Tufts Medicine: Shields PET-CT, LLC

DoN # NA-22091411-RE

APPLICANT QUESTIONS

Responses should be sent to DoN staff at 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
- We accept answers on a rolling basis however, when providing the answer to the final question, submit all questions and answers in order in one final document.
- Submit responses in WORD or EXCEL; only use PDF's if absolutely necessary. **Whenever possible, include a table in data format (NOT pdf or picture) with the response.**

In order for us to review this project in a timely manner, please provide the responses by **November 2, 2022**.

Project Description

1. In order to better understand the Patient Panel's current access to PET-CT services, please provide additional information on the following:
    a. What are the ages of the current equipment and the proposed PET-CT unit?

    The existing unit was purchased under the GE GoldSeal Refurbished Systems Program. The unit is a 2009 scanner and it was installed in December of 2009.

    The proposed unit is a Siemens Horizon mCT 16, 2018 model.

    b. Will the PET-CT scanner in the Proposed Project have any advantages in comparison to the current equipment?

    Yes, the PET-CT scanner in the Proposed Project has a few advantages over the current unit which include:

    - Time of Flight (TOF) technology – TOF offers higher image quality for more accurate detection of masses and lesions;[1]
    - Higher CT slice[2] configuration, which helps ensure optimum image quality; and
    - Dose control technology, which allows for optimization of a personalized dosage via the as low as reasonably achievable ("ALARA") principle.

    c. As an IDTF, the Proposed Project is reported to be lower cost per scan than hospital rates. How do the rates for the proposed project compare to the cost per scan currently in place?

    The contemplated rate structure for the proposed project is similar to the cost structure of the current Montvale PET-CT joint venture relationship. Montvale PET-CT is an Independent

[1] A more accurate system gives you better information, and better information makes it easier to declare a more definitive diagnosis and pursue a more specialized treatment plan.

[2] PET-CT scans create cross-sectional images (slices).

Diagnostic Testing Facility (IDTF). The proposed project is also slated to be an IDTF and will bill accordingly.

The Hospital Outpatient Prospective Payment System (HOPPS) rates used by CMS to reimburse for hospital outpatient services, are generally higher than IDTF rates.

d. Please fill out the table below comparing the current availability of the PET-CT equipment compared to the Proposed Project equipment.

	Current PET-CT Equipment	Proposed Project Equipment
Location	41 Montvale Ave, Melrose	888 Main St, Wakefield
Days/ Week of Availability	Tues 6:00-5:00 Thurs 6:00-5:00	One weekday 7-5
Hours of Availability	22	10

It is important to note that by deploying more advanced state of the art technology and protocols, historic scan times will decrease. This efficiency will allow for the number of weekly scan appointments/availability to remain the same even though the service will operate on a more limited hourly schedule.

2. The Factor 4 Form shows Construction Line Items of a Construction Contract, Architectural Costs, and Planning/ Development Costs totaling $845,000 in new construction costs. Please explain the specific construction activities needed to implement the Proposed Project.

The construction activities related to this proposed project include constructing a small-scale addition to existing building to accommodate a corridor, and a dock/vestibule for patients to access the mobile PET-CT. The plans include optimization of the current space.

Patient Panel

3. The application provides historical volume of PET-CT scans (pg.9). Please provide data on the number of unique patients receiving the PET-CT scans referenced in your data.

	FY19	**FY20**	**FY21**
Total scans	450	455	522
Unique patients	364	359	431

4. Please provide a race, age, and town breakdown for unique patients receiving PET-CT scans referred to Montvale PET-CT for diagnostic imaging in FY19, FY20, and FY21.

	FY19		**FY20**		**FY21**	
Race	**Unique Patients**	**% of all**	**Unique Patients**	**%**	**Unique Patients**	**% of all**
Caucasian	340	93%	326	91%	382	89%
Asian	9	2%	7	2%	12	3%

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African American/Black	8	2%	5	1%	9	2%
Unknown/ Not Specified	7	2%	21	6%	28	6%
TOTAL	**364**		**359**		**431**	

	FY19		FY20		FY21	
Age Cohort	**Unique Patients**	**% of all**	**Unique Patients**	**% of all**	**Unique Patients**	**% of all**
18-34	4	1%	7	2%	8	2%
35-44	7	2%	10	3%	9	2%
45-64	88	24%	94	26%	104	24%
65-74	112	31%	115	32%	155	36%
75-84	114	31%	99	28%	126	29%
85+	39	11%	34	9%	29	7%
TOTAL	**364**		**359**		**431**	

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	FY19		FY20		FY21	
Town of Origin	**Unique Patients**	**% of all**	**Unique Patients**	**% of all**	**Unique Patients**	**% of all**
MEDFORD	49	13%	49	14%	53	12%
MALDEN	40	11%	53	15%	51	12%
MELROSE	46	13%	41	11%	43	10%
SAUGUS	35	10%	35	10%	38	9%
WAKEFIELD	34	9%	27	8%	27	6%
REVERE	18	5%	14	4%	28	6%
EVERETT	13	4%	11	3%	26	6%
STONEHAM	18	5%	10	3%	16	4%
READING	12	3%	16	4%	12	3%
WINTHROP	11	3%	9	3%	9	2%
WOBURN	7	2%	4	1%	13	3%
All Other	81	22%	90	25%	115	27%
TOTAL	**364**		**359**		**431**	

5. To better understand the demographic makeup of the Patient Panel, please provide definitions of the following terms that are used in the application:
    a. On Page 6 of the Narrative, the Gender breakdowns for the Overall Patient Panel list "Unknown." Please define the data that falls into the Unknown category.

    "Unknown"' were either not captured or declined to choose from the binary options provided.

    b. On Page 6-7 of the Narrative, the Race breakdowns for the Overall Patient Panel list "Other/Unknown". Please define the data that falls into the Other/ Unknown category.

    Since Race and Ethnicity are self-reported, there may be an inclination by the patient to not participate in the answering of the question. Furthermore, we have found that for patients that may identify as having more than one race, they may opt to choose "Other/Unknown". And lastly, the "Office of Management and Budget" (OMB) defines "Hispanic or Latino" as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin regardless of race. We have found that many patients that identify with an ethnicity that meets the OMB definition of "Hispanic or Latino" may choose "Other/Unknown" as their race.

    c. On Page 7 of the Narrative, the Payer Mix table lists "Dual" and "Behavioral" categories. Please define these categories.

    "Dual" is defined as patients who are dually-eligible for Medicare and Medicaid. "Behavioral" is defined as insurances products that are behavioral health carve out utilized by several local and national insurers.

Patient Panel Need

6. In the Projected Volume Table generated by Veralon projections (pg. 9), are the data referring to growth in the number of scans or the number of patients?

    The data refer to growth in the number of scans.

Factor 1b.ii. Public Health Value/ Outcomes Oriented

7. Describe any Clinical Decision Support tools or Preauthorization tools currently in use to curb unnecessary PET-CT imaging.

    Commercial insurers utilize 3rd party utilization management platforms via eviCore and AIM Specialty Health (AIM) to ensure health plan members receive the appropriate test or treatment necessary for their individual case presentation or condition. Commercial insurers utilize these platforms to reduce inappropriate utilization, unnecessary radiation exposure, and invasive procedures and thereby improves patient safety. Shields Health works with the provider, the payer and 3rd party utilization platforms to ensure that patients receive the necessary advance preauthorization approval in order to complete an imaging scan. This process represents roughly 40% of Shields' referrals.

The Centers for Medicare & Medicaid Services (CMS) does not require pre-authorization, only medical necessity. Additionally, CMS announced it has delayed the mandate for referring providers to use appropriate use criteria (AUC) and clinical decision support (CDS) tools. Once the mandate for referring providers to use AUC goes into effect, Shields will have the capability of reporting:

- The percent of ordering physicians using the mechanism;
- Data showing yearly changes in "low utility" or "marginal utility;'
- Percent of ordering providers' response to alerts provider by CDS tools; and
- Analysis of data and policy changes instituted as a result of these data.

Factor 1F **(Please note that this quote can be found in the Project Description but is relevant to the Competition section)**

8. On Page 2 of the Narrative, Applicant states, "The transition will allow Shields to implement both operational optimization initiatives to further drive down cost and allow the team to leverage use of centralized patient management services across the Shields network of service partnerships." Please describe in further detail the operational optimization initiatives that drive down costs.

   State of the art imaging equipment allows Shields to use a part time mobile unit, with costs shared across multiple customers to provide access in less time. In this case, one day versus two. In addition, Shields has no fixed site overhead. Further, Shields has a specialized PET-CT team scheduling patients versus a general call center, who may manage a full radiology department. The scheduling efficiency allows for more customers to be added to the system, which in turn reduces the overall cost.

   There are several operational efficiencies that Shields is exploring through the optimization of Artificial Intelligence (AI) and software to reduce manual efforts. Three examples that are in the beta phases of development are: 1) Plenful, which is an automation platform that cleans and connects all text-based healthcare data; and 2.) Shields has also contracted with Subtle Medical to develop an AI tool to reduce patient time on the scanner. 3. Shields has enlisted outside development support to continue to automate the administrative activities and improve the patient experience.

Consultation **(Page 29 of Narrative)**

9. The Applicant notes that they "conducted a formal consultative process with individuals at various regulatory agencies regarding the Proposed Project. The following individuals are <u>some</u> of those consulted about the Proposed Project:" and lists 3 individuals from DPH. Were there any additional regulatory agencies consulted?

   The individuals recited in the Narrative were the only regulatory experts consulted.

Relative Merit **(Pages 34-37 of the Narrative)**

10. Why was the option of renewing the joint venture with Montvale not considered as an alternative option to the project?

    MelroseWakefield Hospital has enjoyed a successful partnership with Alliance Imaging in providing clinical care to the community at the Montvale PET-CT location for more than a decade. Looking to the future, MelroseWakefield Hospital and Tufts Medicine thought dissolving the partnership and moving to

a local based partner with a track record of delivering low cost, high quality, community care, was the right decision for our patients. Tufts Medicine and Shields Healthcare have multiple partnerships, including a PET-CT in Boston. Expanding the relationship with a PET-CT in the MelroseWakefield market will allow for most consistent patient experiences, and greater efficiencies, and standardization.

11. In Alternative Option 2, Patients are referred to Tufts' Boston location to fulfill PET-CT scan referrals while Alternative Option 1 does not list any information on fulfilling PET-CT scan referrals. Please clarify how the Patient Panel would fulfill referrals to PET-CT in Alternative Option 1.

    In option 1, MelroseWakefield would look to send patients to any PET-CT's throughout the region. This would lead to insufficient access and less care coordination as opposed to the proposed low cost, new partnership in Wakefield.