

Massachusetts Department of Public Health Determination of Need Application Form

Version:	11-8-17

Application Type: Amendment			,	Application	Date: 03/20/2	025 9:45 ar	n
Applicant Name: Shields Imaging of Eastern Massachusetts, L	LLC						
Mailing Address: 700 Congress Street							
City: Quincy	State:	Massachusett	S	Zip Code:	02169		
Contact Person: Kerry Whelan		Title: Vice Pre	sident c	of Governme	ent Affairs		
Mailing Address: 700 Congress Street, Suite 204							
City: Quincy	State:	Massachusett	S	Zip Code:	02169		
Phone: 6173767421 Ext:	E-mail:	kerry@shiel	ds.com				
Facility Information List each facility affected and or included in Proposed Proje	ect						
1 Facility Name: Shields Imaging of Eastern Massachuse	etts, LLC						
Facility Address: 55 Fogg Road							
City: Weymouth	State:	Massachusetts	;	Zip Code:	02190		
Facility type: Clinic			CMS	Number: 32	7088		
Add additional Faci	ility		D	elete this Fa	cility		
1. About the Applicant							
1.1 Type of organization (of the Applicant): for profit							
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	?					SIEM	
1.4 Is Applicant a registered provider organization as the term	is used	l in the HPC/CI	HIA RPO	program?		○ Yes	No
1.5 Is Applicant or any affiliated entity an HPC-certified ACO?						○ Yes	No
1.6 Is Applicant or any affiliate thereof subject to M.G.L. c. 6D, 5 Change to the Health Policy Commission)?	§ 13 an	d 958 CMR 7.0	0 (filing	of Notice of	Material	○ Yes	No
1.7 Does the Proposed Project also require the filing of a MCN	with th	ne 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
.9	Complete the Affiliated Parties Form		
).	Project Description		
	Provide a brief description of the scope of the project.		
Th Sh cu	e proposed request is filed with respect to the previously approved DoN Project #4-4886, which established mobile ields Imaging of Eastern Massachusetts, ("SIEM" or "Applicant") located at 55 Fogg Road, South Weymouth, MA 02 rrently operates two days per week. The Applicant requests approval to add five days of PET/CT services at this located in the conject") for a total of seven days.	190. The se	ervice
2.2	and 2.3 Complete the Change in Service Form		
3.	Delegated Review		
	Do you assert that this Application is eligible for Delegated Review?	Yes	○ No
3.1	a If yes, under what section? Certified ACO/DoN-Required Service or Equipment		
1.	Conservation Project		
	Are you submitting this Application as a Conservation Project?	○ Yes	No
	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
5.2	If yes, is Applicant or any affiliated entity thereof a HPC-certified ACO?	○ Yes	No
5.3	See section on DoN-Required Services and DoN-Required Equipment in the Application Instructions		
5.	Transfer of Ownership		
	Is this an application filed pursuant to 105 CMR 100.735?	○ Yes	No
7.	Ambulatory Surgery		
	Is this an application filed pursuant to 105 CMR 100.740(A) for Ambulatory Surgery?	○Yes	No
3.	Transfer of Site		
3.1	Is this an application filed pursuant to 105 CMR 100.745?	○Yes	No
_	Descript Everyntian		
	Research Exemption Is this an application for a Research Exemption?	○ Yes	No
	is this an application for a nescuren Exemption.	() Tes	(NO
10	. Amendment		
	1 Is this an application for a Amendment?	Yes	○ No
ი 1	2 This Amendment is:		
		7	
ıU.	3 Original Application number: 4-4886		

10.3.a Original Applic	ation Type:
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DoN-Required Equipment

10.3.b Original Application filing date:

02/01/2001

10.3.c Have there been any approved Amendments to the original Application?

Yes No

10/01/2018

03/31/2021

03/27/2023

10.3.d Fo	10.3.d For each approved Amendment list all Amendment Numbers, Amendment types, and Approval Dates.			
Add/Del Row	Amendment Number	Amendment Change Type	Approval Date	
+ -	Project #4-4886	Significant	04/03/2003	
+ -	Project #4-4886	Significant	09/27/2005	
+ -	Project #4-4886	Minor	08/09/2006	
+ -	Project #4-4886	Significant	10/12/2011	
+ -	Project #4-4886	Significant	02/13/2013	

Significant

Significant

Significant

For Significant Amendment Changes:

Project #4-4886

Project #4-4886

Project #4-4886

10.5.a Describe the proposed change.

The Applicant currently operates a licensed clinic that provides mobile PET/CT services two days per week at its primary location, 55 Fogg Road, South Weymouth, MA 02190. The Proposed Project seeks approval to add five additional days of PET/CT services in South Weymouth, for a total of seven days of operation.

10.5.b Describe the associated cost implications to the Holder.

The Proposed Project will have no capital cost implications to the Applicant. The PET/CT service is an existing service operated by the Applicant, and the Proposed Project will not result in any additional capital costs to operate the PET/CT five additional days per week.

10.5.c Describe the associated cost implications to the Holder's existing Patient Panel.

The Proposed Project will have no capital cost implications to the Applicant's patient panel. The Applicant currently provides PET/CT services in South Weymouth two days per week and upon DoN Approval will provide a total of seven days of service. All pricing with remain consistent with current charges.

10.5.d Provide a detailed narrative, comparing the approved project to the proposed Significant Change, and the rationale for such change.

The Applicant is Shields Imaging of Eastern Massachusetts, LLC ("SIEM"). Shields Imaging of Massachusetts, LLC was a consortium that received Determination of Need ("DoN") approval in 2002 for Project #4-4886 to acquire a mobile positron emission tomography ("PET/CT") unit to provide services at three host sites. The consortium was comprised of Shields Imaging of Eastern Massachusetts, LLC, Shields Imaging of Worcester, LLC, and Shields Imaging of Springfield, LLC. The host sites offering the mobile PET/CT services included Baystate Medical Center, UMass Memorial Medical Center, and South Shore Hospital. Pursuant to a DoN amendment, each host site was licensed as a separate clinic, one for each member of the original consortium. The three licensed clinics that now hold the approval to provide PET/CT pursuant to Project #4-4886 are Baystate MRI and Imaging Center, LLC ("BMIC"), and UMass Memorial MRI and Imaging Center (UMMIC), and SIEM.

Pursuant to the original DoN and subsequent amendment, SIEM currently operates the mobile PET/CT service two (2) days per week at South Shore Hospital, 55 Fogg Road, South Weymouth, MA 02190. Demand for PET/CT services at South Shore Hospital has increased, resulting in the need for additional PET/CT capacity at that location. The mobile PET/CT unit currently operates at South Shore Hospital on Tuesday from 6:30 AM to 10:00 PM, and Thursday from 6:30 AM to 10:00 PM. Demand for PET/CT services at SIEM has increased, resulting in the need for additional PET/CT capacity at this location.

Historical utilization data shows an increase in individual patients and scans over the past five years. The Applicant performed 1628 scans in 2020; 1770 in 2021; 2018 scans in 2022; 2132 in 2023; and 2758 scans in 2024;. This represents an approximate 69% increase in scans between 2020 and 2024. Moreover, SIEM experienced an increase in unique patients presenting for scans. The Applicant saw 1235 unique patients in 2020, 1400 in 2021, 1568 in 2022, 1743 in 2023, and 2198 in 2024. This is an increase of 63.3% from 2020 to 2024. The Proposed Project seeks to meet the need for increased access to PET/CT for the Applicant's patient panel. As described above,

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demand has significantly increased for PET/CT scans at SIEM over the past five years. This data demonstrates an increased need for access to PET/CT at the clinic, and has resulted in an average wait time of 15 days from referral to the date of the scan. The Applicant also began offering amyloid brain scans in 2024, which is expected to further increase the number of PET/CT scans performed at the clinic in 2025 and beyond. Further, SIEM will expand to offer cardiac PET perfusion scans in 2025 only increasing the number of scans performed at this clinic. Five additional days of service will improve wait times, preventing delays in care. As PET/CT is utilized to detect and monitor high acuity and progressive diseases such as cancer, heart disease, or neurological abnormalities, timely imaging is an essential element of the patient's treatment plan. For example, the top reasons for PET/CT scans at SIEM include all solid tumors, prostate cancer, Neuroendocrine cancer, Cardiac Sarcoidosis, Alzheimer 's disease, Amyloid plaque. With cancer screening standards for lung, prostate, breast and colorectal cancer alone, follow up exams post screening frequently include PET/CT to determine malignancy. Those patients are then monitored through treatment using the same technology that established the malignancy. PET/CT serves this role in a noninvasive, outpatient procedure. Moreover, SIEM anticipates increased demand for PET/CT services as the population ages, with age being the most important risk factor for cancers , Based on 2024 data, approximately 76% of SIEM patient population is over the age of 64; and 96% are over the age of 50. Accordingly, due to the nature of the patient conditions primarily presenting to SIEM and the age of the existing patient panel, it is important that patients have timely and convenient access to this service. The additional five days of service will allow the Applicant to meet the need for patients requiring PET/CT services that would otherwise have to travel to another less convenient facility or would be subject to extended wait times at SIEM. The Applicant projects the five additional days of service would result in approximately 3,104 scans in 2025; 3,414 scans in 2026; 3,756 scans in 2027 and 4,131 scans in 2028. By increasing capacity five additional days per week, The Applicant will be able to accommodate the needs of its existing patient panel, for whom PET/CT is an integral modality as part of their diagnosis and treatment planning, particularly for cancers. Accordingly, the Applicant seeks to add five days of PET/CT service at Shields Imaging of Southeastern Massachusetts, LLC to meet the demonstrated need of its patient panel for additional access. The Holder hereby swears or affirms that the above statements with respect to the proposed Significant Change are True. 11. Emergency Application 11.1 Is this an application filed pursuant to 105 CMR 100.740(B)? Yes No 12. Total Value for Significant Amendments 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 a: Significant Amendment

Filing Fee: \$0

12.1 Proposed increase in total value of this project:

12.2 Total increase in CHI commitment expressed in dollars: (calculated)

12.3 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.

\$0.00

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

\boxtimes C	Copy of Notice of Intent
× A	Affidavit of Truthfulness Form
E	lectronic copy of Staff Summary for Approved DoN
E	lectronic copy of Original Decision Letter for Approved DoN
E	lectronic Copy of any prior Amendments to the Approved DoN
\boxtimes C	Change in Service Tables Questions 2.2 and 2.3
□ C	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:

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Date/time Stamp: 03/20/2025 9:45 am

E-mail submission to Determination of Need

Application Number: -25020312-AM

Use this number on all communications regarding this application.

Community Engagement-Self Assessment form