EMERGENCY APPLICATION FOR DETERMINATION OF NEED

TUFTS MEDICAL CENTER

DON APPLICATION #TUFTS-22081208-EA

Submitted by

TUFTS MEDICINE, INC.
800 DISTRICT AVE, SUITE 1520
BURLINGTON, MA 01803

OCTOBER 21, 2022

TUFTS MEDICINE, INC.
DON APPLICATION #TUFTS-22081208-EA

Table of Contents

APPENDIX 1

APPLICATION FORM

Massachusetts Department of Public Health
Determination of Need
Application Form

Version: 11-8-17

Application Type: Emergency Application

Application Date: 10/21/2022

Applicant Name: Tufts Medicine, Inc.

Mailing Address: 800 District Ave, Suite 1520

City: Burlington State: Massachusetts Zip Code: 01803

Contact Person: Crystal Bloom Title: Regulatory Counsel

Mailing Address: One Beacon Street, Ste 1320

City: Boston State: Massachusetts Zip Code: 02108

Phone: 6175986783 Ext: E-mail: crystal.bloom@huschblackwell.com

Facility Information

List each facility affected and or included in Proposed Project

1 Facility Name: Tufts Medical Center

Facility Address: 115 Lincoln St

City: Framingham State: Massachusetts Zip Code: 01702

Facility type: Hospital CMS Number: 220116

Add additional Facility Delete this Facility

1. About the Applicant

1.1 Type of organization (of the Applicant): nonprofit

1.2 Applicant's Business Type: (•) Corporation ( ) Limited Partnership ( ) Partnership ( ) Trust ( ) LLC ( ) Other

1.3 What is the acronym used by the Applicant's Organization? TUFTS

1.4 Is Applicant a registered provider organization as the term is used in the HPC/CHIA RPO program? (•) Yes ( ) No

1.5 Is Applicant or any affiliated entity an HPC-certified ACO? (•) Yes ( ) No

1.5.a If yes, what is the legal name of that entity? Tufts Medicine, Inc.

1.6 Is Applicant or any affiliate thereof subject to M.G.L. c. 6D, § 13 and 958 CMR 7.00 (filing of Notice of Material Change to the Health Policy Commission)? ( ) Yes (•) No

1.7 Does the Proposed Project also require the filing of a MCN with the HPC? ( ) Yes (•) No

1.8 Has the Applicant or any subsidiary thereof been notified pursuant to M.G.L. c. 12C, § 16 that it is exceeding the health care cost growth benchmark established under M.G.L. c. 6D, § 9 and is thus, pursuant to M.G.L. c. 6D, §10 required to file a performance improvement plan with CHIA? ○ Yes ◉ No

1.9 Complete the Affiliated Parties Form

2. Project Description

2.1 Provide a brief description of the scope of the project.

See attached narrative.

2.2 and 2.3 Complete the Change in Service Form

3. Delegated Review

3.1 Do you assert that this Application is eligible for Delegated Review? ◉ Yes ○ No

3.1.a If yes, under what section? Emergency Application

4. Conservation Project

4.1 Are you submitting this Application as a Conservation Project? ○ Yes ◉ No

5. DoN-Required Services and DoN-Required Equipment

5.1 Is this an application filed pursuant to 105 CMR 100.725: DoN-Required Equipment and DoN-Required Service? ○ Yes ◉ No

6. Transfer of Ownership

6.1 Is this an application filed pursuant to 105 CMR 100.735? ○ Yes ◉ No

7. Ambulatory Surgery

7.1 Is this an application filed pursuant to 105 CMR 100.740(A) for Ambulatory Surgery? ○ Yes ◉ No

8. Transfer of Site

8.1 Is this an application filed pursuant to 105 CMR 100.745? ○ Yes ◉ No

9. Research Exemption

9.1 Is this an application for a Research Exemption? ○ Yes ◉ No

10. Amendment

10.1 Is this an application for a Amendment? ○ Yes ◉ No

11. Emergency Application

11.1 Is this an application filed pursuant to 105 CMR 100.740(B)? ◉ Yes ○ No

11.2 Is the emergency situation due to a government declaration? ○ Yes ◉ No

11.3 If No, Please describe the destruction/substantial damage to the Applicant's Health Care Facility and its impact upon public health.

See attached narrative.

12. Total Value and Filing Fee

Enter all currency in numbers only. No dollar signs or commas. Grayed fields will auto calculate depending upon answers above.

Your project application is for: Emergency Application

12.1 Total Value of this project:	$7,078,647.00
12.2 Total CHI commitment expressed in dollars: (calculated)	$0.00
12.3 Filing Fee: (calculated)	$0.00
12.4 Maximum Incremental Operating Expense resulting from the Proposed Project:	$3,083,011.00
12.5 Total proposed Construction costs, specifically related to the Proposed Project, If any, which will be contracted out to local or minority, women, or veteran-owned businesses expressed in estimated total dollars.	

13. Factors

Required Information and supporting documentation consistent with 105 CMR 100.210

Some Factors will not appear depending upon the type of license you are applying for.

Text fields will expand to fit your response.

Documentation Check List

The Check List below will assist you in keeping track of additional documentation needed for your application.

Once you have completed this Application Form the additional documents needed for your application will be on this list. E-mail the documents as an attachment to: DPH.DON@state.ma.us

- ☐ Copy of Notice of Intent
- ☐ Certification from an independent Certified Public Accountant
- ☐ Articles of Organization / Trust Agreement

Document Ready for Filing

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To submit the application electronically, click on the"E-mail submission to Determination of Need" button.

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E-mail submission to Determination of Need

Application Number: TUFTS-22081208-EA

Use this number on all communications regarding this application.

☐ Community Engagement-Self Assessment form

APPENDIX 2

NARRATIVE

1. Identity of the Applicant

Tufts Medicine, Inc. ("Applicant") located at 800 District Avenue, Burlington, MA 01803 is filing a Notice of Determination of Need ("Application"), pursuant to *105 CMR 100.740: Emergency Applications,* with the Massachusetts Department of Public Health ("Department" or "DPH") for the establishment of a cancer service to ensure the continuation of critically needed radiation therapy services. The Applicant is requesting immediate permission to have the authority to operate a linear accelerator ("LINAC") unit to be located at 115 Lincoln Street, Framingham, Massachusetts 01702 ("Proposed Project").

Tufts Medicine is a regional health system based in Burlington, Massachusetts. The system includes four hospitals – Tufts Medical Center, MelroseWakefield Hospital, Lawrence Memorial Hospital, and Lowell General Hospital; an integrated care network; home health and hospice; and affiliate physician practices. Tufts Medical Center ("Tufts MC") is an academic medical center located in Boston, Massachusetts. It is the principal teaching hospital of Tufts University School of Medicine and includes Tuft's Children's Hospital. Tufts MC is a national leader in the prevention, diagnosis, and treatment of cancer. The Tufts MC Cancer Center is an 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"). Services are currently offered at the Tufts MC Cancer Center in downtown Boston and the Tufts MC Cancer Center in Stoneham. Through these locations, Tufts MC provides wide range of services to prevent, diagnose and treat cancer. 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. Most importantly, Tufts MC specialists work with each patient individually to determine the best treatment plan for their cancer type, health history and lifestyle.

2. Nature of the Emergency

On April 13, 2022, the City of Framingham and surrounding communities learned critical outpatient oncology services provided by MetroWest Medical Center ("MWMC") were facing eminent closure. Due in part to the lasting effects of the COVID-19 pandemic, MWMC is no longer able to continue to offer radiation therapy through its Cancer Center and will be discontinuing services effective October 31, 2022. Therefore, MWMC's outpatient cancer services will transition to St. Vincent's Hospital in Worcester, MA later this year where existing patients can choose to continue their treatment.

However, recognizing the compromised physical and emotional state of the patients receiving daily therapy treatment over the course of several weeks, traveling to Worcester is an undue burden for many patients and present an insurmountable challenge for others due to limited transportation options, the high cost of traveling to Worcester, and/or the amount of time needed to travel between Framingham and Worcester. As a result, it is clear that an access to care emergency exists and that radiation oncology services must be maintained in Framingham with minimal disruption to patient care. To that end, the Applicant seeks to immediately take over MWMC's radiation therapy service in order to maintain the highest degree of care continuity.

Therefore, unless this Emergency Application is approved, radiation therapy treatment services will no longer be available within the greater Framingham community when MWMC discontinues its radiology oncology services on October 31, 2022. In order to provide the community with continued access to lifesaving, critically needed services, the Applicant is seeking to operate the service in the same location through Tufts MC. To that end, this Application respectfully seeks an Emergency Determination of Need ("DoN") for Tufts MC to operate a LINAC unit at 115 Lincoln Street, Framingham, Massachusetts 01702.

3. Nature, scope, location, and projected costs of the Proposed Project

The Proposed Project includes the acquisition of one LINAC unit the Applicant will lease from MWMC. The LINAC unit will remain in its current location at MWMC to further ensure continuity and familiarity for patients. Additionally, the Applicant will lease the surrounding space to provide critically needed radiation oncology services as well as medical oncology services, including infusion therapy (e.g., chemotherapy). The Proposed Project addresses just one aspect of the care the Applicant seeks to provide within the greater Framingham community.

Specifically, the Applicant seeks approval to operate a LINAC machine for the delivery of external beam radiation therapy. The machine is able to direct high-energy x-rays to the patient's tumor with the goal of damaging cancerous cells and leaving healthy cells unharmed.[1] 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.[2]

[1] https://www.radiologyinfo.org/en/info/linac
[2] https://www.mayoclinic.org/tests-procedures/radiation-therapy/about/pac-20385162

Through the Proposed Project, Tufts MC will provide patients in the Framingham community with greater access to services, academic medical center specialists, seamless transitions to Boston if needed and more resources locally. As with its other cancer centers, Tufts MC will offer a range of necessary outpatient oncology services at MWMC. Services will include radiation therapy, hematology/oncology care, infusion services, pharmacy and laboratory services. The care teams, including the physicians, nurses and support staff, will be supplemented with Tufts MC Cancer Center resources and specialists. This arrangement will provide more convenient access to clinical trials, easier access to specialty oral cancer medications, access to comprehensive genetic programs, enhanced electronic medical records and check-in processes, and a higher level of coordinated care with local specialists and a seamless transfer to Boston if additional specialized care is needed.

The cost of the Proposed Project is estimated to be $7,078.647.

4. Demonstrate that the Proposed Project will address the Emergency Situation, and without issuance of a Notice of Determination of Need, that the public health will be measurably harmed.

The Proposed Project is necessary to ensure continued access to radiation therapy in the Framingham community. Without access to radiation therapy closer to home, patients will need to travel significant distances for treatment, or potentially miss or forego treatment altogether. Through the Proposed Project, existing and future patients will continue to access radiation therapy services in their community. Accordingly, the continuation of radiation therapy is necessary to ensure the community has timely, convenient and equitable access to cancer services that historically have been provided by MWMC. In the absence of local radiation therapy and expert medical care teams, the public health of the Framingham community will be measurably harmed as a result of the hardship placed upon patients seeking access to critically needed cancer treatment. Through the Applicant's Proposed Project, the community will maintain access to convenient, high-quality oncology services in furtherance of improved health care outcomes and quality of life.

APPENDIX 3

CHANGE IN SERVICE

Massachusetts Department of Public Health
Determination of Need
Change in Service

Version: DRAFT 6-14-17

DRAFT

Application Number: TUFTS-22081208-EA Original Application Date: 10/21/2022

Applicant Information

Applicant Name: Tufts Medicine, Inc.

Contact Person: Crystal Bloom Title: Regulatory Counsel

Phone: 6175986783 Ext: E-mail: crystal.bloom@huschblackwell.com

Facility: Complete the tables below for each facility listed in the Application Form

1 Facility Name: Tufts Medical Center CMS Number: 220116 Facility type: Hospital

Change in Service

2.2 Complete the chart below with existing and planned service changes. Add additional services with in each grouping if applicable.

Add/Del Rows		Licensed Beds	Operating Beds	Change in Number of Beds (+/-)		Number of Beds After Project Completion (calculated)		Patient Days	Patient Days	Occupancy rate for Operating Beds		Average Length of Stay	Number of Discharges	Number of Discharges
		Existing	Existing	Licensed	Operating	Licensed	Operating	(Current/ Actual)	Projected	Current Beds	Projected	(Days)	Actual	Projected
	Acute													
	Medical/Surgical									0%	0%			
	Obstetrics (Maternity)									0%	0%			
	Pediatrics									0%	0%			
	Neonatal Intensive Care									0%	0%			
	ICU/CCU/SICU									0%	0%			
+ -										0%	0%			
	Total Acute									0%	0%			
	Acute Rehabilitation									0%	0%			
+ -										0%	0%			
	Total Rehabilitation									0%	0%			
	Acute Psychiatric													

Add/Del Rows		Licensed Beds Existing	Operating Beds Existing	Change in Number of Beds (+/-) Licensed	Operating	Number of Beds After Project Completion (calculated) Licensed	Operating	Patient Days (Current/ Actual)	Patient Days Projected	Occupancy rate for Operating Beds Current Beds	Projected	Average Length of Stay (Days)	Number of Discharges Actual	Number of Discharges Projected
	Adult									0%	0%			
	Adolescent									0%	0%			
	Pediatric									0%	0%			
	Geriatric									0%	0%			
+ -										0%	0%			
	Total Acute Psychiatric									0%	0%			
	Chronic Disease									0%	0%			
+ -										0%	0%			
	Total Chronic Disease									0%	0%			
	Substance Abuse													
	detoxification									0%	0%			
	short-term intensive									0%	0%			
+ -										0%	0%			
	Total Substance Abuse									0%	0%			
	Skilled Nursing Facility													
	Level II									0%	0%			
	Level III									0%	0%			
	Level IV									0%	0%			
+ -										0%	0%			
	Total Skilled Nursing									0%	0%			

2.3 Complete the chart below If there are changes other than those listed in table above.

Add/Del Rows	**List other services** if Changing e.g. OR, MRI, etc	Existing Number of Units	Change in Number +/-	Proposed Number of Units	Existing Volume	Proposed Volume
+ -	LINAC	0	1	1	0	2,631

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APPENDIX 4

AFFILIATED PARTIES FORM

Massachusetts Department of Public Health
Determination of Need
Affiliated Parties

Version: DRAFT 3-15-17

DRAFT

Application Date: 10/21/2022 Application Number: TUFTS-22081208-EA

Applicant Information

Applicant Name: Tufts Medicine, Inc.

Contact Person: Crystal Bloom Title: Regulatory Counsel

Phone: 6175986783 Ext: E-mail: crystal.bloom@huschblackwell.com

Affiliated Parties

1.9 **Affiliated Parties:**
List all officers, members of the board of directors, trustees, stockholders, partners, and other Persons who have an equity or otherwise controlling interest in the application.

Add/ Del Rows	Name (Last)	Name (First)	Mailing Address	City	State	Affiliation	Position with affiliated entity (or with Applicant)	Stock, shares, or partnership	Percent Equity (numbers only)	Convictions or violations	List other health care facilities affiliated with	Business relationship with Applicant
+ -	Anstiss	Raymond	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Barginere	Cynthia	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Bhathena	Firdaus	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Campbell	Gary	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Campbell	Patricia	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Collins	Scott	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Crage	Michele	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No	Winchester Hospital	No
+ -	Criss	David	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Dandorph	Michael	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee; President & CEO			No		No
+ -	Folch	Damian	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Long	Genia	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Monaco	Anthony	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Shames	Jeffrey	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Valdes Lupi	Monica	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No

Add/ Del Rows	Name (Last)	Name (First)	Mailing Address	City	State	Affiliation	Position with affiliated entity (or with Applicant)	Stock, shares, or partnership	Percent Equity (numbers only)	Convictions or violations	List other health care facilities affiliated with	Business relationship with Applicant
+ -	Vincze	Christopher	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Yang	Clarissa	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No		No
+ -	Green	Susan	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Treasurer			No		No
+ -	Weinstein	Jeffrey	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Secretary			No		No
+ -	Prendergast	Naomi	800 District Ave, Suite 520	Burlington	MA	Tufts Medicine, Inc.	Trustee			No	D'Youville Life and Wellness Community	No
+ -					MA							
+ -					MA							
+ -					MA							

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APPENDIX 5

AFFIDAVIT OF TRUTHFULNESS AND COMPLIANCE

Massachusetts Department of Public Health
Determination of Need
Affidavit of Truthfulness and Compliance with Law and Disclosure Form 100.405(B)

Version: 7-6-17

Instructions: Complete Information below. When complete check the box "This document is ready to print:". This will date stamp and lock the form. Print Form. Each person must sign and date the form. When all signatures have been collected, scan the document and e-mail to: **dph.don@state.ma.us** Include all attachments as requested.

Application Number: TUFTS-22081208-EA

Original Application Date: 10/21/2022

Applicant Name: Tufts Medicine, Inc.

Application Type: Emergency

Applicant's Business Type: ☒ Corporation ☐ Limited Partnership ☐ Partnership ☐ Trust ☐ LLC ☐ Other

Is the Applicant the sole member or sole shareholder of the Health Facility(ies) that are the subject of this Application? ☒ Yes ☐ No

The undersigned certifies under the pains and penalties of perjury:

1. The Applicant is the sole corporate member or sole shareholder of the Health Facility[ies] that are the subject of this Application;
2. I have ~~read~~* 105 CMR 100.000, the Massachusetts Determination of Need Regulation;
3. I understand and agree to the expected and appropriate conduct of the Applicant pursuant to 105 CMR 100.800;
4. I have ~~read~~* this application for Determination of Need including all exhibits and attachments, and ~~certify that~~** all of the information contained herein is accurate and true;
5. I have submitted the correct Filing Fee and understand it is nonrefundable pursuant to 105 CMR 100.405(B);
6. I have submitted the required copies of this application to the Determination of Need Program, and, as applicable, to all Parties of Record and other parties as required pursuant to 105 CMR 100.405(B);
7. I have caused, as required, notices of intent to be published and duplicate copies to be submitted to all Parties of Record, and all carriers or third-party administrators, public and commercial, for the payment of health care services with which the Applicant contracts, and with Medicare and Medicaid, as required by 105 CMR 100.405(C), et seq.;
8. I ~~have caused~~** proper notification and submissions to the Secretary of Environmental Affairs pursuant to 105 CMR 100.405(E) and 301 CMR 11.00; will be made if applicable
9. If subject to M.G.L. c. 6D, § 13 and 958 CMR 7.00, I have submitted such Notice of Material Change to the HPC - in accordance with 105 CMR 100.405(G);
10. Pursuant to 105 CMR 100.210(A)(3), I certify that both the Applicant and the Proposed Project are in material and substantial compliance and good standing with relevant federal, state, and local laws and regulations, as well as with all ~~previously issued~~ Notices of Determination of Need ~~and the terms and conditions attached therein~~***;
11. I have ~~read~~* and understand the limitations on solicitation of funding from the general public prior to receiving a Notice of Determination of Need as established in 105 CMR 100.415;
12. I understand that, if Approved, the Applicant, as Holder of the DoN, shall become obligated to all Standard Conditions pursuant to 105 CMR 100.310, as well as any applicable Other Conditions as outlined within 105 CMR 100.000 or that otherwise become a part of the Final Action pursuant to 105 CMR 100.360;
13. Pursuant to 105 CMR 100.705(A), I certify that the Applicant has Sufficient Interest in the Site or facility; and
14. Pursuant to 105 CMR 100.705(A), I certify that the Proposed Project is authorized under applicable zoning by-laws or ordinances, whether or not a special permit is required; or,
    a. If the Proposed Project is not authorized under applicable zoning by-laws or ordinances, a variance has been received to permit such Proposed Project; or,
    b. The Proposed Project is exempt from zoning by-laws or ordinances.

Corporation:

Attach a copy of Articles of Organization/Incorporation, as amended

Michael Dandorph		10/19/2022
CEO for Corporation Name:	Signature:	Date
Gary Campbell		10/19/2022
Board Chair for Corporation Name:	Signature:	Date

*been informed of the contents of

**have been informed that

***issued in compliance with 105 CMR 100.00, the Massachusetts Determination of Need Regulation effective January 27, 2017 and amended December 28, 2018

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