#### **Memorandum to the Commissioner**

**APPLICANT:** Tufts Medicine, Inc.

800 District Ave, Suite 1520 Burlington, MA 01803

PROJECT NUMBER: DoN #TUFTS-22081208-EA (Emergency DoN)

Filing DATE: October 21, 2022

# **Introduction**

This memorandum presents, for Commissioner's Review and action, the Determination of Need (DoN) Program's recommendation pertaining to a request by Tufts Medicine, Inc. ("Tufts"), for an Emergency DoN pursuant to 105 CMR 100.740. The Applicant seeks to expand its existing Radiation Therapy service by assuming control of an existing linear accelerator (LINAC) located at 115 Lincoln Street, Framingham, Massachusetts 01702 (Proposed Project). As described further herein, the Applicant seeks approval for an Emergency DoN due to an Imminent closure of the Radiation Oncology service at MetroWest Medical Center ("MWMC").

The total value of the Proposed Project is \$7,078,647.00. There is neither Community Health Initiative (CHI) contribution nor a DoN filing fee required for an Emergency DoN.

### 1. Nature of the Emergency

On April 13, 2022, MWMC informed the Department and local communities and the Patient Family Advisory Council (PFAC) of the closure of the Medical and Radiation Oncology Services at the Framingham Union Campus. Due in part to the lasting effects of the COVID-19 pandemic, MWMC announced that it can no longer offer radiation therapy through its Cancer Center, it will be discontinuing care at that site and will, in the future, transition cancer services to St. Vincent's Hospital in Worcester, MA.

Consequently, when MWMC discontinues its radiation oncology services, radiation therapy treatment services will no longer be available within the greater Framingham community. In order to provide the community with continued access to timely, lifesaving, critically needed services, the Applicant, Tufts Medicine, Inc., seeks approval for an Emergency DoN for the authority to operate the existing linear accelerator (LINAC)<sup>ii,iii</sup> that provides radiation therapy. The LINAC unit will remain at MWMC, its current location. Approval is required for such a transfer, because a LINAC is DoN-Required Equipment.<sup>iv</sup> Following approval, the LINAC will be added as a satellite to Tufts MC's license.

# 2. Identity of The Applicant

Tufts Medicine, Inc. (Applicant) located at 800 District Avenue, Burlington, MA 01803 is a regional

health system based in Burlington, Massachusetts. The system includes four hospitals – Tufts Medical Center (Tufts MC), MelroseWakefield Hospital, Lawrence Memorial Hospital, and Lowell General Hospital; an integrated care network; home health and hospice; and affiliate physician practices.

Tufts MC, an academic medical center located in Boston, Massachusetts, is the principal teaching hospital of Tufts University School of Medicine. It is a national provider in the delivery of care for the prevention, diagnosis, and treatment of cancer and is accredited by the American College of Surgeons' Commission on Cancer as an "Academic Comprehensive Cancer Program" and is a member of the Association of American Cancer Institutes ("AACI"). Cancer Services are currently offered at Tufts MC Cancer Center (Boston) and the Tufts MC Cancer Center (Stoneham) where it provides wide range of services to prevent, diagnose and treat cancer.

#### 3. Proposed Project: Nature, Scope, Location, and Projected Costs

As previously described, the Proposed Project includes the acquisition of one LINAC unit which the Applicant will lease from MWMC and will remain in its current location at MWMC to further ensure continuity of care and familiarity for patients. Additionally, Tufts MC will lease the surrounding space to provide the critically needed radiation oncology services, and also the medical oncology services, including infusion therapy (e.g., chemotherapy) and become the licensee of this service. vi

The Applicant notes that the radiation therapy treatments that for some cancer patients may be needed daily over the course of several weeks, can leave patients in a compromised physical and emotional state. Consequently, traveling to the Saint Vincent's site in Worcester is an undue burden for many patients and most importantly, for others, may present an insurmountable challenge due to limited transportation options, and the time and/or cost of traveling between Framingham and Worcester. As a result, the Applicant asserts, it is clear that an emergency exists related to access to care and that radiation therapy services must be maintained in Framingham with minimal disruption to patient care. To that end, the Applicant seeks to immediately take over MWMC's LINAC. The Applicant projects there will be 2,632 treatments annually.

# **Staff Analysis**

Staff notes that the Department held a public hearing on July 6, 2022, regarding MWMC's proposed plans to discontinue Oncology Infusion and Radiation Oncology services, and subsequent to that hearing "the Department made a finding that the services provided by the Hospital {MWMC} are in fact necessary for preserving access and health status within the Hospital's service area." vii Accordingly, the Hospital was required to prepare a plan that details how access to Oncology Infusion services and Radiation Oncology Services will be maintained for the residents of the service area. As such, the negotiations with Tufts MC have been under way for several months according to the documents in the record. viii

The Applicant made a convincing case that residents of the service area do face challenges and potential disruptions in their ongoing cancer treatment plan if the closure of the LINAC radiation

service at MWMC occurs, and consequently, that there is an urgent need for patients residing in Framingham and surrounding communities, who are currently undergoing cancer treatments to have uninterrupted continuity of care and access to radiation therapy services as such treatments may be required daily. ix Requiring patients to travel extensive distances to access radiation therapy creates an undue burden on them, and their accompanying family/caregivers and their outcomes may be negatively impacted by the reduction in access to this service.

#### **Findings**

Based upon a review of the Proposed Project as submitted by the Applicant, DoN staff recommend that the Commissioner determine that there is an Emergency Situation, as defined in 105 CMR 100.100, and staff recommend that the Commissioner issue a Notice of Determination of Need, subject to all Standard Conditions set out in 105 CMR 100.310(A) except 100.310(A)(10).

Staff further recommend that, in light of the urgent need to maintain access to and continuity of treatment, certain notice and comment regulations be waived, specifically 105 CMR 100.435(D) and 105 CMR 100.440 (B), and the related sections of 105 CMR 100.405(C)(2).

<sup>&</sup>lt;sup>1</sup> https://www.mass.gov/doc/120-day-notice-of-intent-to-discontinue-services-pdf-metrowest-medical-center-2022/download

<sup>&</sup>quot;https://www.radiologyinfo.org/en/info/linac

https://www.mayoclinic.org/tests-procedures/radiation-therapy/about/pac-20385162

LINACs are an established technology for the treatment of many cancers through the delivery of external beam radiation therapy. They direct high-energy x-rays to the patient's tumor with the goal of damaging cancerous cells and leaving healthy cells unharmed. Over a series of treatment sessions, the cancer cells will die from repeated exposure and will lose the ability to spread or multiply. Radiation therapy may be used as the only treatment course for a patient's cancer; Before surgery, to shrink a cancerous tumor; After surgery, to stop the growth of any remaining cancer cells; In conjunction with other treatment options, such as chemotherapy; Or to alleviate symptoms of advanced cancers, rather than as part of a patient's treatment plan.

<sup>&</sup>lt;sup>v</sup> Preventative services include state-of-the- art genetic testing and risk-assessment counseling to help patients stay cancer-free throughout their lifetime. To diagnose cancer in the earliest and most treatable stages, Tufts MC employs the latest technology, including 3-D mammography, magnetic resonance imaging, and computed tomography and specialists work with each patient to determine the best treatment plan for their cancer type, health history and lifestyle.

vi These are not DoN required services, and if under the capital expenditure minimums do not require a DoN submission.

vii https://www.mass.gov/doc/dph-determination-of-essential-service-pdf-metrowest-medical-center-2022/download

viii https://www.mass.gov/doc/facility-plan-to-assure-access-pdf-metrowest-medical-center-2022/download

