STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	Shields Healthcare of Cambridge, Inc.
Applicant Address	700 Congress Street, Suite 204, Quincy, MA 02169
Filing Date	March 1, 2022
Type of DoN Application	DoN-Required Equipment
Total Value	$2,292,401.00
Project Number	# 22020311-RE
Ten Taxpayer Groups (TTG)	Yes
Community Health Initiative (CHI)	$114,620.05 (CHI statewide initiative)
Staff Recommendation	Approval with Conditions
Public Health Council	July 13, 2022

Project Summary and Regulatory Review

Shields Healthcare of Cambridge, Inc., the Applicant, which is a member of the Shields Health Care Group ("Shields"), proposes to reinstate a 1.5 Tesla (1.5T) magnetic resonance imaging (MRl) unit at Shields MRI Brighton at 385 Western Ave, Brighton, Massachusetts 02135. Shields MRI Brighton currently hosts the offline Siemens Espree 1.5T MRI unit (Espree 1.5T) that was taken offline in November 2020. The total value of the Proposed Project is $2,292,401.00; the Community Health Initiatives (CHI) contribution is $114,620.05, which will go towards the CHI Statewide Initiative. In order to accurately reflect the capital expenditure for the entirety of the recent changes to the MRI units, in agreement with DoN staff, the costs that are being attributed to this project.

This DoN application falls within the definition of DoN-Required Equipment and Services, 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.

Two Taxpayer Groups (TTGs) were formed. The Department held a virtual public hearing on May 24, 2022. Two additional written comments were received.

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Background: Shields Healthcare of Cambridge, Inc. and Application Overview

Shields Healthcare of Cambridge, Inc. is located in Quincy, Massachusetts. Shields MRI Brighton, the location of Proposed Project, merged with Shields Healthcare of Cambridge, Inc. in 2017 and is a member of the Shields Health Care Group ("Shields"). Shields was founded in 1972 in Brockton, Massachusetts. Shields manages more than 40 MRI and PET-CT facilities throughout New England, many of which are joint venture partnerships with community hospitals. While most Shields locations operate as licensed clinics, they are often on the campuses of or situated nearby partner hospitals.

Proposed Project

The Applicant proposes to expand its imaging services to reinstate a 1.5 Tesla (1.5T) magnetic resonance imaging (MRl) unit at Shields MRI Brighton at 385 Western Ave, Brighton, Massachusetts 02135. Shields MRI Brighton had taken offline its Siemens Espree 1.5T MRI unit (Espree 1.5T) in November 2020 as it had replaced this unit with the Hitachi Oasis (Hitachi 1.2T) to meet the Patient Panel needs at that time, specifically the need for an open-sided 1.2T unit at the facility for claustrophobic and bariatric patient populations.[1] Currently, Shields MRI Brighton hosts both the offline Espree 1.5T and the operational Hitachi 1.2T units.

[1] Boston area providers with Hitachi 1.2T magnets include: MGH Chelsea Imaging, COi Woburn (now known as Rayus Radiology), and COi Dedham (now known as Rayus Radiology).

Patient Panel[2]

Shields MRI Brighton is a member of the Shields Health Care Group ("Shields") and operates as a licensed clinic. The Applicant reviewed its Patient Panel to determine the need for the Proposed Project.[3] Table 1 shows the number of scans for patients in FY18 through FY21. There was a decrease in scans performed in 2020 as a result of the COVID-19 pandemic. Of note, Shields MRI Brighton fiscal year (FY) follows the calendar year.

Table 1: Shields MRI Brighton Historical Scan Volume, FY18-FY21

	2018	2019	2020	2021
Number of Scans	4,441	4,337	3,288	4,323

The Applicant provided demographic data for the Patient Panel, which is presented in Table 2. The Applicant does not have race/ethnicity data due to historic platform limitations, which has been addressed, and they plan to collect this data moving forward. Staff notes the following observations about these data below:

- **Age:** Most of the patients are between the ages of 19-64 years (77%), with the 19-30 and, 51-64 age cohorts each comprising nearly one quarter of the patients (24% each) and the 65+ cohort representing 23%. A small portion of patients are between the ages of 0-18 years (1%).
- **Patient Origin:** The top 10 zip codes based on patient volume were from Middlesex, Suffolk and Norfolk Counties. For FY20, ~58% of patients were from Middlesex County and ~24% from Suffolk County. About 6% of volume came from counties outside of MA, primarily driven by out-of-state students attending school in Massachusetts (Harvard, BU, Northeastern, etc.).
- **Payer Mix:** Most patients served have commercial insurance (69%) followed by Medicare (16%). Two percent of Shields MRI Brighton Patient Panel had MassHealth.
- **Payer** ACO-Managed Care account for 2% of managed care patients.

Table 2: Overview of Shields MRI Brighton Patient Panel, FY20

	Total
Total Volume	3,288
Gender	
Female	52%
Male	48%
Age	
0-18	1%
19-30	24%
31-40	16%

[2] 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.
[3] All Patient Panel Data was sourced from Shields Internal Business Intelligence Reporting (BI) tool. Shields leverages QlikView software for the BI system, and eRad as the RIS system. Patient data is stored/collected in eRad and is fed into our BI system for reporting purposes.

41-50	13%
51-64	24%
65+	23%
Patient Origin	
Cambridge (02138)	10%
Watertown (02472)	7%
Brighton (02135)	7%
Belmont (02478)	5%
Cambridge (02139)	5%
Somerville (02143)	3%
Allston (02134)	2%
Cambridge (02140)	2%
Somerville (02144)	2%
Brookline (02446)	2%
Payer Mix	
Commercial (HMO/POS & PPO/Indemnity)	69%
MassHealth	2%
Medicare	16%
Medicare Advantage	2%
Other	6%
Private Medicaid/MCOs	5%
Payer	
ACO-Managed Care	2%
Non-ACO Managed Care	98%

Factor 1a: Patient Panel Need

In this section, staff assesses if the Applicant has sufficiently addressed Patient Panel need for the Proposed Project.

Patient Panel Need

The Applicant attributes the need for the expansion of imaging services to two factors:

1. need to meet the growing volume and demand for imaging services, based upon data related to:
    a. current unit at operating capacity,
    b. growth in referrals from local college athletic/health services,
    c. projected increase of aging population, and
    d. increased local need for higher strength imaging;
2. clinical appropriateness.

1. Growing volume and demand for imaging services

a. Current unit at operating capacity

Historical and projected volume needs show the need for additional MR imaging services at Shields MRI Brighton. The current Hitachi 1.2T unit has a lower scan capacity than a traditional 1.5T unit, and it is estimated that the 1.2T unit can perform 3,800-4,400 scans (Table 3 shows the methodology for the Applicant's estimate).

Table 3: Estimated Scan Capacity Range for Hitachi 1.2T Unit

	Scan Capacity (85%)	Scan Capacity (100%)	Hours/Day	Days/Week	Number of Weeks	Utilization Rate	Scan Times (in minutes)
Hitachi 1.2T (M-F)	3,264	3,840	12	5	48	85%	45
Hitachi 1.2T (Sat)	490	576	9	1	48	85%	45
Total	**3,754**	**4,416**					

As highlighted in Table 1, in FY2021 the facility performed over 4,300 scans, which is near full capacity. The Applicant asserts that reinstating the Espree 1.5T unit will enable it to meet the total projected volume in the coming years (Table 4). The 1.2T Hitachi unit will do the larger share of scans because the magnet is better suited for a larger portion of the scan types expected to be performed.

Table 4: Total Scan Volume Projections by Unit

	Current (2021)	Year 1 (2022)	Year 2 (2023)	Year 3 (2024)	Year 4 (2025)	Year 5 (2026)
Hitachi 1.2T	4,300	3,800	4,050	4,150	4,300	4,400
Espree 1.5T	--	1,200	1,650	2,150	2,700	3,200
Total Volume	**4,300**	**5,000**	**5,700**	**6,300**	**7,000**	**7,600**

There have been increased wait times since the Hitachi 1.2T unit has been operational. This is partly due to challenges associated with serving claustrophobic patients, which adds to the scan time.[4] Moreover, longer scan times have led to delays for other patients. In 2021, ~35% of all exams were considered "late," and wait times increased by 12% compared to 2020. The average scan time in 2021 on this unit was about 40 minutes for routine study and 55 minutes for contrast studies, and the scan time can be over 60 minutes for claustrophobic patients. This presents scheduling challenges for Shields MRI Brighton as scans often exceeds its standard time slots (30 minutes for routine and 45 minutes for contrast).

Currently, it takes 10-14 days for patients to get an appointment/exam on the Hitachi 1.2T. The Applicant hopes that by shifting some of the volume to the 1.5T unit, the 1.2T unit will be available to those who need it, and the average scan duration time on the 1.2 unit will decrease, while also accommodating all patient needs.

[4] Staff notes that the literature also highlights serving claustrophobic patients reduces workflow and impacts scanning time. [Nguyen XV, Tahir S, Bresnahan BW, et al. Prevalence and Financial Impact of Claustrophobia, Anxiety, Patient Motion, and Other Patient Events in Magnetic Resonance Imaging. *Top Magn Reson Imaging*. 2020;29(3):125-130. doi:10.1097/RMR.0000000000000243]

b. Growth in referrals from local college athletic/health services

Historically, Shields MRI Brighton had seen the referral numbers from colleges and universities grow (compound annual growth rate (CAGR) ~+10% between 2015-2019). Due to the COVID-19 pandemic, there was a decrease in MRI referrals from college athletic/health services[5] in 2020-2021. As students are returning to school in-person, these college/university departments are seeing increased volume, similar to the historical CAGR between 2015-2019. Applying the same growth rate percentage, the Applicant anticipates an additional growth of +800 scans projected over the next five years from these colleges/universities (Table 5). Staff notes that given that the existing Hitachi 1.2T is close to full capacity, the Applicant may not be able to timely accommodate the estimated growth in these referrals.

Table 5: College Athletics/Health Services Referral Growth

	Year 1 (2022)	Year 2 (2023)	Year 3 (2024)	Year 4 (2025)	Year 5 (2026)
Total Referrals	+130	+144	+158	+175	+193

c. Projected increase of aging population

Statewide population projections by the University of Massachusetts Donahue Institute are expected to increase by 11.8% from 2010 to 2035[6] and by 22.5% during the same period in the Greater Boston area[7]. The largest part of the population growth is attributed to residents aged 50+. The 65+ age cohort is expected to increase at a greater rate compared to all other age cohorts, and this age group will be about a quarter of the state's population by 2035. Shields MRI Brighton's population is older than the general state population (in 2019 average age 47 and 39 years, respectively). Further, age is associated with higher incidences of a variety of diseases and conditions for which MR imaging aids in diagnosis and treatment, such as neurological disorders musculoskeletal conditions, cardiovascular diseases, and cancers.

d. Increased local need for higher strength imaging

As previously stated, in November 2022, Shields determined that there was a need for claustrophobic and bariatric patient populations to access an open-sided 1.2T unit at Shields MRI Brighton.[8] As such, to meet the patient need, the Hitachi 1.2T was brought online and the Espree 1.5T was put offline. Shields MRI Brighton has since experienced an increase in the number of unique patients seeking imaging on the 1.2T unit (~570 new patients by end of 2021). However, this replacement has resulted in patients who were formerly able to access

[5] List of schools of schools that currently leverage the Brighton location for MRI services include Harvard University, Boston University, MIT, Boston College, Northeastern University, Tufts University, as well as several other small Division II and III schools in the greater Boston area.
[6] UNIVERSITY OF MASSACHUSETTS DONAHUE INSTITUTE, LONG-TERM POPULATION PROJECTIONS FOR MASSACHUSETTS REGIONS AND MUNICIPALITIES 11 (Mar. 2015), available at: http://pep.donahueinstitute.org/downloads/2015/new/UMDI LongTermPopulationProjectionsReport 2015%2004%20 29.pdf. The Massachusetts Secretary of the Commonwealth contracted with the University of Massachusetts Donahue Institute ("UMDI") to produce population projections by age and sex for all 351 municipalities.
[7] Data USA: Harvard University. Online at: https://datausa.io/profile/university/harvard-university#enrollment
[8] Boston area providers with Hitachi 1.2T magnets include: MGH Chelsea Imaging, COi Woburn (now known as Rayus Radiology), and COi Dedham (now known as Rayus Radiology).

the 1.5T unit at the Brighton facility having to travel greater distances.[9] Reinstating the Espree 1.5T unit will enable these displaced patients to locally access high-resolution imaging at low costs.

Additionally, based on the Advisory Board's Outpatient Imaging Estimator Tool, it is anticipated that freestanding MRI volumes will increase 16.6% over a five-year period (2019-2024) within the 5-mile radius of Brighton and bringing the 1.5T unit back online will help meet this market demand.

2. Clinical appropriateness

Many scans are clinically more appropriate for a 1.5T unit than 1.2T because of the higher resolution imaging enabled by the stronger magnet. The stronger magnet allows for higher quality images for shoulder, abdomen, chest, hip/thigh, and pelvis exams. According to the American College of Radiology, a scan for prostate must be at least 1.5T, and the minimum recommended equipment for breast MRI is a 1.5T unit. Also, due to limitations within a 1.2T machine, breast scans cannot be performed on the Hitachi 1.2T. Magnetic resonance cholangiopancreatography ("MRCP")[10] scans also have better imaging quality on the Espree 1.5T. Also, the quality of examinations for Multiple Sclerosis and Epilepsy patients are higher on the Espree 1.5T. The historical volume estimates that about 935 scans (~20%) of the 2021 volume would be more clinically appropriate on the Espree 1.5T unit. The Applicant states that at least 22% of the patients have scanning needs that must be met with a stronger image quality.

Analysis

Staff finds that the anticipated increased volume of scans at Shields Brighton MRI as well as the increased need for higher strength imaging warrant to bring the Espree 1.5T back online. Reinstating this unit will help to meet the needs of the local patient population including the increasing referrals from colleges/universities that the existing unit alone may not be able to accommodate in the future. Further, with the growing aging population in the state and in the Greater Boston area as well as their older patient population, the need for convenient local access to services becomes more important. Based on a review of the literature and other DoN applications, staff concurs that the majority of demand lies in the 50+ population as incidences of cancer, neurologic, and cardio-vascular conditions increase as the population ages.

Factor 1: b) Public Health Value, Improved Health Outcomes and Quality of Life; Assurances of Health Equity

In this section staff will assess if the Proposed Project adds measurable public health value in terms of improved health outcomes and quality of life for the Applicant's existing patient panel, while providing reasonable assurances of health equity.

[9] Travel to proximate Shields locations in Winchester, Dorchester (Mass Bay}, Tufts MC, Dedham, Brockton, Weymouth, Framingham, and Wellesley
[10] MRCP uses a powerful magnetic field, radio waves and a computer to evaluate the liver, gallbladder, bile ducts, pancreas and pancreatic duct for disease.

Public Health Value, Health Outcomes, and Quality of Life
The Applicant asserts that the reinstatement of the Espree 1.5T unit will improve health outcomes and quality of life by "expanding access to higher quality, low cost, imaging services that can be performed in less time, while both maintaining the ability [to] continu(e) to offer scans on the 1.2T to accommodate claustrophobic/bariatric patients and by accommodating the growing volume demands." The 1.5T unit allows for faster scans for the patient, which improves timely access to imaging services for local patients and in turn can improve quality of life for patients as patient outcomes can be enhanced with early detection and treatment of disease. The Applicant cited the literature that highlighted that shorter perceived and actual appointment wait times were correlated with higher patient satisfaction; and satisfied patients are more likely to be compliant with their medical care plan which results in improved outcomes and more efficient utilization of healthcare resources.

Analysis: Public Health Value, Health Outcomes, and Quality of Life
Through the expansion of MRI services, the Applicant will be able to provide more timely access to imaging services that can improve patient outcomes and increase patient satisfaction. Staff finds that the Proposed Project has to potential to add to public health value in terms of improved health outcomes and quality of life of the Applicant's Patient Panel.

Health Equity and Social Determinants of Health (SDoH)
The Applicant states that it plans to ensure health equity to all populations, including those deemed underserved, and that the Proposed Project will not adversely affect accessibility of the Applicant's services for poor, medically indigent, and/or Medicaid eligible individuals. The Applicant accepts all forms of insurance and asserts that it will not discriminate based on ability to pay or payer source. Shields has price transparency tools so that all patients have information on current pricing. Further, they provide financial counselors for assistance in understanding insurance benefits and also offers financing options through Care Credit for patients on a high-deductible health plan or without insurance coverage. Shields MRI Brighton has rates that are up to 60% less expensive than hospital-based MRI scans.

Shields asserts that to provide effective, understandable, and respectful care with an understanding of patients' cultural health beliefs and practices and preferred languages," it has ongoing staff education and training in culturally and linguistically appropriate care." Through the scheduling process, Shields' staff note a patient's preferred language and whether language assistance services is needed for the appointment. It uses In Demand for video and voice interpreting via iPads during the appointment (preferred option), and Language Line Solutions phone interpreting if In Demand is not properly working. Language services are provided for free to people whose primary language is not English.

The Applicant pre-screens patients related to certain social determinants of health (SDoH) issues, specifically those issues that are relevant to an imaging appointment. One such issue is transportation, and transportation assistance is available via ride-share and cab vouchers to patients, as needed. More information on SDoH is provided below under Factor 2.

Analysis: Health Equity and SDoH
The DoN Staff's review assessed the Proposed Project's impact on equitable access to care. The Applicant ensures that it will enable access for all patients regardless of patients' ability to pay and

offer financial options as well as language interpreter services. Further, the Applicant has staff trainings on culture, linguistically appropriate services, and transportation assistance that can reduce barriers to care. Staff finds that the Applicant has sufficiently generally outlined a case for improved health outcomes and health equity.

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

The Applicant states that it promotes continuity and coordination of care for its patients through physician engagement with patients' care team and utilization of technology infrastructure. The technology infrastructure includes streamlined patient access tools that offer pre-registration functionality which interface with an electronic medical record (EMR). This allows capture of the necessary patient health information, such as medical history, allergies, and medications. Patients are referred to Shields Brighton MRI by a physician by phone, fax, or EMR. Shields collaboratively works with patients' providers to assist in addressing patients' immediate medical needs. A radiologist dictates a clinical report which includes images and shares the report with the referring provider immediately by fax, portal, or EMR. The EMR functionality enables radiologists to share diagnostic information with physicians, so that patients' treatment progress may be tracked.

The Applicant states the reinstatement of the 1.5T unit will also create volume efficiencies, help to address scheduling challenges, and reduce time spent at appointments. As previously mentioned, the scans on the 1.5T unit can be performed more quickly. Having both the 1.5T and 1.2T units will enable Shields Brighton MRI by using the unit that is more appropriate to meet the varied needs of the patient and clinical team.

Analysis

Staff finds that the Applicant's care coordination and use of technology infrastructure will contribute positively to efficiency, continuity, and coordination of care. Bringing the 1.5T unit back online will increase efficiencies enabling the Applicant to conduct more scans on appropriate MRI units.
The EMR supports communication between the radiologist and patients' physicians that can foster better collaboration.

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[11] 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."[12]

[11] Community Engagement Standards for Community Health Planning Guideline. https://www.mass.gov/doc/community-engagement-guidelines-for-community-health-planning-pdf/download.
[12] DoN Regulation 100.210 (A)(1)(e). https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf.

The Applicant used different channels to communicate about the Proposed Project. It published a legal notice on the Shields website to raise awareness to all patients, family members, local residents, and resident groups of the Project and efforts to address access and capacity constraints. Shields MRI Brighton also engaged residents and resident groups in a virtual community engagement forum in December 2021. While patients who received care at the center were invited and a poster was placed in the center, no patients participated in the forum, however one did communicate via email with the Applicant. An overview of the Proposed Project and the benefits of "enhanced" MR imaging services were presented. Community members asked questions about the DoN process and the current capacity of MR imaging services and did not provide any additional feedback regarding the Proposed Project.

Analysis

Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the 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

Through expanding MR imaging capacity at Shields MRI Brighton, the Applicant asserts that it will compete on the basis of price, TME, provider costs and other measures of health care spending. Shield's stated goal with this Project is to accommodate volume demands, provide further, higher quality, low-cost MRI services to Shields MRI Brighton patients through operation of an additional MRI unit that is already located at the Shields MRI Brighton site.

The Applicant asserts that its continued focus on providing imaging services will result in more efficiencies and savings for patients. Shields MRI Brighton is up to 60% less expensive than hospital-based MRI scans.[13] There are only two freestanding/Independent Diagnostic Testing Facility (IDTF) locations in the Boston area (Shields Brighton & Longwood MRI) with a 1.5T unit. With the Proposed Project, patients will have an alternative to local, lower cost imaging services and will not require them to travel to downtown to academic medical centers where costs are higher.

Analysis

The Proposed Project has the potential to reduce costs by providing imaging services at lower costs compared to hospital-based imaging services. While advanced imaging improves clinical care, it is also the source of overuse and added healthcare costs.[a] Staff notes that the Applicant has protocols in place to support appropriate use of imaging and minimize overuse. Shields provides a Clinical Decision Support tool (American College of Radiology) to referring physician, which physicians use to identify if an MRI scan is appropriate/necessary and determine the final order (e.g., (MRI, CT, or no imaging). 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.

[13] Data to support the same is available on the Shields online calculator, which compares Shields rates to hospital-based imaging sites.

Summary, FACTOR 1

As a result of the information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project meets Factor 1.

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

Cost Containment

The Applicant asserts that Shields MRI Brighton will contribute to the Commonwealth's goals for cost containment. The Applicant plans to expand its services without increasing the net TME while ensuring provision of low-cost care alternatives without affecting the quality of imaging services. The Applicant asserts the additional MRI unit available at its Brighton location will enable patients to access and receive the right type of imaging scan locally at a significantly lower price in a timely manner. The 1.5T unit's shorter scan times allows for volume efficiency. Additionally, the Applicant states that this will help promote faster diagnosis, intervention and treatment for their Patient Panel, which supports improving quality of care and thus reducing overall health care costs.

Analysis: Cost Containment

Staff finds that the Applicant has adequately explained how it aligns with cost containment goals through the expansion of high-quality, low-cost imaging services provided locally. The Health Policy Commission's (HPC) has found that clinical services are less expensive in non-hospital outpatient departments (HOPDs),[b] and imaging tests are more expansive in HOPD compared to free standing imaging centers.[c] Further, Massachusetts is more likely to use HOPDs.[b] Increasing access to imaging services in local, free standing facilities has the potential to reduce healthcare spending in the state.

Improved Public Health Outcomes

With Shields MRI Brighton increasing the type of and access to MR imaging services, clinicians will be able to properly diagnose and treat patients, which in turn will improve patient health outcomes. The Applicant notes that "MR imaging is a powerful modality that allows clinicians to better understand the disease process and make treatment decisions," and these imaging services are needed for certain cancers, such as prostrate and breast cancer. As mentioned previously, with the growing aging population there will likely be an increased need for high quality imaging services to diagnose and treat age-related conditions. The Applicant states that expanding services will allow it to meet the increased need.

Analysis: Public Health Outcomes

Staff finds that the Proposed Project is planned to ensure more timely access to imaging services that has the potential to improve health outcomes and patient satisfaction. Timely access can reduce delays in diagnosis and treatment that can adversely impact health outcomes.

Delivery System Transformation

The Applicant has plans to support patients' needs around social determinants of health (SDoH). As described earlier, the Applicant has a SDoH screening process in place for issues related to imaging appointments. The Applicant's staff is informed of a SDoH issue that comes up during a pre-screen process or during the appointment. Staff confirms that there is an assistance request, and the staff can

address the issue directly (e.g., transportation) or refer patients back to their primary care physician for linkage to community-based support (e.g., food insecurity). Shields MRI Brighton will implement numerous initiatives that include patient access tools, such as preregistration functionality, a cost transparency application, linkages to financial counselors, culturally competent staff, and a robust translation services program. These initiatives will enable easier access to care for vulnerable and at-risk populations.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant conducts pre-screens on relevant SDoH factors. If staff are made aware of an SDoH issue during the pre-screening process or at any time during a patient's appointment, the staff will either assist the patient directly (e.g., in the case of transportation) or refer the patient back to his/her primary care physician ("PCP") for linkage to community-based support (e.g., in the case of hunger and access to food).

Summary, FACTOR 2

As a result of information provided, staff finds that the Proposed Project has sufficiently met the requirements of 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 this Factor will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

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 examined a range of documents and information in developing its report including Shields MRI Brighton Financials prepared December 1, 2020, volume assumptions, payer mix and per-case reimbursement assumptions, and the Shield's company website. Additionally, it calculated key liquidity and operating metrics[14] to assist in determining reasonableness of the Applicant's assumptions.

Revenues

Prospective volume for Shields MRI Brighton was based on its historical and forecasted imaging volume for 2021. Prospective revenue per scan was determined based on Shields MRI Brighton actual 2021 payer mix and reimbursement rates.

[14] These are standard financial metrics used in determining the financial health and feasibility of an Applicant. Liquidity ratios measure the quality and adequacy of assets to meet current obligations as they come due. Operating metrics are used to assist in the evaluation of management performance. Additionally, certain metrics can be applicable to multiple categories.

CPA report determined that the prospective Shields MRI Brighton volumes provided by Management were reasonable. The review of payer mix included a summary of Shields MRI Brighton's payer mix and Shields historical reimbursement rates. The CPA determined the reimbursement rates provided by Management were reasonable for Shields MRI Brighton.

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 Shields MRI Brighton. The CPA calculated an operating expense compound annual growth rate (CAGR) of 12% with Year 5 expenses totaling $552,168. Facilities and equipment related expenses include depreciation, and other expenses for Shields MRI Brighton, 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 3% from Year 2 through Year 5.

Salaries and Benefits include radiology, technologists, and operations expenses. The CPA calculated a CAGR of 8% from Forecast 2021 through Year 5, which the CPA determined to be reasonable.

Selling, General, and Administrative (SG&A) expenses include support services, management, and other SG&A expenses. The CPA calculated a CAGR of 11% from Forecast 2021 through Year 5.

Interest expense for Hitachi MRI is projected to decrease from $44,818 in Forecast 2021 to less than $100 in Year 5.

The CPA found that the prospective expenses did not warrant any additional adjustment and are reasonable.

Capital Expense and Cash Flows

The CPA reviewed the capital expenditure and cash flows for Shield MRI Brighton, which was $155,493 in capital asset acquisitions in Forecast 2021, to determine if sufficient funds would be available to sustain the operations of Shield MRI Brighton. There were no capital expenditures expected from Year 1 through Year 5. The CPA determined the prospective capital requirements and resulting impact on cash flows of Shield MRI Brighton are reasonable.

The CPA report states that Shields MRI exhibits a cumulative cash surplus in the financials, after any scheduled distributions, of 14% 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 Shield MRI Brighton and not likely to have a negative impact on the Patient Panel or result in a liquidation of its assets.

Analysis
Staff is satisfied with the CPA's analysis of Applicants 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

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 one alternative to the Proposed Project.

Maintain the status quo by not reinstating the Espree 1.5T. This was rejected because it would overall reduce the quality of care, patient access, and efficiency. Patients would have longer wait times and hamper timely access to necessary diagnostic information. Further, growing volume demands would not be met. There would be no additional capital expenses and operating costs would remain similar.

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

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

1. The total required CHI contribution of $114,620.05 will be directed to the Massachusetts Statewide Community Health Funds.
2. To comply with the Holder's obligation to contribute to the Massachusetts Statewide Community Health Funds, the Holder must submit the first installment, a check for $57,310.03, to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
   i. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
   ii. The Holder must submit the second installment of funds to HRiA within one year from the date of the Notice of Approval.
   iii. The Holder must promptly notify DPH (CHI contact staff) when each payment has been made.

Payment should be sent to:
Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: Ms. Bora Toro

Public Comments on the Application

Any person, and any Ten Taxpayer group, may provide written or oral comment at any time during the first 30 days following the Filing Date of an Application, or during the first ten days after a public hearing.

Public Hearing

The Department held a virtual public hearing in connection with the Proposed Project on May 24, 2022. A total of 12 people provided oral comments at the public hearing. Oral comments provided at the public hearing for consideration in DoN's review and analysis would be ones that address the Applicant's ability to meet the requirements of each of the relevant factors. All of the oral comments at the public hearing were in support of the Proposed Project. The transcript of the public hearing is available online on the DoN website.

Written Comments

The Department received two written comments, both opposed to the Proposed Project. Pursuant to the DoN regulation, the Department determines whether need exists for a Proposed Project, based upon whether the Applicant meets each of the relevant factors set out in those regulations. Comments for consideration in the review and analysis would be ones that address the Applicant's ability to meet the requirements of each of the relevant factors. The names of those submitting written comments and a summary of the issues raised are provided in Appendix A. The full text of written comments is available online on the DoN website.

Ten Taxpayer Groups (TTGs)

Per the DoN Regulation, any ten taxpayers, organized as a group, may participate in the review of an Application for Determination of Need or request to amend a previously issued Notice of Determination of Need. Said group must register with the Department at any time during the first 30 days following the Filing Date of an Application, or during the first ten days after a public hearing held pursuant to 105 CMR 100.445.

Two ten taxpayer groups (TTGs) registered in connection with the Proposed Project. Registration information for each TTG is available on the DoN website. Table 6 below provides a brief overview of each registered TTG and their participation in the application review process.

Table 6: TTGs Overview

TTG Name	Date Formed	Representative	Requested Public Hearing	Requested Independent Cost Analysis (ICA)	Oral Comments Provided at Public Hearing	Written Comments Provided
Mass General Brigham	April 14, 2022	Kevin B. Sanginario	✓	✓		
Saint Elizabeth Medical Center	April 14, 2022	Adam Marx	✓			

Conditions

Based upon a review of the materials submitted, Staff finds that 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 Conditions.

The Holder shall provide, in its annual report to the Department, the following outcome measures. These metrics will become part of the annual reporting on the approved DoN, required pursuant to 105 CMR 100.310(A)(12). Reporting will include a description of numerators and denominators.

i. 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.

Based on expected scan volume of 5,000 year 1 MRI scans/ 12 months *40%, the minimum monthly patient participation is expected to be ~40% response rate. This translates into on average 167 responses monthly in year 1. (5,000 year 1 MRI scans/ 12 months) * (40%). The overall satisfaction minimum per month is 90% satisfaction rating. Any critical responses will be acted upon within 30 days.

Projections: Baseline: 90%; Year 1: 90% Year 2: 91% Year 3: 92%

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

ii. Wait Times: Access-Backlog: 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 access for the MRI service. This measure tracks how fast patients are able to get into the schedule once an order is received, with the target being less than 48 hours.

Measure: Timeframe between the “Order Date” and “Date of Appointment”.
Date of order/referral to date of appointment.

Projections Baseline: <10%; Year 1: <10%; Year 2: <10%; Year 3: <8%

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

iii. 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: Number of critical value reports radiologists conducted on cases being interpreted.
Number of IFA/Total Volume Number.

Note—All MRI scans that trigger an IFA need to have a corresponding critical value/finding report from the Radiologist.

Projections: Baseline: 100%; Year 1: 100%; Year 2: 100%; Year 3: 100%

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.

iv. 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.
The number of patients who returned for a scan within 48-hour time period / total scans.

Projections: Baseline: <1%; Year 1: <1%; Year 2: <1%; Year 3: <1%

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.

Appendix A: Names of People Who Submitted Written Comments & Summary of Comments

First Name	Last Name	Title and Organization
Cari	Rivera	Vice President, Health Systems 1199SEIU United Healthcare Workers East – MA Division
Michael	Callum	Interim President St. Elizabeth's Medical Center

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

1. If Applicant increases the volume with an additional MRI unit and/or increases share of commercial patients or holds payer mix constant can impact finances of a local hospital.

Factor 2: Cost Containment

1. Expanding imaging services in the Brighton area by adding a third MRI unit may increase cost.

REFERENCES

[a] Hendee WR, Becker GJ, Borgstede JP, Bosma J, Casarella WJ, Erickson BA, Maynard CD, Thrall JH, Wallner PE. Addressing overutilization in medical imaging. Radiology. 2010 Oct;257(1):240-5. doi: 10.1148/radiol.10100063. Epub 2010 Aug 24. PMID: 20736333.

[b] Massachusetts Health Policy Commission: Opportunities for Savings in Health Care. (2018). Retrieved from: https://www.mass.gov/doc/opportunities-for-cost-savings-in-health-care-2018.

[c] Massachusetts Health Policy Commission. HPC DataPoints, Issue 7: Variation in Imaging Spending. (2018). Retrieved from: https://www.mass.gov/service-details/hpc-datapoints-issue-7-variation-in-imaging-spending.