

**STAFF REPORT TO THE PUBLIC HEALTH COUNCIL
FOR A DETERMINATION OF NEED**

Applicant Name	Dana-Farber Cancer Institute, Inc.
Applicant Address	450 Brookline Avenue, Boston, MA 02215
Filing Date	November 19, 2025
Type of DoN Application	Substantial Change in Service: DoN-required Equipment and DoN-required Service
Total Value	\$50,500,633.00
Project Number	DFCI-25090516-RS
Ten Taxpayer Group (TTG)	3
Community Health Initiative (CHI)	\$2,525,031.65
Staff Recommendation	Approval with Conditions
Public Health Council	April 8, 2026

Project Summary and Regulatory Review

Dana-Farber Cancer Institute, Inc. (DFCI or Applicant) seeks a Determination of Need (DoN) from the Massachusetts Department of Public Health (Department) to establish proton beam therapy (PBT) services through construction of an approximately 4,500 square-foot PBT center (the Center), servicing adult and pediatric patients, to be located at 35 Binney Street, Boston, MA (Proposed Project). The proposed Center will include the following:

- An upright single-gantry proton therapy system with a dedicated accelerator which includes a computed tomography (CT) scanner for image-guidance;
- A separate vertical CT for simulation and treatment planning; and
- Clinical and administrative spaces.

The capital expenditure for the Proposed Project is \$50,500,633.00. The CHI contribution is \$2,525,031.65.

This DoN falls within the definition of Substantial Change in Service, which are reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

Three groups registered as Ten Taxpayer Groups (TTGs). The Department received written comments and held a virtual public hearing on January 14, 2026. A list of commenters and a summary of the comments received can be found in Appendices II through IV.

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Background and Application Overview

Dana-Farber Cancer Institute, Inc. (Applicant)

Dana-Farber Cancer Institute, Inc. (DFCI or Applicant) is a nonprofit, acute care cancer hospital and research institute dedicated to pediatric and adult cancer treatment and research.^a DFCI's main campus, located in the Longwood Medical Area of Boston, provides care for adult and pediatric patients with cancer. The Applicant provides outpatient care at its main campus as well as at numerous satellite locations under its license.¹ Dana-Farber/Harvard Cancer Center (DF/HCC), a collaboration of academic medical institutions and Harvard Schools, is one of 57 National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers², and is the only NCI-Designated Comprehensive Cancer Center in New England.^{b,c}

The Applicant and The Children's Hospital Corporation (Boston Children's Hospital or BCH) have been collaborating since 1947 to provide comprehensive, integrated care for children with cancer and blood disorders. Together, the Applicant and BCH provide pediatric oncology care across the cancer care continuum. The Applicant's clinicians work alongside BCH clinicians, to treat patients in BCH beds.

As part of its clinical collaboration with Beth Israel Deaconess Medical Center (BIDMC) and Harvard Medical Faculty Physicians at BIDMC (HMFP), the Applicant is continuing to coordinate in the planning and development of the new freestanding, inpatient hospital (Future Cancer Hospital or FCH) that received DoN approval in March 2025. The Applicant does not anticipate that the clinical affiliation with BIDMC and HFMP will have any effect on the Proposed Project or its associated need projections.

Application Overview

The Proposed Project includes the construction of an approximately 4,500 square-foot proton beam therapy (PBT) center (the Center), servicing adult and pediatric patients, to be located at 35 Binney Street, Boston, MA. The Applicant is seeking to establish PBT services through the Center, which will include the following:

- An upright single-gantry proton therapy system with a dedicated accelerator which includes a computed tomography (CT) scanner for image-guidance;
- A separate vertical CT for simulation and treatment planning; and
- Clinical and administrative spaces.

¹ This includes Dana-Farber Cancer Institute-Chestnut Hill, Dana-Farber Cancer Institute-Foxborough, Dana-Farber Cancer Institute at Milford Regional Medical Center, Dana-Farber Cancer Institute at South Shore Health, Dana-Farber Cancer Institute - Merrimack Valley, Dana-Farber Cancer Institute at Boston Medical Center, Dana-Farber Cancer Institute at Whittier Street Health Center, and DFCI-Mobile Mammography Service.

² There are 73 NCI-Designated Cancer Centers, 57 are Comprehensive Cancer Centers. Comprehensive Cancer Centers demonstrate reasonable depth and breadth of research activities in each of three major areas: basic laboratory; clinical; and prevention, control and population-based research.

The DoN-required Equipment and Services Guidelines categorize PBT as megavoltage radiation therapy (MRT), a DoN-Required Service, and list CT scanners as DoN-required Equipment.

Table 1 provides an overview of the Proposed Project.³

Table 1: Overview of the Proposed Project

	Total Number at Current Location	Number of New at the Proposed Site (the Center)	Total Number After Project Completion
PBT System	0	1	1
Vertical CT unit	0	1	1

The Applicant is proposing to construct and operate a new PBT system on the Applicant’s campus in Boston in order to provide patients who would benefit from PBT, such as pediatric patients with solid tumors, with “the most effective treatment options, improved health outcomes, and enhanced quality of life.” The Applicant cites the comparative benefits of PBT relative to traditional photon-based radiation therapy (RT), due to its ability to deliver radiation in a more localized region, while reducing the integral dose to normal tissue making PBT particularly useful in the treatment of pediatric cancers, certain types of adult cancers, and the preferred treatment for oncology patients requiring re-irradiation.

The Applicant states that it recognized for a significant portion of Massachusetts residents diagnosed with cancer, PBT is the most clinically appropriate course of treatment. However, the Applicant states that with only one PBT system currently operating in Massachusetts, many of the Applicant’s pediatric and adult patients report that they are unable to access PBT in Massachusetts because of insufficient capacity to meet the current need. As a result, some patients travel out of state to access PBT, while others forgo PBT altogether. The Applicant states that when its patients travel elsewhere to receive PBT, it displaces them from their primary care team and clinical setting for weeks or months at a time, which is stressful for children and families, often leads to treatment delays, and puts patients at risk for communication errors in transferring care. Traveling elsewhere to receive PBT is also not feasible for very sick children, is too emotionally stressful for some families that would need to leave their support systems, and can pose a financial and logistical burden which can be insurmountable.

The Applicant is proposing the first PBT Center in Massachusetts with upright patient rotation. PBT will be delivered to patients in a seated or inclined position, where the patient moves around the beam rather than moving the beam around a supine patient as is the case with standard PBT. The Applicant states that the upright position may decrease the need for daily sedation through

³ The Applicant states that the Proposed Project will include interior demolition as needed, construction of radiation-shielded treatment and clinical support rooms, and that additional spaces for clinical staff, patient intake, anesthesia support, and administrative operations will be integrated into the Center’s design.

distraction techniques⁴, reduce anxiety for pediatric and adult patients, improve scheduling efficiency, and reduce time required for treatment. Additionally, upright PBT treatment allows for the Center to be small enough to be located on the Applicant's campus in the Longwood Medical Area of Boston, where it will have physical connectivity to BCH, DFCI's Jimmy Fund Clinic, the Yawkey Center for Cancer Care, and the Applicant's FCH being constructed. The Applicant states further that the location is also accessible by public transportation and is therefore convenient for adult patients from across the socioeconomic strata. The Applicant asserts that the Proposed Project will increase the availability of PBT for Massachusetts residents and improve timely access to PBT for cancer treatment.

BACKGROUND: PROTON BEAM THERAPY (PBT)

Radiation therapy (RT), also referred to as radiotherapy, irradiation, x-ray therapy, radiation treatment, or radiation, is one of the four pillars of cancer treatment alongside surgery, chemotherapy, and immunotherapy.^{d,e} Radiation is a critical component of cancer treatment and one of the most common, with approximately 50% of cancer patients in North America undergoing RT, predominantly using photon-based (traditional radiation therapy) treatment modalities.^{5,f,g} The goal of RT is to maximize the dose delivered to the target (tumor) while minimizing the dose to normal, non-targeted healthy tissue.^h External Beam Radiation (EBR) is the most common form of radiation treatment used for cancer treatment. EBR delivers radiation beams generated by a machine, from outside of the body into the tumor, causing damage to the deoxyribonucleic acid (DNA) in the cells, which keeps the cells from growing and dividing, ultimately leading to cell death.^{i,j} EBR therapy is usually administered during an outpatient visit.

Traditional RT, the most common form of EBR to treat cancer, uses photons or x-rays as the delivery mechanism for RT to treat certain kinds of cancer. Photon therapy relies on high-energy photons generated by linear accelerators.^k Technological advancements have generated process improvements in photon therapy including intensity modulation (IM) and image guidance (IG).^l These features along with compact systems, cost efficiency, and reproducibility, have made photon therapy an essential component of cancer care.⁶

With traditional RT, it is estimated 30% to 40% of photon beams continue passing through the tumor and radiate healthy tissues beyond the tumor.⁷ The residual radiation that is deposited in surrounding normal tissues beyond the treatment target is called the exit dose.⁸ Despite the current

⁴ Patients must remain still during treatment, and distraction techniques are used to reduce or eliminate the need for daily sedation.

⁵ Most commonly, LINAC treatments.

⁶ Langen K, Mehta M. Proton Beam Therapy Basics. *J Am Coll Radiol*. 2015 Nov;12(11):1204-6. doi: 10.1016/j.jacr.2015.08.002. Epub 2015 Sep 26. PMID: 26419311.

⁷ Johns Hopkins Medicine. Proton Therapy.

<https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/proton-therapy>

⁸ *What is Proton Therapy*. National Association for Proton Therapy.

<https://proton-therapy.org/wp-content/uploads/2023/08/Screenshot-2023-08-16-at-9.04.49-AM.png>

(Visual representation of exit dose and its impact on surrounding tissues).

advanced treatment planning techniques, normal tissue exposure from the exit dose can lead to long-term complications, called radiotherapy-induced adverse effects (“RIAE”) or late effects which can be severe, including 1) organ dysfunction and 2) secondary malignancies.^{m,n,o} Depending on the treatment site, these complications may include: early menopause, infertility, heart and vascular problems, hypothyroidism, increased risk of other cancers, increased risk of stroke, intestinal problems, lung disease, lymphedema, cognitive and memory issues, osteoporosis, cavities and tooth decay, liver problems, kidney problems, cataracts, vision loss, hearing loss, and nerve damage.^{p,q} The resource use and costs of these RIAE have not been comprehensively documented and studied.^r

PBT is a Food and Drug Administration (FDA) approved type of EBR that uses protons, or positively charged particles for the delivery of radiation to treat both benign and malignant tumors.^s A notable difference between proton and photons is that photons are massless, have no charge, and will pass through the body and have an exit dose, whereas protons have physical mass and are positively charged and can be stopped at different depths inside tissue, with minimal exit dose.^t Because of their distinct properties, protons deliver a more limited and precise dose of radiation to tumor tissue, which significantly reduces exposure of non-targeted surrounding healthy tissue and organs to radiation, thus allowing for the use of a higher dose of radiation to be delivered for some cancers, while minimizing side effects.^u This has potential benefits for patients such as for those with long life expectancy (including children), those who would otherwise experience significant toxicities from photons due to the site of treatment, and those who have reduced tissue tolerance such as those who require re-irradiation treatments due to recurrence of disease. To date, several studies suggest there may be fewer secondary malignancies for patients treated with PBT.^v Therefore, for some cancer disease categories, PBT provides an alternative to photon therapy.^w Staff also note that indications are limited. Evidence supports superiority over photon therapy only for specific indications and does not support broad use outside of these indications which is described in more detail under Factor 1(a), need methodologies.

The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 33 leading cancer centers dedicated to patient care, research, and education, defines clinical practice guidelines for cancer treatment. These guidelines recognize PBT as an important modality for multiple cancer types, especially when minimizing normal tissue toxicity is critical, or when photon-based therapy limitations arise.^x DFCI (as part of the Dana-Farber/Brigham and Women's Cancer Center and Massachusetts General Hospital Cancer Center group) is a member of the NCCN.^{y,z}

BACKGROUND: AVAILABILITY OF PBT IN MASSACHUSETTS

Currently, the Mass General Brigham Cancer Institute has the only operational proton therapy site in Massachusetts, with two proton therapy centers, both of which are located on Massachusetts General Hospital’s (MGH’s) main campus in Boston.^{aa} The Francis H. Burr Proton Therapy Center opened in 2001 (three-room) and was operational until February 14, 2025 at which point the Applicant states that it closed for renovations. The Gordon-Browne Proton Therapy Center opened

in 2020 (one-room). The Applicant states that the three-gantry Francis H. Burr Proton Therapy Center averaged 537 patients per year from 2018 to 2022, which the Applicant states is insufficient to meet the existing need for PBT among the Applicant’s pediatric patients alone.

On December 10, 2025, UMass Memorial Health Care, Inc. (UMass) received DoN approval to add a proton beam service on the Marlborough Hospital campus. The President and CEO of DFCI submitted written comment (Public Comments #4) in support of UMass’ proposal, citing “a critical shortage of proton therapy capacity in New England.” The Applicant maintains that even with the approved PBT treatment at UMass, additional PBT capacity is still needed in Massachusetts, and unlike the PBT capacity at UMass, the additional PBT capacity and proximity to BCH that the Proposed Project would provide would maintain the continuum of care for the Applicant’s pediatric patients with cancer.

Patient Panel⁹

Table 2 shows the Applicant’s Patient Panel, defined as unique patients seen from fiscal year (FY) 2022 to FY24. The Applicant states that its Patient Panel encompasses an “extensive geographic area” that includes patients from Boston and surrounding areas, patients from other New England states, and patients from states outside of New England. The Applicant’s Patient Panel, increased by 14.5% from FY22 to FY24.

Table 2: DFCI Patient Panel, FY22 to FY24

	FY22	FY23	FY24	% Change FY22 to FY24
Total Unique Patients	103,795	110,560	118,830	14.5%

Table 3 shows the Applicant’s Massachusetts patients. The Applicant’s Massachusetts patients increased by 14.8% from FY22 to FY24, slightly more than the Applicant’s Patient Panel.

Table 3: DFCI Massachusetts Patients, FY22 to FY24

	FY22	FY23	FY24	% Change FY22 to FY24
Total Unique Patients	77,996	82,885	89,515	14.8%

Patient Information

Table 4 provides a demographic and geographic profile of the Applicant’s Total patients and Massachusetts patients for FY24. The demographic profile is similar across the two patient

⁹ As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder.

populations.¹⁰

Staff note the following about the data presented in Table 4:

- **Age:** Almost 50% of the Applicant’s Total and Massachusetts patients are aged 65 and older. Approximately 3% of the Applicant’s Total and Massachusetts patients are age 21 and under.
- **Race/Ethnicity:** 73% of the Applicant’s Total patients, and 71% of the Applicant’s Massachusetts patients identified at White. Approximately 7% of the Applicant’s Total patients and almost 9% of the Applicant’s Massachusetts patients identified as Hispanic or Latino.
- **Patient Origin:** 78.5% of the Applicant’s patients were from Massachusetts, approximately 17.5% were from other New England states, and 4% were from outside New England. Of the Applicant’s Massachusetts patients, the largest percentage originated from Norfolk (18.8%) and Middlesex (18.6%) Counties.

Table 4: DFCI Patient Information (Total and Massachusetts), FY24

	Total			Massachusetts	
	Count	Percent		Count	Percent
Total Unique Patients	118,830	100.0%	Total Unique Patients	89,515	100.0%
Gender			Gender		
Male	44,810	37.7%	Male	32,067	35.8%
Female	74,012	62.3%	Female	57,444	64.2%
Unknown	Masked ¹¹	Masked	Unknown	Masked ¹²	Masked
Age¹³			Age¹⁴		
21 and Under	3,671	3.1%	21 and Under	2,560	2.9%
22-35	7,504	6.3%	22-35	5,783	6.5%
36-55	27,103	22.8%	36-55	20,558	23.0%
56-64	24,247	20.4%	56-64	17,781	19.9%
65+	58,520	49.2%	65+	44,441	49.6%
Race/Ethnicity¹⁵			Race/Ethnicity¹⁶		

¹⁰ The Applicant notes that the demographics for the overall Patient Panel and the Massachusetts Patient Panel differ from the patient demographics provided in responses submitted for the DoN filed for the Applicant’s future cancer hospital (FCH) DoN because the Patient Panels (Total and Massachusetts) for this Application include pediatric patients scheduled in pediatric departments, while the FCH DoN Patient Panel included pediatric patients only if they were scheduled in adult departments. Like the Patient Panel of the FCH DoN, this Application also includes patient encounters from the Applicant’s Longwood Medical Area location, Chestnut Hill, and other satellite locations.

¹¹ For HIPAA compliance, numbers below 11 are not included.

¹² For HIPAA compliance, numbers below 11 are not included.

¹³ Patients with encounters in the same year before and after attaining age 65 will appear in both age categories.

¹⁴ Patients with encounters in the same year before and after attaining age 65 will appear in both age categories.

¹⁵ Race/Ethnicity/Other includes NULL, Unknown, Multiracial, Non-Hispanic.

¹⁶ Race/Ethnicity/Other includes NULL, Unknown, Multiracial, Non-Hispanic.

Asian, Non-Hispanic or Latino	3,762	3.2%	Asian, Non-Hispanic or Latino	3,053	3.4%
Black of African American	5,288	4.5%	Black of African American	4,757	5.3%
Hispanic or Latino	8,687	7.3%	Hispanic or Latino	7,887	8.8%
White or Caucasian, Non-Hispanic or Latino	87,136	73.3%	White or Caucasian, Non-Hispanic or Latino	63,846	71.3%
Other	13,957	11.7%	Other	9,972	11.1%
Geography¹⁷			Geography¹⁸		
Massachusetts	89,515	75.3%	Norfolk	16,838	18.8%
New Hampshire	8,193	6.9%	Middlesex	16,639	18.6%
Rhode Island	4,174	3.5%	Plymouth	12,293	13.7%
Maine	3,814	3.2%	Essex	10,827	12.1%
New York	2,749	2.3%	Suffolk	9,962	11.1%
Connecticut	2,741	2.3%	Worcester	8,545	9.5%
Florida	1,788	1.5%	Bristol	5,746	6.4%
Vermont	1,058	0.9%	Barnstable	3,444	3.8%
			Hampden	1,751	2.0%
			Unknown	1,056	1.2%

Table 5 shows the payer mix for the Applicant’s adult patients, and Table 6 shows the payer mix for the Applicant’s pediatric patients.

Table 5: DFCI Payer Mix (Gross Revenues) - Adult, 2022 to 2024¹⁹

Payer Mix Category	FY22	FY23	FY24
Commercial Medicare (Private Medicare/Medicare Advantage)	11.1%	12.2%	13.6%
Medicare FFS	37.3%	38.2%	37.3%
Managed Medicaid (Private Medicaid/Medicaid MCOs)	2.9%	3.8%	4.8%
MassHealth	4.5%	3.9%	3.1%
Commercial (PPO/Indemnity and HMO/POS)	43.3%	41.1%	40.1%
Other ²⁰	0.9%	0.8%	1.2%
Total	100%	100%	100%

¹⁷ Represents only certain states, and therefore will not add to 100%.

¹⁸ Top 10 locations (Massachusetts county or state if located outside of Massachusetts) of patient origin.

¹⁹ For adult patients (age 22 and older), including all of the Applicant’s sites, derived based on hospital billing excluding clinical trials and retail pharmacy.

²⁰ “Other” for adult patients includes Self-Pay, Commonwealth of Massachusetts, National Donor Program, United VA Community Care Network, Health Safety Net (full and partial), CHAMPVA, Tricare (East Region Prime, East Region Select, West Region), Nashua Street Jail, Essex County Jail, Generic County Jail, Generic Other Government, MA State MCI Correctional Center, Veterans Choice, Veterans Administration Special Billing, Martins Point USFHP, COVID-19 HRSA Uninsured Testing and Treatment Fund, Works Compensation, U.S. Department of Labor (FECA Federal and DEEOIC Energy), and City of Boston Fire Department.

Table 6: DFCI Payer Mix (Gross Revenues) - Pediatric, 2022 to 2024²¹

Payer Mix Category	FY22	FY23	FY24
Commercial Medicare (Private Medicare/Medicare Advantage)	0.0%	0.0%	0.0%
Medicare FFS	0.0%	0.0%	0.0%
Managed Medicaid (Private Medicaid/Medicaid MCOs)	20.2%	24.7%	34.4%
MassHealth	7.1%	4.5%	4.1%
Commercial (PPO/Indemnity and HMO/POS)	72.2%	68.6%	60.3%
Other ²²	0.4%	2.1%	1.2%
Total	100%	100%	100%

Table 7 shows the Accountable Care Organization (ACO) and Alternative Payment Method (APM) percentages for the Applicant’s Patient Panel.

Table 7: DFCI ACO and APM Contract Percentages, 2024²³

APM Contracts	Percent
ACO and APM Contracts	36.4%
Non-ACO and APM Contracts	63.6%
Total	100%

Factor 1: a) Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently addressed Patient Panel need for the Proposed Project.

PATIENT PANEL NEED

The Applicant’s explanation of Need for the Proposed Project discusses the following key issues:

1. *Patient Panel Barriers to accessing PBT; and*
2. *Unmet Need for PBT in the Applicant’s Patient Panel*

1. *Patient Panel Barriers to accessing PBT*

As noted above, MGH is currently the only PBT provider in Massachusetts with two PBT treatment centers: The Gordon-Browne Proton Therapy Center (one-room), which is in operation, and the Francis H. Burr Proton Therapy Center (three-room) which was operational until February 14, 2025 at which point the Applicant states that it closed for renovations. The Applicant states that the Francis H. Burr Proton Therapy Center averaged 537 patients per year from 2018 to 2022. The Applicant’s clinicians report that some craniospinal irradiation or CSI (a complex radiation therapy

²¹ For pediatric patients 21 and younger, including all of the Applicant’s sites, derived based on hospital billing excluding clinical trials and retail pharmacy.

²² “Other” includes Self-Pay, National Marrow Donor Program, Health Safety Net (partial and full), CHAMPVA, Tricare (East Region Prime, East Region Select, West Region), Martins Point USFHP.

²³ Based on the Applicant’s contractual payments, including Medicaid ACOs/MCOs & the Applicant’s commercial APM contracts (i.e., BCBSMA & Point32Health).

technique that is primarily used to treat central nervous system (CNS) tumors, and select cases of hematologic malignancies^{bb}) patients, are not able to obtain treatment at MGH. Staff note the limitations in assessing MGH's capacity as the Applicant was unable to provide written confirmation from MGH about access for CSI patients. Additionally, staff can only make statements about current capacity, and cannot assume insufficient capacity in the future after renovations. Staff inquired about the Applicant's decision to site the proposed Center in close physical proximity to MGH's established PBT services. The Applicant states that MGH is constrained by high demand across adult and pediatric indications, resulting in access limitations. The Applicant states that even when renovations are completed on the Francis H. Burr Proton Therapy Center, MGH will not have the capacity to meet the need for PBT in the region.

Centers for Medicare and Medicaid Services (CMS) publishes local coverage determinations (LCDs) and related Billing and Coding Articles that include diagnosis codes that support medical necessity for PBT. The codes are structured into two groups: Group 1 patients, for whom PBT is considered medically necessary, and Group 2 patients, for whom PBT is covered for certain indications. The Applicant states that it encourages all Group 1 patients and some Group 2 patients to obtain PBT, despite reported widespread difficulty for patients to access PBT. The Applicant notes that PBT is the standard of care across a range of intra- and extra-cranial pediatric tumors. The Applicant refers out all patients for which PBT is standard of care. The Applicant states that because of the challenges patients report in obtaining PBT at MGH or out of state, DFCI does not have a standard referral process or protocol for PBT referrals. Referrals are case-specific, and can depend on whether a patient has the means to travel out of state frequently for treatment. The Applicant states that before closure of The Francis H. Burr Proton Therapy Center for renovations, it more routinely referred its patients to MGH, but with the current reduced capacity, referrals to MGH are extremely limited.

While the Applicant notes that its patients experience "widespread difficulty" accessing PBT, it does not track referrals to other PBT providers, and is unable to access data from MGH or out-of-state PBT providers. The Applicant states that DFCI clinicians report that patients have been able to obtain PBT from MGH, the New York Proton Center, and Penn Medicine's and Children's Hospital of Philadelphia's PBT centers. The Applicant states that while it does not have data from MGH or out-of-state providers allowing it to estimate the number of its patients that are ultimately unable to receive PBT, DFCI clinicians and patients continue to report significant barriers to accessing PBT, pointing to difficulty in accessing PBT at MGH or out-of-state providers. The Applicant states further that DFCI providers' decisions regarding referrals will be supported by dialogue with patients, and will include discussion of whether the patient has the means to travel, and has the family or other social supports near an available PBT center.

The Applicant states that referring its patients to other providers for PBT compromises continuity of care, because patients are no longer receiving care with their DFCI oncologists and nurses. Additionally, many children receiving care from DFCI and BCH that travel out of state to receive PBT, are displaced from their primary care team and clinical setting for approximately six weeks, which

can be stressful for children and families. The Applicant states that there are significant costs and time burdens for patients that must travel out of state to receive PBT. Traveling out of state to receive PBT is not feasible for very sick children, and some families may forgo it because of the financial and logistical burden, and the emotional stress of leaving their support system. The barriers to accessing PBT can lead some patients to forgo PBT treatment for more convenient yet comparatively less effective radiation therapies. At the same time, staff note that some patients currently travel from out of state to Massachusetts to receive care and, with anticipated PBT capacity coming online in other states, they may be able to access PBT services at another location closer to home.

In its comment on the UMass Proton Beam DoN application (Public Comments #4), the Applicant stated “There is a critical shortage of proton therapy capacity in New England. We believe the region requires 14 to 19 treatment rooms to serve all patients eligible for proton therapy, yet only four licensed rooms exist, all at Massachusetts General Hospital (MGH).” In addition to the approval of the UMass Proton Beam DoN application (one room), three other PBT services have been recently approved in New England but are not yet operational; one is in Johnston, Rhode Island (one-room), one is in Danbury, Connecticut (one-room), and one is in Wallingford, Connecticut (one-room).²⁴ Staff inquired further about the Applicant’s methodology for determining need for PBT treatment rooms in New England. The Applicant states that to determine the number of treatment rooms required to serve all patients eligible for PBT it multiplied the *Population of New England* (15,400,000 individuals) by the *Cancer Incidence Rate* (471.8 per 100,000 people) which equals a total of 72,657 cancer cases per year. The Applicant states that research indicates that approximately 50% of those cases or 36,329 cases, are cases where RT is the most appropriate treatment, and in 14% of those cases, or 5,086 cases, PBT is the most clinically appropriate treatment.^{cc,dd} Staff note that one limitation of the Applicant’s 14% estimate of the number of cases for whom PBT would be appropriate is that it is based on a modeling study from 2005 in a Swedish population, and therefore may not be applicable to the United States (US) population using US guidelines for PBT in 2026.

Letters of support for DFCI’s application from practicing oncologists in Boston, commented on the unmet need for PBT in Massachusetts, and the resulting challenges that patients and families encounter, when trying to access PBT. Dr. Peter Orio, III, a radiation oncologist practicing in the greater Boston area and Chair of the Department of Radiation Oncology at DFCI stated, “*There is currently only one operational proton therapy facility serving Massachusetts, and the entire New England region, a catchment area of more than 15 million residents. Existing regional capacity is insufficient to meet current clinical demand, even under optimal utilization scenarios. As a result, patients face prolonged treatment delays, referral outside the Commonwealth, or the inability to receive proton therapy altogether. These barriers disproportionately affect pediatric patients,*

²⁴ The Connecticut Proton Therapy Center, a collaboration between Yale New Haven Health and Hartford HealthCare, is under construction in Wallingford, CT and is expected to be open by the end of 2026. Danbury Proton will begin construction of a PBT in Danbury in 2026. American Shared Hospital Services is constructing a PBT center in Johnston RI that is expected to be operational in 2027 or early 2028.

medically complex patients, and families with limited resources, directly conflicting with state goals related to access and equity.”

The Applicant states that geographic access, travel burden, and logistical and care coordination issues are primary barriers to receiving PBT, citing a study investigating the drive-time accessibility of all full-service proton facilities operational in the US as of September 2023. The study findings were that “Drivetime accessibility presents a substantial barrier to the delivery of PBT at scale for the US population today,” with 36.6% of the population living within one hour of a currently operating facility, and 16.4% living at a driving distance of four or more hours.^{ee} Additionally, access to PBT in the US was found to be inequitable with individuals aged 65 years and older, those living below the federal poverty line, and residing in suburban and rural areas at greatest risk of having long commutes (4 hours) to PBT for cancer treatment.^{ff} The study goes on to state that “Drivetime accessibility presents a substantial barrier to the delivery of PBT at scale for the US population today. While temporary overnight accommodations near a proton therapy facility are an option, most people with cancer prefer to receive their treatments in a location that allows for continued residence in the home environment.”^{gg} Staff note that the study was published in May 2024, before the UMass PBT Service approval in 2025, and the PBT center approvals in Johnston Rhode Island (2024), and Danbury Connecticut (2025).

2. *Unmet Need for PBT in the Applicant’s Patient Panel*

The Applicant estimated its Patient Panel need for PBT, and states that current limited access to PBT in Massachusetts is not sufficient to meet the needs of its Patient Panel. To estimate Patient Panel need for PBT, the Applicant started with historical data from New Patient Consults by disease area. This is shown in Table 8. The Applicant then applied a methodology to determine New Patient Consult eligibility for PBT. This is discussed in more detail below.

Table 8: DFCI New Patient Consult Volume, FY22 to FY24²⁵

	FY22 Count	FY22 Percent	FY23 Count	FY23 Percent	FY24 Count	FY24 Percent
Medical Oncology Regional Sites ²⁶	10,795	28.8%	11,224	28.6%	11,178	27.7%
Breast Oncology Center	4,821	12.9%	4,840	12.3%	5,003	12.4%
Gastrointestinal Oncology	3,789	10.1%	3,763	9.6%	4,013	9.9%
Genitourinary Oncology	3,033	8.1%	3,568	9.1%	3,901	9.7%
Thoracic Oncology Program	2,111	5.6%	2,225	5.7%	2,297	5.7%
Gynecological Oncology	1,911	5.1%	2,075	5.3%	2,117	5.2%

²⁵ The Applicant states that 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.)

²⁶ Volume includes the Applicant’s sites at Boston Medical Center – Brighton, Milford Regional Medical Center, South Shore Health, Merrimack Valley, Foxborough, and Londonderry, NH. The Applicant states that if the majority of the patient’s encounters occurred at a satellite location, such satellite will be designed as the patient’s derived disease center for purposes of new consult volume determinations.

Lymphoma	1,774	4.7%	1,644	4.2%	1,688	4.2%
Multiple Myeloma	1,357	3.6%	1,514	3.9%	1,547	3.8%
Head and Neck Oncology	1,153	3.1%	1,280	3.3%	1,276	3.2%
Hematology Services	1,052	2.8%	1,035	2.6%	830	2.1%
Pediatric Oncology	1,012	2.7%	1,023	2.6%	974	2.4%
Leukemia	879	2.3%	982	2.5%	1,159	2.9%
Melanoma	843	2.3%	901	2.3%	978	2.4%
Neuro-Oncology Center	835	2.2%	897	2.3%	950	2.4%
Sarcoma and Bone Oncology	794	2.1%	808	2.1%	1,007	2.5%
Cutaneous Oncology Center	691	1.8%	766	2.0%	709	1.8%
Transplant	590	1.6%	656	1.7%	709	1.8%
Total	37,440	100.0%	39,201	100.0%	40,336	100.0%

The Applicant states that the referral sources for its adult patients are any licensed provider, including the Applicant’s medical oncologists and surgical oncologists, community oncologists, urologists, colorectal surgeons, Ear, Nose and Throat Specialists (ENTs), neurosurgeons, thoracic surgeons, gynecological surgeons, breast surgeons, neurologists, pulmonologists, primary care physicians (PCPs), self-referrals, and referrals from tumor boards and multidisciplinary clinics. The Applicant states that its pediatric patients may be referred by any oncologist, however, more pediatric patients seek care initially from the Applicant or BCH. The Applicant anticipates that out-of-state patients will be referred to the Center in the same manner as in-state patients, directly through a physician, by phone or through a self-referral.

To identify and assess New Patient Consults that were eligible for PBT, the Applicant used CMS’ Local Coverage Determination (LCD) for Proton Beam Therapy (LCD ID L35075) which outlines the conditions for which PBT is considered medically reasonable and necessary (Group 1) as well as certain other conditions which is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in the peer-reviewed medical literature (Group 2).^{hh} CMS’ groupings are outlined below in Table 9. The Applicant states that PBT is widely accepted as the most appropriate radiation modality for children with access to it, and notes that CMS’ Group 1 includes all pediatric patients with solid tumors.

Table 9: CMS Local Coverage Determination (LCD), Proton Beam Radiotherapy (35075)

Group 1
On the basis of the above medical necessity requirements ²⁷ and published clinical data, disease

²⁷ **Indications For Coverage**

PBT is considered reasonable in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient. Examples of such an advantage might be:

1. The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).
2. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive

sites that frequently support the use of PBT include the following:

- Ocular tumors, including intraocular melanomas
- Tumors that approach or are located at the base of skull, including but not limited to:
 - Chordoma
 - Chondrosarcomas
 - Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated
- Unresectable benign or malignant central nervous system tumors to include but not be limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations
- Primary hepatocellular cancer treated in a hypofractionated regimen
- Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply
- Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients
- Pituitary neoplasm
- Advanced staged (e.g., T4) and/or unresectable malignant lesions of the head and neck
- Malignant lesions of the paranasal sinus, and other accessory sinuses
- Unresectable retroperitoneal sarcoma.

PBT is one of the acceptable forms of external beam radiation therapy that may be used to administer Stereotactic Body Radiation Therapy (SBRT) or Stereotactic Radiosurgery (SRS). When PBT is used to administer SBRT or SRS, the delivery and management codes relevant for SBRT or SRS apply, and the same clinical indications apply as for those treatment strategies.

Group 2

Coverage of proton beam therapy in Group 2 is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in the peer-reviewed medical literature.

- Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
- Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
- Breast cancers
- Unresectable pancreatic and adrenal tumors

-
3. A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity.
 4. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

- Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
- Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
- Prostate cancer, without distant metastases
- Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)
- Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy.

Prostate Cancer

Coverage and payments of proton beam therapy for prostate cancer will require:

- a. Physician documentation of patient selection criteria (stage and other factors as represented in the NCCN guidelines);
- b. Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits.

Medicare coverage is “limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).”ⁱⁱ Through an evidence-based process, CMS makes National Coverage Determinations (NCDs) to grant, limit, or exclude coverage for items and services for Medicare beneficiaries.^{jj} If a NCD does not exist, an item or service may be covered based on a LCD, which are established by each of the Medicare Administrative Contractors (MAC)²⁸ (private entities that process claims for health care items and services submitted by enrolled Medicare providers and suppliers) to specify coverage rules in its jurisdiction.^{kk} CMS has not issued a NCD for PBT, and the first LCDs for PBT went into effect in 2009.^{ll}

The Applicant grouped its internal New Patient Consult data into Group 1 or Group 2, using patients’ top three diagnosis codes from the tenth revision of the International Classification of Diseases (ICD-10), and matching them with CMS’ classification of Group 1 or Group 2 (LCD ID L35075). The Applicant’s grouping of New Patient Consults is shown in Table 10. Table 10 is broken down by pediatric and adult patients, based on the department in which the patient was scheduled.

Table 10: DFCI New Patient Consult PBT 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

²⁸ A local coverage determination is a decision made by a MAC to cover a particular item or service on a MAC-wide basis, in accordance with the Social Security Act (i.e., a determination as to whether the item or service is reasonable and necessary). MACs are to publish local coverage determinations to provide guidance to the public and medical community within their jurisdictions. <https://www.gao.gov/assets/gao-15-372.pdf>

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

The Applicant notes the following about Table 10:

- 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 PBT based on their Group 1 diagnoses.
- 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 PBT was not offered, and does not reflect existing patients who would be eligible for PBT.

Table 11 shows the combined adult and pediatric PBT Eligibility totals by CMS grouping. The Applicant states that in FY24, the total 3,466 adult and pediatric patients in Group 1 that needed PBT, could not access the treatment in Massachusetts, given the state’s current operational PBT capacity.²⁹

Table 11: DFCI New Patient Consult PBT Eligibility, Group 1 and Group 2 Totals

Patient Population	CMS Group	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Adult and Pediatric	Group 1 Total	2,573	3,274	3,104	3,281	3,466
Adult and Pediatric	Group 2 Total	11,201	14,100	14,109	14,351	15,263
Grand Total		13,774	17,374	17,213	17,632	18,729

Staff inquired about the impact of recently approved PBT services at UMass, in RI, and in CT, on the Applicant’s estimated need for PBT among its Patient Panel. The Applicant states that it welcomes the addition of multiple new PBT providers, given the need for PBT within its Patient Panel. The Applicant asserts that “out-of-state capacity should not displace in-state access planning for pediatric and other complex PBT patients.” The Applicant states that even with new approved market entrants, the need for PBT services among the Applicant’s pediatric patients is sufficient to warrant the Proposed Project, because it addresses cases where PBT coordinated with oncology and

²⁹ Staff note that based on recent PBT approvals in RI and CT, and the UMass approval, four additional PBT treatment rooms will be available in New England in the next few years.

other care is essential to minimize long-term risks. The Applicant categorized Group 1 patients by their proximity to a facility (DFCI or another approved regional facility) based on their respective zip codes. This is shown in Table 12. Of the Applicant’s Group 1 patients, almost 47% reside closest to DFCI and the remaining 53% are in closer proximity to other approved regional PBT sites. Staff note that travel has been cited as a consideration in determining where patients receive PBT services, and that patients in closer proximity to other approved facilities will have the option to choose one of those approved facilities for their PBT treatment once they become operational. With the capacity to serve 216 patients per year, the proposed PBT system will address approximately 10% of the Applicant’s estimated need for PBT. The Applicant has demonstrated that there is sufficient need to fill this capacity within their Group 1 patients alone, even if some Group 1 patients choose to obtain PBT services from another approved regional PBT facility.

Table 12: DFCI Group 1 Patients Proximity to DFCI and Approved PBT sites in New England

Facility/Operator	Location	Group 1 Patients	% of Total Group 1 Patients
DFCI	Boston, MA	1,568	47%
UMass Memorial Health	Marlborough, MA	634	19%
Danbury Proton	Danbury, CT	493	15%
American Shared Hospital Services	Johnston, RI	462	14%
The Connecticut Proton Center	Wallingford, CT	196	6%
Total		3,353	100%

The Applicant anticipates that many patients requiring PBT are already receiving care from the Applicant, and the Center’s location will be proximate to patients’ other existing care at DFCI. The Applicant states that DFCI’s long collaboration with BCH, and the excellence in pediatric oncology, and comprehensive care that it provides for its pediatric patients, uniquely positions the Applicant to offer a pediatric focus and capabilities that the other approved (yet not operational) PBT centers will not have. The Applicant states that its patients are in need of PBT, are oftentimes already receiving care at DFCI and BCH, and therefore proximity between the Center and BCH is critical to the delivery of their existing care, regardless of the geographic location of their residences. Many of the Applicant’s patients who would be undergoing PBT have multiple other specialty appointments at DFCI/BCH during their course of PBT treatment. For those patients it is more convenient to go to one site for all of their oncology care.

Staff requested a demographic breakdown for adult Group 1 and Group 2 patients. This is shown in Tables 13 and Table 14. The category “Geography” shows the top 10 locations of patient origin for adult Group 1 and Group 2 patients. Similar to the Applicant’s Patient Panel and Massachusetts patients, the age 65 and older population make up greater than 40% of adult Group 1 patients, and more than 50% of adult Group 2 patients. The percentage of the Applicant’s Total Patient Panel and Massachusetts patients identifying as White is slightly more than 70%, while for adult Group 1 and Group 2 patients it is 80% and 77%, respectively. Similar to the Massachusetts patients, Norfolk and Middlesex Counties, are the largest counties represented for patient origin or geography. For the Applicant’s adult patients (Table 5), Medicare is the largest payer category, followed by commercial,

which is the same for adult Group 2 patients, but for adult Group 1 patients, commercial is the largest payer category followed by Medicare.

Table 13: DFCI Adult Group 1 and Group 2 Demographic Information, FY24

	Group 1			Group 2	
	Count	%		Count	%
Total	3,190	100%	Total	15,116	100%
Age³⁰	Count	%	Age³¹	Count	%
21 & Under ³²	20	1%	21 & Under ³³	23	0%
22-35	210	7%	22-35	408	3%
36-55	828	26%	36-55	3,137	21%
56-64	751	24%	56-64	3,451	23%
65+	1,389	44%	65+	8,131	54%
Race & Ethnicity	Count	%	Race & Ethnicity	Count	%
White or Caucasian, Non-Hispanic Latino	2,541	80%	White or Caucasian, Non-Hispanic Latino	11,634	77%
Other ³⁴	247	8%	Other ³⁵	1,393	9%
Hispanic or Latino	131	4%	Hispanic or Latino	677	4%
Asian, Non-Hispanic or Latino	114	4%	Asian, Non-Hispanic or Latino	652	4%
Black or African-American	108	3%	Black or African-American	549	4%
Multiracial, Non-Hispanic	49	2%	Multiracial, Non-Hispanic	211	1%
Geography³⁶			Geography³⁷		
Middlesex	371	12%	Norfolk	1,944	13%
Norfolk	309	10%	Middlesex	1,891	13%
Plymouth	259	8%	Plymouth	1,555	10%
New Hampshire	233	7%	New Hampshire	1,081	7%
Worcester	226	7%	Worcester	1,064	7%
Maine	192	6%	Suffolk	937	6%
Essex	184	6%	Essex	918	6%

³⁰ Patients may be counted more than once if they have an encounter before and after their date of birth in the same fiscal year.

³¹ Patients may be counted more than once if they have an encounter before and after their date of birth in the same fiscal year.

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

³³ Includes only patients 18 or younger seen in adult clinical departments. Excludes patients seen in pediatrics departments.

³⁴ Includes patient responses not in list as well as NULL entries.

³⁵ Includes patient responses not in list as well as NULL entries.

³⁶ By Massachusetts County or state of residence if outside of Massachusetts

³⁷ By Massachusetts County or state of residence if outside of Massachusetts

Bristol	166	5%	Bristol	813	5%
Suffolk	159	5%	Rhode Island	673	4%
New York	153	5%	Maine	620	4%

Table 14: DFCI Adult Group 1 and Group 2 Payer Mix, FY24

Group 1		Group 2	
Payer Mix Category	Percent	Payer Mix	Percent
Commercial Medicare	12.1%	Commercial Medicare	13.6%
Medicare FFS	28.9%	Medicare FFS	33.6%
Managed Medicaid	6.6%	Managed Medicaid	5.4%
MassHealth	4.1%	MassHealth	3.6%
Commercial	46.4%	Commercial	42.5%
Other ³⁸	2.0%	Other ³⁹	1.3%
Total	100%	Total	100%

Staff also requested a demographic breakdown for pediatric Group 1 and Group 2 patients. This is shown in Tables 15 and Table 16. A smaller percent of pediatric Group 1 and Group 2 patients identified at White compared to the Applicant’s Patient Panel and Massachusetts patients, and a much larger percentage of pediatric Group 1 or Group 2 patients comprised the race/ethnicity category “Other”. Commercial payer mix is the largest payer followed by Medicaid, similar to the payer mix for the Applicant’s pediatric patients (Table 6). “Other” and “Other MA counties”, both representing combined counts with less than 11, were the largest groups representing patient origin or geography for pediatric Group 1 and Group 2 patients, respectively. Staff note that the Geography Category “Other” for Group 2 pediatric patients, includes states (New York, Connecticut, Rhode Island, Maine, Virginia, Vermont, North Carolina, Illinois, and Florida) from which patients may be unlikely to travel to Massachusetts to seek PBT treatment, because patients could instead seek PBT treatment closer to home.

³⁸ “Other” for adult patients includes Self-Pay, Commonwealth of Massachusetts, National Donor Program, United VA Community Care Network, Health Safety Net (full and partial), CHAMPVA, Tricare (East Region Prime, East Region Select, West Region), Nashua Street Jail, Essex County Jail, Generic County Jail, Generic Other Government, MA State MCI Correctional Center, Veterans Choice, Veterans Administration Special Billing, Martins Point USFHP, COVID-19 HRSA Uninsured Testing and Treatment Fund, Works Compensation, U.S. Department of Labor (FECA Federal and DEEOIC Energy), and City of Boston Fire Department.

³⁹ “Other” for adult patients includes Self-Pay, Commonwealth of Massachusetts, National Donor Program, United VA Community Care Network, Health Safety Net (full and partial), CHAMPVA, Tricare (East Region Prime, East Region Select, West Region), Nashua Street Jail, Essex County Jail, Generic County Jail, Generic Other Government, MA State MCI Correctional Center, Veterans Choice, Veterans Administration Special Billing, Martins Point USFHP, COVID-19 HRSA Uninsured Testing and Treatment Fund, Works Compensation, U.S. Department of Labor (FECA Federal and DEEOIC Energy), and City of Boston Fire Department.

Table 15: DFCI Pediatric Group 1 and Group 2 Demographic Information, FY24

	Group 1			Group 2	
	Count	%		Count	%
Total	276	100%	Total	147	100%
Race & Ethnicity⁴⁰	Count	%	Race & Ethnicity⁴¹	Count	%
White or Caucasian, Non-Hispanic Latino	125	45%	White or Caucasian, Non-Hispanic Latino	80	54%
Other ⁴²	118	43%	Other ⁴³	45	31%
Hispanic or Latino	14	5%	Hispanic or Latino	Masked	Masked
Asian, Non-Hispanic or Latino	Masked	Masked	Asian, Non-Hispanic or Latino	Masked	Masked
Black or African-American	Masked	Masked	Black or African-American	Masked	Masked
Multiracial, Non-Hispanic	Masked	Masked	Multiracial, Non-Hispanic	Masked	Masked
Geography			Geography		
Other ⁴⁴	53	19%	Other MA Counties ⁴⁵	43	29%
Middlesex	38	14%	Other ⁴⁶	35	24%
New Hampshire	31	11%	Middlesex	25	17%
Other MA Counties ⁴⁷	28	10%	Suffolk	15	10%
Worcester	21	8%	New Hampshire	15	10%
Norfolk	17	6%	Bristol	14	10%
Essex	17	6%	Total	147	100%
Connecticut	17	6%			
Maine	15	5%			
Plymouth	14	5%			
Suffolk	13	5%			
New York	12	4%			

⁴⁰ Masked for HIPAA compliance purposes when the number of patients is fewer than 11.

⁴¹ Masked for HIPAA compliance purposes when the number of patients is fewer than 11.

⁴² Other includes patient responses not in list as well as NULL entries.

⁴³ Other includes patient responses not in list as well as NULL entries.

⁴⁴ Other includes states with 11 or fewer patients, and have been combined for HIPAA compliance purposes. These states include Rhode Island, Florida, Vermont, New Jersey, South Carolina, Maryland, Kentucky, Washington, Texas, Pennsylvania, Ohio, Minnesota, Louisiana, Iowa, Delaware, California, and Unknown. The category “Unknown” was combined because the total number of patients is under 11.

⁴⁵ Other MA counties include counties with 11 or fewer patients, and have been combined for HIPAA compliance purposes. These counties include Essex, Worcester, Plymouth, Norfolk, Hampden, Hampshire, Dukes, Berkshire, Barnstable, and Unknown. The category “Unknown” was combined because the total number of patients is under 11.

⁴⁶ Other includes states with 11 or fewer patients, and have been combined for HIPAA compliance purposes. These states include New York, Connecticut, Rhode Island, Maine, Virginia, Vermont, North Carolina, Illinois, Florida, and Unknown. The category “Unknown” was combined because the total number of patients is under 11.

⁴⁷ Other include counties with 11 or fewer patients, and have been combined for HIPAA compliance purposes. These counties include Barnstable, Hampshire, Hampden, Berkshire, Franklin.

Total	276	100%			
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Table 16: DFCI Pediatric Group 1 and Group 2 Payer Mix, FY24

Group 1		Group 2	
Payer Mix	Percent	Payer Mix	Percent
Commercial Medicare	4.4%	Commercial Medicare	0.0%
Medicare FFS	0.0%	Medicare FFS	0.0%
Managed Medicaid	27.0%	Managed Medicaid	42.7%
MassHealth	2.3%	MassHealth	2.7%
Commercial	60.9%	Commercial	54.5%
Other ⁴⁸	5.4%	Other ⁴⁹	0.1%
Total	100.0%	Total	100.0%

To better understand need for PBT among the Applicant’s pediatric patients, the Applicant provided a breakdown of Group 1 and Group 2 pediatric patients by Massachusetts residency and out-of-state residency. This is shown in Table 17. Of the 423 Group 1 and Group 2 pediatric patients in FY24, 59% were Massachusetts residents. Staff note that the Applicant’s out-of-state residents may elect to seek PBT treatment at a facility in closer proximity than DFCI, nonetheless, the Applicant has established that need for PBT therapy among the Applicant’s pediatric patients in Massachusetts alone is greater than the capacity of the Applicant’s proposed PBT system.

Table 17: DFCI Group 1 and Group 2 Pediatric Patients by In-state and Out-of-state

Pediatric Patient Population	MA Residents	Out-of-State Residents
Group 1	152	124
Group 2	97	50
Pediatric Total	249	174

The Applicant estimates that the Proposed Project will allow it to treat a total of 216 patients per year. To arrive at that number the Applicant projected PBT treatments required for patients of each treatment type. This is shown in Table 18. The Applicant states that using its clinical experience, it made assumptions 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 RT 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.

⁴⁸ “Other” for pediatric patients includes Self-Pay, National Marrow Donor Program, Health Safety Net (partial and full), CHAMPVA, Tricare (East Region Prime, East Region Select, West Region), Martins Point USFHP.

⁴⁹ “Other” for pediatric patients includes Self-Pay, National Marrow Donor Program, Health Safety Net (partial and full), CHAMPVA, Tricare (East Region Prime, East Region Select, West Region), Martins Point USFHP.

Table 18: PBT Treatment Assumptions, by Treatment Type

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

The Applicant states that it considered a number of factors when calculating the treatment capacity of the proposed Center, including the time required to warm up the machine at the beginning of the day, the time required to perform quality assurance testing at the end of the day, the time required to conduct necessary and preventative maintenance, and time required to conduct research. The Applicant states that this results in a 17 to 19 hours operating day, of which 12 hours will be used for PBT treatment. There are typically 251 treatment days per year after accounting for weekends and holidays. The Applicant anticipates that the machine will run at 97% uptime, resulting in 243 treatment days.

Based on the assumptions outlined in Table 18 and the equations included below, the Applicant then calculated the number of treatments per day and per year that the Center could provide, assuming the Center would be operational for 12 hours per day, 243 days per year. This is shown in Table 19.

<p>Patients Treated Per Year = $\frac{\text{Annual Treatment Appointments}}{\text{Sessions Required per Patient per Year}}$</p> <p>Annual Treatment Appointments = $\frac{\text{Daily Operating Time (minutes)} \times \text{Operating Days (per year)}}{\text{Treatment Length (minutes per treatment)}}$</p>
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Table 19: DFCI PBT Capacity Calculations

Type of Treatment	Treatments/Day ⁵⁰	Treatments/Year ⁵¹	# of Total Treatments/Patient	Number of Patients/Year ⁵²
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

⁵⁰ Reflects the total minutes in a 12-hour day divided by the treatment length in minutes.

⁵¹ Assumes the Center is operational 243 days per year.

⁵² Reflects the treatments per year divided by the total number of treatments per patient.

Projected Number of Patients Treated: Based on the Applicant's calculations, the Proposed Project would allow the Applicant to treat approximately 216 patients per year. The Applicant determined that this would amount to approximately 10% of the Applicant's estimated Patient Panel need for PBT by dividing the estimated annual capacity (216) by the sum of eligible Group 1 adult patients (3,190) and Group 1 and Group 2 pediatric patients (423) in FY24 (total of 3,613 patients).⁵³ The Applicant notes that the projected number of patients treated relied on the Applicant's historical data and assumptions, and does not take into consideration trends which the Applicant expects will increase need for PBT, such as the increase in early-onset cancer, and an increasing aging population in the Commonwealth that is expected to live longer.

The Applicant states that cancer morbidity and mortality data for Massachusetts demonstrate increasing need for cancer treatment. Cancer is the leading cause of death in Massachusetts.^{mm} There were 196,399 new cancer cases and 63,231 cancer deaths in Massachusetts between 2016 and 2020.ⁿⁿ Cancer is the second most common cause of death among children aged one to 14 years in the US, surpassed only by accidents, and is the fourth most common cause of death among adolescents aged 15 to 19 years.^{oo} Pediatric and adult cancer rates are highest in the Northeast compared with other US Census regions (Midwest, South, and West).^{pp,qq} While the overall five-year survival rate for childhood cancers is 85%^{rr,ss}, pediatric cancer survivors are at much higher risk of developing late toxicity from RT. Staff note that while we acknowledge these demographic trends, it is not known the exact impact this will have on PBT utilization, particularly for adults, given the possible impact of other emerging treatments for cancer.

Implementation: The Applicant estimates that the Proposed Project will be operational by December 2027. The Applicant states that it anticipates that approximately half of the proposed volume (108) will be treated during the Center's first year of operation. The Applicant expects to be able to fully ramp up operation in the second year, with annual capacity reaching 216 patients. The Applicant notes that it is possible that optimization of scheduling, case-mix adjustments, and ongoing improvement in workflow processes, may allow modest incremental increases in projected volume without exceeding safe staffing ratios or compromising quality.

Referral for the Center's PBT services: The Applicant states that any licensed oncologist in Massachusetts may refer a patient for evaluation for the Center's services. Furthermore, materials submitted by referring oncologists will be reviewed by a Proton Utilization Tumor Board or an equivalent body (PUR-TB).

Proton Utilization Tumor Board or Equivalent Body(PUR-TB): The Applicant states that referrals for PBT will be reviewed by a multidisciplinary committee that the Applicant anticipates will include adult and pediatric radiation oncologists, medical physicists, dosimetrists, and ethicists. The Applicant states that the PUR-TB will implement best practices and use defined clinical criteria to assess the magnitude of proton benefit, with the aim of ensuring that each case is reviewed with

⁵³ Rounded to the nearest 10th.

rigor, consistency, and transparency. The PUR-TB's criteria will include the following:

- 1) magnitude of clinical benefit compared to photon therapy;
- 2) risk reduction for acute and late toxicity;
- 3) proximity of tumor to critical organs;
- 4) pediatric and adolescent/young adult status;
- 5) need for re-irradiation; and
- 6) urgency of disease course.

The Applicant maintains that the PUR-TB's prioritization structure will be applied uniformly and transparently in order to ensure that patients with the greatest clinical benefit and need receive access to PBT. The Applicant states that once patients are approved by the PUR-TB, they will proceed through coordinated navigation, insurance review, and simulation scheduling.

Staff inquired about PBT coverage guidelines for patients insured through MassHealth and for patients with commercial insurance. The Applicant states that MassHealth does not have specific coverage guidelines for PBT and that commercial insurance plans generally cover PBT for specific conditions. As an example, the Applicant referenced Aetna's PBT clinical policy bulletin in which PBT is medically necessary for the curative treatment of certain tumors.^{tt,54}

The Applicant asserts that the increased access to PBT that will be attained through the Proposed Project will help to:

- Reduce treatment delays associated with limited local access to PBT,
- Decrease reliance on less effective forms of RT,
- Decrease the interruptions to employment and school that long distance travel to access PBT can create,

⁵⁴ PBT is medically necessary for the following conditions: Primary CNS tumors; or Head and neck tumors (T4 or unresectable, excluding T1-T2N0M0 laryngeal cancer); or Paranasal sinus, other accessory sinus, or nasopharyngeal tumors; or Skull-based tumors (e.g., chordomas or chondrosarcomas); or Malignancies in children (21 years of age and younger); or Esophageal cancer; or Malignancies requiring craniospinal irradiation (CSI) in persons with no active malignancy outside of the craniospinal axis; or Mediastinal lymphomas; or Thymomas and thymic carcinoma; or Thoracic sarcomas; or Nonmetastatic retroperitoneal sarcomas; or Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid); or Primary or metastatic tumors of the spine where the spinal cord tolerance would be exceeded with photon radiotherapy approaches; or Primary malignant or benign bone tumors; or Reirradiation of an in-field or marginal recurrence being treated with curative intent, where other radiotherapy approaches would exceed acceptable constraints; or Localized unresectable hepatocellular carcinoma (HCC) or intrahepatic cholangiocarcinoma in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy techniques, including intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), selective internal radiation spheres, and transarterial therapy (for example, chemoembolization); or Non-metastatic pelvic tumors that are advanced and unresectable, with significant pelvic or periaortic non-metastatic bulky nodes, where other radiotherapy approaches would exceed acceptable constraints; or Persons with a single kidney or transplanted pelvic kidney with treatment of an adjacent target volume and in whom maximal avoidance of the organ is critical; or Persons with genetic syndromes making total volume of radiation minimization crucial, such as, but not limited to NF-1 patients, BRCA1/2, deleterious ATM mutations, Li-Fraumeni, Lynch syndrome, and retinoblastoma; or Pituitary neoplasms.

- Support continuity of care with BCH and DFCI providers,
- Allow patients to remain close to their support systems over the course of their treatment, and
- Support equitable access to PBT, particularly for those patients for whom access is currently limited due to transportation and financial barriers associated with traveling out of state to receive treatment which can last for several weeks. The Applicant notes that the location of the Center will allow Massachusetts patients and families access to free housing through Hope Lodge operated by the American Cancer Society, and through Ronald McDonald House.

IMAGING EQUIPMENT

The Applicant affirms that imaging is an essential component of radiation treatment planning. Imaging equipment assists in the detection and diagnosis of cancers, the determination of a cancer's spread, the approach for delivering certain treatments, and the assessment of the efficacy of a particular treatment. CT is the most common form of imaging used for radiation treatment planning and tissue density determined by CT imaging is necessary for proton treatment planning. Treatment planning attempts to generate a radiation treatment plan that delivers a therapeutic dose of radiation to the tumor while also sparing nearby normal tissue.^{uu}

The Applicant states that two CT machines are needed for the Proposed Project: one CT is part of the proton beam system and will be used to guide radiation oncologists during treatment, and the second CT is a separate, vertical CT that is required for treatment planning. The Applicant states that the CT that is part of the proton therapy system is an integrated vertical CT that will be used to provide upright imaging during the treatment itself.

Vertical CT Scanner

The Applicant states that the proposed separate, vertical CT scanner is needed for simulation of proton patients that matches their positioning during PBT. The proposed vertical scanner is needed, and cannot be accomplished with the Applicant's existing CT capacity, because the Applicant's existing CT capabilities can only accommodate patients imaged in horizontal (supine) positions, which does not align with the upright proton therapy system. The Applicant states further that the proposed vertical CT will also be used for studies that are necessary and that compare upright versus supine simulation, including upright versus supine comparative anatomy, lung and mediastinal motion assessment, new immobilization devices for upright treatment, and education of staff in upright imaging.

Table 20 shows the capacity, projected utilization, and scans per patient of the proposed vertical CT scanner.

Table 20: Projected Vertical CT Utilization

Hours per Day Available for Simulation	Number of Operational Days per Year	Annual Available Simulation Hours
8	243	1,944
Patients per Year	Number of Scans per Patient	Number of Scans per Year
216	1.3	281
Hours required per Scan	Number of Scans per Year	Required Hours per Year
1.25	281	351

Staffing

The Applicant states that it employs 250 oncology and hematology physicians as well as pediatric oncology advanced practice providers. The Applicant states that when the Center is fully operational, and ramped up, it will include approximately 28 full-time employees (FTEs). This is shown in Table 21.

Table 21: The Center’s Proposed Staffing

Type of Staff	Number of FTEs
Therapists	8.2
Physicians	4.9
Billing/Pre-Auth/Intake	3.2
Treatment Planners	2.0
Practice Support Staff	2.0
Nursing/APP	1.8
Medical Assistants	1.5
Research Personnel	1.5
Medical Director	1.0
Child Life Specialist	1.0
IT	1.0
Total	28

To staff the Center, the Applicant states that it will leverage resources from the Applicant’s existing Radiation Oncology Department, and that it will focus on recruiting talent from the communities that it serves.

Analysis

Staff find that the Applicant has demonstrated, with data, need for additional PBT capacity in Massachusetts to address an unmet need for PBT in its Patient Panel. The Applicant has shown how existing PBT in Massachusetts is insufficient to meet the needs of its patients for whom PBT is the most clinically appropriate treatment based on CMS’ Group 1 criteria, for patients for whom PBT is reasonable and necessary. To better understand the Applicant’s methodology for determining Patient Panel eligibility for PBT, staff requested ICD-10 diagnosis codes for adult and pediatric Group

1 and Group 2 patients for the most recent year. The list of ICD-10 codes can be found online in Responses to DoN Questions #2. Staff took a random sample of Group 1 and Group 2 codes from the ones provided by the Applicant and compared them to the ICD-10 diagnosis codes included in CMS' Billing and Coding: Proton Beam Therapy (A56827). Staff note that because some of the characteristics of Group 2 malignancies are not adequately reflected by ICD-10 codes, such as whether or not a malignancy is unresectable, the Applicant's methodology to achieve Group 2 estimates using ICD-10 diagnosis codes may overestimate the number of patients for whom PBT would be clinically necessary. However, the Applicant's Patient Panel need for PBT is met by CMS' Group 1 indications alone.

As shown in Table 22, 839 adult Group 1 patients and 68 pediatric Group 1 patients (907 total) reside in either Suffolk County, where the proposed Center will be located, or in Middlesex or Norfolk counties, which both border Suffolk county. The Applicant's proposed PBT system will treat an estimated 216 patients per year, or approximately 24% of Massachusetts Group 1 patients residing in close proximity to the proposed Center.

Table 22: Suffolk County, Middlesex County, and Norfolk County, Group 1 Patients

Massachusetts County	Adult Group 1	Pediatric Group 1
Suffolk County ⁵⁵	159	13
Middlesex County ⁵⁶	371	38
Norfolk County ⁵⁷	309	17
Total	839	68

Staff notes, the Center for Health Information and Analysis (CHIA) analyzed the Massachusetts All-Payer Claims Database (APCD) data set to see where Massachusetts residents needing PBT go for their care based on claims submitted. It found that Massachusetts patients are traveling to 17 states, and the District of Columbia, for PBT treatments. CHIA highlighted the following caveat: *"... it is important to note that the overall claim volumes are lowered relative to the true MA population denominator, since the MA APCD excludes Medicare fee-for-service and, following Gobeille v. Liberty Mutual, has an approximately 40% reduction in commercial claims due to the absence of self-funded ERISA plan data."*^{vv}

CHIA filtered the medical claims for the proton beam CPT procedure codes 77520, 77522, 77523,

⁵⁵ Suffolk County includes Boston, Chelsea, Revere, and Winthrop.

⁵⁶ Middlesex County includes Acton, Arlington, Ashby, Ashland, Ayer, Bedford, Belmont, Billerica, Boxborough, Burlington, Cambridge, Carlisle, Chelmsford, Concord, Dracut, Dunstable, Everett, Framingham, Groton, Holliston, Hopkinton, Hudson, Lexington, Lincoln, Littleton, Lowell, Malden, Marlborough, Maynard, Medford, Melrose, Natick, Newton, North Reading, Pepperell, Reading, Sherborn, Shirley, Somerville, Stoneham, Stow, Sudbury, Tewksbury, Townsend, Tyngsborough, Wakefield, Waltham, Watertown, Wayland, Westford, Weston, Wilmington, Winchester, and Woburn.

⁵⁷ Norfolk County includes Avon, Bellingham, Braintree, Brookline, Canton, Cohasset, Dedham, Dover, Foxborough, Franklin, Holbrook, Medfield, Medway, Millis, Milton, Needham, Norfolk, Norwood, Plainville, Quincy, Randolph, Sharon, Stoughton, Walpole, Wellesley, Westwood, Weymouth, and Wrentham.

and 77525 for calendar years 2021, 2022, 2023, and the first six months of 2024. The results are displayed in Table 23, which shows the ten highest-volume providers by state, and in Table 24, which shows PBT utilization by provider state.⁵⁸

Table 23. Top 10 Proton Beam Providers in MA APCD by State

Rank	Provider
1	MASSACHUSETTS GENERAL HOSPITAL, Massachusetts
2	PROTON INTERNATIONAL - DELRAY, LLC, Florida
3	BAPTIST HOSPITAL, Georgia
4	THE NEW YORK PROTON CENTER, New York
5	ACKERMAN CANCER CENTER, Pennsylvania
6	WILLIAM BEAUMONT HOSPITAL, Michigan
7	HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA, Pennsylvania
8	MARYLAND PROTON TREATMENT CENTER, LLC, Maryland
9	NORTHWESTERN MEDICINE CHICAGO PROTON CENTER, Illinois
10	FLORIDA PROTON THERAPY INSTITUTE INC, Florida

Table 24: Volume of MA APCD Medical Claims Proton Beam Procedures, CY2023⁵⁸

Provider State Top 10 based on Volume	Volume
MA	3,449
FL	569
NY	185
IL	84
TN	83
MI	56
MD	56
VA	42
TX	39
WA	34

Based on staff analysis, the Applicant has demonstrated that need for PBT in its Patient Panel is significant and surpasses existing capacity that includes all existing PBT systems in Massachusetts, and UMass’ recently approved PBT project. Staff agree that lack of local access to PBT can result in challenges and barriers to accessing PBT, that have been cited in the literature, and that can delay or even prevent access to PBT for clinically appropriate patients. Staff note that with the approval of PBT in Central, MA (UMass), and in neighboring New England States, (RI and CT), the Applicant’s adult patients residing in closer proximity to those approved PBT systems, than to DFCI, could be more likely to seek PBT treatment at one of those facilities, closer to home. The Applicant is

⁵⁸ Most recent full year of data.

proposing to treat a small percentage of the total number of Group 1 patients for whom PBT is clinically appropriate. Therefore, there will still be an unmet need for PBT among the Applicant's patients that can be met by other approved regional PBT providers. As a result of the foregoing, staff finds that with additional analysis, the Applicant has made reasonable projections of the need for and number of patients for whom PBT could be medically appropriate within its Patient Panel. Staff finds that with the "Other Conditions" outlined below requiring the Applicant report on ICD-10 diagnosis codes and medical necessity criteria for PBT patients, the Proposed Project meets the requirements of Factor 1(a).

Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity

For this element of Factor 1, the Applicant must demonstrate that the Proposed Project adds public health value in terms of improved health outcomes and quality of life for the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

Public Health Value: Improved Outcomes and Quality of Life

As noted above, there are early (acute) side effects and late side effects associated with RT, caused by the radiation dose to normal tissues.^{xx} Early side effects occur shortly after treatment, tend to be short-term, mild and treatable, and the most common ones are fatigue and skin changes, while late side effects can occur months or years after treatment ends, are more permanent, and include physical and cognitive impacts including second cancers (also known as secondary cancers).^{yy,zz} Late effects are correlated with patient age at time of treatment, radiation dose and volume, and can be impacted by chemotherapy or surgery.^{aaa} The chance of late effects occurring increases over time, and with childhood cancer survivors living longer due to better treatments, an increasing number will have late effects.^{bbb} In 2022, there were more than 521,000 pediatric cancer survivors living in the US and the number is projected to increase to 580,000 by 2040.^{ccc}

Because of the long-term and late-effects associated with RT, reducing cumulative radiation dose to normal, surrounding tissue, while achieving optimal control of the tumor has been a focus of RT. A 2010 study on the long-term health effects of cancer treatment using data from The Childhood Cancer Survivor Study (CCSS), a retrospective cohort of over 14,000 survivors of childhood cancer diagnosed between 1970 and 1986, stated "Radiation therapy has been an essential element of treatment of childhood cancer, resulting in improvements in survival for some of the most common malignancies, including childhood ALL (prophylactic cranial irradiation), medulloblastoma, and many solid tumors. However, the increased use of radiation therapy has also resulted in an increase in long-term treatment-related adverse outcomes."^{ddd}

PBT's clinical benefits include reduced toxicities while maintaining survival rates.^{eee} The Applicant states that PBT "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." Included below is a brief summary of the Applicant's presentation of clinical evidence

on PBT's contribution to improved health outcomes and quality of life for adult and pediatric patients. Staff notes PBT's efficacy for specific clinical indications, and that PBT is not a treatment applied generally across all cancer types.

PBT and Pediatric Patients

The American Cancer Society estimated that in 2025, 9,550 children (aged birth to 14 years), and 5,140 adolescents aged 15 to 19 years would be diagnosed with cancer.^{fff} Cancer is the second most common cause of death among children aged one to 14 years old, and the fourth most common cause among adolescents aged 15 to 19 years old.^{ggg} Pediatric patients treated with traditional RT as opposed to PBT, are at higher risk for life-altering toxicities of radiation, secondary tumors, neurocognitive decline, hearing loss, hormone deficiency, and growth abnormalities.^{hhh} Potential long-term side effects of RT in children and adolescents can include problems related to growth, intelligence, endocrine function, fertility, and organ function.ⁱⁱⁱ Low doses of radiation can impact bone and soft tissue growth and development and can lead to limb length differences, limited movement and facial deformation or asymmetry.

PBT has been recognized as the superior choice to photon-based RT “for tumors with complex anatomy surrounded by critically sensitive tissues and for childhood cancers.”^{jjj,kkk} A survey of pediatric cancer patients treated at 40 proton centers in 11 countries, estimated that 15% of pediatric patients (less than 22 years) receiving radiotherapy in the U.S. were treated with PBT, and that protons were being used to treat 50% to 70% of pediatric patients with aggressive tumor types, including rhabdomyosarcoma (the most common soft tissue sarcoma in children and adolescents), medulloblastoma (the most common cancerous brain tumor in children), ependymoma (a tumor that grows from cells of the brain and spinal cord that is common in children and adolescents), Ewing's sarcoma (common cancer in children and adolescents that forms in the bones or soft tissues), and atypical rhabdoid tumors (cancer of the central nervous system (CNS) primarily affecting infants and young children).^{lll}

CNS tumors are the second most common childhood cancer, and the most common cancer in adolescents.^{mmm} The most common indication for RT in pediatric patients is for brain tumors. Radiation exposure to the brain can predispose one to neurocognitive effects, hearing loss, vascular anomalies and neuroendocrine dysfunction.ⁿⁿⁿ Younger pediatric brain tumor patients are more vulnerable to brain damage due to ongoing brain development.^{ooo} PBT may reduce risk of adverse neurocognitive effects through better sparing of healthy brain tissue.^{ppp} Within the cranium, it leads to lesser dose to normal sensitive regions like the hippocampus and temporal lobes which can reduce radiation-associated endocrine dysfunction (hormonal disorders).^{qqq} PBT use in pediatric medulloblastoma eliminates the exit doses to the heart, lungs, abdomen, and pelvis, which eliminates risk for radiation-induced cardiac, pulmonary, gastrointestinal, and reproductive adverse side effects, which studies have reported in patients treated with photons.^{rrr} Studies of proton and photon use in pediatric medulloblastoma patients have also shown an association with improved global IQ, perceptual reasoning and working memory for PBT, and improved endocrine outcomes and reduced requirement for endocrine replacement therapy.^{sss} Ependymoma, a type of CNS tumor,

is treated with RT post-operatively, and has been associated with lower toxicity in those treated with PBT, which spares radiation to critical structures reducing risk of growth hormone deficiency, hearing loss, and neurocognitive function. Growth hormone deficiency in children has been linked to multiple co-morbidities including poor growth and cognitive impairment, and growth hormone monitoring and replacement for pediatric patients can be costly.^{ttt}

A literature review of PBT use in non-CNS pediatric tumors such as retinoblastoma, Hodgkin Lymphoma, Wilms Tumor, and bone and soft tissue sarcoma, reported that PBT reduced radiation doses to healthy, growing organs, which can reduce risk of side effects from RT, including radiation-induced secondary malignant neoplasms (SMNs).^{uuu} A study comparing PBT and photons (IMRT) for pediatric rhabdomyosarcoma, a non-CNS tumor, found that PBT reduced radiation dose to multiple structures in the CNS and non-CNS, including to the hypothalamus, which controls the secretion of growth hormone, and to the temporal lobes where memory function is located.^{vvv}

Letters of support from DFCI practicing oncologists in Boston, emphasized the improved health outcomes and quality of life that can result from expanding access to PBT, especially for pediatric patients. Dr. Lisa Diller, a pediatric oncologist and Vice Chair of the Department of Pediatric Oncology at DFCI stated, *“Over my more than 30 years of practicing as a pediatric oncologist, I have cared for patients who are long-term survivors of photon therapy, and have noted how the ‘exit dose’ associated with photon radiation (and avoided with protons) has caused irrevocable harm to reproductive organs, to normal muscle and bone, and to parts of the brain. In the modern era of pediatric oncology, when we need to use radiation therapy to cure cancer, proton beam therapy is much preferred for most cases; children with retinoblastoma (a tumor of the retina, occurring in infants), rhabdomyosarcoma and brain tumors will live better lives after treatment due to improved long-term outcomes with proton therapy.”*

Dr. Ryan Nagy, BCH President and System COO states, *“Neuro-oncology stands out as an area that will particularly benefit [from the Proposed Project], given the delicate nature of brain and nervous system tumors and the critical importance of preserving surrounding neurological function.”*

PBT and Adult Patients

Adults receiving traditional RT can experience damage to healthy tissues, which increases the risk of developing secondary conditions that require additional medical interventions, such as organ dysfunction, secondary cancers, infertility, and prolonged supportive care. PBT is used to treat certain adult cancers, including brain and spinal cord cancers, head and neck cancers, and many sarcoma.^{www} Included below are some examples of PBT’s superior clinical effectiveness over traditional RT due to PBT’s ability to more precisely target the tumor while minimizing radiation dose to surrounding healthy tissue, resulting in improved treatment outcomes, and a reduction in treatment-related side effects.

Sarcomas are a group of rare, malignant cancers that develop in bone and or connective tissue such as fat, muscle, blood vessels, nerves and the tissue that surrounds bones and joints.^{xxx} Sarcomas are

found in the lower and upper extremities, trunk/chest wall/abdomen/pelvis and head and neck.^{yyy} Treatment is multidisciplinary and often includes surgery, chemotherapy and RT. Sarcomas often recur, require higher doses of radiation, and pose a challenge due to their location near critical structures, making them difficult to treat. The improved precision that PBT provides compared to traditional RT, allows for higher doses of radiation to be delivered while reducing radiation dose to surrounding tissue and organs, which can help to reduce risk of side effects from treatment and improve health outcomes.^{zzz} A large study evaluating PBT's use in sarcoma patients found that patients receiving PBT had better overall survival than patients receiving photon-based RT, with improved overall survival found in patients diagnosed with chordoma (rare, malignant bone tumor that forms in the spine or base of the skull), rhabdomyosarcoma (the most common soft tissue sarcoma in children and adolescents), and chondrosarcoma (rare, malignant bone tumor).^{aaaa} The authors state that the study "revealed that the use of PBT among sarcoma patients has increased, but there is still a large gap between the number of patients who should receive PBT and patients who are receiving PBT."^{bbbb}

Chordomas and chondrosarcomas of the skull base and spine are radioresistant tumors with a high risk of local recurrence, and which can often require higher doses of radiation, but pose a challenge due to their location near critical structures. The use of high-dose photon-based RT is limited by the ability to spare critical organs, which is particularly important for treatment of the base of the skull which often involves the brainstem, optic chiasm, and spinal cord.^{cccc} PBT can be used safely and effectively to improve outcomes, with one study that examined treatment of chordomas and chondrosarcomas of the skull base and spine reporting "favorable feasibility, local tumor control, survival, and toxicity after high-dose proton therapy for chordomas and chondrosarcomas."^{dddd}

Head and Neck cancer can form in the oral cavity, throat, voice box, paranasal sinuses, nasal cavity, and salivary glands. Because many critical structures are located in the head and neck area, treating head and neck cancers with high doses of radiation can lead to significant side effects. Since PBT offers superior dosimetric precision, it has been shown to significantly lower the risk of treatment-related toxicities for head and neck cancers^{eeee}, thereby decreasing acute and late side effects, including mucositis (inflammation of oral tissues), dry mouth, gastrostomy tube dependence, and limits need for opioid pain medication. Traditional RT is an integral component of treatment of oropharyngeal cancer, a type of head and neck cancer that originates in the middle section of the throat, however it is associated with severe toxicity. Staff point to a recent study on the use of protons (IMPT) and photons (IMRT) in oropharyngeal cancer which found that patients treated with protons lived longer (overall Survival of 91% for protons vs. 81% with photons) and experienced fewer side effects and improved quality of life, with protons lowering the risk of severe swallowing problems by 13% and reducing the need for feeding tubes by more than 13%.^{ffff,gggg}

PBT and Reduced Risk of Secondary Cancers

RT increases the risk of second cancers by 1.2-fold to 3-fold in adults, and by 6-fold to 10-fold in pediatric patients.^{hhhh} Secondary cancers require additional treatments and lifelong care. A study of second cancers after prostate therapy found that PBT reduced the risk of radiation-induced second

cancers by 26% to 36% compared to photon-based RT (IMRT) with the reduction attributed to PBT's ability to reduce radiation dose in nearby sensitive organs.ⁱⁱⁱⁱ A study examining 450,000 adult and pediatric patients treated with proton-based and photon-based (IMRT and 3DCRT⁵⁹) radiation found a lower risk of second cancer associated with PBT, especially for patients treated for head and neck, breast, and prostate cancers.^{jjjj} Staff note that despite these data, prostate and breast cancer are not considered Group 1 indications for PBT based on CMS' LCD.

PBT offers significant advantages for pediatric patients by reducing risks of long-term RIAE and preserving quality of life due to their longer life expectancy. Studies show that PBT minimizes radiation exposure to vital organs and healthy tissues compared to traditional photon-based RT, reducing the risk of long-term damage and secondary malignancies.^{kkkk} Specifically, PBT significantly lowers radiation exposure to critical organs such as the bowels, stomach, liver, kidneys, and spleen, potentially reducing damage to these vital areas.^{llll} A comparative study on the risks of second cancer and cardiac mortality in pediatric patients with medulloblastoma found that proton craniospinal irradiation⁶⁰ reduced the incidence of second cancers and cardiac mortality compared to photon craniospinal irradiation as a result of protons lower dose to surrounding organs.^{mmmm}

PBT and Decreased Acute and Late Toxicities

Because the precise targeting of PBT minimizes radiation exposure to healthy tissues, patients experience a reduction in short- and long-term side effects such as fatigue, nausea, skin reactions, and organ damage.ⁿⁿⁿⁿ A study of 48 pediatric patients with malignant brain tumors found patient experience of acute toxicity (fatigue, headache, insomnia, anorexia, nausea, vomiting, alopecia, and dermatitis), which can affect morbidity and quality of life, to be low-grade and manageable with PBT.^{oooo}

PBT for Patients Requiring Irradiation

PBT is also beneficial for oncology patients requiring re-irradiation, which entails retreating a site with radiation. Organs can only tolerate a certain amount of radiation exposure over time, and radiation levels beyond this threshold can damage healthy tissues and result in organ dysfunction. The likelihood of developing RT-associated toxicity is dependent on the dose of radiation used, younger age at exposure, and volume of tissue irradiated.^{pppp} PBT can be beneficial for patients who develop local or regional recurrences or new primary malignancies within the field of a previous RT treatment course because of its ability to control disease, and reduce toxicity compared to photon-based RT, and because of its ability to offer a safer and more effective course of reirradiation.^{qqqq} Studies state that reirradiation is a well-established treatment option in the multidisciplinary management of head and neck cancers, where an estimated 40% of patients develop a second cancer or locoregional recurrence.^{rrrr,ssss}

⁵⁹ 3D Conformal Radiation Therapy

⁶⁰ A specialized radiation technique used for patients with central nervous system malignancies.

PBT and Improved Quality of Life

RT increases risk for chronic conditions like heart disease, pulmonary fibrosis, and cognitive impairments. By reducing side effects and complications, PBT allows patients to maintain their daily activities and overall well-being throughout the course of treatment, which can lead to faster recovery times and a quicker return to normal life.^{tttt} Patients treated for oropharyngeal cancer often experience work disability and impairment during and after RT treatment. Staff point to a study of patients with oropharyngeal cancer treated with either proton therapy (IMPT)⁶¹ or photon therapy (IMRT)⁶², where patients treated with protons showed increased return to work and greater work productivity than patients treated with photons.^{uuuu} Pediatric brain tumor survivors treated with RT are at risk for decreased Health-Related Quality of Life (HRQoL) due to the late effects of RT treatment. Studies comparing HRQoL outcomes in pediatric brain tumor patients treated with photons and protons found better HRQoL outcomes in pediatric patients treated with protons.^{vvvv}

Paris Prinsen, a two-time cancer survivor and current patient at DFCI, provided written comment that addressed the quality of life issues that can arise with traditional RT: *“While my treatment saved my life, I continue to live with significant long-term health effects related to radiation exposure. These include pituitary dysfunction, secondary benign growths, and damage to other organs. These late effects require ongoing medical care and have a lasting impact on my quality of life...Access to this technology [PBT] could help future patients avoid or lessen many of the long-term complications that survivors like myself now face, particularly pediatric and young adult patients who have decades of life ahead of them.”*

Measures for Reporting

The Applicant proposed measures to assess the Applicant’s proposed therapy services. The measures are presented in Appendix I and, with the additional measures suggested by staff, will be reported to DPH on an annual basis following implementation of the Proposed Project. The Applicant states that it will also monitor clinical outcomes unique to PBT that include local control, disease-free and overall survival, acute and late toxicities, treatment-interruptions, and dose-volume metrics related to organs at risk. Additionally, pediatric patients will be followed for neurocognitive and developmental outcomes. The Applicant states that it will collect patient-reported quality-of-life measures and will review these measures regularly to ensure alignment with national benchmarks and evolving evidence.

Public Health Value: Health Equity

The Applicant states that the Proposed Project will improve accessibility of the Applicant’s services for poor, medically indigent, and/or Medicaid eligible individuals whose access to PBT is limited by the financial barriers associated with traveling out-of-state to access treatment.

Interpreter Services: The Applicant has adopted the Communication and Language standard under

⁶¹ Intensity-modulated proton therapy.

⁶² Intensity-modulated photon therapy.

the national Culturally and Linguistically Appropriate Services (CLAS) standards. To support patient access to high-quality oncology services, the Applicant provides medical interpreters at no charge to patients and families who speak a language other than English. The Applicant provides interpreter services in three modalities: in-person, video remote interpreting, and over-the-phone interpreting and prioritizes providing patients with in-person interpreters whenever possible. Through an automated workflow in Epic, patients identified as preferring a language other than English are presented to interpreter service staff so that an interpreter can be assigned prior to an initial appointment. The Applicant's interpreter services program covers over 200 languages and completed 95,490 interpretations and 727 translations in FY25. The list of languages offered can be found online in Responses to DoN Questions #1. The Applicant anticipates that its interpreter services department will partner with its radiology oncology department to prepare the team for PBT-related assignments.

Accessibility: The Applicant states that it uses an integrated, institute-wide accommodation model to ensure that patients with physical and cognitive disabilities receive timely, individualized support. With a focus on effective communication, accessible care environments, patient dignity and shared understanding, the model links ADA leadership with Medical Interpreter Services, Facilities & Real Estate, clinical teams, and specialized support systems so that accommodation needs are identified early, documented in Epic, and addressed consistently across care settings.⁶³

The Applicant states that the Center's design supports patients with disabilities, mobility impairments, and children, and the layout will foster an inclusive environment for patients of all gender identities and sexual orientations. The proposed location for the Center incorporates universal-design principles. The hallways, treatment, and exam rooms, seating and restrooms meet or exceed American with Disabilities Act (ADA) requirements. Treatment and exam rooms include adjustable-height furniture and layouts to accommodate mobility devices and caregivers. Pediatric spaces incorporate calming visual elements and child-appropriate design. The Applicant states that private, gender-neutral changing spaces and clear, universal graphic wayfinding signage will allow for all patients, regardless of physical ability, age, or gender identity, to experience an environment that is respectful, inclusive, and easy to navigate.

The Center is proximate to BCH which enhances access for the Applicant's pediatric patients requiring specialized care. The Center's location in the Longwood Medical Area of Boston allows for close coordination with patients' current oncology practices and supports multidisciplinary care. The Center is accessible by public transportation reducing travel-related barriers to accessing care that can disproportionately impact socioeconomically disadvantaged and racially minoritized populations.^{www} Patients and caregivers will also have access to existing free radiotherapy parking.

⁶³ Key elements include proactive screening of patients and documentation in Epic; maintaining physically accessible spaces; providing neuro-inclusive supports when requested, and cross-team collaboration among the ADA Coordinator, Interpreter Services, Social Work, the Neuro-Inclusive Program, Facilities, and clinical staff to meet accommodation needs to the greatest extent possible.

The Applicant states that it will track data on barriers to access to PBT, including barriers to access for MassHealth beneficiaries, and intends to design and implement evidence-based interventions to address such barriers, including through the Applicant's existing initiatives and new partnerships with community health centers, community-based organizations, and government entities.

Community Initiatives: The Applicant states that it partners with community-based organizations that share in its goal of reducing cancer-related disparities, to strengthen its initiatives and embed them within the fabric of the communities it serves. The Applicant mentions initiatives that further its work in the community and extend its work beyond treating patients to include educating them about their diagnoses, through 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 in Boston and the region. The Applicant states that its Cancer Care Equity Program - a community-based partnership that includes primary and specialty care practices, patients navigation programs that assist vulnerable populations, and institutional diversity, equity, and inclusion initiatives, focused on reducing structural barriers to cancer care - will support equitable access to the Center by reducing logistical, financial, and cultural barriers to cancer treatment.

Patient Experience: The Applicant states that its patient-experience strategy is grounded in equity and cultural responsiveness. Activities include interpreter and multilingual engagement services, navigation teams, and all staff training in cultural humility and implicit bias. The Applicant states that all staff working at the proposed Center will have the opportunity to participate in the Applicant's Inclusive and Engagement educational framework. The Framework includes biennial nursing cultural competence education and ongoing workforce development that the Applicant states is grounded in evidence-based inclusive care; Disability Competent Care Training, that was launched in alignment with MA Hospital Quality and Equity Incentives Program requirements and that was made available to all workforce members beginning in 2024; and Healthcare Equality Index (HEI)-aligned LGBTQ+ inclusive care practices, including communication norms, patient intake considerations, and affirming clinical interactions.⁶⁴

The Applicant states that it embeds inclusion in operational practices, such as respect for name, pronoun, and family information documentation. The Applicant evaluates patient experience through multiple lenses including Press Ganey surveys stratified by race, ethnicity, language and insurance type; patient-reported experience metrics; adherence and appointment-completion data; and direct feedback from the Applicant's Adult and Pediatric Patient and Family Advisory Councils (PFACs) all of which allow the Applicant to identify disparities, implement targeted improvements, and refine care delivery on a continuous basis. The Applicant notes its receipt of the Excellent Health Outcomes for All Certification, for meeting Joint Commission criteria advancing health equity, accessibility, and inclusive care.

⁶⁴ Healthcare Equality Index 2024. <https://www.hrc.org/resources/healthcare-equality-index>

Analysis

Staff finds the Proposed Project will add public health value in terms of improved health outcomes, quality of life, and equity for the Applicant's Patient Panel. The side effects from RT can negatively impact individual quality of life and the ability to care for oneself. Staff point to a cross-sectional study examining the prevalence of disabilities among adult cancer survivors in the US which found that more than a quarter of US cancer survivors surveyed reported mobility disability and more than 7% reported self-care disability, which were both higher than the noncancer population.^{xxxx} Racial/ethnic minorities, underserved groups and individuals with comorbidities, were associated with a higher prevalence of mobility and self-care disability in cancer survivors.^{yyyy}

The Proposed Project will increase local access to PBT for the Applicant's Patient Panel, helping to reduce barriers associated with accessing PBT, and to support coordinated and integrated care cancer treatment. The Applicant states the proposed upright single-gantry photon therapy system may decrease the need for daily sedation through distraction techniques and reduce time requirements for treatment. Written letters of support note that the upright system will benefit patients who may not tolerate traditional treatment setups. Staff find that with the "Other Conditions" outlined below that include reporting on PBT patient payer mix, race and ethnicity, and language, and the annual reporting measures outlined in Appendix 1, the requirements of Factor 1(b) have been met.

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

Continuity and Coordination of Care: The Applicant states that the proposed Center will have physical connectivity to DFCI's Jimmy Fund Clinic, BCH, the Yawkey Center for Cancer Care, and the Applicant's FCH currently in construction, supporting coordination and continuity of care among the Center's adult and pediatric patients.

The Applicant asserts that the Center will provide a level of coordinated pediatric oncology care that is currently not available in the Commonwealth, including continuous on-site access to pediatric emergency services, pediatric anesthesia, and complex pediatric subspecialty teams offered by the Center that cannot be replicated in a community setting. The Applicant states that BCH cares for the majority of children in Boston with pediatric cancer, and while some pediatric patients may receive certain radiology services at BCH satellite locations outside of Boston, all other pediatric services including oncology and stem cell care are provided at BCH's Boston location. DFCI's leading experts collaborate with multidisciplinary teams at BCH with expertise in surgical and supportive care disciplines. This level of coordinated care reduces risk for medically complex, immunocompromised, and high-acuity patients. The Center's location will be easily accessible for pediatric patients receiving concurrent chemotherapy at the Applicant's Jimmy Fund clinic and at BCH as the Center will be able to be accessed through physical connectors between the hospitals, reducing patient travel to multiple locations for care; and because BCH's specialized anesthesia staff will be easily accessible for children with additional special needs.

BCH patients will be able to access the Center without going outside, which the Applicant states will minimize fragmentation, reduce patient burden, and ensure consistent oversight by the same care teams coordinating chemotherapy and radiation. The Center's co-location with BCH and the Jimmy Fund Clinic will support coordinated care for both inpatient and outpatient pediatric oncology patients, as the Applicant's clinicians estimate that at least one in ten inpatient pediatric oncology patients are eligible for PBT. With this integrated continuum of care, patients will not require ambulance transfers from an off-site facility to Dana-Farber or BCH should complications arise, reducing the avoidable clinical risk inherent in such transfers, and eliminating delays associated with patient transport and handoffs which can exacerbate emergency conditions, and compromise airway safety, and particularly so for patients who are sedated, and for patients with central lines or cardiopulmonary vulnerabilities.

A letter of support from Dr. Eric Dickson, UMass Memorial Health's President and CEO states: *"Given Dana-Farber Cancer Institute's Jimmy Fund Clinic and proximity to Boston Children's Hospital, we believe this proton therapy service will prove particularly beneficial to pediatric cancer patients and their loved ones, making access to this lifesaving technology convenient and enabling close clinical coordination with pediatric patients' primary care teams and other sites of care."* The Applicant anticipates that UMass will continue referring pediatric patients needing PBT to DFCI and BCH, who the Applicant states already serve most pediatric patients needing PBT.

The Applicant's combined pediatric program with BCH will assume responsibility for the oncology care of patients referred for PBT and that will require subspecialty care. Dr. Ryan Nagy, BCH's President and System COO states, *"Our integrated model with Dana-Farber provides a comprehensive approach to pediatric oncology, combining the unique strengths of both institutions. This collaborative effort enhances the continuum of care from high-complexity surgeries to outpatient ancillary services."*

The Applicant states that the Center's close proximity to the Applicant's Yawkey Center for Cancer Care and the Applicant's FCH will ensure the same level of coordination for the Applicant's adult patients. The Applicant states care fragmentation will be minimized and patient outcomes will be optimized among DFCI's adult and pediatric patients as a result of DFCI's multidisciplinary care teams and nurse navigators that will facilitate provider communication and treatment planning for the Center's patients, and social workers and resource specialists that will support care coordination and address logistical and financial barriers to care.

The Applicant asserts that inclusion of PBT at Dana-Farber facilities "minimizes fragmented scheduling, reduces cumulative travel and care burden, improves adherence to complex regimens, and supports consistent oversight by the same oncology and supportive care teams coordinating chemotherapy, surgery, and radiation." The Applicant states that in many cases, the Center's pediatric and adult patients will already be visiting DFCI for other components of their outpatient care, including chemotherapy infusion. RT is commonly added to other treatments such as surgery

and chemotherapy, to enhance treatment efficacy, improve outcomes and reduce recurrence. PBT may be delivered concurrently with chemotherapy, and often mid-treatment for both pediatric and adult patients. The current PBT referral process requires patients to transfer care, including oncology care, ancillary care, and psychosocial care, mid-treatment because PBT is unavailable locally, and this can result in delays in resumption of chemotherapy and initiation of control radiotherapy. Additionally, when a patient is referred to another provider for their PBT, the patient and family need to navigate introductions to a new oncology team, a new hospital, and are subject to different care algorithms, treatment philosophies, and incongruent management of therapy, toxicity, and related supportive care.

The Applicant states that the Proposed Project will improve continuity of care, because it will support continued access to the Applicant's oncologists and oncology nurses. The Applicant's staff will continue existing formal processes for linking patients with cancer with referring physicians, which are often PCPs, and other specialists, for follow-up care. The Applicant notes that it maintains strong collaborations with referral centers through its bone marrow transplant and surgical programs.

Electronic Health Record (EHR): The Applicant states that it has a fully interoperable EMR system and that its care teams routinely communicate with outside providers. The Applicant's EHR system, EPIC, is used across all of its facilities to coordinate care. The Center's patients will be tracked and managed in DFCI's existing EMR system, to facilitate continuity and coordination of care for the Center's adult and pediatric patients. DFCI uses Epic for its EMR system for both its adult and pediatric practices to coordinate care, share clinical notes, and track patient progress, which enables integrated workflows, patient safety for pediatric and adult oncology patients, and supports multidisciplinary care and communication across specialties. The Applicant states that its service lines are fully integrated through EPIC, which connects medical oncology, surgical oncology, radiation oncology, pediatric, imaging, and supportive service. EPIC's shared note functionality allows DFCI's clinical staff to provide necessary information to patients' referring physicians. Depending on the type of cancer, some physicians also follow-up thorough email and phone to connect to referring providers and local care providers. The Applicant states that multidisciplinary disease-center clinics and tumor boards allow clinicians to jointly plan treatment, align sequencing, and coordinate follow-up. Additionally, nurse navigators manage communication across teams, monitor treatment milestones, facilitate specialty referrals, and ensure seamless and timely movement of patients between chemotherapy, surgery, and radiation services. The Applicant states that its pediatric oncology program has longstanding, collaborative relationships with all regional referral centers in Upstate New York, Maine, New Hampshire, Vermont, Rhode Island, Connecticut and Massachusetts.

Analysis

Staff finds that the Applicant has demonstrated how the Proposed Project will support coordination and continuity of care for the Applicant's Patient Panel. The Applicant has cited a number of existing processes and resources in place that support patients through their cancer care journey.

Additionally, the Applicant explained how the Proposed Project's location will support improved continuity of care for pediatric patients accessing the Center. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1c.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report.

Factor 1: e) Evidence of Sound Community Engagement Through the Patient Panel

The Department's Guideline for community engagement defines "community" as the Patient Panel, and requires that at minimum, the Applicant must "consult" with groups representative of the Applicant's Patient Panel. ^{zzzz} Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."^{aaaaa}

To reduce burden on the community, the Department advised the Applicant to leverage the community engagement plan related to the Applicant's FCH DoN. The Applicant met with its External/DoN Advisory Committee, which includes leaders from key organizations in the Applicant's priority neighborhoods⁶⁵, who voted to adopt the Proposed Project's plan into the FCH plan.

The Applicant states that it engaged in ongoing discussions with key community stakeholders that include Community Benefits/DoN External Advisory Committee, BCH, physicians, and key thought leaders. During these discussions, the Applicant solicited feedback on the development of the Proposed Project, sought feedback on the Public Health Value of the Proposed Project, and addressed concerns as appropriate. The Applicant states that it considered the feedback received during its community engagement activities in identifying its Patient Panel need for the Proposed Project and to ensure the Proposed Project will have a positive impact on the Public Health Value on the community.⁶⁶ The Longwood Medical Area in Boston was identified as the best location for the Center during the Applicant's community engagement activities because it provided an integrated, accessible location. The Applicant states that Committee members expressed enthusiasm and support for the Proposed Project, and Committee member questions focused on

⁶⁵ Allston Brighton Health Collaborative, Boston Public Health Commission, Charles River Community Health, Enhance Asian Community on Health, Madison Park Development Corporation, Roxbury Tenants of Harvard, and Sociedad Latina and the Applicant's Community Programs Board of Trustees Committee.

⁶⁶ The Applicant states that this DoN Application has been filed only four (4) months after final approval of the Applicant's FCH DoN (DFCI-230409915), and 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 Future Cancer Hospital (FCH) DoN also should be used for this Application.

patient eligibility, the financial impact on patients, and PBT capacity.

The Applicant's community engagement framework included regular process reviews, stakeholder input sessions, and early engagement with regulatory authorities. The Applicant is continuing its community engagement efforts in the next edition of its Community Newsletter, which includes an email feedback mechanism, and which will be distributed to residents in the Applicant's priority neighborhoods, local Main Street organizations, and City of Boston community liaisons.

Adult and Pediatric Patient and Family Advisory Councils (PFACs): The Applicant engaged its Adult and Pediatric PFACs as part of the community engagement process for the Proposed Project. The Applicant states that the PFACs are comprised of patients, family, and staff members, and that Adult and Pediatric PFACs share an ongoing mission to 1) help disseminate information and implement services that affect patients and their families, 2) support patients and their families becoming informed advocates for their own care, 3) offer a patient and family voice, 4) initiate ideas for policies, programs, projects, and services within the patient care environment, and 5) provide ongoing opportunities to hear the voices, experiences, and perspectives of patients and their families.

- **Adult PFAC:** September 9, 2024 DFCI's Chair, Radiation Oncology and DFCI's Chief Medical Office met with DFCI's Adult PFAC to inform them of the Proposed Project. The PFAC members offered their views on the need for the Proposed Project, including increased access to care, and enhanced patient experience and satisfaction. There were 15 attendees at the Adult PFAC meeting.
- **Pediatric PFAC:** September 23, 2024 DFCI's Vice-President and Pediatric Chief Medical Officer, in collaboration with PFAC Co-Chairs, presented the Proposed Project at DFCI's Pediatric PFAC meeting. The Applicant's representatives provided PFAC members with background information on the Proposed Project, and provided an opportunity for PFAC members to ask questions. The Applicant states that those in attendance engaged in a discussion about the impact of the Proposed Project, as it pertains to patient care and overall patient experience during the next two years. There were 19 attendees at the Pediatric PFAC meeting.

The Applicant submitted the presentation materials from the PFAC meetings.

Government Stakeholders: As part of its community engagement efforts, the Applicant also met with individuals representing the following government entities prior to the submission of this DoN application: 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, and the Centers for Medicare and Medicaid Services.

Analysis

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the required community engagement standard of Consult in the planning phase of the Proposed Project. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1e.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

Current Market and Competition: The Applicant states that the Proposed Project will promote competition in the Massachusetts market because there is currently only one PBT provider in Massachusetts, which limits patient access, patient choice and competition. The Applicant maintains that the increased competition that the Proposed Project would provide, will serve to drive down costs, improve access, and foster market-driven innovation. The Applicant states that the majority of patients in Dana-Farber's Patient Panel are insured through public payers. The Applicant states further that the availability of multiple PBT providers will serve to encourage commercial price competition, and that for commercially insured patients, payers will seek to leverage the competition among providers to negotiate more favorable rates for PBT which may exert downward pressure on prices. The Applicant expects this to be the case even with its Prospective Payment System (PPS) – Exempt designation whereby DFCI will be reimbursed on a cost-basis for purposes of Medicare fee-for-service reimbursement.⁶⁷

The Health Policy Commission has noted DFCI's higher commercial outpatient prices relative to other Massachusetts hospitals.^{bbbb} In response to staff inquiry about the Applicant's higher relative prices for some commercial payers compared to MGH and UMass, the Applicant asserts that DFCI's pricing reflects the resource intensive care provided to its patients, which is not comparable to general acute care hospitals. The Applicant states that as a specialty hospital, it treats the highest proportion of metastatic site disease patients compared to other US cancer hospitals, including Academic medical centers (AMCs), and NCI-designated comprehensive cancer centers, and that it provides cancer care to a Patient Panel that is more acute and more costly to care for than other providers. While the Applicant's relative prices only account for oncology care, for other general acute care providers like MGH and UMass, relative prices include other, less costly care. The Applicant maintains that CHIA's relative price metric is limited in its ability to estimate and compare reimbursement between specialty cancer hospitals and general acute care hospitals because CHIA focuses only on service mix, and does not adjust for differences in patient acuity or service intensity, and because relative price has inherent limitations due to variations in data and different reimbursement methodologies used by payers.

⁶⁷ There are 11 specialized cancer centers designated as PPS-exempt hospitals (PCHs), meaning they are exempted from Medicare's Acute Inpatient Prospective Payment System (IPPS) and receive specialized reimbursement based on their reasonable costs rather than fixed Diagnosis-Related Group (DRG) rates. These facilities also receive payment adjustments under the outpatient PPS.

Cost Effectiveness: The Applicant states that PBT can offer cost savings through reducing long-term medical expenses associated with side effects, radiation-induced cancers, and diminished quality of life. As noted in Factors 1a and 1b, PBT provides long-term health benefits for eligible pediatric patients, including a reduction in adverse effects of treatment, which can reduce need for long-term supportive care, and reduce spending.^{ccccc} The Applicant cited a study evaluating the cost effectiveness of PBT compared with photon therapy in treating pediatric medulloblastoma⁶⁸, which found that “Despite the increased upfront cost of proton therapy, we observed that protons were cost saving compared with photons over the lifespan of a population of patients because of decreased costs associated with radiation-induced medical problems.”^{dddd} The authors did note the limitations of translating the results of the study to other types of cancers: “Although proton therapy may dominate photon therapy in pediatric medulloblastoma, the prevalence of the disease is low and may not provide sufficient patient volume for the cost-effective use of many facilities.”^{eeee} A study detailing the collaboration between a large academic cancer center with a statewide self-funded employer on an insurance coverage pilot demonstrated that total medical costs for patients treated with PBT were much lower when compared with patients treated with traditional RT.^{ffff} One limitation of the study was the modest sample size (22 treated with PBT and 25 treated with photons).

Lower Treatment Costs: The Applicant states that the proposed PBT system is competitive because it will offer PBT at a lower cost than traditional proton beam centers. Advanced technology, and optimized workflows such as compact proton accelerators reduce treatment delivery costs by 15% to 20% compared to traditional proton systems. The Applicant anticipates a reduction in per-treatment costs which could lead to lower TME for patients and payers. To address concerns about high upfront costs, the Applicant will implement a sliding-scale payment model for uninsured patients and will leverage the resources of its existing, long-standing clinical affiliation with BCH, including access to pediatric anesthesia, transport, emergency services, floor communication, and child life specialists, to share infrastructure costs. The Applicant does not have an estimate of how projected treatment costs of PBT will compare to current costs for photon beam RT.

Lower Capital Investment: The upfront capital investment in PBT today is significantly lower than it was when the first PBT centers were constructed in the 1990’s. Capital investment has been cited as a major obstacle to the broader adoption of PBT, with capital investment needed for the equipment and the building contributing to a majority of the costs.^{gggg} The costs of setting up a proton therapy 20 years ago has been estimated at \$150 million, while today costs have been reduced to \$40 to \$50 million, with one reason being the shift from more expensive, multiroom systems, to newer single-room systems.^{hhhh} The Applicant states that it is undertaking a cost-conscious approach to the Proposed Project that will require the least upfront costs. The Center’s small footprint and innovative design require less capital investment than is typically required for traditional gantry style

⁶⁸ The article states that medulloblastoma is the most common malignant cancer of the central nervous system in children, and RT is considered the standard of care for any child aged >3 years

PBT, and without costly and time-consuming renovations to the existing space.

Analysis

Although the utilization of PBT in the Commonwealth has been limited, partly due to the cost of acquisition, the advancements in proton technology, allow this service to be brought to patients at a lower capital cost than was previously available. Staff concur that PBT's ability to reduce adverse side effects of radiation treatment, as compared to photon-based RT, can lead to reduced costs of treatment for complications, particularly for pediatric cancer survivors. However, there is limited data on cost effectiveness for PBT across all cancer types, and staff maintains there remains the potential for costs to increase. A 2016 review of PBT's cost-effectiveness has noted "it is highly unlikely that PBT will be the most economic option for all cancers or even for all patients with a given type of cancer. Rather, the major goal for ongoing and future research will be to identify the subpopulation(s) of each cancer type for whom PBT is most cost effective," finding PBT most cost-effective for several pediatric brain tumors and select high-risk head and neck cancers.ⁱⁱⁱⁱ

The Applicant has stated that with the addition of another provider of PBT in Massachusetts, the Proposed Project will offer expanded patient access and alternative choices to both patients and insurance payers which can foster competition that can lead to reductions in costs. A 2026 study examining hospital compliance with CMS' price transparency requirements regarding PBT, and charge variability, found that PPS-exempt centers had similar compliance rates to non-exempt hospitals, and found variation in charges among all hospitals.^{jjjj} The study also stated that due to the specialized nature of PBT, and limited regional access, transparency around pricing may not create direct competition, however, "At centers offering both modalities (PBT and photon based alternatives with potentially comparable clinical benefit), transparency may place downward pressure on proton therapy prices by revealing cross-modality differences, requiring hospitals to justify large price gaps and encouraging benchmarking against photon-based treatments. This visibility can also strengthen insurer leverage during negotiations and promote more consistent pricing practices."^{kkkk}

Staff finds that, with the "Other Conditions" described below, requiring the Applicant to establish baseline commercial reimbursement rates for the Center's PBT services that do not exceed the then-highest commercial reimbursement rates in the Commonwealth, and ensure that year-over-year percentage increases in the Center's weighted average commercial reimbursement rates for PBT services do not exceed 2.599%⁶⁹, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending and therefore, the requirements of Factor 1f have been met.

⁶⁹ This percentage reflects MassHealth's Inflation Factor for Operating Costs price changes between RY23 and RY24 in the most recent Rate Year where an Inflation Factor is established.

Summary, Factor 1

The Applicant has described the challenges and barriers that its patients experience in accessing PBT in Massachusetts, as well as how the Proposed Project will address those barriers for clinically appropriate patients within its Patient Panel, including for the Applicant's pediatric patients, for whom PBT is particularly effective. The Applicant has used a method for estimating eligibility for PBT within its Patient Panel that aligns with CMS' LCD criteria. As a result of information provided by the Applicant and additional analysis, staff finds that with the "Other Conditions" described below, regarding the Applicant's commercial reimbursement rates for the Center's PBT services, and demographic information, medical necessity criteria and ICD-10 codes for PBT patients, the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f).

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

For Factor 2 the Applicant must demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation beyond the Patient Panel.

Cost Containment

The Applicant states that the Proposed Project will increase access to PBT for Massachusetts residents for whom PBT is the most clinically appropriate course of treatment. PBT is associated with less exposure and damage to normal, healthy tissue than photon-based RT, which can reduce costs of medical care to manage treatment-related side effects. The Applicant states further that increased access to PBT will reduce the incidental costs associated with treatment and reduce reliance on less effective photon-based RT. The Applicant maintains that patients receiving PBT rather than comparatively less effective photon-based RT may see costs of care reduced as a result of PBT's association with fewer side effects, less damage to critical and developing tissues and organs, and a reduction in the possibility of secondary cancer diagnoses compared to photon-based RT. The Applicant cites a systemic review on the cost effectiveness of PBT for head and neck cancer treatment, which reported that PBT has the potential to be cost effective when patients are chosen appropriately, such as for younger patients in which PBT reduces adverse effects and the need for long-term supportive treatment.^{lllll} One of the studies examined in the review stated that managing appropriate access to PBT helped to control medical costs and that the direct costs of PBT are higher up front, but patients can benefit from fewer medical expenses over their lifetime.^{mmmmm} Staff note that due to limitations of the study surrounding the estimation and measurement of costs, some caution is warranted in the interpretation of the findings.ⁿⁿⁿⁿⁿ

The Applicant understands that the Proposed Project will not address its entire Patient Panel need for PBT, but states that the Center is the best option for increasing access from a cost and space perspective and is most consistent with the Commonwealth's cost containment goals.

Analysis: Cost Containment

Staff concur that increasing access to PBT for clinically appropriate patients can reduce the costs associated with RT-associated side effects, the costs assumed by patients and families traveling out of state to receive such care, and can reduce costs through improved outcomes that result from timely access to PBT treatment. Staff also note the lower capital investment required to implement the Proposed Project compared to traditional gantry style proton therapy. Staff find that additional data is needed to further quantify the cost savings that can be achieved through the use of PBT compared to traditional RT. Staff maintain that CMS' LCD for Group 1 supports appropriate use of PBT, that can help to reduce overuse, and associated costs. As the Applicant has noted above, currently there is only one PBT provider in Massachusetts. Staff maintain that increasing appropriate PBT capacity can promote competition on price for a necessary service, which can support a reduction in PBT medical costs. Staff finds that with the "Other Conditions" outlined below, regarding the Applicant's commercial reimbursement rates for the Center's PBT services, DoN Staff conclude that the Proposed Project will likely meet the cost containment component of Factor 2.

Improved Public Health Outcomes

As described above in Factor 1b: Public Health Value, the benefits of PBT when compared to traditional RT or photon-based RT include more precise, targeted dose of radiation to the tumor while reducing radiation doses to normal, healthy tissues, resulting in fewer side effects and complications and improved quality of life. PBT is especially beneficial for pediatric patients "due to the high radiosensitivity of developing tissues and the long life-expectancy of childhood cancer survivors." The Applicant also argues that the Proposed Project will, support increased access to PBT by reducing the time burden and costs associated with traveling elsewhere to receive PBT given the insufficient PBT capacity in Massachusetts. In addition, patient experience will be improved because receiving local access to PBT will allow patients to receive treatment closer to home, and to their support systems, with less time taken away from employment and school. The location of the Center will facilitate an easy to navigate location that will improve the patient experience for pediatric patients, who are cared for jointly by the Applicant and BCH.

Analysis: Public Health Outcomes

Staff find that the Applicant has demonstrated that the Proposed Project can improve health outcomes and quality of life for its Patient Panel by increasing timely access to PBT locally for clinically appropriate patients, thereby reducing the challenges and barriers to timely access to such care identified in Factor 1a. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the Public Health Outcomes component of Factor 2.

Delivery System Transformation

The Applicant affirmed its commitment to promoting equitable access to cancer care and to reducing barriers to accessing high-quality cancer care for medically underserved patients. The Applicant states that its community outreach mission, formally adopted by the Applicant's board in 1995 and revised in 2022, seeks to (1) expand access to the Applicant's programs in early detection, screening, and cancer prevention and education to reach at-risk, historically marginalized, and

diverse populations; and (2) partner with community health centers, community-based organizations, and government entities to assess, enhance, and improve the overall health and well-being of the members of the Applicant’s communities. The Applicant provided examples of its partnerships with social services and community-based organizations that link its Patient Panel to resources that help to address health disparities.⁷⁰

The Applicant states that it screens adult patients for the social determinants of health (SDoH) in both the ambulatory setting and the inpatient setting. Table 25 provides an overview of the Applicant’s SDoH screening.

Table 25: DFCI Adult SDoH Screening

	Ambulatory Setting	Inpatient Setting
Date started	April 2023	January 2024
Domains Screened	Food security, utilities, housing security, paying bills, medication cost, transportation needs, employment, family and childcare, and education	Digital access, utilities, food security, transportation needs, housing security, medication cost, education, and employment
Patients Screened (Dec 2024 to December 2025)	28,767	1,247
Patients reporting one or more SDoH needs	16%	13%
Most frequent SDoH need reported	Food insecurity: 5% Utility Costs: 5% Housing Security: 4%	Digital Access: 5% Utilities: 3% Food Insecurity: 3%

The Applicant states that patients reporting SDoH needs in the ambulatory setting are referred to the Applicant’s Adult Resource Office, where staff provide tailored support to patients, connecting them with internal and external community-based resources. In the inpatient setting, patients reporting SDoH needs prior to discharge are provided support by inpatient nursing teams, care coordination staff, and/or social work.

The Applicant is engaging in ongoing work to implement SDoH screening for its pediatric patients in both the ambulatory and the inpatient setting. The Applicant anticipates having a SDoH screening program in place for the ambulatory setting by Fall of 2026 to screen pediatric patients and families for SDoH in the Applicant’s Jimmy Fund Clinic. BCH has implemented a SDoH screening process for

⁷⁰ These partnerships include: Boston Breast Cancer Equity Coalition, Boston CHNA/CHIP Collaborative, the Boston Public Health Commission, CHNA partners, Dana-Farber/Harvard Cancer Center for Cancer Equity & Engagement (DF/HCC CCEE), Dana-Farber’s Center for Community-Based Research (CCBR), Massachusetts Coalition for HPV, ongoing partnerships with the Massachusetts Department of Public Health (Department), the Prostate Cancer Foundation (PCF) and VA Boston Healthcare System, the Prostate Health Education Network (PHEN), the Tobacco Free Mass Coalition, Union Capital Boston (UCB), and, the Rian Immigrant Center (Rian) and Health Law Advocates (HLA).

the inpatient setting, which the Applicant is working to ensure aligns with its ambulatory workflows. SDoH screening in both the ambulatory and inpatient setting will include the following domains: housing, utilities, transportation, food, education, and medication costs.

The Applicant states that both adult and pediatric patients of the proposed Center will be screened for SDoH using the Applicant's existing (adult) or planned (pediatric) processes. Patients will be provided with resources using existing referral pathways. The Applicant plans to evaluate gaps in SDoH for patients of the Center and will expand screening accordingly to ensure that the Center's patients are receiving the same level of support as patients in the Applicant's other ambulatory settings.

The Applicant offers its patients a comprehensive array of supportive resources and services that support care coordination that includes patient navigators, resource specialists, social workers, clinical nurse navigators, and others, who often work together to help address patient barriers to high-quality care including cultural, linguistic, and transportation barriers.

- *Patient navigation* provides a wide range of support to help people with cancer overcome barriers to obtain optimal and timely cancer services and effectively use available care resources to improve their cancer outcomes.^{ppppp,qqqqq} Patient navigators can work with patients with different types of cancer on one or more phases of the cancer continuum – the phases through which a person moves to prevent and control cancer- from prevention to treatment to survivorship.^{rrrrr} Patients facing barriers to accessing cancer care may delay or forgo receiving cancer screening and treatment which can lead to adverse outcomes, including one study reporting an association between a four-week treatment delay in radiotherapy and increased mortality.^{sssss,71} Patient navigators have been shown to be effective in helping patients to access and receive timely care and follow-up and treatment.^{ttttt,uuuuu}
- *Social workers* provide support on a number of issues, including behavioral health concerns, coping with advanced cancer, and identifying supportive local resources.
- *Resource specialists* assist patients in obtaining access to resources to address a special need such as transportation, food, and fuel.
- *Financial counselors* assist patients with understanding insurance coverage, costs and accessing MassHealth benefits, and the Applicant's Patient Financial Assistance Program.⁷²
- *Pharmacy Resource Specialists* assist with high co-payments for cancer-related medications.

The Applicant states that the programs are available to any patient that requires them, and patients may self-refer to the Applicant's resources. The Applicant states further that it has created a patient navigation database for tracking patient data to support a team approach to patient care and to connect patients with the resources they need.

⁷¹ The systematic review considered seven major cancer types (bladder, breast, colon, rectum, lung, cervix, and head and neck) and three treatment modalities (surgery, systemic treatment, and radiotherapy).

⁷² Notice to Dana-Farber Cancer Institute Patients: Availability of Financial Counseling, Payment Plans, and Financial Assistance: <https://dfci.widen.net/s/8hhndjfk2/financial-assistance-summary-2025.pdf>

Analysis: Delivery System Transformation

Central to the goal of delivery system transformation is the integration of social services and community-based expertise. A study on disparities in childhood cancer survival pointed to “routine screening and standardized measurement of social determinants of health and household material hardship” as one of a number of actions that can be taken to help address the gap in childhood cancer survival.^{vvvv} The Applicant has explained how adult patients are screened for SDoH needs, and referred to resources to address those needs, and the Applicant described its plans for implementing SDoH screening for its pediatric patients. The Applicant has a number of resources in place and community partnerships that help patients manage a variety of issues that can pose barriers to accessing the Applicant’s services. DoN Staff can conclude that the Proposed Project will likely meet the Delivery System Transformation component of Factor 2.

Summary, Factor 2

The Applicant has demonstrated that the Proposed Project can increase access to PBT services in Massachusetts where there is currently only one PBT provider, and, in doing so, increase competition among PBT providers which can influence how payers negotiate rates for PBT. The Applicant is proposing a lower-cost proton therapy system compared to traditional gantry style proton therapy which will reduce treatment delivery costs, and provide superior clinical effectiveness compared to traditional RT, improving the value offered by the proposed Center. The Applicant has demonstrated PBT’s effectiveness for pediatric patients, and for certain adult patients, confirming the benefits of increasing local access to PBT to address an unmet need within its Patient Panel. The Applicant has several processes and resources in place to support patients experiencing barriers to accessing its services, and which can support the Applicant’s goal of increasing access to PBT for clinically appropriate patients, particularly pediatric patients who are also patients at BCH. As a result of the information provided by the Applicant and additional analysis, Staff finds that with the “Other Conditions” outlined below, regarding the Applicant’s commercial reimbursement rates for the Center’s PBT services, the Applicant has demonstrated that the Proposed Project has met Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and this will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

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

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such finding must

be supported by an analysis conducted by an independent CPA. The Applicant submitted a report performed by BDO (CPA Report).

The scope of the CPA Report, performed by BDO, is limited to an analysis of the thirteen-year financial projections for the Applicant for the fiscal years ending September 30, 2025 through September 30, 2037 (Projection Period), prepared by the Management of Dana-Farber Cancer Institute (Management), and the supporting documentation to render an opinion as to the reasonableness of the assumptions used in the preparation and feasibility of the Projections. Reasonableness is defined within the context of this report as supportable and proper, given the underlying information. Feasibility is defined as, based on the assumptions used, the Proposed Project is not likely to result in a liquidation of the underlying assets or the need for reorganization.

The CPA reviewed documents produced by Management as well as third party industry data sources, and historical results to formulate its conclusions; these documents included:

1. Financial model for DFCI on consolidated basis, including the operation of Proton Therapy Service for the periods ending September 30, 2025 through September 30, 2037;
2. Financial model for DFCI proton on stand-alone basis for the periods ending September 30, 2025 through September 30, 2068;
3. Multi-Year financial plan presented to DFCI dated as of April 7, 2025;
4. DFCI revenue analysis by payor for the period ending September 30, 2023 through September 30, 2032;
5. Draft DON narrative report as of May 20, 2025;
6. Proton lease financing proposal dated as of March 5, 2025;
7. Factor 4 capacity staffing for Proposed Project;
8. Future Cancer Hospital Debt Bridge;
9. Term Sheet between Mevion Medical Systems and DFCI dated as of February 11, 2025 for Mevion Proton System;
10. Proton Budget Development Summary Construction Costs as of May 29, 2025;
11. Audited Financial Statements for Dana-Farber Cancer Institute, Inc. and its subsidiaries for Fiscal Years Ended September 30, 2023 and 2024;
12. Management discussion and analysis quarterly statement for the quarter ended December 31, 2024;
13. Philanthropy Projection as of February 27, 2025;
14. Definitive Healthcare data as of January 2024;
15. Data obtained from Integra Information, A Division of Microbilt Corporation as of February 5, 2025; and,
16. IBISWorld Industry Report, Hospitals in the US, dated March 2025.

To assess the reasonableness of the Projections, the CPA calculated key metrics which compared the operating results of the Projections to market information from Integra Reports, IBISWorld, and Definitive Healthcare, as well as the Applicant's historical performance. The key metrics fall into

three categories: profitability, liquidity, and solvency.⁷³

Revenue

The CPA analyzed the revenue forecast within the Projections. Revenue streams include patient service revenue, direct grants and contracts revenue, gift related research revenue, indirect grants and contracts, unrestricted gifts and other operating revenue.

- The cumulative patient service revenue comprises approximately 84.7% of the Applicant's cumulative total operating revenue from FY25 through FY37.
- Projected patient service revenue is projected to increase by 11.2% in FY25 as compared to FY24.
- Patient service revenue is projected to increase for each fiscal year from FY26 to FY37, with increases ranging from 7.9% to 17.7%.
- The Applicant's revenue growth strategy is to achieve steady increases over the coming years.

Management relied on historical operating results, specific market assumptions, and expected demographic trends within DFCI's service area for the projected revenue. The anticipated consolidated total operating revenue growth for DFCI for FY25 (11.3%) is below the three-year (2021-2024) compounded annual growth rate (CAGR)(14.9%), and is within the range of the annual growth rates (11.0%-18.7%) observed between FY22 and FY24. The anticipated revenue growth for DFCI for FY26 to FY37 (7.4%-15.7%) of the Projection Period is expected to be more moderate compared to the higher growth rates experienced during the historical period from 2022 to 2024.

The CPA concluded that the revenue growth projected by Management is based on reasonable assumptions and is feasible for the combined operations of DFCI.

Operating Expenses

The CPA analyzed each of the categorized operating expenses for reasonableness and feasibility related to the Projections. Operating expenses include direct patient care expenses, direct research/restricted gifts, institute supported research (including fringe), general, administrative and plant, depreciation and amortization, and interest expenses.

- Operating expenses are expected to increase within a range of 6.2% to 14.8% during the Projection Period, which the CPA states aligns with the expected revenue growth.
- Primary drivers of change in operating expenses during the initial years of the projections include growth in staffing, increased operational costs, investments in technology, and additional expenses related to patient care and general administration.

The growth in expenses in FY25 (10.1%) is below the 2021-2024 CAGR (14.7%) and within the range

⁷³ Profitability metrics are used to assist in the evaluation of management performance in how efficiently resources are utilized. Liquidity metrics, including common ratios such as "days of available cash and investments on hand", measure the quality and adequacy of assets to meet current obligations as they come due. Solvency metrics measure the company's ability to take on and service debt obligations.

of the annual expense growth rate between FY22 and FY24 (12.1%-17.5%). The CPA notes that the projected total operating expenses for DFCI, expressed as a percentage of total operating revenue, are expected to range from 96.5% to 99.0% between FY25 and FY37, which aligns with DFCI's historical operating expenses, which ranged from 96.5% to 98.0% of total operating revenue from FY21 to FY24.

The CPA concluded that the operating expenses within the Projections reflect reasonable estimation of future expenses of the Applicant.

Capital Expenditures and Proposed Project Financing

The CPA reviewed the project costs related to the Proposed Project and discussed the anticipated financing of the Proposed Project with Management. The cost of the proton equipment will be funded through a financing lease arrangement, and the remaining expenses for the Proposed Project will be funded through DFCI's operating cash flows. The CPA states that these costs are incorporated into the Applicant's consolidated financial projections.

The CPA states that the Proposed Project represents a small percentage of the total projected capital expenditures for a multi-year period. As of the FY24 balance sheet, the Applicant held \$81.1 million in cash, and the Applicant's financial model projects the average cash balance to be approximately \$202.6 million over the thirteen-year projection period, excluding the Applicant's various assets available to fund the Proposed Project.

Feasibility

The CPA concluded, *"Within the projected financial information, the Projections exhibit a cumulative operating EBIDA surplus of approximately 5.2 percent of cumulative projected operating revenue for the thirteen years from FY 2025 through FY 2037. Based upon our review of the relevant documents and analysis of the Projections, we determined the anticipated EBIDA surplus is a reasonable expectation and based upon feasible financial assumptions. Accordingly, we determined that the Projections are reasonable and feasible, and not likely to have a negative impact on the patient panel or result in a liquidation of major assets of DFCI."*

Analysis

Staff is satisfied with the CPA's analysis of the Applicant's decision to proceed with the Proposed Project. As a result, staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

Factor 5: Assessment of the Proposed Project's Relative Merit

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based

strategies and public health interventions.

The Applicant states that it has been exploring opportunities to provide PBT treatment for years, given the overwhelming need, and during this exploratory process PBT technology has evolved, along with the Applicant's planning, from a PBT center with cyclotron, requiring a significant capital expenditure and often multiple rooms, to a single-room PBT system with gantry-mounted proton accelerator. The Applicant maintains that the evolution of technology made the Proposed Project featuring upright PBT feasible. Upright PBT has a smaller facility footprint, and lower costs, allowing the Applicant to site the Center in a location that integrates PBT into DFCI's existing campus amidst the Applicant's Jimmy Fund Clinic and BCH, which supports continuity of care.

The Applicant's explanation of the alternatives considered to the Proposed Project consolidates several alternatives considered along two dimensions: location (Boston vs. outside Boston), and technology (upright, single-room unit vs. three-room supine PBT Center).

The Proposed Project: An upright single-gantry proton therapy system

Quality: The Applicant states that the Proposed Project will provide similar quality of cutting edge treatment and care as Alternative #1.

Efficiency: The Applicant states that the Proposed Project offers similar efficiency, patient treatment times, and throughput as Alternative #1.

Capital Expense: The estimated capital expense for the Proposed Project is \$50.5 million.

Operating Costs: The Applicant states that the operating costs of the Proposed Project are similar to the operating costs of Alternative #1.

Timeline to Completion: The Proposed Project's estimated time to completion/implementation is 20 months.

Projected Number of Patients: The Proposed Project will provide access to PBT services for approximately 216 patients per year. The Applicant states that the more limited capacity of the Center will be disproportionately impacted by more complex, longer treatment cases.

Alternative #1: Establish a three-treatment-room PBT center located outside of Boston.

Quality: The Applicant states that Alternative #1 would provide similar quality of cutting edge treatment and care as the Proposed Project.

Efficiency: The Applicant states that Alternative #1 has similar efficiency, patient treatment times, and throughput as the Proposed Project.

Capital Expense: The estimated capital expense of Alternative #1 is \$300 million.

Operating Costs: The Applicant states that the operating costs of Alternative #1 are similar to the Proposed Project.

Timeline to Completion: Alternative #1's estimated time to completion/implementation is 44 months.

Projected Number of Patients: The Applicant estimates that Alternative #1 would provide access to PBT service to approximately 750 patients per year, stating the multi-gantry capacity of the alternative option would allow the Applicant to load balance complex cases

and improve throughput.

The Applicant considered and ultimately rejected this alternative because of the difficulties identifying appropriately zoned space, permitting difficulties, inability to reach agreement to proceed, and higher capital costs.

Alternative #2: Establish a single-room upright PBT unit outside of Boston.

The Applicant considered and ultimately rejected this alternative because it would not provide the physical connectivity to BCH and existing DFCI buildings, that would be achieved through the Proposed Project. The Applicant states that a PBT center with physical connectivity to DFCI's buildings, provides a care model with significant advantages over the Proposed Project.

Alternative #3: Establish a three-treatment-room PBT center within Boston.

The Applicant considered and rejected this alternative because of insufficient space on DFCI's campus to accommodate such a center.

The Applicant states that while the Proposed Project will serve a fewer number of patients than establishing a three-treatment-room PBT center, it will be operational within two years, compared to the four years required for Alternative #1. The Proposed Project's projected number of patients treated per year aligns with the Applicant's calculation for the proposed therapy system's throughput capacity, which was explained further above in Factor 1(a): Patient Panel Need. The Applicant notes that the projected number of patients treated per year will not address its entire Patient Panel need for PBT services, but it is the quicker option for increasing local access to PBT services.

The Applicant expects efficiency to be the same across all alternatives, but that each of the alternatives would involve greater capital expense and time to completion. The Proposed Project offers a lower initial capital expense than a three-treatment room PBT center due to the Applicant's choice of a compact proton accelerator, which the Applicant states will reduce treatment costs by 15% to 20% compared to traditional proton systems. The clinical benefits of an upright PBT system include reduced need for daily sedation in pediatric patients, more comfort and less intimidation for pediatric patients, the ability to use distraction techniques which will improve the pediatric patient experience, and a reduction in treatment times. For patients that cannot be treated on the upright PBT system, the Applicant will use existing or new referral sources to outside PBT providers.

Additional Considerations: The Applicant states that it ultimately dismissed alternatives to establish PBT outside of Boston and chose the Proposed Project predominantly because of the proposed Center's proximity to the Applicant's main cancer hospital, the Jimmy Fund pediatric clinic, and BCH. The Applicant states that there are high numbers of its patients spread across Norfolk, Middlesex, and Plymouth counties and that the Center's proximity to the Applicant's existing facilities will enable uninterrupted multidisciplinary pediatric and adult oncology care, and access to BCH's specialized pediatric anesthesia services. The Applicant states that locating the proposed Center

within the existing academic and clinic hub minimizes care fragmentation, ensures rapid access to subspecialists, and supports access for medically complex patients who cannot safely travel to distant facilities. The Center's Boston location will also allow access to the Jimmy Fund Clinic, allowing for continuity of care for pediatric patients receiving concurrent chemotherapy and PBT. The Applicant considered the following additional criteria for selecting the site of the proposed Center: accessibility for patients and staff, proximity to public transportation, and other site-specific considerations. The Applicant asserts that its referral footprint spans across every region of the Commonwealth through its established network of community practices and partner hospitals, and maintains that transparent eligibility criteria, transportation support, payer-neutral acceptance policies, and proactive community engagement will support access to PBT beyond those living closest to the proposed Center.

The Applicant maintains that it has evaluated many options over the years for developing PBT centers in Boston or in the community, however, none of the options explored were viable, for a number of reasons that include inadequate space, permitting or zoning requirements, inability to reach an agreement to proceed, and prohibitive costs, and, as a result, these possibilities did not progress to the point where they can be detailed as alternatives to the Proposed Project.

Analysis

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to a potential alternative. As a result of information provided by the Applicant and additional analysis, staff finds the Applicant has reasonably met the standards of Factor 5.

Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline

The Applicant will pool the local CHI funding with an existing DoN project ([#DFCI-23040915-HE](#)) approved in March 2025. The Applicant will also contribute to the Statewide Community Health and Healthy Aging Fund.

Since the local CHI funding will be pooled with an existing CHI project, DPH agreed that the Applicant could utilize the CHI required documents submitted for DoN project #DFCI-23040915-HE to fulfill Factor 6 requirements. Due to timing of the current project, the Applicant shared initial findings from DFCI's Cancer-Focused 2025 CHNA/CHIP with DPH. DFCI plans to utilize these findings in the ongoing CHI planning and implementation activities.

DFCI will continue working with its DoN Advisory Committee to determine the most appropriate distribution of the CHI funding associated with the Proposed Project. The timeline, processes, and use of evaluation and administrative funds are appropriate and in line with CHI planning guidelines.

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

Public Comments on the Application

Any person, and any Ten Taxpayer group, may provide written or oral comment at any time during the first 30 days following the Filing Date of an Application, or during the first ten days after a public hearing.

Public Hearing

The Department held a virtual public hearing in connection with the Proposed Project on January 14, 2026. A total of seven people provided oral comments at the public hearing. Pursuant to the DoN regulation, the Department determines whether need exists for a Proposed Project, based upon whether the Applicant meets each of the relevant factors set out in those regulations. Oral comments provided at the public hearing for consideration in DoN's review and analysis would be ones that address the Applicant's ability to meet the requirements of each of the relevant factors. The transcript of the public hearing is available online on the DoN website. The names of those testifying at the hearing are listed in Appendix II, and a summary of comments is in Appendix IV.

Written Comment

The Department received a total of 19 written comments. Pursuant to the DoN regulation, the Department determines whether need exists for a Proposed Project, based upon whether the Applicant meets each of the relevant factors set out in those regulations. Comments for consideration in DoN's review and analysis would be ones that address the Applicant's ability to meet the requirements of each of the relevant factors. The names of those submitting written comments are listed below in Appendix II and a summary of the written comments is provided below in Appendix IV. The full text of written comments is available online on the DoN website.

Ten Taxpayer Groups (TTGs)

Pursuant to the DoN Regulation, any ten Taxpayers, organized as a group, may participate in the review of an Application for Determination of Need or request to amend a previously issued Notice of Determination of Need. Said group must register with the Department at any time during the first 30 days following the Filing Date of an Application, or during the first ten days after a public hearing held pursuant to 105 CMR 100.445.

Three Ten taxpayer groups (TTGs) registered in connection with the Proposed Project. Registration information for each TTG is available on the DoN website. The names of the TTGs and their participation in the review process can be found in Appendix V. Additional information including full text of comments is available on the DoN website.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the

recommended Conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project and recommends that the Department approve this Determination of Need, subject to all applicable Standard and Other Conditions.

Other Conditions

1. Factor 6: CHI Contribution

- a. Of the total required CHI contribution of \$2,525,031.65
 - i. \$612,320.17 will be directed to the CHI Statewide Initiative.
 - ii. \$1,836,960.53 will be dedicated to local approaches to the DoN Health Priorities.
 - iii. \$75,750.95 will be designated as the administrative fee.

- b. To comply with the Holder's obligation to contribute to the CHI Statewide Initiative, the Holder must submit a check for \$612,320.17 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative) **within 30 days** from the date of the Notice of Approval.
 - i. Payments should be made out to:
Health Resources in Action, Inc. (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116 Attn: MACHHAF c/o Bora Toro
DoN project: # DFCI-25090516-RS

 - ii. Please send a PDF image of the check or **confirmation of payment** to DONCHI@Mass.gov and dongrants@hria.org. If you should have any questions or concerns regarding the payment, please contact the CHI team at DONCHI@Mass.gov.

2. Factor 1(a): The Holder shall track and report the following:

- a. Total number of patients who meet the Medical Necessity Criteria for PBT service pursuant to the CMS Local Coverage Determination Letter L35075 and related Billing and Coding Articles or any successor CMS Coverage Guidance; and
- b. Treatments by ICD- 10 codes including staging and also, differentiating the patients needing re-irradiation where cumulative critical structure dose exceeds tolerance dose.

For 2a-2b, the Holder will provide data for all PBT patients, and will provide data for adult and pediatric patients separately.

3. Factor 1(b): To demonstrate that the Holder is advancing equitable access to PBT services, the Holder will report annually on the following:

- a. Age (Birth-21, 22-35, 36-55, 56-64, and 65+), Payer-mix, race, ethnicity,

- Massachusetts county or state of residence if outside of Massachusetts, and preferred language of the Holder's Patients Panel receiving PBT;
- b. Age (Birth-21, 22-35, 36-55, 56-64, and 65+), Payer-mix, race, ethnicity, Massachusetts county or state of residence if outside of Massachusetts, and preferred language of the Holder's entire Patient Panel;
 - c. Total percentage of PBT patients denied coverage by payer;
 - d. Number of the Center's patients referred for the Applicant's sliding-scale payment and financial assistance program; and
 - e. Identified barriers to accessing the Center as well as any evidence-based interventions the Holder implements to address those barriers.

For 3a-3d, the Holder will provide data for all patients and will provide data for adult and pediatric patients separately

If the Department determines the Holder's payer-mix for the PBT service is materially different from the overall DFCI payer-mix overall, the Holder shall provide the Department with an explanation of such differences to allow the Department to determine whether the differences are the result of determinations outside the control of the Holder. If the Department determines the payer-mix differences are not due to forces outside the Holder's control, the Holder shall develop a plan as agreed to with the Department to address such payer-mix disparities.

- 4. Factor 1(f) and Factor 2: Cost Containment:** To ensure that the Proposed Project competes on the basis of price, the Department will establish a baseline commercial rate of reimbursement for PBT services (the "Baseline") pursuant to a methodology selected in consultation with the Holder, with the intent to ensure that the Holder's commercial reimbursement rates for PBT services do not exceed the then-highest commercial reimbursement rates in the Commonwealth. The Holder shall ensure that its initial weighted average commercial rates of reimbursement rates for PBT services at the Center do not exceed the Baseline. For each subsequent year during the Reporting Period, the Holder shall ensure that its year-over-year percentage increase in weighted average commercial reimbursement for PBT services at the Center will not exceed 2.599%.⁷⁴

The DoN Program shall review the information received from DFCI in accordance with Condition 4 to determine whether one or more of the following "Referral Indicators" is present:

1. In the initial year PBT is provided, the Holder's weighted average commercial reimbursement rates for PBT services at the Center exceeded the Baseline; or

⁷⁴ This percentage reflects MassHealth's Inflation Factor for Operating Costs price changes between RY23 and RY24 in the most recent Rate Year where an Inflation Factor is established.

2. In any subsequent year, the Holder's year-over-year increase in weighted average commercial reimbursement rates exceeded 2.599%.

If the DoN Program finds one or more of the Referral Indicators, the matter shall be referred to the Public Health Council (PHC) for review. Upon referral to the PHC, the Holder shall have an opportunity to show cause why the PHC should not find the Holder out of compliance with this Condition.

Pursuant to 100.310(A)(13), if the PHC determines that the Holder has failed to sufficiently demonstrate compliance with this Condition, the Holder shall fund projects which address one or more of the Health Priorities set out in Department Guideline, as approved by the Department, which in total, shall equal up to 2.5% of the total Capital Expenditure of the approved project. Said projects shall address one or more of the Health Priorities set out in Department Guideline, and shall be in addition to those projects approved by the Department in fulfillment of 105 CMR 100.210(A)(6). The Holder may satisfy this funding requirement through an additional contribution to the CHI statewide Initiative.

APPENDIX I: Outcome Measures

Below is a list of measures to assess the impact of the Proposed Project. The Applicant will report this information to the Department's DoN Program staff as part of its annual report required by 105 CMR 100.310(A)(12) following implementation of the Proposed Project. For all measures, the Applicant will provide to the program a baseline upon implementation of each project component, along with updated projections, which the program will use for comparison with the annual data submitted. Reporting will include a description of numerators and denominators.

The Annual Reports must include, but are not limited to, the following:

- 1. Metric:** Access
Measure: Number of unique patients obtaining PBT at the Center each year.
- 2. Metric:** Access
Measure: As it relates to the Applicant's Patient Panel seeking PBT services, the number of days between simulation and first treatment; stratified by modality and disease type. The Applicant will report findings as aggregate quarterly statistics using the median number of days from simulation to first treatment.
- 3. Metric:** Hospitalizations
Measure: Number of hospitalizations required due to sequelae of PBT each year. The Holder will provide data for all PBT patients, and will provide data for adult and pediatric patients separately.
- 4. Metric:** Patient-reported quality-of-life measures (PROMS)
Measure: PROMS will be collected systematically and reviewed regularly to ensure alignment with national benchmarks and evolving evidence. The Applicant is currently using PRO-CTCAE and will plan to continue to do so upon the Center's opening.⁷⁵
- 5. Metric:** SDoH Screening for the Center's patients.
Measure: Reporting will include the number of SDoH screens completed in the last year, the domains screened for, the number of positive screens, and the top domains identified for SDoH needs. The Holder will provide data for all PBT patients, and will provide data for adult and pediatric patients separately.

⁷⁵ National Cancer Institute. Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®). <https://healthcaresdelivery.cancer.gov/pro-ctcae/>

Appendix II: Speakers at the Public Hearing

Name	Affiliation
William C. Hahn, MD, PhD	Chief Operating and Transformation Officer, Dana-Farber Cancer Institute
Peter F. Orio III, DO, MS, FABS, FASTRO	Chair of the Department of Radiation Oncology, Dana-Farber Cancer Institute; Clinicians of Dana-Farber Cancer Institute TTG Member
Allison O’Neill, MD	Clinical Director, Solid Tumor Program, Dana-Farber Cancer Institute; Director, Liver Tumor of Excellence, Dana-Farber Cancer Institute; Associate Professor and Senior Physician; VP, Clinical Performance Management, Dana-Farber Cancer Institute; Clinicians of Dana-Farber Cancer Institute TTG Member
Alexander Owen-Post	Dana-Farber Cancer Institute employee and patient, and Massachusetts resident
Susan N. Chi, MD	Clinical Director, Pediatric Neuro-Oncology; Dana-Farber Cancer Institute and Boston Children’s Hospital, Institute Physician, Dana-Farber Cancer Institute; Associate Professor of Pediatrics, Harvard Medical School; Clinicians of Dana-Farber Cancer Institute TTG Member
Andrew Place, MD	Vice President & Pediatric Chief Medical Officer, Dana-Farber/Boston Children’s Cancer and Blood Disorder Center; Clinicians of Dana-Farber Cancer Institute TTG Representative
Suzy Amor	Massachusetts resident; Patients and Family Advocates of Dana-Farber Cancer Institute TTG member

Appendix III: Written Commenters

Name	Affiliation
Ryan Nagy, MD	President and System COO, Boston Children’s Hospital
William N. Brownsberger	State Senator, Suffolk and Middlesex District
Lisa Diller, MD	Vice Chair, Department of Pediatric Oncology, Dana-Farber Cancer Institute; Clinicians of Dana-Farber Cancer Institute TTG Member
Judy Fine-Edelstein, MD, MS	Clinical Assistant Professor Neurology, Tufts University School of Medicine; Resident of Lexington, MA; Patient at Dana-Farber Cancer Institute; Patients and Family Advocates of Dana-Farber Cancer Institute TTG Member
Austin Sarat	Resident of Amherst, MA; Patient at Dana-Farber Cancer Institute, Patients and Family Advocates of Dana-Farber Cancer Institute TTG Member
Shelly Plumb	Resident of Brookline, MA; Patient at Dana-Farber Cancer Institute
Wayne C. Gietz, MA	Executive Vice President and Chief Operating Officer, Study Health
Andrew E. Place, MD, PhD	Vice President & Pediatric Chief Medical Officer, Dana-Farber/Boston Children’s Cancer and Blood Disorder Center; Clinicians of Dana-Farber Cancer Institute TTG Representative
Brian Crompton, MD	Pediatric Hematology/Oncology, Dana-Farber Cancer Institute; Clinicians of Dana-Farber Cancer Institute TTG Member
Peter F. Orio III, DO, MS, FABS, FASTRO	Chair of the Department of Radiation Oncology, Dana-Farber Cancer Institute; Clinicians of Dana-Farber Cancer Institute TTG Member
Kimberly Stegmaier, MD	Chair, Department of Pediatric Oncology, Dana-Farber Cancer Institute; Associate Chief, Division of Hematology/Oncology at Boston Children’s Hospital; David G. Nathan Professor of Pediatrics, Harvard Medical School; Clinicians of Dana-Farber Cancer Institute TTG Member
Allison O’Neill, MD	Clinical Director, Solid Tumor Program; Director, Liver Tumor of Excellence; Associate Professor and Senior Physician; VP, Clinical Performance Management; Dana-Farber Cancer Institute; Clinicians of Dana-Farber Cancer Institute TTG Member
Eric W. Dickson, MD, MHCM, FACEP	President and CEO, UMass Memorial Health
Alex Owen-Post	Employee of Dana-Farber Cancer Institute, Patient of Dana-Farber Cancer Institute
Susan N. Chi, MD	Clinical Director, Pediatric Neuro-Oncology; Dana-Farber Cancer Institute and Boston Children’s Hospital, Institute Physician, Dana-Farber Cancer Institute; Associate Professor of Pediatrics, Harvard Medical School; Clinicians of Dana-Farber Cancer Institute TTG

	Member
Chynah Tyler	State Representative, 7 th Suffolk
Paris Prinsen	Patient at Dana-Farber Cancer Institute; Patients and Family Advocates of Dana-Farber Cancer Institute TTG Member
Mariella G. Filbin, MD PhD	Pediatric Neuro-Oncologist, Dana-Farber Cancer Institute and Boston Children's Hospital; Clinicians of Dana-Farber Cancer Institute TTG Member

Appendix IV: Summary of Comments

Commenters include elected officials, patients of DFCI, employees of DFCI, and representatives from other healthcare providers in the region including the President and System COO of Boston Children’s Hospital, President and CEO of UMass Memorial Health, and Executive Vice President and Chief Operating Officer of Sturdy Health. All written comments submitted to the Department are available on the DoN website.

Factor 1: a) Patient Panel Need

Commenters mentioned an “unmet need” for PBT services in Massachusetts, due to the fact that there is currently only one provider of such services. Commenters state that there is only one operational PBT site in New England, and even if the non-operational machine was operational, the need for PBT outweighs the existing capacity. The Proposed Project will help to meet current demand and growing demand as cancer incidence and survivorship increase, and the number of patients eligible for PBT increases.

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

Exiting radiation from photon-based RT can have adverse side effects, especially for developing bodies. PBT offers highly precise, targeted radiation that minimizes damage to surrounding healthy tissue and reduces long-term side effects, which is especially important for pediatric patients and those with tumors near critical organs. Traveling to access PBT results in barriers and delays in accessing the service, financial burden, and time away from work and school, and can be emotionally and physically overwhelming. More patients will receive PBT closer to home with the increased access to PBT that will be achieved through the Proposed Project. The proposed PBT system will be the first in the region to deliver PBT in a seated or inclined position, which will benefit patients who may not tolerate traditional treatment setups.

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

Patients must leave their established oncology teams and travel to outside institutions, a disruption that complicates care coordination, increases risk, and places avoidable burdens on patients and families. The Center will be located adjacent to other clinical and treatment space at DFCI, allowing patients to move between appointments and maintain continuity of care with their care teams. Patients will be able to remain with established, multidisciplinary care teams improving continuity of care.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

DFCI’s choice of a compact cyclotron system, lowers costs and reduces the footprint of PBT, allowing for the Proposed Project to be implemented faster.

Appendix V: TTGs Overview

TTG Name	Requested Public Hearing	Requested ICA	Oral Comments Provided at Public Hearing	Written Comments Submitted
Patients and Family Advocates of Dana-Farber Cancer Institute			✓	✓
Clinicians of Dana-Farber Cancer Institute			✓	✓
Mass General Brigham TTG	✓	✓		

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