Shields Signature Imaging, LLC DON APPLICATION# N/A-24102913-AM

SIGNIFICANT AMENDMENT Shields Signature Imaging, LLC

December 2, 2024

BY Shields Signature Imaging, LLC 700 CONGRESS STREET, SUITE 204 QUINCY, MA 02169

Shields Signature Imaging, LLC

DON APPLICATION# N/A-24102913-AM

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Attachment 1:

DoN Application



Massachusetts Department of Public Health Determination of Need Application Form

Application Type:	:: Amendment			A	Application	Date: 12/10/2024 12:10 pm	
Applicant Name:	Shields Signature Imaging, LLC						
Mailing Address:	700 Congress Street, Suite 204						
City: Quincy		State: N	lassachusetts	Zip Code:	02169		
Contact Person: Kerry Whelan			Ti	Title: Vice President Government Affairs			
Mailing Address: 700 Congress Street							
City: Quincy			State: N	lassachusetts	Zip Code:	02169	
Phone: 6173767	421	Ext:	E-mail:	kerry@shields.com			

Facility Information

List each facility affected and or included in Proposed Project							
1 Facility Name: Shields Signature Imaging, LLC							
Facility Address: 680 Center Street							
City: Brockton State: Ma	Assachusetts Zip Code: 02302						
Facility type: Clinic	CMS Number: S300291877						
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: Corporation Limited Partnership Partnership Trust CLC Other							
1.3 What is the acronym used by the Applicant's Organization?	N/A						
1.4 Is Applicant a registered provider organization as the term is used in	n the HPC/CHIA RPO program? C 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? Signature Healthcare	2						
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)?							
1.7 Does the Proposed Project also require the filing of a MCN with the HPC?							

- 1.8 Has the Applicant or any subsidiary thereof been notified pursuant to M.G.L. c. 12C, § 16 that it is exceeding the C Yes · No 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?
- 1.9 Complete the Affiliated Parties Form

2. Project Description

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

The proposed request is filed with respect to DoN Project #5-4958 which established mobile PET/CT services at Shields Signature Imaging, LLC ("Shields Signature" or "Applicant") located at 680 Center Street, Brockton, MA 02302. The service currently operates one day per week on Thursdays. The Application requests approval to add one day of PET/CT services at this location ("Proposed Project") for a total of two days.

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 CNO 3.1.a If yes, under what section? Certified ACO/DoN-Required Service or Equipment 4. Conservation Project 4.1 Are you submitting this Application as a Conservation Project? C 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 5.2 If yes, is Applicant or any affiliated entity thereof a HPC-certified ACO? Yes (No 12/27/2023 5.2.a If yes, Please provide the date of approval and attach the approval letter: 5.3 See section on DoN-Required Services and DoN-Required Equipment in the Application Instructions 6. Transfer of Ownership 6.1 Is this an application filed pursuant to 105 CMR 100.735? C 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? CYes · No 9. Research Exemption 9.1 Is this an application for a Research Exemption? C Yes (No 10. Amendment 10.1 Is this an application for a Amendment? · Yes CNO

C Immaterial Change C Minor Change Significant Change 10.2 This Amendment is:

DoN Project #5-4958

10.3.a Original Application Type:

DoN-Required Equipment

10.3.b Original Application filing date: 07/31/2015

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

For Significant Amendment Changes:

10.5.a Describe the proposed change.

The Applicant currently operates a licensed clinic that provides mobile PET/CT services one day per week at its primary location, 680 Center Street, Brockton, MA 02302. The Proposed Project seeks approval to add one additional day of PET/CT services in Brockton, for a total of two days of operation.

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

The Proposed Project will have no 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 one additional day per week.

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

The Proposed Project will have no cost implications to the Applicant's patient panel. The Applicant currently provides PET/CT services in Brockton one day per week and upon DoN approval will provide two 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.

Shields Signature Imaging, LLC is a joint venture between Shields Imaging, LLC ("Shields") and Signature Healthcare Brockton Hospital ("Brockton Hospital") that received DoN approval to operate a mobile positron emission tomography ("PET/CT") unit to provide services at Brockton Hospital one day per week (DoN Project #5-4958). The PET/CT service is currently provided on Thursdays from 7:00 AM to 5:00PM. Demand for PET/CT services at Shields Signature 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 three years and year-to-date ("YTD"). The Applicant performed 674 scans in 2021; 764 scans in 2022; and 847 scans in 2023. This represents an approximate 15% increase in scans between 2021 and 2022. YTD, the Applicant has performed 651 scans. Moreover, Shields Signature experienced an increase in unique patients presenting for scans. The Applicant saw an increase of 140 unique patients in 2021; an increase of 90 unique patients in 2022; and an increase of 83 unique patients in 2023. The Applicant has seen an increase of 44 unique patients YTD.

The Proposed Project seeks to meet the need for increased access to PET/CT for the Applicant's patient panel. As described above, demand has significantly increased for PET/CT scans at Shields Signature over the past three years. This data demonstrates an increased need for access to PET/CT at the clinic, and has resulted in an average wait time of 16 days from referral to the date of the scan. Furthermore, demand for this service is expected to increase based on the recent migration of over 100 cancer patients from Steward Good Samaritan Hospital in Brockton to Signature Healthcare Brockton Hospital. Shields Signature clinic will also begin offering amyloid and FDG brain scans in 2025, which is expected to further increase the number of PET/CT scans performed at the clinic.

An additional day 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 Shields Signature include all solid tumors, prostate and neuroendocrine cancers and will also include amyloid and FDG brain scans in 2025. 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, Shields Signature anticipates increased demand for PET/CT services as the population ages, with age being the most important risk factor for cancers , Based on 2023 data, approximately 72% of Shields Signature's patient population is over the age of 64; and 95% are over the age of 50. Accordingly, due to the nature of the patient conditions primarily presenting to Shields Signature and the age of the existing patient panel, it is important that patients have timely and convenient access to this service.

The additional day 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 Shields Signature. The Applicant projects the additional day of service would result in approximately 1,080 scans in 2025; 1,242 scans in 2026; and 1,468 scans in 2027. By increasing capacity one additional day 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 one day of PET/CT service at Shields Signature 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)?

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:	\$0.00				
12.2 Total increase in CHI commitment expressed in dollars: (calculated)	\$0.00				
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.					

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
- Affidavit of Truthfulness Form
- Electronic copy of Staff Summary for Approved DoN
- Electronic copy of Original Decision Letter for Approved DoN
- Change in Service Tables Questions 2.2 and 2.3
- 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.							
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	E-mail submission to Determination of Need						
Application N	umber: N/A-24121012-AM	л					
Use this number on all communications regarding this application.							
Community Engagement-Self Assessment fo	orm						