UMass Memorial Health Care, Inc.

Determination of Need Application # UMMH-25021208-HE

Attachments

Substantial Change in Service

Substantial Capital Expenditure

Addition of Proton Therapy Service

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Submitted By

UMass Memorial Health Care, Inc. One Biotech Park 365 Plantation Street Worcester, Massachusetts 01605

Table of Contents

- 1. Narrative
 - Introduction
 - **Project Description**
 - Factor 1 Patient Panel, Need, Public Health Values and Operational Objectives
 - **Factor 2 Health Priorities**
 - Factor 5 Relative Merit
 - Factor 6 Community-Based Health Initiatives
 - Exhibits
- 2. Certification from an Independent Certified Public Accountant
- 3. Notice of Intent
- 4. Articles of Organization
- 5. Affidavit of Truthfulness and Compliance
- 6. Filing Fee Check
- 7. Affiliated Parties Form
- 8. Change in Service Form

ATTACHMENT 1

Introduction

UMass Memorial Health Background

UMass Memorial Health Care, Inc. (the Applicant or UMMH) is the largest integrated health care delivery system and employer in Central Massachusetts with more than 20,000 employees and 2,400 physicians.¹ The UMMH system includes one academic medical center, UMass Memorial Medical Center (UMMMC), four acute care community member hospitals, including UMass Memorial-Marlborough Hospital (Marlborough Hospital), UMass Memorial Medical Center Cancer Center at Marlborough (Cancer Center), UMass Memorial Medical Group, and the UMass Memorial Hospital at Home Program. The University of Massachusetts Medical Center (UMMC) was created through an act of the legislature 40+ years ago to be the primary clinical partner to the University of Massachusetts T.H. Chan Medical School (UMass Chan), the Commonwealth's only medical school. UMMH was formed in 1998 through the merger of UMMC with Memorial Hospital.

UMMH is the only safety net health system in Central Massachusetts, caring for a diverse patient population, with almost 70 percent of UMMH's patients insured by Medicare or Medicaid. Four of UMMH's acute care hospitals are designated as Disproportionate Share Hospitals (DSH) because of the high percentage of patients insured by government payors. UMMH's mission is to deliver culturally sensitive, excellent clinical care. UMMH strives to make health and wellness services available to its patients close to their homes and regardless of their ability to pay. UMMH has been widely recognized for its excellence in cancer care and for successfully advancing health equity.²

Advanced Oncology Services and Improved Outcomes

UMMH provides advanced oncology services treating every type of cancer, as well as access to more than 150 clinical trials and academic medical expertise through its long-standing affiliation with UMass Chan. UMMH's cancer services are supported by the academic partnership with UMass Chan, which continues to grow as both organizations work collaboratively to conduct clinical trials in cancer and train and educate the next generation of physicians, nurses, and allied health professionals in cancer treatment. In addition, UMMH has access to valuable resources and expertise through its affiliation with the Dana-Farber Cancer Care Collaborative.³

¹ System Statistics, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/about-us/system-statistics</u> (last visited March 3, 2025).

² In 2024, the Lown Institute awarded UMMH an "A" grade for social responsibility and performance in health equity, value, and outcomes. In the same year, *U.S. News & World Report* recognized UMMMC as the fifth "Best Regional Hospital" in Massachusetts, one of the "Best Regional Hospitals for Equitable Access," and "High Performing" in colon, lung, and prostate cancer surgery, as well as leukemia, lymphoma, and myeloma treatment. The Applicant was also listed by *Becker's Hospital Review* as one of the "Hospitals and Health Systems with Great Oncology Programs" in 2024

³ UMass Memorial Medical Center and the Dana-Farber Cancer Institute, UMASS MEMORIAL HEALTH, <u>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</u> (last visited Feb. 24, 2025).

UMMH's approach to cancer care delivers comprehensive treatment of the full range of its patients' health care needs.⁴ UMMH provides 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. UMMH enables patients to receive comprehensive cancer care as well as other primary and specialty care locally, across five sites of care, using a single, integrated electronic medical record (Epic) throughout the UMMH delivery system.

UMMH is a well-recognized leader in the provision of excellent cancer care as a result of its strong clinical and academic expertise and advanced treatment technology. In 2013, UMMMC expanded cancer care in the region by opening the Cancer Center in Marlborough, which provides patients across the system with access to distinguished specialists, advanced medical and radiation technology, innovative cancer treatment, and support services. Since its inception, the Cancer Center and its multidisciplinary programs have grown significantly to address the comprehensive cancer needs of UMMH's patients, as well as patients of the broader Commonwealth. UMMH is recognized for its efforts to improve oncology patient health outcomes through the delivery of modern technological innovations, procedures, and therapies. UMMH is distinguished as the first system 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 as having the only facility in Central and Western Massachusetts to offer accredited CAR T-cell therapy for the treatment of malignancies. Notably, UMMH is accredited by five different professional societies for oncology related services.⁵

The growth in cancer care services at UMMH is due, in large part, to UMMH's and UMass Chan's collaborative development of strong clinical and academic departments focused on oncology, particularly in medicine, surgery, and radiation oncology. UMMH's Radiation Oncology Department (Department) treated its first patient in the fall of 1984, and today is one of the most established clinical and academic departments across UMMH and UMass Chan. The Department is managed by a single, centralized leadership team across five campuses and supported by an informatics system specific to radiation oncology (Aria). The Department is well-recognized in the region as a leading provider of radiation therapy clinical services and for academic excellence. Notably, TJ FitzGerald, MD, Professor and Chair of the Department, is a nationally recognized physician for his clinical, educational, and academic contributions to the field of radiation oncology. With a strong clinical and academic foundation and academic expertise in radiation oncology, UMMH is well positioned to continue advancing cancer services for patients in Central Massachusetts and beyond.

Proton Therapy: The Growing Need for Investment in Technology and Improved Access

The need for cancer care and the corresponding need for investment in the most advanced treatment therapies and technologies in Massachusetts continue to grow, particularly in Central Massachusetts where population growth and cancer diagnoses are increasing. According to

⁴ Cancer Care, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/services-treatments/cancer-center</u>, (Last visited Feb. 24, 2025).

⁵ UMMH is accredited by: (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.

estimates of the American Cancer Society, there were more than 44,000 new cancer cases in the Commonwealth in 2024.⁶ Of those patients, it is estimated that up to 66 percent will require radiation therapy and 15 percent of those requiring radiation or approximately 4,432, may benefit from proton therapy radiation treatment (Proton Therapy) specifically.⁷ Patient demand for Proton Therapy may be even greater than the foregoing estimate, given UMMH's proximity to residents of neighboring New England states and the relative geographic scarcity of Proton Therapy Centers. According to the National Association of Proton Therapy, 70 percent of U.S. residents live more than 100 miles away from a Proton Therapy Center.⁸

Proton Therapy is a form of external beam radiation therapy that uses particles (protons), rather than conventional x-ray (photon) radiation therapy, to target and kill cancer cells. Unlike conventional radiation therapy, which delivers radiation that has the potential to injure healthy tissue, Proton Therapy is a highly effective and proven cancer treatment that improves the precision of radiation in targeting tumors and reduces potential damage to healthy tissue in the body.⁹ This significantly reduces sequelae and the acute/chronic side effects of treatment. Depending on a patient's condition, Proton Therapy involves daily treatment and an average of 24 treatments.¹⁰

For years, Proton Therapy has been offered in New England exclusively at Massachusetts General Hospital, which is planning to take one of its two proton beam machines offline from 2025 until 2027. The next closest operating Proton Therapy Center is located out of state, in New York City.¹¹ Access to Proton Therapy has been challenging for patients in New England because of the distance to a Proton Therapy center and the daily and extended treatment regimen. Limiting Proton

⁶ 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].

⁷ Studies suggest between 50-66% of new cancer patients require radiation therapy. See HEALTH COUNCIL OF NETHERLANDS, PROTON RADIOTHERAPY, HORIZON SCANNING REPORT, Table 7.1 Estimated total number of patients eligible for proton radiotherapy in the Netherlands, 69-71 (2009) [hereinafter Dutch Report on Patient Eligibility], https://www.healthcouncil.nl/binaries/healthcouncil/documenten/advisory-reports/2009/12/11/proton-

radiotherapy/advisory-report-proton-radiotherapy.pdf (estimating total number of eligible patients for proton radiotherapy for all indications in the Netherlands based on 2005 Dutch Cancer Registry); see also Geoff Delaney et al., The Role of Radiotherapy in Cancer Treatment: Estimating Optimal Utilization from a Review of Evidence-Based Clinical Guidelines, 104 CANCER 1129-37, (2005); Radiation Therapy, ADVANCING MEDICAL TECHNOLOGY ASSOCIATION, https://www.advamed.org/our-work/sectors/radiationtherapy/#:~:text=Radiation%20therapy%20is%20a%20safe.some%20point%20during%20their%20care

^{(&}quot;Approximately 50%-60% of all people diagnosed with cancer receive radiation therapy at some point during their

care.") (last visited Feb. 24, 2025).

⁸ 2023 NAPT Member Survey: Executive Summary – Key Data on Proton Therapy in the U.S., NATIONAL ASSOCIATION OF PROTON THERAPY, <u>https://proton-therapy.org/wp-content/uploads/2023/10/Member-Survey-Exec-Summary.pdf</u> ("Proton therapy currently represents less than 1% of all radiation oncology treatments by modality, and approximately 70% of the U.S. population lives more than 100 miles from a treatment center.") (Last visited Feb. 24, 2025).

⁹ See discussion of clinical indications of Proton Beam Therapy *supra* Section F1.b.i.

¹⁰ UMMH clinical experts estimate the average number of treatments as 24, depending on the patient's condition and diagnosis. The National Association of Proton Therapy estimates the range as 5-39 treatments, depending on diagnosis. *See What is Proton Therapy, FAQs*, NATIONAL ASSOCIATION OF PROTON THERAPY, <u>https://proton-therapy.org/faq/#1691680097447-a702e83c-265a</u> (last visited Feb. 24, 2025).

¹¹ The mapping feature of The National Association of Proton Therapy demonstrates the relative dearth of currently operational proton therapy centers in New England. *See Find a Proton Therapy Center Near You*, THE NATIONAL ASSOCIATION FOR PROTON THERAPY, <u>https://proton-therapy.org/findacenter/</u> (last visited Feb. 24, 2025).

Therapy treatment to higher-cost Boston health care providers is neither beneficial to UMMH's patient panel, nor the Commonwealth. It restricts access to this highly effective, advanced cancer treatment by making it both financially burdensome and geographically difficult to access for thousands of patients whose lives and wellbeing could be improved by having access to Proton Therapy in a more affordable health care system that is more convenient and closer to home.

The cost of developing a Proton Therapy center has historically been prohibitive for most health care institutions. However, due to the miniaturization of the Proton Therapy unit with a smaller footprint and circular design, the cost of developing a Proton Therapy service has decreased considerably, making it feasible for more health care institutions.¹² Given the clinical efficacy of Proton Therapy to improve patient outcomes in both adult and pediatric care, as well as the new affordability of Proton Therapy, the number of Proton Therapy centers nationally and worldwide has increased in the past decade, with more than 100 facilities operating worldwide.¹³

In furtherance of its commitment to financial and geographic equity, UMMH aims to reduce the burden of accessing state of the art cancer care for individuals and their families by offering Proton Therapy in Marlborough. UMMH expects that the development of a Proton Therapy Service in Marlborough will improve patient outcomes and address the existing financial and geographic disparity between patients who can easily access Proton Therapy in Boston and those who cannot. Accordingly, the Applicant submits this application (the Application) in support of the development of a Proton Therapy Service in Marlborough.

¹² Yan et al., *Global democratization of proton radiotherapy*, 24 THE LANCET ONCOLOGY 245, e245-e254 (2023), <u>https://pubmed.ncbi.nlm.nih.gov/37269856/;</u> *see also*, JOANNE KIM ET AL., PROTON BEAM THERAPY FOR THE TREATMENT OF CANCER IN CHILDREN AND ADULTS: A HEALTH TECHNOLOGY ASSESSMENT [INTERNET] (2017), <u>https://www.ncbi.nlm.nih.gov/books/NBK531700/</u>.

¹³ Maria Giulia Vincini et al., *More than Five Decades of Proton Therapy: A Bibliometric Overview of the Scientific Literature*, 15 CANCERS (BASEL) 5545 (2023), <u>https://www.mdpi.com/2072-6694/15/23/5545</u>.

Project Description

The Applicant, with a principal place of business at One Biotech Park, 365 Plantation Street, Worcester, MA 01605, files this Application for Notice of Determination of Need (DoN) with the Massachusetts Department of Public Health for a substantial change in service and substantial capital expenditure. The Application includes: the acquisition of a single-gantry proton therapy system by UMMMC; the addition of Proton Therapy; and the physical expansion of 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). The maximum capital expenditure for the Proposed Project is estimated to be \$53,598,043.

UMMMC is an 826-bed academic medical center with multiple campuses and satellites in Worcester and the surrounding communities. UMMMC provides the full spectrum of tertiary acute care, including emergency care, inpatient and outpatient medical and surgical services, including radiology, cardiology, neurology, and oncology. Marlborough Hospital is a community hospital of UMMH providing emergency care as well as a wide range of services including inpatient, surgical, outpatient, and diagnostic services.

The Applicant decided to locate the Proton Therapy Service at the Cancer Center in Marlborough because it was determined to be the best site in terms of constructability, existing site and infrastructure conditions, and patient ease of access. The Cancer Center was also determined to be the most cost-effective location. In addition, the placement of the Proton Therapy Service at the existing Cancer Center provides patients and caregivers with contiguous, convenient access to advanced cancer care, including support services.

UMMMC plans to purchase the MEVION S250i System with HYPERSCAN pencil beam scanning technology, ¹⁴ which offers high-quality cancer treatment with reduced space and infrastructure requirements compared to traditional multi-room Proton Therapy services. The Proton Therapy Service will be equipped with advanced imaging and treatment planning capabilities, including 4D CT simulation and adaptive radiotherapy, allowing for precise targeting of tumors while minimizing damage to surrounding healthy tissues. The Proton Therapy Service will incorporate the latest advancements in patient positioning, imaging, and immobilization systems to ensure optimal treatment accuracy and reproducibility.

As discussed more fully below, the Proposed Project seeks to address the growing need for Proton Therapy in Central Massachusetts and beyond. The Proposed Project will provide the Applicant's patient panel with access to highly effective, advanced cancer care in Central Massachusetts. The need for the Proposed Project is supported by the volume of cancer cases requiring radiation therapy, the specific cancer indications treated by Proton Therapy, cancer growth trends in the UMMH Total Service Area as well as in Massachusetts more broadly, and regional population growth in Central Massachusetts. The Proposed Project is consistent with UMMH's history of clinical innovation and commitment to providing the most advanced life-saving treatment options available. The establishment of a Proton Therapy Service in Central Massachusetts will enhance

¹⁴ *MEVION S250 Proton Therapy System*, MEVION MEDICAL SYSTEMS, <u>https://mevion.com/products/mevion-s250-proton-therapy-system</u> (last visited Feb. 24, 2025).

UMMH's Cancer Center, offering residents the most cutting-edge radiation treatment option for certain types of cancers including, notably, pediatric cancers and an increasing number of adult malignancies. The Proposed Project will compete based on price, total medical expenses, provider costs, and other recognized measures of health care spending because the Project will provide patients with access to Proton Therapy from a more affordable health system without having to travel to a more expensive site of care. Accordingly, as more fully described below, the Proposed Project meets the factors for Determination of Need approval.

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

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

F1.a.i Patient Panel:

Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measures, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status, and other priority populations relevant to the Applicant's existing patient panel and payer mix.

A. UMass Memorial Health Care Patient Panel

Demographics

UMMH serves a large and diverse patient panel, caring for over 430,000 patients each year at its hospitals. The UMMH patient panel during FY22 through FY24 was approximately 56% female and 44% male in each of the three years. Age demographics show that the majority (approximately 58%) of patients were ages 18-64. Approximately 25% of UMMH patients are ages 65 plus and 17% are ages 0-17.

With respect to race, as self-reported by UMMH patients for FY22-FY24, the predominant race served by UMMH hospitals self-identified as White, making up approximately 74% of the patient panel. Additionally, approximately 7% of the patient panel self-identified as Black/African American and 3% as Asian. Because these numbers are self-reported, there is a significant percentage (14.6% in FY22, 15.3% in FY23 and 14.8% in FY24) of patients who reported their race as other or unknown. With respect to ethnicity, during FY22 through FY24, approximately 17% of the UMMH patient panel self-reported as Hispanic or Latino. Approximately 2% of the patient panel chose not to report their ethnicity and over 1% reported their ethnicity as unknown.

The majority of UMMH's hospital patients (approximately 90%) reside in Central Massachusetts, approximately 6% from the rest of Massachusetts, and approximately 4% reside out of state. See **Exhibit A** for a more detailed breakdown of patient panel demographics for FY22 through FY24.

Patient Panel Requiring Radiation Treatment¹⁵

From FY22 through FY24, an average of 1,600 UMMH patients received radiation oncology services in the form of X-ray based linear accelerator (LINAC) treatment (1,578 in FY22, 1,597 in FY23, and 1,697 in FY24).¹⁶ Like the general patient panel, the majority (approximately 93%)

¹⁵ UMMH has focused on the patient panel requiring radiation therapy rather than all cancer prevalence because not all patients with a cancer diagnosis receive radiation treatment. The focus on patients requiring radiation treatment more accurately represents the patient panel who would benefit from Proton Beam Therapy.

¹⁶ This data is based on UMMH patients who received LINAC treatment at one of the following campuses: UMMMC, HealthAlliance Clinton, or Marlborough Hospital. UMMH does not have information on the patient panel requiring radiation treatment for Harrington Hospital which joined UMMH as of October 1, 2024, or for Milford Hospital because UMMH does not provide radiation oncology services at Milford (cancer services are provided through a third-party affiliate).

of UMMH's cancer patients receiving LINAC treatment reside in Central Massachusetts. See **Exhibit B** for a more detailed breakdown of patient panel demographics by patients receiving LINAC treatment.

Payor Mix

UMMH serves a large percentage of patients who participate in government insurance programs. As demonstrated on <u>Exhibit C</u>, from FY22 through FY24, UMMH served approximately 25% of patients insured by Medicare Fee-For-Service, 19% insured by Managed Medicare, and 24% insured by MassHealth. Collectively, public payers make up almost 70% of UMMH's payor mix in FY22 through FY24.

B. UMass Memorial Medical Center Patient Panel

UMMMC served over 313,000 unique patients in FY24, representing the majority of the overall UMMH patient panel described above. As reported above and described on <u>Exhibits A-C</u>, the UMMMC patient panel is very similar to the overall UMMH 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.

F1.a.ii Need by Patient Panel:

Provide supporting data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question F1.a.i that demonstrates the need that the Proposed Project is attempting to address. If an inequity or disparity is not identified as relating to the Proposed Project, provide information justifying the need. In your description of Need, consider the principles underlying Public Health Value (see instructions) and ensure that Need is addressed in that context as well.

The Applicant seeks approval to expand the Cancer Center to add Proton Therapy at the Cancer Center in Marlborough. The Proton Therapy Service will be integrated with UMMMC's existing radiation oncology and medical oncology programs at the Cancer Center. As further described in this Application, the addition of the Proton Therapy Service will address the growing need of the UMMH patient panel, surrounding communities, and the Commonwealth for advanced cancer treatment technology which provides superior clinical efficacy for certain cancer indications, in a more accessible geographic setting with lower out-of-pocket costs and travel burden. The introduction of Proton Therapy to UMMH will increase the availability and accessibility of advanced cancer treatment technology, effectively meeting the growing need of UMMH's patient panel.

Availability of Modern Proton Therapy Systems

Until recently, access to Proton Therapy nationally has been limited, primarily due to its high capital and operational costs which made it prohibitively expensive for most healthcare systems. Advancements in technology and the development of a compact, single-gantry system have

significantly reduced these costs in recent years.¹⁷ As a result, Proton Therapy has become a more affordable and more viable treatment option for healthcare systems like UMMH, enabling them to better serve patients who meet the clinical criteria for this advanced therapy.

Need for Equitable Access to Proton Therapy in Massachusetts

Currently, there are only two Proton Therapy units in Massachusetts, both of which are operated by Massachusetts General Hospital at a single facility in Boston. For individuals with a cancer diagnosis living in Central and Western Massachusetts, the primary option for receiving Proton Therapy is to travel to Boston. As discussed below, travel to Boston may be challenging for many cancer patients because of travel-related expenses and other financial barriers associated with Proton Therapy's often daily treatment regimen and extended course of treatment. As a practical matter, the geographic disparity in access to advanced Proton Therapy may result in a higher standard of cancer care for patients for whom the expense and burden of travel to Boston is not prohibitive, compared to patients elsewhere in the state, including UMMH's patient panel.¹⁸

UMMH's existing patient panel would benefit from the higher standard of cancer care associated with Proton Therapy. As a health system with several DSH hospitals, UMMH's efforts to improve access to Proton Therapy may also advance health equity for its patients insured through government insurance programs. Further, the addition of a Proton Therapy Service in Marlborough will address geographic disparities in access to advanced cancer treatment and technology for UMMH's patient panel and the surrounding communities.

Need Based on Projected UMMH Proton Therapy Patient Panel

UMMMC is a tertiary academic medical center that provides a wide range of oncology services to residents of Central Massachusetts in the following subspecialty areas: bone marrow treatment, medical oncology, surgical oncology, and radiation oncology. UMMH currently does not provide Proton Therapy. As a result, UMMH does not maintain or receive reliable data (i.e., claims data) about the number of patients in its patient panel that ultimately receive Proton Therapy at another health care facility. UMMH has determined its projected patient panel for medically appropriate

¹⁷ Yan, et al., *supra* note 12 ("less than 1% of patients undergoing radiotherapy worldwide currently receive proton therapy, 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 proton therapy equipment. A single-room treatment unit costs from US\$30 to \$50 million, whereas conventional x-ray systems cost up to about \$6 million. The global democratization of proton radiotherapy aims to make this form of treatment accessible to more patients worldwide."); KIM ET AL., *supra* note 12 (evaluating relative costs of not providing proton beam therapy in Canada, constructing a Mevion single-vault PBT system, and constructing a multi-vault system, and concluding that "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 (<u>Table 24</u>). This is because the 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.").

¹⁸ Reshma Jagsi et al., *Real-Time Rationing of Scarce Resources: The Northeast Proton Therapy Center Experience*, 22 J. OF CLINICAL ONCOLOGY 2246, 2246-2250 (2004), <u>https://ascopubs.org/doi/10.1200/JCO.2004.10.083</u> (discussing rationing scarce proton therapy treatment slots to patients at Massachusetts General Hospital, and theoretical approaches to prioritization).

Proton Therapy based on its existing patient panel that receives LINAC treatment and would or may be eligible for Proton Therapy using the model Proton Therapy clinical coverage, as well as medical necessity policies from the American Society for Radiation Oncology (ASTRO).¹⁹ The ASTRO PBT Model Policies establish medical appropriateness of Proton Therapy in two groups: **Group 1** which includes certain disease sites that meet medical necessity requirements and published clinical data, and are, therefore, suitable for coverage of Proton Therapy; and **Group 2** which includes all other indications that may be suitable for coverage with further clinical evidence development under a Coverage with Evidence Development (CED) paradigm in which the patient is enrolled in a clinical trial or patient registry program.²⁰

Based on the ASTRO PBT Model Policies and UMMH LINAC patient panel data for FY24 as set forth on **Exhibit D**, UMMH estimates that 136 patients receiving LINAC services per year at UMMH would meet medical necessity criteria for Proton Therapy coverage as defined in Group 1 on an annual basis. In addition, UMMH has identified 1,533 of its patients receiving LINAC services per year that would fall in Group 2 diagnosis codes that could be covered under the CED paradigm on an annual basis. Although not all patients who fall in Group 2 are expected to meet medical necessity criteria for coverage, it is likely that the criteria for coverage will expand with further analysis and the development of clinical evidence under the CED paradigm.

These estimates reflect the existing UMMH patient panel that would or may qualify for Proton Therapy based on the ASTRO PBT Model Policies. Accordingly, UMMH can demonstrate the demographics and payor mix of the estimated Proton Therapy patient panel, as set forth on **Exhibit D** for FY22-FY24. Over 90% of this estimated Proton Therapy patient panel currently resides in Central Massachusetts, reinforcing the need for more equitable access to Proton Therapy in Central Massachusetts. In addition, and consistent with the overall UMMH patient panel, almost 70% of the estimated Proton Therapy patient panel is covered by a government insurance program and would benefit from more equitable provision of cancer care utilizing advanced technology.

Need Based on Projected Proton Therapy Population within the Geographic Region

In addition to UMMH's projected patient panel need for Proton Therapy, which is based on the existing LINAC patient panel, establishing a Proton Therapy Service in Marlborough is anticipated to support the growing need for advanced treatment technologies for cancer treatment based on the increasing cancer incidence in the region. Because Proton Therapy is still not widely available, UMMH utilized two different approaches to project the patient panel that would benefit from Proton Therapy treatment. Both approaches utilize population data and existing new cancer incidence rates to estimate the population that could benefit from both traditional radiation and Proton Therapy in UMMH's total service area and in Massachusetts, as follows.

A. <u>Methodology using American Cancer Society (ACS) Cancer Incidence Data (Exhibit F)</u>:

¹⁹ See AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO), PROTON BEAM THERAPY (PBT) MODEL POLICIES 1-21 (2022), <u>https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTROPBTModelPolicy.pdf</u> [hereinafter "ASTRO PBT Model Policies"].

This model utilizes a combination of new cancer incident rates per 1M population by disease type published by the American Cancer Society (ACS) in 2017²¹ and the estimates of the percentage of patients for whom Proton Therapy would reduce the risk of side effects as set forth in the 2009 Proton Radiotherapy – Horizon Scanning Report.²² In the Horizon Scanning Report, researchers estimated both the percentage of the population that would receive radiation treatment as well as those patients that would benefit from Proton Therapy by disease type. Based on these sources, UMMH projects the following patient panel for both UMMH's total service area and the Commonwealth:

1. UMMH Total Service Area (TSA) Proton Therapy Projected Patient Panel Need

Utilizing the ACS and Horizon Scanning Report estimates, UMMH estimates that of the almost 1.2M residents in UMMH's total service area, there were approximately 7,386 newly diagnosed cancer patients in 2024. Of those newly diagnosed cancer patients, UMMH estimates that there would be approximately 4,924 patients that would need some form of radiation treatment with about 15% of them or 743 patients that would meet clinical criteria for Proton Therapy. The ACS data suggest that by 2034, the annual number of patients needing Proton Therapy would increase to 1,017 patients, which is an increase of 37% compared to 2024's patient count. The supporting calculations for these estimates based on the ASC data are included as **Exhibit F**.

2. Massachusetts Proton Therapy Projected Patient Panel Need

Given the limited number of Proton Therapy units in Massachusetts, UMMH has determined that the Proposed Project can also support the needs of eligible Proton Therapy patients that reside outside of its existing service area. Utilizing the same American Cancer Society (ACS) and Horizon Scanning Report data, UMMH estimates that of the 7.1M Massachusetts residents that approximately 44,040 new cancer patients that were diagnosed in 2024. Of those patients, UMMH estimates that 29,360 patients that will need some form of radiation treatment with about 15% of them or 4,432 patients that would meet Proton Therapy clinical criteria. The ACS data suggest that by 2034, the annual number of patients needing Proton Therapy would increase to 6,065 patients, which is an increase of 37% compared to the patient count in 2024. The supporting calculations for these estimates based on the ASC data are included as **Exhibit F**.

B. <u>Methodology using National Cancer Institute (NCI) Cancer Incidence Rates (Exhibit G)</u>:

The second approach utilizes data from the NCI State Cancer Profiles.²³ The NCI State Cancer Profiles website provides interactive data tables and an interactive map engine produced in collaboration between the National Cancer Institute and Centers for Disease Control and Prevention, which provides a geographic profile of cancer burden in the United States and reveals geographic patterns of cancer incidence, mortality, risk factors for cancer, and cancer screening, across different population

 ²¹ AMERICAN CANCER SOCIETY CANCER, FACTS & FIGURES (2017), <u>https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/cancer-facts-and-figures-2017.pdf</u>.
²² Dutch Report on Patient Eligibility, supra note 7.

²³ Cancer Profiles: See NCI State 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).

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

1. UMMH Total Service Area (TSA) Proton Therapy Projected Patient Panel Need

According to the NCI State Cancer Profiles website and as set forth on <u>Exhibit G</u>, the annual cancer incidence rate results in 4,854 cases from Worcester County which constitutes the largest county serviced by UMMH. Utilizing the ACS and Horizon Scanning Report estimates described above, UMMH estimates that of the 4,854 annual cancer cases, 15% or 728 cases would meet clinical criterial for Proton Therapy. This closely approximates the estimates provided in the above approach "A" using ACS data, which results in 743 cases.

In addition, it is notable that, according to the NCI State Cancer Profiles, Worcester, Berkshire, and Plymouth counties, which are served by UMMH, all have the highest incidence rates of cancer in the Commonwealth.²⁴ See <u>Exhibit G</u> for a mapping of cancer incident rates by Massachusetts county.

2. Massachusetts Proton Therapy Projected Patient Panel Need

According to the NCI State Cancer Profiles website and as set forth on <u>Exhibit G</u>, the annual cancer incidence rate results in 38,523 cases in Massachusetts. Utilizing the ACS and Horizon Scanning Report estimates described above, UMMH estimates that of the 38,523 annual cancer cases, 15% or 5,778 cases would meet clinical criteria for Proton Therapy. This is reasonably close to the estimates provided in the above approach "A" using ACS data, which results in 4,432 cases.

Need for Geographically Accessible Proton Therapy in Massachusetts

UMMH reviewed available claims data for patients in its Accountable Care Organization (ACO) programs and identified a small number of patients who received Proton Therapy between November 2023 and November 2024.²⁵ As illustrated in **Figure 1** below, the sample of four patients live between 38 and 46 miles away from the Proton Therapy facility at Massachusetts General Hospital in Boston where the patients received Proton Therapy. The distance from the patients' home addresses to the proposed Proton Therapy Service in Marlborough ranges from 17 to 32 miles, or 22.5 miles shorter, on average, than the distance from the patients' home addresses to the Massachusetts General Hospital facility in Boston.

²⁴ See NCI State Cancer Profiles: Incident Rates Tables, supra note 23; NCI State Cancer Profiles: Interactives Maps – Massachusetts, NATIONAL CANCER INSTITUTE, https://statecancer.gov/map/map.withimage.php?25&county&001&001&00&0&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).

²⁵ UMMH's access to claims data for services provided by Massachusetts General Hospital is very limited and therefore, the data may not reflect all patients receiving Proton Radiation Treatment Delivery at Massachusetts General Hospital.



Figure 1: Patient examples (Black Circles) from UMMH Commercial and Medicare ACO populations that have received Proton Beam Radiation Treatment Delivery (CPT® Code 77525) at Massachusetts General Hospital between Nov. 2023 – Nov. 2024 based on claims data available to UMMH. Distance to Massachusetts General Hospital (Red Square) is estimated to be double the distance to the UMMH Marlborough Facility (Blue Circle). <u>Note</u>: Patient locations have been shifted from their actual location by 1.1km both longitudinally and latitudinally to protect the identity of these patients. UMMH's access to claims data for services provided by Massachusetts General Hospital is highly limited and therefore, data does not reflect all the patients receiving Proton Beam Radiation Treatment Delivery at Massachusetts General Hospital.

While the above **Figure 1** represents a small sample of the existing patient panel, to further demonstrate patient need for Proton Therapy outside of the Boston area, in **Figure 2** and **Table 1** below, UMMH analyzed the geographic accessibility of the 136 UMMH patients in the ASTRO Proton Group 1 relative to the proposed Proton Therapy Service in Marlborough. Patients in this Group 1 would need to drive an average of 51.1 miles to the Proton Therapy facility at Massachusetts General Hospital, taking approximately 60 to 80 minutes each way depending on the time of day. However, patients traveling to the Cancer Center in Marlborough would need to travel 29.3 miles on average, taking approximately 35 minutes each way regardless of the time of day. Traveling to Marlborough instead of downtown Boston could save patients in Group 1 who would be eligible for Proton Therapy between 19 and 36 hours of driving time, depending on the

time of day, over the 24 treatments in the average course of treatment.²⁶ When totaled across all 136 patients, traveling to Marlborough instead of downtown Boston could save a total of between 2,500 and 4,900 hours of driving for patients receiving Proton Therapy during their course of treatment, depending on the time of day of travel.²⁷ Shorter travel times—along with lower ancillary costs such as parking, food, and gas—can affect a patient's decision of whether and where to receive a clinically appropriate course of treatment.



<u>Figure 2</u>: UMMH's ASTRO Proton Therapy Group 1 patient examples (Black Circles) representing distances from Massachusetts General Hospital (Red Square) and Marlborough Hospital (Blue Circle). <u>Note</u>: Patient locations have been shifted from their actual location by 1.1km both longitudinally and latitudinally to protect the identify of these patients.

	Driving Distance		Travel Time – 9AM		Travel Time – 2PM	
Metric	Driving Distance to Marlborough Hospital	Driving Distance to Mass General Hospital	Travel Time to Marlborough Campus at 9:00AM EST	Travel Time to Mass General Hospital at 9:00AM EST	Travel Time to Marlborough Camus at 2:00PM EST	Travel Time to Mass General Hospital at 2:00PM EST
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)	1406 miles	2452 miles	28.08 hours	64.16 hours	27.36 hours	46.24 hours

²⁶ This is calculated based on the data in **Table 1** as the difference in driving time between the patient's residence to MGB and the patient's residence to the Cancer Center in Marlborough, multiplied by 2 for each direction, multiplied by 24 treatments, when driving at 9AM and at 2PM.

 $^{2^{7}}$ This is calculated as the saved driving time from the calculation in the preceding footnote multiplied by 136 patients in Group 1.

Total travel for	191,270 miles	333,580	3,819 hours	8,726 hours	3,721 hours	6,289 hours
treatment (24 two-		miles				
way trips for 136						
patients)						
putients)						

Table 1: This table corresponds with the mapping of UMMH's ASTRO Proton Therapy Group 1 patient examples. This table provides estimated average and total travel times for these 136 patients from MA and CT. In this table, UMMH calculates the average driving distance and travel time of the 136 Group 1 patients in the first row, the average driving distance and travel time of the 136 group 1 patients over the course of 24 treatments in the second row, and the total driving distance and travel time of the 136 Group 1 patients have been shifted from their actual location by 1.1km both longitudinally and latitudinally to protect the identify of these patients.

In summary, UMMH anticipates that with only two Proton Therapy units in Massachusetts, the addition of a Proton Therapy service in Marlborough would not only support the needs of UMMH's existing patient panel, but also those patients residing both in and beyond UMMH's total service area and would help alleviate geographic disparities in access to advanced technology cancer care.

F1.a.iii Competition:

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

The Proposed Project encourages competition in the Massachusetts health care market by making innovative, advanced cancer treatment available outside of Boston and Central Massachusetts. The Proposed Project is anticipated to compete effectively based on price, total medical expense, and provider costs.

As discussed above, patient access to Proton Therapy in Massachusetts is currently limited because there are only two Proton units, both of which are located in Boston, and offered by a single provider, Massachusetts General Hospital. The Proposed Project to establish a Proton Therapy Service in Marlborough will increase competition by providing access to Proton Therapy for patients outside of Boston. Massachusetts General Hospital plans to take one of its Proton Therapy units out of operation in the near future for replacement. As a result, there will likely be an increased need for access to Proton Therapy because one of the two existing Proton Therapy units in the Commonwealth will not be in operation for a period of time. The Proposed Project to open a Proton Therapy Service in Marlborough will address this need and access challenge, foster market competition by introducing another provider, as well as create technological redundancy in case a Proton unit requires downtime or replacement in the future.

UMMH can compete effectively on price for Proton Therapy services compared to other Boston academic medical centers as a lower-cost, high-quality alternative, and referral partner. As reflected in the Center for Health Information and Analysis (CHIA) relative price data set for in

Exhibit E, UMMMC is one of the lowest cost academic medical centers in the Commonwealth.²⁸ Massachusetts General Hospital is the only other hospital providing Proton Therapy in Massachusetts and the surrounding communities, and has rates that are higher than UMMMC's rates based on the CHIA relative price data for academic medical centers on **Exhibit E**. Advancements in Proton Technology have also lowered the capital cost to enter the market, enabling UMMH to offer its patient panel and surrounding communities, as well as third-party payors, a cost-effective choice for receiving clinically appropriate Proton Therapy. In addition, UMMH has decided to locate the Proton Therapy Service at the existing Cancer Center in Marlborough in order to avoid costly new building and operational expenses.

In summary, the Proposed Project will foster real market competition and improve access to Proton Therapy in the Commonwealth. The Proposed Project will allow for greater patient access in a growing, underserved market outside of Boston, which will create more competition that offers expanded patient and insurance choices and has the potential to lower downstream total medical expenses due to potential reductions in side effects and post-treatment complications which might reduce the need for additional clinical services. Although the utilization of Proton Therapy in the Commonwealth has been limited largely due to the cost of entry, today's advancements in proton technology allow these services to be brought to the market in a more cost-effective manner and in a more affordable, lower cost health system. For these reasons, UMMH has determined that the Proposed Project will compete effectively on price, provider costs, and total medical expenses.

F1.b.i Public Health Value / Evidence-Based:

Provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need that Applicant has identified.

Clinical Efficacy of and Need for Proton Therapy Treatment

Cancer care necessitates continuous innovation to address the growing need for highly effective, yet minimally harmful treatments. Approximately 52% of cancer patients in North America undergo radiation therapy, predominantly using photon-based (traditional radiation therapy) modalities.²⁹ Despite significant advances in photon therapy, its well-known and fundamental limitations remain. These limitations, particularly the unavoidable "exit dose" (defined below), and consequent harmful exposure of normal tissue, underscore the pressing need for advanced modalities like Proton Therapy, as seen in <u>Exhibit H</u>.³⁰ Proton Therapy offers significantly improved therapeutic outcomes. The following sections describe the comprehensive evidence and scientific underpinnings that validate the integration of Proton Therapy into existing cancer care treatment as a pivotal advancement in the field of cancer care.

²⁸ CHIA, *CY 2022 Relative Price and Provider Price Variation*, Databook (Excel) (2024), <u>https://www.chiamass.gov/relative-price-and-provider-price-variation/</u>.

²⁹ Delaney et al., *supra* note 7.

³⁰ See What is Proton Therapy, infra note 36.

Photon Therapy: Current State and Limitations

Photon therapy relies on high-energy photons generated by linear accelerators.³¹ Over the years, significant technological advancements have generated process improvements in photon therapy including intensity modulation and image guidance.³² For example, new tools allow radiation oncologists to shape radiation beams, improving tumor targeting while reducing damage to normal tissue.³³ Engineering advancements have allowed for the integration of diagnostic imaging and therapeutic processes into the linear accelerator footprint, streamlining quality assurance metrics through computer-controlled systems.³⁴ These features have made photon therapy a cornerstone of cancer care, offering compact systems, cost efficiency, and reproducibility.³⁵

However, photon beams inherently pass through the target tissue and exit the body. This "exit dose" is the residual radiation deposited in surrounding normal tissues beyond the intended treatment volume, as seen in **Exhibit H**.³⁶ Despite advanced planning techniques, unintended normal tissue exposure leads to complications, including organ dysfunction and secondary malignancies.³⁷ This limitation of photon therapy cannot be entirely mitigated, even with optimal engineering and treatment planning.³⁸ The persistent challenges and relative risk to patient safety associated with exit dose necessitate the consideration of alternative cancer treatment modalities that inherently avoid these drawbacks, particularly for specific types of cancer and specific patient populations. The process improvements in modulated therapy and image guidance are now incorporated into Proton Therapy.³⁹

Proton Therapy: The Evidence for Addressing Photon Therapy's Weaknesses

Proton Therapy, a form of charged particle therapy, provides a transformative and highly effective alternative to traditional photon therapy.⁴⁰ With Proton Therapy, Protons deliver precise doses to

³¹ WP Levin et al., *Proton Beam Therapy*, 93 BRITISH JOURNAL OF CANCER 849, 849-54 (2005), <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC2361650/</u>.

 $^{^{32}}$ Levin et al., *supra* note 31.

³³ Levin et al., *supra* note 31.

³⁴ Levin et al., *supra* note 31.

³⁵ Langen & Mehta, *infra* note 40.

³⁶ See What is Proton Therapy, NATIONAL ASSOCIATION FOR PROTON THERAPY, <u>https://proton-therapy.org/wp-content/uploads/2023/08/Screenshot-2023-08-16-at-9.04.49-AM.png</u> (depicting a visual representation of exit dose and its impact on surrounding tissues).

³⁷ Kyle Wang & Joel E. Tepper, *Radiation Therapy-Associated Toxicity: Etiology, Management, and Prevention*, 71 CA CANCER J. CLIN. 437, 437-54 (2021), <u>https://pubmed.ncbi.nlm.nih.gov/34255347/</u>.

³⁸ 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) <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC7358352/</u>.

³⁹ Levin et al., *supra* note 31.

⁴⁰ Levin et al., *supra* note 31 ("Proton beam radiotherapy, one form of charged particle therapy, allows for excellent dose distributions, with the added benefit of no exit dose. These characteristics make this form of radiotherapy an excellent choice for the treatment of tumors located next to critical structures such as the spinal cord, eyes, and brain, as well as for pediatric malignancies."); 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 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).").

tumors without an exit dose, thereby minimizing normal tissue exposure.⁴¹ Because Proton Therapy does not generate an exit dose, patients receiving Proton Therapy have fewer instances of treatment-related toxicity due to decreased dose to normal tissue volumes.⁴² To date, there are fewer secondary malignancies, and improved quality of life.⁴³

For example, in one large study involving 1483 patients with multiple cancer types, proton chemoradiotherapy was associated with highly 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.⁴⁴

Further, Proton Therapy demonstrates clear clinical benefits across multiple cancer types, as described below and in <u>Exhibit H</u>.⁴⁵ Some of the most common applications include:

1. Pediatrics: Proton Therapy offers significant advantages for pediatric patients by reducing long-term risks and preserving quality of life. Studies show that Proton Therapy minimizes radiation exposure to vital organs and healthy tissues compared to traditional photon therapy, reducing the risk of long-term damage and secondary malignancies.⁴⁶ Specifically, at least one study demonstrated that Proton Therapy significantly lowers radiation exposure to critical organs such as the bowels, stomach, liver, kidneys, and spleen, potentially reducing damage to these vital areas.⁴⁷ The 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.⁴⁸ Importantly, no cases of local or marginal cancer recurrence were recorded, further validating the treatment's effectiveness. Proton Therapy also preserves cognitive function, including full-scale IQ, processing speed, and working memory, due to its superior dose-sparing capabilities for healthy brain tissue, leading to more stable intellectual outcomes over time.⁴⁹ These findings underscore Proton

⁴¹ Levin et al., *supra* note 31; Langen & Mehta, *supra* note 40.

⁴² Levin et al., *supra* note 31; Langen & Mehta, *supra* note 40.

⁴³ Bree R. Eaton et al., *Secondary Malignancy Risk Following Proton Radiation Therapy*, 5 FRONTIERS IN ONCOLOGY 1, 1-6 (2015).

⁴⁴ Brian C. Baumann, et al. Comparative Effectiveness of Proton vs Photon Therapy as Part of Concurrent Chemoradiotherapy for Locally Advanced Cancer, 6 JAMA ONCOLOGY 237, 237–246 (2019), https://pubmed.ncbi.nlm.nih.gov/31876914/.

⁴⁵ 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 Proton Therapy. *See Clinical Research*, THE NAT'L ASS'N FOR PROTON THERAPY, <u>https://proton-therapy.org/clinical-research/</u> (last visited Feb 26, 2025).

⁴⁶ Jiang et al, *Outcomes of Proton Therapy to Infradiaphragmatic Sites in Pediatric Patients with Hodgkin Lymphoma*, 71 PEDIATRIC BLOOD & CANCER 1, 1-10 (2024); *see also* Christine S. Chung et al., *Incidence of Second Malignancies Among Patients Treated with Proton Versus Photon Radiation*, 87 INT'L J. OF RADIATION, ONCOLOGY, BIOETHICS, PHYSICS 46, 46-54 (2013).

⁴⁷ Jiang et al., *supra* note 46.

⁴⁸ Chung et al., *supra* note 46.

⁴⁹ Lisa S. Kahalley et al., *Superior Intellectual Outcomes After Proton Radiotherapy Compared with Photon Radiotherapy for Pediatric Medulloblastoma*, 38 J. OF CLINICAL ONCOLOGY 454, 454-61 (2019) https://ascopubs.org/doi/full/10.1200/JCO.19.01706.

Therapy's importance as a safer and more effective radiation treatment option for pediatric patients.

- 2. Central Nervous System (CNS): Proton Therapy spares surrounding brain tissue while accommodating expanded target volumes derived from advanced imaging modalities.⁵⁰ Neuro-radiation oncology is greatly expanding its horizon with new techniques and modalities of care. Protons offer our best opportunity to optimize the therapeutic ration for care by limiting radiation exposure to normal tissue. 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.⁵¹ This will serve to limit late effects of management and optimize care moving forward.
- **3. Head and Neck:** Proton Therapy offers superior dosimetric precision that reduces radiation exposure to healthy tissues and significantly lowers the risk of treatment-related toxicities for head and neck cancers.⁵² Studies highlight Proton Therapy's ability to decrease acute and late side effects, including mucositis (inflammation of oral tissues), dry mouth, gastrostomy tube dependence, and opioid pain medication requirements, which are common complications associated with photon therapy.⁵³ This reduction in toxicities not only minimizes hospitalizations and improves patients' quality of life but also preserves critical structures near the tumor, supporting better functional outcomes.⁵⁴ While the upfront costs to UMMH for Proton Therapy may be higher, its potential to reduce long-term healthcare expenses for patients associated with retreatment and improve overall patient outcomes makes it a compelling treatment option for head and neck cancer management.⁵⁵

⁵⁰ *Proton Therapy for Brain Tumors*, JOHNS HOPKINS MEDICINE <u>https://www.hopkinsmedicine.org/health/conditions-and-diseases/brain-tumor/proton-therapy</u> (last visited Feb. 26, 2025).

⁵¹ Ludmir e, Mahajan A, Ahern V et al., *Assembling the brain trust: the multidisciplinary imperative in neurooncology*, NAT REV CLIN ONCOL 2019 16 (8) 521-22 doi 10.1038/s41571-019-0235-z, https://mdanderson.elsevierpure.com/en/publications/assembling-the-brain-trust-the-multidisciplinary-imperative-inne.

⁵² Paul B. Romesser et al., *Proton Beam Radiation Therapy Results in Significantly Reduced Toxicity Compared with Intensity-Modulated Radiation Therapy for Head and Neck Tumors that Require Ipsilateral Radiation*, 118 RADIOTHERAPY & ONCOLOGY 286, 286-92 (2016) ("PBRT allowed greater sparing of normal tissue without sacrificing target coverage when irradiating the ipsilateral neck. This dosimetric advantage translated into significantly lower rates of acute treatment-related toxicity including dysgeusia, mucositis, and nausea.").

⁵³ Gohar S. Manzar et al., Comparative Analysis of Acute Toxicities and Patient Reported Outcomes between Intensity-Modulated Proton Therapy (IMPT) and Volumetric Modulated Arc Therapy (VMAT) for the Treatment of Oropharyngeal Cancer, 147 RADIOTHERAPY AND ONCOLOGY 64, 64–74 (2020); see also Mark W. McDonald, Acute Toxicity in Comprehensive Head and Neck Radiation for Nasopharynx and Paranasal Sinus Cancers: Cohort Comparison of 3D Conformal Proton Therapy and Intensity Modulated Radiation Therapy, 11 RADIATION ONCOLOGY 1, 1-10 (2016).

⁵⁴ Samir H. Patel et al., *Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-analysis*, 15 THE LANCET ONCOLOGY 1027, 1027-38 (2014); Pierre Blanchard et al., *Proton Therapy for Head and Neck Cancers*, 28 SEMINARS IN RADIATION ONCOLOGY 53, 53-63 (2018).

⁵⁵ Bharathi R Poovizhi, Ms. Athiyamaan, and Kamath Ashwin, *A Systematic Review of the Economic Burden of Proton Therapy in Head and Neck Cancer*, 1 ASIAN PAC J CANCER PREV. 3643, 3643-3653 (2023), https://pubmed.ncbi.nlm.nih.gov/38019221/.

- 4. Thoracic: Proton Therapy limits cardiac and pulmonary exposure, reducing risks of heart and lung damage.⁵⁶ A 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 Proton Therapy had statistically significant decrease in symptoms than those patients treated with photon therapy. Esophageal cancer is increasing in prevalence. 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 comparing proton and photon therapy with primary endpoints being progression free survival and toxicity burden. 145 patients were randomized and 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. Mediastinal lymphoma likewise is a cohort of patients who would greatly benefit from decreased dose to cardiac and pulmonary structures. An additional advantage to cardia sparing by Proton Therapy is lymphocyte sparing. If the cardia 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. By sparing more normal tissue, patient outcomes for thoracic malignancies improve.
- 5. Hepatocellular Carcinoma (Liver Cancer): Proton Therapy demonstrates superiority over photon therapy and stereotactic body radiation therapy (SBRT) for treating hepatocellular carcinoma by improving survival outcomes, reducing toxicity, and better preserving liver function. Studies show that patients treated with Proton Therapy experience higher overall survival and progression-free survival rates compared to photon-based radiation therapies and SBRT, even in complex cases.⁵⁷ Proton Therapy allows for higher radiation doses to the tumor while minimizing radiation-induced liver disease and protecting healthy liver tissue, which is crucial for patients with compromised hepatic function.⁵⁸ Additionally, Proton Therapy offers better local control, fewer post-treatment

⁵⁶ Lung Cancer, MD ANDERSON CANCER CENTER, <u>https://www.mdanderson.org/patients-family/diagnosis-treatment/care-centers-clinics/proton-therapy-center/conditions-we-treat/lung-cancer.html</u> (last visited Feb. 26, 2025); Steven H. Lin et al., *Randomized Phase IIB Trial of Proton Therapy Versus Intensity-Modulated Radiation Therapy for Locally Advanced Esophageal Cancer*, 10 J CLIN ONCOL. 1569, 1569-1579 (2020), <u>https://pubmed.ncbi.nlm.nih.gov/32160096/;</u> Penny Fang et al., *Lymphocyte Sparing Effect of Proton Therapy in Patients with Esophageal Cancer Treated with Definitive Chemoradiation*, 4 INT J PART THER 23, 23-32 (2017), <u>https://pubmed.ncbi.nlm.nih.gov/30079369/;</u> Liao Z. and Simone C., *Particle Therapy for non-small cell lung carcinoma*, TRANS LUNG CANCER RESEARCH 2018 7 (2): 141-52 doi 10.21037/tler.2018.04.11, https://pmc.ncbi.nlm.nih.gov/articles/PMC5960664/.

⁵⁷ Nina N. Sanford et al., Protons versus Photons for Unresectable Hepatocellular Carcinoma: Liver Decompensation and Overall Survival, 105 INT'L J. OF RADIATION ONCOLOGY, BIOLOGY, PHYSICS 64, 64-72 (2019), https://pubmed.ncbi.nlm.nih.gov/31602338/; see also Shakir Hasan et al., Proton Beam Therapy versus Stereotactic Body Radiotherapy for Hepatocellular Carcinoma: Practice Patterns, Outcomes, and the Effect of Biologically Effective Dose Escalation, 10 J. OF GASTROINTESTINAL ONCOLOGY 999, 999-1009 (2019), https://pubmed.ncbi.nlm.nih.gov/31602338/.

⁵⁸ Jen-Yu Cheng et al., *Proton versus Photon Radiotherapy for Primary Hepatocellular Carcinoma: A Propensity-Matched Analysis*, 15 RADIATION ONCOLOGY 1, 1-10 (2020), <u>https://pubmed.ncbi.nlm.nih.gov/32605627/</u>.

hospitalizations, and reduced overall costs compared to transarterial chemoembolization, highlighting its clinical and economic advantages.⁵⁹

- 6. Breast Cancer: Proton Therapy offers significant 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. The precision of Protons allows for highly targeted radiation delivery, sparing surrounding healthy tissues. ⁶⁰ This is particularly critical for left-sided breast cancer, where minimizing cardiac exposure is essential to reduce the risk of ischemic heart disease. ⁶¹ As a result, Proton Therapy treatment is particularly beneficial for patients unable to hold their breath during traditional photon breast cancer radiation treatment, which would otherwise reduce the cardiac exit dose. Compared to photon-based therapies, Proton Therapy demonstrates superior dosimetric outcomes, reducing radiation doses to the heart and left anterior descending artery, which are associated with improved long-term cardiac health. ⁶² Additionally, patients undergoing Proton Therapy experience lower rates of acute and late toxicities, contributing to a better quality of life during and after treatment.⁶³
- 7. Abdomen, Pelvis, and Extremities: Enhanced protection of bowel and kidney reduces organ toxicity. Bone and soft tissue sarcoma patients benefit from improved functional outcomes due to limited exposure to joint structures.⁶⁴

Additionally, 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, which increasingly recognize Proton Therapy as an important option for multiple cancer types, especially when minimizing normal tissue toxicity is critical, or when photon-based therapy limitations arise.⁶⁵ Furthermore, it is the preferred

⁵⁹ Transarterial chemoembolization (TACE) is a minimally invasive, image-guided procedure used primarily for treating Liver Cancer (Hepatocellular Carcinoma) and liver-dominant metastases. *See* David A. Bush et al., *Proton Beam Radiotherapy versus Transarterial Chemoembolization for Hepatocellular Carcinoma: Results of a Randomized Clinical Trial*, 129 CANCER 3354, 3354-3563 (2023), https://pubmed.ncbi.nlm.nih.gov/37503907/.

⁶⁰ Eugen B. Hug, *Proton Therapy for Primary Breast Cancer*, 13 KARGER 168, 168-72 (2018), <u>https://karger.com/brc/article-abstract/13/3/168/52755/Proton-Therapy-for-Primary-Breast-</u> Cancer?redirectedFrom=fulltext.

⁶¹ Ebbe Laugaard Lorenzen et al., *Radiation-Induced Risk of Ischemic Heart Disease Following Breast Cancer Radiotherapy in Denmark, 1977–2005*, 152 RADIOTHERAPY & ONCOLOGY 103, 103-110 (2020), https://pubmed.ncbi.nlm.nih.gov/32858067/.

⁶² Id.

 ⁶³ Lior Z. Braunstein & Oren Cahlon, Potential Morbidity Reduction with Proton Radiation Therapy for Breast Cancer, 28 SEMINARS IN RADIATION ONCOLOGY 138, 138-149 (2018), <u>https://pubmed.ncbi.nlm.nih.gov/29735190/</u>.
⁶⁴ Proton Therapy Case Study—Truncal Soft Tissue sarcoma, JOHNS HOPKINS MEDICINE (June 2, 2023),

https://www.hopkinsmedicine.org/news/articles/2023/06/proton-therapy-case-study-truncal-soft-tissue-sarcoma.

⁶⁵ See NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), NATIONAL COMPREHENSIVE CANCER NETWORK, <u>https://www.nccn.org/guidelines</u>; *Review of NCCN Guidelines: Discussion of Proton Therapy*, NATIONAL COMPREHENSIVE CANCER NETWORK (last reviewed: July 23, 2024) (consolidating and analyzing applications of Proton Beam Therapy under the NCCN Guidelines for Treatment of Cancer by Site, as available at <u>https://www.nccn.org/guidelines/category_1</u>).

treatment when there is a focus on reducing toxicity – particularly in pediatric, Carney complex, lung, esophageal cancers – and in cases where prior radiation was delivered.⁶⁶

Enhancing Survival Rates, Reducing Secondary Malignancies, and Improving Quality of Life

Proton Therapy offers unmatched precision in targeting tumors while sparing healthy tissues, making it one of the most effective treatments for cancers located near critical organs. This precision enables higher doses of radiation to be delivered directly to the tumor, improving tumor control, and enhancing survival rates.

For example, as described above, pediatric cancer patients benefit significantly from Proton Therapy because it minimizes the risk of long-term developmental delays and secondary cancers.⁶⁷ Further, Proton Therapy is associated with a lower risk of secondary cancers when compared to traditional radiation.⁶⁸ Similarly, for lung and esophageal cancer patients, Proton Therapy minimizes damage to vital organs such as the heart and lungs, reducing complications like radiation pneumonitis and cardiotoxicity—key factors that impact survival.⁶⁹

By reducing secondary malignancies and chronic conditions often associated with conventional radiation therapy, Proton Therapy improves not only patients' survival rates but also patients' quality of life.⁷⁰ 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.⁷¹ By minimizing damage to healthy tissues, Proton Therapy reduces the risk of secondary malignancies and chronic conditions often associated with conventional radiation, decreasing the need for ongoing medical interventions and enhancing patients' independence. These benefits are particularly vital in an era where cancer survivors are living longer, underscoring the importance of therapies that preserve quality of life while achieving effective tumor control.⁷²

This collective impact of improving survival, reducing secondary malignancies, and improving quality of life solidifies the role of Proton Therapy as a transformative modality in modern oncology care.

⁶⁶ Id.

⁶⁷ See discussion of Pediatric indications for Proton Beam Therapy, *supra* Section F1.b.i.

⁶⁸ See Chung et al., supra note 46 ("After we adjusted for sex, age at treatment, primary site, and year of diagnosis, proton therapy was not associated with an increased risk of second malignancy (adjusted hazard ratio, 0.52 [95% confidence interval, 0.32-0.85]; P=.009)....The use of proton radiation therapy was not associated with a significantly increased risk of secondary malignancies compared with photon therapy.")

⁶⁹ Michael Xiang et al., Second Cancer Risk after Primary Cancer Treatment with Three-Dimensional Conformal, Intensity-Modulated, or Proton Beam Radiation Therapy, 126 CANCER 3560, 3560-3568 (2020), https://pubmed.ncbi.nlm.nih.gov/32426866/; Radhe Mohan, A Review of Proton Therapy – Current Status and Future Directions, 6 PRECISION RADIATION ONCOLOGY 164, 164-76 (2022), https://pubmed.ncbi.nlm.nih.gov/36160180/.

⁷⁰ Raees Tonse et al., *Hospitalization Rates from Radiotherapy Complications in the United States*, 12 SCI. REP. 1, 1-7 (2022), <u>https://www.nature.com/articles/s41598-022-08491-8</u>.

⁷¹ Baumann et al., *supra* note 44; *see also* Vivek Verma et al., *Quality of Life and Patient-Reported Outcomes Following Proton Radiation Therapy: A Systematic Review*, 110 J. OF THE NAT'L CANCER INST. 341, 341-53 (2018), <u>https://pubmed.ncbi.nlm.nih.gov/29028221/</u>.

⁷² Mohan, *supra* note 69; *see also* Chung et al., *supra* note 46.

Effect of Geographic Proximity to Proton Therapy on Access to Care

Massachusetts reports over 44,000 new cancer cases annually,⁷³ many of which may benefit from the superior capabilities of Proton Therapy. As discussed above in section F.1.a.ii, current gaps in access to Proton Therapy disproportionately impact patients in underserved areas, such as Central and Western Massachusetts, where long travel distances to existing facilities in Boston or New York create significant barriers to care and may result in a different standard of care.⁷⁴ Studies, such as the one conducted by the University of Kentucky's Markey Cancer Center, highlight that geographic proximity is a critical factor in increasing access to Proton Therapy and reducing delays in treatment.⁷⁵ A recent study in JAMA Network Open found that the median drive time to the nearest Proton Therapy facility was 96.1 miles through the contiguous U.S., with more than 16% of U.S. residents living more than 4 hours from a Proton Therapy facility.⁷⁶ The study also found that poor access to Proton Therapy was associated with individuals living below the federal poverty line, individuals ages 65 and older, and individuals living in a rural area.⁷⁷ In addition, the Massachusetts Health Policy Commission recently warned in its February 27, 2025 report 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."⁷⁸

⁷³ ACS, supra note 6.

⁷⁴ Todd Burus et al., *Travel-Time Disparities in Access to Proton Beam Therapy for Cancer Treatment*, 7 JAMA NETWORK OPEN 1, 1-11 (2024), <u>https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2818955</u>; *see also, Addressing Travel-Time Disparities in Proton Beam Therapy Access*, NATIONAL ASSOCIATION OF PROTON THERAPY (May 29, 2024), <u>https://proton-therapy.org/addressing-travel-time-disparities-in-proton-beam-therapy-access</u> (Last viewed Feb. 27, 2025).

⁷⁵ Elizabeth Chapin, *Markey Study Finds Gaps in Access to Proton Beam Therapy*, UNIVERSITY OF KENTUCKY (July 29, 2024) <u>https://www.research.uky.edu/news/markey-study-finds-gaps-access-proton-beamtherapy#:~:text=A%20new%20University%20of%20Kentucky,advanced%20form%20of%20radiation%20treatment ; see also, Sierra Silverwood et al., *Distance Traveled by Patients Globally to Access Radiation Therapy: A Systematic Review*, 118 INT'L J. OF RADIATION, ONCOLOGY, BIOLOGY, PHYSICS 891, 891-99 (2024), https://pubmed.ncbi.nlm.nih.gov/37949324/.</u>

⁷⁶ Burus et al., *supra* note 74; *see also*, 2023 NAPT Member Survey: Executive Summary – Key Data on Proton Therapy in the U.S., NATIONAL ASSOCIATION OF PROTON THERAPY, <u>https://proton-therapy.org/wp-content/uploads/2023/10/Member-Survey-Exec-Summary.pdf</u> ("Proton therapy currently represents less than 1% of all radiation oncology treatments by modality, and approximately 70% of the U.S. population lives more than 100 miles from a treatment center.") (Last viewed Feb. 24, 2025).

⁷⁷ Burus et al., *supra* note 74.

⁷⁸ 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 the Literature. 20 The Oncologist 1378. 1378-1385 (2015).of 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-nationpart-2-patient-economic-burdencancer-care-more-21-billion-united-states-2019.).

<u>Clinical Efficacy of Proton Therapy May Result in Potential Cost-Savings Associated with Better</u> <u>Health Outcomes</u>

Research has shown that Proton Therapy can lead to lower rates of complications, hospitalizations, and secondary cancers, resulting in improved patient outcomes and cost savings related to the avoidance of complications, hospitalizations and secondary cancers.⁷⁹ Reduced treatment complications associated with Proton Therapy may lower certain long-term health care costs.⁸⁰ For example, fewer hospitalizations, less reliance on medications, and a reduced need for long-term supportive care may yield potential cost savings to the overall health system.

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

Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.

As further described below, the Project is expected to result in positive health outcomes for the patient panel including higher survival rates and reductions in complications and secondary malignancies, improved quality of life related to reductions in tissue damage, and advancements in health equity by providing this highly effective treatment in a more affordable health system that is closer to patients' homes, thereby reducing treatment-related financial burdens.

Overview of Expected Health Outcomes, Quality of Life and Health Equity

Improved Clinical Outcomes

- Enhanced Tumor Control: Proton Therapy's superior dose distribution will result in better tumor targeting while sparing surrounding normal tissues.
- **Reduced Treatment-Related Toxicity:** The absence of an exit dose will minimize adverse effects, lowering the incidence of treatment-related organ dysfunction and secondary malignancies.

Cost and Health Equity Improvements

- **Potential Lower Downstream Costs for Patients and the Commonwealth:** Given Proton Therapy's ability to minimize short- and long-term complications of treatment, UMMH anticipates lower long-term healthcare costs for patients and the Commonwealth through reduction in unplanned hospitalizations and reduction of secondary cancers.
- Health Equity: The Proton Therapy Service is expected to reduce disparities in access to advanced radiation oncology services by increasing geographic accessibility of Proton

⁷⁹ Baumann et al., *supra* note 44.

⁸⁰ See discussion of clinical benefits of Proton Therapy and effect on cost-containment *infra* Section F2.a.

Therapy for patients in Central and Western Massachusetts, many of whom are insured by government payors and have travel-related financial barriers to access.⁸¹

Expanded Access to Advanced Cancer Care and Quality of Life Improvements

• **Regional Access:** Marlborough's location near major highways reduces travel barriers for patients from Worcester County and Western Massachusetts. By locating the Proton Therapy Service in Marlborough, diverse populations will have easier access to this cutting-edge radiation therapy which will reduce complications of care, improve quality of life, and improve outcomes.⁸²

Monitoring Outcomes

To assess the impact of the Project, UMMH will monitor and report the following metrics and projections:

- 1. Metric: Patient access
 - a. Measure: New patient volume at the Proton Therapy Service.
 - **b. Projections:** 300 new patients treated each year from UMMH 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 Proton Therapy.
 - **b. Projections:** Less than 1% of Proton Therapy patient population will be hospitalized due to sequelae of management.⁸³
 - 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.

⁸¹ Simona Gaito et al., *Assessing Equity of Access to Proton Beam Therapy: A Literature Review*, 35 CLINICAL ONCOLOGY 528, 528-36 (2023), <u>https://pubmed.ncbi.nlm.nih.gov/37296036/</u> ("All the studies evaluated in this review showed disparities in the access to PBT. As pediatric patients make up a significant proportion of the PBT-eligible patients, equity of access to PBT also raises ethical considerations. Therefore, further research is needed into the equity of access to PBT to reduce the care gap.").

⁸² Sierra Silverwood et al., *Distance Traveled by Patients Globally to Access Radiation Therapy: A Systematic Review*, 118 INT'L J. OF RADIATION, ONCOLOGY, BIOLOGY, PHYSICS 891, 891-899 (2024), <u>https://pubmed.ncbi.nlm.nih.gov/37949324/</u> ("Geographic location, urban versus rural residence, and patient population characteristics affected the distance patients traveled for radiation therapy.").

⁸³ Tonse et al., *supra* note 70.

- **b.** Projections: Baseline satisfaction scores are 90% and are projected to increase to > 90% within two (2) years.
- **c.** Monitoring: Survey results are reported monthly and analyzed biannually by a patient advisory committee.

F1.b.iii Public Health Value /Health Equity-Focused:

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need-base, please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g., culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

UMMH serves as a safety net health system, providing access to high-quality care for all patients, regardless of financial or geographic barriers. As discussed below, the proposed Proton Therapy Service in Marlborough will address the critical need for equitable access to advanced cancer treatment, including for UMMH's predominantly Medicare and Medicaid patient panel.⁸⁴ By reducing travel and financial burdens, the UMMH Proton Therapy Service in Marlborough is expected to improve treatment adherence and patient outcomes, especially for patients who previously found accessing Proton Therapy prohibitive.

Addressing Geographic Barriers for Underserved Communities

Across the nation, access to Proton Therapy varies widely due to geographic proximity of Proton Therapy centers, disproportionately limiting access for rural and senior patients, as well as those living below the federal poverty line.⁸⁵ Currently, the only viable options for patients in Central and Western Massachusetts who need Proton Therapy are to travel to Boston or out of state. For many cancer patients, treatment in Boston or out of state is infeasible due to travel-related and financial barriers associated with the often-daily Proton Therapy treatment regimen, effectively leading to a disparity in cancer care between those in the Boston area and those in the UMMH patient panel and surrounding communities. By offering a closer alternative in Marlborough, the Proposed Project will help expand access to advanced cancer treatment across the region and the Commonwealth.

Addressing Financial Barriers for Medicare and Medicaid Patients

Financial constraints may further limit access to Proton Therapy for the UMMH patient panel, which is made up of a high percentage of Medicare and Medicaid patients who may struggle with

⁸⁴ 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)."

⁸⁵ Burus et al., *supra* note 74; Gaito et al. *supra* note 81.

out-of-pocket costs of lodging, transportation, and extended treatment regimens.⁸⁶ These financial burdens may be felt more acutely by low-income Massachusetts residents without flexible jobs, affordable childcare, or a reliable source of transportation, as well as by Massachusetts' senior residents who may not have caretakers, a means of travel, or the physical health for lengthy travel on a daily basis.

With respect to lodging costs, a cost comparison reveals that hotel rates in Boston are 39% higher than those in Marlborough, making extended stays associated with the potential extended course of Proton Therapy treatment prohibitively expensive.⁸⁷ By establishing a closer Proton Therapy Service in Marlborough, patients will have the option to stay at home without additional cost, or, if necessary, secure accommodations at much lower costs compared to Boston. Additionally, validated parking at Mass General Hospital costs \$13 per visit, adding up to approximately \$300 over an average 24-session treatment course—whereas parking at UMMH Marlborough is free, eliminating this expense.⁸⁸

Proton Therapy centers typically serve a higher proportion of commercially insured patients, leaving those insured through government insurance programs with limited access. The Proton Therapy Service in Marlborough will directly address these challenges by providing a local, cost-effective alternative to enable the UMMH patient panel, including its Medicare and Medicaid patients, and the surrounding communities to have local access to the same high-quality, advanced cancer care available to others.

Improving Accessibility Through Local Care

Establishing a Proton Therapy Service in Marlborough strategically addresses long-standing challenges associated with traveling into Boston to access specialized cancer care. Located at the intersection of three major highways (I-90, I-495, and I-290), the Service will serve as an easily accessible hub for patients in Central and Western Massachusetts, and potentially from neighboring states like New Hampshire and parts of Connecticut.

Public transportation in the Marlborough region is also expanding and may provide patients in the region with affordable, daily transportation to reach the Proton Therapy Service. The MetroWest Regional Transit Authority (MWRTA) now offers Route 7C, which stops at the Marlborough

⁸⁶ URBAN INSTITUTE (2023), Kimá Jov Tavlor. et al., Guide to Equity in Medicaid, https://www.urban.org/sites/default/files/2024-01/Guide%20to%20Equity%20in%20Medicaid.pdf ("Medicaid members may have limited access to reliable transportation, sick leave, and paid time off, making it difficult to access health care... 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 (2024), INSTITUTE https://www.urban.org/sites/default/files/2024-02/Guide%20to%20Equity%20in%20Medicare.pdf ("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.").

⁸⁷ Boston Average Hotel Costs: Nightly Room Prices by Accommodation Type, BUDGET YOUR TRIP, https://www.budgetyourtrip.com/hotels/united-states-of-america/boston-4930956 (last visited Feb. 26, 2025); see also, Marlborough Average Hotel Costs: Nightly Room Prices by Accommodation Type, BUDGET YOUR TRIP, https://www.budgetyourtrip.com/hotels/united-states-of-america/marlborough-4943170 (last visited Feb. 26, 2025).

⁸⁸ Parking at Mass General, MASSACHUSETTS GENERAL HOSPITAL, <u>https://www.massgeneral.org/visit/parking-and-shuttles/parking</u> (last visited Feb. 26, 2025).

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.

Savings in Travel Time

As described in F1.a.ii, for the estimated 136 UMMH patients in the ASTRO Proton Therapy Group 1, there would be significant travel time reductions achieved by traveling to Marlborough instead of Boston:

- <u>*Per Trip Time Savings*</u>: Each one-way trip to Marlborough can save a patient 20 miles and 25 to 45 minutes of driving time, adding up to 19 to 36 hours over the full course of treatment.
- <u>*Total Time Savings*</u>: When multiplied across the 136 patients in ASTRO Group 1, the total time savings ranges from 2,500 to 4,900 hours, thereby significantly reducing the burden of travel.

By locating the proposed Proton Therapy Service in Marlborough, UMMH offers its patient panel and the surrounding communities a more convenient and accessible location, removing a major obstacle to specialized cancer care

Enhancing Patient Convenience and Quality of Life

In addition to time, distance, and cost-related barriers, convenient access to specialty care is a critical factor in a patient experience and medical decision making.⁸⁹ Many patients who need Proton Therapy undergo daily treatment for several weeks, making frequent long-distance travel highly stressful and disruptive. While some may stay overnight near treatment centers, most prefer to receive care closer to home to maintain their support system and daily routines where they live. Locating the Proton Therapy Service in Marlborough would offer more patients with access to convenient advanced cancer treatment, in close proximity of their homes.

⁸⁹ 2023 Patient Consumer Survey, JLL (2023), <u>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), <u>https://www.fsg.org/wp-content/uploads/2021/08/Equity-in-Specialty-Series-Brief-2_FSG-Increasing-Specialty-Care-Availability.pdf</u> ("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.").</u>

Promoting Health Equity Through UMMH's Health Equity Initiatives

In addition to improving access and affordability, the Proton Therapy Service will promote health equity through UMMH's longstanding systems and programs that advance health equity.⁹⁰ For years, UMMH has worked to improve health equity, as required by UMMH's CEO and Board. In 2018, the UMMH Board approved the system's 'Anchor Mission', a commitment to leverage UMMH's strength and resources to drive upstream changes in social determinants of health and equitable community development.⁹¹ To date, UMMH has invested more than \$5M into local projects across Central Massachusetts to address the growing housing crisis, support small business, and provide needed social services. In 2021, UMMH was recognized with the first Joint Commission / Kaiser Permanente Bernard Tyson Award for Health Equity Improvement, recognizing its work in reducing the disparity associated with well child visits between white, Black and Hispanic children.⁹² UMMH's culturally proficient staffing initiatives are an outgrowth of its commitment to inclusive and equitable care, with all UMMH staff trained to address the needs of patients of diverse socioeconomic and cultural backgrounds. The Proposed Project will utilize trained staff and receive the support of UMMH's dedicated health equity committee that oversees the implementation and continuous improvement of initiatives aimed at reducing disparities among UMMH patients.

Other health equity initiatives include financial assistance programs⁹³, social drivers of health screening and referral program, partnerships with local health centers and advocacy groups, community outreach efforts to identify and address barriers specific to underserved populations, and robust translator and interpreter services to support non-English speaking patients⁹⁴. For example, 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.

The Proton Therapy Service represents a transformative step in advancing health equity in cancer care. By reducing barriers to access, financial burdens, and disparities in treatment availability, the Proton Therapy Service will provide an inclusive and patient-centered model for delivering cutting-edge proton therapy. UMMH plans to engage in regular monitoring and collaboration with community partners in order to allow the benefits of the Proposed Project to be experienced by its patient panel, improving the health outcomes and quality of life for all of UMMH's patients.

⁹⁰ *Health Equity Strategy*, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/about-us/mission-vision-and-values/health-equity-strategy</u> (last visited Feb. 26, 2025).

⁹¹ Anchor Mission, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/anchor-mission</u> (last visited Feb. 26, 2025).

⁹² Health Equity Project Wins Tyson Award, UMASS MEMORIAL HEALTH: THE PURSUIT, (Feb. 28, 2024) https://pursuit.ummhealth.org/articles/health-equity-project-wins-tyson-award.

⁹³ *Financial Assistance Program Policy Summary*, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/sites/default/files/MH-FAP%20plain%20language%20summary%20051916.pdf</u> (last visited Feb. 26, 2025).

⁹⁴ Interpreter Services, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/patients-visitors/interpreter-services</u> (last visited Feb. 26, 2025).

F1.b.iv Provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

The establishment of the Proton Therapy Service is designed to improve cancer care for UMMH's existing patient panel, the majority of whom are Medicare and Medicaid beneficiaries. Almost 70% of UMMH's patient panel is comprised of individuals covered by these government insurance programs. By offering this state-of-the-art therapy locally, UMMH aims to enhance health outcomes, improve quality of life, and promote health equity for these underserved populations, who often face barriers to accessing advanced specialty care, and who may not have access to this more effective/safer modality which is currently only provided in the Boston area.

In summary, the Project's key expected health outcomes and improvements to quality of life are as follows:

A. Health Outcomes:

- Enhanced Targeting and Precision: Proton Therapy offers precise tumor targeting, which is especially beneficial for complex cases involving pediatric, neurological, or head and neck cancers. By minimizing damage to healthy tissues and reducing side effects, Proton Therapy improves both immediate treatment effectiveness and long-term health outcomes, a crucial benefit for the older, chronically ill population we primarily serve.
- **Reduction in Side Effects and Complications:** Proton Therapy's precision also leads to fewer side effects, which translates to fewer hospitalizations, quicker recovery, and a higher quality of life. This is particularly beneficial for older Medicare recipients and patients with multiple comorbidities, who may face more severe complications from traditional radiation therapies.
- Innovative Care Models for Improved Health Outcomes: UMMH has pioneered initiatives such as the Hospital at Home, Subacute Rehab at Home, and remote monitoring programs. These programs provide care in patients' homes, reducing readmission rates and improving overall patient outcomes. With more than 3,000 patients having already benefited from our Hospital at Home program, UMMH continues to find ways to reduce healthcare costs and improve health outcomes— critical factors for the Medicare and Medicaid population.

B. Quality of Life:

• Geographic Accessibility and Fewer Side Effects: Proton Therapy's ability to target tumors more precisely means fewer side effects, allowing patients to experience a better quality of life during and after treatment. This is especially critical for UMMH's high percentage of Medicare and Medicaid patients, who may already be chronically ill and may face additional challenges during and post traditional treatments.

• Comprehensive and Community-Based Care: UMMH's integrated care model ensures that patients not only receive Proton Therapy, but also have access to a range of support services, such as counseling, rehabilitation, and nutrition programs, improving overall quality of life.

C. Health Equity:

- Increased Access to Advanced Treatment for Medicare and Medicaid Patients: The new Proton Therapy Service will care for UMMH's predominately Medicare and Medicaid patient base, ensuring that these vulnerable populations have local access to cutting-edge cancer treatment, likely improving adherence to treatment plans.
- **Cost-Effective Care for Medicare and Medicaid Populations:** Providing Proton Therapy in the community helps mitigate the need for UMMH's patients to seek treatment at higher-cost Boston facilities and is expected to result in certain cost savings for the healthcare system in the Commonwealth and UMMH's patients, while still providing the advanced care they need.
- Eliminating Barriers to Access: Travel is a key barrier to accessing care for Medicare and Medicaid patients, as many of these individuals are older or live in rural areas. With the Proton Therapy Service located locally, these patients will have easier access to care without the burden of travel, significant travel related costs, or the difficulty of navigating large, urban healthcare facilities.
- **Commitment to Cultural Competency and Inclusion:** UMMH is deeply committed to diversity and inclusion in healthcare. UMMH's staff is trained to deliver culturally competent care, addressing the unique needs of our diverse patient base, including those covered by Medicare and Medicaid. UMMH is dedicated to making sure all patients, regardless of background or insurance status, receive respectful, high-quality care.

D. Reasonable Assurances of Health Equity:

- **Collaborative Community Engagement:** To promote equitable access, UMMH will continue efforts to engage underserved and minority communities, including by partnering with local organizations and providing outreach. UMMH will raise awareness about the Proton Therapy Service's availability and educate patients about the benefits of Proton Therapy, especially for those on Medicare and Medicaid.
- **Financial Assistance Programs:** UMMH offers a robust financial assistance program designed to reduce financial barriers to necessary care for qualifying low-income patients, particularly those on Medicare and Medicaid. UMMH's Proton Therapy Service will be fully integrated into this program, to overcome financial barriers to access for patients in need of Proton Therapy.
- Advancing Local, Cost-Effective Healthcare Services: The Proton Therapy Service is not only a step toward improving health outcomes but also aligns with UMMH's

broader strategy to lower healthcare costs over the long term. By keeping advanced treatments like Proton Therapy within the local community, patients may avoid costs associated with patient transfers to higher-cost Boston facilities.

F1.c Provide evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, how the Proposed Project will create or ensure appropriate linkages to patients' primary care services.

The Proposed Project will operate efficiently and effectively within UMMH's robust existing operational infrastructure that integrates health care across the health system. UMMH's established systems and processes for integrated care will allow for the incorporation of this advanced cancer treatment option, furthering continuity, and coordination of care for the patient panel. In addition, UMMH will bring its clinical expertise to effectively operate a Proton Therapy Service, in addition to continuing to operate an outstanding, integrated, highly effective cancer program with world-recognized leaders in radiation therapy.

A. Clinical Expertise

As described above, the Cancer Center is nationally recognized for delivering high quality cancer care, with "High Performing" outcomes in a number of cancer domains, according to US News and World Report. In addition, UMMH maintains radiation oncology accreditation with the American College of Radiology which provides the highest level of quality assurance. UMMH's Radiation Oncology Department (Department) has a complete portfolio of advanced technology patient care, including brachytherapy, stereotactic therapy treatment (SRS/SBRT), total body radiation therapy (TBI), and total skin radiation therapy (TSI). The Department 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. 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 UMMH faculty members as authors.⁹⁵ Dr. FitzGerald's expertise extends to Proton Therapy. UMMH also has a physicist on staff with experience with dosimetry in proton radiation therapy. If approved, UMMH anticipates recruiting additional experts during the planning and implementation process to develop and operate the Proton Therapy Service in order to provide high-quality patient care, operational effectiveness and coordination.

⁹⁵ See THOMAS J. FITZGERALD ET AL., RADIATION THERAPY (2023), <u>https://doi.org/10.5772/intechopen.104154</u>; THOMAS J. FITZGERALD & MARYANN BISHOP-JODOIN, *PROTON THERAPY - CURRENT STATUS AND FUTURE DIRECTIONS* (2021), <u>https://doi.org/10.5772/intechopen.91072</u>; THOMAS J. FITZGERALD & MARYANN BISHOP-JODOIN, DOSIMETRY (2022), <u>https://doi.org/10.5772/intechopen.98044</u>; THOMAS J. FITZGERALD, PROTON THERAPY – SCIENTIFIC QUESTIONS AND FUTURE DIRECTION (2024), <u>https://doi.org/10.5772/intechopen.111250</u>; THOMAS J. FITZGERALD, MEDULLOBLASTOMA – THERAPEUTIC OUTCOMES AND FUTURE CLINICAL TRIALS (2025), <u>https://doi.org/10.5772/intechopen.1002105</u>.

B. Integrated EMR

UMMH has long demonstrated excellence in system-wide coordination through its integrated Epic electronic medical record system (EMR). UMMH has been recognized as an "Epic Gold Stars Level 10" organization. The Epic Gold Stars Level 10 designation is the highest achievement for organizations using Epic's electronic health record (EHR) system, placing them in the top 3% of Epic users internationally and signifying excellence in EHR utilization and patient care. The Proton Therapy Service will utilize Epic, enabling seamless data sharing among oncology specialists, primary care providers, other clinical specialties, and support staff across the health system, to deliver integrated cancer care across all disciplines. Epic will enable real-time information sharing through system-wide access to treatment plans, imaging, and patient progress notes, thereby reducing the risk of errors and redundancies. When necessary and in accordance with applicable law, Epic also facilitates information sharing with caregivers outside of the UMMH system. The advanced reporting capabilities of Epic allow providers to better identify appropriate candidates for the Proton Therapy Service.

As described above, the integration of the Proton Therapy Service into the existing EMR framework is expected to enhance efficiency by allowing providers across disciplines to communicate and collaborate effectively, ensuring that patients receive consistent, high-quality care throughout their treatment journey.

C. Cancer Center Services & Supports

Patients who receive care at the Proton Therapy Service will be able to access all of the services and benefits of the Cancer Center, including care coordination, social work, financial counseling. Patients will be evaluated by UMMH'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 Proton Therapy.

D. Multidisciplinary Care Teams

Multidisciplinary care teams, a hallmark of UMMH's approach to managing complex patients, will serve as a cornerstone of the Proton Therapy Service's operations. 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 collaborative approach will allow patients to benefit from a wide range of expertise, improving treatment precision and outcomes. UMMH's multidisciplinary model also fosters continuity of care by reducing fragmentation and ensuring that all aspects of a patient's care are aligned.

E. Collaboration with PCPs and Other Specialists

The Proton Therapy Service will collaborate closely with primary care providers to create and monitor individualized care plans. Regular updates and feedback loops will be established to ensure comprehensive patient management. For example, radiation oncologists currently, and will continue to, 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 collaboration will facilitate patient-centered and holistic health care by addressing the full spectrum of patients' health concerns.

UMMH's focus on population health initiatives will further enhance the Proton Therapy Service's ability to deliver coordinated care. Nurse navigators will work closely with patients, oncologists, and primary care providers to 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 are receiving Proton Therapy, reducing delays in care, optimizing treatment outcomes, and providing holistic care for the patient.

F. Patient Navigation Services

As described above, patients of the Proton Therapy Service will also be able to receive UMMH's dedicated patient navigation services which are anticipated to foster improved coordination and continuity of care. In addition to the strategies above, nurse navigators will assist patients with scheduling, transportation, and understanding their care plans. By providing these services, the Proton Therapy Service will facilitate smoother transitions between different phases of care and reduce the likelihood of treatment interruptions. These nurse navigators will also serve as a critical point of contact for patients, addressing their concerns and ensuring that they remain engaged throughout their treatment journey.

G. Remote Follow-up

To support continuity of care for patients who cannot travel frequently for post-treatment visits to the Proton Therapy Service, patients may utilize UMMH's award winning telehealth services. Telehealth technologies will allow providers to follow up with patients remotely, so that any issues are addressed promptly. Additionally, UMMH clinicians also have the ability to order remote monitoring at the home, so that caregivers will be notified if a patient's condition changes in between visits, caregivers can proactively reach out to provide follow up care and adjust care if indicated.

H. Research and Medical Training

Through UMMH's partnership with UMass Chan, UMMH participates in a number of clinical trials of new cancer treatments. The addition of a Proton Therapy Service will facilitate further study of the efficacy of Proton Therapy for new patient populations and for new clinical indications, along with other treatments being studied. Additionally, having a Proton Therapy Service at the Cancer Center will allow UMMH to better attract and train oncology fellows and residents in radiation therapy, who will be able to more effectively learn the role of Proton Therapy in the overall treatment of patients. This will also allow UMMH to attract and retain high-quality faculty, who will have access to this new advanced tool to offer this highly effective care to their patients. Having a Proton Therapy Service may also allow UMMH to more effectively collaborate with the radiation physicist residency program operated by the University of Massachusetts - Lowell and allow more trainees in radiation oncology to gain valuable exposure to this unique treatment modality.
I. Other Staff Training & Operational Efficiency

UMMH anticipates that its commitment to training and workforce development will also contribute to the Proton Therapy Service's value to UMMH's patients. The Proton Therapy Service may 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, UMMH will maintain a high standard of care delivery and support long-term operational efficiency.

The existing infrastructure at UMMH already supports efficient and effective clinical operations and permits the integration of Proton Therapy within that existing framework. The Proton Therapy Service will reflect UMMH's established strengths in cancer care, care coordination, multidisciplinary collaboration, and patient-centered services. In summary, UMMH's existing expertise, systems and operations make UMMH well-positioned to establish and successfully operate the proposed Proton Therapy Service.

F1.d Provide evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

The Applicant has communicated with the following agencies:

- Executive Office of Health and Human Services, MassHealth Office of Providers and Pharmacy Programs;
- Massachusetts Office of Attorney General;
- Department of Public Health: Office of Legal Counsel, Determination of Need Program, Bureau of Health Care Safety and Quality (Division of Health Care Facility Licensure & Certification), Office of Health Equity and Community Engagement;
- Health Policy Commission; and
- Center for Information and Analysis.

F1.e.i Process for Determining Need/Evidence of Community Engagement: For assistance in responding to this portion of the Application, Applicant is encouraged to review <u>Community</u> <u>Engagement Standards for Community Health Planning Guideline</u>. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the Proposed Project.

Community Engagement Planning

UMMH leaders, including representatives from Marlborough Hospital, UMMMC, the UMMH Marketing and Communications, Community Benefits, and Public and Government Relations Departments collaborated to develop a comprehensive, multi-faceted community engagement plan to ensure robust communications to and with patients, community members, partners, and other relevant stakeholders. This community engagement plan includes the following activities:

- 1. Developing a detailed list of internal and external stakeholders and related communications channels to ensure a comprehensive approach to engaging all constituents in the community engagement process.
- 2. Developing appropriate educational materials to convey a shared understanding of the benefits to UMMH's patients and community about the Proposed Project.
- 3. Identifying and facilitating conversations with community-based organizational leaders that embrace the UMMH mission and vision of service to UMMH's most vulnerable communities.
- 4. Conducting presentations about the Proposed Project to community collaboratives and coalitions to enhance breadth of reach, and internal groups that steer and advise UMMH's community efforts including Marlborough Hospital and UMMMC Community Benefits Advisory Councils (CBACs), and Patient Family Advisory Council (PFACs).
- 5. Developing and implementing a public facing messaging and outreach effort which leverages UMMH's social media footprint, websites, and other media for equitable community access and education; and
- 6. Assigning responsible parties to complete all steps in these communication efforts.

F1.e.ii Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value".

Initial Community Engagement

UMMH has taken steps to implement the Community Engagement Plan described in the prior section through the following actions:

- Throughout the month of January 2025, a robust, multi-faceted community engagement plan was implemented, reaching various internal and external stakeholders.
- Specific messaging was developed and sent to internal leadership, board members, employees across Marlborough Hospital and UMMH, as well as providers regarding the Proposed Project and the Determination of Need.
- CBACs and PFACs from both Marlborough Hospital and UMMMC were informed of the Proposed Project and Determination of Need and were invited to attend meetings to learn more.
- Marlborough Hospital leaders held two sessions for members of the public including neighbors of Marlborough Hospital and presented to Worcester Together a coalition of partners from Greater Worcester.

- Direct outreach was conducted with elected officials across Marlborough and Worcester, business leaders from the Marlborough community and union leaders.
- Additional direct 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, Marlborough Economic Development Council, 495 Partnership and Corridor 9.
- Paid advertising, social media and website copy was widely distributed to both internal and external stakeholders in all UMMH service areas.

Outcome of Community Engagement

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*, UMMH'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)

The response from stakeholders at the foregoing meetings and outreach has been very positive with strong support for the Proposed Project. Stakeholders expressed support for UMMH'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, the timeline and noise associated with construction, and the effect of the Proposed Project on parking and traffic.

Ongoing Community Engagement

- Maintaining ongoing dialogue with all key stakeholders (internal and external) will remain a top priority both during and after the regulatory review process. Specifically, UMMH plans to take the following actions:
- 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.
- In response to questions and concerns that arise from Marlborough employees, FAQs and other messaging will be developed and shared with employees.
- Across UMMH, updates and the opportunity to share questions and concerns will be offered through systemwide communications channels including system Town Halls and the systemwide newsletter.
- The topic of merger and Proton Therapy investments in Marlborough Hospital, will also be a standing agenda item on future Marlborough CBAC and PFAC meetings, as well as at other meetings with community leaders such as the Marlborough Economic Development Corporation and the 495/MetroWest Partnership.
- The following additional presentations and meetings have been scheduled: March 5, 2025: 495/Metrowest Partnership Board Meeting March 5, 2025: Rotary Club of Hudson

March 27, 2025: Marlborough Economic Development Corporation Board Meeting

Factor 2 – Health Priorities

Factor 2: Health Priorities. Addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

F2.a. Cost Containment:

Using objective data, please describe, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment.

Proton Therapy represents a significant advancement in cancer treatment, offering substantial benefits in terms of cost containment, patient outcomes, and health care efficiency in the Commonwealth. By leveraging its superior dose distribution capabilities, Proton Therapy minimizes unnecessary radiation exposure to healthy tissues, leading to reduced treatment-related toxicities. Due to its enhanced clinical accuracy, Proton Therapy has the potential to reduce associated financial burdens on patients, employers, and healthcare systems.

As further described below, investing in a Proton Therapy Service and offering Proton Therapy have been found to be more cost-effective than traditional radiation when there is a clinically significant reduction in toxicities for patients and the appropriate identification of risk categories for targeted proton treatment. UMMH anticipates that the use of Proton Therapy by the existing UMMH patient panel for whom treatment is clinically appropriate, may reduce downstream healthcare costs such as readmissions and post treatment complications requiring expensive follow up clinical care. UMMH expects that the clinical benefits and anticipated downstream healthcare cost savings could partially offset the costs of expanding Proton Therapy in the Commonwealth.

Reduction in Acute Adverse Events and Hospitalizations

Proton Therapy has been shown to reduce the incidence of severe treatment-related toxicities, which translates into fewer emergency room visits and hospitalizations. A comparative effectiveness study demonstrated that Proton Therapy leads to a two-thirds reduction in severe adverse events requiring hospitalization in patients undergoing concurrent chemoradiotherapy, with no compromise in disease control or overall survival.⁹⁶ This reduction in acute complications can lower the overall cost of care by mitigating the need for additional interventions and extended hospital stays.

Preferred Treatment for Pediatric Patients

For pediatric cancer patients, Proton Therapy is the optimal treatment modality due to its reduced risk of secondary malignancies and lower impact on neurocognitive development. A study comparing proton radiotherapy (PRT) with photon therapy (XRT) in pediatric medulloblastoma found that PRT was associated with significantly better long-term intellectual outcomes, preserving cognitive function in domains such as working memory and perceptual reasoning.⁹⁷ By

⁹⁶ Baumann et al., *supra* note 44.

⁹⁷ Kahalley et al., *supra* note 49.

preventing lifelong cognitive impairments, Proton Therapy has the potential to reduce the need for long-term special education services, rehabilitation, and disability-related costs.

Lower Insurance Costs for Employers

A statewide insurance pilot study demonstrated that employer-sponsored insurance plans covering Proton Therapy did not experience a significant increase in medical costs compared to traditional radiation therapy.⁹⁸ In fact, analysis indicates that employer health plans could see a 4.7% reduction in overall insurance costs due to fewer long-term complications and hospital admissions.

Increased Workforce Productivity and Lower Disability Rates

Proton Therapy 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 Proton Therapy exhibited a 26% absolute improvement in return-to-work rates at two years compared to those treated with traditional radiation.⁹⁹ Additionally, patients treated with Proton Therapy experienced fewer instances of treatment-induced work impairment, allowing them to maintain employment and productivity.

Superior Outcomes for Head and Neck Cancer Patients

Patients receiving Proton Therapy for head and neck cancers benefit from a significantly lower incidence of severe side effects, such as mucositis and dysphagia, which often necessitate feeding tube placement. A comparative study found that Proton Therapy reduces the need for feeding tubes by two-thirds compared to conventional radiation, improving patient quality of life, and reducing the costs associated with malnutrition, specialized diets, and supportive care.¹⁰⁰ Another study concerning the cost-effectiveness of head and neck cancer treatment using Proton Therapy concluded that "appropriate patient selection can make Proton Therapy cost-effective" and specifically, that HPV-associated tumors can be cost-effectively treated with Proton Therapy and that in younger patients, Proton Therapy can lower the incidence of adverse effects and reduce long-term supportive care.¹⁰¹

More Affordable Access for Patients

As noted above in F1.a.ii Need by Patient Panel, establishing a Proton Therapy Service at the Cancer Center in Marlborough provides an affordable and equitable option for patients for whom Proton Therapy is the most effective treatment, because it substantially reduces the driving time to the treatment and capital costs due to advances in proton technology. Reduced driving time may result in lower costs of travel, time away from work, and less need for extended childcare. At the

⁹⁸ Matthew S. Ning, et al., *Three-Year Results of a Prospective Statewide Insurance Coverage Pilot for Proton Therapy: Stakeholder Collaboration Improves Patient Access to Care.* JCO ONCOL PRACT 16, e966-e976(2020). DOI:10.1200/JOP.19.00437

⁹⁹ Grace L. Smith et al., *Work Outcomes after Intensity-Modulated Proton Therapy (IMPT) versus Intensity-Modulated Photon Therapy (IMRT) for Oropharyngeal Cancer*, 25 INT J PART THER. 319, 319-327 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8270077/#:~:text=At%201%20year%2C%2071%25%20(,among%20IM RT%20patients%20over%20time.

¹⁰⁰ Gohar S. Manzar, et al., *supra* note 53.

¹⁰¹ Bharathi, Athiyamaan, and Ashwin, *supra* note 55.

most recent Health Policy Commission (HPC) cost trend hearing in November 2024, Governor Maura Healey acknowledged the ongoing challenges that residents of the Commonwealth face due to increasingly unaffordable and inaccessible health care.¹⁰² She indicated that her administration is actively pursuing policies to meet patient affordability goals. The addition of the Proton Therapy Service in Marlborough advances these goals to lower the cost of healthcare and increase accessibility for patients in the Commonwealth by reducing patients' out-of-pocket costs related to Proton Therapy and by providing this highly effective treatment in a lower cost, more affordable health care system.

Cost-Effective Technology and Location

The modern footprint of the Mevion proton system further contributes to the reduced cost of the overall capital costs for the project. In a 2017 Canadian analysis of the budget impact of implementing Proton Therapy services, reviewers specifically evaluated the relative costs of not providing Proton Therapy in Canada, constructing a Mevion single-vault Proton Therapy system, and constructing a multi-vault system, and concluded that savings could be generated over an extended time horizon with a Mevion single-vault Proton Therapy system, notwithstanding the upfront cost. ¹⁰³ In addition, UMMH has decided to locate the Proton Therapy Service at the existing Cancer Center in Marlborough in order to avoid costly new building and operational expenses. This strategy is expected to more efficiently integrate care with the existing radiation oncology services provided at the same location.

In summary, the development of a Proton Therapy Service in Marlborough presents a compelling case for cost containment with its potential to reduce hospitalizations, improve patient quality of life, lower insurance costs, enhance workforce productivity, and mitigate the long-term financial burden of treatment-related side effects. As health care costs continue to rise, investment in advanced treatment modalities such as Proton Therapy represents a fiscally responsible strategy to optimize both economic and clinical outcomes.

F2.b. Public Health Outcomes:

Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

Improved Clinical Outcomes

As described in Section F1.b.i regarding the evidence base for the Proposed Project and F1.b.iv regarding health outcomes resulting from the Proposed Project, Proton Therapy offers significant clinical benefits compared to traditional radiation therapy. These clinical benefits include:

¹⁰² Press Release, MASSACHUSETTS HEALTH POLICY COMMISSION, *2024 Health Care Cost Trends Recap* (November 25, 2024), <u>https://masshpc.gov/news/press-release/2024-health-care-cost-trends-hearing-recap</u>.

¹⁰³ KIM ET AL., *supra* note 12 ("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.").

- 1. **Reduced Side Effects:** The precise targeting of Proton Therapy minimizes radiation exposure to healthy tissues, leading to a reduction in acute and long-term side effects such as fatigue, nausea, skin reactions, and organ damage.¹⁰⁴
- 2. **Improved Quality of Life:** By reducing side effects and complications, Proton Therapy allows patients to maintain their daily activities and overall well-being throughout the treatment process. This can lead to faster recovery times and a quicker return to normal life.¹⁰⁵ This can also translate to improved quality of life for patients during and after treatment.
- 3. **Potentially Improved Survival Rates:** For certain cancer types, Proton Therapy has shown promising results in improving survival rates compared to conventional radiation therapy. This is particularly true for pediatric cancers and tumors located near critical organs, where minimizing radiation exposure is crucial for long-term health.¹⁰⁶

Equitable Access and Timely Care

As discussed in Section F1.b.iii regarding health equity, for many patients, traveling to Boston for treatment is logistically and financially challenging. By reducing the need for costly travel and lodging, UMMH expects to enable patients to begin optimal treatment sooner, adhere to their care plans, and experience better outcomes.¹⁰⁷ This is particularly critical for patients whose cancers require immediate and precise interventions, such as head and neck, lung, and pediatric cancers.

Improving Quality of Life and Potential Resulting Effects on Patients' Costs

As described in Section F1.b.i regarding the evidence base, Proton Therapy 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. UMMH anticipates that Proton Therapy patients will experience fewer side effects and faster recovery, allowing patients to remain in the workforce and community, and resulting in less financial and emotional strain on families which may enable them to remain active in the workforce and community. The potential downstream cost savings and costs avoided may include fewer out-of-pocket costs and co-pays for patients, travel and lodging expenses, lost earnings for patients and caregivers, as well as the avoidance of supportive care costs.

Potential Cost-Savings and Economic Benefits to the Commonwealth

The establishment of the Proton Therapy Service at Marlborough offers the potential for certain cost-savings and economic advantages to the Commonwealth. A reduction in treatment-related complications and long-term healthcare needs for Medicaid and Medicare patients will help control rising public healthcare costs. Keeping patients healthier generally allows them to remain in the workforce and reduces disruption in their employment. The savings associated with reduced

¹⁰⁴ Baumann et al, *supra* note 44.

¹⁰⁵ Verma et al., *supra* note 71.

¹⁰⁶ Mohan, *supra* note 69.

¹⁰⁷ MASSACHUSETTS HEALTH POLICY COMMISSION, *supra* note 78.

disruption on employment are critical given the high percentage of UMMH's population insured through government-funded healthcare programs. By preventing secondary cancers and chronic conditions, Proton Therapy may help alleviate the significant financial burden associated with treating these conditions over a patient's lifetime. This is especially important for younger patients, who face higher lifetime risks of secondary malignancies.¹⁰⁸

In addition, keeping care local at UMMH reduces the need for patients to travel to Boston, saving both direct and indirect costs, such as travel expenses, lodging, and lost workdays. Furthermore, the Proton Therapy Service may spur regional economic growth through job creation, medical innovation, and research partnerships, furthering Massachusetts' reputation as a leader in cutting-edge healthcare.

Investment in Research and Clinical Training to Support Public Health

As described above, UMMH's investments in Proton Therapy will also support the recruitment and retention of exceptional radiation oncology, medical oncology, surgical oncology physicians and technicians to provide high-quality care in the Commonwealth. UMMH will continue to partner with UMass Chan in clinical trials of new cancer treatments, which will facilitate further study of the efficacy of Proton Therapy for new patient populations and for new clinical indications. The addition of a Proton Therapy Service will help promote UMMH's oncology fellowship and the radiation physicist graduate program operated through UMass Lowell and allow trainees to gain valuable training of this limited resource. UMMH also expects to able to better recruit and retain high-quality faculty with access to advanced Proton Therapy, which will provide faculty with advanced care options for their patients. Additionally, the Proton Therapy Service will participate in investigator driven and national cooperative group clinical trials in Proton Therapy treatment. Dr. FitzGerald is one of the principal investigators of the Imaging and Radiation Oncology Core of the National Cancer Institute and both credentials and evaluates individual patients treated with protons on study.

F2.c: Delivery System Transformation:

Because the integration of social services and community-based expertise is central to goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

Regional Access to Proton Therapy

The establishment of a Proton Therapy Service at Marlborough will enhance access to advanced life-saving treatments utilizing proven technology that is not currently offered in this region of the state. UMMH proposes to establish its Proton Therapy Service in Marlborough, which is conveniently located in the western part of Middlesex County and convenient to three interstate highways (I-90, I-495, I-290). This location allows greater access to residents of central and western Massachusetts, along with parts of Connecticut, Rhode Island, New Hampshire, Vermont, and Maine, saving patients the time it takes to travel into Boston and the additional time related to

¹⁰⁸ Chung et al, *supra* note 46.

traffic congestion, and costs related to parking.

Addressing Social Drivers of Health

UMMH has a long-standing commitment to integrating social services and addressing social drivers of health (SDOH) to provide comprehensive, patient-centered care. The proposed Proton Therapy Service reflects this commitment by attempting to address patients' social needs as described below along with their clinical conditions. This approach builds on UMMH's established infrastructure and partnerships, which have been developed to holistically address the barriers faced by underserved populations.

Assessing the SDOH Needs of the Patient Panel

In 2024, UMMH launched a system-wide process for screening patients for their SDOH needs.¹⁰⁹ As part of this effort, in 2024, UMMH 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). Nine percent of patients screened requested help getting connected to community resources. While these data are not specific to the patient population who will utilize Proton Therapy, UMMH anticipates that there will likely be many similarities between the social needs of the UMMH patients screened in 2024 and the patients who will utilize the Proton Therapy Service. All Proton Therapy Service providers and staff will be able to deliver the SDOH screening and view patient screening results in the electronic medical record.

Creating Linkages to Social Services

To address social needs of its patients, the Proton Therapy Service will leverage existing UMMH processes and partnerships to link patients to a range of community social service organizations and community programs, enabling the Proton Therapy Service to meet the diverse needs of its patient population:

- 1. SDOH Resource Navigation: All patients who request help getting connected to resources during their SDOH screening process automatically receive a text message or telephone call with information about community resources in the social need domain requested. That patient can further engage with a UMMH-contracted virtual navigator for additional resources and referrals. In some settings, social workers and community health workers are available to help patients get connected to community resources during their visit. The Proton Therapy Service will also provide resources in the area that the patient lives; these resources are reviewed and updated regularly to ensure accurate information.
- 2. CommunityHELP Resource Repository: UMMH supports and maintains the CommunityHELP SDOH resource repository, which is UMMH's instance of the

¹⁰⁹ See UMass Memorial Health Expands Use of Get Well Platform with SDOH Screening Solution, UMASS MEMORIAL HEALTH, (Mar. 12, 2024), <u>https://www.ummhealth.org/umass-memorial-medical-center/umass-memorial-health-expands-use-get-well-platform-sdoh-screening-solution,Bethesda%2C%20Md.</u>

FindHelp platform. UMMH's navigators, social workers and case managers leverage this tool for connecting patients to resources. Patients can also use the public website (<u>www.communityhelp.net</u>) to identify a broad range of health and social care resources in their local communities. UMMH is actively working to improve the quality of resources available on this platform.

Integrating SDOH into Care Planning

To further address the SDOH needs of patients at the Proton Therapy Service, UMMH will implement the following programs and initiatives as part of a comprehensive, patient-centered treatment plan.

- 1. **Transportation Solutions**: Leveraging a recent grant from the American Cancer Society, the Proton Therapy Service will provide free or subsidized transportation for patients facing transportation insecurity. By reducing missed appointments, these services are expected to improve adherence to treatment schedules and enhance patient outcomes.
- 2. Financial Assistance Programs: UMMH's existing financial assistance initiatives 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.
- 3. Language Concordant Care: The Proton Therapy Service will maintain robust interpreter services, including access to remote interpretation, to provide non-English-speaking patients with language concordant care. This effort builds on UMMH's existing commitment to provide inclusive and equitable healthcare services.
- 4. Nutritional and Psychological Support: Nutritional support programs and psychological services are integrated into the wrap-around care provided by the interdisciplinary team of providers and support staff working in UMMH's radiation oncology program and will be available for patients at the Proton Therapy 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 programs 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.
- 5. Cancer Survivorship Program: All UMMH cancer patients, including all Proton Therapy Service patients, are eligible to participate in the cancer survivorship program¹¹⁰, which helps patients put together a comprehensive plan to address

¹¹⁰ Cancer Survivorship Program, UMASS MEMORIAL HEALTH, <u>https://www.ummhealth.org/services-treatments/cancer-center/cancer-survivorship-program#:~:text=Cancer%20Survivorship%20Services%20in%20Central%20Massachusetts&text=UMass%20M</u>

lingering health concerns and provides connections to a broad range of community resources and programs.

Incorporating Social Drivers of Health into Strategy

UMMH addresses community and patient SDOH needs into its overarching strategy for providing and delivering excellent care. For the patients of the Proton Therapy Service, this includes:

- 1. **Transportation Costs**: Localizing access to the Proton Therapy Service will reduce the financial burdens on patients who would otherwise travel to Boston. By decreasing travel distances and associated costs, the Proton Therapy Service will improve the affordability and accessibility of Proton Therapy, particularly for low-income and rural populations.
- 2. **Economic Stability**: By keeping Proton Therapy local, the Proton Therapy Service will help patients and their caregivers maintain employment, reducing income disruptions that occur for prolonged treatment periods when care is in Boston. This improvement in the economic stability of patients and caregivers fosters better long-term health outcomes.¹¹¹
- 3. **Health Equity**: The Proton Therapy Service will expand access to advanced cancer treatment for underserved populations, including rural residents, racial and ethnic minorities, and low-income families. This focus on equity aims to provide all patients with the opportunity for state-of-the-art Proton Therapy.
- 4. **Community Engagement and Partnerships**: Through its Anchor Mission and community benefits strategy, UMMH actively collaborates with local organizations to address food, housing, transportation, and workforce development needs. The Proton Therapy Service at Marlborough will further these efforts by fostering a healthier and more economically stable community.

The Proton Therapy Service will reflect UMMH's deep commitment to addressing social drivers of health and health equity. By leveraging its established partnerships and proven strategies, UMMH 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.

emorial%20Health%27s%20Cancer%20Survivorship,with%20a%20cancer%20survivorship%20specialist (last visited Feb. 26, 2025).

¹¹¹ Paula Braveman et al., WEALTH MATTERS FOR HEALTH EQUITY, ROBERT WOOD JOHNSON FOUNDATION at 1, 1-25 (2018), <u>https://www.rwjf.org/en/insights/our-research/2018/09/wealth-matters-for-health-equity.html</u>.

Factor 5 – Relative Merit

F5.a.i Description of Proposal and Alternatives:

Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to $105 \ CMR \ 100.210(A)(1)$. When conducting this evaluation and articulating the relative merit determination, Applicant shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

Proton Therapy Service Proposal

Recent technology advances in the development of single-gantry Proton Therapy unit allows for the expansion of this life- saving, high-quality, precise cancer treatment machines that requires less space and infrastructure at a significantly lower cost, in comparison to the historical traditional multi-room centers including those used in Boston and New York. The Proposed Project will expand the current Cancer Center in Marlborough by adding a 3,800 square foot addition that will include a Mevion S250I Proton Therapy System manufactured in Littleton MA, the only proton therapy vendor in North America.

A. Quality

The Proposed Project will provide improved needed access seamlessly through electronical integration with complete focus on providing the highest level of quality. As described above, Proton Therapy leads to better cancer outcomes, including better disease-free survival, better quality of life, and reduced treatment associated toxicity. In addition, the Applicant currently maintains Radiation Oncology Accreditation with American College of Radiology which provides the highest level of quality assurance.

B. Efficiency

The Proposed Project will integrate and expand the existing Cancer Center facility, staffing and resources. As described in this Application, Proton Therapy can reduce treatment complications and has the potential to lower long-term healthcare costs. Additionally, patients living west of Boston and in neighboring states will also have lower secondary costs (particularly travel costs and accommodations) while accessing Proton Therapy in Marlborough compared to accessing Proton Therapy in Boston.

C. Capital Expense

The Proposed Project utilizes existing operational space at the Cancer Center in Marlborough which helps to reduce capital expense. Advances in Proton Therapy machine design and beam delivery have reduced the footprint and cost of Proton Therapy systems. The Applicant proposes to use the modern single-gantry proton units, which are more efficient than earlier Proton Therapy facilities in terms of the size and cost (e.g., ~\$25 million compared to \$300 million for earlier

proton facilities). Circular designs of the single-room proton units have replaced traditional linear footprints, enabling greater accessibility and cost-efficiency in the design.¹¹²

D. Operating Costs

Proton Therapy technology continues to evolve as innovations in single room units allow for operational cost improvements in contrast to multi room centers used at several existing centers throughout the United States. These advancements recently resulted, in part, in the closure of one multi-room facility as well as a halt of construction at two others.¹¹³ The operational cost of Proton Therapy can be challenging to quantify given these recent technology changes. Improved access to Proton Therapy will necessitate improvements in clinical efficacy, which will provide greater amounts of historical data to quantify the operating costs, and cost benefit impact on specific diseases.

Alternative Proposal

The Applicant considered not establishing the Proton Therapy Service. Under this alternative, UMMH's Patient Panel would continue to travel and incur costs to access Proton Therapy from the only provider currently in Massachusetts located in Boston or would forgo Proton Therapy as an option in lieu of an alternative radiation treatment with higher treatment and complication risks. The next closest Proton Therapy facility is the New York Proton Center at 225 East 126th St, New York, NY 10035.

A. Quality

This alternative is not sufficient to meet the Patient Panel's need for highly accessible, low cost and high-quality Proton Therapy. Insufficient local access effects the quality of care for the patients served as they may avoid travel and access less advance care.

B. Efficiency

Not establishing the Proton Therapy Service continues to restrict convenient local access for the patients and would not support localized care.

C. Capital Expense

Taking no action to establish a Proton Therapy Service would not result in additional capital expenses associated with the Proton Therapy Service but would still necessitate some additional capital expansion of the Cancer Center as the incidence of cancer in the Commonwealth continues to increase.

¹¹² THOMAS J. FITZGERALD AND MARYANN BISHOP-JODOIN, PROTON THERAPY: CURRENT STATUS AND FUTURE DIRECTIONS (2021), <u>https://www.intechopen.com/books/10231</u>.

¹¹³ Peter A. S. Johnstone et al., *Proton Facility Economics: The Importance of "Simple" Treatments*, 9 J. AM. COLL. OF RADIOLOGY 560, 560-63 (2012); Vivek Verma et al., *Cost-Comparativeness of Proton versus Photon Therapy*, 5 CHINESE CLINICAL ONCOLOGY 1, 1-10 (2016), <u>https://cco.amegroups.org/article/view/11097/11904</u>.

D. Operating Costs

Taking no action to establish a Proton Therapy Service would not result in additional operating costs but can impact additional healthcare cost associated with retreatment and secondary malignancies without this advance technology.

Factor 6 – CHI Narrative

Community Health Initiative Monies

The breakdown of Community Health Initiative ("CHI") monies for the Proposed Project is as follows. Please note, all totals are presented in the order calculated, beginning with the Maximum Capital Expenditure (MCE).

	Total	Description
MCE	\$53,598,043	
Total CHI	\$2,679,902.15	(5% of Maximum Capital Expenditure)
Administrative Fee	\$80,397.06	(3% of the CHI Monies, retained by UMMH)
Remaining Monies	\$2,599,505.09	(CHI Monies minus the Administrative fee)
Statewide Initiative	\$649,876.27	(25% of remaining monies, paid to Statewide Initiative)
Local Initiative	\$1,754,665.93	(90% of remaining monies)
Evaluation Monies	\$194,962.88	(10% of Local Initiative Monies, retained by UMMH)
Local Disbursement	\$1,559,703.05	

Overview and Discussion of CHNA/CHI Processes

The CHI for the Proposed Project to establish a Proton Therapy Center in Marlborough will be led by UMMH. The total CHI for the Proposed Project is \$2,679,902.

The Applicant participated in the 2024 Greater Worcester Community Health Assessment (the Greater Worcester CHNA)¹¹⁴ and the 2023 MetroWest Community Health Assessment (the Marlborough CHNA)¹¹⁵ which will serve as the basis for the CHI. The Greater Worcester CHNA was collaboratively developed and carried out by the Worcester Division of Public Health, Fallon Health, The Coalition for a Healthy Greater Worcester, and UMMH. The entities have collaborated since 2008 to plan and conduct regional assessments aimed at identifying community health issues, barriers to care, inequities in care, disparities in outcomes, and gaps in the health service system. The Marlborough CHNA was developed by an advisory committee comprised of a range of organizations and partners working across the MetroWest region since 2010.

¹¹⁴ 2024 GREATER WORCESTER COMMUNITY available HEALTH ASSESSMENT, at: https://www.ummhealth.org/sites/default/files/Documents/About/Community benefits/2024-CHA reduced design.pdf. 115 2023 METROWEST COMMUNITY HEALTH ASSESSMENT, available at: https://d2yy08d49bfgoo.cloudfront.net/documents/publications/FINAL-COPY-101023-updated.pdf.

A. Worcester

The City of Worcester, the second largest city in New England, is very ethnically diverse, with a high poverty rate and many social-economic challenges. The 2024 Greater Worcester CHNA focuses on the City of Worcester and the outlying towns of the Central Massachusetts Regional Public Health Alliance (CMRPHA), which include Grafton, Shrewsbury, and West Boylston, subsections of its primary service area. This specific geographic area is the focus for the City of Worcester Division of Public Health's regionalization initiative and overlaps with UMass Memorial Medical Center's service area and of many other local organizations. Focusing on this geographic area facilitates the alignment of the UMMMC's efforts with community and governmental partners, specifically the city public health department, the area's Federally Qualified Health Centers, and multiple community-based organizations. According to the 2020 decennial census, the City of Worcester has a population of 206, 518 people living in an area of 37.37 square miles. This represents an 11.8% growth in the population within the past 10 years. The median age of Worcester citizens is estimated at 33.6 +/- 1.3 years, 6.3 years lower than the median age of the state of Massachusetts (39.9 +/-0.1 years). The most populated age groups are the 20 - 24 years (18,744 persons), the 15 - 19 years (16,612 persons), and the 25 - 29 years (15,758 persons).

The population of the City has reported various racial and ethnic profiles. The most commonly reported races are White (53.3%) and Black/African American (14.8%). Compared to the 2010 census, not only the overall population of the city has increased, but so has its diversity. Indeed, the percentages of races other than White have increased compared to the White population. Hispanic or Latino origin of any race accounts for 23.9%. Race distribution also varies depending on the nativity of the population. Indeed, the foreign-born population displays a higher proportion of non-white races compared to the native population.

Nearly one-fifth (19.3%) of the Worcester City population lives below the federal poverty level. Another fifth lives between 100 and 199% of the federal poverty line (18.5%). The mean annual income in households with earnings is \$ 85,305 \pm 2,390 and \$ 16,523 \pm 510 in households with social security income. The unemployment rate in the city is estimated at 3.9%. Among the people 25 years and older, 85.8% have graduated high school or have higher education levels.

In order to understand the health issues facing Greater Worcester, the Greater Worcester CHNA utilized a mixed-methods assessment approach that integrates quantitative and qualitative data and sought information on the lived experiences of the community's diverse populations. The full CHNA 2024 effort focused on compiling information through an extensive community engagement effort that involved stakeholder interviews, focus groups, and a community health survey, as described below. Data and findings from recent local assessment and planning efforts were also incorporated into the CHNA. Accordingly, the CHNA was completed in close partnership with local stakeholders, including health and social service providers, advocates, elected and appointed officials, faith leaders, community organizations, Boards and Commissions, and community residents.

The Greater Worcester CHNA sought to include an engaged and representative sample of individuals from Greater Worcester residents. To that end, hundreds of individuals participated through 45 interviews, nine (9) focus groups, and one (1) Community Health Survey. Furthermore, the 2024

Greater Worcester CHNA was developed in consideration of the strategic plan established as part of the Greater Worcester Community Health Improvement Plan ("CHIP").¹¹⁶ The CHIP was led by the Coalition for a Healthy Greater Worcester, a facilitating partner of the current 2024 Greater Worcester CHNA.

The Greater Worcester CHNA process used a participatory approach that involved engaging all members to provide feedback on data collection instruments, guiding the assessment methodology, organizing data collection efforts such as focus groups, and conducting the focus groups themselves or engaging with community partners to do so.

B. Marlborough

The Marlborough CHNA aims to identify the health-related needs and strengths of the MetroWest region by defining health in the broadest sense and recognizing numerous factors – from employment to housing to access to care – that have an impact on the community's health. Social, economic, and health data were drawn from existing data sources, such as the Massachusetts Department of Public Health, the U.S. Census Bureau, the U.S. Bureau of Labor Statistics, Centers for Disease Control and Prevention, 495/MetroWest Partnership, MetroWest Health Foundation, National Cancer Institute, UMass Memorial Health Center of Clinical Integration and UMass Memorial Health – Marlborough Hospital. Additionally, as part of the Marlborough CHNA, a community health survey was offered in English, Spanish and Portuguese, seven focus groups were facilitated, and 10 key informant interviews were held to gather feedback on community strengths, challenges, priority health concerns, and opportunities for the future from hundreds of area residents, as well as community stakeholders and multi-sector organizations.

C. 495/MetroWest Region

Marlborough Hospital serves the Massachusetts MetroWest region which consists of cities and towns that span east to west from Framingham to Westborough and north to south from Bolton to Hopkinton. During 2019-2022, 34.5% of the hospital's patient encounters were residents of Marlborough, 15.9% were from Hudson. The remaining 49.6% of patient encounters were from surrounding towns, with the majority within a 15-mile radius of Marlborough.

Detailed local data from the 2020 census, published in August 2021 by the U.S. Census Bureau, shows that the 495/MetroWest Region consisting of 36 cities and towns grew at a faster rate than Massachusetts between 2010 and 2020. The region has also become substantially more diverse over the previous decade. The population of the 495/MetroWest Region grew by 9.1%, surpassing the state's 7.4% rate of growth. The population of the 495/MetroWest region now comprises 9.2% of the state's total population up from its 9.05% share in 2010.

The MetroWest region has become more diverse, with the percentage of residents who identify as White dropping from 83.6% in 2010 to 73% in 2020. Census data shows an increase in residents identifying as Asian (from 7.93% in 2010 to 10% in 2020), Latino (4.63% in 2010 to 6.7% in

¹¹⁶ 2021-2026 GREATER WORCESTER COMMUNITY HEALTH IMPROVEMENT PLAN (CHIP), available at: <u>https://drive.google.com/file/d/1tsfAokBCJAb_uRlgLbloAKQ0rsYHII9A/view</u>.

2020), Black (1.87% in 2010 to 2.43% in 2020), and Multi-Racial/ Two or More Races (1.8% in 2010 to 5.39% in 2020).

Hudson is the 97th most populated town in the Commonwealth of Massachusetts out of 351 cities and towns and is located in Middlesex County. The population in Hudson is 20,032. In 2010, the population was 14,907. The largest Hudson racial/ethnic groups are white (83.7%), followed by Hispanic (6.4%) and Asian (4.5%).

Marlborough is the 37th most populated city in the Commonwealth of Massachusetts out of 351 cities and towns and is located in Middlesex County. The population of Marlborough is 41,505. In 2010, the population was 38,584. The largest Marlborough racial/ethnic groups are white (64.4%) followed by Hispanic (16.2%) and two or more races (6.6%).

67.32% of Marlborough residents speak only English, while 32.68% speak other languages. The non-English language spoken by the largest group is Other Indo-European, which is spoken by 17.49% of the population. Spanish, Portuguese-Continental and Portuguese Brazilian are the most common Indo-European languages spoken in the Marlborough Public Schools.

75.39% of Hudson residents speak only English, while 24.61% speak other languages. The non-English language spoken by the largest group is Other Indo-European, which is spoken by 18.09% of the population. Spanish, Portuguese-Continental and Portuguese Brazilian are the most common Indo-European languages spoken in the Hudson Public Schools.

In 2021, the median household income of Marlborough households was \$86,230. However, 5.5% of Marlborough families live in poverty.

In 2021, the median household income of Hudson households was \$94,191. However, 4.1% of Hudson families live in poverty.

The Marlborough CHNA process, including the development of the Community Health Improvement Plan, engaged community members, local boards of health, community-based organizations, schools, social service agencies, local municipalities, caregivers and health care providers, reflecting the diverse communities served by Marlborough Hospital. Ongoing assessment and review of the CHIP is the responsibility of the Community Benefits Advisory Council.

Oversight of the CHI Process

The Applicant will leverage its robust and well-represented Determination of Need Committee (the Advisory Committee) to oversee the development and implementation of the CHI. The Advisory Committee will be comprised of community members, leaders, and stakeholders, as well as key employees across the Applicant's organization.

Advisory Committee Duties

The Advisory Committee's scope of work includes:

• Selecting the CHI's Health Priorities based upon the needs identified in the Greater

Worcester CHNA and the Marlborough CHNA in alignment with DPH's and EOHHS's Health Priorities and Focus Areas.

- Providing oversight of the evaluation of CHI-funded projects.
- Conducting a conflict-of-interest disclosure process to determine which members also will comprise the Allocation Committee.
- Ongoing monitoring and reporting to DPH.

Allocation Committee Duties

The Allocation Committee will be comprised of individuals from the Advisory Committee who do not have a conflict of interest with respect to funding CHI strategies. The scope of work that the Allocation Committee will carry out includes:

- Selecting Strategies for the noted Health Priorities consistent with DPH's CHI guidelines.
- Carrying out a formal request for proposal ("RFP") process (or an equivalent, transparent process) for the disbursement of CHI funds.
- Engaging resources that can support and assist applicants with their responses to the RFP.
- Disbursement of CHI funding.
- Providing oversight to the evaluation process.

Timeline for CHI Activities

Upon a Notice of Determination of Need being issued by the Public Health Council, the Advisory Committee will commence meeting and begin the CHI Process. The timeline for CHI activities is as follows:

- <u>Six weeks post-approval</u>: The Advisory Committee will meet to review their responsibilities and the Greater Worcester CHNA and Marlborough CHNA in furtherance of selecting Health Priorities.
- <u>Two months post-approval</u>: The Advisory Committee determines Health Priorities and Strategies for funding.
- <u>Three months post-approval</u>: The Advisory Committee conducts a Conflicts of Interest process to determine which members will form the Allocation Committee.
- <u>Three months post-approval</u>: The Allocation Committee develops the funding process for the selected strategies.
- <u>Four months post-approval</u>: The RFP for funding is released.
- <u>Five months post-approval</u>: Responses are due for the RFP.

- <u>Five-Six months post-approval</u>: Funding decisions are made, and the disbursement of funds begins.
- <u>Annually post-approval</u>: Ongoing evaluation efforts and reporting to DPH.

The Applicant requests flexibility with respect to the foregoing timeline.

Request for Multi-Year Funding

The Applicant is requesting the flexibility to extend the life of the CHI grants for up to five (5) years depending on the number and nature of applications received and ultimately funded. The Applicant plans to allocate the CHI grants equitably across the Greater Worcester community and the Marlborough community.

Administrative Monies

UMMH is requesting to use up to \$80,397.06 in administrative funding. These monies will be used to fund support staff, provide support to Advisory Committee and Allocation Committee members, and assist with the development of community communication materials, including publicizing and facilitating the RFP process.

Evaluation Overview

The Applicant anticipates using the allowed 10% of local CHI funding (\$194,962.88) for evaluation efforts. The money will be used to develop and implement an evaluation plan for CHI-funded projects.

NARRATIVE EXHIBITS

EXHIBIT A: UMMH AND UMMMC PATIENT PANEL DEMOGRAPHICS

Source: UMMHC EPSI patient data results; includes all hospitals

Period: FY22-FY24 Actual

Comments:

The following tables present demographic results for UMMH hospital facilities, including UMMH Data Results (including Marlborough Data Results), UMMMC Data Results, Harrington Data Results, and Milford Data Results. Counts reflect the number of patients, not number of visits to a UMMH facility.

*Results for FY22-FY24 do not combine Milford patient panel with UMMH patient panel, because Milford joined UMMH on October 1, 2024, and there is a potential overlap of patients in both patient panels, which could not be identified due to each system having their own unique medical record numbers for each patient. The Milford patient panel is presented separately.

*Results for FY22-FY23 do not combine Harrington patient panel with UMMH patient panel, because Harrington joined UMMH July 1, 2021 and there is a potential overlap of patients in both patient panels, which could not be identified due to each system having their own unique medical record numbers for each patient. However, results for FY24 include the Harrington patient panel. The Harrington patient panel is presented separately.

**To stay in compliance 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.

	UMMHC I	Data Results*					Medical C	enter Data	Results			
	FY22		FY23	-	FY24		FY22		FY23		FY24	
	Count	%	Count	%	Count	%	Count	%	Count	%	Count	%
Gender												
FEMALE	214,408	55.9%	216,417	56.2%	245,102	56.0%	168,243	55.8%	169,331	56.2%	176,813	56.5%
MALE	168,741	44.0%	168,654	43.8%	192,000	43.9%	133,036	44.1%	131,753	43.7%	136,244	43.5%
UNKNOWN	348	0.1%	320	0.1%	426	0.1%	106	0.0%	103	0.0%	120	0.0%
Total Gender	383,497	100.0%	385,391	100.0%	437,528	100.0%	301,385	100.0%	301,187	100.0%	313,177	100.0%
Age		-	_	-	-	-		-	-	-		-
0-17	71,898	18.7%	69,375	18.0%	73,694	16.8%	58,653	19.5%	56,589	18.8%	58,193	18.6%
18-64	223,299	58.2%	222,616	57.8%	253,683	58.0%	173,109	57.4%	170,918	56.7%	176,801	56.5%
65+	88,300	23.0%	93,400	24.2%	110,151	25.2%	69,623	23.1%	73,680	24.5%	78,183	25.0%
Unknown	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Age	383,497	100.0%	385,391	100.0%	437,528	100.0%	301,385	100.0%	301,187	100.0%	313,177	100.0%
Race												
American Indian or Alaska Native	1,071	0.3%	1,156	0.3%	1,283	0.3%	933	0.3%	974	0.3%	991	0.3%
Asian	13,044	3.4%	12,555	3.3%	12,867	2.9%	11,067	3.7%	10,968	3.6%	10,477	3.3%
Black or African American	25,271	6.6%	27,309	7.1%	30,081	6.9%	21,084	7.0%	22,042	7.3%	24,193	7.7%
Declined	4,086	1.1%	4,404	1.1%	6,044	1.4%	3,514	1.2%	3,818	1.3%	4,790	1.5%
Multi Racial	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Native Hawaiian or Other Pacific Islander	322	0.1%	405	0.1%	587	0.1%	249	0.1%	315	0.1%	477	0.2%
Other/Unknown	55,982	14.6%	58,980	15.3%	64,878	14.8%	44,538	14.8%	45,406	15.1%	48,254	15.4%
White	283,721	74.0%	280,582	72.8%	321,788	73.5%	220,000	73.0%	217,664	72.3%	223,995	71.5%
Total Race	383,497	100.0%	385,391	100.0%	437,528	100.0%	301,385	100.0%	301,187	100.0%	313,177	100.0%
Ethnicity												
Decline to Answer	6,146	1.6%	6,731	1.7%	8,761	2.0%	5,368	1.8%	5,767	1.9%	6,626	2.1%
Hispanic or Latino	63,214	16.5%	66,490	17.3%	75,387	17.2%	48,664	16.1%	50,816	16.9%	54,605	17.4%
Not Hispanic or Latino	307,066	80.1%	306,110	79.4%	349,791	79.9%	241,903	80.3%	240,304	79.8%	250,262	79.9%
Unknown	7,071	1.8%	6,060	1.6%	3,589	0.8%	5,450	1.8%	4,300	1.4%	1,684	0.5%
Total Ethnicity	383,497	100.0%	385,391	100.0%	437,528	100.0%	301,385	100.0%	301,187	100.0%	313,177	100.0%
Patient Origin												
Central Mass	344,096	89.7%	349,550	90.7%	389,285	89.0%	268,007	88.9%	269,256	89.4%	280,086	89.4%
Eastern Mass	15,574	4.1%	13,947	3.6%	15,831	3.6%	12,692	4.2%	11,782	3.9%	12,122	3.9%
Western Mass	9,127	2.4%	9,315	2.4%	14,421	3.3%	8,729	2.9%	9,201	3.1%	9,864	3.1%
Out of State	14,700	3.8%	12,579	3.3%	17,991	4.1%	11,957	4.0%	10,948	3.6%	11,105	3.5%
Total Patient Origin	383,497	100.0%	385,391	100.0%	437,528	100.0%	301,385	100.0%	301,187	100.0%	313,177	100.0%

Exhibit A Page **2**

	Harrington Data Results**							Data Results	5			
	FY22		FY23		FY24		FY22		FY23		FY24	
	Count	%	Count	%	Count	%	Count	%	Count	%	Count	%
Gender												
FEMALE	36,928	54.6%	36,230	54.9%	35,863	55.5%	76,809	57.2%	77,697	57.6%	79,796	57.7%
MALE	30,672	45.4%	29,762	45.1%	28,703	44.4%	57,145	42.6%	56,886	42.2%	58,239	42.1%
UNKNOWN	0	0.0%	0	0.0%	69	0.1%	329	0.2%	253	0.2%	323	0.2%
Total Gender	67,600	100.0%	65,992	100.0%	64,635	100.0%	134,283	100.0%	134,836	100.0%	138,358	100.0%
Age												
0-17	8,291	12.3%	7,643	11.6%	6,864	10.6%	10,069	7.5%	10,185	7.6%	10,531	7.6%
18-64	41,949	62.1%	40,029	60.7%	39,094	60.5%	87,549	65.2%	87,728	65.1%	89,018	64.3%
03+	17,300	25.7%	18,520	27.8%	18,077	28.9%	30,003	27.5%	30,923	27.4%	38,809	28.0%
Unknown	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Age	67,600	100.0%	65,992	100.0%	64,635	100.0%	134,283	100.0%	134,836	100.0%	138,358	100.0%
Race												
American Indian or Alaska Native	79	0.1%	79	0.1%	206	0.3%	125	0.1%	136	0.1%	142	0.1%
Asian	546	0.8%	498	0.8%	552	0.9%	3,488	2.6%	3,763	2.8%	4,043	2.9%
Black or African American	1,149	1.7%	1,211	1.8%	1,806	2.8%	2,345	1.7%	2,312	1.7%	2,938	2.1%
Declined	0	0.0%	0	0.0%	808	1.3%	373	0.3%	394	0.3%	448	0.3%
Multi Racial	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Native Hawaiian or Other Pacific Islander	0	0.0%	0	0.0%	63	0.1%	124	0.1%	145	0.1%	107	0.1%
Other/Unknown	12,899	19.1%	12,350	18.7%	6,591	10.2%	13,793	10.3%	14,528	10.8%	16,067	11.6%
White	52,927	78.3%	51,854	78.6%	54,609	84.5%	114,035	84.9%	113,558	84.2%	114,613	82.8%
Total Race	67,600	100.0%	65,992	100.0%	64,635	100.0%	134,283	100.0%	134,836	100.0%	138,358	100.0%
Ethnicity												
Decline to Answer	0	0.0%	0	0.0%	1,590	2.5%	0	0.0%	0	0.0%	0	0.0%
Hispanic or Latino	7,363	10.9%	7,145	10.8%	8,308	12.9%	5,147	3.8%	5,835	4.3%	6,513	4.7%
Not Hispanic or Latino	54,709	80.9%	53,654	81.3%	54,176	83.8%	95,613	71.2%	103,640	76.9%	109,114	78.9%
Unknown	5,528	8.2%	5,193	7.9%	561	0.9%	33,523	25.0%	25,361	18.8%	22,731	16.4%
Total Ethnicity	67,600	100.0%	65,992	100.0%	64,635	100.0%	134,283	100.0%	134,836	100.0%	138,358	100.0%
Patient Origin												
Central Mass	55,041	81.4%	53,770	81.5%	52,986	82.0%	77,793	57.9%	78,813	58.5%	79,640	57.6%
Eastern Mass	813	1.2%	764	1.2%	660	1.0%	49,626	37.0%	49,619	36.8%	51,026	36.9%
Western Mass	5,393	8.0%	5,285	8.0%	5,492	8.5%	280	0.2%	261	0.2%	269	0.2%
Out of State	6,353	<u>9.4</u> %	6,173	<u>9.4</u> %	5,4 <u>9</u> 7	8.5%	6,584	4.9%	6,143	4.6%	7,423	5.4%
Total Patient Origin	67,600	100.0%	65,992	100.0%	64,635	100.0%	134,283	100.0%	134,836	100.0%	138,358	100.0%

Exhibit A Page **3**

EXHIBIT B: UMMH PATIENT PANEL RECEIVING LINAC TREATMENT

Source: UMMHC EPSI patient data results

Period: FY22-FY24 Actual

Comments: This data is based on UMMH patients who received LINAC treatment at one of the following campuses: UMMMC, HealthAlliance Clinton, or Marlborough Hospital. UMMH does not have information on the patient panel requiring radiation treatment for Harrington Hospital which joined UMMH as of October 1, 2024, or for Milford Hospital because UMMH does not provide radiation oncology services at Milford (cancer services are provided through a third-party affiliate). For reporting purposes, UMMH reported patient panel information to meet CHIA data requirements by reporting groupings that had 11 patients or more.

	UMMH LINAC Patient Panel									
	FY22		FY23		FY24					
	Count	%	Count	%	Count	%				
Gender										
FEMALE	887	56.2%	910	57.0%	947	55.8%				
MALE	691	43.8%	687	43.0%	749	44.1%				
UNKNOWN	0	0.0%	0	0.0%	0	0.0%				
Total Gender	1,578	100.0%	1,597	100.0%	1,697	99.9%				
Age										
0-64	649	41.1%	637	39.9%	651	38.4%				
65+	929	58.9%	960	60.1%	1,046	61.6%				
Unknown	0	0.0%	0	0.0%	0	0.0%				
Total Age	1,578	100.0%	1,597	100.0%	1,697	100.0%				
Race										
Asian	38	2.4%	29	1.8%	23	1.4%				
Black or African American	48	3.0%	70	4.4%	68	4.0%				
Other/Unknown	132	8.4%	145	9.1%	143	8.4%				
White	1,360	86.2%	1,353	84.7%	1,463	86.2%				
Total Race	1,578	100.0%	1,597	100.0%	1,697	100.0%				
Ethnicity										
Hispanic or Latino	130	8.2%	127	8.0%	132	7.8%				
Not Hispanic or Latino	1,423	90.2%	1,432	89.7%	1,530	90.2%				
Unknown	25	1.6%	38	2.4%	35	2.1%				
Total Ethnicity	1,578	100.0%	1,597	100.0%	1,697	100.0%				
Patient Origin										
Central Mass	1,463	92.7%	1,494	93.6%	1,589	93.6%				
Eastern Mass	28	1.8%	21	1.3%	24	1.4%				
Western Mass	37	2.3%	29	1.8%	36	2.1%				
Out of State	50	3.2%	53	3.3%	48	2.8%				
Total Patient Origin	1,578	100.0%	1,597	100.0%	1,697	100.0%				

EXHIBIT C: UMMH AND UMMMC PAYOR MIX

Source: FY22 to FY23 Based on CHIA 403 Cost Report Data

Period: FY22-FY24 Actual

Comments: Data is for UMMH hospital only payor mix reporting for all payors, and summary of public payors. Because Milford Regional Medical Center (Milford) was not part of UMMH until October 1, 2024, Milford is not included in historical payor mix rations.

	UMMH (e	xcluding M	ilford)	UMMMC Only				
	FY22	FY23	FY24	FY22	FY23	FY24		
	Total	Total	Total	Total	Total	Total		
	Payor	Payor	Payor	Payor	Payor	Payor		
Payor Mix List (all):	Mix	Mix	Mix	Mix	Mix	Mix		
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%		
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%		
Managed Medicare (Medicare	16.3%	17.8%	18.8%	15.1%	16.6%	17.4%		
Advantage)								
Medicare FFS	27.0%	25.9%	25.5%	27.0%	25.9%	25.2%		
All other (e.g., HSN, self-pay, TriCare)	3.6%	3.4%	4.1%	3.5%	3.3%	4.0%		
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%		
Public Payors Only:								
Medicare Fee-for-Service	67.9%	67.7%	67.7%	27.0%	25.9%	25.2%		
Managed Medicare	27.0%	25.9%	25.5%	15.1%	16.6%	17.4%		
MassHealth (combined)	16.3%	17.8%	18.8%	25.0%	24.3%	24.0%		
Total	24.6%	24.1%	23.4%	67.1%	66.8%	66.7%		

EXHIBIT D: NEED BASED ON ESTIMATED UMMH PATIENT PANEL RECEIVING LINAC TREATMENT

Source: ASTRO PBT Model Policies; UMMH LINAC Patient Panel Data

Period: FY22-FY24

Comments: This data presents the demographics and payor mix of UMMH's Patient Panel receiving LINAC treatment that would satisfy the medical and coverage criteria under the ASTRO PBT Model Policies for Group 1 and Group 2. The data presented utilizes UMMH's internal decision support tool (EPSI) and a patient's primary diagnosis code to determine which patients would fall within each of the two ASTRO groups. Because the data are derived from the existing UMMH Patient Panel receiving LINAC treatment as set forth in Exhibit B, certain categories containing small numbers are consolidated in accordance with CHIA guidelines to shield patient privacy.

	Proton Therapy Data Results (Grp 1 Only) P						Proton Therapy Data Results (Grp 2 Only)							
	FY22		FY23		FY24		FY22		FY23		FY24			
	Count	%	Count	%	Count	%	Count	%	Count	%	Count	%		
Gender														
FEMALE	49	30.6%	43	28.5%	44	32.4%	823	59.0%	855	59.9%	890	58.1%		
MALE	111	69.4%	108	71.5%	92	67.6%	571	41.0%	572	40.1%	643	41.9%		
UNKNOWN	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%		
Total Gender	160	100.0%	151	100.0%	136	100.0%	1,394	100.0%	1,427	100.0%	1,533	100.0%		
Age														
0-64	87	54.4%	71	47.0%	60	44.1%	549	39.4%	560	39.2%	577	37.6%		
65+	73	45.6%	80	53.0%	76	55.9%	845	60.6%	867	60.8%	956	62.4%		
Unknown	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%		
Total Age	160	100.0%	151	100.0%	136	100.0%	1,394	100.0%	1,427	100.0%	1,533	100.0%		
Race		-	-	-	-	=		=	-	=	-	-		
Other/Unknown	28	17.5%	27	17.9%	23	16.9%	185	13.3%	213	14.9%	197	12.9%		
White	132	82.5%	124	82.1%	113	83.1%	1,209	86.7%	1,214	85.1%	1,336	87.1%		
Total Race	160	100.0%	151	100.0%	136	100.0%	1,394	100.0%	1,427	100.0%	1,533	100.0%		
Ethnicity														
Not Hispanic or Latino	143	89.4%	136	90.1%	118	86.8%	1,259	90.3%	1,277	89.5%	1,394	90.9%		
Unknown	17	10.6%	15	9.9%	18	13.2%	135	9.7%	150	10.5%	139	9.1%		
Total Ethnicity	160	100.0%	151	100.0%	136	100.0%	1,394	100.0%	1,427	100.0%	1,533	100.0%		
Patient Origin														
Central Massachusetts Outside Central	143	89.4%	141	93.4%	123	90.4%	1,297	93.0%	1,337	93.7%	1,442	94.1%		
Massachusetts	17	10.6%	10	6.6%	13	9.6%	97	7.0%	90	6.3%	91	5.9%		
Total Patient Origin	160	100.0%	151	100.0%	136	100.0%	1,394	100.0%	1,427	100.0%	1,533	100.0%		

	Payor Mix									
	Proton Thera	apy Data Resi	ılts (Grp 1	Proton Therapy Data Results (Grp 2						
	Only)			Only)						
	FY22 Total Payor Mix	FY23 Total Payor Mix	FY24 Total Payor Mix	FY22 Total Payor Mix	FY23 Total Payor Mix	FY24 Total Payor Mix				
Commercial PPO/Indemnity	0.0%	0.0%	1.0%	0.2%	0.2%	0.2%				
Commercial HMO/POS	30.2%	30.5%	23.4%	28.3%	29.0%	25.7%				
MassHealth	15.8%	10.2%	6.1%	11.0%	6.5%	5.1%				
Managed Medicaid (ACO/ MCO)	7.7%	8.1%	7.6%	4.1%	4.9%	6.4%				
Managed Medicare (Medicare										
Advantage)	19.6%	20.6%	26.7%	20.3%	23.7%	27.6%				
Medicare FFS	24.3%	27.9%	30.8%	33.7%	31.6%	31.8%				
All other (e.g., HSN, self-pay,										
TriCare)	2.4%	2.6%	4.3%	2.3%	4.2%	3.2%				
Total	100%	100%	100%	100%	100%	100%				

EXHIBIT E: CHIA RELATIVE PRICE DATA ANALYSIS

Source: CHIA, CY2022 Relative Price and Provider Price Variation, Databook, <u>https://www.chiamass.gov/relative-price-and-provider-price-variation/</u>.

Period: CY2022

Comments: Results represent CY2022 Academic Medical Center (AMC) hospital relative price for major payors in Massachusetts, with respect to all product types for commercial insured (self and fully insured).

Hospital OrgID	Hospital Name	Hospital Cohort	Inpatien t RP	Outpatient RP	IP RP % Variance to Med Ctr	OP RP % Variance to Med Ctr
Blue Cross Blu	e Shield of Massachusetts					
3115	UMass Memorial Medical Center	Academic Medical Center	1.15	1.03		
12662	Massachusetts General Hospital - Urban	Academic Medical Center	1.30	1.48	13%	44%
12664	Brigham and Women's Hospital - Urban	Academic Medical Center	1.30	1.48	13%	44%
8702	Beth Israel Deaconess Medical Center	Academic Medical Center	1.19	1.00	3%	-3%
3107	Boston Medical Center	Academic Medical Center	1.02	0.86	-11%	-17%
12667	Tufts Medical Center - Non-Floating	Academic Medical Center	1.06	1.10	-8%	7%
12666	Tufts Medical Center - Floating	Academic Medical Center	1.28	1.27	11%	23%
				Har	vard Pilgrim H	Health Care
3115	UMass Memorial Medical Center	Academic Medical Center	1.23	0.90		
91	Massachusetts General Hospital	Academic Medical Center	1.29	1.14	5%	27%
8702	Beth Israel Deaconess Medical Center	Academic Medical Center	1.24	0.95	1%	6%
3107	Boston Medical Center	Academic Medical Center	1.15	0.85	-7%	-6%
12666	Tufts Medical Center - Floating	Academic Medical Center	1.17	1.13	-5%	26%
		, ,	Tufts Associ	ated Health Maint	enance Organi	zation, Inc.
3115	UMass Memorial Medical Center	Academic Medical Center	1.43	1.03		
91	Massachusetts General Hospital	Academic Medical Center	1.47	1.26	3%	22%
8702	Beth Israel Deaconess Medical Center	Academic Medical Center	1.19	1.11	-17%	8%
3107	Boston Medical Center	Academic Medical Center	0.99	0.76	-31%	-26%
				Fallo	n Community l	Health Plan
3115	UMass Memorial Medical Center	Academic Medical Center	1.33	1.13		
91	Massachusetts General Hospital	Academic Medical Center	1.81	1.65	36%	46%
8702	Beth Israel Deaconess Medical Center	Academic Medical Center	1.20	0.82	-10%	-27%
3107	Boston Medical Center	Academic Medical Center	0.77	1.01	-42%	-11%

EXHIBIT F: Attachment supporting projections of Patient Panel Need by Geographical Region using ACS and Horizon Scanning Report Cancer and PBT Statistics

Table A. Modeled projections of Proton Therapy patient panel growth within the UMMH Total Service Area.

Name	State of Massachusetts
Population	1,191,894
Medicare Administrative Contractor	NGS
State	MA
State Population	7,106,597
Number of New Cancer (2024)*	44,040
New Cancer In Region	7,386

*Source: American Cancer Society - Cancer Facts and Figures 2024

	Source: A	Source: American Cancer Society - Cancer in 2024 and Proton Therapy - Clinical Needs in Netherlands									
	2024				2029				2034		
	# of New Cancer	# treated with RT	# treatable with PT		# of New Cancer	# treated with RT	# treatable with PT		# of New Cancer	# treated with RT	# treatable with PT
CNS - Base of skull/paraspinal tumors	61	55	55		69	62	62		77	69	9
CNS - Malignant Brain Tumors	28	26	6		32	29	7		35	32	8
CNS - Meningioma	32	16	8		36	18	9		40	20	10
CNS - re-irradiation	9	9	4		10	10	5		11	11	6
H&N - Parnasal Sinus	27	27	20		31	31	24		36	36	27
H&N - Nasopharyngeal	5	5	4		6	6	4		6	6	5
H&N - Oral Cavity	119	93	23		141	110	27		161	126	31
H&N - Salivary	15	13	1		18	16	2		21	18	2
H&N - Pharyngeal	62	62	43		73	73	51		84	84	59
H&N - Laryngeal	49	49	24		58	58	29		66	66	33
H&N - re-irradiation	28	28	21		33	33	25		37	37	28
Prostate	589	353	71		713	428	86		842	505	101
Bladder	289	167	33		346	201	40		415	241	48
Non-small Cell lung Cancer	690	525	184		849	645	226		1,029	782	274
Small Cell Lung Cancer	122	93	14		150	114	17		182	138	21
Breast	932	773	85		1,081	897	99		1,239	1,028	113
Vulva/Vagina	40	28	3		45	32	3		50	35	4
Cervix	47	27	7		49	29	7		52	30	8
Corpus	224	103	26		262	121	30		298	137	34
Esophageal	62	49	12		75	60	15		88	71	18
Gastric	102	20	5		121	24	6		142	28	7
Rectal	494	302	30		578	353	35		677	413	41
Pancreatic	196	39	4		233	47	5		278	56	6
Hodgkin	30	20	4		32	21	4		35	23	5
Non-Hodgkin	264	79	16		306	92	18		356	107	21
Sarcoma retroperitoneal	14	14	14		14	14	14		14	14	14
Sarcoma Extremities	52	52	13		52	52	13		52	52	13

Pediatric - medulloblastoma	1	1	1	1	1	1	1	1	1
Pediatric - Other Brain	17	8	7	17	8	7	17	8	7
Testis	32	6	5	32	6	5	32	6	5
Other Cancers	2,755	1,882	-	3,252	2,221	-	4,555	3,105	-
Total Cancer Patients	7,386	4,924	743	8,716	5,811	876	10,932	7,288	1,017
			15%						

Table B. Modeled projections of Proton Therapy patient panel growth in Massachusetts.

Name	State of Massachusetts
Population	7,106,597
Medicare Administrative Contractor	NGS
State	MA
State Population	7,106,597
Number of New Cancer (2024)*	44,040
New Cancer In Region	44,040

*Source: American Cancer Society - Cancer Facts and Figures 2024
	Source: A	merican Ca	ncer Society	- (Cancer in 2024 and Proton Therapy - Clinical Needs in Netherla						erlands	
	2024				2029				2034			
	# of New Cancer	# treated with RT	# treatable with PT		# of New Cancer	# treated with RT	# treatable with PT		# of New Cancer	# treated with RT	# treatable with PT	
CNS - Base of skull/paraspinal tumors	362	326	326		413	372	372		460	414	414	
CNS - Malignant Brain Tumors	166	153	38		189	174	43		211	194	48	
CNS - Meningioma	190	95	47		216	108	54		241	120	60	
CNS - re-irradiation	52	52	26		59	59	30		66	66	33	
H&N - Parnasal Sinus	159	159	119		188	188	141		215	215	161	
H&N - Nasopharyngeal	28	28	21		34	34	25		38	38	29	
H&N - Oral Cavity	711	555	139		839	655	164		960	749	187	
H&N - Salivary	92	80	8		109	95	9		125	109	11	
H&N - Pharyngeal	370	370	259		437	437	306		500	500	350	
H&N - Laryngeal	291	291	145		343	343	172		393	393	196	
H&N - re-irradiation	165	165	124		195	195	146		223	223	167	
Prostate	3,512	2,107	421		4,250	2,550	510		5,023	3,014	603	
Bladder	1,720	998	200		2,064	1,197	239		2,477	1,437	287	
Non-small Cell lung Cancer	4,117	3,129	1,095		5,064	3,848	1,347		6,134	4,662	1,632	
Small Cell Lung Cancer	726	552	83		894	679	102		1,082	823	123	
Breast	5,555	4,610	507		6,443	5,348	588		7,388	6,132	675	
Vulva/Vagina	236	167	17		266	189	19		297	211	21	
Cervix	279	162	40		293	170	42		310	180	45	
Corpus	1,336	615	154		1,563	719	180		1,777	817	204	
Esophageal	369	295	74		446	357	89		527	422	105	
Gastric	609	122	30		719	144	36		847	169	42	
Rectal	2,948	1,798	180		3,449	2,104	210		4,039	2,464	246	
Pancreatic	1,168	234	23		1,390	278	28		1,659	332	33	

Hodgkin	180	117	23	191	124	25	207	134	27
Non-Hodgkin	1,573	472	94	1,824	547	109	2,123	637	127
Sarcoma	85	85	85	85	85	85	85	85	85
retroperitoneal									
Sarcoma Extremities	313	313	78	313	313	78	313	313	78
Pediatric -	8	4	3	8	4	3	8	4	3
medulloblastoma									
Pediatric - Other Brain	99	49	39	99	49	39	99	49	39
Testis	193	39	31	193	39	31	193	39	31
Other Cancers	16,428	11,219	-	19,392	13,242	-	27,162	18,510	-
Total Cancer Patients	44,040	29,360	4,432	51,967	34,645	5,224	65,179	43,453	6,065
			15%						

Exhibit G: NATIONAL CANCER INSTITUTE, STATE CANCER PROFILES: CANCER INCIDENCE RATES FOR MASSACHUSETTS BY COUNTY

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

		2023 Rural- Urban	Age- Adjusted Incidence Rate ([rate	Lower	Upper				
		Continuum	note]) -	95% Carfidana	95% Carfilana	CI*Rank		User of CI	Average
County	FIPS	urban note])	cases per 100,000	Interval	Interval	([rank note])	Lower CI (CI*Rank)	(CI*Rank)	Annual Count
Massachusetts(7)	25000	N/A	437.2	435.2	439.2	N/A	N/A	N/A	38523
US (SEER+NPCR)(1)	0	N/A	444.4	444.1	444.7	N/A	N/A	N/A	1744459
Plymouth County(7)	25023	Urban	476.5	469.1	484	1	1	2	3415
Berkshire County(7)	25003	Urban	458.4	444.5	472.7	2	1	7	949
Worcester County(7)	25027	Urban	457.1	451.2	463.1	3	2	6	4854
Norfolk County(7)	25021	Urban	454.3	448	460.6	4	2	6	4198
Bristol County(7)	25005	Urban	453.8	446.8	460.9	5	2	7	3357
Barnstable County(7)	25001	Urban	447.4	437.4	457.7	6	2	8	1982
Hampden County(7)	25013	Urban	436.4	428.6	444.3	7	6	9	2568
Essex County(7)	25009	Urban	433.6	427.7	439.5	8	7	10	4509
Nantucket County(7)	25019	Rural	419.9	375.8	468	9	2	14	70
Middlesex County(7)	25017	Urban	414	409.9	418.2	10	9	13	8022
Franklin County(7)	25011	Rural	410.7	392.8	429.3	11	9	14	452
Hampshire County(7)	25015	Urban	406.8	393.8	420.2	12	9	14	823
Suffolk County(7)	25025	Urban	405.5	399.1	412	13	10	14	3187
Dukes County(7)	25007	Rural	403.3	371.4	437.6	14	7	14	137

Created by statecancerprofiles.cancer.gov on 03/03/2025 1:14 pm.

State Cancer Registries may provide more current or more local data.

Trend

Rising when 95% confidence interval of average annual percent change is above 0. Stable when 95% confidence interval of average annual percent change includes 0. Falling when 95% confidence interval of average annual percent change is below 0.

[rate note] Incidence rates (cases per 100,000 population per year) are age-adjusted to the 2000 US standard population [http://www.seer.cancer.gov/stdpopulations/stdpop.19ages.html] (19 age groups: <1, 1-4, 5-9, ..., 80-84, 85+). Rates are for invasive cancer only (except for bladder cancer which is invasive and in situ) or unless otherwise specified. Rates calculated using SEER*Stat. Population counts for denominators are based on Census populations as modified [https://seer.cancer.gov/popdata/] by NCI. The US Population Data File [https://seer.cancer.gov/popdata/] is used for SEER and NPCR incidence rates.

[trend note] Incidence data come from different sources. The Average Annual Percent Change (AAPC) is based on the APCs calculated by Joinpoint. Due to data availability issues, the time period used in the calculation of the Joinpoint regression model may differ [https://statecancerprofiles.cancer.gov/historicaltrend/differences.html] for selected counties.

Rates and trends are computed using different standards for malignancy. For more information see malignant.html.

^ All Stages refers to any stage in the Surveillance, Epidemiology, and End Results (SEER) Summary/Historic Combined Summary Stage (2004+) [https://seer.cancer.gov/tools/ssm/].

[rank note]Results presented with the CI*Rank statistics help show the usefulness of ranks. For example, ranks for relatively rare diseases or less populated areas may be essentially meaningless because of their large variability, but ranks for more common diseases in densely populated regions can be very useful. More information about methodology can be found on the CI*Rank website.

[rural urban note] Rural-Urban Continuum Codes provided by the USDA [https://www.ers.usda.gov/data-products/rural-urban-continuum-codes].

1 Source: National Program of Cancer Registries [https://www.cdc.gov/cancer/npcr/index.htm] and Surveillance, Epidemiology, and End Results [http://seer.cancer.gov] SEER*Stat Database - United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Based on the 2023 submission.

7 Source: SEER November 2023 submission.

8 Source: Incidence data provided by the SEER Program. (http://seer.cancer.gov) AAPCs are calculated by the Joinpoint Regression Program (https://surveillance.cancer.gov/joinpoint/) and are based on APCs. Data are age-adjusted to the 2000 US standard population (http://www.seer.cancer.gov/stdpopulations/single_age.html) (19 age groups: <1, 1-4, 5-9, ..., 80-84,85+). Rates are for invasive cancer only (except for bladder cancer which is invasive and in situ) or unless otherwise specified. Population counts for denominators are based on Census populations as modified by NCI. The US Population Data (http://seer.cancer.gov/popdata/) File is used with SEER November 2023 data.

Data for the United States does not include data from Indiana.

Data for the United States does not include Puerto Rico.

Incidence Rates for Massachusetts by County



Created by statecancerprofiles.cancer.gov on 02/19/2025 11:44 am.

State Cancer Registries may provide more current or more local data.

+ Incidence rates (cases per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ..., 80-84, 85+). Rates are for invasive cancer only (except for bladder cancer which is invasive and in situ) or unless otherwise specified. Rates calculated using SEER*Stat. Population counts for denominators are based on Census populations as modified by NCI. The US Population Data File is used for SEER and NPCR incidence rates.

+ Incidence data come from different sources. The Average Annual Percent Change (AAPC) is based on the APCs calculated by Joinpoint. Due to data availability issues, the time period used in the calculation of the joinpoint regression model may differ for selected counties.

Rates and trends are computed using different standards for malignancy. For more information see malignant.html.

^ All Stages refers to any stage in the Surveillance, Epidemiology, and End Results (SEER) Summary/Historic Combined Summary Stage (2004+).

¹ Source: <u>National Program of Cancer Registries</u> and <u>Surveillance, Epidemiology, and End Results</u> SEER*Stat Database - United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Based on the 2023 submission.

⁷ Source: SEER November 2023 submission.

⁸ Source: Incidence data provided by the <u>SEER Program</u>. AAPCs are calculated by the <u>Joinpoint Regression Program</u> and are based on APCs. Data are age-adjusted to the <u>2000 US</u> <u>standard population</u> (19 age groups: <1, 1-4, 5-9, ..., 80-84,85+). Rates are for invasive cancer only (except for bladder cancer which is invasive and in situ) or unless otherwise specified. Population counts for denominators are based on Census populations as modified by NCI. The <u>US Population Data</u> File is used with SEER November 2023 data.

Data for the United States does not include data from Indiana. Data for the United States does not include Puerto Rico.

EXHIBIT H: SUPPLEMENTAL APPENDIX FOR PROTON THERAPY¹¹⁷

Proton Therapy and Graphic Comparisons to Photon Therapy.

Figure 1: Graphic depicting differences between Proton Therapy and Photon Radiation Therapy.



¹¹⁷ This Appendix contains slides from a presentation given by Dr. FitzGerald to the UMass Chan Dean/Chancellor.

Figure 2: Graphic depicting differences in radiation dose to normal tissue in a head/neck cancer patient treated with proton and photon therapy, and graphic depicting exit dose and no exit dose.

Proton Therapy is Rapidly Expanding as a Precise Necessary Tool in Cancer Care

X-Ray Therapy (IMRT)

Proton Therapy (IMPT)



Exit Dose

Source: Health Council of the Netherlands. Proton radiotherapy. Horizon scanning report. The Hague: Health Council of therNetis 2009; publication no. 2009/17E

No Exit Dos

Clinical Indications Treated by Proton Therapy. The indications for Proton Therapy are increasing in most adult malignancies of the central nervous system, head/neck, thorax, abdomen, pelvis, and extremities. Re-treatment of targets is becoming increasingly important in the oncology population and these patients greatly benefit from Proton Therapy as dose to normal tissue is further decreased compared to photon therapy. As can be seen in <u>Figure 1</u>, the disease sites treated with Proton Therapy have greatly expanded into both adult and pediatric clinical care.



Figure 3: The expanding role of proton therapy in cancer care.

The indications for Proton Therapy have likewise greatly expanded over the past decade. As can be seen in <u>Figure 4</u>, there has been a significant increase in the use of proton therapy for adult malignancies according to the National Association for proton therapy. There has been a significant expansion for proton therapy for re-irradiation of previously treated patients and 60% of NCCN centers have and/or are developing proton centers.



Figure 4. Four diagrams, depicting the increasing disease site utilization for Proton Therapy including the significant increase in the use of protons for re-irradiation.

Expanded Clinical Guidelines for Proton Therapy. The National Comprehensive Cancer Network (NCCN) also provides guidelines for cancer care, which are used to guide treatment decisions and insurance coverage. The NCCN has recognized the expanding role of Proton Therapy in the care of patients with cancer. The figure below depicts how the guidelines have expanded over the past several





Figure 5. Graphic demonstrating clinical improvements noted in patients treated with protons.