

Memorandum to the Commissioner

APPLICANT: Shields Signature Imaging, LLC
700 Congress Street, Suite 204
Quincy, MA 02169

SITE: Shields Signature Imaging, LLC
680 Centre Street
Brockton, MA 02302

PROJECT NUMBER: 5-4958 (Original)
N/A-24121012-AM (Amendment)

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Introduction

This memorandum presents, for Commissioner's Review, the Determination of Need (DoN) Program's recommendation pertaining to a request by Shields Signature Imaging, LLC ("Shields Signature" or "Holder") for a Significant Change to the Shields Signature DoN Application #5-4958 for a Substantial Change in Service ("Original DoN") to establish an additional day of operation per week to the part-time mobile positron emission tomography-computed tomography ("PET-CT") diagnostic imaging unit at Signature Healthcare Brockton Hospital, 680 Centre Street, Brockton, MA ("Brockton Hospital") for a total of 2 days of operation per week. There is no increase to the Maximum Capital Expenditure (MCE) associated with the Significant Change Application and therefore no change to the Community Health Initiatives (CHI) contribution.

This request falls within the definition for Significant Change that includes "... (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;" and will be reviewed pursuant to 105 C.M.R. 100.635(A)(3), which requires that the proposed change falls within the scope of the Notice of Determination of Need and is reasonable.

No Ten Taxpayer Groups (TTGs) were formed in connection with DoN Application #5-4958. The Department has received no comment from Parties of Record on this request for Significant Change.

Background

December 18, 2015, Shields Signature, a joint venture between Shields Imaging, MA, LLC ("Shields") and Brockton Hospital, received DoN approval for a Substantial Change in Service.

The Original DoN included, among other things, approval for the establishment of a part-time mobile PET-CT diagnostic imaging unit 1 day per week at Brockton Hospital. The total approved MCE was for the Original DoN was \$290,500 (2015 dollars).

On February 27, 2023, Shield Signature, submitted a DoN application seeking a Transfer of Site for the PET-CT unit in response to a fire that occurred at Brockton Hospital on February 7, 2023. The Department determined the transaction did not require a DoN as either a Substantial Capital Expenditure or Substantial Change in Service, as the Transfer of Site was temporary. The Holder states that the PET-CT unit will return to the original site in the second quarter of 2025.

Proposed Amendment

With this Significant Amendment, the Holder proposes to establish an additional day of operation of the part-time PET-CT diagnostic imaging unit at Brockton Hospital for a total of 2 days per week. The PET-CT service is currently provided on Thursdays from 7:00AM to 5:00PM. The Holder is proposing to add an additional day of service on Saturdays, with the hours of operation being 7:00AM to 5:00PM. The Holder states that it will operationalize the second day of PET-CT services upon receipt of regulatory approval.

The Holder states that PET-CT diagnostic imaging scans are used to detect and monitor high acuity and progressive diseases such as cancer, heart disease and neurological conditions. The Holder states further that PET-CT service is an integral part of their existing Patient Panel's diagnosis and treatment planning, and especially so for cancers. The Holder maintains that an additional day of PET-CT services will reduce wait times and prevent delays in care for patients, as well as support convenient access to PET-CT services.

The Holder asserts that an additional day of PET-CT services is needed to address increasing demand for PET-CT services.

Historical Utilization:

The Holder states that it has experienced an increase in unique patients presenting for scans. Table 1 shows the number of unique patients per year that received a PET-CT scan. The Holder states that a patient may undergo multiple scans during the course of one appointment. The number of unique patients per year is defined as those patients that had at least one scan per year, but are only counted once even if they had multiple scans done in a year. The Holder points to the 13% increase in the number of unique patients from 2022 to 2024. The number of unique patients increased 93% from 2018 to 2024.

Table 1: Annual Number of Unique Patients, 2018-2024

	2018	2019	2020	2021	2022	2023	2024	% Change 2018-2024
Unique Patients	376	472	416	526	641	709	724	93%

Table 2 shows the number of scans performed per year based on the current schedule. Annual scan volume increased 14% from 2022 to 2024 and 47% from 2018 to 2024. Annual scan volume is more than double the amount anticipated in the Original DoN Application. At the time of approval of the Original DoN Application, the Holder projected approximately 256 scans in 2018 and 269 scans in 2019.

Table 2: Annual PET-CT Scan Volume, 2018-2024

	2018	2019	2020	2021	2022	2023	2024	% Change 2018 to 2024
Scan Volume	594	557	534	674	764	847	873	47%

Table 3 shows year-over-year changes in annual scan volume from 2018 to 2024.

Table 3: Year Over Year Change in PET-CT Scan Volume, 2018-2024

2018-2019	2019-2020	2020-2021	2021-2022	2022-2023	2023-2024
-6.2%	-4.1%	26.2%	13.4%	10.9%	3.1%

Table 4 shows year-over-year changes in projected scan volume in the Original DoN. The year-over-year changes in the Holder's annual scan volume from 2020 to 2023 (Table 3), are greater than the projected year-over-year changes in PET-CT volume in the Original DoN.

Table 4: Year Over Year Change in Projected PET-CT Scan Volume, 2015

2016-2017	2017-2018	2018-2019
10.1%	6.7%	5.1%

In accordance with the *Guidelines for Positron Emission Tomography* ("Guidelines"), the minimum volume requirement (1,250 scans annually) to operate a one day per week mobile service applied to the Original DoN was 178.6 scans per year, which the Holder exceeded each year from 2012 to 2014. The Determination of Need *Guidelines for Positron Emission Tomography* were rescinded in 2017, along with all other DoN Guidelines and Policy Advisories issued prior to January 26, 2017, as part of the revision of the DoN Regulations. Staff note that the volume requirement under previous Guidance to operate 2 days a week would have been 357 scans.

The Holder states that on average Shields is providing 17 scans per day with a capacity of 20

scans per day (for the standard “skull base to mid-thigh” PET-CT scan)¹, which represents 85% utilization. The Holder notes that some scans may deviate from the protocol, taking more time, which then reduces the scan capacity per day. The Holder cites the example of a whole body PET-CT scan, which the Holder states take up to ten minutes longer than the standard PET-CT scan.

Increasing Utilization:

The Holder asserts there is a need to address increased demand for PET-CT services in the existing Patient Panel, as demonstrated in the utilization data in **Table 1** and **Table 2**.

The Holder states further that increasing utilization has resulted in long patient wait times for a scan. The Holder states that PET-CT scan is used predominately in the treatment of patients with cancer, and because PET-CT scans are an important component of treatment planning, timely receipt of PET-CT services is important to patient care. The current wait time is 16 days from referral to the date of the scan. The Holder states that the wait time was 18 days in 2021, 14 days in 2022, and 18 days in 2023. The Holder states that it is not aware of any industry standard related to optimal wait times for PET-CT services.

The Holder anticipates that an additional day of operation of the PET-CT diagnostic imaging unit would reduce current wait times to approximately 7 to 10 days because the additional day of PET-CT service would increase the maximum scan capacity from 20 scans per week to 40 scans per week, and would reduce patient wait times between PET-CT scan availability from 7 days to 2 days and 4 days. The Holder anticipates a reduction in wait time in year 1 of project implementation with expanded access to PET-CT services.

Other Sources of Increasing Demand:

The Holder identified additional changes anticipated to increase demand and utilization for PET-CT services, including:

1. The expansion of the available diagnostic imaging provided by the unit. In particular, the launch of amyloid PET-CT scans and fluoro-D-glucose Positron Emission Tomography (FDG/PET) brain scans in 2025.^{2,3} The Holder received approval from the Centers for Medicare and Medicaid (CMS) services for payment for amyloid PET-CT

¹ The Holder states that patients gets either a whole body image or “skull base to mid-thigh” based on indication.

² Amyloid PET imaging uses a class of radiopharmaceuticals that detect levels of amyloid in the human brain. <https://www.cms.gov/medicare/coverage/evidence/amyloid-pet>

³ FDG PET is a minimally-invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=331&ncdver=4#:~:text=FDG%20\(2%2D%5BF18%5D%20fluoro,disease%2C%20and%20some%20neurologic%20disorders](https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=331&ncdver=4#:~:text=FDG%20(2%2D%5BF18%5D%20fluoro,disease%2C%20and%20some%20neurologic%20disorders).

scans in 2024⁴. Additionally, the Holder anticipates its recent transition back to the permanent location following the reopening of Brockton Hospital will permit the part-time mobile PET-CT support the establishment of amyloid PET-CT scans and FDG/PET brain scans; and

2. The presenting patient conditions in the Holder's overall patient population. Currently, 72% of the Holder's patient population is over age 64, and 95% are over age 50. The Holder anticipates additional demand for PET-CT services as a result of patient conditions reflected by an aging population.

Projected Volume:

Table 5 shows the Holder's projected volume if the proposed Significant Amendment is approved. The Holder states that it expects the new offering of amyloid and FDG brain scans to contribute to 7% to 10% of the increase in the number of scans, FDG tumor imaging to increase scans by 5% to 7% annually and Prostate-Specific Membrane Antigen (PSMA) imaging to increase scans from approximately 7% to 10% annually, as a result of broader adoption. With projected increases to current volumes and new volumes associated with amyloid PET-CT scans, the Holder is projecting 1,468 annual scans in 2027 or on average 28 scans per day, which cannot be achieved on one unit.

Table 5: Projected PET-CT Scan Volume

	2025	2026	2027	% Change 2025-2027
Scan Volume	1,080	1,242	1,468	36%

Analysis

Staff has reviewed the Significant Change Amendment request and has determined that it falls within the scope of the Original DoN Approval. Staff finds that the Holder's Patient Panel is PET-CT experiencing increasing need for PET-CT services based on increasing patient volume and scan volume, and that increasing demand is resulting in long wait times for access to services. Based on these points, staff finds that the Holder has established a reasonable basis for the addition of 1 day per week of PET-CT service at its primary location for a total of 2 days per week. Therefore, staff finds that the Holder 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. Staff recommends as a Condition of Approval, that the Holder provide to the specific information about scan capacity, volume, and utilization in any future requests to increase the number of days of operation.

⁴ The closure of Brockton Hospital from February 2023 to August 2024, delayed the Holder's anticipated launch of the amyloid program to 2025.

Impact on Cost to the Holder's Existing Patient Panel

The regulation requires that a Holder submit a description of the proposed change along with associated cost implications for the Holder and the Patient Panel. The Holder states that PET-CT is an existing service and that no additional capital costs are required to operate an additional day of PET-CT service per week. Operating costs impacted by the Proposed Project and the additional day of service include the daily equipment fee for the mobile unit and the staffing of the unit.

The Holder states that its Patient Panel will not experience any impact on cost from the Project Change. The Holder states further that all pricing will remain consistent with current charges.

Staff notes the following:

- This Significant Change Amendment does not include any request for the addition of infrastructure or space; and
- The additional part-time PET-CT diagnostic imaging unit services at a primary site would only include operating costs related to staffing and a daily equipment fee.

Impact on Community Health Initiative Funding

There is no capital expenditure associated with the Proposed Change and therefore no change to the Community Health Initiatives (CHI) contribution.

Staff Summary and Findings

Staff reviewed the 2015 Staff Report and Decision Letter to determine whether the request falls within the scope of the Original DoN Approval.

Based upon the information submitted, and information in the record, the Department finds that "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)(3), meeting the requirements for approval of this Significant Change Amendment.

Conditions to the DoN

1. The Holder, Shields Signature Imaging, LLC, shall provide services only at the approved site, and only for two days indicated in this approval. Any request for change in either number of days or specific site served shall require the Department's approval. Any request to increase the number of days of operation shall include but not be limited to the following:
 - a. Maximum scan capacity per day and per week of operation,
 - b. Annual number of scans completed per day and per week of operation,
 - c. Annual number of Unique Patients,
 - d. Average wait times for scans, and

- e. Projected scan volume.

Additional Standard Conditions: Annual Reporting

Pursuant to 105 CMR 100.310(A)(12), the Holder will provide Annual Reports to the Department for a period of five years following implementation of the Proposed Project. The Holder will provide to the Department baselines for Wait Times and Utilization upon implementation of the Proposed Project, along with updated projections, which the Department will use for comparison with the annual reporting data submitted. Reporting will include a description of numerators and denominators.

The Annual Reports must include, but are not limited to, the following:

1. Wait Times: The Holder will monitor access for their part-time PET-CT diagnostic imaging unit services. This measure tracks the timeframe between the “Order Date” and “Date of Appointment”.
2. Utilization: The Holder will monitor annual PET-CT scan volume (as shown in Table 2 above) and annual number of unique patients (as shown in Table 1 above). The Holder will also report annually on the following:
 - a. Number of slots used per day for each day of operation
 - b. Number of PET-CT scans per day for each day of operation