plates, decreasing the risk of scoliosis or growth asymmetry. Matthew M. Ladra et al., *A Dosimetric Comparison of Proton and Intensity Modulated Radiation Therapy in Pediatric Rhabdomyosarcoma Patients Enrolled on a Prospective Phase II Proton Study*, 113(1) RADIOTHER. ONCOL. 77 (2014). In brain tumors like medulloblastoma, proton therapy spares the cochlea, reducing hearing loss, and limits dose to the thyroid and heart, decreasing endocrinopathies and cardiac risks. Torunn I. Yock, et al., *Long-term toxic effects of proton radiotherapy for paediatric medulloblastoma: a phase 2 single-arm study*, 17(3) LANCET ONCOL. 287 (2016), *Erratum* in: 21(3) LANCET ONCOL. e132 (2020).

neurocognitive and functional deficits,[24] and infertility. Proton therapy significantly reduces that exposure during treatment and provides a much safer treatment option for children than traditional photon-based radiation.[25]

Proton-based therapy treatment for adults can offer similar benefits, including equivalent or superior tumor control with reduced side effects. Proton therapy is particularly advantaged over photon therapy for tumors near critical structures, such as those in the brain and spine, with lower toxicity than photon therapy.[26] Further, the proton therapy allows escalated tumor doses while sparing normal tissues, thereby improving outcomes for radio-resistant tumors such as chordomas and chondrosarcomas, and enhancing survival and quality of life. Studies have reported a 26–39% reduction in secondary cancer risk for both adult and pediatric patients using proton therapy.[27] Proton therapy is more effective for patients undergoing repeat radiation. Every organ and tissue has a certain tolerance level for radiation, which, when surpassed, leads to organ disfunction. Using the more precise proton therapy allows for more rounds of treatment before that tolerance level is reached.

Patient Panel Demand

The Proposed Project will meet approximately 10% of the estimated patient panel need. As noted in Table 6 above, in fiscal year 2024, 423 children and 3,190 adults in Group 1 needed proton beam therapy. For the most part, those patients simply could not access this treatment within the Commonwealth. The Applicant estimates that the Proposed Project would allow the Applicant to treat approximately 216 patients per year, as shown in Table 8. To calculate this estimate, the Applicant performed a weighted average calculation, by type of treatment as shown in Table 7 below, that divides the estimated annual session capacity of the Proposed Project by the average number of sessions each patient would require during the year as shown in Table 7.

To estimate the annual session capacity, the Applicant calculated: (a) the daily operating time of the Center multiplied by (b) the annual operating days of the center divided by (c) average session length as shown in Table 7.

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[24] By sparing healthy brain tissue, proton therapy reduces neurocognitive impairments, particularly in young children with brain tumors. A study of pediatric patients with central nervous system ("CNS") tumors treated with proton therapy showed better preservation of IQ and memory compared to photon therapy, with significant benefits in non-germinomatous germ cell tumors. Margaret B. Pulsifer et al., *Early Cognitive Outcomes Following Proton Radiation in Pediatric Patients with Brain and Central Nervous System Tumors*, 93 INT. J. RADIAT. ONCOL. BIOL. PHYS. 400 (2015).

[25] For instance, in Hodgkin lymphoma, proton therapy reduces dose to the heart, lungs, and breasts, lowering risks of cardiac events and secondary breast cancer, particularly in young females. Yolanda D. Tseng et al., *Evidence-based Review on the Use of Proton Therapy in Lymphoma From the Particle Therapy Cooperative Group (PTCOG) Lymphoma Subcommittee*, 99 INT. J. RADIAT. ONCOL. BIOL. PHYS. 15 (2017). Studies also show better functional outcomes in sarcomas, with preserved limb function and reduced cosmetic deficits. Barbara Rombi et al., *Proton Radiotherapy for Pediatric Ewing's Sarcoma: Initial Clinical Outcomes*, 82 INT. J. RADIAT. ONCOL. BIOL. PHYS. 1142 (2012). The National Association for Proton Therapy notes that proton therapy's precision contributes to over 80% five-year survival rates in pediatric cancers, with fewer long-term complications. National Association for Proton Therapy, 2023. https://proton-therapy.org/pediatric-proton-therapy/#:~:text=Proton%20Therapy%20is%20the%20Standard,surrounding%20healthy%20tissue%20is%20crucial.

[26] Rupesh Kotecha, Alonsdo La Rosa & Minesh P. Mehta, *How Proton Therapy Fits Into the Management of Adult Intracranial Tumors*, Mar. NEURO ONCOL. S26 (2024); Abdul Karim Ghaith et al., *Proton Versus Photon Adjuvant Radiotherapy: A Multicenter Comparative Evaluation of Recurrence Following Spinal Chordoma Resection,* May NEUROSURG. FOCUS (2024).

[27] Myrsini Ioakeim-Ioannidou et al., *Long-Term Clinical Outcomes Following Proton-Based Radiation for Chordomas and Chondrosarcomas of the Mobile Spine and Sacrum,* 123 INT. J. RADIAT. ONCOL. BIOL. PHYS. 63 (2025); Michael Xiang, Daniel T. Chang & Erqi L. Pollom, *Second Cancer Risk After Primary Cancer Treatment with Three-Dimensional Conformal, Intensity-Modulated, or Proton Beam Radiation Therapy,*126(15) CANCER 3560 (2020); Russell F. Palm et al., *The Role of Dose Escalation and Proton Therapy in Perioperative and Definitive Treatment of Chondrosarcoma and Chordoma: An Analysis of the National Cancer Data Base,* 125(4) CANCER (2019); Roshan V. Sethi et al., *Second Non Ocular Tumors Among Survivors of Retinoblastoma Treated with Contemporary Photon and Proton Radiotherapy,* 120(1) CANCER 126 (2014).

$$Patients\ Treated\ Per\ Year = \frac{Annual\ Treatment\ Appointments}{Sessions\ Required\ per\ Patient\ per\ Year}$$

$$Annual\ Treatment\ Appointments = \frac{Daily\ Operating\ Time\ (minutes)\ x\ Operating\ Days\ (per\ year)}{Treatment\ \ Length\ (minutes\ per\ treatment)}$$

The Applicant made assumptions, informed by its clinical experience, regarding (1) the distribution of the proton therapy cases among pediatric cases, adult cases, stereotactic body radiation therapy ("SBRT"), and craniospinal irradiation ("CSI"), the latter two of which are special courses of radiation therapy that require longer treatment times; (2) the length of treatment for each treatment type; and (3) the total number of treatments required for patients of each treatment type, each as shown below in Table 7.

Table 7
Proton Therapy Treatment Assumptions, by Treatment Type

Type of Treatment	% of Total Cases	Treatment Length (in minutes)	# of Total Treatments/Patient
Pediatric	40	40	27
Standard Course	50	30	24
SBRT/CSI	10	40	5
Total/Weighted Average	100	35	23

Based on the assumptions described in Table 7, the Applicant calculated the number of treatments per day and per year the Center could provide (assuming the Center operates for 12 hours per day and for 243 days per year, as is the current plan). With those numbers and, using the assumptions regarding the total number of treatments per patient, the Applicant was able to derive the total number of patients per year who would be able to be treated at the Center.

This need estimate relies on historical data and assumptions only and does not consider trends or projections in the demand for cancer treatment in coming years. Due to the widely reported increase in cancer incidence among young people,[28] as well as the aging Commonwealth population that is expected to live longer[29] (and therefore at increased risk of cancer diagnosis),[30] the Applicant only expects the demand for proton therapy to increase in the coming years.

[28] *See*, *e.g.*, LIVE ON BLOOMBERG TV, "Why are More Young Adults Getting Cancer?", at 11:36 a.m. (BLOOMBERG.COM Aug. 19, 2025), https://www.bloomberg.com/news/videos/2025-08-19/why-are-more-young-adults-getting-cancer-video; Carmen Phillips, NIH, *As Rates of Some Cancers Increase in Younger People, Researchers Search for Answers*, NAT'L CANCER INST. (May 14, 2025), https://www.cancer.gov/news-events/cancer-currents-blog/2025/early-onset-cancer-research-environment-genetics-support; and Jamie Ducharme, *The Race to Explain Why More Young Adults Are Getting Cancer*," TIME MAGAZINE (Feb. 13, 2025), https://time.com/7213490/why-are-young-people-getting-cancer/.
[29] U. Mass. Donahue Inst., *Mass. Population Projections – EXCEL Age_Sex_Details UMDI_V2015* (2015), http://pep.donahue-institute.org/downloads/2015/Age_Sex_Details_UMDI_V2015.xls.
[30] Nat'l Cancer Inst., NIH, *Age and Cancer Risk* (May 2, 2025), https://www.cancer.gov/about-cancer/causes-prevention/risk/age.

Table 8
Proton Therapy Capacity Calculations

Type of Treatment	Treatments/Day[1]	Treatments/Year[2]	# of Total Treatments/Patient	Number of Patients/Year[3]
Pediatric	9.6	2,322	27	86
Standard Course	10.7	2,592	24	108
SBRT/CSI	0.5	110	5	22
Total	20.8	5,024	23.3	**216**

[1] Reflects the total minutes in a 12-hour day divided by the treatment length in minutes as shown in Table 7.
[2] Assumes the Center is operational 243 days per year.
[3] Reflects the treatments per year divided by the total number of treatments per patient shown in Table 7.

Existing Proton Beam Therapy Capacity

At present, many children receiving care from the Applicant and BCH must travel elsewhere to receive proton therapy, displacing them from their primary cancer care team and clinical setting for approximately six weeks. This is stressful for children and families that are already undergoing treatment at BCH, often leads to treatment delays, and puts patients at risk for communication errors in transferring care. For very sick children, it is not feasible. For some, the pros of proton therapy are weighed against the transfer to a new oncology team that the primary team does not know. For some families, it is too emotionally stressful to leave their support system and for others the financial or logistical burden is insurmountable. In addition, due to the lack of radiation oncologists familiar with proton therapy being present at tumor boards with other cancer care providers, there exists a lack of education regarding the degree of benefit from proton therapy.

Currently, there is only one proton beam unit operating in Massachusetts. The Gordon Browne single room proton center is in operation. A second two-gantry and one fixed beam (or three-room proton center) was operational until February 14, 2025, when it closed for renovations. Both centers are in the Massachusetts General Hospital ("MGH"). From 2018-2022, the three-gantry Francis H. Burr Proton Therapy Center reported an average of 537 patients per year. As discussed above, this capacity falls significantly short of the estimated incremental demand for proton beam therapy services from the Applicant's pediatric patient panel alone.

Additionally, UMass Memorial Health Care, Inc. has submitted a DoN application to add a proton beam service on the campus of Marlborough Hospital, which as of the date of this Application, has not been approved. However, none of existing potential proton beam therapy capacity would be as effective at maintaining pediatric patients' care continuum as the Proposed Project.

Need for CT Machines

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.[31] The Applicant estimates that approximately two CT machines are needed for the Proposed Project. One CT is part of the proton beam system and is used to guide a radiation oncologist during treatment. The other CT is a vertical CT that is necessary for treatment planning. Currently the Applicant does not operate any vertical CT scanners. To the extent there is additional capacity on the vertical CT scanner, the

[31] *See CT Scan for Cancer,* AM. CANCER SOC'Y (Apr. 29, 2025), https://www.cancer.org/cancer/diagnosis-staging/tests/imaging-tests/ct-scan-for-cancer.html.

Applicant anticipates that this scanner will be used for research purposes, in order for its clinicians to learn the most effective ways to treat patients undergoing proton beam therapy.

F1.a.iii. Competition

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

The Proposed Project aligns with the objectives of the Regulations, which encourages competition within the health care delivery system to ensure equitable access to resources at the lowest reasonable aggregate cost. By introducing a new proton therapy facility, the Proposed Project will promote competition in a market currently dominated by a single provider, MGH, which publicly positions itself as the "only proton therapy site in all of New England" in various advertising campaigns. This limits patient access and choice, and constrains competitive pressures that could drive down costs and improve access to this specialized treatment. The introduction of a competing proton therapy provider will foster market-driven innovation, encouraging all providers to enhance quality, accessibility, and affordability. This aligns with the DoN program's emphasis on transforming the health care delivery system to benefit all residents of the Commonwealth.

Competitive Pricing and Total Cost of Care

Proton beam therapy is often perceived as more expensive per treatment than conventional photon-based radiation therapies, such as intensity-modulated radiation therapy ("IMRT"). However, when evaluated holistically, proton therapy offers significant cost savings by reducing long-term medical expenses associated with side effects, radiation-induced cancers, and diminished quality of life. Its ability to minimize radiation exposure to healthy tissues reduces long-term costs associated with secondary cancers (estimated at $100,000 per case) and improves quality-adjusted life years ("QALYs"), adding an average of 1.5 QALYs per patient compared to IMRT.[32] For example, in a study comparing proton therapy to IMRT for head and neck cancers it was found that, despite higher upfront costs (approximately $50,000 per patient for proton therapy vs. $30,000 for IMRT), proton therapy resulted in equivalent or lower total costs over five years due to fewer hospitalizations and reduced treatment of radiation-related toxicities.[33] For some pediatric cancers, proton therapy's precision minimizes damage to developing tissues, yielding cost savings estimated at $20,000 to $33,000 per patient over a lifetime compared to photon therapy.[34]

The Proposed Project will offer proton therapy at a lower cost structure compared to traditional beam centers. By leveraging advanced technology and optimized workflows, such as compact proton accelerators which reduce treatment delivery costs by 15-20% compared to traditional proton systems, the Proposed Project anticipates a reduction in per-treatment costs, which could ultimately translate to lower total medical expenses for patients and payers. Further, to address

[32] Raymond B. Mailhot Vega et al., *Cost Effectiveness of Proton Therapy Compared with Photon Therapy in the Management of Pediatric Medulloblastoma*. 119 CANCER 4299 (2013).
[33] Chia-Lun Chang et al., *Comparing the Oncologic Outcomes of Proton Therapy and Intensity-Modulated Radiation Therapy for Head and Neck Squamous Cell Carcinoma,* RADIOTHER. ONCOL. (Oct. 2023).
[34] Vega et al., *supra* note 32.

concerns about high upfront costs, the Proposed Project will implement a sliding-scale payment model for uninsured patients and partner with local hospitals to share infrastructure costs, reducing financial barriers. These cost savings support the Commonwealth's goals of cost containment and improved public health outcomes.

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 comparative benefits of proton beam therapy relative to other types of cancer radiation treatments are well-known and generally derived from the fact that protons are more targeted than are photons and can deliver radiation to a more localized region. Targeting the radiation this way ensures that it is directed at and adversely affects the tumor and reduces damage done to nearby organs. Proton beam therapy may improve patient survival by improving the local tumor control while reducing injury to normal organs, which may result in fewer radiation-induced adverse effects.[35] As discussed above, proton therapy is particularly successful and beneficial in the treatment of pediatric cancers, several adult cancers, and is also the preferred treatment for oncology patients requiring re-irradiation.

***Pediatric Patients*[36]**

Proton Therapy is widely accepted as the most appropriate radiation modality for children that have access to this form of radiation. Because proton therapy allows for avoidance of low and moderate doses to healthy tissues and organs that are more sensitive than fully developed tissues and children have high rates of cure but also high rates of late and life altering toxicities of radiation, pediatric patients are often given priority for proton radiation. The most common indication for radiation in the pediatric population is for brain tumors, and proton therapy decreases the risks of neurocognitive decline, hearing loss, and the need for lifelong hormone replacement. Secondary tumors caused by radiation are another primary reason for the use of proton therapy, as children may be more genetically prone to the formation of another cancer, and they are more likely to develop another tumor due to the anticipated longer lifespan and the fact that most radiation-induced malignancies occur ten years or more after radiation. The growth of bones is also impacted by low doses of radiation, leading to growth abnormalities such as limb length discrepancies and facial deformities, which can sometimes be avoided by using proton radiation, depending on the location. Very low doses of radiation also impair fertility. For many indications, proton radiation allows for complete avoidance of the ovaries and testicles, omitting this radiation-induced side effect for children and adults of childbearing age. For some patients, this allows for avoidance of fertility treatments and procedures that may delay the initiation of cancer treatments. As more young adults are diagnosed with cancer, the adolescent and young adult population should also be considered strongly for proton therapy as they share some of the benefits that are seen for children.

[35] Xiufang Tian, et al., *The Evolution of Proton Beam Therapy: Current and Future Status,* 8 MOL. CLIN. ONCOL. 15 (2018).
[36] Greenberger & Yock, *supra* note 20.

- **Reduced Risk of Secondary Cancers**: Proton therapy's precise dose delivery significantly reduces the integral dose to surrounding healthy tissues, lowering the risk of radiation-induced secondary malignancies. This is particularly critical for pediatric patients with long life expectancies, as children are more susceptible to secondary cancers due to their developing tissues. A study comparing proton and photon therapy for pediatric medulloblastoma found that proton therapy reduced the risk of second malignancies by approximately 50% due to lower doses to normal tissues.[37] The Pediatric Proton and Photon Therapy Comparison Cohort, analyzing 10,000 patients receiving proton and 10,000 patients receiving photon therapy from 2007–2022, aims to quantify this reduction, estimating an 80% power to detect a relative risk of 0.8 for subsequent cancers.[38]

- **Preservation of Growth and Development**: Proton therapy minimizes radiation exposure to growth plates, bones, and vital organs, preserving physical development. For example, in spinal tumors, proton therapy reduces dose to vertebral growth plates, decreasing the risk of growth impairment and shortened height[39] In brain tumors like medulloblastoma, proton therapy spares the cochlea, reducing hearing loss, and limits dose to the pituitary gland, hypothalamus, thyroid and heart, decreasing endocrinopathies and cardiac risks.[40] A patterns-of-care survey noted that 15% of pediatric radiotherapy patients in the U.S. received proton therapy by 2016, with half under 10 years old, highlighting its role in protecting developing tissues.[41]

- **Lower Neurocognitive and Functional Deficits**: By sparing healthy brain tissue, proton therapy reduces neurocognitive impairments, particularly in young children with brain tumors. A study of pediatric patients with CNS tumors treated with proton therapy showed better preservation of IQ and memory compared to photon therapy, with significant benefits in localized brain tumors such as CNS germ cell tumors.[42] For example, proton therapy for medulloblastoma reduced hippocampal dose, correlating with less cognitive decline.[43] This is especially important for tumors near critical areas like the brainstem or optic chiasm, where precision minimizes neurological deficits.

- **Decreased Acute and Late Toxicities**: Proton therapy's ability to avoid healthy tissue reduces acute toxicities (e.g., nausea, fatigue) and late effects (e.g., endocrinopathies, cardiovascular disease). A review of proton therapy for pediatric CNS tumors reported lower rates of acute toxicity compared to photon therapy, with fewer hospitalizations.[44] For non-CNS tumors like rhabdomyosarcoma, proton therapy achieved comparable local control (94% at 2 years) with reduced toxicity to surrounding organs.[45] The Pediatric

[37] A study comparing proton and photon therapy for pediatric medulloblastoma found that proton therapy reduced the risk of second malignancies by approximately 50% due to lower doses to normal tissues. Zhang et al., *supra* note 22.
[38] Amy Berrington de González et al., *The Pediatric Proton and Photon Therapy Comparison Cohort: Study Design for a Multicenter Retrospective Cohort to Investigate Subsequent Cancers After Pediatric Radiation Therapy*, 8 ADV. RADIAT. ONCOL. 101273 (2023).
[39] Ladra et al., *supra* note 21.
[40] Yock et al., *supra* note 23.
[41] Journy et al., *Patterns of proton therapy use in pediatric cancer management in 2016: An international survey Pediatric Blood & Cancer,* 132 RADIOTHER. ONCO. 155-161 (2019).
[42] Pulsifer et al., *supra* note 24.
[43] Yock et al., *supra* note 23.
[44] Suneja et al., *supra* note 21.
[45] Ladra et al., *supra* note 21.

Proton Consortium Registry (PPCR), with over 1,800 enrolled children, supports these findings, showing reduced late effects across various tumor types.[46]

- **Improved Quality of Life**: By minimizing damage to healthy tissues, proton therapy enhances long-term quality of life. For instance, in Hodgkin lymphoma, proton therapy reduces dose to the heart, lungs, and breasts, lowering risks of cardiac events and secondary breast cancer, particularly in young females.[47] Studies also show better functional outcomes in sarcomas, with preserved limb function and reduced cosmetic deficits.[48] The National Association for Proton Therapy notes that proton therapy's precision contributes to over 80% five-year survival rates in pediatric cancers, with fewer long-term complications.[49]

- **Effectiveness in Specific Pediatric Tumors**: Proton therapy is particularly effective for tumors requiring high doses near critical structures, such as ependymoma, rhabdomyosarcoma, and neuroblastoma. A study of proton therapy for high-risk neuroblastoma reported 2-year and 5-year local control rates of 94% and 87%, respectively, with minimal toxicity to surrounding organs.[50] For retinoblastoma, proton therapy achieved excellent tumor control while sparing orbital bones and reducing cosmetic side effects.[51] These outcomes highlight proton therapy's role as a standard of care for many pediatric tumors.

Oncology Patients Requiring Re-irradiation

In addition to pediatric patients, proton therapy is beneficial for oncology patients requiring re-irradiation. As every organ and tissue has a "tolerance" for radiation which when surpassed leads to organ dysfunction, proton therapy is frequently used for repeat radiation. Benefits are primarily the reduction in risk of high-grade or life-threatening toxicity and often this is the only option for radiation. Despite frequent use and high likelihood of approval, research is less easily interpreted as many publications include a variety of tumors and indications. However, it is noted as a growing indication due to the longer lifespan for patients with cancer and the increased emphasis on quality of life for patients living with their cancers.

Proton therapy's precision allows re-irradiation of recurrent tumors while minimizing additional dose to previously treated normal tissues, reducing cumulative toxicity risks.[52] In cases like head and neck cancers or gliomas, proton therapy can deliver therapeutic doses to recurrent tumors near critical structures, improving local control without exceeding normal tissue tolerance.[53] Proton

[46] Clayton B. Hess et al., *An Update from the Pediatric Proton Consortium Registry*, 8 FRONT. ONCOL., Article 165 (2018).
[47] Tseng et al., *supra* note 25.
[48] Rombi et al., *supra* note 25.
[49] National Assoc. for Proton Therapy, *Proton Therapy is the Standard of Care for Children and Young Adults* (2023) https://proton-therapy.org/pediatric-proton-therapyl.
[50] Hill-Kayser et al., *supra* note 21.
[51] Sardaro et al., *supra* note 21.
[52] Mark W. McDonald et al., *Reirradiation of Recurrent and Second Primary Head and Neck Cancer With Proton Therapy*, 96(4) INT. J. RADIAT. ONCOL. BIOL. PHYS. 808 (2016).
[53] Shane Mesko et al., *Estimating PTV Margins in Head and Neck Stereotactic Ablative Radiation Therapy (SABR) Through Target Site Analysis of Positioning and Intrafractional Accuracy*, 106 INT. J. RADIAT. ONCOL. BIOL. PHYS. 185 (2020).

therapy is particularly useful for re-irradiation in areas with prior high-dose exposure, such as the spinal cord or brainstem, where photon therapy may be contraindicated.[54]

General Efficacy Across Cancer Types

Across cancer types, proton therapy offers equivalent or superior tumor control with reduced side effects. Proton therapy particularly has a dosimetric advantage for tumors near critical structures, such as those in the brain and spine, with lower toxicity than photon therapy.[55] Further, proton therapy enables escalation of tumor doses while sparing normal tissues, thereby improving outcomes for radio-resistant tumors such as chordomas and chondrosarcomas, and enhancing survival and quality of life. For chordomas and chondrosarcomas, more data exist for the use of proton therapy than for photon therapy.

Photon radiation's entry and exit dose increases risks of secondary cancers, cardiac events, and other toxicities, imposing significant costs. Studies have reported a 26–39% reduction in secondary cancer risk for both adult and pediatric patients using proton therapy.[56] Secondary cancers require extensive treatments—surgery, chemotherapy, and lifelong care—far surpassing proton therapy's initial cost differential.

Proton therapy's precision also reduces chronic conditions like heart disease, pulmonary fibrosis, and cognitive impairments, lowering economic burdens. By investing in proton therapy, the Commonwealth can prevent these downstream expenses, aligning with the principles of value-based care.

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 Applicant will continuously evaluate the Proposed Project to ensure the Applicant is providing the highest quality of equitable care to all appropriate patients requiring proton therapy. The following quality metrics and reporting schematic, as well as metric projections for quality indicators will be monitored:

Access: The proportion (per 1,000 patients) of patients travelling from the New England region that are able to obtain the Applicant's proton beam therapy services stratified by patient race, ethnicity, and language.

Access: As it relates to the Applicant's patient panel seeking proton beam therapy services, the number of days between simulation and first treatment; stratified by modality and disease type.

[54] Katharina Seidensaal et al., *Re-Irradiation with Protons Or Heavy Ions with Focus On Head And Neck, Skull Base And Brain Malignancies*. 93 BR. J. RADIOL. (2020).
[55] Almut Dutz et al., *Identification of Patient Benefit from Proton Beam Therapy in Brain Tumour Patients Based on Dosimetric and NTCP Analyses*, 160 RADIOTHER. ONCOL. 69 (2021).
[56] Tai-Ze Yuan, Ze-Jiang Zhan & Chao-Nan Qian, *New Frontiers in Proton Therapy: Applications in Cancers,* 39 CANCER COMMUN. 61 (2019).

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.

Site Accessibility

Consistent with its mission, the Applicant is committed to developing the Center in a manner that ensures broad access to effective cancer care for all patients across the Commonwealth. The selection of 35 Binney Street as the site of the Proposed Project reflects a strategic effort to reduce barriers to comprehensive treatment, particularly for vulnerable populations throughout New England.

Geographic access is a major barrier for underserved populations, exacerbating disparities in cancer outcomes.[57] The Applicant must refer away patients requiring proton beam therapy, which leads to continuity of care issues as patients are no longer obtaining treatment from the Applicant's oncologists or oncology nurses. Given the limited local capacity, the vast majority of Massachusetts patients, and most certainly those without the resources to travel meaningful distances and take the time to receive a series of treatments over the course of weeks or months, are left without a viable option to obtain proton beam therapy. Those patients face significant costs to arrange for transportation and, if needed, lodging, time off from work or school, childcare, and other costs associated with travel to receive treatments, or to forgo proton beam therapy treatment for more convenient, but comparatively less effective radiation therapies. This creates additional challenges for patients from underserved populations, who may forgo more effective treatment because of the costs of accessing such treatment.

Geographical access and travel burden, as well as logistical and care coordination issues, are primary barriers to receiving proton therapy.[58] Given the number of pediatric and adult cancer patients receiving care from the Applicant and BCH, it is critical to have this service available to avoid radiation treatment delays or the use of a suboptimal form of radiation for patients who must receive treatment on site due to their medical condition and for those without adequate means to cover the cost of long distance travel and lodging accommodations. For adult patients, staying local allows for minimal job interruptions and for children and adolescents minimizing school disruptions. For both adults and pediatric patients remaining local permits them to remain close to their family and friend support systems.

The location is highly accessible by public transportation and leverages existing free radiotherapy parking to accommodate patients and caregivers. The Center will be designed for universal

[57] Robert Praeder, Timothy Solberg & Afua A. Yorke, Editorial, *Underserved Communities in the Radiation Therapy Land of Plenty - Physicists' Perspective,* 25(1) J. APPL. CLIN. MED. PHYS. 1 (2024).
[58] Todd Burus et al., *Time Travel Disparities in Access to Proton Beam Therapy for Cancer Treatment*, JAMA NETW. OPEN 1(2024); *see also* S. Gaito et al., *Assessing Equity of Access to Proton Beam Therapy: A Literature Review*, 35 CLIN. ONCOL. 528 (2023).

accessibility, including features to support patients with disabilities, mobility impairments, and children. Its proximity to BCH further enhances access for pediatric patients requiring specialized care, while the Longwood Medical Area location ensures close coordination with patients' current oncology practices and supports truly multidisciplinary care. The Center's layout will foster an inclusive environment for patients of all gender identities and sexual orientations. The Applicant recognizes the profound burden cancer places on individuals and communities, and the Proposed Project reflects the Applicant's commitment to lessening that burden by providing high-quality, equitable, and culturally responsive care to every patient who needs proton therapy.

Ensuring Health Equity to the Applicant's Patients

As a leading center for cancer prevention, treatment, and discovery, the Applicant is committed to providing the best possible care for patients with cancer and seeking tomorrow's cures through research. Central to this mission is the Applicant's dedication to meet the health needs of high-risk and medically underserved populations in the region. The Applicant recognizes the profound burden that cancer has on residents in Massachusetts, 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.

In many ways, the Applicant's involvement in the community is a direct extension of its work in the lab and the clinic. The Applicant's experience in treating patients and educating them about their disease, combined with research into cancer biology and prevention, inform the programs it has launched in the Greater Boston area and reflect its longstanding commitment to addressing these important issues. These initiatives include public awareness efforts about cancer risk; screening programs for early detection of certain cancers; and projects to increase access to cancer care and clinical research to people across Boston and the region.

The Applicant is making significant progress in providing breast cancer screenings, educating residents about sun safety, and more. 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 who share the goal of reducing cancer-related disparities in Boston and across the state.

The Proposed Project will improve accessibility of the Applicant's services for poor, medically indigent, and/or Medicaid eligible individuals. Limiting access to proton therapy for patients with limited financial means based on short-term costs exacerbates healthcare inequities. These patients are often unable to afford travel for out-of-state treatment, and their health outcomes should not be compromised due to financial constraints. The Applicant does not discriminate based on ability to pay or payer source and this practice will continue following implementation of the Proposed Project. As further detailed throughout this narrative, the Proposed Project will increase access to high quality oncology services by expanding access to proton beam therapy services for patients.

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 has developed the Proposed Project to provide equitable access to proton beam therapy for communities throughout Massachusetts. As discussed in Factor 1.b.i, proton beam therapy promotes better health outcomes and quality of life for patients with certain cancer diagnoses. The Applicant is positioned to provide cancer care to all Massachusetts residents, regardless of ability to pay, and intends to similarly provide access to the Proposed Project to any patient in the Commonwealth who might benefit from such treatment. As discussed in Factor 1.b.iii, the Applicant has designed the Proposed Project to ensure community access to proton beam therapy throughout Massachusetts.

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 further support the coordination of on-site care, the Applicant chose this system in part because the Center will be located on-site at the Applicant's facility, where pediatric cancer patients receive treatment and have access to the specialized services that BCH and the Applicant jointly provide. It is anticipated that the upright position will decrease the need for daily sedation through distraction techniques and reduced time requirements for treatment. The location is easily accessible for pediatric patients receiving concurrent chemotherapy at both the Applicant's Jimmy Fund Clinic as well as BCH; the proposed Center can be accessed through physical connectors between the hospitals and patients will not need to travel between multiple locations for care. Additionally, the location and environment are crucial for this effort, and particularly for children with additional special needs who are supported by the specialized anesthesia staff at BCH.

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, as well as patient navigation/social work/resource specialty support to ensure patients have access to resources around social determinant of health needs.

The Applicant's combined pediatric cancer program with BCH will be capable of assuming the oncology care of referred patients that receive proton therapy and will require subspecialty care. In addition, the Applicant currently maintains strong collaborations with referral centers because of the Applicant's bone marrow transplant and surgical programs. The Proposed Project will streamline the cancer care experience for patients and families, and patients will benefit from the Applicant's world-class pediatric oncology care.

The Applicant provides care coordination services in numerous ways. First, the Applicant offers a comprehensive array of supportive resources and services, including patient navigators, resource specialists, social workers, clinical nurse navigators, among others to help address cultural, language, transportation and other barriers for patients. Through one program, the Applicant offers patient navigation services for high-risk patients. Studies have found that cancer patient navigation programs result in increased access to and utilization of cancer care for poor and underserved individuals.[59] A patient navigator is an individual trained to help identify and resolve real and perceived barriers to care, enabling cancer patients to adhere to care recommendations, thereby improving their cancer outcomes.[60] Patient navigators work with the Applicant's social workers, resource specialists, and financial counselors to maximize assistance to patients, consistent with applicable laws. Patient navigators are tasked with identifying high-risk patients, conducting outreach to minority groups, and assisting patients in accessing the Applicant's cancer care and supportive services. Research shows that patients who face the greatest barriers in accessing care are at risk for 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 addition to navigation services, the Applicant provides linkages to its social work program, resource specialists, financial counseling program, as well as interpreter services. Social workers provide assistance 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. Resource specialists assist patients in obtaining local transportation, short-term accommodations during treatment, and other special needs (such as, fuel and food pantry assistance). Financial counselors aid patients in understanding their coverage for services provided by the Applicant, provide estimates for the cost of services, and help patients complete applications for MassHealth and the Applicant's Patient Financial Assistance program, as needed.

The Applicant is committed to reducing barriers to high-quality cancer care for medically underserved patients and their loved ones and is committed to addressing the socio-economic disparities and cultural differences that affect cancer risk. As such, the Applicant offers a comprehensive financial assistance program.

In 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 U.S. 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. Through all of these efforts, the Applicant ensures that all patients have access to high quality oncology services.

[59] Kathryn L. Braun et al., *Cancer Patient Navigator Tasks across the Cancer Care Continuum*, 23 J. HEALTH CARE POOR UNDESERVED 398, 398-413 (2012).
[60] *Id.*

Additionally, the Applicant utilizes a comprehensive electronic health record ("EHR") system, Epic, across all of its hospital facilities to coordinate care. This technology will be used by all clinicians and other support staff at the Center to ensure continuity of care. Through Epic, the Applicant's EHR system, clinical staff provide necessary information to patients' referring physicians (including primary care physicians) through shared clinical note functionality. Depending on the type of cancer, some physicians also follow-up through email and phone to connect to referring providers and local care providers if applicable.

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.

Throughout the planning and development of the Proposed Project, the Applicant has sought, and continues to seek, discussions with individuals at various regulatory agencies within the Commonwealth. While there will be continued discussions with additional regulatory agencies as the Proposed Project proceeds, the following agencies and public officials are some of those with whom the Applicant has consulted regarding the Proposed Project:

- Executive Office of Health and Human Services
- Massachusetts Office of the Attorney General
- Massachusetts Health Policy Commission
- Boston Public Health Commission
- Senator William Brownsberger, Suffolk and Middlesex
- Representative Chynah Tyler, 7th Suffolk
- Department of Public Health: Office of the Commissioner, Office of Legal Counsel
- DoN Program
- Center for Health Information and Analysis

F1.e.i. Process for Determining Need/Evidence of Community Engagement

For assistance in responding to this portion of the Application, Applicant is encouraged to review Community Engagement Standards for Community Health Planning Guideline. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the Proposed Project.

As discussed above in Factor 1.a.i, 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 traditionally has, and continues to, work with providers throughout the Commonwealth to ensure that all patients can access world-class, cutting-edge cancer care, regardless of ability to pay. The Applicant is pursuing this Proposed Project because it recognizes that for a significant portion of those Massachusetts

residents diagnosed with cancer, proton beam therapy is the most clinically appropriate course of treatment.

To ensure appropriate patient and family engagement, the Applicant's staff presented the Proposed Project to the Applicant's Adult and Pediatric Patient and Family Advisory Council ("PFAC"). The councils are 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 9, the Applicant's Chair, Radiation Oncology and Chief Medical Officer met with the Adult PFAC to inform them 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 proton capacity, inability to access care, and enhanced patient experience and satisfaction. Further, on September 23, the Applicant's Vice President and Pediatric Chief Medical Officer, in collaboration with the PFAC Co-Chairs, presented on the Proposed Project at the Pediatric PFAC meeting, providing the Pediatric PFAC with background and an opportunity to ask questions. A discussion took place reiterating the impact of the Proposed Project to patients, patient care and the overall patient experience during the next two years. The materials from these meetings are attached in Attachment 1.

The Applicant has also met with government stakeholders prior to 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. Evidence of Community Engagement/Public Health Value

Please provide evidence of sound Community Engagement and consultation through 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".

In designing and selecting the Proposed Project, the Applicant considered several sites for its Center. The Applicant's site selection criteria included accessibility for patients and staff in terms of distance and drive times, proximity to public transportation, centricity to patient origin and cancer incidence density, and access to ancillary services, hotels, amenities, and other site-specific considerations.

As noted in this Application, to further support the coordination of on-site care, the Applicant chose this system in part because it is small enough to be housed on-site, where pediatric cancer patients receive treatment and have access to the specialized services that BCH and the Applicant jointly provide. It is anticipated that the upright position will decrease the need for daily sedation through distraction techniques and reduced time requirements for treatment. The location is easily accessible for pediatric patients receiving concurrent chemotherapy at BCH; the proposed Center can be accessed through physical connectors between the hospitals and patients will not need to travel between multiple locations for care. Additionally, the location and environment are crucial for this effort, and particularly for children with additional special needs who are supported by the specialized staff at BCH. While community engagement indicated that the Longwood Medical area was best location for the Center, the Applicant will continue to assess and engage with the community to determine whether it may be best to include community-based proton beam therapy centers in the future to address the overwhelming need for this treatment.

The Applicant engaged their community by ongoing discussions with key community stakeholders, including presenting the Proposed Project to its PFAC members, Community Benefits/DoN External Advisory Committee, key community stakeholders, BCH, physicians, and key thought leaders to 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.[61]

The Applicant's project management framework will include regular progress reviews, stakeholder input sessions, and risk mitigation planning to ensure on-time and on-budget delivery. Early engagement with regulatory authorities and comprehensive commissioning of all clinical, safety, and information technology systems will be integral to the implementation plan.

[61] This Application has been filed only four (4) months after final approval of the Applicant's FCH DoN (DFCI-230409915). Given the size and scope of that project, the Applicant engaged in extensive community engagement efforts. Therefore, in order to prevent overburdening the community with this process, and in consultation with the Department of Public Health, Community Health unit, it was agreed and approved by the Applicant's DoN External Advisory Committee that the Community Engagement Plan used for the FCH DoN also should be used for this Application.

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, 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 traditionally has, and continues to, work with providers throughout the Commonwealth to ensure that all patients can access world-class, cutting-edge cancer care, regardless of ability to pay. The Applicant is pursuing this Proposed Project because it recognizes that for a significant portion of those Massachusetts residents diagnosed with cancer, proton beam therapy is the most clinically appropriate course of treatment.

Currently, the vast majority of Massachusetts patients, and most certainly those without the resources to travel meaningful distances and take the time to receive a series of treatments over the course of weeks or months, are left without a viable option to obtain proton beam therapy. Those patients face significant costs to arrange for transportation and, if needed, lodging, time off from work or school, childcare, and other costs associated with travel to receive treatments, or to forgo proton beam therapy treatment for more convenient, but comparatively less effective radiation therapies.

The Proposed Project will increase the accessibility of proton beam therapy for Massachusetts residents, reducing the incidental costs associated with treatment. Patients who are able to receive proton beam therapy as a result of the Proposed Project, rather than a comparatively less effective photon radiation therapy, may see reduced costs related to side effects, damage to critical and developing tissues and organs, and improved outcomes that may reduce the possibility of secondary cancer diagnoses.

The Proposed Project will improve patient quality of life and reduce exposure and damage to normal, healthy tissue, thereby reducing the downstream costs of medical care to manage treatment side effects. In addition, the patients who receive proton therapy have fewer long-term side effects, including a reduced risk for secondary cancers, thus leading to more productive and healthier individuals. The Proposed Project will also provide much needed additional proton capacity in the Commonwealth, will ensure continuity of care for the Applicant's patients, and will allow the Applicant to engage in proton research.

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 greatly enhance oncology services in Massachusetts, offering residents the best treatment option for pediatric patients and oncology patients requiring re-irradiation and patients with certain types of cancer, including head and neck and thoracic.

As discussed in Factor 1.b.i, compared to traditional radiation therapy, proton beam therapy results in less exposure time to radiation. Reduced radiation doses to normal tissues allows for faster recovery after proton beam therapy, with fewer complications. A multi-institutional analysis of treatment for esophageal cancer found that the average length of stay was 9.3 days for proton beam therapy versus 11.6 and 13.2 days, respectively, for three-dimensional conformal radiation therapy and intensity-modulated radiation therapy (two standard photon-based radiation approaches). Additionally, the mortality rate for proton beam therapy was substantially lower than for the other two modalities: 0.9% for proton beam therapy after 90 days versus 4.2% and 4.3%, respectively, for three-dimensional conformal radiation therapy and intensity-modulated radiation therapy.[62]

Additionally, as discussed in Factor 1.b.iii, the Applicant has developed the Proposed Project to improve access to proton beam therapy services, especially for disadvantaged Massachusetts residents who currently may not have access to the most clinically appropriate care. Expanding access to proton therapy within the Commonwealth is an essential step in ensuring equitable cancer treatment for patients who would otherwise need to seek care out of state. The establishment of a local proton therapy center will reduce travel burdens, improve timely access to treatment, and enhance overall cancer care infrastructure, solidifying Massachusetts as a leader in cutting-edge oncology services. Moreover, by reducing treatment-related toxicities and their associated costs, proton therapy presents an opportunity to deliver both clinical and financial value aligning with broader healthcare goals of quality, efficiency, and sustainability. The location of the Center allows Massachusetts residents access to free housing through Hope Lodge and Ronald McDonald House, reducing financial toxicity and travel burden.

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.

The Applicant participates in outreach activities aimed at the reduction of cancer incidence, morbidity and mortality, conducts community-based research, and supports community-based programs. 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

[62] Steven H. Lin, et al., *Multi-Institutional Analysis of Radiation Modality Use and Postoperative Outcomes of Neoadjuvant Chemoradiation for Esophageal Cancer.* 123 RADIOTHER. ONCOL. 376-81 (2017).

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 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.

In addition, the Applicant partners with a wide variety of community-based organizations and social service agencies that provide resources to their patients and partner on cancer control programming. These partnerships and collaborations with local organizations, such as community health centers, governmental agencies, and support networks enable the Applicant's programs to reach racially and ethnically diverse groups, and those for whom socioeconomic circumstances, financial obstacles, or cultural barriers may have stood in the way of learning about cancer risk or seeking treatment and screening services. Some of these partnerships, include:

- **Boston Breast Cancer Equity Coalition**: Launched in 2014 by the Applicant, this cross-sector 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 the Applicant'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 the Department of Public Health's Chronic Disease Prevention and Control Unit, programs in colorectal, prostate, skin and women's cancers have been established with the Department of Public Health 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.

- **Madison Park Development Corporation ("MPDC")**: The Applicant has a longstanding history of collaboration with MPDC and continues to partner with MPDC to implement mutually agreed upon community health improvement strategies, including providing health and wellness programming for MPDC residents.

Further, a social determinants of health perspective guides the evaluation of health needs of the Applicant's local community and patient panel, which is strongly reflected in the Applicant's CHNA Report and Implementation Plan. Through this lens, it is critical to look beyond proximal, individual-level factors in accounting for a community's health problems and towards upstream factors such as housing, education, employment status, racial/ethnic disparities, and neighborhood-level resources that critically impact population health. To this end, the Applicant's CHNA examines how these larger social and economic factors are associated with good and ill health, specifically across the cancer continuum, and identifies key areas for intervention.

The realities reflected by the Applicant's CHNA, which include challenges related to broader upstream socioeconomic issues that go beyond cancer, such as community violence, substance use, and opioid addiction, high rates of unemployment, lack of affordable housing, behavioral and mental health issues, and inadequate availability of nutritious food, highlight the profound burden of cancer experienced by residents in the Applicant's surrounding neighborhoods. The Applicant recognizes that efforts to reduce the cancer burden must go beyond cancer care and treatment, and as such the Applicant continues its unwavering commitment to reducing the cancer burden and promoting survivorship programming. Consequently, the Applicant remains committed to educating the community and raising awareness about the importance of cancer prevention, outreach, screening, early detection, clinical trials and survivorship.

As previously discussed in Section F.1.b.iii, the Applicant has a vast array of programs to address the needs of its patient panel and ensure appropriate linkages to social services. First, through its patient navigation and adult social work programs, the Applicant provides a comprehensive and streamlined continuum of care for patients and families 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, during treatment. Consequently, the Applicant has created a patient navigation database for tracking patient data to maximize the team approach to care and ensure patients have the resources they need. Second, the Applicant provides patients with linkages to resource specialists who address patients' social determinant of health needs. Resource Specialists are focused primarily on alleviating the financial burden that cancer places on individuals and their family 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. Providing patients with these services ensures patients have reduced barriers to care through the provision of necessary support and tools to complete their treatment regiments, thereby reducing unnecessary readmissions and visits. Finally, to ensure equal access to care, the Applicant provides financial counselors who help enroll patients in insurance and other assistance programs. Accordingly, any patient in need of supportive programming is provided with these services and may self-refer to these resources.

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 Proposed Project will expand access to proton beam therapy services for all Massachusetts residents. The Applicant evaluated two project options for establishing a proton therapy center. The first was a standalone, three-treatment-room proton center located outside of Boston. The second, the Proposed Project, consists of a single, compact treatment room situated in the Longwood Medical Area, adjacent to the Applicant's Jimmy Fund pediatric clinic and BCH. After careful consideration, the Applicant selected the Proposed Project due to its strategic proximity to comprehensive pediatric oncology services allowing for fully coordinated pediatric care, significantly lower capital investment and operating expenses, and the ability to provide patient access within just two years. The proximity to BCH includes the added benefit of direct pediatric patient access and limits the risk of ambulance transport to receive proton treatment.

Appendix A

DoN-required Service and/or DoN-required Equipment

For any new, additional, expansion or conversion of a DoN-required Service and/or DoN-required Equipment Applicant shall, in addition to providing the required Information and supporting documentation consistent with 105 CMR 100.210 (Factors 1-6), address with specificity the manner in which an approval of this Application for a DoN-Required Services and DoN-Required Equipment, if received, would:

• Lead to improved patient health outcomes (Quality);

• Result in a demonstrable increase in access, including but not limited to a decrease in price (Access);

• Result in a reduction in the Commonwealth's Total Health Care (Cost); and

In addition, discuss how the DoN-Required Services and DoN-Required Equipment will impact Health Systems Sustainability, that is, the financial viability of health care providers that represent critical access points for underserved residents.

Improved Patient Health Outcomes

For those patients with cancer diagnoses for which proton beam therapy is the most clinically appropriate treatment, proton beam therapy may improve patient survival by improving the local tumor treatment rate while reducing injury to normal organs, which may result in fewer radiation-induced adverse effects, as discussed in detail in the above responses to Factor 1.b.i and Factor 2.b.

Demonstrable Increase in Access

Currently, Massachusetts patients for whom proton beam therapy is the most clinically appropriate treatment may not be able to access such care, as MGH is the only hospital with proton beam therapy center in the Commonwealth and the greater Northeast Region. As discussed above in response to Factor 1.a.ii, demand for proton beam therapy among Massachusetts residents far exceeds the current capacity of the Francis H. Burr Proton Therapy Center. The Applicant has carefully considered its design of the Proposed Project to ensure that in developing a proton beam therapy center, it does so in a way that will ensure access to all Massachusetts residents, especially vulnerable populations, as discussed in the above responses to Factor 1.b.iii.

Reduction in Total Health Care Cost

As discussed above in Factors 1.a.iii and 2.a, while proton beam therapy requires significant upfront capital investment, that investment is considerably lower today than it was when the first proton beam therapy centers were constructed in the 1990s. Proton beam therapy is often perceived as more expensive per treatment than conventional photon-based radiation therapies. However, The Proposed Project will improve patient quality of life and reduce exposure and

damage to normal, healthy tissue, thereby reducing the downstream costs of medical care to manage treatment side effects.

Health Systems' Sustainability

As the only freestanding, NCI-designated Comprehensive Cancer Center in New England, the Applicant maintains a unique role in the continuum of care in the region by providing high-quality, sub-specialized services to patients with cancer. The Applicant provides cancer care to Massachusetts residents, including underserved residents, regardless of ability to pay. The Applicant has developed a number of established linkages with such residents, their primary care physicians, social workers and other specialists who support coordination of care, as discussed in Factor 1.c.The Applicant's providers will continue to utilize these linkages when providing services at the Proposed Project to ensure that patients are receiving not only the most clinically appropriate treatment for their cancer diagnoses, but also that each patient receives the highest quality of equitable and culturally appropriate care.