| **STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR DETERMINATION OF NEED** |  |
| --- | --- |
| Applicant Name  | Shields PET-CT at Heywood Healthcare, LLC |
| Applicant Address  | 700 Congress Street, Suite 204Quincy, MA 02169  |
| Filing Date | July 29, 2021 |
| Type of DoN Application | Substantial Change in Service – DoN-Required Equipment |
| Total Value | $2,570,562.00  |
| Project Number | 21021213-HS |
| Ten Taxpayer Group (TTG) | None |
| Community Health Initiative (CHI)  | $128,528.10 |
| Staff Recommendation | Approval  |
| Delegated Review | Commissioner Approval |
| Project Summary and Regulatory ReviewShields PET-CT at Heywood Healthcare, LLC (Applicant) submitted a DoN Application for a Substantial Change in Service to establish a licensed clinic to provide magnetic resonance imaging (MRI) services at Heywood Hospital six days a week and mobile positron emission tomography-computed tomography (PET-CT) imaging services at Athol Hospital one day a week. The Applicant is a newly formed joint venture between Shields Health Care Group, Inc. and Heywood Healthcare, Inc. that replaces an existing contract with an imaging vendor for the same service. The existing contract with the imaging vendor is ending and the Applicant seeks to fulfill the need for MRI and PET-CT services. The capital expenditure for the Proposed Project is $2,570,562.00; the Community Health Initiatives (CHI) contribution is $128,528.10.This DoN application falls within the definition of Substantial Change in Service, which are reviewed under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation. |

**Application Overview**

**Background**

The Applicant, Shields PET-CT at Heywood Healthcare, LLC, was formed in 2021 as a joint venture between Shields Healthcare Group, Inc. (Shields) and Heywood Healthcare, Inc. (Heywood) for the purpose of establishing a licensed clinic to provide fixed MRI services at Heywood Hospital and mobile PET-CT imaging services at Athol Hospital. MRI and PET-CT imaging services are currently provided at Heywood Hospital and Athol Hospital through an arrangement with another imaging vendor. The existing contract with the existing imaging vendor is ending and the Applicant seeks to fulfill the need for continued access to MRI and PET-CT services.

The relevant parties to the transaction are:

**Heywood Healthcare, Inc. (Heywood),** a healthcare system that provides healthcare services to residents of North Central Massachusetts, including acute care services, emergency services, primary care, behavioral health, and substance use treatment. Heywood Healthcare is comprised of Athol Hospital, Heywood Hospital, Heywood Medical Group, Heywood Rehabilitation Center, Murdock School-based Health Center, The Quabbin Retreat, and Winchendon Health Center.

The two hospitals in the healthcare system are:

* **Heywood Hospital,** a High Public Payer (HPP) community hospital located in Gardner, MA.[[1]](#footnote-1) Heywood Hospital has 134 licensed beds and provides a range of acute care services, including emergency services, primary and specialty care, and behavioral health services.
* **Athol Hospital,** a High Public Payer (HPP) community hospital located in Athol, MA. Athol Hospital has 21 licensed beds and is designated by the Centers for Medicare & Medicaid Services (CMS) as a Critical Access Hospital.[[2]](#footnote-2)

**Shields Healthcare Group, Inc.** (Shields) was founded in 1972 and opened its first MRI center in 1986. Shields manages multiple facilities throughout New England, offering MRI and PET-CT services. Many of these sites are joint venture partnerships with community hospitals. Many of the Shields locations operate as licensed clinics but remain in close proximity to the local hospital-partner, an arrangement which improves access to care and coordination of care.

**Proposed Project**

MRI and PET-CT services are currently offered at Heywood and Athol Hospitals through an arrangement with an existing imaging vendor. The contract is coming to an end and the Applicant is proposing to establish a licensed clinic to provide fixed MRI services at Heywood Hospital and mobile PET-CT imaging services at Athol Hospital to ensure continued access to these imaging services for the Patient Panel. MRI is a well-established, non-invasive imaging modality that is used to visualize internal, and anatomical structures, without the use of ionizing radiation.[[3]](#footnote-3) Combined PET-CT is a dual-modality diagnostic imaging technology.[[4]](#footnote-4) The Applicant assesses and documents the need for continuation of the existing imaging services and future demand for such imaging services based on historical and projected volume of scans, the aging of the Patient Panel, and the increasing age 60+ age cohort in Massachusetts that will experience increased risk for age-related conditions that will require the proposed imaging services. The Applicant states through the Proposed Project, it will meet demand for high-quality MRI and PET-CT imaging services, in a cost-effective manner.

**OVERVIEW of PROPOSED PROJECT AND FACTOR REVIEW**

| Description | What’s Needed to Meet Factor 1: Demonstration of need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending. | What’s Needed to Meet Factor 2: Demonstration of cost containment, improved public health outcomes, and delivery system transformation | Factors 3, 4 & 5[[5]](#footnote-5) | What’s Needed to Meet Factor 6: Demonstration of plans for fulfilling … responsibilities … in the DPH Community-based Health Initiatives Guideline. |
| --- | --- | --- | --- | --- |
|  | ***Staff Report finds*** |  |
| **MEETS** | **MEETS** | **MEETS** | **MEETS** |
| The Applicant is proposing to establish a licensed clinic to provide MRI services at Heywood Hospital and mobile PET-CT services at Athol Hospital. The imaging services are currently provided through a different vendor whose contract is ending.  | ✓ | ✓ | ✓ | ✓ |

**Patient Panel[[6]](#footnote-6)**

The Applicant is a newly formed joint venture and does not have its own Patient Panel. The Applicant reviewed the Patient Panels of Heywood and Athol Hospitals from fiscal year (FY)18 to FY20 and the first quarter of FY21 to define its Patient Panel and to determine need for the Proposed Project.[[7]](#footnote-7) The Patient Panel data for FY18-20 are provided in Table 1 below. Heywood and Athol Hospitals served ~49,000 and ~ 15,000 patients annually.

**Table 1: Patient Panel (Fiscal Years 2018-2020)**

| **Hospital** | **FY18** | **FY19** | **FY20** |
| --- | --- | --- | --- |
| **Heywood Hospital** | 48,691 | 49,580 | 48,237 |
| **Athol Hospital** | 14,884 | 15,638 | 14,802 |

The Applicant provided demographic information on the Heywood Hospital and Athol Hospital patient populations. This information is presented in Table 2 below for FY20. Staff notes the following observations about these data below:

* **Age.** The age 60 and over population make up ~30% of the Heywood Hospital and Athol Hospital patient populations.
* **Race/Ethnicity.** Caucasian is the largest race category represented among Athol Hospital and Heywood Hospital patient populations. The Applicant did not include Hispanic in their initial reporting of their patient population, so it was not included in Table 2. DoN staff inquired about Hispanic patients and the Applicant reported that percentage of Hispanic patients for FY20 is 3% for Heywood Hospital and 2% for Athol Hospital.
* **Primary Service Area.** Athol Hospital and Heywood Hospital share five of the top zip codes for their patient populations.

**Table 2: Demographic Profiles (FY20)**

|  | **Heywood Hospital** | **Athol Hospital** |
| --- | --- | --- |
| Patients | 48,237 | 14,802 |
| Gender Male or data unavailableFemale  | 43.3%56.6% | 44%56% |
| Age 0-1718-5960+ | 13.7%56%30.3% | 12.7%54.2%33.1% |
| Race/Ethnicity[[8]](#footnote-8)White/CaucasianBlackAsianHawaiian or Pacific Islander,American Indian or Alaska Native[[9]](#footnote-9)Unknown, identified as race/ethnicity not listed, or declined to respond | 87.73%1.70%0.55%0.04%9.98% | 92.8%1.3%0.4%5.5% |
| Patient Origin[[10]](#footnote-10) | Gardner (25.2%) Winchendon (11.5%)Athol (11.0%)Templeton (9.0%) Ashburnham (5.5%) Westminster (5.4%)Fitchburg (4.8%)Orange (4.8%)Hubbardston (3.3%)Reside in another town or city in Massachusetts or reside outside of Massachusetts (19.5%) | Athol (45.8%)Orange (24.2%)Gardner (3.6%)Templeton (3.6%)Petersham (2.4%)Royalston (2.3%)Winchendon (2.2%)New Salem (1.7%)Warwick (1.1%)Reside in another town or city in Massachusetts or reside outside of Massachusetts (13.1%) |

Table 3 below presents FY20 payer mix for Athol and Heywood Hospitals.

**Table 3: Payer Mix**

|  | **Heywood Hospital** | **Athol Hospital** |
| --- | --- | --- |
| Payer MixCommercialCommercial HMOCommercial PPO/IndemnityMedicaidMedicare Other GovtAll Other[[11]](#footnote-11) | 1.1%34.7%10.9%22.2%24.0%1.6%5.5% | 1.4%31.7%8.9%24.6%27.9%1.7%3.7% |

**Factor 1: a) Patient Panel Need**

The Applicant attributes Patient Panel need for the Proposed Project to the following:

1. Need for Heywood Healthcare to maintain access to MRI and PET-CT services for the Patient Panel.
	1. MRI and PET-CT Historical Demand
	2. Aging Population
	3. Population and Demand Projections
2. **Need to Maintain Access to MRI and PET-CT Services.**

***Background***

Heywood Healthcare currently arranges for access to on-site MRI and PET-CT services at Heywood Hospital and Athol Hospital through an agreement with an outside vendor. The contract with the existing vendor is ending and Heywood Healthcare has determined that it will not be renewed. The Applicant seeks to bring the imaging services under the Applicant to maintain access to high-quality imaging services for the Patient Panel and fulfill the continued need for these services. The MRI and PET-CT imaging equipment owned by the joint venture will be newer and as a part owner, Heywood Healthcare will have more control over imaging services. Newer imaging equipment will be more efficient and will shorten scan times, allowing more appointments to be scheduled daily, which will reduce wait times and expand access to imaging services. Further, efficiencies may be realized as the newer unit will also improve the quality of imaging, potentially reducing the need for repeat imaging. Additional benefits of the Proposed Project include enhanced disease detection, reduced delays in diagnosis and treatment, and improved health outcomes and patient satisfaction. The Applicant notes that streamlining physician access to higher-quality imaging records will improve physician satisfaction as well.

The Applicant assessed historical utilization and physical space to accommodate services and its proposed siting of the MRI services at Heywood Hospital and mobile PET-CT services at Athol Hospital aligns with their findings. Most notably, the proposed scheduling is reflective of the Applicant’s finding that utilization of MRI at Athol is very low and that the newer PET-CT unit will be more efficient allowing more scans in fewer hours of operation.

MRI Services: Currently, both Hospitals offer MRI services:

* mobile MRI on the Athol campus (operating Monday, Tuesday, and Thursday) and
* a fixed MRI located within Heywood Hospital (operating Monday-Friday). [[12]](#footnote-12)

Through the Proposed Project, MRI services will only be offered at Heywood Hospital, in roughly the same location as the current unit. The mobile unit at Athol Hospital averages only five to six MRI patients per day, and the Applicant has determined that this low volume makes it unsustainable to continue to operate in this location. Heywood Hospital, the remaining site for MRI services, is 14 miles from Athol Hospital, and currently Heywood Healthcare patients already access MRI services at this location. The current MRI services at Athol Hospital serve primarily outpatients. There are a limited number of non-urgent inpatients requiring MRI (typically zero to two patients per month) who are transported to Heywood Hospital when an inpatient MRI is needed. When an urgent MRI is requested by Athol Hospital, Heywood Hospital is able to accommodate those transported patients immediately. Heywood Hospital currently reserves three emergency slots per day for MRI requests and the Applicant states that this will continue, and the availability of emergency slots will be adjusted to accommodate any increase in demand from Athol Hospital. For outpatient MRI visits, the Applicant states that there is a minibus (via Montachusett Regional Transit Authority) available to patients that runs between Athol and Gardner and that stops right in front of both hospitals, and that transportation assistance is available for eligible patients (further described in Factor 1b below).

PET-CT Services: Currently, both Hospitals offer PET-CT services one day a week (Saturday). The total hours PET-CT services are now offered across both sites is 11.5 hours. Heywood Hospital offers PET-CT services through a mobile unit one day per week in the hospital parking lot. Primarily due to too much congestion in the parking lot during the week, mobile PET-CT services are only available on Saturdays. Athol Hospital parking lot does not have the same space constraints, so through the Proposed Project, PET-CT services for Heywood Healthcare patients will be offered at Athol Hospital in the same location as the existing mobile MRI unit. Operating hours will be Saturday 7am-5pm, for a total of 10 hours. While this represents a reduction of 1.5 hours, with the newer, more efficient unit the new vendor will provide, the Applicant anticipates it will be able to accommodate patient demand for PET-CT services. Although PET-CT will initially be offered only on Saturdays. Siting PET-CT services at Athol Hospital will allow the Applicant more flexibility in scheduling these services as volume dictates.[[13]](#footnote-13)

1. **MRI and PET-CT Historical Demand**

The Applicant relies on data on its MRI and PET-CT patient populations served over the last three years to establish need for the Proposed Project.[[14]](#footnote-14),[[15]](#footnote-15) Table 4 below shows MRI and PET-CT volume from CY18 to CY20.[[16]](#footnote-16) Table 4 shows a 0.7% (36 scans) decrease in MRI scan volume from CY18 to CY19 and a 0.45% (1 scan) increase in PET-CT scans during this same time period. The Applicant states that the 2020 volume decreased as a result of the COVID-19 pandemic.

**Table 4: MRI and PET-CT Patients**

|  | **MRI Patients** | **PET-CT Patients**  | **MRI + PET-CT** |
| --- | --- | --- | --- |
| **CY18** | 4,873 | 221 | 5,094 |
| **CY19** | 4,837 | 222 | 5,059 |
| **CY20** | 4,542 | 214 | 4,756 |
| **Total** | 14,252 | 657 | 14,909 |

The Applicant provided demographic information on MRI and PET-CT patients which is presented in Table 5 below. The Applicant notes that race/ethnicity data for MRI and PET-CT patients is not currently tracked and therefore unavailable for inclusion in the table. MRI is used more predominantly by women than PET-CT which is more evenly distributed across gender. Utilization of PET-CT is heavily weighted to the 60+ population while MRI utilization is more evenly distributed across ages.

**Table 5: Demographic Profiles (CY20)**

|  | **MRI Patients** | **PET-CT Patients** |
| --- | --- | --- |
| Patients  | 4,542 | 214 |
| Gender Male Female  | 39.6%60.4% | 43.5%56.5% |
| Age 0-1920-5960+ | 7.1%50.2%42.7% | 18.7% (0-59)81.3%  |
| Patient Origin[[17]](#footnote-17)Based on Zip Code Data | 71% of MRI patient population originate from the following ten communities: Gardner, Athol, Winchendon, Orange, Templeton, Ashburnham, Westminster, Baldwinville, Fitchburg, and Hubbardston | 80% of the PET-CT patient population originates from the following ten communities: Gardner, Athol, Orange, Winchendon, Templeton, Fitchburg, Royalston, Ashburnham, Westminster, Baldwinville.  |

The Applicant also provided information on the payer mix of MRI patients for FY20, which is shown in Table 6 below. The Applicant notes that because the existing vendor bills for PET-CT services, it does not have access to the payer mix data for this patient population.

**Table 6: Payer Mix[[18]](#footnote-18)**

|  | **MRI Patients** |
| --- | --- |
| Payer MixCommercial HMOCommercial PPO/IndemnityMedicaid HMOMedicareMedicare HMOOther GovernmentOther HMO/Self-Pay | 43%4.1%15.3%28%2.7%70%6.1% |

1. **Aging Population.** The Applicant asserts that need for continued access to MRI and PET-CT services is supported by an aging Patient Panel and an aging population in Massachusetts. As shown in Table 5 above, 42.7% of Heywood Healthcare’s MRI patients and 81.3% of Heywood Healthcare’s PET-CT patients are aged 60 and older. Additionally, the Applicant cites UMass Donohue population projections which suggest that by 2035, the age 65 and older population will represent a quarter of the state’s population and will make up 23% of the population in the Central Region (compared to 13% in 2010) of MA where the Applicant states the majority of the Heywood Healthcare population reside.[[19]](#footnote-19),[[20]](#endnote-1) The Applicant asserts that an increasing aging population will contribute to an increasing demand for healthcare services in general, and a sustained need for MRI and PET-CT services which are used in the diagnosis and treatment of conditions seen in an aging population. This is discussed further in Factor 1b.
2. **Population and Demand Projections**

**Table 7: MRI Volume Projections**

|  | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| --- | --- | --- | --- | --- | --- |
| Heywood MRI | 4,999 | 5,213 | 5,358 | 5,575 | 5,751 |

**Table 8: PET-CT Volume Projections**

|  | **Year 1** | **Year 2** | **Year 3** | **Year 4** | **Year 5** |
| --- | --- | --- | --- | --- | --- |
| Athol Mobile PET-CT | 222 | 249 | 278 | 312 | 343 |

The Applicant provided MRI and PET-CT volume projections for five years as is shown in Tables 7 and 8 above. The first year of operation is 2022. The Applicant states the projections are based on historical utilization of MRI and PET-CT services, market forecasting data, and an increasing aging population that will contribute to increasing demand for MRI and PET-CT imaging services. The Applicant notes that the majority of the PET-CT patient population is aged 60 and older and increasing (up 4.4% between 2018 and 2020), and that PET-CT services are beneficial to the diagnosis, evaluation and treatment monitoring of certain conditions, the risk and prevalence of which increase with age, including brain/neurologic cancer and cardiovascular conditions. The projections show a 15% (752 scans) increase in MRI volume over the five-year period and a 54.5% (121 scans) increase in PET-CT volume over this same period.

***Analysis***

Staff concurs that the Proposed Project will support ongoing access to MRI and PET-CT services for the Patient Panel and that the proposed siting of MRI and PET-CT imaging is designed to ensure appropriate access for the Patient Panel based on historical utilization of these imaging services. The five-year volume projections show yearly increases in MRI volume ranging from 2.8% to 4.3% and yearly increases in PET-CT volume ranging from 9.9% to 12.2%.[[21]](#footnote-20) Through the Proposed Project, the Applicant will attain greater control over the provision of imaging services at Heywood and Athol Hospitals, and with the operating model provided by Shields, the Applicant will be able to sustain local access to high-quality imaging services for the Patient Panel, and support continuity of care and improve patient satisfaction.

**Factor 1: b) Public Health Value, Improved Health Outcomes And Quality Of Life; Assurances Of Health Equity**

**Improved health outcomes and quality of life**. The Applicants states that through the Proposed Project it will maintain timely access to imaging services, and this will promote patient care and patient experience. Clinicians use MRI and PET-CT imaging to better understand disease processes and to make treatment decisions. Continued access to these imaging services will contribute to appropriate and timely diagnosis and treatment as well as improved health outcomes. The transition from one vendor to the next will come with newer, more efficient technology that will expand its usage. The MRI unit will be important to individuals most at risk for cancer, including those with a family history and those with advancing age whose risk for cancer increases. Advanced MRI scans that will be performed include prostate MRI with and without contrast to diagnose prostate cancer, and breast MRI with and without contrast to diagnose breast cancer. Advanced PET-CT services will also be beneficial to those individuals at risk for cancer and include tumor finding fluorodeoxyglucose scans for standard tumor imaging. The Applicant described the clinical applications and benefits of MRI and PET-CT imaging.

**Patient satisfaction and convenience**. The Applicant asserts the Proposed Project will sustain patient satisfaction by ensuring continued access to on-campus MRI and PET-CT services so that patients will not need to travel outside the Heywood system to access the imaging services. Citing the literature, the Applicant notes that patient satisfaction is an important indicator for measuring quality in healthcare; patient satisfaction impacts clinical outcomes, patient retention, medical malpractice claims; and timely, efficient, and patient-centered care directly influence patient satisfaction.[[22]](#endnote-2)

***Analysis***

Staff concur that providing timely access to imaging services contributes to improved health outcomes and patient satisfaction. Advanced imaging can improve disease detection, diagnosis and treatment allowing for more accurate diagnosis and treatment and the avoidance of more invasive and costly procedures.[[23]](#endnote-3) Not having adequate access to advanced imaging leads to delays in diagnosis and treatment, which can negatively affect health outcomes. Staff confirms ongoing need for continued access to MRI and PET-CT services, especially among the 65 and over population which comprises about one-third of the Applicant’s patient population, and a significant percentage of MRI and PET-CT patient populations. Risk for cancer, cardiovascular disease, and Alzheimer’s, the leading causes of death in Massachusetts, increase with age, and consequently demand for the proposed imaging services is likely to increase with a growing aging population.[[24]](#endnote-4)

***Health Equity and Social Determinants of Health (SDOH)***

The Applicant states that to ensure equity to all populations in Heywood Healthcare’s service area, it will not discriminate based on payer source or ability to pay. Additionally, the Proposed Project will promote health equity and ensure equal access to MRI and PET-CT services for all of Heywood Health and the Applicant’s patients through the following ways:

* **Language access.** The Applicant will provide interpreter services through Heywood Healthcare’s existing interpreter services program. Need for interpreter services is identified prior to the patient’s appointment. In-person interpreter services are provided whenever possible. Multiple translation services are offered to address language barriers, including Language Line, which offers phone and video interpretation services from trained professionals in more than 240 languages, and InDemand interpreting which provides medical interpreting solutions (i.e. video interpretations) to facilitate access to care for limited English proficient, and Deaf and Hard of Hearing patients. On-site interpreters are available Monday through Friday and phone or video remote interpreting (VRI) services are available 24/7 for interpretation needs when an on-site interpreter is not available.
* **Cultural competence training**. The Applicant has developed arrangements to provide ongoing education and training in culturally and linguistically appropriate care for staff through a vendor.
* **Social determinants of health (SDoH).** The Applicant will provide programs to address issues associated with the SDoH and improve care pathways influenced by SDoH, ensure all patients have equal access to care, and ensure linkages to social service organizations when indicated. The Applicant states that it works to ensure that patients receive timely care and to alleviate any transportation barriers to accessing care. The Applicant works to identify patients experiencing transportation challenges and has provided transportation vouchers mostly funded through grants, to patients with transportation needs.

***Analysis***

Staff finds that through their planned language access, cultural competence training, and SDoH screening, the Applicant has provided reasonable assurances of improved health equity.

**Factor 1: c) Efficiency, Continuity of Care, Coordination of Care**

The Applicant asserts that the Proposed Project will support integrated care because patients will be able to receive all their care within Heywood Healthcare System. The Proposed Project will allow the Applicant to prevent a lapse in access to imaging services once the current agreement with the existing imaging vendor ends. A lapse in access to imaging services could result in patients traveling further distances outside of Heywood Healthcare System to access MR and PET-CT imaging services. The Applicant notes that care fragmentation often results when healthcare delivery is spread across a number of separately located and operated providers and is a source of inefficiency and ineffectiveness in healthcare and a source of dissatisfaction for patients.[[25]](#endnote-5)

Co-located services address fragmented care and improve access through increasing collaboration among providers and increasing efficiencies, both of which contribute to improved health outcomes. The Applicant states that maintaining access to MRI and PET-CT services on the Hospitals’ main campuses will allow patients to schedule and attend appointments in a single location on the same day.

Heywood Healthcare will be an owner of the new clinic, allowing imaging to be fully integrated into patients’ medical records and allowing Heywood to have input into the provision of services by the clinic. Through the current set-up, imaging is obtained by Alliance Imaging MRI, and then transferred into Heywood Healthcare’s Picture Archiving and Communication System (PACS) where it can be accessed and interpreted by radiologists.

Through the Proposed Project, imaging records will become a part of a fully integrated medical record available to patients’ primary care and specialty providers across the Heywood Healthcare System and will be integrated into the Shields system. This will, the Applicant asserts, improve care coordination and collaboration among providers, and health outcomes. Additionally, Shields’ national operations will allow the Applicant to obtain patient images captured from another provider or specialist more efficiently, with the patient’s approval. The Applicant notes that maintaining local access to these imaging services is particularly beneficial for older and low-income populations as it will minimize transportation challenges, which can pose a barrier to accessing care.

With the replacement of the current vendor’s older units with Shields’ newer MRI technology, Heywood Hospital will offer certain advanced MRI and PET-CT scans that are beneficial to individuals at risk for cancer, and that are currently unavailable to its patients at either Heywood or Athol Hospitals. The newer units will thereby enhance care coordination and prevent fragmented care. Shields’ newer technology is expected to yield improvements in the quality of imaging, a reduction in imaging turnaround times to improve access to imaging, and operational efficiencies. Shields Management will utilize its operational and management service expertise in outpatient services to maximize operational and scheduling efficiencies to improve patient and referring provider satisfaction.

***Analysis***

Review of the literature points to evidence which suggests access to integrated health information technology systems directly impacts health outcomes through reducing fragmentation and improving coordination among care providers.[[26]](#endnote-6),[[27]](#endnote-7) Similarly other studies show that integrated health information technology systems directly affect health outcomes, as access to a single, integrated health record, can reduce errors, improve patient safety, and support better patient outcomes.[[28]](#endnote-8)

**Factor 1: d) Consultation**

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report.

**Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel**

The Department’s Guideline[[29]](#footnote-21) for community engagement defines “community” as the Patient Panel, and requires that at minimum, the Applicant must “consult” with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging “community coalitions statistically representative of the Patient Panel.”[[30]](#footnote-22)

To ensure sound community engagement throughout the development of the Proposed Project, the Applicant took the following actions:

**Presentation to Heywood Healthcare’s Patient and Family Advisory Council (PFAC) and Multicultural Group on March 30, 2021.[[31]](#footnote-23)** The Applicant states that the PFAC was engaged because it is an important forum for creating partnerships among patients, family, and staff. Heywood PFAC membership consists of 14 members, 12 family/community and two Heywood employees. Athol PFAC membership includes 12 members, nine family/community and three Athol employees. The combined PFAC is representative of the demographic of the Patient Panel based on gender (men and women), age (40-79), employment status (some retired), race/ethnicity (Caucasian, Black, Hispanic/Latino and several identifying as biracial and multiethnic), language (Spanish and Swahili speakers), and geography (representation from almost all towns in Heywood Healthcare’s service area). A total of 41 members representing many different organizations (i.e. Gardner Area Interagency Team (GAIT), Community Health Centers, Leominster Haitian American Community Center, and the North Central Mass Minority Coalition), are invited to Multicultural Group meetings, which is now called Diversity, Equity, and Inclusion.

Seven people attended the March 30th meeting including four Heywood Healthcare staff members and three community PFAC members. The Applicant sought input from the PFAC on existing MRI service and age of equipment, impending expiration of existing PET-CT and MRI vendor arrangement, and impact of service adjustment on the patient population. The discussion of the Proposed Project included imaging modality upgrades; improved access to PET-CT and MR imaging services and operational efficiencies resulting from the Proposed Project. The Applicant notes the feedback received during the presentation was overwhelmingly positive.

***Analysis***

Staff finds that the Applicant met the minimum required community engagement standard of Consult in the planning phase of the Proposed Project.

**Factor 1: f) Competition On Price, Total Medical Expenses (TME), Costs And Other Measures Of Health Care Spending**

The Applicant asserts that the Proposed Project will not have an adverse effect on competition in the Massachusetts healthcare market based on price, TME, provider costs, or other recognized measures of healthcare spending based on the following:

* Shields’ operating model allows for improved scheduling, workflow, technology, and customer service, which the Applicant asserts will have a positive impact on the cost to provide care.
* The clinic will operate as an independent diagnostic testing facility (IDTF) which is reimbursed at lower rates than hospital-based imaging.[[32]](#footnote-24)
* The Proposed Project will allow the Applicant to provide PET-CT services without a significant capital expenditure.

Of note, overuse of imaging may translate into lower quality care as a result of worry, and unnecessary healthcare interventions including follow-up tests, treatments, visits, hospitalizations, and increased healthcare spending.[[33]](#endnote-9) The Applicant states that in order to ensure that the appropriate imaging exam is being performed in the correct modality and whether to do it with contrast, radiologists protocol all orders prior to moving forward with the MRI.

***Analysis***

Staff notes that the Applicant seeks to replace an existing service that is currently provided through a different imaging vendor to provide access to imaging services that corresponds to historical utilization. While advanced imaging improves clinical care, it is also the source of overuse and added healthcare costs.[[34]](#endnote-10) Staff notes that excessive imaging remains a concern in the Commonwealth with Massachusetts ranking fourth in the nation in Medicare spending for imaging.[[35]](#endnote-11)

The Applicant has protocols in place to support appropriate use of imaging and minimize overuse. Staff also note that CMS Clinical Decision Support Mechanism (CDSM) mandate will require new compliance measures when healthcare professionals order outpatient advanced imaging. Currently, the penalty phase is set to begin Jan. 1, 2022, but CMS has proposed delaying implementation of the payment penalty phase of the Appropriate Use Criteria program to the later of Jan. 1, 2023, or the Jan. 1 to follow the end of the COVID-19 public health emergency. Staff finds that, on balance, the requirement that the Proposed Project will likely compete on the basis of price, TME provider costs, and other measures of health care spending have been met.

**Proposed Reporting Measures for FACTOR 1**

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project has met Factor 1(a-f). The Applicant proposed specific outcome, and process measures to track the impact of the Proposed Project which staff has reviewed, and which will become a part of the reporting requirements. The measures are listed below in Appendix 1.

**Factor 2: Cost Containment, Improved Public Health Outcomes and Delivery System Transformation**

**Cost Containment**

The Applicant states that the Proposed Project seeks to align with the Commonwealth’s goals for cost containment which include the provision of low-cost, high-quality care, through supporting continued access to high-quality MRI and PET-CT services in a cost-effective setting for the Patient Panel. The Applicant notes that the clinic will provide MRI and PET-CT imaging locally and will operate as an IDTF, where reimbursement rates are lower than those of a hospital. Further, the Proposed Project will facilitate access to integrated health care services and timely access to care to promote lower healthcare costs.

***Analysis: Cost Containment***

As described above, the Proposed Project seeks to provide continued access to imaging services within a lower-cost reimbursement setting and improve the quality of such services. Therefore, DoN Staff can conclude that the Proposed Project will likely meet the cost containment factor.

**Improved Public Health Outcomes**

The Applicant states that ensuring continued access to MRI and PET-CT services, and the benefits they provide for detecting, managing, and treating a variety of conditions, will improve public health outcomes and patient experience. The Applicant notes that the risk of certain conditions increases with age and the need for such imaging services will increase with a growing aging population in Massachusetts and among the Applicant’s Patient Panel.

**Analysis: Public Health Outcomes**

As mentioned above, ensuring timely access to coordinated imaging services can reduce delays in diagnosis and treatment (which can adversely impact health outcomes), and thus contribute to improved health outcomes and patient satisfaction.

**Delivery System Transformation**

The Applicant has processes in place to screen for the SDoH and referral process to community-based organizations (CBOs) to address positive SDoH screens. The Applicant notes that SDoH impact the physical and mental well-being of the population and impact a range of health risks and outcomes.[[36]](#endnote-12) The Applicant plans to implement specific patient access tools to facilitate easier access to care for vulnerable and at-risk populations. These include preregistration functionality, a cost transparency application, linkages to financial counsels, culturally competent staff, and a robust translation services program. The Applicant also provided the number of Heywood and Athol patients participating in ACO contracts, which is shown in Table 9 below.[[37]](#footnote-25)

**Table 9: ACO Participation**

|  | **Heywood** | **Athol** |
| --- | --- | --- |
| Total Patient Population | 26,481 | 6,900 |
| ACO Patients  | 1,101 (4% total Heywood population) | 2,268 (32% of total Athol population) |

**Analysis: Delivery System Transformation**

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. SDoH screening is integrated into the Applicant’s care processes, to address health risks and improve health outcomes. Persistent disparities in a number of health outcomes, including the leading causes of death, indicate the important influence of the social determinants in health prevention and disease promotion.[[38]](#endnote-13)

**SUMMARY for FACTOR 2**

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project has met Factor 2.

**Factor 3: Relevant Licensure/Oversight Compliance**

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and will not be addressed further in this report.

**Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis**

Under Factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing Patient Panel. Documentation sufficient to make such finding must be supported by an analysis by an independent CPA. The CPA report notes that while Shields Heywood will be a single legal entity, two separate sets of six-year consolidated prospective financial schedules (one set for Shields MRI, and one set for Shields PET-CT) were prepared to reflect Management’s view that Shields Heywood will be a single legal entity: Shields MRI and Shields PET-CT will operate as two separate lines of business. The financials that were prepared by Management include separate prospective statements of profit and loss, balance sheets, and statements of cash flow for Shields MRI and Shields PET-CT. The CPA examined a range of documents and information in developing its report including an analysis of separate sets of six-year consolidated prospective financial schedules for Shields MRI and PET-CT, volume assumptions, payer mix and per-case reimbursement assumptions, and relevant websites. Additionally, it calculated key liquidity and operating metrics to assist in determining reasonableness of the Applicant’s assumptions and feasibility of the Projections.

**Revenues**

Prospective volume for Shields MRI and Shield PET-CT was based on Heywood Healthcare’s historical imaging volume: MRI volume included Heywood 2019 historical inpatient and Athol Hospital outpatient imaging volume, and PET-CT volume at Athol Hospital was estimated to be the same as Heywood’s 2019 PET-CT volume. The impact of COVID-19 was considered in the development of the prospective financials.

Prospective revenue per scan was determined based on Heywood’s 2019 payer mix and Shield’s historical reimbursement rates. CPA report determined that the prospective Shields MRI and Shields PET-CT volumes provided by Management were reasonable. The review of payer mix included a summary of Heywood’s payer mix and Shields historical reimbursement rates for MRI and PET-CT.[[39]](#footnote-26) The CPA determined the reimbursement rates provided by Management were reasonable for both Shields MRI and Shields PET-CT.

The CPA found that the revenue growth estimated by Management reflects a reasonable estimation of future revenue of Shields Heywood based on estimated volumes and reimbursements.

**Expenses**

Operating expenses include support services, billing, and bad debt expense for both Shields MRI and Shields PET-CT. The CPA report notes that the financials included bad debt expenses due to the period needed to obtain accreditation to be reimbursable for the operations of Shields MRI and Shields PET-CT. The CPA calculated an operating expense compound annual growth rate (CAGR) of 2% for Shields MRI and 10% for Shields PET-CT. Facilities and equipment related expenses include depreciation, and other expenses for Shields MRI and Shields PET-CT, which the CPA determined to be reasonable. Service-related expenses for Shields MRI include contrast/film expense, equipment maintenance, and other expenses. The CPA calculated a CAGR of 1% from year 2 through year 6.

Salaries and Benefits include radiology, technologists, and operations expenses for both Shields MRI and Shields PET-CT. The CPA calculated a CAGR of 2% for Shields MRI and 4% for Shields PET-CT from year 1 through year 6, which the CPA determined to be reasonable.

Selling, General, and Administrative (SG&A) expenses include support services, management, and other SG&A expenses for Shields MRI and support services, marketing, management, and other SG&A expenses for Shields PET-CT. The CPA calculated a CAGR of 6% for Shields MRI and 7% for Shields PET-CT from year 2 through year 6.

Interest expense for Shields MRI ranges from $72K in year 1 to $8K in year 6. There was no interest expense for Shields PET-CT.

The CPA found that the prospective expenses didn’t warrant any additional adjustment and are reasonable.

**Capital Expense and Cash Flows**

The CPA reviewed the capital expenditure and cash flows for Shield MRI which was $2,000,511 in capital acquisitions in year 1 and for Shields PET-CT which was $75K in capital acquisitions in year 1, to determine if sufficient funds would be available to sustain the operations of Shields Heywood. There were no capital expenditures expected from year 2 through year 6 for Shields MRI or Shields PET-CT. The CPA determined the prospective capital requirements and resulting impact on cash flows of Shields Heywood are reasonable.

The CPA report states that Shields MRI exhibits a cumulative cash surplus in the financials, after any scheduled distributions, of ~20% and Shields PET-CT of 29% of cumulative projected revenue for the project for six years. The CPA determined that the financials are based on feasible assumptions and are feasible and sustainable for Shields MRI and Shields PET-CT and not likely to have a negative impact on the Patient Panel or result in a liquidation of assets of Shields Heywood.

***Analysis***

Staff is satisfied with the CPA’s analysis of Applicant’s decision to proceed with the Proposed Project. As a result, Staff finds the CPA analysis to be acceptable and that the Applicant has met the requirements of Factor 4.

**Factor 5: Assessment of the Proposed Project’s Relative Merit**

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

The Applicant considered and rejected two alternatives to the Proposed Project.

1. **Maintain the current arrangement with the outside vendor**. The Applicant dismissed this alternative because it would not allow for a fully integrated medical record which would result in improved care coordination and efficiency, and because it would not provide the benefits associated with a more technologically advanced MRI unit as well as PET-CT, which includes the ability to perform advanced scans not currently available.
2. **Provide MRI and PET-CT services directly through hospital-based departments**. The Applicant explored the option to provide MRI services at Heywood Hospital and PET-CT services at Athol Hospital through hospital-based departments. The Applicant dismissed this alternative because establishing a hospital-owned MRI unit at Heywood Hospital and a PET-CT at Athol Hospital would require a significant capital expense. The Applicant states the current MRI unit is at the end of its useful life and with the relationship with the previous vendor ending, Heywood Healthcare would need to acquire a new MRI unit. In addition, it would be inefficient to purchase a new PET-CT unit because PET-CT services are only needed one day a week. This alternative would result in higher operating costs for both hospitals due to the need to hire additional employees to staff the imaging units and provide administrative and support functions, and additional maintenance costs. The Applicant determined that this second alternative was not financially viable for two community hospitals with limited resources.

***Analysis***

Staff finds that the Applicant has appropriately considered the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives. As a result of information provided by the Applicant and additional analysis, staff finds the Applicant has reasonably met the standards of Factor 5.

**Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application**

*Summary and relevant background and context for this application:* This DoN project is one of two current DoN applications under consideration and given that (subject to DoN project approval) CHI related activities would be implemented concurrently, the Applicant and DPH have agreed to one Factor 6 analysis for both DoN projects. Combined across DoN projects, the CHI requirement is a Tier 2 CHI project. This analysis will appear in the staff report for both DoN projects with the corresponding respective CHI contribution amount. The Applicant’s proposed project is the first CHI that will be implemented under the CHI Guidelines approved in 2017.

To fulfill Factor 6 for both DoN projects, the Applicant submitted its existing Community Health Needs Assessment (CHNA) for Heywood Healthcare, its current Community Health Improvement Plan (CHIP), a single Self-Assessment for streamlining purposes, Stakeholder Assessments, and a CHI Narrative.

**The Community Health Needs Assessment** was conducted in 2018 by Heywood Healthcare, and Heywood Hospital will implement CHI activities. The final Community Health Assessment utilized secondary data sources and primary data gathered from focus groups, a community survey, and qualitative interviews with key healthcare professional informants. The CHNA describes quantitative and qualitative data collection methods and outlines demographic characteristics of the participating communities as well as key findings in community health areas. These findings and areas include social and economic factors, injures and violence, maternal and infant health, among others. The CHNA also informs the health system’s Community Health Improvement Plan in four Priority Areas: Social Determinants, Interpersonal Violence and Injuries, Mental Health and Substance Use, and Wellness and Chronic Disease.

**The Self-Assessment** provided a summary of community engagement processes and socio-demographic information, data and highlights related to topics and themes of community needs. Through data analysis, community surveying, focus groups, and key informant interviews, the participating community groups and residents identified the key concerns outlined in the 2018 CHNA.

**Stakeholder Assessments** submitted provided information on the individuals’ engagement levels including their level of participation and role, and their analysis of how the Applicant engaged the community in community health improvement planning processes. The information provided in these forms were largely consistent with the self-assessment conducted by the Applicant.

**The CHI Narrative** provided background and overview information for the CHI processes. The narrative also outlines duties for the community benefit advisory committee (CBAC) and planned structure for seeking feedback and further engagement.

There are differences in approach and alignment between the Applicant’s existing Community Health Implementation Plan and Assessment and CHI framework. If used as a guide for choosing CHI strategies, the activities outlined in the Implementation Plan will need to focus in the areas best aligned with the CHI framework to sufficiently meet Health Priority guideline approaches. The CHIP priority areas likely to support identifying needs and implementing activities at the root cause level include the Social Determinants of Health and elements of other areas including food insecurity and violence. Through ongoing communication with DPH staff, the Applicant has agreed to continue to work closely with its Advisory Committee to ensure processes and selected strategies will align with the Health Priorities Guideline. The Applicant will be recruiting for missing constituencies on the existing CBAC, and DPH will work with them to ensure the group’s make up is sufficient to help them make decisions in line with the Health Priority framework. Specifically, DPH will work with the Applicant to ensure resident voice is engaged in decision making through the Advisory Committee. DPH staff will support the Applicant as necessary in outlining future Advisory Committee meetings and reviewing community engagement and RFP processes. The Applicant will also connect with DPH staff to establish processes for planning and implementation work moving forward. Regarding the implementation of specific CHI strategies, DPH will work with the Applicant in moving upstream, and identifying needs at the root cause to support sustainable systems level solutions.

The timeline, RFP processes, and use of administrative funds are all appropriate and in line with CHI planning guidelines.

The anticipated timeline for CHI activities includes continued meeting of the Advisory Committee, identifying the Health Priorities Strategies within 3 months post approval, and releasing an RFP within six months post approval, with funding awarded to successful RFP applicants 3-4 months thereafter.

With the administrative funds, the applicant’s early plans are to support consultant time for CBAC coordination, communication, and the facilitation of grantmaking.

*Summary Analysis*: As a result of information provided by the Applicant and additional analysis, staff find that with the conditions outlined below, and the ongoing communication on items for improvement outlined above, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

**Findings and Recommendations**

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project, and recommends that the Department approve this Determination of Need, subject to all applicable standard and Other Conditions.

**Conditions to the DoN**

1. Of the total required CHI contribution of $128,528.00
	1. $12,338.69 will be directed to the CHI Statewide Initiative
	2. $111,048.19 will be dedicated to local approaches to the DoN Health Priorities
	3. $5,141.12 will be designated as the administrative fee.
2. To comply with the Holder’s obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $12,338.69 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
	* 1. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
		2. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

**Appendix I**

*MRI Measures*

1. **Patient Experience/Satisfaction**: Patients that are satisfied with care are more likely to seek additional treatment when necessary. The Applicant will review patient satisfaction levels with the MRI service.

**Measure:** To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients receiving MRI services with specific questions around a) satisfaction with pre-appointment communication; and b) satisfaction with the wait time for services.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** Any category receiving a less than exceptional rating (satisfactory level) on an annual basis will be evaluated and policy changes instituted if needed.

1. **Wait Times:** The timeliness of MRI scans is important for appropriate diagnosis and treatment, contributes to patient satisfaction, and can be used to measure patient access. The Applicant will monitor wait times for the MRI service.

**Measure:** Time interval from when the case was initiated for scheduling to the next available appointment.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** The Applicant will assess average wait times and implement service adjustments if necessary.

1. **Important Finding Alert (“IFA”):** The Applicant will review the percentage of MRI scans that triggered an IFA for which the radiologist conducted a critical value report.

**Measure:** The Applicant will provide the following data: a) % of IFAs where critical value report indicated; and b) % of critical value reports radiologists performed over the total number of IFAs.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** IFAs will be monitored and follow up will be conducted with the referring physician. The radiologist will be made available to answer any questions.

1. **Quality of Care - Quality of MRI Scan:** The quality of an MRI scan is imperative to its interpretation. Accordingly, the Applicant will evaluate the number of scans that need to be repeated within a 48-hour period from the date of the original scan to ensure radiology technicians are performing appropriate scans.

**Measure:** The number of repeat MRI scans performed on patients within a 48-hour period from the date of the original scan.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** MRI technologists will track the number of scans that are repeated and scheduled for the next scan day. Technologists will document each case and conduct a monthly comparison to total volume that meets or exceeds the metric.

*PET-CT Measures*

1. **Patient Satisfaction:** Patients that are satisfied with care are more likely to seek additional treatment when necessary. The Applicant will review patient satisfaction levels with the PET- CT imaging service.

**Measure:** To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients receiving imaging services with specific questions around a) satisfaction levels with pre-appointment communication; and b) satisfaction with the wait time for services.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** Any category receiving a less than exceptional rating (satisfactory level) on an annual basis will be evaluated and policy changes instituted.

1. **Quality of Care – Critical Value Reporting:** When critical values or abnormal test results are registered within an electronic medical record for a patient, the referring physician is notified via electronic communication. A benefit of having an integrated electronic medical record and PACS system is the ability to send these messages to a referring physician, so that clinical decisions may be expedited.

**Measure:** Number of contracted radiologists conducting critical value reporting on cases being interpreted.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** PET-CT scans will be monitored and follow up will be conducted with the referring physician. The radiologist will be made available to answer any questions.

1. **Quality of Care – Quality of PET-CT Scan:** The quality of a PET-CT scan is imperative to its interpretation. Accordingly, the Applicant will evaluate the number of scans that need to be repeated over the course of a week to ensure radiology technicians are performing appropriate scans. Given that the PET-CT equipment will only be available one day per week, the next opportunity for a scan would be seven days later.

**Measure:** The number of repeat PET-CT scans performed on patients within a seven-day period (day of scan to next day of scan).

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** PET-CT technologists will track the number of scans that are repeated and scheduled for the next scan day. Technologists will document each case and conduct a monthly comparison to total volume to meet or exceed the metric.

1. **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.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** A random selection of cases based on ACR Peer to Peer criteria will be reviewed. Radiologists will evaluate scans documenting any inconsistencies and discuss outstanding issues with the original reading radiologist.

1. **Access** – Backlog Reporting: The Proposed Project seeks to ensure access to PET-CT imaging services. Accordingly, the Applicant will track any backlogs associated with the service.

**Measure:** The number of times scanning day utilization is greater than 90% and adjustments need to be made to the schedule.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** Applicant’s staff will assess daily hours of service and implement adjustments if necessary.

1. **Provider Satisfaction** – Value Assessment: Ensuring provider satisfaction with PET-CT scans and their overall value when treating patients is necessary to assess the impact on patient care. The Applicant will survey referring physicians to validate scan utility.

**Measure:** Confirmation with the referring physician about the utility of PET-CT Scans.

**Projections:** As the Applicant will be a new clinic and does not have a baseline, the Applicant will provide baseline numbers and projections in its first annual report.

**Monitoring:** The Applicant will query the PET-CT referral physician population to validate scan utility via surveys.

**Description of numerators and denominators where applicable**

* **Patient Satisfaction Measures:** To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients receiving imaging services with specific questions around a) satisfaction levels with pre-appointment communication; and b) satisfaction around the wait time for services.
	+ **MRI:** The minimum monthly patient participation is expected to be 40% response rate. This translates into on average 166 responses per month in year 1. (5,000 year 1 annual MRI scans divided by 12 months times 0.4). The overall satisfaction minimum per month is 90% satisfaction rating.
	+ **PET-CT:** The minimum monthly patient participation is expected to be 40% response rate. This translates into on average 7.4 responses per month in year 1. (222 year 1 annual PET scans divided by 12 months times 0.4). The overall satisfaction minimum per month is 90% satisfaction rating. Any critical responses will be acted upon within 30 days.
* **Wait Time Measure:** Time interval from when the case was initiated for scheduling to the next available appointment.
	+ **MRI:** Applicant will measure from the date and time order received to the date and time exam scheduled
	+ **PET-CT**: Projections: PET-CT values timeliness to treatment in correlation with the referring and treating community. The proposed project will maintain a traditional 7-10-day appointment time and will measure wait times for new referrals monthly for deviation. Many returning patients are booked for future appointments at time of first PET-CT appointment. These cases will be taken into consideration when measuring true wait time from referral to appointment.
* **Quality of Care - Important Finding Alert (IFA) & Critical Findings Measure:**
	+ **MRI:** When important findings or abnormal test results are registered within an electronic medical record for a patient, the referring physician is notified via electronic communication. A benefit of having an integrated electronic medical record and PACS system is the ability to send these messages to a referring physician, so that clinical decisions may be expedited.
	+ **PET-CT: Projections:** Baseline: 100% Year 1: 100% Year 2: 100% Year 3: 100%
* **Quality of Care Measure – Repeat Scans**: The number of repeat MRI scans performed on patients within a 48-hour period from the date of the original scan.
	+ **MRI:** Applicant flags the return visits by additional value-Applicant is able to monitor the number of additional values by the flag in electronic room
	+ **PET-CT Projections:** Baseline: 0.3% Year 1: 0.3% Year 2: 0.3% Year 3: 0.3%
	+ **PET-CT Provider Satisfaction**: **Projections:** Baseline: 95% Year 1: 96% Year 2: 97% Year 3: 100%**REFERENCES**
1. High Public Payer Hospitals (HPP) receive a minimum of 63% of gross patient service revenue from public payers. [↑](#footnote-ref-1)
2. Critical Access Hospital is a designation given to eligible rural hospitals by the Centers for Medicare and Medicaid Services (CMS). The CAH designation is designed to reduce the financial vulnerability of rural hospitals and improve access to healthcare by keeping essential services in rural communities. To accomplish this goal, CAHs receive certain benefits, such as cost-based reimbursement for Medicare services. [at https://www.ruralhealthinfo.org/topics/critical-access-hospitals](https://www.ruralhealthinfo.org/topics/critical-access-hospitals) [↑](#footnote-ref-2)
3. MRI is a non-invasive medical imaging procedure that uses strong magnetic fields and radio waves to produce detailed images of internal bodily structures. MRI machines used for diagnosis and treatment commonly have a magnetic field strength of 1.5T or 3T and the stronger magnet improves image quality allowing for visualization of anatomical features in greater detail. Higher field strength also requires less scanning time to produce high quality images. [↑](#footnote-ref-3)
4. PET provides images of bio-chemical metabolic activity in the body without the anatomical structural information that CT captures. CT provides 3D images with anatomic specificity of bones and tissues within the body. When overlaid, CT images aid in defining the precise location of any metabolic abnormality identified with PET. Both modalities have been in use for several decades. Performed simultaneously, the images provide a more accurate picture since there are no changes in patient positioning that would occur if the patient had to undergo each type of scan separately at different times on different units. [↑](#footnote-ref-4)
5. 3: Sufficient evidence of compliance and good standing with federal, state, and local laws and regulations

4: Sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Project without negative impacts or consequences to the Applicant's existing Patient Panel 5: The … Project, on balance, is superior to alternative and substitute methods for meeting … Patient Panel needs. [↑](#footnote-ref-5)
6. As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder…(2) If the Proposed Project is for a new facility and there is no existing patient panel, Patient Panel means the anticipated patients. [↑](#footnote-ref-6)
7. The Applicant notes that combining Patient Panel data for Heywood Hospital and Athol Hospital would result in some patients being counted more than once. [↑](#footnote-ref-7)
8. Self-reported. [↑](#footnote-ref-8)
9. Race/ethnicity categories for Athol Hospital include the following: Asian, Black, Caucasian, and All Other. [↑](#footnote-ref-9)
10. Based on Zip Code Data [↑](#footnote-ref-10)
11. All Other includes the following: Self-pay, Worker’s Compensation, and all other payer sources not already listed. [↑](#footnote-ref-11)
12. For operational purposes, part-time imaging services equates to less than five days per week and/or less than 24 hours per day. [↑](#footnote-ref-12)
13. If additional days of service are determined to be needed, an amendment to a Notice of Determination of Need can be filed. [↑](#footnote-ref-13)
14. The Applicant notes the existing vendor is unable to provide patient data on a unique bases and therefore some of the data may include duplicate patients. [↑](#footnote-ref-14)
15. The Applicant notes that the 2020 MRI scan volume decreased as a result of the COVID-19 pandemic. [↑](#footnote-ref-15)
16. The most common areas of the body scanned for MRI patients include lumbar; brain; lower extremity joint; abdomen; upper extremity, other than joint; cervical; neck; pelvis; and lower extremity, other than joint. The most common areas of the body scanned for PET-CT patients include skull, whole body, and brain. [↑](#footnote-ref-16)
17. The Applicant states that the remaining patients are either from other cities and towns within Massachusetts or do not reside in the state. [↑](#footnote-ref-17)
18. The Applicant notes that the existing vendor bills for PET-CT services and the Applicant does not have access to the payer mix data for PET-CT patients. [↑](#footnote-ref-18)
19. The report states that the Central Region includes 46 communities anchored by the city of Worcester, with secondary industrial/population centers, Leominster, and Fitchburg, to the north. [↑](#footnote-ref-19)
20. Long-term Population Projections for Massachusetts Regions and Municipalities. March 2015. [Available at http://pep.donahue-institute.org/downloads/2015/new/UMDI\_LongTermPopulationProjectionsReport\_2015%2004%20\_29.pdf](http://pep.donahue-institute.org/downloads/2015/new/UMDI_LongTermPopulationProjectionsReport_2015%2004%20_29.pdf) [↑](#endnote-ref-1)
21. MRI yearly changes: 4.3% (Y1-Y2), 2.8% (Y2-Y3), 4.1% (Y3-Y4), and 3.2% (Y4-Y5).

 PET-CT yearly changes: 12.2% (Y1-Y2), 11.6% (Y2-Y3), 12.2% (Y3-Y4), and 9.9% (Y4-Y5). [↑](#footnote-ref-20)
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26. HealthIT.gov. Improve Care Coordination. [Available at https://www.healthit.gov/topic/health-it-basics/improve-care-coordination](https://www.healthit.gov/topic/health-it-basics/improve-care-coordination) [↑](#endnote-ref-6)
27. Alain Pinsonneault, Shamel Addas, Christina Qian, Vijay Dakshinamoorthy & Robyn Tamblyn (2017) Integrated Health Information Technology and the Quality of Patient Care: A Natural Experiment, Journal of Management Information Systems, 34:2, 457-486, DOI: 10.1080/07421222.2017.1334477. [↑](#endnote-ref-7)
28. HealthIT.gov, https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/improved-diagnostics-patientoutcomes [↑](#endnote-ref-8)
29. Community Engagement Standards for Community Health Planning Guideline [↑](#footnote-ref-21)
30. DoN Regulation 100.210 (A)(1)(e). [Available at https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf](https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf) [↑](#footnote-ref-22)
31. Heywood Healthcare has one combined PFAC for both Heywood and Athol Hospitals since the onset of the COVID-19 pandemic. [↑](#footnote-ref-23)
32. An IDTF is a facility that is independent both of an attending or consulting physician’s office and of a hospital. [Available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICN909060-IDTF-Fact-Sheet.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICN909060-IDTF-Fact-Sheet.pdf) [↑](#footnote-ref-24)
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39. The CPA states Shields noted that while contractual rate increases from their payers are possible, they are not guaranteed. [↑](#footnote-ref-26)