

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-20120208-AM (Significant Change)
DoN #4-4886.6

Filing DATE: January 26, 2021

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, (a.k.a. Shields MRI At UMass Memorial Shrewsbury Street or UMMIC), located 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 two additional days of service 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 Change¹ 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), which requires that the proposed change falls within the scope of the original Notice of Determination of Need and is reasonable. The

¹ 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.

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

Background

The Proposed Project is the sixth Amendment to a DoN that was approved in 2002, project #4-4886, called Shields Imaging of Massachusetts, LLC. The original DoN, was 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, and 2005 the DoN was amended to add two additional host sites: Berkshire Medical Center and HealthAlliance Hospital’s Burbank Campus.
- A DoN amendment was approved in 2006, 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 of UMMIC 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.

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, UMMIC currently operates the PET/CT services at Shrewsbury on Monday and Wednesday from 7:00am to 5:30pm. Demand for PET/CT services has increased, resulting in the need for additional PET/CT capacity at this location. The existing PET/CT service is at capacity and seeks to add two days of service, Sunday and Thursday from 7:00am to 5:30pm, to accommodate increased demand for a total of four 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.² The Holder reports that UMMIC’s PET-CT patient population served is growing as is the volume of scans. In 2017 it served 1,037 unique patients; in 2018 it served 1,062 unique patients; and in 2019 it served 1,368 unique patients. The site had seen 1,183 unique patients at the time of Amendment submission in 2020.

Table 1 below shows that the number of PET-CT performed, shows an average annual growth rate of 12.4%

Table 1: Annual PET-CT Volume

Year	# Scans
2017	1248
2018	1315
2019	1677
2020	1771

As a result of the increasing demand, the Applicant reports delayed access as demonstrated by the increase in the average wait time from referral to the date of the scan to 7-10 days. Accordingly, the Proposed Project seeks to meet the need for access to PET-CT for this growing patient population. The additional two 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.¹ Based on 2019 data, approximately 58.1% of its patient population is over the age of 64; and 89% are over the age of 50.

UMMIC projects the additional two days of service would result in approximately 1,846 scans in 2021; 1,994 scans in 2022; and 2,153 scans in 2023. By increasing capacity two 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 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 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. 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.

² 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.

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’s patient panel. All pricing with remain consistent with current charges.”

Staff notes the following:

- This Amendment does not include any addition of infrastructure or space.
- The addition services at an existing site would only include operating costs related to staffing, maintenance and repairs to the mobile unit.
- It will be more cost effective to operate than if placed at a new location which would require capital expense, such as constructing a concrete docking pad, establishing electrical connections for the mobile unit, as well as renovating or constructing a dedicated patient registration area.
- Further, 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 two additional days and that it is needed and within the scope of the original DoN approval.

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

Conditions to the DoN

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

ⁱ See, e.g., Age and Cancer Risk, NATIONAL CANCER INSTITUTE, [https://www.cancer.gov/about-cancer/causesprevention/risk/age#:~:text=Advancing%20age%20is%20the%20most,cancer%20diagnosis%20is%2066%20years\(April 29, 2015\)](https://www.cancer.gov/about-cancer/causesprevention/risk/age#:~:text=Advancing%20age%20is%20the%20most,cancer%20diagnosis%20is%2066%20years(April%2029,%202015).).