

APPLICATION FOR DETERMINATION OF NEED

EMERGENCY APPLICATION

RADIATION THERAPY OF SOUTHEASTERN MA, LLC

DON APPLICATION #-24102910-EA

Submitted by

RADIATION THERAPY OF SOUTHEASTERN MA, LLC

375 LONGWOOD AVE, FLOOR 1

BOSTON, MA 02115

OCTOBER 29, 2024

**RADIATION THERAPY OF SOUTHEASTERN MA, LLC
DON APPLICATION # -24102910-EA**

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APPLICATION FORM



Massachusetts Department of Public Health

Determination of Need

Application Form

Version: 11-8-17

Application Type:	Emergency Application	Application Date:	10/29/2024 11:52 am
Applicant Name:	Radiation Therapy of Southeastern MA, LLC		
Mailing Address:	375 Longwood Ave, Floor 1		
City:	Boston	State:	Massachusetts
		Zip Code:	02115
Contact Person:	Daphne Haas-Kogan, MD	Title:	Manager
Mailing Address:	375 Longwood Ave, Floor 1		
City:	Boston	State:	Massachusetts
		Zip Code:	02115
Phone:	6176322291	Ext:	
E-mail:	dhaas-kogan@bwh.harvard.edu		

Facility Information

List each facility affected and or included in Proposed Project

1 Facility Name:	Brigham and Women's/Sturdy Hospital Radiation Therapy Center		
Facility Address:	89 Forbes Boulevard		
City:	Mansfield	State:	Massachusetts
		Zip Code:	02048
Facility type:	Clinic	CMS Number:	0000569
Add additional Facility		Delete this Facility	

1. About the Applicant

1.1 Type of organization (of the Applicant):	for profit
1.2 Applicant's Business Type:	<input type="radio"/> Corporation <input type="radio"/> Limited Partnership <input type="radio"/> Partnership <input type="radio"/> Trust <input checked="" type="radio"/> LLC <input type="radio"/> Other
1.3 What is the acronym used by the Applicant's Organization?	
1.4 Is Applicant a registered provider organization as the term is used in the HPC/CHIA RPO program?	<input type="radio"/> Yes <input checked="" type="radio"/> No
1.5 Is Applicant or any affiliated entity an HPC-certified ACO?	<input checked="" type="radio"/> Yes <input type="radio"/> No
1.5.a If yes, what is the legal name of that entity?	Mass General Brigham Incorporated, inclusive of Mass General Brigham ACO, LLC
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)?	<input type="radio"/> Yes <input checked="" type="radio"/> No
1.7 Does the Proposed Project also require the filing of a MCN with the HPC?	<input type="radio"/> Yes <input checked="" type="radio"/> 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:	\$13,300,000.00
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:	
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

Document Ready for Filing

When document is complete click on "document is ready to file". This will lock in the responses and date and time stamp the form.

To make changes to the document un-check the "document is ready to file" box. Edit document then lock file and submit

Keep a copy for your records. Click on the "Save" button at the bottom of the page.

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

This document is ready to file:



Date/time Stamp: 10/29/2024 11:52 am

E-mail submission to
Determination of Need

Application Number: -24102910-EA

Use this number on all communications regarding this application.

☐ Community Engagement-Self Assessment form

APPENDIX 2

NARRATIVE

1. Identity of the Applicant.

Radiation Therapy of Southeastern MA, LLC (“Applicant”) 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 expansion of radiation therapy services at its existing DPH licensed clinic, Brigham and Women’s/Sturdy Hospital Radiation Therapy Center located at 89 Forbes Boulevard in Mansfield (“Clinic”). The approval of this request will ensure the continued access for the community to critically needed radiation therapy services following the closure of the Norwood Hospital Cancer Center at Foxboro located at 70 Walnut Street in Foxboro (“Cancer Center”). The Applicant is requesting DoN approval for the right to operate a second linear accelerator (“linac”) at the Clinic to continue to serve the same population displaced by the closure of the Cancer Center (“Proposed Project”).

The Clinic provides radiation oncology services to patients throughout the region. The Clinic is jointly owned by Sturdy Memorial Hospital and Brigham and Women’s Physicians Organization, bringing the resources and expertise of Brigham and Women’s Radiation Oncology services to the community setting. The care team is comprised of board-certified radiation oncologists, highly skilled radiation therapists and physicists, and compassionate nurses who are trained to utilize the most advanced treatment technologies to provide expert, individualized cancer care. The Clinic is a freestanding facility that is not reimbursed at hospital rates, providing a low-cost option for patients in the region.

2. Nature of the Emergency.

On October 7, 2024, Norwood Hospital filed a Notice of Hospital Closure with DPH. The closure of Norwood Hospital includes the discontinuation of services at the Cancer Center, a licensed satellite of Norwood Hospital. As a practical matter, Steward has ceased clinical operations at the Cancer Center and has already begun transitioning patients from the Cancer Center to other providers. The Cancer Center will officially close on November 5, 2024, contemporaneous with the expiration of the Norwood Hospital license. As a result of the closure, patients from the region no longer have access to radiation therapy services at the Cancer Center, resulting in a disruption in access to critically needed cancer treatment close to home.

It is important to recognize that even if the Cancer Center were able to remain in operation, the equipment at this site poses significant patient safety concerns that the Applicant became aware of through extensive due diligence to determine whether the Applicant could operate at the Foxboro site following the closure of the Cancer Center. Following on-site visits to the Cancer Center, the Applicant concluded that the current equipment is not safe for patient use and cannot provide today’s standard of care. Specifically, the Cancer Center provides radiation oncology services on one linear accelerator that is 21 years old, approximately double the life-expectancy of a linear accelerator. The vendor for the unit (Varian) no longer services this treatment unit, exposing a significant safety gap and leaving patients at risk of interrupted services when the unit goes down. The current unit also lacks a multitude of standard of care technologies, including on-board KV imaging to verify daily positioning and prevent radiation dose errors; surface imaging (necessary for breast cancer treatment among other disease types); a robotic couch for accurate positioning of the patient and treatment delivery, precluding the ability of the machine and the Cancer Center to deliver modern, technologically-appropriate radiation treatments. Moreover, the Cancer Center

does not have a functioning CT simulator necessary for treatment planning, requiring transportation of patients, staff, & immobilization equipment to an adjacent facility for treatment planning. This is less than ideal for patients who are undergoing cancer care. While the continuation of services at the Cancer Center may be a temporary stopgap, there are risks to patient safety and continuous access to care. For example, to replace the existing unit at the Cancer Center, the service would need to be taken offline for approximately 12 months. Any continued operation of the existing linear accelerator at the Cancer Center may have current and longer-term detriments for patients.

By contrast, the Clinic's linear accelerator has all the capabilities that are lacking at the Cancer Center. The Clinic also has a CT Simulator on-site allowing for patients to receive all their radiation therapy services in one location. Both units are only four (4) years old. The Clinic's linear accelerator is fully matched in capabilities, technology, and dosimetry with other linear accelerators in the community and Boston. This allows the Clinic to provide the same level of care and expertise that patients can obtain at an academic medical center while not having to travel out of their community for regular treatments (i.e., often daily over several weeks).

It is also important to recognize that the Applicant's Clinic has already met much of the demand of patients displaced by Steward. The Clinic is located 1.8 miles or a four (4) minute drive from the Cancer Center. As such, patients have already begun to seek care at the Clinic. In fact, the Clinic has seen a steady increase in referrals from all Steward sites, and in particular from Norwood Hospital, over the past two years. The number of referrals to the Clinic for Steward patients has doubled since FY22 when compared to years prior. The Clinic has effectively accommodated and treated all referred patients and will be able to accommodate the estimated 5-10 additional patients per day that were being treated at the Cancer Center most recently prior to the cessation of clinical services and its official closure on November 5, 2024. Moreover, the Clinic has undertaken a regionalized approach to ensure that patients receive safe, personalized, high quality cancer treatments close to home. This regionalized approach to care will further ensure that patients will receive the same treatment planning and high-quality equipment should demand at Mansfield outpace capacity before the second unit comes online. Accordingly, the Clinic has met the demand for radiation therapy services locally and will continue to do so following the official closure of the Cancer Center.

While the Clinic has been able to manage increased demand due to the declining state of Steward's operations in recent years, in the long-term, a second linear accelerator will be needed at the Clinic. The Clinic is currently operating at 94% capacity and extended hours to meet demand, but this is not a long-term solution. Over the long-term, the Clinic will require a second unit to sustainably meet increased and continuing demand for radiation therapy in the region. A second unit will ensure the following: timely access for all patients to the safest and most technologically appropriate radiation treatment close to home; redundancy for machine repairs and replacements to prevent detrimental interruptions in care; and additional capacity to accommodate an anticipated aging population with forecasts of increased cancer incidence in this region. With the right to operate a second unit through this emergency DoN, the Clinic will be able to seamlessly meet the needs of the community for access to radiation therapy services without disruption.

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

The Proposed Project includes the acquisition of one linear accelerator unit for operation at the Mansfield Clinic. The Applicant will expand the Clinic to accommodate the second unit through renovation to add a second vault. The cost associated with the unit and associated construction of a second vault is \$13.3M.

The Proposed Project will ensure continued access for patients in the region while the second unit is being implemented. The time to bring a second unit online through an emergency DoN process is significantly reduced, allowing the Applicant and the Commonwealth to meet the needs of patients in the region affected by the closure of the Cancer Center through the provision of services on a safe unit that will ultimately provide a higher quality of care, reduced toxicities, and improved outcomes. Moreover, the time associated with implementation of the unit is not significantly greater than the time it will take to replace the existing linac at the Cancer Center and avoids any additional disruption in care for patients because the Cancer Center will have to close temporarily for at least a year to replace the failing unit. Moreover, if patients at the Cancer Center need to transfer their care during the course of treatment, new treatment planning will need to occur for the patient to receive care on a different machine. This can add to the cost of care for both insurers, including the Commonwealth, and patients. Through the Proposed Project, these potential adverse impacts will be avoided, providing patients with care continuity in a safe, high-quality setting close to home, thereby improving patient outcomes.

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 safe, high-quality radiation therapy for the community. As has slowly occurred over the past two (2) years, Steward patients have been seeking radiation therapy at the Applicant's Clinic and volume has declined at the Cancer Center. Accordingly, the continued operation of the Cancer Center is not needed with the Clinic only 1.8 miles away already caring for the displaced patients. The Applicant has met this demand through a number of operational initiatives and will continue to do so; however, a second unit at the Clinic is ultimately needed as the operational measures are not sustainable long-term as cancer incidence and demand will continue to grow and the existing linac at the Cancer Center is unfit for safe, standard-of-care treatment of patients. Through the Applicant's Proposed Project, the community will maintain access to convenient, safe, high-quality radiation oncology services without further disruption for a community that has already faced uncertainty and meaningful disruption in accessing health care services in recent years.

APPENDIX 3

CHANGE IN SERVICE



Massachusetts Department of Public Health
Determination of Need
Change in Service

Version: DRAFT
6-14-17

DRAFT

Application Number: -24102910-EA

Original Application Date: 10/29/2024

Applicant Information

Applicant Name: Radiation Therapy of Southeastern MA, LLC

Contact Person: Daphne Haas-Kogan, MD

Title: Manager

Phone: 6176322291

Ext:

E-mail: dhaas-kogan@bwh.harvard.edu

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

1 Facility Name: Brigham and Women's/Sturdy Hospital Radiation Therapy Center

CMS Number: 0000569

Facility type: Clinic

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 (Current/ Actual)	Patient Days Projected	Occupancy rate for Operating Beds		Average Length of Stay (Days)	Number of Discharges	Number of Discharges
		Existing	Existing	Licensed	Operating	Licensed	Operating			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%			
<div>+ -</div>										0%	0%			
	Total Acute									0%	0%			
	Acute Rehabilitation									0%	0%			
<div>+ -</div>										0%	0%			
	Total Rehabilitation									0%	0%			
	Acute Psychiatric													

Add/Del Rows		Licensed Beds		Operating Beds		Change in Number of Beds (+/-)		Number of Beds After Project Completion (calculated)		Patient Days		Occupancy rate for Operating Beds		Average Length of Stay (Days)	Number of Discharges	
		Existing		Existing		Licensed	Operating	Licensed	Operating	(Current/ Actual)	Projected	Current Beds	Projected		Actual	Projected
	Adult											0%	0%			
	Adolescent											0%	0%			
	Pediatric											0%	0%			
	Geriatric											0%	0%			
<div><div>+</div><div>-</div></div>												0%	0%			
	Total Acute Psychiatric											0%	0%			
	Chronic Disease											0%	0%			
<div><div>+</div><div>-</div></div>												0%	0%			
	Total Chronic Disease											0%	0%			
	Substance Abuse															
	detoxification											0%	0%			
	short-term intensive											0%	0%			
<div><div>+</div><div>-</div></div>												0%	0%			
	Total Substance Abuse											0%	0%			
	Skilled Nursing Facility															
	Level II											0%	0%			
	Level III											0%	0%			
	Level IV											0%	0%			
<div><div>+</div><div>-</div></div>												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
<div><div>+</div><div>-</div></div>	Linear Accelerator					1	1	2	9,338	13,000

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Edit document then lock file and submit Keep a copy for your records. Click on the "Save" button at the bottom of the page.

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

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Date/time Stamp: 10/29/2024 12:12 pm

E-mail submission to
Determination of Need

APPENDIX 4

AFFILIATED PARTIES



Massachusetts Department of Public Health
Determination of Need
Affiliated Parties

Version: DRAFT
3-15-17

DRAFT

Application Date: 10/29/2024 Application Number: -24102910-EA

Applicant Information

Applicant Name: Radiation Therapy of Southeastern MA, LLC

Contact Person: Daphne Haas-Kogan, M.D Title: Manager

Phone: 6176322291 Ext: E-mail: dhaas-kogan@bwh.harvard.edu

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
<div>+ -</div>	Haas-Kogan	Daphne	44 Binney Street	Boston	MA		LLC Manager				Brigham and Women's Hospital Massachusetts General Hospital Mass General Brigham	
<div>+ -</div>	Patel	Brian	211 Park Street	Attelboro	MA		LLC Manager				Sturdy Memorial Hospital	

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E-mail submission to
Determination of Need

APPENDIX 5

CERTIFICATE OF FORMATION

https://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSearchRedirector.aspx?Action=PDF&Pat h=CORP_DRIVE1/2006/0213/000160537/0008/200634354090_1.pdf

https://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSearchRedirector.aspx?Action=PDF&Pat h=CORP_DRIVE1/2015/0225/000000000/4285/201517206840_1.pdf

APPENDIX 6

AFFIDAVIT



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: -24102910-EA

Original Application Date: 10/29/2024

Applicant Name:

Application Type: Hospital/Clinic Substantial Capital Expenditure

Emergency Application

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

Describe the role /relationship: Owner

The undersigned certifies under the pains and penalties of perjury:

1. The Applicant is ;
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 95B 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.

LLC

All parties must sign. Add additional names as needed.

Type name here

Name: Signature: D. Haer kg 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

Type name here

Name: Signature: Date

This document is ready to print: ☐ Date/time Stamp: