STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	UMass Memorial Health Care, Inc.
Applicant Address	One Biotech Park, #65 Plantation Street, Worcester, MA 01605
Filing Date	March 28, 2025
Type of DoN Application	Substantial Change in Service Substantial Capital Expenditure
Total Value	~~$122,294,056.00~~ $53,598,043
Project Number	# UMMH-25021208-HE
Ten Taxpayer Groups (TTG)	12
Community Health Initiative	$2,679,902.15
Staff Recommendation	Approval with Conditions
Public Health Council	December 10, 2025

Project Summary and Regulatory Review

UMass Memorial Health Care, Inc. (the "Applicant" or "UMMHC"), with a principal place of business at One Biotech Park, 365 Plantation Street, Worcester, MA 01605, seeks a Determination of Need ("DoN") from the Massachusetts Department of Public Health ("DPH") to: 1) Acquire one single-gantry proton beam therapy unit; 2) Establish Proton Therapy; and 3) Expand the UMass Memorial Medical Center Cancer Center at Marlborough ("UMMMC Cancer Center") to provide Proton Therapy Services which if approved will be located at Marlborough Hospital, 157 Union Street, Marlborough, MA 01752 ("Proposed Project"). The capital expenditure for the Proposed Project is ~~$122,294,056.00~~ $53,598,043; the Community Health Initiatives ("CHI") contribution is $2,679,902.15.

This DoN Application for Proton Beam Therapy constitutes DoN Required Equipment which falls within the definition of a Substantial Change in Service and Substantial Capital Expenditure and is 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 DoN Factor within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

This page only has been amended due to scrivener's errors.

Background and Application Overview

UMass Memorial Health Care, Inc.

The Applicant, UMass Memorial Health Care, Inc. ("UMMHC"), is a Massachusetts nonprofit corporation that owns and operates an integrated health care system comprised of a network of health care providers serving the residents of Central Massachusetts. The UMMHC system encompasses one academic medical center (UMass Memorial Medical Center or UMMMC), four acute care community hospitals, [1, 2] and UMass Memorial Medical Center Cancer Center at Marlborough (Cancer Center). Additionally, Hospital level of care services are provided through the UMass Memorial Hospital at Home Program. [3]

Table 1: UMMHC Acute Care Hospitals

Acute Hospital	Type (Per CHIA Category[i])	HPP* % 2022	HPP % 2023
UMass Memorial Medical Center	Academic Medical Center HPP	66.7%	68.2%
Marlborough Hospital [4]	Transitioning from Community to Satellite HPP	66.1%	68.5%
Harrington Memorial Hospital	Community HPP	68.8%	71.4%
HealthAlliance Clinton	Community HPP	72.8%	74.2%
Milford Regional Medical Center	Community Hospital	55.8%	57.5%

[i] Center for Health Information and Analysis. Massachusetts Hospital Profiles. https://www.chiamass.gov/assets/docs/r/hospital-profiles/2023/ummc.pdf
*High Public Payer Hospital

UMMHC's mission is to care for the diverse communities of Central Massachusetts, provide health care services to under resourced patient populations, and serve as the research, teaching and clinical partner to UMass Chan Medical School ("UMass Chan"), the only public medical school in the state.

[1] HealthAlliance Clinton Hospital is a 152-bed community-HPP hospital with campuses in Clinton and Leominster. Harrington Memorial Hospital is a 119-bed community-HPP hospital with two campuses. The Department approved the affiliation with Milford Regional Medical Center ("MRMC") # UMMHC-24021420, July 17,2024; it is a 148-bed community hospital located in Milford.
[2] On July 10, 2025, UMMHC's DoN Application (# UMMHC-25012116-TO) seeking transfer of ownership of Marlborough Hospital through a proposed merger between Marlborough Hospital and UMass Memorial Medical Center ("UMMMC"). Following the proposed merger, UMMHC will establish Marlborough Hospital as a licensed campus of UMMMC.
[3] Including the following non acute services: UMass Memorial Medical Group, Inc. which is an integrated multispecialty group medical practice in Worcester and throughout Central Massachusetts. UMass Memorial Managed Care Network is a group of primary and specialty care physicians who are either employed by their hospitals or medical groups or are in independent private practice. UMass Memorial Accountable Care Organization is an ACO that was developed to participate in the Medicare Shared Savings Program (MSSP). Community Healthlink is a community-based provider of mental health, substance abuse, rehabilitation, homeless and related services in Central Massachusetts.
[4] MH is transitioning to be a UMMMC satellite. The Department approved a Transfer of Ownership of MH to the UMMMC hospital license on July 9, 2025.

UMMHC's hospitals are consistently high public-payer ("HPP") hospitals (Table 1).[5] Further, staff notes that the most recently published 2023 data indicates the percentage of payments from public payers has increased across all hospitals within the UMMHC system.

UMass Memorial Medical Center ("UMMMC") is a licensed 825-bed tertiary academic medical center that operates at the University Campus located at 55 Lake Avenue North, Worcester, MA 01655 ("University Campus"), the Memorial Campus located at 119 Belmont Street, Worcester, MA 01605 ("Memorial Campus"), and the recently approved Marlborough Hospital Campus. The University Campus operates the only Level 1 Adult and Pediatric Trauma Center in Central Massachusetts, is a designated Primary Stroke Service hospital, and is one of nine organ transplant centers in Massachusetts. The University Campus is approximately 15 miles (24 minutes' drive) from the site of the Proposed Project; the Memorial Campus is approximately 18 miles (24 minutes' drive) from the site of the Proposed Project, the Cancer Center at the Marlborough Hospital Campus. Using a single, integrated electronic medical record (Epic) throughout the UMMHC delivery system, patients receive comprehensive cancer care as well as other primary and specialty care locally, across all of its sites of care.

UMMHC Cancer Care

The Applicant shared that UMMHC provides advanced oncology services treating every type of cancer, including adult bone marrow transplants, surgical oncology, medical oncology, radiation oncology, nursing, nutrition, psychiatry, health psychology, social work, palliative care, and pain management, as well as outstanding care in pediatric oncology. UMMHC is the first provider in New England to offer Robotic One Anesthetic Diagnosis and Treatment ("ROADAT"), which combines biopsy and tumor removal in one procedure for lung cancer, and it is the only facility in Central and Western Massachusetts to offer accredited CART-cell therapy for the treatment of malignancies.

The Applicant states that UMMHC is recognized for its efforts to improve oncology patient outcomes through the delivery of modern technological innovations, procedures, and therapies and UMMHC is accredited by five different professional societies for oncology related services: (1) the American College of Surgeons' Commission on Cancer; (2) the National Accreditation Program for Breast Centers; (3) the American College of Radiology for medical imaging and radiation oncology; (4) the National Pancreas Foundation as a Center of Excellence for treatment of pancreatic disease; and (5) the Foundation for the Accreditation of Cellular Therapy (FACT) for its well-established bone marrow transplant program.

The Applicant states that it has extensive experience leading and participating in national clinical trials and registries and has access to more than 150 clinical trials and academic medical expertise through its long-standing affiliations with UMass Chan and with the Dana-Farber Cancer Care Collaborative.[6] The Chair of the Radiation Oncology Department at UMMMC, Dr. T.J. Fitzgerald, oversees the

[5] With the exception of Milford Regional Medical Center. As described above, UMMHC became the parent organization of Milford Regional Medical Center in July 2024.

[6] *UMass Memorial Medical Center and the Dana-Farber Cancer Institute*, UMASS MEMORIAL HEALTH, https://www.ummhealth.org/umass-memorial-medical-center/services-treatments/cancer-care/cancer-resources-and-support/umass-memorial-medical-center-and-the-dana-farber-cancer-institute (last visited Feb. 24, 2025).

credentialing of all proton therapy centers participating in research through his responsibilities with the National Institutes of Health ("NIH"), and the Imaging and Radiation Oncology Core ("IROC"). If the Proposed Project is approved, UMMHC and Dr. Fitzgerald plan to launch investigator-initiated trials for UMMHC's patient panel that will focus on a comparison of outcomes observed for patients treated with Proton Beam Therapy ("PBT") and outcomes observed for patients treated with photon therapy as well as the downstream potential cost savings of PBT that result from treatment.

The Proposed Project

The Applicant seeks approval to 1) acquire a single-gantry proton therapy system, 2) establish PBT Service; and 3) expand the building that houses UMMMC's Cancer Center to include a Proton Therapy Service ("Proton Therapy Service") on the campus of Marlborough Hospital, 157 Union Street, Marlborough Massachusetts. The Proposed Project is intended to provide patients with contiguous, convenient access to an additional advanced cancer treatment modality within the continuum of cancer care services. The Applicant asserts the site is the best option in terms of care coordination, constructability, existing infrastructure, and cost effectiveness.

The Applicant proposes to operate one modern single-gantry proton unit, which is more efficient than earlier PBT units in terms of the size and cost. The newer units cost approximately $25 million as compared to $300 million for earlier proton units. Circular designs of the single-room proton units have replaced traditional linear footprints, enabling greater accessibility and cost-efficiency in the design.[a] Along with the PBT unit, the Service will be equipped with advanced imaging and treatment planning capabilities, including 4D CT simulation and adaptive radiotherapy, and the latest advancements in patient positioning, and immobilization to support optimal treatment accuracy and reproducibility.[7]

The Applicant asserts the Proposed Project will provide cancer patients who meet the clinical criteria for PBT with access to an advanced cancer treatment technology that will improve outcomes and quality of life and may also prove to be cost effective as discussed further in this report.

Radiation Therapy Systems- Photon and Proton Systems

Massachusetts reports over 44,000 new cancer cases annually, according to the American Cancer Society.[b] Additionally, approximately 50% of cancer patients in North America undergo radiation therapy, predominantly using photon-based (traditional radiation therapy) treatment modalities.[8, c, d] Photon therapy relies on high-energy photons generated by linear accelerators.[e] Technological advancements have generated process improvements in photon therapy including intensity modulation and image guidance.[f] These features along with compact systems, cost efficiency, and reproducibility, have made photon therapy an essential component of cancer care.[9]

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[7] The equipment is the MEVION S250i System with HYPERSCAN pencil beam scanning technology.

[8] most commonly, LINAC treatments

[9] Katja Langen & Minesh Mehta, *Proton Beam Therapy Basics,* 12 J of the Am. Coll. Of Radiology 1204, 1204-06 (2015), https://www.sciencedirect.com/science/article/abs/pii/S1546144015008066 ("Protons have less entrance and essentially no exit dose, reducing the integral dose, with resultant potential decrease in toxicities. This is particularly beneficial for

However, with traditional radiation therapy, it is estimated 30-40% of photon beams continue passing through body beyond the target tissue.[10] The residual radiation that is deposited in surrounding normal tissues beyond the treatment target is called the exit dose.[11, 12] Despite the current 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.[g, h, i] 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.[j, k] The resource use and costs of these RIAE have not been comprehensively documented and studied.[l] The Applicant asserts the complications of photon therapy, described herein, can negatively impact quality of life and health outcomes, and underscore the need for access to advanced modalities like PBT.

PBT delivers targeted precise doses to tumors with lower entrance and virtually no exit dose, therefore normal tissue exposure is minimized, which is supported by several studies cited by the Applicant that have shown fewer instances of treatment-related toxicity for patients have occurred.[m, n] Therefore, for some cancer disease categories, PBT provides an alternative to photon therapy.[o] As discussed throughout this report, 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. [p]

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.[q]

Availability of PBT

The Applicant asserts that patient access to PBT has been limited nationally partially due to its historically high capital and operating costs which made it prohibitively expensive for most healthcare systems. However, due to advancements in the technology, the costs have been significantly reduced, which are making PBT a more viable treatment option for healthcare systems like UMMHC, thereby

patients with long life expectancy, those who experience significant toxicities from photons (e.g., head and neck cancer), and those who have reduced tissue tolerance (e.g., retreatment patients).").

[10] https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/proton-therapy

[11] To see a visual depiction, view DoN Application **Exhibit H.**

[12] *See What is PBT,* NATIONAL ASSOCIATION FOR PBT, https://proton-therapy.org/wp-content/uploads/2023/08/Screenshot-2023-08-16-at-9.04.49-AM.png (depicting a visual representation of exit dose and its impact on surrounding tissues).

enabling them to better serve patients who meet the clinical criteria for this advanced therapy.[13] 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 Applicant reports that PBT became available in Massachusetts nearly 50 years ago at MIT. It was transitioned to clinical care at Massachusetts General Hospital ("MGH") approximately 30 years ago. Currently, there are two PBT units in New England; both are operated by MGH in Boston.[14] The next closest operating PBT Center is in New York City. Recently two other PBT services have been approved in New England but are not yet operational; one is in Johnston, Rhode Island, and one is in Danbury, Connecticut.
According to the Applicant, and some of the Ten Taxpayer Groups ("TTGs") and letters of support from other providers, because of the limited supply of appointments, and the extensive service area that MGH serves, access for UMMHC patients is limited as discussed further herein.

Patient Panel[15]

Table 2 shows three years of Patient Panel information for the Applicant which shows that UMMHC experienced growth from 2022-24 of 14.1%.

Table 2: UMMHC[16] and UMMMC's Patient Panels- FY-FY22-24

Year	FY 22	FY 23	FY24	FY 22 vs. 24
Unique Patients	Count	Count	Count	% Change
UMMHC	383,497	385,391	437,528	14.1%

[13] Yan, et al., *supra* note 12 ("less than 1% of patients undergoing radiotherapy worldwide currently receive PBT, although conservative estimates suggest that 15–50% of these patients could benefit from it. This number could be even higher for specific disease sites. The main reason for this discrepancy is the high capital cost and the size of the PBT equipment. The global democratization of proton radiotherapy aims to make this form of treatment accessible to more patients worldwide."); KIM ET AL., *supra* note 12 ("…These savings increase as the time horizon of the analysis is extended beyond 10 years (Table 24). This is because the single-vault system has a high up-front fixed cost but is less costly each year thereafter. Therefore, construction of a single-vault PBT facility becomes relatively more desirable when longer time horizons are assessed, eventually becoming a cost-saving approach over a sufficiently long time horizon.").
[14] One of its two proton beam units will be offline from 2025 until 2027, according to the Applicant.
[15] 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.
[16] Results for FY22-FY24 do not combine Milford patient panel with UMMHC patient panel, because Milford joined UMMHC on October 1, 2024, and there is a potential overlap of patients in both patient panels, The Milford patient panel is presented separately. *Results for FY22-FY23 do not combine Harrington patient panel with UMMHC patient panel, because Harrington joined UMMHC July 1, 2021 and there is a potential overlap of patients in both patient panels. The Harrington patient panel is presented separately. See DoN Narrative p 61 Exhibit A https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download To comply with CHIA reporting requirements, Harrington FY22-FY23 results for unknown gender patients were combined with female patients and results for Native Hawaiian or Other Pacific Islander patients were combined with Other/Unknown patients.

Year	FY 22	FY 23	FY24	FY 22 vs. 24
UMMMC	301,385	301,187	313,177	3.9%

Table 3: Demographic Profile of the Patient Panels of UMMHC and UMMMC Patients- FY22-24

	UMMHC	UMMHC	UMMHC	UMMMC	UMMMC	UMMMC
	FY22 %	FY23 %	FY24 %	FY22 %	FY23 %	FY24 %
Gender						
Female	55.9%	56.2%	56.0%	55.8%	56.2%	56.5%
Male	44.0%	43.8%	43.9%	44.1%	43.7%	43.5%
Gender: Unknown	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%
Age						
Age: 0-17	18.7%	18.0%	16.8%	19.5%	18.8%	18.6%
Age: 18-64	58.2%	57.8%	58.0%	57.4%	56.7%	56.5%
Age: 65+	23.0%	24.2%	25.2%	23.1%	24.5%	25.0%
Race-Ethnicity						
Race: American Indian/ Alaska Native	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Race: Asian	3.4%	3.3%	2.9%	3.7%	3.6%	3.3%
Race: Black or African American	6.6%	7.1%	6.9%	7.0%	7.3%	7.7%
Race: Declined	1.1%	1.1%	1.4%	1.2%	1.3%	1.5%
Race: Native Hawaiian/Other Pacific Islander	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%
Race: Other/Unknown	14.6%	15.3%	14.8%	14.8%	15.1%	15.4%
Race: White	74.0%	72.8%	73.5%	73.0%	72.3%	71.5%
Ethnicity: Decline to Answer	1.6%	1.7%	2.0%	1.8%	1.9%	2.1%
Ethnicity: Hispanic or Latino	16.5%	17.3%	17.2%	16.1%	16.9%	17.4%
Ethnicity: Not Hispanic or Latino	80.1%	79.4%	79.9%	80.3%	79.8%	79.9%
Ethnicity: Unknown	1.8%	1.6%	0.8%	1.8%	1.4%	0.5%
Patient Origin						
Origin: Central Mass	89.7%	90.7%	89.0%	88.9%	89.4%	89.4%
Origin: Eastern Mass	4.1%	3.6%	3.6%	4.2%	3.9%	3.9%
Origin: Western Mass	2.4%	2.4%	3.3%	2.9%	3.1%	3.1%
Origin: Out of State	3.8%	3.3%	4.1%	4.0%	3.6%	3.5%

Table 3 shows key demographic characteristics of the UMMHC patients from fiscal years ("FY") 2022-2024. UMMMC served over 313,000 unique patients in FY24, representing the majority of the overall UMMHC patient panel described above. As reported, the UMMMC patient panel is very similar to the overall UMMHC patient panel in terms of race, ethnicity, age, gender, and residence, payor mix, as well as the number and demographics of patients receiving LINAC treatment.

Gender: The UMMHC patient mix during FY21 through FY23 was approximately 56% female and 44% male.
Age: 18-64 comprised ~ 58% at UMMHC; patients aged 65 and older increased from 23% in FY22 to 25.2% in FY24 at UMMHC. Approximately 17% of UMass Memorial's patients are aged 0-17.
Race: The self-reported UMMHC racial mix is ~73% white, ~6.8% Black or African American, ~3.9% Asian, ~17.2% Hispanic, and ~0.3% American Indian or Alaska Native. These are self-reported figures and there is a significant percentage (14.2% in FY21, 15.5% in FY22 and 15.9% in FY23) of the population that either chose not to report or whose race is unknown.
Patient Origin UMMHC provides care to patients primarily from Massachusetts (97%), with ~90% residing in Central Massachusetts.

Table 4: Payor Mix for UMMHC and UMMMC

	UMMHC	UMMHC	UMMHC	UMMMC	UMMMC	UMMMC
Payer Mix	**FY22**	**FY23**	**FY24**	**FY22**	**FY23**	**FY24**
Commercial PPO/ Indemnity	3.5%	4.4%	4.3%	3.9%	5.1%	5.2%
Commercial HMO/ POS	25.0%	24.4%	23.8%	25.5%	24.7%	24.1%
Total Commercial	**28.5%**	**28.8%**	**28.1%**	**29.4%**	**29.8%**	**29.3%**
MassHealth	18.1%	15.0%	11.9%	19.5%	16.0%	12.7%
Managed Medicaid (ACO/MCO)	6.5%	9.0%	11.5%	5.5%	8.3%	11.3%
Total Medicaid	**24.6%**	**24.0%**	**23.4%**	**25.0%**	**24.3%**	**24.0%**
Managed Medicare (Medicare Advantage)	16.3%	17.8%	18.8%	15.1%	16.6%	17.4%
Medicare FFS	27.0%	25.9%	25.5%	27.0%	25.9%	25.2%
Total Medicare	**43.3%**	**43.7%**	**44.3%**	**42.1%**	**42.5%**	**42.6%**
Total Public Payers	**67.9%**	**67.7%**	**67.7%**	**67.1%**	**66.8%**	**66.6%**
All other (e.g. HSN, self-pay, TriCare)	3.6%	3.4%	4.1%	4.6%	4.0%	4.8%
Total	100.0%	100.0%	100.0%	100.0%	100.0 %	100.0 %

Payor Mix: Both UMMHC and UMMMC serve a large percentage of patients who participate in government insurance programs: collectively, public payers make up ~68% of UMMHC's payer mix and ~67% of UMMMC's payer mix.

The age cohorts for the patients who are currently receiving LINAC services who are potentially eligible for PBT, as discussed further under Factor 1(a), is below. The 65 and over and the 22-64 age cohorts are the largest and second largest categories with less than 1% being children.[17]

[17] When asked where the children with cancer are receiving their treatments, the Applicant stated that the majority go to the pediatric specialty servicer at DFCI.

Age	2022 % Total	2023 % Total	2024 % Total
0-21	0.3%	0.3%	0.3%
22-64	40.6%	39.7%	37.9%
65+	59.1%	60.0%	61.8%
Total	100.0%	100.0%	100.0%

Factor 1a: Patient Panel Need

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

1. High Incidence Rates of Cancer in Worcester County
2. Limited Access to Proton Beam Therapy due to travel burden: Frequency, Distance and Cost
3. Limited Access Limited Supply
4. Projections of Patients Who Would Benefit from Proton Beam Treatments

1. High Incidence Rates of Cancer in Worcester County

To support their assertion of need for PBT, the Applicant cited the National Cancer Institute ("NCI") State Cancer Profiles (2017-21), which indicate a higher incidence rate for cancer in Worcester County, than for the Commonwealth overall, 457.1 and 437.2 per 100,000 population, respectively.[18, 19] Worcester County, has the third highest incidence rate in Massachusetts after Plymouth (476.5 per 100,000) and Berkshire (458.4 per 100,000) counties.[20] (See Table 5) As explained further in this section, and in Factor 1(b) PBT is not the appropriate treatment for all types of cancer. Staff notes that the incidence data in Table 5 is not sufficiently specific, such as types of cancers, to determine that the PBT- responsive cancers are what are driving these incidence rates. These types of cancers are described more fully under section 4, and Factor 1(b) Evidence Base.

[18] *See NCI State Cancer Profiles: Incident Rates Tables*, NATIONAL CANCER INSTITUTE, https://statecancerprofiles.cancer.gov/incidencerates/index.php?stateFIPS=25&areatype=county&cancer=001&race=00&sex=0&age=001&type=incd&sortVariableName=rate&sortOrder=default&output=0#results (generating data table: "Incidence Rate Report for Massachusetts by County, All Cancer Sites (All Stages), 2017-2021, All Races (includes Hispanic), Both Sexes, All Ages, Sorted by Rate") (last visited Feb. 26, 2025).

[19] The NCI State Cancer Profiles utilizes data collected from public health surveillance systems through published reports or public use files.

[20] *See NCI State Cancer Profiles: Incident Rates Tables*; *NCI State Cancer Profiles: Interactives Maps – Massachusetts*, NATIONAL CANCER INSTITUTE, https://statecancerprofiles.cancer.gov/map/map.withimage.php?25&county&001&001&00&0&01&0&1&5&0#results (generating map: "Incidence Rates For Massachusetts by County, All Cancer Sites (All Stages), 2017-2021, All races (includes Hispanic), Both Sexes, All ages") (last visited Feb. 26, 2025).

Table 5: Overall Cancer Incidence Rates and Annual New Cancer Cases in Massachusetts[21]

	CA Incidence Rates	Average Annual
County	**Cases per 100,000**	**Count**
Plymouth Co Total	476.5	3,415
Berkshire Co Total	**458.4**	**949**
Worcester Co Total	**457.1**	**4,854**
Norfolk Co Total	454.3	4,198
Bristol Co Total	453.8	3,357
Barnstable Co Total	447.4	1,982
Hampden Co Total	**436.4**	**2,568**
Essex Co Total	433.6	4,509
Middlesex Co Total	414.0	8,022
Franklin Co Total	**410.7**	**452**
Hampshire Co Total	**406.8**	**823**
Suffolk Co Total	405.5	3,187
Dukes Co Total	403.3	137
MA Total	**437.2**	**38,533**

The Applicant anticipates a portion of their referrals would come from the four counties west of Worcester County (Franklin, Hampshire, Berkshire and Hamden, in blue) where the aggregated combined count of new cancer patients is 4,792 on average annually. One letter supporting the assertion that UMMMC will serve patients beyond the primary service area was received from the Chairman of the Baystate Health Cancer Center which highlights the longstanding collaborative relationship between the Baystate and UMMMC cancer programs and also calls attention to the "significant Patient backlog" at MGH that has served as a barrier and prevented new patients from being seen at MGH.[22] Further, the round trip from Springfield to MGH is ~4 to 5 hours whereas the roundtrip from Springfield to Marlborough is 2 to 3 hours, depending on the time of day.

2. Limited Access to Proton Beam Therapy Due to Travel Burden: Frequency, Distance and Cost

To emphasize the need for localized patient access to PBT, the Applicant emphasized that the frequency of treatment, the daily distances patients must travel, and the associated costs of travel poses a significant burden on patients. Since the average course of consecutive treatments is 24 treatments, the toll on patients and families is significant, and prohibitive at times, both practically and physically.

The Applicant provided mapping of distances and time traveled to Boston as compared to Marlborough by patients and their caregivers residing within the service area. The Applicant calculated

[21] Massachusetts Cancer Registry 2018-2022.
[22] See Public Comments #4 https://www.mass.gov/doc/public-comment-4-pdf-umass-memorial-health-care-inc-substantial/download

the average savings per patient of 1,406 miles, ~19 hours at 2PM and 36 hours at 9AM over the course of their treatment as Table 6 shows. [23]

Table 6: Travel Distance and Travel Time for Each Patient Over the Course of Treatment

	Driving Distance	Driving Distance	Travel Time 9 AM	Travel Time 9 AM	Travel Time 2 PM	Travel Time 2PM
Metric	**To Marlborough Campus**	**to Mass General Hospital**	**To Marlboroug h Campus**	**To Mass General Hospital**	**To Marlboroug h Campus**	**To Mass General Hospital**
Average One-Way Trip	29.3 miles	51.1 miles	35.1 mins	80.2 mins	34.2 mins	57.8 mins
Average Travel for Treatment (24 two-way trips)	1,406 miles	2,452 miles	28.1 hours	64.2 hours	27.4 hours	46.2 hours

In addition to the time traveled, the Applicant provided cost comparisons. Travel associated costs include parking. The Applicant found that validated parking at Mass General Hospital costs $13 per visit, adding up to approximately $300 over an average 24-session course of treatment. In contrast, parking at UMMHC Marlborough is free, therefore this daily expense would be eliminated if the Proposed Project is approved.[r] The Applicant did not compute gas expenses,[24] however, the Applicant did a comparison of hotel rates that shows that Boston rates are 39% higher than those in Marlborough, making extended stays associated with the course of PBT treatment cost prohibitive for many. [s] By establishing a closer PBT Service in Marlborough, UMMMC's patients will have the option to stay at home with minimal additional cost. For those traveling from outside of the primary service area, accommodations costs are significantly lower compared to Boston.

Additional letters of support from other medical centers and oncologists stress the need for access to PBT for their patients included those from Dana Farber Cancer Institute, and Cape Cod Hospital suggesting they will refer patients for PBT care. The CEO of Dana Farber Cancer Institute's letter of support for the Proposed Project stressed the need for additional PBT resources and added their patient origin analysis below.

> *"Dana-Farber analyzed our own patient base from central & western Massachusetts, the Albany NY area, Northern CT, Vermont, and New Hampshire, which are areas closer to Marlborough than traveling to Boston. In FY'24, Dana-Farber saw over 37,000 patients from those areas – most of who were ultimately treated in their community by a local provider via collaboration on treatment plans. We estimate that, of patients appropriate for radiation therapy, about 15% of those patients are eligible for proton therapy. We estimate that, due to lack of access, just a small fraction of those*

[23] See Figures 1 and 2 pp 155-16 Don Application https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download

[24]Staff calculates that at $3.00 per gallon the savings is approximately $3,138 per course of treatment.

patients are ultimately receiving proton therapy during their cancer journey." [25,26]

3. Limited Access Due to Limited Supply

Since patients must leave the UMMMC system to receive PBT, the Applicant states it does not have reliable data (i.e., claims data) about the number of its patients or Worcester county's cancer patients that ultimately receive PBT at another health care facility. As noted earlier, the only other provider in Massachusetts is MGH, which has two units with three gantries, however, the DoN program does not have data regarding the volume, throughput and capacity of those units. Data reported to the Particle Therapy Co-Operative Group ("PTOG"), suggests that the average annual number of patients receiving PBT in Boston was approximately 640 patients per year over a 3-year period from 2021 to 2023.[27] Further, because of the limited supply of proton beam units in New England, the total number of patients treated in Boston is likely not limited to patients residing in Massachusetts.[28]

Additionally, staff notes, the Center for Health Information and Analysis ("CHIA") recently analyzed the all payer claims data set ("APCD") 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. There is not a total count of treatments available nor with limited access is it an indication of total need. 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."*

4. Projections of Patients Who Would Benefit from Proton Beam Treatments

UMMHC utilized different approaches to estimate the number of patients that would benefit from PBT treatment. These approaches entailed adapting existing models using various parameters that have been in the public domain for many years and used for the purposes of technology planning for PBT.[29] As described more fully below, Model 1 applied the coverage criteria of the American Society for Radiation Oncology ("ASTRO") to UMMMC's existing LINAC cancer patients by cancer type. The Applicant also considered a second model (Model 2), the Horizon Scanning Report, based on an international model of expected PBT use rates by cancer type being applied to regional cancer incidence rates.

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[25] See Public Comments #4 https://www.mass.gov/doc/public-comment-4-pdf-umass-memorial-health-care-inc-substantial/download

[26] Further the letter states, *"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 (4) licensed rooms exist, all at Massachusetts General Hospital (MGH). Three (3) of these rooms rely on equipment over 20 years old, recently taken offline for extensive, years-long repairs."*

[27] Particle Theory Co-Operative Group, 2025. This is not publicly reported.

[28] Historical information on MGH's patient panel had stated that ~17% of MGB's patient panel is from out of state, underscoring that a significant portion of the Proton Beam capacity is likely serving patients from out of the Commonwealth. Overall, about 4.5% of the MGH Patient Panel is from Central MA. (HSA 2)

[29] They have been revised and updated as the utilization has evolved.

Staff found that Model 1 was the most useful starting point as it more appropriately aligns with the current state of PBT utilization and Center for Medicare and Medicaid Services ("CMS") coverage decisions within the United States. Following additional data analysis and questioning of the Applicant, additional refinements to the Model 1 projections were made to more appropriately identify likely patients requiring re-irradiation who would likely benefit from PBT and therefore meet group 1 criteria, as described herein.

Model 1: American Society for Radiation Oncology ("ASTRO")[t] PBT Model
The first model that UMMHC used to determine its projected patient need for medically appropriate PBT is based on UMMMC's existing cancer patients that receive LINAC (photon) treatment and ASTRO's PBT clinical coverage criteria, as well as CMS medical necessity policies.

The ASTRO PBT Model Policies establish medical appropriateness of PBT in two groups:

- **Group 1**: includes conditions where PBT is considered medically necessary; these disease sites that meet *Medical Necessity Criteria* are based on published clinical data and are considered suitable for insurance coverage of PBT.
- **Group 2**: includes conditions suitable for *Coverage with Evidence Development ("CED")* paradigm where disease sites or patient populations coverage decisions are guided by individualized clinical criteria,[30] and where prospective data collection can contribute to ongoing evaluation of the treatment value of PBT. Under CED, PBT is considered for coverage if the patient is enrolled in either an Institutional Review Board (IRB)-approved clinical trial, or multi-institutional registry that adheres to Medicare's CED requirements.[31]

The ASTRO Model Policy is closely aligned with Medicare Local Coverage Determination (LCD) L35075, whereby coverage is likely for Group 2 patients when clinical documentation observes at least one of the following indications:

- Photon therapy exceeds organs-at-risk (OAR) dose constraints
- The target is adjacent to critical structures (i.e., the cancer is next to a critical body organ or area)
- The patient requires re-irradiation (i.e., the patient has already received radiation therapy and requires additional radiation therapy)
- Dose-volume histogram ("DVH") comparison supports proton use over photon use

Following these criteria, UMMMC analyzed its internal decision support tool (EPSI) and a photon therapy patient's primary diagnosis code to determine which patients fall within either of the two ASTRO groups to arrive at the count of patients who would be suitable for PBT and determine whether

[30] The CED paradigm is a CMS policy that enables Medicare to provide patients with coverage to gain access for promising medical services and technologies - such as PBT - in defined clinical scenarios, and to collect data to support the evidence base for the innovative service or technology through clinical trials or registries.
[31] *Id.* at 4-5.

there was sufficient patient volume to support providing access to this technology for its Patient Panel.

Based on the ASTRO PBT Model Policies and UMMHC LINAC (photon) patient panel data for FY24,[32] UMMHC estimates that 136 UMMHC patients receiving LINAC services per year at UMMHC would meet the Group 1 *Medical Necessity Criteria* ("criteria") for PBT coverage based on diagnosis. Staff inquired as to whether the Applicant had a count of the number of its patients who meet the criteria and are referred to other PBT centers. The Applicant responded that their EHR system cannot retrospectively search for and count such information. As a result of this missing data, the count of patients in this category is likely higher.

In addition, for FY 24, UMMHC identified 1,533 of its patients receiving LINAC services that potentially could meet the Group 2 *Coverage with Evidence Development ("CED")* paradigm. Realizing that not all of the Group 2 patients would meet the more limited clinical documentation requirements, additional approaches were utilized in an attempt to estimate how many of those patients could be added to the total count.

With additional staff questions, the Applicant looked at the CED paradigm of the explicitly mentioned *cancers for coverage* by body site for likely proton beam therapy coverage, and applied the Dutch Horizon (described more fully below under Model 2) percentage estimates for those tumor sites including Prostate (10%), Breast (5%), Lung & Bronchus (15%), Pancreas (10%), Liver & Bile Duct (10%), Oral Cavity and Pharynx (Head &Neck, 25%), and Bladder (pelvic, 10%). The Applicant notes that this is not an exhaustive count of the total potentially eligible cancer types, and that it does not include re-irradiation.[33] Using this sub-set of Group 2, estimates of 187 patients in Worcester County could be eligible annually.[34]

Table 7 below shows the number of patients in the refined count of Group 2 Astro Model patients based on UMMMC's LINAC patients and a subset of likely eligible diagnostic codes.

Table 7

Model 1	**FY 24**
ASTRO UMMMC LINAC patients	Patients
Group 1	136
Group 2	1,533
Select Subset of Group 2 patients who meet the CED criteria and applying the Horizon percents	187
Total	323

[32] See Exhibit D pp 65-67 https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download

[33] Reirradiation, in the context of cancer treatment, refers to administering a new course of radiation therapy to a region of the body that has previously received radiation.

[34] See responses to DoN questions page 4-5, https://www.mass.gov/doc/responses-to-don-questions-pdf-umass-memorial-health-care-inc-substantial/download

Considering the uncertainty surrounding the clinical superiority of PBT treatments over Photon therapy for the subset of Group 2 patients that UMMMC analyzed, and the fact that patients requiring re-irradiation who meet Group 1 criteria were not counted in the initial Group 1 projections based on diagnosis, the Department requested the Applicant attempt to identify patients requiring retreatment where the re-irradiation criteria are met, specifically where "*cumulative critical structure dose exceeds tolerance dose*." Since there is no diagnostic or procedural code that identifies these patients, UMMHC was able engage a radiation oncologist to perform a sample chart review on 218 of the FY24 combined Group 1 and Group 2 patients (1,669).[35] The chart review found that of the 68 patients sampled in Group 1, 10 patients (or 14.7%) met re-irradiation criteria for proton therapy, and that of 150 patients sampled in Group 2, 14 patients (9.3%) met re-irradiation treatment criteria and therefore could be re-categorized as ASTRO Group 1 patients.[36]

Based on the findings of the chart review, the Applicant multiplied the 9.3% estimated re-irradiation rate to the previously identified UMMHC ASTRO Model Group 2 patients for FY22 and FY24; this calculation estimates that the Group 2 patients that could be re-categorized as Group 1 because they meet the "*cumulative critical structure dose exceeds tolerance dose*" criteria is between 130 and 143 patients. UMMHC then added the re-irradiation patient counts to the Group 1 patient count of 136 to 160 (FY24 and FY22, respectively). As a result, UMMHC estimates that the total number of patients who would qualify for Proton Therapy ranges between 279 to 290 patients, as presented in Table 8.

Table 8: Projected Patients for Whom PBT is Medically Indicated for Re-Irradiation

Lines		FY22 Patient Counts	FY24 Patient Counts
1	**Group 2 sample chart review results:**		
2	Re-irradiation Patient Count	14	14
3	Patient Sample Size	150	150
4	**Re-irradiation % (rate) (Line 2 /Line 3)**	**9.3%**	**9.3%**
5	Group 2 Patient Count[37]	1,394	1,533
6	**Est. Grp 2 Pt count that could be re-categorized to Grp 1 (Line 4 X Line 5)**	**130**	**143**
7	**Group 1 Patient Panel***	**160**	**136**
8	**Total Est. PBT Patients (Line 6 + Line 7)**	**290**	**279**

[35] identified in Exhibit D of the DoN application p. 66 https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download

[36] The combined Group 1 and 2 chart review suggests that the estimated percentage of UMMMC LINAC cancer patients that would meet re-irradiation criteria for proton therapy is 11% (24 out of 218) which falls within the range that other studies have identified as a normal re-irradiation rate. Peer reviewed estimates of LINAC patients who could benefit range from 13% to 50%,[36] with the majority of estimates being ~15%.

[37] Exhibit D of the DoN Application p. 66 https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download

Lines		FY22 Patient Counts	FY24 Patient Counts
9	Unit Capacity at 30 mins per treatment	291.7	291.7
10	**Percent Utilization**	**99.4%**	**75%**

*** Includes both re-irradiation and non-re-irradiation patients**

With these estimates of existing UMMHC cancer patients that could qualify for PBT when applying the ASTRO PBT Model Policies, UMMHC states that 90% of these projected PBT patients currently reside in Central Massachusetts. The Applicant asserts, this reinforces the need for more equitable access to PBT in Central Massachusetts as it would eliminate an estimated 22-36 hours of travel per patient. (See Table 6) As with the overall UMMHC patient panel, almost 70% of the estimated PBT patients are covered by a government insurance program and would benefit from more equitable provision of cancer care utilizing this advanced technology. As cited in Factor 1(b) Health Equity, review of the literature showed disparities in access to PBT.

Model 2: Dutch Model Horizon Scanning Report (and 2016 update) [38] is a regionally based, by county, approach to projecting PBT patients counts that estimates the percentage of patients by tumor site, patients "for whom PBT may be indicated with the aim to reduce the risk of side effects, using Normal Tissue Complication Probability ("NTCP") calculations." Specifically, the Applicant used the following process:

1) UMMHC used American Cancer Society ("ACS") cancer incidence rates by tumor type to estimate the total number of new cancer patients per year based on total Massachusetts population, and UMMHC total service area population.[39]
2) Next, using these estimates, UMMMC referred to the Dutch Model - Horizon Scanning Report[40] ("Horizon Report") to calculate the estimated total number of radiation therapy patients and from that, estimated PBT patients by tumor type. These counts were then summed up to arrive at an estimated total number of patients who would benefit from these treatments.

Based on the above, the Applicant found that 743 patients residing in UMMHC's service area or approximately 15% of new cancer patients receiving radiation therapy could benefit from PBT.[41] Statewide using the same model, 4,434 patients could benefit from receiving this treatment. Table 9 shows Model 2 results of the number of patients and treatments for UMMMC's service area (central Massachusetts) and for all of Massachusetts. The Department notes that the Dutch Horizon Model, depending on the tumor type, tends to apply percentages that are higher and are applied to a broader number of cancer types than are the current approved usages in the United States; therefore, Staff

[38] The Dutch PBT planning model is a widely referenced benchmark for estimating the clinical appropriateness of PBT. Originally developed by the Dutch Health Council and refined in the 2016 Update Report.
[39] derived from population estimates produced by the UMass Donahue Institute
[40] Knottnerus, Professor J. A. *Proton Radiotherapy Horizon Scanning Report*. 14 Dec. 2009, www.healthcouncil.nl/binaries/healthcouncil/documenten/advisory-reports/2009/12/11/proton-radiotherapy/advisory-report-proton-radiotherapy.pdf . Accessed 4 June 2025.
[41] Refer to page 5, and Exhibit F pp 70-74 of the DoN Application which provides the details used in the calculations.

believes that these projections overstate the current demand for PBT.

Table 9: Model 2 Estimates of the Number of PBT Patients

Model 2	FY 24
ACS and Horizon Scanning Report	Patients
UMMHC service area	743
Mass. Total	4,432

Analysis of Need

The projection models use a variety of criteria based on practices used in technology planning found in the cited literature. The projections ultimately resulted in a broad range in patients who could benefit from PBT in the service area of UMMMC, from a low of ~279 to a high of 743 reflecting the difficulty of planning for new technologies as well as the limitations of the data. As noted earlier, given the highest number is based on an international methodology where acceptance for treatment criteria is significantly broader, Staff does not believe that the higher number (743) reflects the need in Massachusetts at this time.

Staff finds that with the current CMS Criteria for Coverage, the more conservative range of 280 to 290 more aptly reflects the initial patient counts for the UMMMC PBT Service based solely on existing UMMHC's cancer patients. (However, staff acknowledges that the Applicant will likely provide PBT treatments to patients beyond its existing service area.) With an average of 24 treatments per patient the total number of treatments would be in the range of 6,720-6,960 treatments.

Staff asked the Applicant about operating hours and capacity of its proposed unit. The Applicant reports that it intends to operate 250 days per year, 14 hours per day, with each treatment lasting initially 30 minutes. Once efficiencies are gained the Applicant anticipates that time will be reduced to 25 minutes. These operating hours and days are based on standard patient care hours and to allow time for necessary unit maintenance and quality assurance. With these parameters staff calculated the capacity of a unit of 292 to 350 patients depending on the average time per treatment. (See Table 10.) Using the project volumes of 280 to 290 the unit could be operating at between a low of 80% and a high of 99% capacity.

Table 10: Calculations of a Proton Beam Unit's Capacity

Row	Year	Year 1	Year 2
1	Days in Operation per Year	250	250
2	Hours in operation per Day (e.g. 7AM-9PM)	14	14
3	Hours per year (row 1 X 2)	3,500	3,500
4	Mins per Year (row 3 X 60)	210,000	210,000
5	Mins per Treatment	30	25
	CAPACITY		
6	Treatments (row 4 / 5)	7,000	8,400
7	Capacity- MAX # of patients (row 6 / # Treatments/ patient 24)	292	350
8	Percent Utilization 2022 2024	 99.4% 75%	 85% 80.0%

Additionally, the Applicant noted the following considerations that have not been factored in:

1. Estimates of growth corresponding to increasing incidences of cancer at younger ages and the aging population.
2. The likelihood that the unit at UMMMC would serve patients beyond its primary service area which is supported by oncologists from other medical centers who stressed the limited access for patients north, south, and west of Boston.

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 service area. Staff finds that with the "Other Conditions" outlined below, the Proposed meets the requirements of Factor 1(a).

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

In this section the Applicant must demonstrate that the Proposed Project adds measurable 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- Evidence base

The Applicant provided an overview of the supporting clinical evidence where PBT, has shown clinical benefits across multiple sites and cancer types, as described below.[42] While not all inclusive, categories 1 through 5 are generally in ASTRO Group 1 (medical necessity), and the others are in ASTRO Group 2 (CED on a case by case basis)

Central Nervous System (CNS): For diseases that require cranial spinal therapy, protons decrease dose to critical normal tissues including constrictor muscles, larynx, heart, lung, small bowel, liver, and pelvis organs which will then limit necessary management of late effects and optimize care moving forward.[u]

Head and Neck: Since PBT offers superior dosimetric precision, it has been shown to significantly lower the risk of treatment-related toxicities for head and neck cancers,[v] 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. These are common complications associated with photon therapy.[w] Consequently, hospitalizations are reduced, as critical structures near the tumor are spared, thereby better functional outcomes and quality of life are experienced by the patient.[x] Accordingly, the Applicant asserts, while the upfront costs to UMMHC for PBT may be higher, its potential to reduce long-term healthcare expenses for patients associated with retreatment and RIAE makes it a compelling treatment option for head and neck cancer management.[y]

Esophageal cancer is increasing in prevalence.[43] Most esophageal cancers in North America are in the middle and distal third of the esophagus which abuts the left atrium/cardia conduction system and lower lobes of both the right and left lung. Investigators at the MD Anderson reported a phase 2B randomized trial of 148 patients comparing proton and photon therapy with primary endpoints being progression free survival and toxicity burden. The toxicity burden was 2.3 times higher in the photon group and the post operative complication rate was 7.6 times higher in the photon group indicating a significant decrease in toxicity with thoracic patients treated with protons due to decrease dose to normal tissue.

Hepatocellular Carcinoma (Liver Cancer): PBT demonstrates superiority over photon therapy and SBRT for treating hepatocellular carcinoma by improving survival outcomes, reducing toxicity, and better preserving liver function. Studies show that patients treated with PBT experience higher overall survival and progression-free survival rates compared to photon-based radiation therapies and SBRT, even in complex cases.[z] PBT allows for higher radiation doses to the tumor while minimizing radiation-

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[42] See Exhibit H of the DoN Application, pp 78- https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download. For a more comprehensive, tumor-specific bibliography of the clinical applications of Proton Beam Therapy, refer to the extensive review conducted by the National Association of PBT. *See Clinical Research*, THE NAT'L ASS'N FOR PBT, https://proton-therapy.org/clinical-research/ (last visited Feb 26, 2025).

[43] "Esophageal cancer is a familiar malignancy with high incidence and mortality, and the overall prognosis is poor. The numbers of cases of and deaths from esophageal cancer have risen rapidly in recent decades. It is one of the most malignant cancers, with more than 0.6 million new cases and 0.54 million deaths worldwide in 2020." Tella SH, Mara K, Chakrabarti S, Jin Z, Mahipal A. A glimpse into the future of esophageal carcinoma in the United States: predicting the future incidence until 2040 based on the current epidemiological data. J Gastrointest Oncol. 2023 Feb 28;14(1):1-10. doi: 10.21037/jgo-22-729. Epub 2023 Feb 23. PMID: 36915445; PMCID: PMC10007944.doi:

induced liver disease and protecting healthy liver tissue, which is crucial for patients with compromised hepatic function.[aa] Additionally, PBT offers better local control, fewer post-treatment hospitalizations, and reduced overall costs compared to trans-arterial chemoembolization, highlighting its clinical and economic advantages.[bb]

Thoracic: PBT limits cardiac and pulmonary exposure, reducing risks of heart and lung damage.[cc] One prospective longitudinal study of 82 patients with unresectable primary or recurrent non-small cell lung cancer were treated with three dimensional RT, IMRT, and protons. Symptom burden was assessed weekly for 12 weeks validated by the MD Anderson symptom inventory. Patients treated with PBT had a statistically significant decrease in symptoms than those patients treated with photon therapy. [dd]Mediastinal lymphoma is a cohort of patients who could benefit from decreased dose to cardiac and pulmonary structures.[ee] An additional advantage to cardiac sparing by PBT is lymphocyte sparing. If the cardiac ventricles are exposed to radiation, the circulating lymphocytes become vulnerable to radiation dose as they die an intermitotic death. Sparing the cardiac ventricles will indirectly limit the damage to lymphocytes.

Breast Cancer: Studies have shown the precision of PBT offers some advantages for treating breast cancer, primarily by reducing radiation doses to the heart and lungs, which minimizes the risk of long-term cardiac toxicity and pulmonary complications thereby contributing to better quality of life during and after treatment.[ff, gg] For left-sided breast cancer, where minimizing cardiac exposure is essential to reduce the risk of ischemic heart disease, limiting exposure to surrounding structures is important as PBT demonstrates superior dosimetric outcomes, reducing radiation doses to the heart and left anterior descending artery, which are associated with improved long-term cardiac health; [hh] some patients undergoing photon treatments are unable to hold their breath to minimize movement and exposure to surrounding tissues and therefore PBT is particularly beneficial.

Abdomen, Pelvis, and Extremities: Enhanced protection of the bowel and kidneys reduces organ toxicity. Bone and soft tissue sarcoma patients benefit from improved functional outcomes due to limited exposure to joint structures.[ii]

Pediatrics: 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 therapy, reducing the risk of long-term damage and secondary malignancies.[jj] 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.[kk] A study also highlighted the low incidence of side effects, with no severe reactions reported and only mild, temporary issues like fatigue (59%) and reduced appetite (36%) observed, [ll] and no cases of local or marginal cancer recurrence were recorded. Relative to photon therapy, for patients undergoing treatment for pediatric medulloblastoma, PBT has been shown to preserve cognitive function, including full-scale IQ, processing speed, and working memory, due to its superior dose-sparing capabilities for healthy brain tissue; this leads to more stable intellectual outcomes over time.[mm] These findings underscore PBT's importance as a safer and more effective radiation treatment for many pediatric patients.

Public Health Value- Health Outcomes, and Quality of Life

The Applicant states that for those patients who meet the clinical criteria for PBT, the Proposed Project will have a direct impact on public health outcomes and quality of life in several ways, including:

1. **Reduced Side Effects:** 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.[nn] The Applicant cited one study involving 1,483 patients with multiple cancer types, proton chemoradiotherapy was associated with statistically significant improved outcomes, including a 69% lower relative risk of 90-day adverse events of at least grade 3 (severe but not life threatening), a 23% reduction in 90-day adverse events of at least grade 2 (moderate symptoms that interfere with daily activities), and a 49% improvement in decline in performance status during treatment.[oo]

2. **Improved Quality of Life:** 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.[pp] UMMHC anticipates that PBT patients will experience fewer side effects and faster recovery, allowing patients to remain in the workforce and community, resulting in less financial and emotional strain on families which may enable them to remain active in the workforce and community. These benefits mean improved quality of life for patients during and after treatment.

3. **Potentially Improved Survival Rates:** For certain types of cancer, PBT has shown promising results in improving survival rates compared to conventional radiation therapy. This is particularly important for pediatric cancers and tumors located near critical organs, where minimizing radiation exposure is crucial for long-term health.[qq]

4. **Equitable Access and Timely Care:** In Factor 1(a) the Applicant described the travel time that would be saved to emphasize one aspect of the need for regional equitable access and further stated that this is particularly critical for patients whose cancers require multiple immediate and precise interventions, such as head and neck, lung, and pediatric cancers. Other aspects are discussed in *Public Health Value/Equity Focused.*

5. **Lower Costs from Fewer Complications:** PBT can lead to lower rates of complications, hospitalizations, and secondary cancers, resulting in both improved patient outcomes and potential downstream cost savings and the avoidance of certain costs for patients, their families, as well as the healthcare system[rr, ss] as described further is Factor 1(f) and Factor 2.

Public Health Value/Health Equity-Focused

The Applicant asserts the Proposed Project will address the need for more equitable access to PBT treatment in the central and western Massachusetts regions. To address the SDOH needs of patients at the PBT Service, the Applicant described its existing programs which will apply to the PBT patients as

needed. Further, UMMHC will implement the following programs and initiatives as part of a comprehensive, patient-centered treatment plan.

Transportation Solutions: With a recent grant from the American Cancer Society, the PBT Service will provide free or subsidized transportation for patients facing transportation needs. This should reduce missed appointments and improve adherence to treatment schedules thereby enhancing patient outcomes. The Applicant notes that in addition to time, distance, and cost-related barriers, convenient access to specialty care is a critical factor in a patient's experience and medical decision making.[44]

Financial Assistance Programs: UMMHC's existing financial assistance initiatives[45] will extend to cover costs associated with treatment, travel, and accommodations for qualifying low-income patients traveling from rural areas. This support is anticipated to alleviate financial burdens and enable more patients to access advanced care.

Nutritional and Psychological Support: These services are integrated into the wrap-around care provided by the interdisciplinary team of providers and support staff working in UMMHC's radiation oncology program and will include patients at the PBT Service. Nutritionists will provide patients with education to help the patient get through sometimes difficult treatments, including monitoring weight loss and recommending nutritional supplements. Psychological services leverage social workers and behavioral health staff to help patients and their families cope with the emotional and mental health challenges associated with cancer care.

Cancer Survivorship Program: All UMMHC cancer patients, including all PBT Service patients, are eligible to participate in the cancer survivorship program,[46] which helps patients create a comprehensive plan to address lingering health concerns and provides connections to a broad range of community resources and programs.

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[44] *2023 Patient Consumer Survey*, JLL (2023), https://www.us.jll.com/en/trends-and-insights/research/2023-patient-consumer-survey?utm_source=public-relations&utm_medium=ol&utm_campaign=am-us-industries-patient-consumer-survey&utm_content=byline (last visited Feb. 26. 2025); *see also,* FSG AND BRISTOL-MYERS SQUIBB FOUNDATION, *Breaking the Barriers to Specialty Care, Brief 2: Increasing Specialty Care Availability* (2016), https://www.fsg.org/wp-content/uploads/2021/08/Equity-in-Specialty-Series-Brief-2_FSG-Increasing-Specialty-Care-Availability.pdf ("The supply of specialty care is not only inadequate, but it is also highly concentrated in urban areas. Estimates suggest, for example, that 97% of medical oncologists in the United States practice in urban areas. For the 20% of the U.S. population that lives in rural areas, this creates a significant challenge. Rural patients often need to travel hundreds of miles for care, a task that is particularly difficult when repeat visits are necessary to complete a course of treatment (e.g., for chemotherapy, radiation, or dialysis). According to the Community Transportation Association (CTA), approximately 3.6 million Americans miss or delay medical care for transportation reasons every year. This is borne out in health outcomes data: research shows that rural cancer patients, regardless of income or insurance coverage, experience higher mortality rates than their urban peers with access as one contributing factor.").

[45] *Financial Assistance Program Policy Summary*, UMASS MEMORIAL HEALTH, https://www.ummhealth.org/sites/default/files/MH-FAP%20plain%20language%20summary%20051916.pdf (last visited Feb. 26, 2025).

[46] *Cancer Survivorship Program*, UMASS MEMORIAL HEALTH, https://www.ummhealth.org/services-treatments/cancer-center/cancer-survivorship-program#:~:text=Cancer%20Survivorship%20Services%20in%20Central%20Massachusetts&text=UMass%20Memorial%20Health%27s%20Cancer%20Survivorship,with%20a%20cancer%20survivorship%20specialist (last visited Feb. 26, 2025).

Improving Health Equity Through Regional Access

The Applicant states that by reducing patients' financial and travel burdens via the proposed UMMHC PBT Service, it anticipates treatment adherence and patient outcomes will improve. For many cancer patients, often daily PBT treatment in Boston or out of state is infeasible due to aforementioned socio-economic barriers and also due to extended disruptions to daily routines for themselves and caregivers, effectively leading to a disparity in cancer care between those in the Boston area and those in the UMMHC patient panel and surrounding communities.

For the estimated 136 UMMHC patients in the ASTRO PBT Group 1 alone, there would be significant travel time reductions achieved by traveling to Marlborough instead of Boston; each one-way trip to Marlborough can save a patient ~20 miles and 25 to 45 minutes of driving time which amounts to ~19 to 36 hours over the full course of treatment. (See Patient Panel Need).

Equitable access to PBT will be improved through local available transportation options. Public transportation in the Marlborough region is expanding and may provide patients in the region with affordable, daily transportation to access their PBT. The MetroWest Regional Transit Authority ("MWRTA") now offers Route 7C, which stops at the Marlborough Campus seven days a week, beginning as early as 6:15 AM on weekdays. Additionally, the Worcester Transit Authority ("WRTA") has partnered with MWRTA to provide direct routes from Worcester to Berlin, with a transfer to Marlborough. Other transportation options include senior transportation services from the Marlborough Senior Center and Hudson Council on Aging, ensuring that older adults have reliable access to care.

For those traveling from other regions, PBT Service in Marlborough, it is conveniently located at the intersection of three major highways (I-90, I-495, and I-290) and can serve as a regional hub for patients in Central and Western Massachusetts, and potentially from neighboring states.

Improving Health Equity for Under Resourced Patients

The Massachusetts Health Policy Commission recently cautioned that "[a]s capacity becomes more concentrated in Boston, oncology patients might have [to] travel an increased distance to receive services, which has been shown to be associated with 'more advanced disease at diagnosis, inappropriate treatment, a worse prognosis, and a worse quality of life'" and that "increased travel burden might impose financial hardships on patients who are likely already struggling with the expense of care."[47]

[47] Massachusetts Health Policy Commission, Preliminary Report: Cost And Market Impact Review Of Dana-Farber Cancer Institute, Beth Israel Deaconess Medical Center, And Harvard Medical Faculty Physicians (HPC-CMIR-2024-1) (2025), https://masshpc.gov/sites/default/files/20250227_Preliminary_BILH-DCFI_CMIR.pdf (citing Massimo Ambroggi et al., *Distance as a Barrier to Cancer Diagnosis and Treatment: Review of the Literature*, 20 The Oncologist 1378, 1378-1385 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4679078/pdf/theoncologist_15110.pdf; *Annual Report to the Nation Part 2: Patient Economic Burden of Cancer Care More Than $21 Billion in the United States in 2019*, NATIONAL INSTITUTE OF HEALTH, (Oct. 26, 2021), https://www.nih.gov/news-events/news-releases/annual-report-nation-part-2-patient-economic-burdencancer-care-more-21-billion-united-states-2019.).

Further the Applicant cited a literature review of equitable access to PBT that found the following: "all studies evaluated in this review showed disparities in access to PBT… Throughout the reviewed literature, several factors were analyzed by the authors as possible indicators of inequitable access to PBT... the most common factors proved to be indicators of disparity in the access to PBT were socioeconomic status (16 of 24 articles), geographical location (13 of 24), age (11 of 24), race (11 of 24), insurance status (12of 24) and gender (1of 24)." [48] This shows a higher proportion of commercially insured patients are generally served by PBT Centers, leaving those insured through government insurance programs with limited access.

The Applicant states UMMMC PBT Service will directly address these challenges by providing local, potentially cost-effective access to PBT for the UMMHC patient panel (including its Medicare and Medicaid patients) and the surrounding communities. As noted in the Background section, the UMMHC patient panel is made up of a high percentage of Medicare and Medicaid patients (~70%) who may struggle with out-of-pocket costs of lodging, transportation, and extended treatment regimens if frequent and extended travel is required. Cost and affordability are among the top concerns for many Medicare beneficiaries who often have fixed incomes but may be experiencing growing health care needs as they age.[49] Further, the Applicant states Massachusetts' senior residents may not have caretakers, a means of travel, or the physical health for lengthy travel on a daily basis; and Medicaid members may have limited access to reliable transportation, sick leave, paid time off, and affordable childcare.

As noted earlier, the Applicant provided a cost comparison of lodging and parking showing that hotel rates in Boston are 39% higher, and parking is $13 in Boston whereas parking in Marlborough is free; if necessary, patients can secure accommodations at significantly lower costs compared to Boston.

Promoting Health Equity Through UMMHC's Health Equity Initiatives

Patients using the PBT Service will also benefit from UMMHC's longstanding systems and programs that advance health equity.[50] In 2018, the UMMHC Board approved the system's 'Anchor Mission', a commitment to leverage UMMHC's strength and resources to drive upstream changes in social determinants of health and equitable community development[51] whereby to date, UMMHC has

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[48] Gaito et al., *supra* note 81 ("Throughout the reviewed literature, several factors were analyzed by the authors as possible indicators of inequitable access to PBT. . . . the most common factors proved to be indicators of disparity in the access to PBT were socioeconomic status (16/24 articles), geographical location (13/24), age (11/24), race (11/24), insurance status (12/24) and gender (1/24)."

[49] Kimá Joy Taylor, et al., ***Guide to Equity in Medicaid***, URBAN INSTITUTE (2023), https://www.urban.org/sites/default/files/2024-01/Guide%20to%20Equity%20in%20Medicaid.pdf ("States can impose measures or limits on covered benefits like prior authorization or asking [Medicaid] members to pay a small amount for getting care or filling prescriptions. These policies can delay or make it more difficult for members to access care."); *see also* Kimá Joy Taylor, et al., ***Guide to Equity in Medicare***, URBAN INSTITUTE (2024), https://www.urban.org/sites/default/files/2024-02/Guide%20to%20Equity%20in%20Medicare.pdf

[50] ***Health Equity Strategy***, UMASS MEMORIAL HEALTH, https://www.ummhealth.org/about-us/mission-vision-and-values/health-equity-strategy (last visited Feb. 26, 2025).

[51] ***Anchor Mission***, UMASS MEMORIAL HEALTH, https://www.ummhealth.org/anchor-mission (last visited Feb. 26, 2025).

invested more than $5M across Central Massachusetts on projects that aim to address the growing housing crisis, support small businesses, and provide needed social services.

In alignment with the goals established by UMMHC's Anchor Mission, the Applicant described several programs below that have been developed to address the needs of patients at UMMMC.

Interpreter Services and Language Accessibility: UMMHC's professional medical interpretation services are a primary intervention to support diverse populations with limited English proficiency and other communication barriers through the provision of interpretation services in over 100 languages (including American Sign Language) around the clock to patients and families. Interpreters facilitate communication not only for medical needs but also for non-medical inquiries.[52] Using various modes including in-person, over the phone, and remote video interpretation, employees can reach live interpreters through all clinical mobile devices, such as iPhones, iPads, and Androids, for immediate and effective communication with non-English speaking patients.

Further, the MyChart Patient Portal in Multiple Languages promotes equal access to healthcare information for non-English speaking patients and helps them stay in contact with their care teams, thereby contributing to improved health equity.

Fostering Culturally Proficient Staff: The Applicant states its commitment to equity involves fostering a culturally proficient workforce. UMMMC established the Office of Diversity, Equity, Inclusion and Belonging ("DEIB"), with dedicated leadership whereby diversity specialists provide racial literacy training around cultural proficiency and unconscious bias to all medical departments.[53] This commitment to inclusivity and cultural competence is instrumental in providing equitable care.

Equity Improvement Initiatives: In 2021, UMMHC identified a disparity in rates of well-child visits among Black, Hispanic and white children. As a result of its proactive interventions, it was able to substantially improve well-child visit rates for Black and Hispanic populations effectively narrowing the gap between Black, Hispanic and White patients while also increasing rates for White children. In 2022, UMMHC broadened its efforts to bridge racial disparities in osteoporosis screening, and in 2023, it dedicated efforts to improving colorectal cancer screening rates for Black, Hispanic and Asian patients to close a statistically significant gap in screening rates. Most recently in 2024, UMMMC focused on improving collection of race, ethnicity, language, disability, sexual orientation, and gender identity data among hospitalized patients.

In each instance, UMMHC achieved measurable improvements across all populations and exceeded its established goals as summarized in the report, *Improving Health Equity at UMass Memorial Health*.[tt] UMMHC continues to measure each clinical initiative described above to ensure the ongoing reduction of the identified disparity and improvement of health outcomes.

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[52] *Interpreter Services*, UMASS MEMORIAL HEALTH, https://www.ummhealth.org/patients-visitors/interpreter-services (last visited Feb. 26, 2025).

[53] UMass Memorial, Diversity and Cultural Awareness, Programming and Education, https://www.ummhealth.org/umass-memorial-medical-center/about-us/diversity-and-cultural-awareness/programming-and-education.

MassHealth Health Equity Incentive Program: UMMMC actively participates in the MassHealth Clinical Quality Incentive and Health Equity Incentive programs. These quality improvement initiatives cover a number of domains, including patient experience and care coordination, as well as perinatal care, safety outcomes, behavioral health, and equity improvements around race, ethnicity, language, disability status, sexual orientation and gender identity ("RELD/SOGI")[uu] and social determinants of health ("SDOH") data collection, improvements with interpreter services, and strategic planning around health equity improvement. These initiatives allow it to assess, compare, and improve on these quality metrics in order to deliver high quality care and identify and address health disparities across its communities, hospitals, and campuses.

Analysis

The establishment of the PBT Service is designed to improve cancer care for UMMHC's patient panel, the majority of whom are Medicare and Medicaid beneficiaries (~70%). By offering this state-of-the-art therapy locally, the Applicant has described how it aims to enhance health outcomes through enhanced tumor control and reduced treatment related toxicities; improve quality of life through reduced travel, RIAE and associated expenses; and promote health equity through its longstanding commitment to culturally competent care for underserved populations and who as cited by the Applicant often face barriers to accessing advanced specialty care, and who may have difficulty accessing PBT in the Boston area.

Staff finds the Proposed Project will add public health value in terms of improved health outcomes, quality of life, and equity for UMMMC's Patient Panels. Staff find that with the "Other Conditions" outlined below 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

The Applicant states UMMHC's established systems and processes for integrated care will allow for the incorporation of PBT as a treatment option, furthering continuity, and coordination of care for the patient panel as described in this section. It further asserts that UMMMC's nationally recognized research and clinical expertise are both essential components to effectively operating this PBT Service, while continuing to operate its integrated, highly effective cancer program.

Clinical Expertise

Clinical expertise is an essential component to the provision of efficient effective cancer care so the correct diagnostic and treatment decisions are made in a timely manner and to avoid unnecessary testing and costly errors. Patients will be evaluated by UMMHC's Tumor Board teams to assure that the patients receive the most appropriate type of therapy for their specific cancer, including whether they are a candidate for PBT.

As a nationally recognized cancer center the Applicant states it will leverage its expertise in delivering cancer care to delivering quality appropriate PBT care efficiently and effectively.[54] UMMHC maintains radiation oncology accreditation with the American College of Radiology which provides the highest level of quality assurance. The Radiation Oncology Department has a complete portfolio of advanced technology patient care, including brachytherapy, SBRT, total body radiation therapy ("TBI"), and total skin radiation therapy ("TSI"). The UMMMC Department of Oncology is recognized as a leading provider of radiation therapy clinical services. The Department Chair, TJ FitzGerald, MD, is nationally recognized for his clinical, educational, and academic contributions to the field of radiation oncology for over 30 years,[55] whose expertise extends to PBT. Additionally, UMMHC also has a physicist on staff with experience with dosimetry in proton radiation therapy. If approved, UMMHC anticipates recruiting additional experts during the planning and implementation process to develop and operate the PBT Service in order to provide high-quality patient care, operational effectiveness and coordination.

Multidisciplinary Care Teams

Multidisciplinary care teams, a hallmark of UMMHC's approach to managing complex patients, will be integral to the PBT Service's operations and will allow patients to benefit from a wide range of expertise, improving treatment precision and outcomes. These care teams, comprised of radiation oncologists, medical oncologists, surgeons, physical therapists, nutritionists, and other specialists, will collaborate closely to develop, and improve treatment protocols for complex cancer cases, delivering a cohesive and comprehensive approach to patient care. This multidisciplinary care model advances continuity of care by reducing fragmentation and aligning all aspects of a patient's care.

Collaboration with PCPs and Other Specialists

The PBT Service will collaborate closely with primary care providers to create and monitor individualized care plans. Currently, radiation oncologists provide detailed treatment updates to medical oncologists, surgical oncologists, and primary care providers, enabling them to manage any comorbidities or supportive care needs effectively. This practice will continue, and regular updates and feedback loops will be strengthened to support comprehensive patient management. This collaboration will facilitate patient-centered and holistic health care by addressing the full spectrum of patients' health concerns.

Integrated Electronic Medical Record System

The Applicant states that UMMHC has demonstrated excellence in system-wide coordination through its integrated Epic electronic medical record system (EMR) and has been recognized as an "Epic Gold Stars Level 10" organization, placing them in the top 3% of Epic users internationally and signifying

[54] with "High Performing" outcomes in a number of cancer domains, according to US News and World Report.
[55] Dr. FitzGerald is a world leader in quality assurance of radiation therapy in clinical trials and has been the principal investigator for the National Cancer Institute funded Imaging and Radiation Oncology Core (IROC) and the Quality Assurance Review Center ("QARC") for over 30 years. Dr. FitzGerald has also edited books on proton radiation therapy, radiation dosimetry, Medulloblastoma and general radiation oncology with multiple UMMHC faculty members as authors.[55]

excellence in EMR utilization and patient care.[56] Through Epic, efficiencies will be enhanced as the PBT Service will have seamless data sharing among UMMHC oncology specialists, primary care providers, other clinical specialties, and support staff across the health system, to enable the delivery integrated cancer care across all disciplines. Through Epic, with real-time information sharing access to treatment plans, imaging, and patient progress notes, the risk of errors and redundancies is reduced. When necessary and in accordance with applicable law, Epic also facilitates information sharing with caregivers outside of the UMMHC system. As a result of these efficiencies patients will receive consistent, high-quality care throughout their treatment journey.

Cancer Center Services, Nurse Navigators & Supports

Patients who receive PBT will be able to access all of the services and benefits of the Cancer Center, including care coordination, social work, financial counseling.

Nurse navigators who work closely with cancer patients, oncologists, and primary care providers develop individualized care plans that address each patient's unique needs. This proactive approach allows for the most effective and efficient management of patients who will be receiving PBT, reducing delays in care, optimizing treatment outcomes, and providing holistic care for the patient.

Nurse navigators will serve as a critical point of contact for patients, addressing their concerns and ensuring that they remain engaged throughout their treatment journey fostering improved coordination and continuity of care. Nurse navigators will also assist patients with scheduling, transportation, and understanding their care plans. By providing these services, the PBT Service will facilitate smoother transitions between different phases of care and reduce the likelihood of treatment interruptions.

Remote Follow-up

To support continuity of care for patients who cannot travel frequently for post-treatment visits to the PBT Service, patients may utilize UMMHC's telehealth services which will allow providers to follow up with patients remotely, so that issues can be addressed promptly. UMMHC clinicians also have the ability to order remote monitoring at home. This allows caregivers to be notified if a patient's condition changes in between visits, enabling adjustments to care if indicated.

Research and Training

The Applicant reports that through UMMHC's partnership with UMass Chan, UMMHC participates in numerous clinical trials of new cancer treatments. The addition of PBT will facilitate further study of the efficacy of PBT for new patient populations and for new clinical indications, along with other treatments being studied.

Having PBT at the Cancer Center will aid UMMHC in attracting and training oncology fellows and radiation therapy residents which will allow them to learn about the evolving role of PBT in the overall

[56] The Epic Gold Stars Level 10 designation is the highest achievement for organizations using Epic's electronic health record (EHR) system.

treatment of cancer patients. Additionally, having the PBT Service may also allow UMMHC to more effectively collaborate with the radiation physicist residency program operated by the University of Massachusetts - Lowell allowing more trainees in radiation oncology to gain valuable exposure to this treatment modality.

UMMHC has an ongoing commitment to training, and workforce development. The PBT Service may also serve as a training center for other healthcare professionals, ensuring a well-qualified workforce proficient in advanced cancer care techniques. By investing in ongoing education and skill development, UMMHC will maintain a high standard of care delivery for its patient population and support long-term operational efficiency.

The Applicant states the PBT Service will build upon UMMHC's existing strengths and expertise described above, in cancer care delivery, care coordination, multidisciplinary collaboration, and patient-centered services, and that these qualities make UMMHC well-positioned to establish and successfully operate the proposed PBT Service.

Analysis

The Applicant has detailed how existing clinical, research, and training expertise, along with its nurse navigators and EMR will enhance the efficiency and coordination of the PBT service for patients. If the project is approved, patients will remain in the UMMHC system and patients will maintain access to the elements that improve coordination and continuity of care which is likely to reduce fragmentation of care generally experienced when patients must receive treatments outside of their care team. Successful care coordination includes strong communication and effective care plan transitions among providers, and the clear communication of information that patients can understand.[ee] All of these elements can improve a patient's experience and satisfaction.

With the Epic system, navigators can facilitate communication among the clinical team and their patients and improve care coordination. Studies show that integrated health information technology systems directly affect health outcomes, as access to a single, integrated health record improves care coordination, can reduce errors, improve patient safety, and support better patient outcomes.[gg] Uniform, integrated IT systems that include scheduling, EHR and patient communication tools, are timesavers which improve efficiencies and patient satisfaction.

Staff find that the Proposed Project will create efficiencies through the support of continuity and coordination of care initiatives for the Patient Panel. As a result, Staff finds the Proposed Project meets the requirements of Factor 1(c).

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[vv] 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. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel." [ww]

UMMHC has taken steps to implement the Community Engagement Plan through a multi-faceted community engagement plan which was implemented during the month of January 2025, reaching various internal and external stakeholders. The foregoing actions have resulted in significant community outreach and engagement to date, as follows:

- January 3, 2025: Phone calls to Marlborough City Councilors Mike Ossing and Trey Fuccillo, and Marlborough Economic Development Corporation Executive Director Meredith Harris
- January 6, 2025: Phone calls with Marlborough Mayor Dumais, Senator Eldridge and Representative Gregoire
- January 7, 2025: Meeting with UMMMC Chairs and Executive Team
- January 8, 2025: Email to Marlborough Hospital Medical Staff
- January 8, 2025: Phone calls to Marlborough State Legislators, Other Elected Officials, Other Health Systems, Insurers, MHHA, and advocacy groups
- January 8, 2025: Union leadership at Marlborough (SHARE and MNA)
- January 9, 2025: Town Hall Virtual Meeting with Marlborough employees
- January 15, 2025: Meetings with Marlborough Hospital's Community Benefits Advisory Council (CBAC), Marlborough Business Leaders, and Marlborough Hospital's Patient Family Advisory Council (PFAC)
- January 15, 2025: Email to UMMMC's CBAC and PFACs
- January 16, 2025: Publication in *The Thread*, UMMHC's internal system publication to UMMH employees
- January 17, 2025: Email to Worcester-based Patient Family Advisory Council (PFAC)
- January 21st and 23rd: Public Forum at Marlborough Hospital
- January 23rd: Presentation to Worcester Together
- January 28th: Presentation to Worcester-based Patient Family Advisory Council (PFAC).

In March the following meetings took place: 495/Metrowest Partnership Board Meeting (March 5, 2025), Rotary Club of Hudson (March 5, 2025), and Marlborough Economic Development Corporation Board Meeting March 27, 2025). Outreach was conducted with the following organizations: Health Foundation of Central MA, Thrive Communities, Coalition for a Healthy Greater Worcester, United Way of Tri-County, Chamber of Commerce. The response from stakeholders at the meetings has been very positive with strong support for the Proposed Project. Stakeholders expressed support for UMMHC's commitment to and investment in the region, the expansion of cancer care by providing more convenient care for patients and families closer to home, and the addition of specialists to the region. Stakeholders' questions have primarily focused on any discontinuation, interruption, or other impact

on services during or as a result of the Proposed Project, and the timeline and noise associated with construction.

The Applicant states that maintaining ongoing dialogue with all key stakeholders (internal and external) will remain a top priority both during and after the regulatory review process with the following planned actions:

- Updates and the opportunity to share questions and concerns will be offered through UMMHC systemwide communication channels including Town Halls and the systemwide newsletter.
- For all Marlborough employees and leaders, leadership will offer listening sessions and updates at key meetings such as manager meetings and Town Halls (open to all employees). As part of these updates, employees and leaders will be encouraged to ask questions and share concerns. FAQs and other messaging will be developed and shared with employees.
- The topic of investments in Marlborough and PBT will also be a standing agenda item for future Marlborough CBAC and PFAC meetings and other meetings such as the Marlborough Economic Development Corporation and the 495/MetroWest Partnership.

Analysis

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

Factor 1: f) Competition on Price, Total Medical Expenses (TME), Costs and Other Measures of Health Care Spending

The Applicant states the Proposed Project is anticipated to compete effectively based on price, total medical expense ("TME"), and provider costs.

The Applicant asserts the Proposed Project is aligned with the DoN regulations "… to encourage competition and the development of innovative health delivery…" [57] as the Proposed Project encourages competition in the Massachusetts health care market by making this innovative, advanced cancer treatment available from a second provider in Massachusetts.[58]

With approval of the Proposed Project, the Applicant states competition will increase by providing an alternative site to access PBT for patients outside of Boston in a lower cost region. The Applicant asserts UMMMC can compete effectively on price for PBT services compared to the current provider,

[57] 100.001: General Provisions "The purpose and objective of 105 CMR 100.000 is to encourage competition and the development of innovative health delivery methods and population health strategies within the health care delivery system to ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation."

[58] As discussed above, patient access to PBT in Massachusetts is limited because there are only two Proton units, both of which are located in Boston, at a single provider, Massachusetts General Hospital ("MGH").

MGH, since UMMMC is a lower-cost, alternative. As consistently reflected in the Center for Health Information and Analysis ("CHIA") relative price data set,[59] both of MGB's academic medical centers ("AMCs") consistently have significantly higher rates than other AMCs including UMMMC's. [60] Competitive prices not only will benefit patients; they also will benefit employers and third-party payors compared to the existing provider.

As noted previously, UMMHC will locate the PBT Service at the existing Cancer Center in Marlborough which not only will be more efficient, but it will also avoid a costly new building and associated operational expenses.

Analysis

Although the utilization of PBT in the Commonwealth has been limited, partly due to the cost of acquisition, the advancements in proton technology, noted herein, allow this service to be brought to patients at a lower capital cost than was previously available. Accordingly, the significantly lowered capital cost, along with UMMMC's continued documented status as a lower cost provider will enable UMMHC to offer its patients, and surrounding communities, a likely lower cost, potentially cost-effective treatment option for receiving clinically appropriate PBT which may generate competition to drive down costs further. Notwithstanding the foregoing, Staff maintains there remains the potential for costs to increase.

The Applicant has been explicit with its intent to perform longer term cost effectiveness analyses of the use of this technology. The Applicant has described how as a lower cost and second provider of PBT, the Proposed Project will offer expanded patient access and alternative choices to both patients and insurance payers which will foster competition. UMMHC's assertion it will remain a lower cost provider can be evaluated pursuant to Standard Condition #18, which requires a DoN Holder to report to DPH upon submission of a performance improvement plan ("PIP") if required by the Health Policy Commission, as well as its ongoing efforts to implement the PIP.

Staff find the Proposed Project, on balance, will likely compete on the basis of price, TME provider costs, and other measures of health care spending and therefore, with the "Other Conditions" required below and standard reporting requirements, including those regarding compliance with cost containment goals, the requirements of Factor 1(f) have been met.

Factor 1 Summary Analysis

The Applicant evaluated several factors including high incidence rates of cancer in Worcester County (albeit without granularity of PBT-responsive cancers), limited access to PBT due to travel burden, and limited access resulting from limited supply to justify their need. To arrive at the need projections of patients who would benefit from proton beam treatments, the Applicant relied on two methodologies, one using their existing cancer LINAC patient volume coupled with the ASTRO clinical criteria for

[59] See DoN Narrative, Exhibit E, https://www.mass.gov/doc/narrative-pdf-umass-memorial-health-care-inc-substantial/download

[60] CHIA, *CY 2022 Relative Price and Provider Price Variation*, Databook (Excel) (2024), https://www.chiamass.gov/relative-price-and-provider-price-variation/.

medical necessity, and another relying more broadly on cancer incidence rates and use rates as determined by the Horizon model, both described more fully above. Because the ASTRO model aligns more closely with the Applicants cancer patients, and also more closely with the CMS criteria for coverage, staff believes that the ASTRO model is a more likely projection of the Applicant's need, notwithstanding the likelihood that there will be a cohort of patients who are referred from beyond the Applicant's service area but acknowledging the lack of data to make such projections.

The Applicant also described how the Proposed Project will allow for greater patient access in a growing, underserved market outside of Boston, and will create more competition that offers expanded patient and insurance choices. Because of its targeted clinical effectiveness for appropriate patients, it has the potential to lower downstream need for additional clinical services due to the technology's cited reductions in side effects and post-treatment complications which consequently might reduce total medical expenses as well and which the Applicant intends to study further if the project is approved. The Applicant provided several measures to track the impact of the Proposed Project, *see* Appendix 1.

As a result of the information provided by the Applicant and additional analysis, staff finds with the "Other Conditions" required below and the standard reporting requirements, that the Applicant has demonstrated that the Proposed Project meets 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 asserts that due to its enhanced clinical accuracy, PBT potentially offers substantial benefits in terms of cost containment and patient outcomes, and it has the potential to reduce associated financial burdens on patients, employers, and healthcare systems.

1. **Reduction In Radiation Induced Adverse Effects Can Reduce Costs of Care**

   UMMHC expects that the clinical benefits and anticipated downstream healthcare cost savings could partially offset the costs of expanding PBT in the Commonwealth. As discussed in Factor 1, UMMHC anticipates that the use of PBT by UMMHC patients for whom treatment meets clinically appropriate criteria, may lead downstream healthcare reductions in ED visits, readmissions and post treatment complications which require increased, and at times lifelong resource use thereby increasing costs.[xx]

2. **Lower Insurance Costs for Employers**

A statewide insurance pilot study demonstrated that employer-sponsored insurance plans covering PBT did not experience a significant increase in medical costs compared to traditional radiation therapy; [yy] the analysis indicated that employer health plans could see a 4.7% reduction in overall insurance costs due to fewer long-term complications and hospital admissions.

3. Increased Workforce Productivity and Lower Disability Rates

PBT has the ability to contribute to economic stability by enhancing workforce retention and reducing disability claims. A randomized study on work outcomes in patients with oropharyngeal cancer revealed that those treated with PBT exhibited a 26% absolute improvement in return-to-work rates at two years compared to those treated with traditional radiation.[zzaaa] Additionally, patients treated with PBT experienced fewer instances of treatment-induced work impairment, allowing them to maintain employment and productivity.

4. More Affordable Access for Patients

The Applicant asserts the addition of the PBT in Marlborough advances the Commonwealth's stated goals to lower the cost of healthcare and increase accessibility for PBT patients in the Commonwealth by reducing patients' out-of-pocket costs related to driving time, parking, lodging, and childcare, and by providing this highly effective treatment in a historically lower cost, more affordable health care system, thereby making it a more equitable option for patients.

5. Cost-Effective Location and New Technology

As noted earlier, by locating the PBT Service at the existing Cancer Center in Marlborough capital costs of a new building and operational expenses are lowered. Further the footprint of the modern proposed type of PBT system contributes to the reduction of the overall capital costs for the Proposed Project. As explained earlier, a 2017 comparative analysis of the budget impact of implementing PBT services in Canada concluded that savings could be generated over an extended time horizon with a single-vault PBT system. [61]

Improved Public Health Outcomes

The Applicant states it anticipates the Proposed Project will serve as a regional resource that will contribute to public health outcomes for clinically appropriate patients in the region which it asserts is supported by research studies related to both clinical effectiveness, outcomes and ensuring access to timely appropriate care. As cited in Factor 1(a) and (b), the focused precision of PBT in targeting

[61] KIM ET AL., *supra* note 46 *(*"constructing a Mevion single-vault PBT system costs an additional $18.19 million over a five-year time horizon, but over a 10-year time horizon, this strategy is expected to save health care payers $12.85 million. These savings increase as the time horizon of the analysis is extended beyond 10 years (Table 24). This is because the single-vault system has a high up-front fixed cost but is less costly each year thereafter. Therefore, construction of a single-vault PBT facility becomes relatively more desirable when longer time horizons are assessed, eventually becoming a cost-saving approach over a sufficiently long time horizon.").

tumors while sparing healthy tissues makes it a preferred treatment for cancers located near critical organs as it enables higher doses of radiation to be delivered directly to the tumor thereby improving tumor control and enhancing survival rates for certain tumors.[bbb]

Additionally, as described in Factor 1, PBT improves not only survival rates but also quality of life for clinically appropriate patients.[ccc] Its ability to reduce treatment-related side effects such as fatigue, skin reactions, and gastrointestinal issues enables faster recovery, better maintenance of daily functioning, and improved treatment compliance,[ddd] thereby enhancing patients' independence. The Applicant posits that since cancer survivors are living longer, the importance of therapies that preserve quality of life along with effective tumor control are important considerations.[eee]

Delivery System Transformation

1. Expanded Regional Access to PBT

As noted in Factor 1, for the region's patients for whom PBT is indicated, access will improve since the Cancer Center is convenient to three interstate highways (I-90, I-495, I-290) making this location accessible to residents of central and western Massachusetts, along with other New England states and thus will save patients' and caregivers' the stress of travel into Boston for daily treatment, and costs related to gas, parking and, for some, lodging.

2. Assessing and Accessing the SDOH Needs of the Patient Panel

The Applicant states UMMHC has a long-standing commitment to integrating social services and addressing social drivers of health (SDOH) to provide comprehensive, patient-centered care. Most recently, UMMHC launched a system-wide process for screening patients for their SDOH needs.[fff] As part of this effort, in 2024, UMMHC screened more than 150,000 patients for SDOH needs. Of these screened patients, 11% of patients identified a social risk related to housing, 6% with food insecurity, 5% with housing insecurity or housing quality concern, 4% with transportation insecurity, and 3% with utilities/financial strain, 9% of patients screened requested help getting connected to community resources. UMMHC anticipates that there will likely be similarities between the social needs of the UMMHC patients screened in 2024 and the patients who will utilize the PBT Service.

All PBT Service providers and staff will be able to deliver the SDOH screening and view patient screening results in the electronic medical record. Existing UMMHC processes and partnerships to link patients to a range of community social service organizations and community programs will enable the PBT Service to meet the diverse needs of its patient population. The Applicant describes how social workers and nurse navigators help connect patients to identified needs; and that navigators, patients, and caregivers can access a **CommunityHELP** SDOH resource repository, which is UMMHC's instance of the **FindHelp** platform.

As described in Factor 1(b), UMMHC addresses community and patient SDOH needs in its core strategy for providing and delivering high quality care. For the patients of the PBT Service, this includes reducing transportation costs, improving economic stability, fostering better long-term health outcomes,[ggg]

providing a needed service to under-resourced patients, and Community Engagement and Partnerships through its Anchor Mission and community benefits strategy,

The PBT Service will reflect UMMHC's commitment to addressing SDOH and health equity. By leveraging its established partnerships and proven strategies, UMMHC works to address patients' social and financial needs along with their clinical needs and clinical care. This holistic approach is anticipated to improve overall patient outcomes, reduce disparities, and promote health equity in Central Massachusetts.

Factor 2 Summary Analysis

In summary, the Applicant provided a number of ways the development of a PBT Service in Marlborough presents a potential case for cost containment. First, as documented in Factor 1(f), the Applicant is historically a lower cost provider than the other provider of PBT in Massachusetts based on years of reporting to CHIA.

While the Applicant has explicitly stated its status as, and intent to remain, a lower-cost provider, Staff points to the potential for the Proposed Project to increase the Applicant's negotiating leverage with commercial insurers which could lead to increases in overall costs. As discussed in Factor 1 above, DPH can evaluate this assertion via Standard Condition #18.

Additionally, a statewide pilot study that demonstrated that employer-sponsored insurance plans covering PBT did not experience a significant increase in medical costs compared to traditional radiation therapy and that they could experience a 4.7% reduction. Further, as described and cited in Factor 1(b) and in this Factor, smaller studies that have shown that patients experienced fewer side effects, ED visits, and hospitalizations than with traditional photon therapy, but these studies have not tracked comparative costs. Although these longer-term studies are limited in scope, other reported potential benefits for cost reduction and improved quality of life include loss from work and mitigating the long-term financial burden of long-term treatment effects for patients and their families. Additionally, the Applicant described a number of credible ways the Proposed Project will improve public health value and lead to delivery system transformation through its health equity initiatives, medical education and fellowship programs and through its extensive experience in radiation oncology research.

As a result of the information provided by the Applicant and additional analysis, with the "Other Conditions" required below and the standard reporting requirements, staff finds the Applicant has demonstrated that the Proposed Project meets Factor 2

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant attested to its compliance and good standing with federal, state, and local laws and regulations.. While the Application was pending, a subsidiary of UMMHC licensed by DPH did not adhere to the Department's substance use disorder treatment program closure requirements set forth

at 105 CMR 164.087; the subsidiary has since closed. Staff note ongoing compliance with federal, state, and local laws is required for both DoN Holders and Applicants and recommends an Other Condition requiring UMMHC's adherence to closure procedures for DPH licensees operating thereunder. As a result of information provided by the Applicant and with inclusion of the "Other Condition" as outlined below, staff finds the Applicant has reasonably met the standards of Factor 3.

Factor 4: Demonstration of Sufficient Funds Independent CPA Analysis

Under Factor 4, the Applicant must demonstrate through sufficient documentation the availability of sufficient funds available for capital and ongoing operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such a finding must be supported by an analysis by an independent CPA. The Applicant submitted a report performed by BDO, USA, Inc. (CPA Report). Additionally, the Department considered the Applicant's most recent public financial release for the quarter ended June 30, 2025.

CPA Analysis

The CPA analysis included a review of numerous documents in order to form an opinion as to the reasonableness and feasibility of the projections regarding the Proposed Project including:

1. Financial Model for UMMHC on a consolidated basis including the operation of the PBT Service from September 30, 2025, through September 30, 2032;
2. Proposed FY's 2024 and 2025 UMMHC Budget Presentation dated as of September 24, 2024;
3. Final Fiscal year 2025 budget for UMass Memorial Health – Milford Regional Medical Center ("MRMC") dated as of September 30, 2024;
4. Draft DoN Narrative Report as of February 26, 2025;
5. Purchase Agreement for Mevion S250i Proton Therapy System;
6. Schematic Design Estimate for UMMHC prepared by Consigli Construction Co., Inc.;
7. Debt Agreement of UMMHC dated as of January 23, 2025;
8. UMMHC's Patient Volume Market Analysis;
9. The Proposed Project's Capital Expenditure Estimate Analysis;
10. Certificate Of Need Application prepared by Danbury Proton LLC, submitted to State of Connecticut's Office of Health Strategy (OHS Version July 18, 2022);
11. Audited Financial Statements for UMass Memorial Healthcare, Inc. and its affiliates for fiscal years ended September 30, 2021 through 2024;
12. Definitive Healthcare data as of January 2024;
13. Data obtained from Integra Information, A Division of Microbilt Corporation as of February 5, 2025; and,
14. IBISWorld Industry Report, Hospitals in the US, dated October 2024.

The CPA calculated standard financial ratios, reflecting profitability, liquidity, and solvency[62] of the forecasted operating results to market information from Integra Reports IBISWorld and Definitive Healthcare to assess the reasonableness of the Projections.[63]

Revenues[64]

Projected net patient service revenue for UMMHC is expected to grow by 12.0% in FY 2025 over FY 2024, and for FYs 2025 and 2026 is projected to grow 3.3% and 0.2%, respectively. For the remainder of the projection period (FY 2026 through FY 2032), the Applicant projected nominal patient service revenue growth. Total operating revenue in FY 2025-2032 for UMMHC represents 95% of the total combined operating revenue within the projections. The total operating revenue for FY 2025 aligns with the budget that was presented to and approved by the UMMHC Finance Committee. Projected drivers of revenue growth in FY 2025 include the successful integration of MRMC which is expected to add 9.7 percent in patient service revenue in 2025, the January 2025 opening of the North Pavilion, which added 72 new beds to UMMMC, enhancing capacity going forward, an annual system price increase, influenced by inflation and other factors along with the retention of higher acuity patients.

The CPA notes in Table 12, the combined total operating revenue growth UMMHC anticipated for FY 2025 is slightly below the three-year compounded annual growth rate ("CAGR") and within the range of annual revenue growth rates for the Applicant between FY 2022 and FY 2024. The consolidated total operating revenue growth for UMMHC for the remainder of the projection period (FY 2026 to FY 2032) is anticipated to be mostly flat.

Table 12: Combined Revenue Growth Historical and Projected for UMMHC and MRMC

	Annual Growth Range (2022 – 2024)	CAGR (2021 – 2024)	2025 Growth	Annual Growth Range (2026-2032)
Revenue Projection	7.9% – 12.9%	10.7%	10.1%	0.0% – 0.2%

In order to determine the reasonableness of the projected revenue, the CPA reviewed the underlying assumptions upon which the Applicant relied, including historical operating results and anticipated demographic trends in the UMMHC service area.

As a result of the analysis, the CPA concludes that the revenue growth projected by the Applicant reflects a reasonable estimation of future revenue of UMMHC.

[62] Profitability metrics, such as EBITDA, EBITDA Margin, Operating Margin and Total Margin are used to assist in the evaluation of management performance in how efficiently resources are utilized. Liquidity metrics, such as Current Ratio, Cash Days on Hand and Days in Accounts Receivable measure the quality and adequacy of assets to meet current obligations as they come due. Solvency metrics, such as Total Assets and Total Equity measure the company's ability to service debt obligations. Certain metrics can be applicable in multiple categories.

[63] See Pages 8-9 of the CPA report https://www.mass.gov/doc/cpa-report-pdf-umass-memorial-health-care-inc-transfer/download

[64] Revenue includes net patient service revenue and other operating revenue. The cumulative patient service revenue comprises 93.3 percent of the cumulative total operating revenue from FY 2024 through FY 2029.

Expenses

The CPA analyzed each category of projected operating expenses for reasonableness and feasibility.[65] Total expenses are projected to grow by 10.5 percent, 0.2 percent and 0.1 percent in FY 2025,[66] FY 2026 and FY 2028, respectively, which is in line with projected revenue growth. Starting in FY 2027, the Applicant maintained relatively flat operating expenses, except for interest expense which is projected based on UMMHC's projected level of debt and current terms, depreciation and amortization, and other direct expenses. The primary factors influencing changes in operating expenses in the initial years of the projections are the staffing costs associated with the North Pavilion and the transition from temporary contractors to permanent employees.

Table 13 indicates that the range of expense growth for FY 2025 is slightly below the three-year CAGR and within the range of annual expense growth rate between FY 2022 and FY 2024. The additional factors other than those noted above for the change in expense growth are inflation which will affect the recruitment and retention and supply chain, integration of MRMC, and continued strategic investments.[67]

Table 13: Expense Growth Historical and Projected

	Annual Growth Range (2022 – 2024)	CAGR (2021 – 2024)	2025 Growth	Annual Growth Range (2026-2032)
Expense Projection	2.6% - 16.8%	11.3%	10.5%	0.0% - 0.2%

The CPA notes the projected total expenses for UMMHC as a percentage of total revenue range from 99.6 percent to 100.1 percent from FY 2025-2032 and that this is consistent with the historical UMMHC's total expenses as a percentage of total revenue which ranged from 96.1 percent to 101.1 percent from FY 2021 to FY 2024.

As a result of its analysis the CPA concluded that operating expenses reflect reasonable estimation of future expenses for the Applicant.

Capital Expenditure

The CPA reviewed the project costs associated with the Proposed Project. As outlined below, the total anticipated capital expenditures for the Proposed Project are estimated at $59.4 million. The capital expenditures are incorporated within the Applicant's financial Projections which account for cumulative routine capital expenditures and major projects totaling $1.88 billion over the next eight years (FY 2025 through FY 2032), including the Proposed Project. The expenditures related to the

[65] Operating expenses include salaries and wages, employee benefits, professional fees, purchased services, pharmacy, medical supplies, non-medical supplies, utilities, insurance, rental leases, other direct expenses, system allocation expenses, depreciation and amortization, and interest expenses.
[66] In FY 2025, the rise in operating expenses, similar to revenue, is primarily attributed to the integration of MRMC, which contributes an additional 9.5% to operating expenses for that year.
[67] while maintaining fiscal discipline, the Applicant notes.

Proposed Project represent approximately 3.2% of the total capital expenditure over this period. As for the balance sheet for FY 2024, the Applicant had of $1.66 billion in cash and short-term investments. Additionally, the financial model indicates that over the eight years of projected financial data, total cash and short-term investments on the balance sheet will average approximately $1.63 billion annually, prior to considering the Applicant's various assets that can be used to fund the Proposed Project.

Based on its review, the CPA determined that the capital expenditure projected reflects a reasonable estimation of future capital outlay of UMMHC.

CPA Conclusion

The CPA concluded "Within the projected financial information, the Projections exhibit a cumulative operating EBIDA surplus of approximately 4.6 percent of cumulative projected operating revenue for the eight years from FY 2025 through FY 2032. Based on 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 likely to have a negative impact on the patient panel or result in a liquidation of major assets of UMMHC."

Supplemental Explanation Request

In its most recent public financial release for the quarter ended June 30, 2025, UMMHC reported a loss of $1M and therefore the Department followed up with the Applicant requesting an explanation as to whether this would have an impact on the Proposed Project or on the Applicant's Patient Panel.

The Applicant responded that this is an improvement compared to the first and second quarters. The earlier reported losses of $59M and $28M, respectively, included significant costs associated with opening the 72 new inpatient beds in the North Pavilion in January and integrating Milford Regional Medical Center into the system on October 1. The Applicant states that the Proposed Project has already been board approved and funds have already been set aside. The Applicant stated the following:

> *"Throughout FY25, UMMHC has continued to make capital investments in its operations and infrastructure while maintaining sufficient cash reserves for approved capital projects, including Proton Therapy, Nashoba Satellite Emergency Facility, and the Marlborough Emergency.*
>
> *Like other healthcare systems in Massachusetts, UMMH continuously monitors current and projected market conditions, along with the financial, operational, and quality performance of its various programs and services. This ongoing review process may sometimes necessitate modifications to meet patient needs and ensure the long-term financial wellbeing of the system, all while complying with the terms and conditions of previously issued DoNs. UMMH must provide a balanced set of programs for our unique patient payer population to operate a sustainable, lower cost academic safety net health care system that keeps patients local for their health care."*

Factor 4 Analysis

Staff is satisfied with the CPA's analysis and the Applicant's assertions regarding their most recent public financial release for the quarter ended June 30, 2025. As a result of information provided by the Applicant, staff finds that the Applicant has met the requirements of Factor 4.

Factor 5: 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 considered and rejected two alternatives to the Proposed Project:

Alternative #1: Not establishing PBT services at UMMHC Cancer Center.

Quality: Under this alternative, UMMHC's patients who meet the clinical criteria for PBT and who are able to secure appointments for PBT would continue to have to travel and incur personal associated expenses to access the only Massachusetts provider located in Boston or New York City or would forgo PBT. (Currently, the next closest PBT facility is the New York Proton Center at 225 East 126th St, New York, NY 10035.) (Staff notes that the recent approval of the two PBT services in Rhode Island and Connecticut does not completely mitigate the toll of travel for patients and their families.)

Efficiency: As described earlier, without the Proposed Project serving those patients who meet the clinical criteria for PBT therapy, insufficient local access affects quality of life during treatments due to daily travel burden; and if they are unable to travel, some may experience late effects of the alternative, photon treatment, which can reduce quality of life, increase associated costs of follow-up treatments, lead to loss of independence and work as described previously described in Factor 1(b).

Operating Costs: There would be no immediate additional operating costs with this alternative, but the Applicant indicates a likely increase in both operating and capital costs associated with retreatment and secondary malignancies.

Alternative #2: Establish the PBT Service at either the University Hospital or at the Memorial Hospital campuses.

A second alternative of locating the PBT Service at a different campus, either the University Hospital or at the Memorial Hospital campus, was rejected after consideration by the applicant. Further, the Applicant reports construction on the site was not feasible. Regarding the University campus, there is no viable buildable site available for a proton center. At the Memorial campus, the electric grid and power supply would not support the amount of electricity required for a proton center. At both

Campuses, the existence of bedrock/ledge would add significant development costs and time to completion. None of those conditions exist at the Cancer Center in Marlborough. Therefore, the Applicant determined the most practical and cost-effective approach would be to place the proton center on the Marlborough Campus which would allow the Applicant to take advantage of the existing coordination of care and efficiencies within the current Cancer Center infrastructure and would facilitate full integration of the service.

Analysis

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

Factor 6: Community-based Health Initiatives

Summary and relevant context for this application: This is a DoN project that will result in a Tier 2 CHI. To fulfill Factor 6 requirements, the Applicant submitted a CHI Narrative, Self-Assessments, Partner Assessments, the 2023 MetroWest Community Health Needs Assessment ("Marlborough CHNA") and the 2024 Greater Worcester Community Health Assessment ("Greater Worcester CHNA").

UMMHC will be recruiting for any missing constituencies on the DoN Advisory Committee ("the Committee") to meet the CHI community engagement requirements and support equitable engagement of Marlborough community partners in the CHI implementation process. The CHI team will work with the Applicant to ensure the group's make up is sufficient to help them make decisions in line with CHI principles. UMMHC and the Committee will then lead the selection of health priorities and strategies to equitably distribute the CHI funds associated with this project.

The 2023 Marlborough CHNA was completed by the MetroWest Health Foundation. This assessment focused on the 25 MetroWest communities, including Marlborough. Data sources included a community survey, key informant interviews, focus groups and secondary data collection. The top health concerns identified by residents included:

- Built and natural environment—*community spaces & transportation*
- Housing insecurity and homelessness—*affordability & quality*
- Food insecurity
- Mental health—*need for providers, especially for youth & individuals who speak a language other than English*
- Substance use—*high correlation between substance use & housing insecurity*

The 2024 Greater Worcester CHNA was led by the Applicant, the City of Worcester's Division of Public Health (WDPH), and the Central MA Regional Public Health Alliance. Assessing the municipalities of Worcester, Grafton, Shrewsbury and West Boylston, the CHNA had increased focus on health equity by highlighting the voices of people who identify as Black, Indigenous,

People of Color, and those living with low incomes. Primary data was collected through institutional leader interviews, health equity population conversations, a public survey, and a 55-member advisory committee. Secondary data was collected from various sources to highlight socio-demographic and health profiles for the region. Key community health priorities identified included:

- Built environment—*transportation & food access*
- Affordable and safe housing
- Access to quality and reliable broadband
- Navigation of public benefits
- Healthcare workforce
- Culturally representative healthcare

Collectively, the Marlborough and Greater Worcester CHNAs captured health outcomes and SDoH needs for their communities of focus. The Applicant will work with the community partners who sit on their DoN Advisory Committee and select health priorities and strategies that allow for CHI implementation and intervention at the SDoH and root cause level.

Self-Assessments for the Marlborough and Greater Worcester CHNAs provided a summary of community engagement processes and socio-demographic information, data and highlights related to topics and themes of community needs. Through data analysis, surveys, focus groups and key informant interviews, the Applicant, participating community groups and residents identified the key priorities and strategies highlighted in the respective CHNAs.

Partner Assessments (formerly known as Stakeholder Assessments) submitted provided information on the individuals' engagement levels (e.g., their personal participation and role) and their analysis of how the Applicant engaged the community in community health improvement planning processes. The information provided in these forms was mostly consistent with the self-assessments conducted by the Applicant.

CHI Narrative provided an overview of the CHI funds breakdown, processes and community engagement and planning activities. It also highlighted the DoN Advisory and Allocation Committee duties, timeline for activities, explanation of administrative monies, and evaluation overview. UMMHC plans to convene their DoN Advisory Committee to select health priorities, establish the Allocation Committee and select funding method(s) within 4 months post approval. Funding decisions, disbursement, and implementation will take place within 5-6 months post approval.

UMMHC plans to utilize administrative funds to promote funding opportunities, develop a Request for Proposal (RFP) process, provide applicants with technical assistance resources and support additional staff time. The CHI team also asks the Applicant to utilize administrative dollars to address barriers to community participation and engagement (e.g., provide interpretation/translation services and/or stipends for resident participation). The proposed timeline and use of administrative and evaluation funds are all appropriate and in line with CHI planning guidelines.

Analysis

As a result of information provided by the Applicant and additional analysis, staff find that with the conditions outlined below, and with their ongoing commitment to meaningful community engagement outlined above, the Applicant has demonstrated that the Proposed Project has met Factor 6.

Ten Taxpayer Groups and Public Comments

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.[68]

Written Comments

The Department received a total of 25 written comments. Pursuant to DoN regulation, the Department determines whether need exists for a Proposed Project, based on whether the Applicant meets each of the relevant factors set out in those regulations. The Department considers those comments that address the Applicant's ability to meet the requirements of each of the relevant factors set out in the Regulations.

The names of those submitting written comments and the full text of the written comments are available online on the DoN website. [69] The 25 submitted written comments were strongly supportive of the Proposed Project. In particular, the written comments A total of 15 state and local representatives signed seven of the letters. All letters, some from patients and support organizations, expressed strong support for the Proposed Project, emphasizing the emotional stress of all cancer diagnoses, and the importance of localized care stressing the difficulty of to avoid the need for daily travel to access treatment. Business organizations added the importance of UMMMC within the community noting that it is the largest employer in Central Massachusetts.

Three of the supporting letters received were from other medical centers including Dana Farber Cancer Institute's Chief Executive Officer, and the Oncology Chairs of Baystate Health, and Cape Cod Health Care. These emphasized the support for the Chair of the radiation oncology department at UMMMC to offset the difficulty in securing appointments for their patients with other existing providers in the Northeast (Boston and NYC).

Ten Taxpayer Groups

Pursuant to the DoN Regulation, any ten Taxpayers, organized as a group, may participate in the review of an Application for a 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

[68] No public hearing was requested or held.

days following the Filing Date of an Application, or during the first ten days after any public hearing held pursuant to 105 CMR 100.445.

Thirteen (13) Ten taxpayer groups (TTGs) registered in connection with the Proposed Project. Registration information, the names of the TTGs and their participation in the review process, the full text of TTG comments are available on the DoN website. [70]

All of the TTGs, expressed support for the Proposed PBT service with the exception of the TTG representing Mass General Brigham. Mass General Brigham has not submitted any comments regarding the Proposed Project.

Findings and Recommendations

Based upon a review of the materials submitted, staff finds that, with the addition of the recommended "Other Conditions"(pursuant to 105 CMR 100.360) detailed below, the Applicant has met each DoN Factor for the Proposed Project and recommends that the Department approve this Determination of Need for the establishment of a Proton Beam Service at the UMMMC Marlborough Cancer, subject to all applicable Standard and Other conditions.

Other Conditions

1. **Factor 6:** CHI Contribution

    a. Of the total required CHI contribution of $2,679,902.15.
        i. $649,876.27 will be directed to the CHI Statewide Initiative.
        ii. $1,949,628.82 will be dedicated to local Health Priority approaches.
        iii. $80,397.06 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 $649,876.27 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 #: UMMH-25021208-HE

        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

[70] Please see Ten Tax Payer Groups, https://www.mass.gov/info-details/umass-memorial-health-care-inc-marlborough-hospital-transfer-of-ownership

or concerns regarding the payment, please contact the CHI team at DONCHI@Mass.gov.

2. **Factor 1(a):** The Holder shall report on the following:
    a. Number of PBT patients by the following age populations:
        - Birth-21
        - 22-64
        - 65+
    b. Patient origin for the PBT service stratified by Massachusetts county or State of residence if outside of Massachusetts; and
    c. Treatments by ICD- 10 codes including staging and also, differentiating the patients needing retreatments specifically where "*cumulative critical structure dose exceeds tolerance dose*."

3. **Factor 1(b) and Factor 2:** The Holder shall track and report the following:
    a. Payer-mix based on charges for the PBT service, the LINAC Service and the payer-mix overall for UMMHC;
    b. Total number of patients who meet the Medical Necessity Criteria for PBT service pursuant to the CMS Local Coverage Determination Letter L35075 or any successor CMS Coverage Guidance;
    c. Total percentage of PBT patients denied coverage by payer; and
    d. Number of PBT patients referred to the Applicant's Financial Assistance Program.

    If the Department determines the Holder's payer-mix for the PBT service is materially different from the overall UMMHC 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 3:** The Holder shall comply with federal, state, and local requirements, including licensure requirements applicable to facility, program, and service closure as set forth in Code of Massachusetts Regulations Title 105. Should the DoN program determine the Holder has failed to comply with such requirements, the Holder shall report to the Department on why the Department should find that the Holder remains in compliance with the terms and conditions of the Notice of Determination of Need. Upon review, the Department may revoke its DoN approval pursuant to 105 CMR 100.640(A) and may not accept additional DoN Applications from UMMHC until the Holder is found to have remedied compliance issues cited by the Department.

Appendix 1 Outcomes Measures

To assess the impact of the Proposed Project, the Applicant has developed the following outcome measures. 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 shall provide annual data on the following metrics and projections: and will include a description of numerators and denominators.

Metric: Patient access

a. **Measure:** New patient volume at the PBT Service.
b. **Projections:** 300 patients treated each year from UMMHC Patient Panel. (180 in Year One)
c. **Monitoring:** Quarterly volume review of patients receiving treatment.

2. **Metric:** Hospitalizations
   a. **Measure:** Number of hospitalizations required due to sequelae of PBT.
   b. **Projections:** Less than 1% of PBT patient population will be hospitalized due to sequelae of management.[hhh]
   c. **Monitoring:** Monthly review with quarterly reports.

3. **Metric:** Patient-Reported Satisfaction Scores
   a. **Measure:** Post-treatment surveys obtained by the Marlborough Campus focusing on convenience, quality of care, and overall experience.
   b. **Projections:** Year one satisfaction scores anticipated to be 90% and projected to increase to > 90% by year three.
   c. **Monitoring:** Survey results are reported monthly and analyzed biannually by a patient advisory committee.

[a] THOMAS J. FITZGERALD AND MARYANN BISHOP-JODOIN, PBT: Current Status and Future Directions (2021), https://www.intechopen.com/books/10231.

[b] *Estimated Number of New Cancer Cases and Deaths by State – 2024*, American Cancer Society, Inc., https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2024/sd3-21-cancers-by-state-2024.pdf (last visited Feb. 24, 2025) [*hereinafter* ACS].

[c] Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment: estimating optimal utilization from a review of evidence-based clinical guidelines. Cancer. 2005;104:1129–1137. doi: 10.1002/cncr.21324. [DOI] [PubMed] [Google Scholar

[d] Begg AC, Stewart FA, Vens C. Strategies to improve radiotherapy with targeted drugs. Nat Rev Cancer. 2011;11:239–253. doi: 10.1038/nrc3007. [DOI] [PubMed] [Google Scholar

[e] WP Levin et al., *Proton Beam Therapy*, 93 BRITISH JOURNAL OF CANCER 849, 849-54 (2005), https://pmc.ncbi.nlm.nih.gov/articles/PMC2361650/.

[f] WP Levin et al., *Proton Beam Therapy*, 93 British Journal of Cancer 849, 849-54 (2005), https://pmc.ncbi.nlm.nih.gov/articles/PMC2361650/.

[g] Kyle Wang & Joel E. Tepper, *Radiation Therapy-Associated Toxicity: Etiology, Management, and Prevention*, 71 CA CANCER J. CLIN. 437, 437-54 (2021), https://pubmed.ncbi.nlm.nih.gov/34255347/.

[h] https://pmc.ncbi.nlm.nih.gov/articles/PMC9139402/#B4-cancers-14-02444

[i] Chen YH, Molenaar D, Uyl-de Groot CA, van Vulpen M, Blommestein HM. Medical Resource Use and Medical Costs for Radiotherapy-Related Adverse Effects: A Systematic Review. Cancers (Basel). 2022 May 16;14(10):2444. doi: 10.3390/cancers14102444. PMID: 35626049; PMCID: PMC9139402.

[j] https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/cancer-survivor/art-20045524#:~:text=Bone%20problems%2C%20such%20as%20joint,late%20effects%20of%20cancer%20treatment.

[k] Laila König et al., *Secondary Malignancy Risk Following Proton vs. X-ray Treatment of Mediastinal Malignant Lymphoma: A Comparative Modeling Study of Thoracic Organ-Specific Cancer Risk*, 10 FRONTIERS IN ONCOLOGY 1, 1-9 (2020) https://pmc.ncbi.nlm.nih.gov/articles/PMC7358352/.

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