

## Memorandum from the Commissioner

**APPLICANT:** UMass Memorial Imaging Center, LLC

**At:** Shields MRI at UMass Memorial, Shrewsbury Street  
214 Shrewsbury Street  
Worcester, MA, 01604

**PROJECT NUMBER:** #UMMIC-22122814-AM (Significant Change)  
DoN #4-4886.6

**Filing DATE:** January 13, 2023

### Introduction

This memorandum presents for review and action the Determination of Need (“DoN”) Program’s recommendation pertaining to a request by UMass Memorial Imaging Center, LLC (“UMMIC”), regarding its primary location Shields MRI at UMass Memorial Shrewsbury Street (“Shrewsbury”) at 214 Shrewsbury Street, Worcester, MA, 01604 for a Significant Change to its previously approved DoN Project (#4-4886). As described further herein, UMMIC seeks approval to add three additional days of service at the Shrewsbury Street location for its existing approved mobile PET-CT clinic service, the Proposed Project. There are no additional gross square feet or capital expenditures requested.

This request falls within the definition for a Significant Change<sup>1</sup> that includes “Any change, modification, or deletion of components within a previously issued Notice of Determination of Need that is not an Immaterial Change, as determined by the Commissioner;” and will be reviewed pursuant to 105 C.M.R. 100.635(A), as the proposed change falls within the scope of the original Notice of Determination of Need and is reasonable.

---

<sup>1</sup> Significant Change means:

- (1) Any change, modification, or deletion of components within a previously issued Notice of Determination of Need that is not an Immaterial Change, as determined by the Commissioner;
  - (2) Any increase or decrease in the maximum Capital Expenditure over 10% of the inflation adjusted originally approved total expenditure. An increase shall be allowed only for contingencies that could not have been reasonably foreseen, that are not reasonably within the control of the Holder, as determined by the Commissioner, and for which the inflationary adjustment contained within 105 CMR 100.310(A)(9) is not appropriate;
  - (3) Any request for modification or deletion of any Standard or Other condition set forth within a Notice of Determination of Need that is determined to be material by the Department;
  - (4) Unless otherwise approved by the Department, any extension of the authorization period of an approved project as specified in a Notice of Determination of Need; or
  - (5) Any build-out of shell space that was subject to a Notice of Determination of Need.
- Any change to a project the Commissioner deems to be so significant that it alters the previously issued Notice of Determination of Need to a degree that it constitutes a new project will require the issuance of a new Notice of Determination of Need.

The Department has received no public comment on this request for Significant Change.

### **Background**

The Proposed Project is the eighth Amendment requested to a DoN that was approved in 2002, project #4-4886, called Shields Imaging of Massachusetts, LLC. The original request for DoN was from a consortium that received Determination of Need approval to provide mobile positron emission tomography (“PET-CT”) 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).

### ***Amendment History***

- In 2003, the DoN was amended to add Berkshire Medical Center as a host site.
- In 2005 the DoN was amended to add HealthAlliance Hospital’s Burbank Campus as a host site.
- In 2006, a DoN amendment was approved to remove Shields Imaging of Massachusetts, LLC as the DoN Holder and to acknowledge the licensure of the sites as three separately licensed clinics: 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 at Wing Memorial Hospital and Medical Center; however, this site was not implemented.
- In 2013, an amendment was approved to add Berkshire Medical Center as a host site of the BMIC clinic.
- 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.
- In 2021, an amendment was approved to add two days of service to the existing PET-CT service at Shrewsbury.

Currently, 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), and UMMIC.

### **The Proposed Project**

Pursuant to the original DoN as amended, UMMIC currently operates the PET-CT services at Shrewsbury on Sunday, Monday, Wednesday, and Thursday from 7:00am to 5:30pm. Since the

most recent amendment in 2021, demand for PET-CT services has increased, resulting in the need for additional PET-CT capacity at this location. The existing PET-CT service operating four days per week is at capacity and seeks to add three additional days of service (Tuesday, Friday, and Saturday from 7:00am to 5:30pm), to accommodate increased demand for a total of seven days of operation.

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.<sup>2</sup> 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 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.

Table 1 below shows that the number of PET-CT performed, shows an approximate 30% increase in scans between 2019 and 2021.

**Table 1: Annual PET-CT Volume**

Year	# Scans
2019	1686
2020	1771
2021	2191
2022 <sup>3</sup>	2230

As a result of the increasing demand since the 2021 amendment, the Applicant reports delayed access as demonstrated by the increase in the average wait time of 7-14 days from referral to the date of the scan. Accordingly, the Proposed Project seeks to meet the need for access to PET-CT for this growing patient population. The Applicant states that an additional three days of service will decrease wait times, preventing delays in care.

UMMIC anticipates demand for PET-CT services will continue to increase as the population ages, since age is a significant risk factor for cancers.<sup>i</sup> Based on 2022 data, approximately 66% of its patient population is over the age of 64; and 91% are over the age of 50.

UMMIC projects the additional three days of service at Shrewsbury 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 patients, for whom PET-CT is an integral modality as part of their diagnosis and

---

<sup>2</sup> Currently, the principal diagnoses of patients needing PET-CT scans at the site are lung cancer, lymphoma, solitary pulmonary nodule, head and neck nodules, breast cancer, melanoma, cervical cancer, colorectal cancer, esophageal cancer, and prostate cancer.

<sup>3</sup> Data through October 31, 2022.

treatment planning, particularly for cancers.

### ***Staff Analysis and Findings***

Staff notes that with the advances in technology and expansion of payments for these procedures by Centers for Medicare and Medicaid Services as well as other payers, it is preferable for patients to receive their treatments closer to home as improved outcomes have been demonstrated when care is available locally. The increase in scan volume since the last amendment, as well as the projected increase in demand due to an aging population support the need for additional availability of PET-CT services. Therefore, staff finds that the Applicant has made a reasonable argument for approval of this expansion of a service that it is needed and within the scope of the original DoN approval.

### **Impact on Cost**

The regulation requires that a Holder submit a description of the proposed change along with associated cost implications.

The Applicant states the Proposed Project will have no cost implications to UMMIC Worcester's Patients and that all pricing will remain consistent with current charges.

Staff notes the following:

- This Amendment does not include any addition of infrastructure or space.
- The additional services at an existing site would only include operating costs related to staffing, maintenance and repairs to the mobile unit.
- Timely access to care has the potential for cost-savings from early diagnosis to monitoring that may prevent the progression of disease which is more costly to treat.

### **Findings, Recommendations, and Conditions of Approval**

Based upon the information submitted, the Department can find that the "the proposed change or modification falls within the scope of the Notice of Determination of Need as previously approved by the Department, and ... is reasonable" 105 C.M.R. 100.635(A) which are requirements for approval of an Amendment.

Staff finds that the Applicant has made a reasonable argument for approval of this expansion of an existing service for three additional days and that it is needed and within the scope of the original DoN approval.

With this approval of three additional days, UMMIC can operate a total of seven days per week at the Shrewsbury location.

### **Conditions to the DoN**

All conditions from the original DoN approval and subsequent Amendments remain in effect.

### **Appendix I: Measures for Annual Reporting**

#### **Outcome Measures**

To assess the impact of the Proposed Project, the Applicant has developed the following outcome measures. The Applicant will report this information to the Department's DoN Program staff as part of its annual report required by 105 CMR 100.310(A)(12) for five years following implementation of the Proposed Project. For all measures, the Applicant will provide to the program a baseline upon implementation of each project component, along with updated projections, which the program will use for comparison with the annual data submitted. Reporting will include a description of numerators and denominators.

- 1. Wait Times: Access-Backlog:** The Applicant will monitor access for their imaging services. This measure tracks how fast patients are able to get into the schedule once an order is received.

Measure: Timeframe between the "Order Date" and "Date of Appointment".  
Date of order/referral to date of appointment.

- 2. Quality of Care – Peer Review Over Read Correlation:** To evaluate the accuracy of scan interpretations, the Applicant will conduct peer review readings to ensure quality outcomes for patients.

Measure: The Applicant will have contracted radiologists conduct peer review readings on a random basis (1 case per scan day) based on the American College of Radiology (ACR) Peer to Peer criteria and will follow-up on all discrepancies with the original reading radiologist.

## REFERENCES

---

<sup>1</sup> See, e.g., Age and Cancer Risk, National Cancer Institute, <https://www.cancer.gov/about-cancer/causes-prevention/risk/age> updated 2021