UMASS MEMORIAL MRI & IMAGING CENTER, LLC

DON APPLICATION# UMMIC-22122814-AM

SIGNIFICANT AMENDMENT SHIELDS MRI AT UMASS MEMORIAL -

SHREWSBURY STREET

December 28, 2022

BY

UMASS MEMORIAL MRI & IMAGING CENTER, LLC 700 CONGRESS STREET, SUITE 204 QUINCY, MA 02169

UMASS MEMORIAL MRI & IMAGING CENTER, LLC APPLICATION # UMMIC-22122814-AM

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ATTACHMENT #1 APPLICATION FORM

 Version: 11-8-17

Massachusetts Department of Public Health
Determination of Need
Application Form

Application Type: Amendment

Application Date: 12/28/2022 2:46 pm

Applicant Name: UMass Memorial MRI & Imaging Center, LLC

Mailing Address: 700 Congress Street, Suite 204

City: Quincy State: Massachusetts Zip Code: 02169

Contact Person: Kerry Whelan

Title: VP Government Affairs

Mailing Address: 700 Congress Street, Suite 204

City: Quincy State: Massachusetts Zip Code: 02169

Phone: 6173767421 Ext: none

Email: kerry@shields.com

**Facility Information**

**List each facility affected and or included in Proposed Project**

1. Facility Name: Shields MRI at UMass Memorial -Shrewsbury Street

Facility Address: 214 Shrewsbury Street

City: Worcester State: Massachusetts Zip Code: 01604

Facility type: clinic CMS Number: 002737301

**1. About the Applicant**

1.1 Type of organization (of the Applicant): for profit

1.2 Applicant’s Business Type: LLC

1.3 What is the acronym used by the Applicant’s Organization: UMMIC

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

1.5 Is Applicant or any affiliated entity an HPC-certified ACO? No

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? No

1.7 Does the Proposed Project also require the filing of a MCN with the HPC? 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? 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

3.1a 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? 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

5.2 If yes, is Applicant or any affiliated entity thereof a HPC-certified ACO? No

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? No

**7. Ambulatory Surgery**

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

**8. Transfer of Site**

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

**9. Research Exemption**

9.1 Is this an application for a Research Exemption? No

**10. Amendment**

10.1 Is this an application for a Amendment? Yes

10.2 This Amendment is: Significant Change

10.3 Original Application number: Project #4-4886

10.3.a Original Application Type: 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

10.3.d For each approved Amendment list all Amendment Numbers, Amendment types, and Approval Dates.

|  |  |  |  |
| --- | --- | --- | --- |
| Add/Del Rows | Amendment Number | Amendment Change Type | Approval Date |
| +/- | Project #4-4886 | Significant | 04/10/2003 |
| +/- | Project #4-4886 | Significant | 11/17/2005 |
| +/- | Project #4-4886 | Minor | 08/09/2006 |
| +/- | Project #4-4886 | Significant | 10/13/2011 |
| +/- | Project #4-4886 | Significant | 02/14/2013 |
| +/- | 18080612-AM | Significant | 10/01/2018 |
| +/- | Project #4-4886 | Significant | 01/26/2021 |

**For Significant Amendment Changes:**

10.5.a Describe the proposed change.: See attached narrative

10.5.b Describe the associated cost implications to the Holder.: See attached narrative

10.5.c Describe the associated cost implications to the Holder's existing Patient Panel.: See attached narrative

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

**The Holder hereby swears or affirms that the above statements with respect to the proposed Significant Change are True.:** checked

**11. Emergency Application**

11.1 Is this an application filed pursuant to 105 CMR 100.740(B)? 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: $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. [blank]

**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: check

Affidavit of Truthfulness Form: check

Electronic copy of Staff Summary for Approved DoN: check

Electronic copy of Original Decision Letter for Approved DoN: check

Electronic Copy of any prior Amendments to the Approved DoN: check

Change in Service Tables Questions 2.2 and 2.3: check

Certification from an independent Certified Public Accountant: unchecked

**Documentation 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? yes Date/time Stamp: 12/28/2022 2:45pm

E-mail submission to Determination of Need

**Application Number: UMMIC-22122814-AM**

**Use this number on all communications regarding this application.**

ATTACHMENT #2 PROJECT NARRATIVE

UMMIC DoN -Amendment

**2. Project Description**

The proposed request is filed with respect to DoN Project #4-4886 which established PET/CT services at Shields MRI at UMass Memorial -Shrewsbury Street ("Shrewsbury"), located at 214 Shrewsbury Street, Worcester, MA 01604. The service currently operates four days per week. The Application requests approval to add three days of PET/CT services at this location ("Proposed Project'').

**10. Amendment**

* + 1. **Describe the proposed change.**

UMass Memorial MRI & Imaging Center, LLC ("UMMIC") currently operates a licensed clinic that provides PET/CT services four days per week at its primary location, Shrewsbury. The proposed significant change will add three days of PET/CT services at Shrewsbury, for a total of seven days of operation.

* + 1. **Describe the associated cost implications to the Holder.**

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

* + 1. **Describe the associated cost Implications to the Holder's existing Patient Panel.**

The Proposed Project will have no cost implications to UMMIC's patient panel. UMMIC currently provides PET/CT services at Shrewsbury four days per week and upon DoN approval will provide seven days of service. All pricing with remain consistent with current charges.

* + 1. **Provide a detailed narrative, comparing the approved project to the proposed Significant**

**Change, and the rationale for such change.**

The Applicant is UMMIC. 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 (Baystate Medical Center, South Shore Hospital and UMass Memorial Medical Center). The consortium was comprised of Shields Imaging of Eastern Massachusetts, LLC (for South Shore Hospital); Shields Imaging of Worcester, LLC (for UMass Memorial Medical Center); and Shields Imaging of Springfield, LLC (for Baystate Medical Center). In 2003, a fourth host site at Berkshire Medical Center was added through a DoN amendment. In 2005, the DoN was further amended to add a fifth host site at HealthAlliance Hospital's Burbank Campus. In 2006, a DoN amendment was approved to acknowledge the licensure of the sites as separately licensed clinics and remove Shields Imaging of Massachusetts, LLC as the DoN holder. Accordingly, the three original sites were licensed to the following entities: Baystate MRI and Imaging Center, LLC (BMIC); Shields Imaging of Eastern Massachusetts, LLC and UMass Memorial MRI and Imaging Center, LLC

("UMMIC"). In 2011, the DoN was again amended to add an additional host site of UMMIC at Wing Memorial Hospital and Medical Center; however, this site was not implemented. Again in 2013, an amendment was approved to add a host site of the BMIC clinic at Berkshire Medical Center. However, in 2017, the Berkshire Medical Center site was converted to a separate DoN approved joint venture known

as Shields PET-CT at Berkshire Medical Center, LLC. The three licensed clinics that now hold the approval to provide PET/CT services pursuant to Project #4-4886 are BMIC, SIEM (South Shore Hospital), UMMIC. Pursuant to the original DoN and amendments, UMMIC currently operates the PET/CT services four days per week at Shrewsbury. Demand for PET/CT services at Shrewsbury has increased, resulting in the need for additional PET/CT capacity at this location. The PET/CT services are currently provided on Monday, Wednesday, Thursday and Sunday from 7:00am to 5:30pm. The existing PET/CT service is at capacity and seeks to add three days of service, Tuesday, Friday and Saturday from 7:00am to 5:30pm, to accommodate increased demand.

Historical utilization data shows an increase in individual patients and scans at Shrewsbury over the past three years and year-to-date ("YTD") through October 31, 2022. Shrewsbury performed 1,686 scans in 2019; 1,771 scans in 2020; and 2,191 scans in 2021. This represents an approximate 30% increase in scans between 2019 and 2021. YTD, Shrewsbury has performed 2,230 scans. Moreover, Shrewsbury experienced an increase in unique patients presenting for scans. Shrewsbury had 1,684 unique patients in 2019; 1,732 unique patients in 2020; and 2,106 unique patients in 2021. Shrewsbury has seen 1,939 unique patients YTD.

The Proposed Project seeks to meet the need for increased access to PET/CT for UMMIC's patient panel. As described above, demand has significantly increased for PET/CT scans at Shrewsbury 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 7-14 days from referral to the date of the scan. An additional three 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 Shrewsbury include lung cancer, lymphoma, solitary pulmonary nodule, head and neck nodules, breast cancer, melanoma, cervical cancer, colorectal cancer, esophageal cancer, and prostate cancer. Moreover, UMMJC anticipates increased demand for PET/CT services as the population ages, with age being a significant risk factor for cancers[[1]](#footnote-1), Based on 2022 data, approximately 66% of Shrewsbury's patient population is over the age of 64; and 91% are over the age of 50.

Accordingly, due to the nature of the patient conditions primarily presenting to Shrewsbury and the age of the existing patient panel, it is important that patients have timely and convenient access to this service.

The additional three daysof service will allow UMMIC 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 Shrewsbury. UMMIC projects the additional three days of service would result in approximately 3,244 scans in 2023; 3,703 scans in 2024; and 4,103 scans in 2025. By increasing capacity three additional days per week, UMMIC 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, UMMIC seeks to add three days of PET/CT service at Shrewsbury to meet the demonstrated need of its patient panel for additional access.

ATTACHMENT #3 CHANGE IN SERVICE

 Version 6-14-17

**Massachusetts Department of Public Health**

**Determination of Need**

**Change in Service**

Application Number: UMMIC-22122814-AM

Original Application Date: 12/28/2022

**Applicant Information:**

Applicant Name: UMass Memorial MRI & Imaging Center, LLC

Contact Person: Kerry Whelan

Title: VP Government Affairs

Phone: 6173767421

E-mail: kerry@shields.com

**Facility:**

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

1 Facility Name: Shields MRI at UMass Memorial – Shrewsbury Street

CMS Number: 002737301

Facility Type: clinic

**Change in Service:**

2.2 Complete the chart below with existing and planned service changes. Add additional services within 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** |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Adult |  |  |  |  |  |  |  |  | 0% | 0% |  |  |  |
|  | Adolescent |  |  |  |  |  |  |  |  | 0% | 0% |  |  |  |
|  | Pediatric |  |  |  |  |  |  |  |  | 0% | 0% |  |  |  |
|  | Geriatric |  |  |  |  |  |  |  |  | 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% |  |  |  |

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** |
| +/- |  | 4 | 3 | 7 | 2,191 | 3,244 |

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

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Email Submission to Determination of Need

ATTACHMENT #4 AFFILIATED PARTIES

 draft version 3-15-2017

**Massachusetts Department of Public Health**

**Determination of Need**

**Affiliated Parties**

Application Date: 12/28/2022

Application Number: UMMIC-22122814-AM

**Applicant Information**

Applicant Name: UMass Memorial MRI & Imaging Center, LLC

Contact Person: Kerry Whelan

Title: VP Government Affairs

Phone: 6173767421

E-mail: kerry@shields.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** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| +/- | Shakman | Alice | 55 Lake Ave North | Worcester | MA | UMass Memorial Health Ventures, Inc. | Applicant Board Member | Partnership | 50% | No | UMass Memorial Medical Center | No |
| +/- | Feldman | Robert | 306 Belmont Street | Worcester | MA | UMass Memorial Health Ventures, Inc. | Applicant Board Member | Partnership | 50% | No | UMass Memorial Medical Center | No |
| +/- | Shields | Thomas | 45 Satuit Meadow Lane | Norwell | MA | Shields Health Care Group | Partnership | Partnership |  | No | See attached | No |
| +/- | Ferrari | Peter | 3 Flintlock Dr. | Bedford | MA | Shields Health Care Group | Partnership | Partnership |  | No | See attached | No |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

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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.

This document is ready to file? yes

Date/time Stamp: 12/28/2022 2:33 pm

E-mail submission to Determination of Need

 Affiliated Parties Supplement: Thomas Shields

| **Legal Name** | **DBA** | **Service Location Address** | **City/Town** | **State** | **Zip** | **Medicare****PTAN** |
| --- | --- | --- | --- | --- | --- | --- |
| Southeastern Massachusetts Regional MRI LimitedPartnership | Shields MRI Brockton | 265 Westgate Dr | Brockton | MA | 02301-1817 | 016469 |
| Fall River-New Bedford Regional MRI Limited Partnership | Shields MRI Dartmouth | 313 Faunce Corner Rd | Dartmouth | MA | 02747-1252 | 018869 |
| Fall River-New Bedford Regional MRI Limited Partnership | Shields MRI at St Luke's Hospital | 361 Allen St | New Bedford | MA | 02740-2107 | 0028894 |
| Shields Healthcare of Cambridge Inc | Shields MRI Brighton | 385 Western Ave | Brighton | MA | 02135-1005 | 020369 |
| South Shore MRI Limited Partnership | Shields MRI Weymouth | 26 Rockway Ave | Weymouth | MA | 02188-3906 | 327033 |
| Massachusetts Bay Regional MRI Limited Partnership | Shields MRI Boston | 161 Granite Ave | Dorchester | MA | 02124-5492 | 020169 |
| Massachusetts Bay Regional MRI Limited Partnership | Shields MRI Dedham | 40 Allied Dr - Ste 112 | Dedham | MA | 02026-6146 | 0034538 |
| Shields MRI & Imaging Center of Cape Cod LLC | Shields MRI & Imaging Center of Cape Cod | 2 Iyanough Rd - Rt 28 | W Yarmouth | MA | 02673-8135 | 327057 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial ShrewsburySt | 214 Shrewsbury St | Worcester | MA | 01604-4629 | 002737301 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial MemorialCampus | 119 Belmont St-U Mass MemorialCampus | Worcester | MA | 01605-2903 | 002737302 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at Wing Hospital | 40 Wright St | Palmer | MA | 01069-1138 | 327040 |
| U Mass Memorial MRI & Imaging Center LLC | Shields PETCT at UMass Memorial Burbank | 275 Nichols Rd | Fitchburg | MA | 01420-1919 | 0027373 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial UniversityCampus Ste B | 55 Lake Ave North Ste H1-713B | Worcester | MA | 01655-0002 | S300166800 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial UniversityCampus Ste A | 55 Lake Ave North Ste H1-351A | Worcester | MA | 01655-0002 | S300563649 |
| Baystate MRI & Imaging Center LLC | Shields MRI and Baystate Health | 80 Wason Ave | Springfield | MA | 01107-1132 | 0018589 |
| Shields Imaging of Eastern Massachusetts LLC | Shields Imaging of Eastern Massachusetts | 55 Fogg Rd | S Weymouth | MA | 02190-2432 | 327088 |
| U Mass Memorial HealthAlliance MRI Center LLC | Shields MRI at UMass Memorial HealthAlliance Campus | 100 Hospital Rd-Ste 1A | Leominster | MA | 01453-2253 | 327082 |
| Shields MRI of Framingham LLC | Shields MRI of Framingham | 14 Cochituate Rd | Framingham | MA | 01701-7915 | 327116 |
| U Mass Memorial MRI-Marlborough LLC | Shields MRI at UMass Memorial MarlboroughCampus | 157 Union St | Marlborough | MA | 01752-1228 | 327115 |
| Frankin MRI Center LLC | Shields MRI at Baystate Franklin MedicalCenter | 164 High St | Greenfield | MA | 01301-2613 | 0010942 |
| Radiation Therapy of Winchester LLC | Winchester Hospital Radiation OncologyCenter | 620 Washington St | Winchester | MA | 01890-1328 | 0000272 |
| Cape Cod PET-CT Services LLC | Shields PET Service of Cape Cod Harwich | 525 Long Pond Dr | Harwich | MA | 02645-1227 | 0010594 |
| Cape Cod PET-CT Services LLC | Shields PET Service of Cape Cod Sandwich | 2 Jan Sebastian Dr | Sandwich | MA | 02563-2377 | 001059401 |
| PET-CT Services By Tufts Medical Center and Shields LLC | Shields PETCT at Tufts Medical Center | 800 Washington St | Boston | MA | 02111-1552 | 0024437 |
| PET-CT Services By Tufts Medical Center and Shields LLC | Metrowest PET-CT at Shields Framingham in Affiliation with Tufts Medical Center | 14 Cochituate Rd-Ste 1A | Framingham | MA | 01701-7915 | S300129479 |
| Shields Imaging of Lowell General Hospital LLC | Shields MRI at Lowell General Hospital | 295 Varnum Ave | Lowell | MA | 01854-2134 | 0025829 |
| Shields Imaging of Lowell General Hospital LLC | Shields MRI at Lowell General HospitalChelmsford | 10 Research Pl | N Chelmsford | MA | 01863-2456 | 002582901 |
| Shields Imaging of Lowell General Hospital LLC | Shields MRI at Lowell General Hospital SaintsCampus | 1 Hospital Dr | Lowell | MA | 01852-1311 | S100138677 |
| Winchester Hospital-Shields MRI LLC | Shields MRI Winchester Hospital at UnicornPark | 200 Unicord Park Dr-Ste 402 | Woburn | MA | 01801-3342 | 0033808 |
| Winchester Hospital – Shields MRI | Winchester Hospital/Shields MRI | 41 Highland Ave - Ste G1 | Winchester | MA | 01890-1446 | S300634235 |
| Shields Signature Imaging LLC | Shields Signature Imaging | 680 Centre St | Brockton | MA | 02302-3308 | S300291877 |
| Shields Sturdy PETCT LLC | Shields Sturdy PETCT | 211 Park St | Attleboro | MA | 02703-3143 | S300305002 |
| Shields PETCT at Cooley Dickinson Hospital LLC | Shields PETCT at Cooley Dickinson Hospital | 30 Locust St | Northampton | MA | 01060-2052 | S300333217 |
| Shields Imaging at Anna Jaques Hospital LLC | Shields Imaging at Anna Jaques Hospital | 25 Highland Ave | Newburyport | MA | 01950-3867 | S300357534 |
| Shields PET-CT at CMMC LLC | Shields PETCT at CMMC | 300 Main St | Lewiston | ME | 04240-7027 | E300352765 |
| Shields PET-CT at CMMC LLC | Shields PETCT at CMMC @ Topsham | 105 Topsham Fair Mall Rd | Topsham | ME | 04086-1773 | E300511797 |
| Shields Imaging at York Hospital LLC | Shields Imaging at York Hospital | 114 Sanford Rd | Wells | ME | 04090-5533 | E100388241 |
| Shields PETCT at Berkshire Medical Center LLC | Shields PETCT at Berkshire Medical Center | 165 Tor Court | Pittsfield | MA | 01201-3001 | S300426507 |
| Shields Imaging of Portsmouth LLC | Shields MRI Portsmouth | 1900 Lafayette Rd | Portsmouth | NH | 03801-5679 | n/a |
| Healthcare Enterprises LLC | The Surgery Center at Shrewsbury | 151 Main St | Shrewsbury | MA | 01545-2101 | S300494903 |
| Shields Imaging with Central Maine Health LLC | Shields Imaging at Central Maine Health,Topsham | 105 Topsham Fair Mall Rd | Topsham | ME | 04086-1773 | E300498988 |
| Shields Imaging with Central Maine Health LLC | Shields Imaging at Central Maine Health,Auburn | 690 Minot Ave, Ste 1 | Auburn | ME | 4210 | E300520539 |
| Baystate Health Urgent Care Center LLC | Baystate Health Urgent Care Longmeadow | 688 Bliss Rd | Longmeadow | MA | 01106-1534 | S100483242 |
| Baystate Health Urgent Care Center LLC | Baystate Health Urgent Care Feeding Hills | 241 S Westfield St | Feeding Hills | MA | 01030-2713 | S100483242 |
| Baystate Health Urgent Care Center LLC | Baystate Health Urgent Care Westfield | 24 Union Street | Westfield | MA | 01085 | S100483242 |
| Natick Surgery Center, LLC | New England Surgical Suites | 313 Speen St - Ste 200 | Natick | MA | 01760 | S300693361 |
| Medford Surgery Center, LLC | Medford Surgery Center | 170 Govenors Ave -Ste 100 | Medford | MA | 02155 | S300777754 |
| Shields Radiology Assoc |  | 214 Shrewsbury St | Worcester | MA | 01604-4629 |  |
| Shields Tufts Medical Center Imaging Management LLC |  | 800 Washington St | Boston | MA | 02111 |  |
| Shields Imaging Management at Emerson Hospital LLC |  | 133 Old Road to 9 Acre Corner | Concord | MA | 01742 |  |
| Shields Imaging Management at Emerson Hospital LLC |  | 133 Littleton Road | Westford | MA | 01886 |  |
| Maine Imaging Services LLC |  | 128 State Street - #3 | Augusta | ME | 04330 |  |
| Cape Cod Imaging Services LLC |  | 27 Park St | Hyannis | MA | 02601 |  |
| Cape Cod Imaging Services LLC |  | 525 Pond Drive | Harwich | MA | 02645 |  |
| Cape Cod Imaging Services LLC |  | 35 Wilkens Lane | Hyannis | MA | 02601 |  |
| Cape Cod Radiation Therapy Services LLC |  | 1 Ter Heun Drive, 1st floor | Falmouth | MA | 02540 |  |
| Chelmsford Surgery Center LLC | The Surgery Center of the Merrimack Valley | 10 Research Pl, Suite 10 | N Chelmsford | MA | 01863 | S300817670 |

Affiliated Parties Supplement: Peter Ferrari

| **Legal Name** | **DBA** | **Service Location Address** | **City/Town** | **State** | **Zip** | **State** | **Zip** | **Medicare****PTAN** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| South Shore MRI Limited Partnership | Shields MRI Weymouth | 26 Rockway Ave | Weymouth | MA | 02188-3906 | MA | 02284-7924 | 327033 |
| Shields MRI & Imaging Center of Cape Cod LLC | Shields MRI & Imaging Center of Cape Cod | 2 Iyanough Rd - Rt 28 | W Yarmouth | MA | 02673-8135 | MA | 02284-7922 | 327057 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial ShrewsburySt | 214 Shrewsbury St | Worcester | MA | 01604-4629 | MA | 02284-7183 | 002737301 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial MemorialCampus | 119 Belmont St-U Mass MemorialCampus | Worcester | MA | 01605-2903 | MA | 02284-7183 | 002737302 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at Wing Hospital | 40 Wright St | Palmer | MA | 01069-1138 | MA | 02284-7183 | 327040 |
| U Mass Memorial MRI & Imaging Center LLC | Shields PETCT at UMass Memorial Burbank | 275 Nichols Rd | Fitchburg | MA | 01420-1919 | MA | 02284-7183 | 0027373 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial UniversityCampus Ste B | 55 Lake Ave North Ste H1-713B | Worcester | MA | 01655-0002 | MA | 02284-7183 | S300166800 |
| U Mass Memorial MRI & Imaging Center LLC | Shields MRI at UMass Memorial UniversityCampus Ste A | 55 Lake Ave North Ste H1-351A | Worcester | MA | 01655-0002 | MA | 02284-7183 | S300563649 |
| Baystate MRI & Imaging Center LLC | Shields MRI and Baystate Health | 80 Wason Ave | Springfield | MA | 01107-1132 | MA | 02284-7915 | 0018589 |
| U Mass Memorial HealthAlliance MRI Center LLC | Shields MRI at UMass Memorial HealthAlliance Campus | 100 Hospital Rd-Ste 1A | Leominster | MA | 01453-2253 | MA | 02284-7927 | 327082 |
| U Mass Memorial MRI-Marlborough LLC | Shields MRI at UMass Memorial MarlboroughCampus | 157 Union St | Marlborough | MA | 01752-1228 | MA | 02284-7937 | 327115 |
| Frankin MRI Center LLC | Shields MRI at Baystate Franklin MedicalCenter | 164 High St | Greenfield | MA | 01301-2613 | MA | 02284-7997 | 0010942 |
| Radiation Therapy of Winchester LLC | Winchester Hospital Radiation OncologyCenter | 620 Washington St | Winchester | MA | 01890-1328 | MA | 02284-7944 | 0000272 |
| Cape Cod PET-CT Services LLC | Shields PET Service of Cape Cod Harwich | 525 Long Pond Dr | Harwich | MA | 02645-1227 | MA | 02284-7479 | 0010594 |
| Cape Cod PET-CT Services LLC | Shields PET Service of Cape Cod Sandwich | 2 Jan Sebastian Dr | Sandwich | MA | 02563-2377 | MA | 02284-7479 | 001059401 |
| PET-CT Services By Tufts Medical Center and Shields LLC | Shields PETCT at Tufts Medical Center | 800 Washington St | Boston | MA | 02111-1552 | MA | 02284-7165 | 0024437 |
| PET-CT Services By Tufts Medical Center and Shields LLC | Metrowest PET-CT at Shields Framingham in Affiliation with Tufts Medical Center | 14 Cochituate Rd-Ste 1A | Framingham | MA | 01701-7915 | MA | 02284-7165 | S300129479 |
| Shields Imaging of Lowell General Hospital LLC | Shields MRI at Lowell General Hospital | 295 Varnum Ave | Lowell | MA | 01854-2134 | MA | 02284-7975 | 0025829 |
| Shields Imaging of Lowell General Hospital LLC | Shields MRI at Lowell General HospitalChelmsford | 10 Research Pl | N Chelmsford | MA | 01863-2456 | MA | 02284-7975 | 002582901 |
| Shields Imaging of Lowell General Hospital LLC | Shields MRI at Lowell General Hospital SaintsCampus | 1 Hospital Dr | Lowell | MA | 01852-1311 | MA | 02284-7975 | S100138677 |
| Winchester Hospital-Shields MRI LLC | Shields MRI Winchester Hospital at UnicornPark | 200 Unicord Park Dr-Ste 402 | Woburn | MA | 01801-3342 | MA | 02284-7931 | 0033808 |
| Winchester Hospital – Shields MRI | Winchester Hospital/Shields MRI | 41 Highland Ave - Ste G1 | Winchester | MA | 01890-1446 | MA | 02284-7931 | S300634235 |
| Shields Signature Imaging LLC | Shields Signature Imaging | 680 Centre St | Brockton | MA | 02302-3308 | MA | 02284-7028 | S300291877 |
| Shields Sturdy PETCT LLC | Shields Sturdy PETCT | 211 Park St | Attleboro | MA | 02703-3143 | MA | 02284-7203 | S300305002 |
| Shields PETCT at Cooley Dickinson Hospital LLC | Shields PETCT at Cooley Dickinson Hospital | 30 Locust St | Northampton | MA | 01060-2052 | MA | 02284-7219 | S300333217 |
| Shields Imaging at Anna Jaques Hospital LLC | Shields Imaging at Anna Jaques Hospital | 25 Highland Ave | Newburyport | MA | 01950-3867 | MA | 02284-7242 | S300357534 |
| Shields PET-CT at CMMC LLC | Shields PETCT at CMMC | 300 Main St | Lewiston | ME | 04240-7027 | MA | 02284-7239 | E300352765 |
| Shields PET-CT at CMMC LLC | Shields PETCT at CMMC @ Topsham | 105 Topsham Fair Mall Rd | Topsham | ME | 04086-1773 | MA | 02284-7239 | E300511797 |
| Shields Imaging at York Hospital LLC | Shields Imaging at York Hospital | 114 Sanford Rd | Wells | ME | 04090-5533 | MA | 02284-7949 | E100388241 |
| Shields PETCT at Berkshire Medical Center LLC | Shields PETCT at Berkshire Medical Center | 165 Tor Court | Pittsfield | MA | 01201-3001 | MA | 02284-7116 | S300426507 |
| Shields Imaging of Portsmouth LLC | Shields MRI Portsmouth | 1900 Lafayette Rd | Portsmouth | NH | 03801-5679 | MA | 02284-7964 | n/a |
| Healthcare Enterprises LLC | The Surgery Center at Shrewsbury | 151 Main St | Shrewsbury | MA | 01545-2101 | MA | 02284-7027 | S300494903 |
| Shields Imaging with Central Maine Health LLC | Shields Imaging at Central Maine Health,Topsham | 105 Topsham Fair Mall Rd | Topsham | ME | 04086-1773 | MA | 02284-7311 | E300498988 |
| Shields Imaging with Central Maine Health LLC | Shields Imaging at Central Maine Health,Auburn | 690 Minot Ave, Ste 1 | Auburn | ME | 4210 | MA | 02284-7311 | E300520539 |
| Baystate Health Urgent Care Center LLC | Baystate Health Urgent Care Longmeadow | 688 Bliss Rd | Longmeadow | MA | 01106-1534 | ME | 04915-4484 | S100483242 |
| Baystate Health Urgent Care Center LLC | Baystate Health Urgent Care Feeding Hills | 241 S Westfield St | Feeding Hills | MA | 01030-2713 | ME | 04915-4484 | S100483242 |
| Baystate Health Urgent Care Center LLC | Baystate Health Urgent Care Westfield | 24 Union Street | Westfield | MA | 01085 | ME | 04915-4484 | S100483242 |
| Natick Surgery Center, LLC | New England Surgical Suites | 313 Speen St - Ste 200 | Natick | MA | 01760 | MA | 02284-7371 |  |
| Medford Surgery Center, LLC | pending | 170 Govenors Ave -Ste 100 | Medford | MA | 02155 | MA | 02284-7367 |  |

ATTACHMENT #5

NOTICE OF INTENT

12/12/22, 3:03 PM Adportal Self Service Advertising Confinnatlon

**THANK YOU for** your **ad submission!**

Your ad has been submitted for publication. Below is a confirmation of your ad placement. You will also receive an email confirmation.

ORDER DETAILS

Order Number:

NY0067456

Order Status: Submitted Classification: Legal Notices Package: Legals MA Final Cost 204.30

Payment Type:

Mastercard User ID: W0018095

Username:

kerry@shields.com

PREVIEW FOR AD NUMBER NY00674560

****

**ACCOUNT INFORMATION**

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kerry@shields.com

Shields Health

**PAYMENT DETAILS** \_

**TRANSACTION REPORT**

**Date**

December 12, 2022 3:03:34 PM EST

**Amount**

204.30

**SCHEDULE FOR AD NUMBER NY00674560**

https://adportal.bostonherald.com/nyRroup.adportal/ma-leRals/home/confinnation.html?ld=S5793&retumto• 1/2

ATTACHMENT #6

COPY OF DOCUMENTS RELATED TO APPROVED DON & AMENDEMENTS

ATTACHMENT #6A

COPY OF STAFF SUMMARY AND ORIGIANL DECISION LETTER FOR APPROVED DON

Category 2

STAFF SUMMARY FOR DETERMINATION OF NEED BY THE PUBLIC HEALTH COUNCIL

January 22, 2002

APPLICANT: Shields Imaging of Massachusetts, LLC PROGRAM ANALYST: Jere **Page**

LOCATION: Crown Colony Office Park REGION: HSA IV 700 Congress Street

Quincy, MA 02169

DATE OF APPLICATION: February 1, 2001 PROJECT NUMBER: 4-4886

PROJECT DESCRIPTION: Provision of Positron Emission Tomography (PET) services through acquisition of a mobile PET body scanner and related equipment. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield.

ESTIMATED MAXIMUM CAPITAL EXPENDITURE:

Requested: $2,564,000 (February 2001 dollars) Recommended: $2,564,000 (February 2001 dollars)

ESTIMATED FIRST YEAR OPERATING COST:

Requested: $3,135,291 (February 2001 dollars) Recommended: $3,135,291 (February 2001 dollars)

LEGAL STATUS: A regular application for substantial changes in service pursuant to M.G.L. c.111, s.25C and the Regulations adopted thereunder.

ENVIRONMENTAL STATUS: No environmental notification form or environmental impact report is required to be submitted for this project since it is exempt under 301 Code of Massachusetts Regulations 11.00, promulgated by the Executive Office of Environmental Affairs pursuant to Massachusetts General Laws, Chapter 30, Sections 61-62H. As a result of this exemption, the project has, therefore, been determined to cause no significant damage to the environment.

OTHER PENDING APPLICATION: None

COMPARABLE APPLICANTS: Brigham and Women's Hospital (Project No. 4-3993), Beth Israel Deaconess Medical Center (Project No. 4-3994), and Children's Hospital Medical Center (Project No. 4-3995)

COMMENTS BY THE DIVISION OF HEALTH CARE FINANCE AND POLICY: None

submitted

COMMENTS BY THE DIVISION OF MEDICAL ASSISTANCE: None submitted

TEN TAXPAYER GROUP(S): The Mark R. Taylor, Mary T. Sweeney, and Stephen M. Weiner Ten Taxpayer Groups (TIGs) registered in connection with the project. The Brockton Ten Taxpayer Group originally registered as well and requested a public hearing, but subsequently rescinded its request on August 6, 2001, and withdrew as a TTG on August 7, 2001.

RECOMMENDATION: Approval with conditions

* + - 1. BACKGROUND AND PROJECT\_DESCRIPTION

Shields Imaging of Massachusetts, LLC ("Shields"), a consortium comprised of Shields Imaging of Eastern Massachusetts, LLC, Shields Imaging of Worcester, LLC, and Shields Imaging of Springfield. LLC, has filed a Determination of Need application to provide Positron Emission Tomography (PET) services through acquisition of a mobile PET scanner. Specifical1y, Shields Imaging of Eastern Massachusetts, LLC will operate a licensed medical clinic in Weymouth in space leased from South Shore Hospital; Shields Imaging of Worcester, LLC will operate a licensed medical clinic in Worcester in space leased from UMass Memorial Medical Center; and Shields Imaging of Springfield, LLC will operate a licensed medical clinic in Springfield in space leased from Baystate Medical Center. The licensed medical clinic at each hospital will be a joint venture between the applicant or one of its affiliates and each of the hospitals or one of their affiliates. The proposed PET service is initially expected to operate six (6) days per week, and the three host hospitals will share the service based on each hospital's demand.

South Shore Hospital is a 282-bed, full service community hospital 1ocated in Weymouth, that offers services including acute care, cardiology, emergency care, home health services, hospice, maternity and pediatric services, oncology, a regional paramedic service, and an outpatient services center.

UMass Memorial Medical Center is a 761-bed tertiary care hospital located in Worcester, and is a member of the UMass Memorial Health Care System that operates five hospitals and is the second largest integrated health care delivery system in Massachusetts, and also serves as the teaching hospital for the University of Massachusetts Medical School. The Medical Center offers specialty care in cancer, cardiology, emergency medicine, pediatric medical services, newborn intensive care, and women's health. Additionally, the Medical Center offers a comprehensive

array of inpatient and outpatient services with a transplant program that offers heart, liver, kidney, pancreas, and bone marrow transplantation, as well as advanced laser technology, off-pump cardiac bypass surgery, minimally invasive surgical techniques, cardiac catheterization, and a breast care center.

Baystate Medical Center is a 599-bed hospital located in Springfield, which serves as a tertiary teaching hospital for Tufts University School of Medicine, as well as a referral center for western Massachusetts. The Medical Center offers a full range of hospital services that include anesthesiology, emergency medicine, general medicine, obstetric and gynecology, oncology, psychiatry, radiology, rehabilitation services, and surgery. Baystate also provides the region's only neonatal intensive care unit, trauma center, cardiac surgery service, and kidney, pancreas, and bone marrow transplantation programs. ·

* + - 1. COMPARABILITY

When reviewing applications that have been declared comparable, Staff follows the procedures set forth in 105 CMR 100.537 of the Determination of Need Regulations, which read as follows:

Whenever the Council is presented with comparable applications, it shall first determine whether each application, considered alone, is capable of being approved and shall exclude from further consideration any application which it determines has to be denied. If under applicable standards and criteria, all remaining applications may not be approved, the Council shall approve the application or applications which, in its judgment, best satisfies or satisfy the factors under 105 CMR 100.533 and the objective set forth at 105 CMR 100.532.

Four (4) comparable applications, including the present application, have applied to provide PET services through acquisition of a PET scanner. The other applications are Brigham and Women's Hospital (Project No. 4-3993), Beth Israel Deaconess Medical Center (Project No. 4- 3994), and Children's Hospital Medical Center (Project No. 4-3995). Staff’s findings, elaborated elsewhere, are that all four of the applications are capable of being approved. As discussed below, the present application is one of the four (4) PET applications, Staff is recommending for approval.

III. STAFF ANALYSIS

The application was reviewed against the November 24, 1998 Determination of Need Guidelines for Positron Emission Tomography (PET Guidelines). The Guidelines do not recommend a statewide planning target of a specific number of PET units, but require each applicant to plan for a service area population of 1.6 million people in order to demonstrate a projected minimum demand of 1,250 annual scans in the service area**.**

PET is a nuclear medicine technique has been used as a research tool for over a decade.

Currently, the clinical use of PET may allow some patients to avoid undergoing invasive procedures and provide information on diagnosis, staging and re-staging of cancer that will increase confidence in management of their care. PET differs from the conventional imaging procedures of computerized axial tomography (CT) and magnetic resonance imaging (MRI), because it allows for the quantitative assessment of physiological function in the living human body and the imaging of the function of an organ system. A PET service usually consists of a cyclotron to produce the radioactively labeled tracers, a radiochemistry facility to mix the tracers into the biological compound which the patient will receive, a PET scanner to measure the

distribution of the radio-pharmaceuticals within the body, and a computer for image reconstruction. The most widely used radio-pharmaceutical in the field of PET today is FDG-18, which was developed over 10 years ago.

Since the PET Guidelines were developed in 1998, several new clinical applications of PET have been approved for reimbursement by the Medicare program, which is used as the standard by

other third-party payors. As of December 15, 2000, the Medicare program covers the use of PET

for six types of cancers – lung, colorectal, lymphoma, melanoma, esophageal, and head and neck (but not brain or thyroid) and includes new, broader coverage of neurologic and cardiac

applications. Coverage of three additional applications – mycearal viability, dementia and breast cancer which was requested but not approved, was referred to the Medicare Coverage Advisory Committee for further review. The coverage for cancer, expanded from the clinical applications referenced in the Guidelines, now includes all clinically appropriate indications, for example, diagnosis, staging and re-staging for any covered cancer. Previous coverage of scans for the covered cancers was more narrow, including characterization of the cancer and initial staging, for example, rather than the broader indications most recently approved.

The Medicare program has decided not to reimburse scans involving the recently approved applications performed with dual-head coincidence (DHC) imaging on gamma cameras. This decision was based on the inability of the DHC technology, unlike the dedicated PET scans, to adequately detect lesions that are small to medium in size, possibly leading to potential harming of patients by critically impacting treatment decisions. While it is not clear how many DHC cameras are in present use in Massachusetts, the Medicare program has estimated that there are 3,366 DHC cameras nationwide. The Medicare coverage decision on DHC is no doubt a factor in the renewed interest in PET in Massachusetts, as evidenced by the recent filing of PET DoN applications.

* + - * 1. Health Planning Process

The Guidelines require that if the PET applicant is a multi-institutional system, a tertiary teaching facility in the service area must be a participant in the system. In this case, the hospital affiliates of the proposed project include UMass Memorial Medical Center and Baystate Medical Center, both of which arc tertiary teaching facilities. Shields reports that through its annual and long term planning process, PET services were identified as a primary diagnostic need at South Shore Hospital, UMass Memorial Medical Center, and Baystate Medical Center based on the volume of oncology, cardiology, neurology, and psychiatric patients served at these hospitals.

Shields, through each of its member clinics indicated previously, has entered into agreements with each of the host hospitals, whereby each of the hospitals have agreed that Shields will provide PET services to that hospital, and under which the responsibilities of the parties relative to the coordination of services are defined. Shields has also included a number of signed letters of support for the proposed PET service from physicians and others involved with services provided at the three host hospitals.

Staff finds the project meets the health planning process of the Guidelines.

* + - * 1. Health Care Requirements

The Guidelines recommend that applicants proposing to establish a PET service document need for a statewide service area of at least 1.6 million people, demonstrate a minimum demand of 1,250 PET scans annually, and present additional data to supplement the demand analysis. However, Staff notes that in the three years since the Guidelines were promulgated (November, 1998), the clinical applications for PET have increased significantly, to the point that reliance on a patient population of 1.6 million to demonstrate need for a single PET unit may serve to underestimate the number of patients who would benefit from PET services. As indicated previously, in December 2000, HCFA reported that it had expanded the number of indications for PET that are Medicare reimbursable and also recommended that its Medical Coverage Advisory Committee continue to study additional applications. These include Alzheimer's disease/dementia, breast cancer, and expanded indications for myocardial viability. Given these changes and potential for increased volume, Staff has relied instead solely on the applicant’s actual and projected patient volume to determine its ability to meet the minimum demand of 1,250 annual scans. Staff also notes that the Guidelines indicate that preference will be given to applicants that are part of a multi-institutional system. such as the Shields project, which will provide mobile PET services to three different hospitals.

Proposed Service Area

Shield’s service area is based mainly on the Department's definition of a primary service areaapplied to each of the three host hospitals. Shields relied further on the broad network of affiliated providers that both the UMass and Baystate systems have in their respective regions, and developed a broader projected service area than would be indicated by each hospital's primary service area. As a result, the UMass and Baystate service areas include essentially all of central and western Massachusetts (HSA's I and II), which currently lack DoN approved PET services. In addition, South Shore Hospital's service area includes a large part of Southeastern Massachusetts

(HSA V), where DoN approved PET services are also not currently provided. Shields assumes that a significant number of patients from Southeastern Massachusetts will use the more accessible PET service at South Shore, instead of the current DON approved PET services in Boston.

Shields' Projected Number of Scans

To project the number of PET scans at the three host hospitals, Shields first reviewed the most recent FY 2000 inpatient discharge and outpatient data for oncological patients treated at South Shore Hospital and UMass Memorial Medical Center, as well as inpatient data for Baystate Medical Center, as reported by the hospitals. Shields reports that the data detailed below in Tables 1-3, indicate that the types or forms of cancer most prevalent in each Hospitals' service areas are among the very types of cancer for which PET scanning is a critical diagnostic tool. Additionally, these types of cancer are also included in the diagnostic categories covered by Medicare reimbursement.

Table 1

South Shore Hospital

FY 2000 Oncology Patient Volume

| Types | Inpatient Cases | Outpatient Cases |
| --- | --- | --- |
| Lung Cancer | 182 | 862 |
| Colorectal Cancer | 39 | 188 |
| Melanoma/Skin Cancer | 1 | 149 |
| Sarcomas | 1 | 35 |
| Lymphomas | 42 | 269 |
| Brain Tumors/Cancers | 14 | 111 |
| Breast Cancer | 52 | 106 |
| Other Cancer | 1,124 | 7,361 |
| Total | 1,455 | 9,081 |

Table 2

UMass Memorial Medical Center

FY 2000 Oncology Patient Volume

| Types | Total Inpatient and Outpatient |
| --- | --- |
| Lung Cancer | 473 |
| Colorectal Cancer | 717 |
| Melanoma/Skin Cancer | 348 |
| Sarcomas | 107 |
| Lymphomas | 409 |
| Brain Tumors/Cancers | 148 |
| Breast Cancer | 2,196 |
| Other Cancer | 4,255 |
| Total | 8,653 |

Table 3

Baystate Medical Center

FY 2000 Oncology Patient Volume

| Types | Inpatient Cases |
| --- | --- |
| Lung Cancer | 94 |
| Colorectal Cancer | 35 |
| Melanoma/Skin Cancer | 6 |
| Sarcomas | 6 |
| Lymphomas | 50 |
| Brain Tumors/Cancers | 191 |
| Breast Cancer | 35 |
| Other Cancer | 1,374 |
| Total | 1,791 |

Shields reports that citations in the literature, which were applied in the previously approved Dana Farber Cancer Institute PET project (DoN No. 4- 3968), indicate that 53% of lung cancer patients will need PET scans for diagnosis of their disease, and 50% of patients will need PET scans for staging of their lung cancer. These percentages were applied to the 1,611 actual lung cancer patients at the three host hospitals in FY 2000, using only inpatients from Baystate and total inpatients and outpatients from UMass and South Shore, to determine the possible total demand for

PET scans for these patients. Shields notes that Baystate outpatient cancer cases were not available at the time the application was filed, so the projected PET volume should be considered conservative. Table 4 below shows lung cancer patients treated at the three host hospitals who would require PET scans for diagnosis of Solitary Pulmonary Nodules (SPN) and for lung cancer staging.

Table 4

Projected Number of PET Scans Based on FY 2000 Inpatient and Outpatient Lung Cancer Patients from South Shore. UMass Memorial, and Baystate

|  |  |  |
| --- | --- | --- |
| 53% of Patients for Diagnosis of SPN | 1,611 | 854 |
| 50% of Patients for Staging of Lung Cancer | 1,611 | 806 |
| Total |  | 1,660 |

In addition, Shields reports that the second largest number of PET scans are for colorectal patients, and that citations in the literature applied in the above-referenced Dana Farber PET project, indicate that 20-50% of colorectal patients will develop local recurrence within two years of surgery to treat the primary tumor. Shields notes that PET scans are indicated for the majority of these patients since conventional imaging techniques are unable to distinguish tumor recurrence from post-treatment scars. Shields further notes that if only 20% of the total volume of 979 colorectal patients treated at the three host hospitals experienced a recurrence, then 196 of the total colorectal patients would have needed a PET scan. As discussed above, only Baystate inpatient cases were included in the total count.

Shields projected total demand for 1,856 PET scans for the three host hospital sites, based on FY 2000 data, which include the estimated 1,660 lung cancer cases in from Table 4 above, and the 196 colorectal patients indicated above. Shields has estimated that, based on current market conditions at the three host hospitals, it will realize approximately an 80% market share for PET services in the host hospitals' expanded service areas. Therefore, Shields anticipates that it will perform at least 1,500 PET scans of the total 1,856 projected scans by FY 2003, well above the

minimum volume requirements of the Guidelines. Staff believes this assumption is accurate, as both the UMass and Baystate systems control a significant number of acute care services in their service areas, which currently do not have DoN approved PET services.

Shields also reports that there are other protocols and conditions for which PET is indicated.

These include cardiology, neurology, and psychiatry. Specifically, Shields notes that PET is particularly cost effective in evaluating myocardial ischemia and in predicting the revascularization potential of the heart muscle, resulting in possible additional volume for the Shields mobile service at the three host hospitals.

Existing Resources

Massachusetts General Hospital (Project No. 4-3801) and Dana-Farber Cancer Institute (Project No. 4.3968) currently operate the only other DoN approved PET services in the state. Both institutions report that their respective PET scanners arc fully utilized with a backlog of patients and appointments currently scheduled three to four weeks in advance.

Conclusion on Need

Based on the above analysis, Staff finds demand for the mobile PET unit proposed by Shields to provide more accessible PET services to patients served by South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield. Staff also finds that the Shields PET service is expected to perform at least 1,250 PET scans, consistent with the Guidelines. The existing PET services at MGH and Dana Farber arc fully utilized with waiting times of 3 to 4 weeks. Staff notes that the number of scans projected by Shields is, in fact, conservative since it does not include several other applications of diagnostic PET.

* + - * 1. Operational Objectives

Shields has submitted documentation as evidence that the proposed PET service will provide the following FTEs: a Medical Director of PET from UMass Memorial Medical Center who is board certified in nuclear medicine with experience and training in PET technology; certified nuclear medicine technologists; nuclear medicine physicians to read PET scans all of whom are board certified; and a nuclear medicine physicist. The duties of the Imaging Processing Laboratory Supervisor (required by the Guidelines) will be performed by nuclear medicine technologists. Support services to patients and families during the course of treatment will be available at each host hospital. Shields reports that at each host hospital there is access to nuclear medicine, SPECT, CT, MRI, cardiac catheterization, ultrasound, and diagnostic radiology, as required by the Guidelines. In addition, each hospital has physicians qualified in thoracic surgery, cardiology, oncology, radiation oncology, neurology, and neurosurgery. Further, both Baystate Medical Center and UMass Memorial Medical Center have physicians qualified to perform cardiac surgery.

As required by the Guidelines, Shields, with the assistance of each member clinic, will develop a Clinical Oversight Committee with appropriate membership and responsibilities as outlined in the Guidelines including the task of providing information on utilization data, clinical data and reports of clinical efficacy as requested by the Department. Both the PET scanner and the radiopharmaceuticals, which Shields plans to purchase, have received pre-market approval from the Food and Drug Administration. The proposed mobile PET service will not include a cyclotron. Shields has indicated that all clinically appropriate patients will have access to the PET service regardless of ability to pay. To ensure patient access to the service, Staff is recommending a condition of approval that ability to pay or insurance status should not be considered in selecting or scheduling patients for the mobile PET

service. In addition, Shields reports that it has developed comprehensive plans for PET training and

education for each hospital for radiologists, physicians, nuclear technologists and other personnel.

Staff finds that the proposed project, with adherence to a certain condition, meets the operational

objectives of the Guidelines.

* + - * 1. Compliance Standards

Because the proposed Shields mobile PET service is a new entity, it has not yet obtained a certificate of registration from the Department's Radiation Control Program, as required by the Guidelines. Since Shields Imaging of Massachusetts, LLC will be the licensed provider, Staff recommends, as a condition of approval, that Shields secure the certificate of registration prior to implementation of the project.

Staff finds that, with adherence to a certain condition. the proposed project meets the compliance standards of the Guidelines.

* + - * 1. Reasonableness of Expenditures and Cost

Maximum Capital Expenditure

The requested and recommended maximum capital expenditure is $2,564,000 (February 2001 dollars) itemized as follows:

|  |  |
| --- | --- |
| Major Movable Equipment | $2,504,000\* |
| Other: Fair Market Value of Shared Space at Host Sites | 60,000\*\* |
| Total Construction Costs | $2,564,000 |
| Total Maximum Capital Expenditure | $2,564,000 |

\*Includes mobile PET scanner, and ancillary equipment including computers and a trailer

\*\*Fair market value was determined to be $20,000 for the existing receiving pad at each host hospital, as well as for electrical and other hook-ups necessary to accommodate the service

Shields will provide the mobile PET service in a trailer sited on existing suitable receiving pads at each of the three host hospitals, and no new construction or renovation at the hospitals will be required to accommodate the service. Shields reports that it will purchase the mobile PET equipment from Siemens Medical Systems, Inc., a major manufacturer of PET equipment, and has provided a quote from Siemens, which indicates that the requested $2,504,000 cost of the mobile PET scanner and related equipment including computer hardware, software, and a trailer is reasonable. The mobile PET unit will be financed through a 23.4% equity contribution ($600,000 in February 2001 dollars), whereby Shields, South Shore, UMass Medical Center and Baystate's hospital affiliate, Baystate Radiology Imaging, LLC, will contribute proportional equity shares that are yet to be determined. The remaining MCE of $1,964,000 (February 2001 dollars) will be financed through the vendor, Siemens Medical Systems, Inc., at an interest rate of 9% for a sixty (60) month term.

Staff finds the recommended MCE reasonable, based on price quotes from Siemens Medical Systems, which, excluding the mobile trailer, arc similar to quotes from vendors for other comparable projects.

Reasonableness of Operating Costs

The requested and recommended operating costs of $3,135,291 (February 2001 dollars) for the project's first full year of operation, FY 2003, are based on a projected volume of 1,500 PET scans in that year, and are itemized as follows:

|  |  |
| --- | --- |
| Salaries, Wages, Fringe Benefits | $ 495,000 |
| Supplies and Other Expenses | 1,685,300 |
| Purchased Services | 315,200 |
| Depreciation | 506,800 |
| Interest | 132,991 |
| Total Operating Expenses | $3,135,291 |

Salaries, Wages and Fringe include the costs related to 8.4 FTE's: 1 Ph.D. Radiochemist, 1 Nuclear Medicine Technician, 2.4 Radiological Technicians, l Scheduler, 1 Transcriptionist, and 2 Billing/Accounting Staff. The greatest operating expense will be for Supplies and Other Expenses, which include the radiopharmaceuticals to be purchased from P.E.T. Net Pharmaceuticals, Inc., which has a cyclotron site in Woburn, Massachusetts. However, Staff notes that while Shields has a letter from P.E.T. Net indicating its willingness to supply the required monthly volume of

radiopharmaceuticals, Shields has not yet secured a formal written agreement for the purchase from

P.E.T. Net or other provider of radiopharmaceuticals, as required by the Guidelines. Therefore, Staff is recommending, as a condition of approval, that Shields secure such an agreement prior to implementation of the project.

Shields' net revenue assumptions are based a projected volume of 1,500 scans in FY 2003, with projected Medicare reimbursement of $2,600 per scan, resulting in a break-even point of 851 scans. However, recent changes in Medicare reimbursement have reduced this reimbursement to $2,300 per scan, which will have some impact on projected revenue. Therefore, given the revised Medicate rate, and taking into account anticipated reimbursement from other payers such as Blue Cross, HMO’s, and private pay patients, Shields estimates reimbursement of approximately $2,375 per scan for 1,500 scans, which results in a slightly higher anticipated break-even point of 900 scans in FY 2003, the first full year of operation.

Shields reports that PET is cost-effective, and notes that various studies have determined that PET, whether used alone or with other imaging technologies, was cost-effective in diagnosing lung nodules, staging for lung, head and neck cancers, and for managing recurrent colorectal cancer and melanoma. Savings resulted from avoiding surgery for patients with either benign lesions or wide­ spread non-operable disease. Shields notes that other studies also indicate that using PET or PET plus CT was cost-effective in selecting lung cancer patients who qualified for surgery, and that as much as $2,000 per patient was saved through the use of PET.

Based on the above analysis, Staff finds the recommended operating costs reasonable for a freestanding mobile PET service.

* + - * 1. Financial Feasibility and Capability

Shields will contribute 23.4% in equity ($600,000 in February 2001 dollars) of the recommended capital expenditure of$2,564,000 (February 2001 dollars), and that the proposed equity will be provided by Shields, South Shore, UMass Medical Center, and the Baystate hospital affiliate, Baystate Radiology Imaging, LLC, with proportionate shares yet to be determined. The debt service coverage ratio projected for FY 2003, the project's first full year, will be 2.18, which exceeds

the DoN minimum standard of 1.4. Staff notes that Shields Imaging of Massachusetts, LLC is a newly formed entity for the purpose of providing the proposed mobile PET service, and therefore does not have audited financial statements, which are required to calculate the current ratio. Shields states that it has a commitment for a line of credit from Rockland Trust that will ensure that Shields has sufficient operating resources to reach the projected 1,500 PET scans by FY 2003, the first full year of operation. Based on this projected volume and anticipated reimbursement by third party payers, Shields projects a gain in operations of $607,209 by FY 2003. However, Staff notes that Medicare is a significant payer for PET services and sets the standard for coverage by other payers. Therefore, based on the recent reduction in Medicare reimbursement per scan discussed previously, Shields still projects an excess of revenues over expenses of $427,209 by FY 2003. Staff notes that Shields has also discussed the provisions it has made for free care for PET patients.

Staff finds the project financially feasible and within the financial capability of the applicant.

* + - * 1. Relative Merit

Shields considered one alternative to the proposed mobile PET service, which involved the addition of a fixed PET scanning service at one of the three host hospitals' campuses, with the other two hospitals referring patients to the fixed site. However, given the wide geographic area between the hospitals, Shields determined that such a service would not provide sufficient and sustainable utilization and would not increase accessibility to PET services in the other two hospitals'

service areas. In addition, Shields determined that a fixed service would not be as cost effective as providing PET services on a mobile basis.

Staff finds that the proposed mobile PET service meets the relative merit provisions of the Guidelines.

* + - * 1. Community Health Initiatives

Shields Imaging of Massachusetts, LLC has agreed to provide a total of $130,000 (February 2001 dollars) over five years at $26,000 per year to fund grant-based prevention programs that support the Healthy People 2010 leading indicators, particularly cancer and heart disease prevention. Each Community Health Network Area (CHNA) associated with the three host sites, including South Shore Hospital (CHNA #20), UMass Memorial Medical Center (CHNA #8), and Baystate Medical Center (CHNA #4), will award its share of the funding through community grants to community based health and wellness organizations, based upon recommendations by the Grant Review Committees of each CHNA. All grants will be awarded by a fiscal agent approved by each CHNA. Specific details of the grant award process will be determined through further consultation with the Department and each CHNA.

Staff finds that, with adherence to a certain condition, the project meets the community health initiatives of the DoN Regulations.

* + - * 1. TEN TAXPAYER GROUP(S)

The Mark R. Taylor, Mary T. Sweeney, and Stephen M. Weiner Ten Taxpayer Groups (TTGs) registered in connection with the project. The Brockton Ten Taxpayer Group originally registered as well and requested a public hearing, but subsequently rescinded its request on August 6, 2001, and withdrew as a TTG on August 7, 2001.

The Taylor TTG has submitted comments in response to a request for data from Staff to the Chiefs of Nuclear Medicine at MGH and Dana Farber, the two existing previously approved PET projects. Staff requested information on volumes of PET scans and length of waiting lists for these PET units. The Taylor TTG submitted utilization data from the New England PET Imaging System in Methuen, which was implemented through a DoN-exempt physician practice. The Taylor utilization data indicated that this PET unit had performed 700 scans in the past 15 months, had no waiting list for non-urgent appointments, and therefore the TTG concluded that there was excess PET capacity in New England PET Imaging System's service area.

Staff notes that New England PET Imaging System's excess capacity, as described by the Taylor TTG, has not eliminated demand for existing PET services at MGH and Dana Farber, as indicated by patient waiting times at these facilities. Staff further notes that Shields has projected demand for PET services based on the patient populations of South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield, all of which are located at greater distances from Methuen than the Boston PET services. Therefore, Staff regards it as unlikely that Shields' patients would chose instead to use the services of New England PET Imaging System.

1. COMPARABILITY ANALYSIS

In reviewing the four comparable applications of Brigham and Women's Hospital (Project No. 4-3993), Beth Israel Deaconess Medical Center (Project No. 4-3994), Children's Hospital Medical Center (Project No. 4-3995), and Shields Imaging of Massachusetts, LLC (Project No. 4-4886), Staff finds that all four applicants are proposing to provide PET services through acquisition of a PET scanner. Because all four of the comparable applicants meet, at a minimum, all of the following review factors of the Guidelines: Health Planning Process, Health Care Requirements, Operational Objectives, Standards Compliance, Reasonableness of Expenditures and Cost, Financial Feasibility, Relative Merit and Community Health Initiatives as elaborated elsewhere, a more detailed comparability analysis was not undertaken.

1. STAFF FINDINGS
2. Shields Imaging of Massachusetts, LLC proposes to provide Positron Emission Tomography (PET) services through acquisition of a mobile PET body scanner and ancillary equipment, including a trailer. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield.
3. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).
4. Shields Imaging of Massachusetts, LLC has demonstrated demand for a mobile PET unit to serve South Shore Hospital, UMass Memorial Medical Center, and Baystate Medical Center, as discussed under the Health Care Requirements factor of the Staff Summary.
5. The project, with adherence to a certain condition. meets the operational objectives of the Guidelines.
6. The project meets the compliance standards of the Guidelines.
7. The recommended maximum capital expenditure of $2,564,000 (February 2001 dollars) is reasonable, based on the price quote from the PET equipment vendor, which, when the trailer is excluded, is similar to comparable projects.
8. The recommended operating costs of $3,135,291 (February 2001 dollars) are reasonable for a freestanding mobile PET service.
9. The project is financially feasible and within the financial capability of the applicant.
10. The project meets the relative merit provisions of the Guidelines.
11. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.
12. The Mark R. Taylor, Mary T. Sweeney, and Stephen M. Weiner Ten Taxpayer Groups (TTGs) registered in connection with the proposed project. The Brockton Ten Taxpayer Group originally registered as well and requested a public hearing, but subsequently rescinded its request on August 6, 2001, and withdrew as a TTG on August 7, 2001. The Taylor TTG submitted written comments, which indicated that there was excess capacity at New England PET Imaging System in Methuen, a DoN exempt physician practice. However, Staff noted that this excess capacity has not eliminated demand for existing PET services at MGH and Dana Farber, as indicated by patient waiting times these facilities. Staff further noted that Shields has projected demand for PET services based on the patient populations of the three host hospitals: South Shore, UMass Memorial, and Baystate, all of which are located further from Methuen than the Boston Pet services. Therefore, Staff regarded it as unlikely that Shields' patients would chose instead to use the services of New England Pct Imaging System.
13. This project is one of four comparable applications filed by Shields Imaging of Massachusetts, LLC, Children's Hospital Medical Center, Brigham and Women's Hospital, and Beth Israel Deaconess Medical Center. When considered alone, all of the applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since the four applications meet all the review factors of the PET Guidelines.
14. STAFF RECOMMENDATION

Based on the above analysis and findings, Staff recommends approval with conditions of Project Number 4-4886 submitted by Shields Imaging of Massachusetts, LLC for provision of a mobile Positron Emission Tomography (PET) service through acquisition of a mobile PET body scanner. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield. Failure of the applicant to comply with the conditions may result in Department sanctions, including possible fines and/or revocation of the DoN. The recommended conditions are as follows:

* 1. Shields Imaging of Massachusetts, LLC shall accept the maximum capital expenditure of

$2,564,000 (February 2001 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 752.

* 1. Shields Imaging of Massachusetts, LLC shall contribute 23.4% in equity ($600,000 in February 200 l dollars) toward the final approved MCE.
	2. Prior to implementation of the mobile PET service, Shields Imaging of Massachusetts LLC will obtain a certificate of registration from the Department's Radiation Control Program.
	3. Prior to implementation of the mobile PET service, Shields Imaging of Massachusetts, LLC shall secure a written agreement with a provider of radiopharmaceuticals to ensure that a reliable supply will be available for the service.
	4. Shields Imaging of Massachusetts, LLC shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.
	5. Shields Imaging of Massachusetts, LLC shall provide a total of $130,000 (February 2001 dollars) over five years at $26,000 per year to fund grant-based prevention programs that support the Healthy People 2010 leading indicators, particularly cancer and heart disease prevention. Each Community Health Network Area (CHNA) associated with the three host sites, including South Shore Hospital (CHNA #20), UMass Memorial Medical Center (CHNA #8), and Baystate Medical Center (CHNA #4), will award its share of the funding through commm1ity grants to community based health and wellness organizations, based upon recommendations by the Grant Review Committees of each CHNA. All grants will be awarded by a fiscal agent approved by each CHNA. Specific details of the grant award process will be determined through further consultation with the Department and each CHNA. Shields will file reports, as specified by the Department, detailing the frequency, content, and formalities of programming resulting from the grants and evaluations of the programming's effect on the health of service area residents. Such reports shall be filed annually or more frequently if so determined by the DoN Program Director. Funding for this initiative will begin upon project implementation, and notification to the Department's Office of Healthy Communities.

The applicant hasagreed to these conditions



JANE SWIFT

Governor

ROBERT P. GITTENS

Secretary

HOWARD K. KOH MD, MPH

Commissioner

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Determination of Need Program

250 Washington Street, Boston, MA 02108-4619

(617) 624-5002

Andrew Levine, Esq.

Donoghue, Barrett & Singal, P.C.

One Beacon Street

Boston, MA 02108

February 5, 2002

CERTIFIED MAIL

RETURNED RECEIPT REQUESTED

NOTICE OF DETERMINATION OF NEED

Project Number 4-4886

Shields Imaging of Massachusetts, LLC

(Establish Mobile PET Service)

Dear Mr. Levine:

At their meeting of January 22, 2002, the Commissioner and the Public Health Council, acting

together as the Department, voted pursuant to M.G.L. c.111, s25C and the Regulations adopted thereunder, to approve with conditions, the application filed by Shields Imaging of Massachusetts, LLC for a Determination of Need. The application, as approved, provides for provision of Positron Emission Tomography (PET) services through acquisition of a mobile PET body scanner and related equipment. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield. This Notice of Determination of Need incorporates by reference the attached Staff Summary and the Public Health Council proceedings concerning this application.

The approved maximum capital expenditure of $2,564.000 (February 2001 dollars) is itemized below:

|  |  |
| --- | --- |
| Major Movable Equipment | $2,504,000\* |
| Other: Fair Market Value of Shared Space at Host Sites | 60,000\*\* |
| Total Construction Costs | $2,564,000 |
| Total Maximum Capital Expenditure | $2,564,000 |

The approved MCE of $2,564,000 (February 2001 dollars) will be funded with a 23.4% equity

contribution ($600.000 in February 2001 dollars)), whereby Shields Imaging of Massachusetts,

UMass Memorial Medical Center, and Baystate Medical Center's hospital affiliate, Baystate

Radiology Imaging. LLC will contribute proportional equity shares that are yet to be determined. The remaining MCE of $1,964,000 (February 2001 dollars) will be financed through the vendor, Siemens

Medical Systems, Inc., at an interest rate of 9% for a sixty (60) month term.

The approved operating costs of $3,135,191 (February 2001 dollars) for the project's first full

year of operation (FY 2003), are based on a projected volume of 1,500 PET scans in that year, and are

itemized as follows:

|  |  |
| --- | --- |
| Salaries, Wages, Fringe Benefits | $ 495,000 |
| Supplies and Other Expenses | 1,685,300 |
| Purchased Services | 315,200 |
| Depreciation | 506,800 |
| Interest | 132,991 |
| Total Operating Expenses | $3,135,291 |

The reasons for this approval with conditions are as follows:

1. Shields Imaging of Massachusetts, LLC proposes to provide Positron Emission Tomography (PET) services through acquisition of a mobile PET body scanner and ancillary equipment, including a trailer. The services will be provided at three host sites: South Shore Hospital in Weymouth, UMass Memorial Medical Center in Worcester, and Baystate Medical Center in Springfield.
2. The Department found that the project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography (Guidelines).
3. The Department found that Shields Imaging of Massachusetts, LLC has demonstrated demand for a mobile PET unit to serve South Shore Hospital, UMass Memorial Medical Center, and Baystate Medical Center, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The Department found that the project with adherence to a certain condition, meets the operational objectives factor of the DoN Regulations.
5. The Department found that the project meets the standards compliance factor of the DoN Regulations
6. The Department found the recommended maximum capital expenditure of $2,564,000 (February 2001 dollars) reasonable, based on the price quote from the PET equipment vendor, which, when the trailer in excluded, is similar to comparable projects.
7. The Department found the recommended incremental operating costs of $3,135,291 (February 2001 dollars) are reasonable for a freestanding mobile PET service.
8. The Department found the project financially feasible and within the financial capability of the applicant.
9. The Department found the project meets the relative merit requirements of the Don Regulations.
10. The Department found the project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.
11. The Mark R. Taylor, Mary T. Sweeney, and Stephen M. Weiner Ten Taxpayer Groups (T TGs)

registered in connection with the proposed project. The Brockton Ten Taxpayer Group originally registered as well and requested a public hearing but subsequently rescinded its request on August 6, 2001, and withdrew as a TTG on August 7, 2001. The Taylor TTG submitted written comments, which indicated that there was excess capacity at New. England PET Imaging System in Methuen, a DoN exempt physician practice. The Department found that this excess capacity has not eliminated demand for existing PET services at Massachusetts General Hospital and Dana Farber Cancer Institute, as indicated by patient waiting times at these facilities.

1. The Department found that this project is one of four comparable applications filed by Shields Imaging of Massachusetts, LLC, Children's Hospital Medical Center, Brighams and Women's Hospital. and Beth Israel Deaconess Medical Center. When considered alone, all of the applications are capable of being approved, since each has demonstrated demand for PET services. A detailed comparability analysis was not undertaken since each of the four applications meets all the review factors of the PET Guidelines.

This Determination is effective twenty (20) days after receipt of this Notice. The Determination is subject to the conditions set forth in Determination of Need Regulation 105 CMR 100.551, including sections 100,551 (C) and (D) which read in part:

1. ... such determination shall be valid authorization only for the project for which made and only for the total capital expenditure approved.
2. The determination…shall be valid authorization for three (3) years. If substantial and continuing progress toward completion is not made during the three (3) year authorization period, the authorization shall expire if not extended by the Department for good cause shown (see 105 CMR. l 00. 756) ... Within the period of authorization., the holder shall make a substantial and continuing progress toward completion; however, no construction may begin until the holder has received final plan approval in writing from the Division of Health Care Quality.

This Determination is subject to the following conditions, in addition to the terms and conditions set forth in 105 CMR 100.551. Failure of the applicant to comply with the conditions may result in Department sanctions, including possible fines and/or revocation of the DoN.

1. Shields Imaging of Massachusetts, LLC shall accept the approved maximum capital expenditure of $2,564,000 (February 2001 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.
2. Shields Imaging of Massachusetts, LLC shall contribute 23.4% in equity ($600,000 in February 2001 dollars) toward the final approved MCE.
3. Prior to implementation of the mobile PET service, Shields Imaging of Massachusetts, LLC will obtain a certificate of registration from the Department's Radiation Control Program.
4. Prior to implementation of the mobile PET service, Shields Imaging of Massachusetts, UC shall secure a written agreement with a provider of radiopharmaceuticals to ensure that a reliable supply will be available for the service.
5. Shields Imaging of Massachusetts, LLC shall not consider ability to pay or insurance status in selecting or scheduling patients for PET services.
6. Shields Imaging of Massachusetts, LLC shall provide a total of $130,000 (February 2001 dollars) over five years at $26,000 per year to fund grant-based prevention programs that support the Healthy People 2010 leading indicators, particularly cancer and heart disease prevention. Each Community Health Network Area (CHNA) associated with the three host sites, including South Shore Hospital (CHNA #20), UMass Memorial Medical Center (CHNA #8), and Baystate Medical Center (CHNA #4), will award its share of the funding through community grants to community based health and wellness organizations, based upon recommendations by the Grant Review Committees of each CHNA. Specific details of the grant award process will be determined through further consultation with the Department and each CHNA. Shields will file reports, as specified by the Department, detailing the frequency, content and formalities of programming resulting form the grants and evaluations of the programming's effect on the health of service area residents. Such reports shall be filed annually or more frequently if so determined by the DoN Program Director. Funding for this initiative will begin upon project implementation, and notification to the Department's Office of Healthy Communities.

Please note that any party wishing to appeal the Department's action stated above must file a claim of appeal with the Health Facilities Appeals Board, Attention of: William Kaleva, Administrator, Boston University School of Law, 765 Commonwealth Avenue, Boston, MA 02215, within fourteen (14) days of receipt of this Notice. Each Appellant trust include a statement that the appeal is not knowingly interposed for delay and must comply with the Board’s “Rules of Procedure” available upon request from the Board. A copy of any claim of appeal filed with the Board must be served up this Department through its Office of General Counsel, 250 Washington Street, Second Floor, Boston, MA 02108.

 FOR THE PUBLIC HEALTH COUNCIL

 [signature on file]

 Linda M. Hopkins

 Secretary to the Council

LMH/JJ/jp

cc: Jean Pontikas, Division of Health Care Quality

Kathleen Coyle, Division of Health Care Quality

Steve McCabe, Division of Health Care Finance and Policy

Elizabeth Pressman, Division of Medical Assistance

Decision Letter File

Public File

MIS

Jere Page. Program Analyst

## ATTACHMENT 6B

COPY OF PRIOR AMENDMENTS TO APPROVED DON (6)



MITT ROMNEY

GOVERNOR

KERRY HEALEY

LIEUTENANT GOVERNOR

RONALD PRESTON

SECRETARY

CHRISTINE C. FERGUSON

COMMISSIONER

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Determination of Need Program

250 Washington Street, Boston, MA 02108-4619

(617) 624-5002

Andrew Levine, Esq.

Donoghue, Barrett & Singal, P.C.

One Beacon Street

Boston, MA 02108

April 10, 2003

CERTIFIED MAIL

RETURNED RECEIPT REQUESTED

NOTICE OF PUBLIC HEALTH COUNCIL ACTION

PREVIOUSLY APPROVED PROJECT NUMBER 4-4886

Shields Imaging of Massachusetts, LLC

Request to Add a Fourth Host Site to the Mobile Positron Emission Tomography Service

Dear Mr. Levine:

At their meeting of April 3, 2003, the Commissioner and the Public Health Council, acting together as the Department, voted pursuant to M.G.L. c.111, s. 25C and the Regulations adopted thereunder to approve with condition a significant change to DoN Project No. 4-4886 filed by Shields Imaging of Massachusetts, LLC. The approval provides for the addition of Berkshire Medical Center located at 725 North Street, Pittsfield, MA as a fourth host site to the mobile Positron Emission Tomography service. One day of mobile service per month will be provided at the fourth site.

The reasons for the Public Health Council's action are as follows:

1. The Department found that pursuant to 105 CMR 100.753(A) of the Determination of Need Regulations, the significant change meets the Procedures for Significant Changes set forth at 105 CMR 100.756.
2. The Department found that after careful consideration, the comments submitted by Alliance Imaging, Inc. provided no basis for the recommendation of denial.

Shields Imaging of Massachusetts, Inc. -2- Project No. 4-4886

The condition accompanying this approval is as follows:

All conditions attached to the original and amended approval of Project No. 4- 4886 shall remain in effect.

 Sincerely,

 [signature on file]

 Linda Hopkins

 Secretary for the Public Health Council

LH/jj

cc: Sherman Lohnes, DHCQ

 Donna Allen, DHCQ

 Steve McCabe, Division of Health Care Finance and Policy

 Elizabeth Pressman, Division of Medical Assistance

 Public File

 Decision Letter File

 MIS

 Secretary for the Public Health Council



MITT ROMNEY

GOVERNOR

KERRY HEALEY

LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY

SECRETARY

PAUL J. COTE, JR.

COMMISSIONER

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Determination of Need Program

2 Boylston Street, Boston, MA 02116

(617) 753-7340

FAX (617) 753-7349

Andrew Levine, Esq.

Donoghue, Barrett & Singal, P.C.

One Beacon Street

Boston, MA 02108

November 17, 2005

CERTIFIED MAIL

RETURNED RECEIPT REQUESTED

NOTICE OF PUBLIC HEALTH COUNCIL ACTION

PREVIOUSLY APPROVED PROJECT NUMBER 4-4886

Shields Imaging of Massachusetts, LLC

Request to Add a Fifth Host Site to the Mobile Positron Emission Tomography Service

Dear Mr. Levine:

At their meeting of September 27, 2005, the Commissioner and the Public Health Council, acting together as the Department, voted pursuant to M.G.L C.111, s. 25C and the Regulations adopted thereunder to approve with condition a significant change to DoN Project No. 4-4886 filed by Shields Imaging of Massachusetts, LLC. The approval provides for the addition of the Burbank campus of HealthAlliance Hospital located at 275 Nichols Road, Fitchburg, MA as a fifth host site to the mobile Positron Emission Tomography service. One day of mobile service per week of the three days per week currently allocated to UMass Memorial Medical Center in Worcester month will be provided at the fifth site.

The reason for the Public Health Council's action is as follows:

 The Department found that pursuant to 105 CMR 100.753(A) of the Determination of Need Regulations, the significant change meets the Procedures for Significant Changes set forth at 105 CMR 100.756.

The condition accompanying this approval is as follows:

Shields Imaging of Massachusetts, Inc. -2- Project No. 4-4886

All conditions attached to the original and amended approval of Project No. 4- 4886 shall remain in effect.

 Sincerely,

 [signature on file]

 Linda Hopkins

 Secretary for the Public Health Council

LH/jj

cc: Sherman Lohnes, DHCQ

 Jill Mazzola, DHCQ

 Steve McCabe, Division of Health Care Finance and Policy

 Elizabeth Pressman, Division of Medical Assistance

 Public File

 Decision Letter File

 MIS



MITT ROMNEY

GOVERNOR

KERRY HEALEY

LIEUTENANT GOVERNOR

TIMOTHY R. MURPHY

SECRETARY

PAUL J. COTE, JR.

COMMISSIONER

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

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Andrew Levine, Esq.

Donoghue, Barrett & Singal, P.C.

One Beacon Street, Suite 1320

Boston, MA 02108

August 9, 2006

Re: Approved DoN Project No. 4-4886

 Establish Mobile PET Service

 Request for Minor Change

Dear Mr. Levine:

This is in response to your letter dated July 12, 2008, requesting a minor change to the approved DoN Project No. 4-4886 referenced above. Shields Imaging of Massachusetts, LLC, (Shields Imaging) a consortium comprised of Shields Imaging of Eastern Massachusetts, LLC, Shields Imaging of Worcester, LLC and Shields Imaging of Springfield, LLC was approved on February 5, 2002 to provide PET services through acquisition of a mobile PET scanner and related equipment As stated In the DoN decision letter, the services were to be provided at three host sites: Baystate Medical Center, UMass Memorial Medical Center and South Shore Hospital. These sites were subsequently licensed as three separate clinics, one for each of the consortium members and the current licensees are: Baystate MRI and Imaging Center, LLC, UMass Memorial MRI ·and Imaging Center, LLC and Shields Imaging of Eastern Mass, LLC.

The minor change-requested in your letter of July 12 involves the deletion of Shields Imaging of Massachusetts, LLC as the provider of service for this project in order to correctly specify the individual consortium members currently licensed to provide the mobile PET services. The reason given for the minor change is that the deletion of Shields Imaging will correctly reflect the three clinics, Baystate MRI and Imaging Center, LLC; UMass Memorial MRI and Imaging Center, LLC and Shields Imaging of Eastern Mass, LLC., as the providers of services under the DoN and all subsequent amendments.

Pursuant to 105 CMR 100.752 of the Determination of Need Regulations, I hereby approve the minor change to Project No.4-4886 as requested for the following reasons:

1. All criteria set forth in 105 CMR 100.755 of the Determination of Need Regulations have been satisfied.
2. The minor change involves no change in the scope of the project or maximum capital expenditure.

Shields Imaging of Massachusetts, Inc. -2- Project No. 4-4886

Please note that all terms and conditions attached to the original approval of Determination of Need Project No. 4-4886 shall remain in effect.

 Sincerely,

 [signature on file]

 Joan Gorga

 Director

 Determination of Need Program

JMG/jmg

cc: Sherman Lohnes, DHCQ

 Public File

 Compliance

 MIS



DEVAL L. PATRICK

GOVERNOR

TIMOTHY P. MURRAY

LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD

SECRETARY

JOHN AUERBACH

COMMISSIONER

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

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Andrew Levine, Esq.

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One Beacon Street, Suite 1320

Boston, MA 02108

October 13, 2011

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

NOTICE OF PUBLIC HEALTH COUNCIL ACTION

PREVIOUSLY APPROVED PROJECT NUMBER 4-4886

UMass Memorial MRI and Imaging Center, LLC

Request to Add a Sixth Host Site to the

Mobile Positron Emission Tomography Service

Dear Mr. Levine:

At their meeting of October 12, 2011, the Commissioner and the Public Health Council, acting together as the Department, voted pursuant to M.G.L C.111, s. 25C and the Regulations adopted thereunder to approve with condition a significant change to DoN Project No. 4-4886 filed by Shields Imaging of Massachusetts, LLC. The approval provides for the addition of the Wing Memorial Hospital and Medical Center located at 40 Wright Street, Palmer. MA as a sixth host site to the mobile Positron Emission Tomography service. One half-day of mobile service every two weeks will be provided at the sixth site.

The reason for the Public Health Council's action is as follows:

 The Department found that pursuant to 105 CMR 100.753(A) of the Determination of Need Regulations, the significant change meets the Procedures for Significant Changes set forth at 105 CMR 100.756.

The condition accompanying this approval is as follows:

Shields Imaging of Massachusetts, Inc. -2- Project No. 4-4886

Please note that all terms and conditions attached to the original approval of Determination of Need Project No. 4-4886 shall remain in effect.

 Sincerely,

 [signature on file]

 Joan M. Gorga

 Director, Determination of Need Program

cc: Sherman Lohnes, DHCQ

 Paul DiNatale, DHCQ

 Steve McCabe, Division of Health Care Finance and Policy

 Terri Yannetti, Division of Medical Assistance

 Public File

 Decision Letter File



DEVAL L. PATRICK

GOVERNOR

TIMOTHY P. MURRAY

LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD

SECRETARY

JOHN AUERBACH

COMMISSIONER

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Determination of Need Program

250 Washington Street, Boston, MA 02108-4619

(617) 624-5002

Andrew Levine, Esq.

Donoghue, Barrett & Singal, P.C.

One Beacon Street, Suite 1320

Boston, MA 02108

February 14, 2013

NOTICE OF PUBLIC HEALTH COUNCIL ACTION

PREVIOUSLY APPROVED DON #4-4886

Baystate MRI and Imaging Center, LLC.

Request for Significant Change

Dear Mr. Levine:

At their meeting of February 13, 2013, the Commissioner and the Public Health Council, acting together as the Department, voted pursuant to M.G.L. c. 111, § 25C and the regulations adopted thereunder, to approve with conditions a significant change to approved Determination of Need ("DoN") Project Number 4-4886 of Baystate MRI and Imaging Center, LLC ( “BMIC” or "Holder"). The change authorizes establishment of an additional host site for the BMIC mobile PET service at Berkshire Medical Center ("Berkshire"), 725 North Street in Pittsfield. The DoN is held jointly by BMIC, Shields Imaging of Eastern Massachusetts, LLC, and UMass Memorial MRI and Imaging Center and currently operates at South Shore Hospital in Weymouth, Baystate Medical Center in Springfield, and at three UMass Memorial Medical Center campuses in Worcester, Fitchburg, and Palmer.

As approved, the significant change will result in one day of PET services per week at Berkshire and a reduction in service at the Springfield host site from two days to one day per week. This change has an associated capital expenditure estimated at $200,000.

The conditions accompanying this approval are as follows:

* 1. Upon implementation of the Berkshire Medical Center site for the mobile PET service, Baystate MRI and Imaging Center, LLC shall contribute an additional $10,000 to fund community health initiatives in the greater Pittsfield area to be approved by the Office of Healthy Communities ("OHC") in consultation with the Community Health Network of Berkshire County (CHNA 1). BMIC shall contact OHC at least three months prior to implementation of the project to begin the planning process

Shields Imaging of Massachusetts, Inc. -2- Project No. 4-4886

2. All other conditions attached to the original and amended approvals of this project shall

remain in effect.

 Sincerely,

 [signature on file]

 Bernard Plovnick, Director

 Determination of Need Program

cc: Steve McCabe, DHCFP

 Sherman Lohnes, DHCQ

 Paul DiNatale, DHCQ

 Daniel Gent, DHCQ

 Cathy O'Connor, OHC

 Kristin Golden, Commissioner's Office

 The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER

Governor

KARYN E. POLITO

Lieutenant Governor

MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH

Commissioner

October 1, 2018

Via Email and first class mail

Andrew Levine, Esq,

Barrett & Singal

One Beacon Street, Suite 1320

Boston, MA 02108-3106

alevine@barrettsingal.com

RE: Notice of Final Action

 Project No. DoN #18080612-AM

 Shields Imaging of Eastern Massachusetts, LLC (SIEM)

Dear Mr. Levine:

This shall serve as notification that, based on the information provided by the Applicant and staff

analysis, and pursuant to M.G.L, c, 111, § 25C and the regulatory provisions of 105 CMR 100.000 et seq,

including 105 CMR 100.635(A)(3) (Amendments to a Notice of Determination of Need), I hereby approve

the request for a significant change to Project #4-4886 (originally filed 02/01/2001) to add a second day

of mobile MRI/PET service to South Shore Hospital (South Shore).

This approval of the request for significant amendment incorporates by reference the Memorandum to

the Commissioner.

Sincerely,

[signature on file]

Monica Bharel, MD, MPH

Commissioner

cc: Sherman Lohnes, Director, Division of Health Care Facility Licensure and Certification

 Rebecca Rodman, Deputy General Counsel

 Daniel Gent, Health Care Facility Licensure and Certification

 Mary Byrnes, Center for Health Information and Analysis

 Stephen Sauter, MassHealth

 Katherine Mills, Health Policy Commission

 Eric Gold, Office of the Attorney General

ATTACHMENT #7 CERTIFICATE OF ORGANIZATION

<https://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSummary.aspx?sysvalue=uyDGbk61ALuXbZlDiRgKKzyV36rR2zR0GWWfWITL9Cs->

ATTACHMENT #7

AFFIDAVIT OF TRUTHFULLNESS AND COMPLIANCE

 Version: 7-6-17

**Massachusetts Department of Public Health**

**Determination of Need**

**Affidavit of Truthfulness and Compliance**

**with Law and Disclosure Form 100.405 (B)**

**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: UMMIC-22122814-AM

Original Application Date: 12/28/2022

Applicant Name: UMass Memorial MRI & Imaging Center, LLC

Application Type: Amendment Significant

Applicant's Business Type: LLC

Is the Applicant the sole member or sole shareholder of the Health Facility(ies) that are the subject of this Application? [unchecked]

|  |
| --- |
| **LLC**All parties must sign. Add additional names as neededThomas Shields <Signature on File> 12/28/2022CEO for Corporation: Signature: Date:  |

**This document is ready to print:** check **Date/time Stamp:** 12/28/2022 2:35 pm

1. See, e.g., Age and Cancer Risk, National Cancer Institute, [https://www.cancer.gov/about-cancer/causes­prevention/risk/age](https://www.cancer.gov/about-cancer/causes%C2%ADprevention/risk/age) updated 2021 [↑](#footnote-ref-1)