**AMENDMENT QUESTIONS #1**

*Responses should be sent to DoN staff at* [DPH.DON@State.MA.US](mailto:DPH.DON@State.MA.US)

|  |
| --- |
| While you may submit each answer as available, please   * List question number and question for each answer you provide * Submit responses as a separate word document, using the above application title and number as a running header and page numbers in the footer * When providing the answer to the final question, submit all questions and answers in one final document * Submit responses in WORD or EXCEL; only use PDF’s if absolutely necessary. If “cutting and pasting” charts, provide them in a PDF so they can be clearly seen * **Whenever possible, include a table with the response** * **For HIPAA compliance Do not include numbers <11.** |

1. The application states demand for PET/CT services at Shields Signature has increased, resulting in the need for additional PET/CT capacity at this location (pg.3)
   1. Explain the reason for increasing demand at this location.

PET/CT has diversified beyond FDG tumor imaging to include prostate PET with PSMA, neuroendocrine tumor imaging with dotate tracer, and brain imaging with amyloid tracers. Further, the continued drive in cancer screening, primarily by CT, leads to a malignancy determination often aided by non-invasive PETCT.

1. The application states that the Holder has also experienced an increase in unique patients presenting for scans (pg.3).
   1. To better understand increasing demand for PET/CT services, provide the number of unique patients for the following years:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **2018** | **2019** | **2020** | **2021** | **2022** | **2023** | **2024** |
| **Unique Patients** | 594 | 557 | 534 | 674 | 764 | 847 | 873 |

* 1. Provide the scan volume for the following years:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **2018** | **2019** | **2020** | **2021** | **2022** | **2023** | **2024** |
| **Scan Volume** | 594 | 557 | 534 | 674 | 764 | 847 | 873 |

1. The application states the current wait time is 16 days from referral to the date of the scan (pg.3)
   1. To better understand delays in accessing PET/CT services, provide average wait time from referral to date of scan, in 2021, 2022, and 2023.

2021 : 18 days

2022: 14 days

2023: 18 days

* 1. By how much does the Holder expect wait times to decrease as a result of the Proposed Project, and, in what year of project implementation does the Holder expect to see a decrease.

The program expects to see wait time improvement in year one of expanded access, with a goal of 7 to 10 days from referral to patient scan.

1. Please provide any industry standard/ national benchmarks for optimal wait times for PET/CT services.

Shields is not aware of any industry standard/national benchmarks related to optimal wait times for PET/CT services, however, our experience in the market suggests that in most hospital settings patients are waiting up to 30 days.

At Shields, we strive to accommodate all patients in a timely manner to improve patient access, enhance medical outcomes and increase patient satisfaction.

1. What day will additional PET/CT services be added, and what will the hours of operation be?

Saturdays, 7AM to 5PM.

1. How will operating costs be impacted by the additional day of PET/CT services?

The only operating costs impacted by the additional day of service is the daily equipment fee for the mobile unit and staffing of the unit.

1. The application states that Shields will begin offering amyloid and FDG brain scans in 2025, which is expected to further increase the number of PET/CT scans performed at the clinic.
   1. Why has the Holder decided to begin offering these scans in 2025?

Though CMS approved payment for Amyloid PETCT scans in 2024, the closure of Brockton Hospital from February 2023 through August 2024 delayed implementation of the amyloid program.

Shields Signature Imaging received DPH approval to temporarily relocate the PETCT service from the hospital campus to another location in Brockton during the hospital’s closure.  During this time, the program prioritized preserving patient access over launching a new program and protocols.  Now that the hospital has reopened and the service will return to its original location, the service now has the ability to implement the amyloid program.

* 1. By how much does the Applicant expect PET/CT volume to increase as a result of the new offering of amyloid and FDG brain scans?

It is projected that 7- 10 percent of total volume going forward will be attributable to amyloid and FDG PET cases.