STAFF REPORT TO THE COMMISSIONER FOR A DETERMINATION OF NEED	
Applicant Name	Cambridge Public Health Commission d/b/a Cambridge Health Alliance
Applicant Address	1493 Cambridge St. Cambridge, Massachusetts 02139
Filing Date	October 19, 2022
Type of DoN Application	DoN-Required Equipment
Total Value	$678,000.00
Project Number	#CHA-22061514-RE
Ten Taxpayer Groups (TTG)	None
Community Health Initiative (CHI)	$33,900.00
Staff Recommendation	Approval with Conditions
Delegated Review	Commissioner Approval

Project Summary and Regulatory Review

Cambridge Public Health Commission, d/b/a Cambridge Health Alliance filed a Determination of Need Application to establish a part-time, mobile positron emission tomography - computed tomography (together "PET-CT") diagnostic imaging service three days a week at its CHA Malden Care Center. The total value of the Proposed Project is $678,000; the Community Health Initiatives ("CHI") contribution is $33,900.

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

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Background: Cambridge Public Health Commission, d/b/a Cambridge Health Alliance and Application Overview

Cambridge Public Health Commission, d/b/a Cambridge Health Alliance ("CHA", "Applicant"), is located in Cambridge, Massachusetts. CHA is a public hospital[1] and operates as a regional integrated healthcare system primarily serving Boston's metro north communities. CHA has a network of primary care and ambulatory care centers[2] across its service area. It also has three hospital campuses, two of which (CHA Cambridge Hospital campus and CHA Everett Hospital campus) provide community level acute care services (including inpatient psychiatry services) and a third (CHA Somerville campus), that provides inpatient child and adolescent psychiatry services. It is also a teaching hospital of Harvard Medical School, Harvard School of Public Health, Harvard School of Dental Medicine, Tufts University School of Medicine.

CHA Malden Care Center at 195 Canal Street, Malden, Massachusetts, 02148 is the location of the Proposed Project. CHA Malden Care Center provides Primary Care, and also houses the CHA Eye Center, CHA Bone & Joint Center, CHA PACE alternative care center, and a CHA Pharmacy.

Proposed Project

The Applicant proposes to establish a part-time, mobile PET-CT diagnostic imaging service three days a week at its CHA Malden Care Center. Currently, CHA does not offer PET-CT services, and many CHA patients in the Boston metro-north reside in a geographic area with no central or convenient access to such imaging. Through the Proposed Project, CHA will offer the PET-CT service to its Patient Panel through a collaboration with Alliance HealthCare Radiology ("Alliance"), an independent provider of PET-CT services. CHA will have a management and service agreement with Alliance to provide the PET-CT service including but not limited to the PET-CT equipment, radiotracers/isotopes, radiology techs, and other ancillary supplies for the PET-CT Service. CHA will be responsible for scheduling, billing, registration, and board-certified CHA radiologists with advanced training in PET will interpret the scans. The PET-CT service will be provided in a mobile van located adjacent to the CHA Malden Care Center with a parking pad to support the weight of the van. Patients will check-in for the PET-CT at CHA Malden Care Center and access the mobile van by a weather protected covered connector. The PET-CT Service will be ADA compliant and accessible to facilitate access for all.[3]

CHA's proposed PET-CT Service will be available to the CHA Patient Panel (defined in the next section) and to members of the wider community. Initially, CHA will offer the PET-CT Service to support patient care in its oncology, neurology, and cardiology services. CHA anticipates that the use of PET-CT will continue to evolve, expanding to other clinical applications as new isotopes are developed and approved.

[1] Created by and existing pursuant to Chapter 147 of the Acts of 1996, as amended

[2] The primary care and ambulatory care centers are licensed as hospital satellites (outpatient departments) on CHA's hospital license.

[3] CHA participates in MassHealth's Disability Access Initiative (DAI) program to increase disability access and reports annually to MassHealth, which includes updates on the purchase of accessible equipment and expansion of accessible services.

Patient Panel[4]

In Fiscal Year ("FY") 2022[5], CHA served 128,856 total unique patients. Table 1 shows the total unique patients served in the Patient Panel for FY2020-FY2022[6].

Table 1: CHA Patient Panel Unique Patients Served

FY2020	FY2021	FY2022
130,291	143,749	128,856

The CHA Patient Panel consists of CHA's primary care patient population and other patients who do not have a CHA primary care provider.[7] The Applicant provided demographic data for the Patient Panel, which is presented in Table 2. Staff notes the following observations about these data below:

- **Age:** Nearly half of patients are in the 30-64 age cohort (49%) and ~12% are aged 65+.
- **Ethnicity Grouping:** 64% of CHA's patients self-identify as an ethnicity other than North American/European. Most notably, ~20% identify as Brazilian, 8% as Latino – Central American/Mexican, 7% as Haitian, 5% as South Asian, 3% as African American/ Black Caribbean, 3% as Latino-Caribbean or Other Latino, and 15% as Other.
- **Patient Origin:** Somerville, Cambridge, Everett, Malden, Chelsea, Revere, and Medford represent the majority of the Patient Panel origin (68%).
- **Payer Mix:** CHA has a public payer mix with 48% Medicaid, 8% Medicare, 1% Health Safety Net.[8]

Table 2: Overview of CHA Patient Panel, FY2022

	Total
Total Unique Patients	128,856
Gender	
Female	55.4%
Male	43.9%
Other/ Unspecified	0.6%
Total	**100.0%**
Age	
0-19	23.0%
20-29	14.8%

[4] 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.
[5] CHA's Fiscal year runs July 1 to June 30.
[6] The FY20 and FY21 CHA Patient Panel data was amplified by unique patients who accessed CHA for one-time services related to COVID-19, including drive-through testing sites established outside of CHA's service area. This led to FY22 Patient Panel data appearing lower in comparison.
[7] CHA delivers care to a small number of patients who self-present to non-primary care services including emergency department/urgent care services, inpatient services, inpatient and outpatient psychiatric services, substance use disorder services, specialty care, and ancillary services (e.g., lab and imaging).
[8] Because of this the Center for Health Information and analysis has designated it a high public payor hospital https://www.chiamass.gov/high-public-payer-hospitals/.

	Total
30-44	26.4%
45-64	23.3%
65+	11.8%
Unspecified	0.6%
Total	**100.0%**
Ethnicity Grouping	
North American/European	36.0%
Brazilian	20.5%
Latino - Central American/Mexican	7.8%
Haitian	7.3%
South Asian	5.2%
African American/Black Caribbean	3.4%
Latino – Caribbean	2.7%
Other Latino	2.5%
All Other	14.6%
Total	**100.0%**
Patient Origin	
Somerville	16.0%
Cambridge	14.0%
Everett	13.0%
Malden	11.0%
Chelsea	3.0%
Revere	6.0%
Medford	5.0%
CHA Secondary Service Area[9]	14.0%
All Other	18.0%
Total	**100.0%**
Payer Mix	
Public/Medicaid/Medicaid MC	48.0%
Medicare/Medicare MC	8.0%
Private/Commercial/HMO	41.0%
Health Safety Net ("HSN")	1.0%
Other (Self-pay, Workers' Comp)	2.0%
Total	**100.0%**

Table 3 below presents information for patient population targeted for this DoN Application. The Applicant identifies that the Proposed Project will provide the PET-CT access to primary care patients who live in underserved geographical areas of Medford, Malden, Everett, Chelsea, Winthrop, and Revere (collectively "MMCREW")[10], though the service will be available to the entire Patient Panel. Some highlights from the data related to the MMCREW part of the patient panel include:

[9] CHA's Secondary Service Area (SSA) includes the following communities: Allston, Arlington, Belmont, Brighton, Charlestown, East Boston, Lynn, Melrose, Saugus, Stoneham, Wakefield, Watertown, Winchester, and Woburn.

[10] Everett-Malden Community Health Needs Assessment 2018/2020 ("CHNA") found that access to care and services was a major concern for these communities.

- **Age:** Similar to the overall Patient Panel, nearly half of the MMCREW patient population is between ages 30 to 64 (49%) and 12% are aged 65+.
- **Ethnicity Grouping:** Seventy-three (73%) of the MMCREW patient population self-identify as an ethnicity other than North American/European (compared to 64% of the overall CHA Patient Panel).
- **Payer Mix:** MMCREW patient population has public payer mix with 44% Medicaid, 8% Medicare, 2% Health Safety Net.

Table 3: Overview of CHA MMCREW Patient Population (Primary Care Only), FY2022

	Total
Total Unique Patients	43,327
Gender	
Female	55.2%
Male	44.8%
Total	**100.0%**
Age	
0-19	24.9%
20-29	13.3%
30-53	36.2%
54-64	13.3%
65+	12.3%
Total	**100.0%**
Ethnicity Grouping	
North American/European	26.9%
Brazilian	26.1%
Latino – Central American/Mexican	10.4%
Haitian	9.7%
South Asian	5.5%
African American/Black Caribbean	2.8%
Latino – Caribbean	3.0%
Other Latino	3.2%
All Other	12.5%
Total	**100.0%**
Payer Mix	
Public/Medicaid/Medicaid MC	44.0%
Medicare/Medicare MC	8.0%
Private/Commercial/HMO	44.0%
Health Safety Net ("HSN")	2.0%
Other (Self-pay, Workers' Comp)	2.0%
Total	**100.0%**

The Applicant notes that comprehensive data on how the current CHA Patient Panel accesses PET-CT imaging services is not available because CHA does not currently provide the service. In analyzing the potential PET-CT patient population, CHA extrapolated patients referred out for PET-CT from its

population health claims data.[11] The Applicant states that there are three factors that impact this extrapolated data: (1) risk-based contracts represent approximately 60% of CHA's payor mix and CHA made an assumption that the prevalence of outmigration for PET-CT services is consistent across all payor sources; (2) population health claims data is from a period that overlaps significantly with COVID when fewer outpatient diagnostic imaging services were being accessed; and (3) the data only included PET-CT claims for older isotopes and does not incorporate the future utilization for expanding clinical applications. The Applicant notes that the data cannot be broken down by referral and/or specialty that ordered the scan. Staff determined that this an acceptable way to determine the PET-CT patient population. Based on these factors, Table 4 represents the data for the PET-CT patient population. Staff notes that there were only 134 Unique Patients based on the conditions of the extrapolated data. Some highlights from the data include:

- **Age:** The largest percentage of PET-CT scans health claims occurred in the 19-64 age cohort, representing 57% of the claims. Significantly, the 65+ age category represented 43% of the claims.
- **Race:**[12] Patients identifying as White represented 65% of the PET-CT population.
- **Risk Contract:** The claims analyzed largely fell under Medicare contracts (45%).

Table 4: Overview of PET-CT Patient Population, Calendar Year 2021

	Total
Total Unique Patients	134
Gender	
Female	49.3%
Male	50.0%
Other/Unspecified	0.7%
Total	**100.0%**
Age	
19-54	28.4%
55-64	28.4%
65-74	27.6%
75+	14.9%
Unknown	0.7%
Total	**100.0%**
Race	
White	64.9%
Black	14.2%
Asian	3.0%
Other	14.2%
Unknown	3.7%
Total	**100.0%**
Payer Mix	
Commercial	23.0%

[11] Extrapolated population health claims data includes Medicaid, Medicare, and Commercial risk contracts.

[12] Extrapolated data broken down by Race, whereas Patient Panel data was broken down by Ethnicity Grouping.

	Total
Medicare	32.0%
Medicare	45.0%
Total	**100.0%**

Factor 1: a) 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 PET-CT to two factors:

1) Need to improve access and continuity of care.
2) Need to address anticipated volume growth resulting from
    a. An aging patient population.
    b. Anticipated increase in specific conditions where PET-CT scans aid in diagnosis and treatment.

1) Need to improve access and continuity of care

CHA does not currently provide PET-CT services and must refer all patients requiring this service to providers outside of the CHA system. The need to coordinate with outside vendors for scheduling, prior authorizations and integrating test results into the CHA electronic medical record causes delays in access to needed services and disruptions in continuity of care. The Applicant notes that referring patients to PET-CT services outside of CHA's system is a hardship that is especially pronounced in the MMCREW area because many patients rely on public transportation, which translates into a significant investment in time and money to access PET-CT services.

The Applicant referred to historical volume statistics to demonstrate the need to improve access to PET-CT imaging services for its Patient Population. The Applicant calculated that, despite the COVID-19 pandemic, there was a 7% increase in the number of PET-CT scans performed for CHA patients in the period from Calendar Year ("CY") 2019 through CY2021. Staff notes that the higher number of scans compared to the number of unique PET-CT patients indicates that patients received multiple scans in CY2021.

Table 5: CHA PET-CT Patient Population PET-CT Scan Volume[13]

	CY2019	CY2020	CY2021
Number of Scans	311	284	334

Based on the historic demand for PET-CT, the Applicant anticipates it will begin the service one day a week in the first year (projected start Summer/ Fall 2023), increase to two days within 12-15 months, and add a third day within 18 months. The Applicant states that three days of operations are necessary because a maximum 6 scans can be completed per day. Since the isotope used varies by type of scan, only the scans using one isotope will be scheduled on a given day. Consequently, cardiac scans must be

[13] CHA extrapolated this data from its population health claims.

done on a different day than oncology/neurology scans. When the Proposed Project is fully implemented, the Applicant plans to operate the PET-CT services two days a week for oncology/neurology scans and use the third day either for cardiac scans or additional oncology/neurology scans based on demand. Table 6 demonstrates the scan capacity for each specialty with two days devoted to oncology/neurology and one day focusing on cardiac scans once fully operational.

Table 6: Three Days Per Week PET-CT Scan Capacity By Specialty

Specialty	Total Scans Possible
Oncology/Neurology	624
Cardiac	312
Total Capacity	**936**

CHA plans to have the mobile PET-CT operating from 8:00am to 5:00pm and will explore adding evening and weekend hours.[14] Staff notes that any future expansion in the number of days of operational capacity would be subject to Determination of Need approval.

2) Need to Address Anticipated Volume Growth

The Applicant projects that it will see 13% growth in the PET-CT Service over the next five years and 24% in the 10-year period.[15] The Applicant notes that the significant growth in volume from year 1 to year 2 in the projections is due to a ramp up period in Year 1 where the Applicant would see 4 patients a day for 2 months and then move to a full schedule of 6 patients per day. In Year 2, the Applicant projects that the PET-CT service will operate 2 per week at full capacity of 6 patients per day. Applying the national average of referrals per provider for PET-CT services to the CHA Patient Panel, the Applicant estimates ~26% compound annual growth rate in 5 years, as detailed in Table 7.

Table 7: Projected PET-CT Patient Panel Scan Volume

Year	1	2	3	4	5	Compound Annual Growth Rate ("CAGR")
Number of PET-CT Scans	296	624	912	936	936	25.89%

In assessing existing and future need for PET-CT Service, CHA looked at historical volume trends from the extrapolated population health data, as well as national service-line specific historic claims data from the Advisory Board. The Applicant notes particular factors in the anticipated volume growth: a) an aging patient population and b) anticipated increase in specific conditions where PET-CT scans aid in diagnosis and treatment.

[14] If CHA adds evening or weekend hours, they must be done in conjunction with the Malden Care Center's hours of operation and availability of the mobile PET-CT from Alliance.

[15] CHA analyzed national service line specific historic claims data from the Advisory Board Company (the "Advisory Board"), a research agency specializing in the healthcare industry. These projections are based on the Advisory Board's data re: outpatient PET-CT average national utilization rates and adjusted for specific markets based on population and other local factors.

a. **Growth in Aging Population:** As noted previously in Table 4, a significant number of PET-CT services are currently ordered for CHA patients who are 65 years and older. Within the next 15-20 years, statewide projections show that the largest part of the Commonwealth's population growth will be attributed to residents within the 50+ age cohort and residents who are 65+ will represent roughly 21% of the Massachusetts population[a]. As this middle-age population grows older, the need for imaging services such as PET-CT for detecting, managing, and treating age-related conditions increases (detailed in the next section).

b. **Increased Incidence of Specific Conditions Where PET-CT Scans Aid in Diagnosis and Treatment:** The Applicant notes that PET-CT services are beneficial to the diagnosis, evaluation and treatment monitoring of cancer, neurological conditions, and cardiovascular disease; the risk and prevalence of which increase with age.
   i) *Cancer:* The 2019 Everett-Malden Community Health Needs Assessment ("CHNA") reported that the mortality rate for cancer in these communities (where the CHA's Patient Panel resides, and the Proposed Project will be located) was higher compared to the rest of Commonwealth. In particular, breast, ovarian and prostate cancers, and cancer mortality in general, are higher in Malden than the Commonwealth.[b] The Applicant cites literature stating that Oncology is the major clinical application for a PET-CT Service[c].
   ii) *Neurological Conditions:* As the size and proportion of the Massachusetts population age 65 and older continues to increase, the number of residents with Alzheimer's or other dementias will grow. In neurology, PET-CT plays an important role in the clinical assessment of dementias, cognitive impairments, and various epileptic syndromes. The PET-CT modality has become a valuable tool in the diagnosis, treatment evaluation and follow-up of patients with a variety of infections and inflammatory conditions and is already the "gold standard" for some neurological indications[d].
   i) *Cardiovascular Disease:* The Applicant states that within the last year, there has been significant development in PET-CT for cardiovascular disease. It has become the preferred test for patients unable to complete a diagnostic-level exercise stress test imaging study, who have known cardiovascular disease, and who meet appropriate criteria for a stress-imaging test.[e] PET-CT is also the only technique that yields sufficient information in one procedure to quickly provide all of the necessary information to make a timely and proper medical decision for coronary artery disease.[f]

Analysis

Staff finds that the historic volume and the anticipated changes in the patient population demonstrate sufficient need for the PET-CT service at CHA Malden. 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 with an aging population. Further, as the population grows and ages, the need for convenient local access to services becomes more important. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1a.

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.

Public Health Value and Health Outcomes

The Applicant states that PET-CT is an established technology that enables clinicians to appropriately diagnose and develop the most effective treatment plans earlier in the disease process across a number of clinical conditions, including those within oncologic, cardiac, and neurologic specialties. The PET-CT technology avoids scanning delays associated with performing two separate or sequential PET and CT scans as the patient has to undergo only one scan,[g] making it more efficient and convenient for both physicians and patients. The PET-CT technology also has a higher level of accuracy than either PET or CT individually, allowing physicians to better diagnose disease, as well as plan and monitor response to treatments more effectively. The Applicant asserts that access to the PET-CT service for the Patient Panel and the wider community in this underserved area will lead to improved health outcomes by allowing clinicians to provide appropriate, comprehensive treatment options in a timely manner.

Quality of Life and Patient Satisfaction

The Applicant anticipates that the Proposed Project will provide CHA's Patient Panel with timely, convenient, and integrated care at a central, accessible location, which they anticipate will positively impact quality of life and patient satisfaction. As previously stated, CHA currently refers its patients to other healthcare systems for PET-CT scans, which causes procedural delays for both the patient accessing PET-CT imaging services and the provider responding to the PET-CT results. The Applicant cited literature indicating that delayed access to healthcare services results in decreased patient satisfaction and can lead to negative health outcomes due to delays in diagnosis and treatment.[h] By having easier access to the PET-CT Service through a patient's regular primary care provider, the Applicant posits that patient satisfaction and quality of life will improve.

Analysis: Public Health Value, Health Outcomes, and Quality of Life

Staff finds that the Applicant's assertions of timely access to PET-CT likely contributes to improved health outcomes and patient satisfaction. Not having adequate access to PET-CT scans can lead to delays in diagnosis and treatment, which can negatively affect health outcomes. Staff confirms the ongoing need for continued access to PET-CT services, especially among the 45 and over age group/cohort which comprises approximately one third of the Applicant's Patient Panel, and a significant percentage of PET-CT patient populations. Risk for cancer, cardiovascular disease, and Alzheimer's (the leading causes of death in Massachusetts), increases with age, and consequently demand for the proposed PET-CT services is likely to increase with a growing aging population.[i] 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 the Proposed Project aligns with CHA's overall mission, "to address health inequities by caring for all members of the community with a specific expertise and commitment in caring for underserved populations." The Applicant states that the Proposed Project will address

inequities arising from income status and linguistic or cultural background by 1) providing increased access and 2) improved patient service through language accessibility.

1) **Increased Access for Underserved Populations:** As discussed herein, the Patient Panel of CHA is culturally and linguistically diverse with a high percentage of public pay patients. CHA's primary care patient population does not currently have convenient access to PET-CT imaging services. CHA Malden Care Center is centrally located in CHA's service area, convenient to public transportation, and has plentiful parking. In addition, having the service stay within CHA helps counter the 1) potential barriers when patients delay or fail to follow-through on testing, and 2) potential fear and distrust from having to access unfamiliar institutions, particularly among the immigrants prevalent in the CHA Patient Panel.[j] Delays and wait time are a burden for many patients who can ill afford the additional time for work. Reliably available services will reduce the need to refer patients to other facilities, thereby reducing the burden of travel, inconvenience, and out-of-pocket costs.
2) **Improved Patient Service through Language Accessibility:** CHA serves a linguistically and culturally diverse patient population. The Applicant notes that over half of its patients speak a language other than English at home and ~42% of CHA's primary care patient population need access to professional medical interpreter services. CHA provides linguistic and cultural support to its patients through its Multicultural Affairs and Patient Services department ("MAPS"). MAPS regularly provides interpreter services in more than sixty languages to all CHA sites at no cost. Interpreter services also handle requests for the deaf or hard of hearing, including American Sign Language and Certified Deaf Interpreter services. To help bridge linguistic and cultural gaps, MAPS provides professional medical interpreters via face-to-face, telephonic, and video conference. The Applicant notes that staff members assist patients who require interpreter services through technological means to ensure that technology proficiency is not a barrier to receiving interpretation services. The MAPS department also provides professional written translation services for forms, signage, and patient materials; cultural and linguistic education for clinical and non-clinical staff; and language proficiency testing for bilingual providers. The Applicant notes that in FY2021, MAPS provided interpreter services to approximately 560 interpreter assisted encounters in 120 different languages. CHA's Patient Panel Language Access is available at the information desk, and site maps are provided in English, Portuguese, Spanish and Haitian Creole. The Applicant states that improving CHA's ability to provide care along the continuum of care will expand CHA's ability to address health inequities.

Analysis: Health Equity and SDoH

The DoN Staff's review assessed the Proposed Project's impact on equitable access to care. The Applicant is responding to the need for accessible care identified in the most recent CHNA by siting PET-CT services in a location central to the most underserved portion of the Patient Panel, where ~42% of patients need access to language interpreter services. The Applicant provides a variety of language access services available at no cost to the Patient Panel and provides staff assistance with the use of language access equipment. Staff finds that the Applicant has sufficiently outlined a case for improved health outcomes and health equity.

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

The Applicant states that the Proposed Project promotes continuity and coordination of care for its patients through a more efficient in-house management of PET-CT services and utilization of technology infrastructure.

In-House Management of PET-CT: CHA will manage all necessary scheduling and prior authorizations for the PET-CT services, thereby eliminating the operational delays related to the current practice of referring patients to third party providers. Alliance will furnish and service the mobile equipment outside of the operational hours to ensure that patients have consistent and reliable access to the PET-CT services.

Technology Infrastructure: The Applicants technology infrastructure for the Proposed Project will streamline access for patients and facilitate improved coordination of care among physicians and other professionals on a patient's CHA care team. When the scans are performed, the images will go directly into CHA's Health Information System and both patient and care team members will be notified of the results. CHA radiologists will have the benefit of comparing previous images within the CHA electronic health record and will be able to immediately alert ordering providers of critical results. Patients will also have all of their results in one place through their electronic health record, enabling them to view their results and easily communicate with their care 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. 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.[k] 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.[l] CHA's Health Information System supports communication between the patient, physician, and all care team members that can foster better collaboration. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1c.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with the following government agencies that have licensure, certification, or other regulatory oversight:

- Deputy General Counsel, Department of Public Health
- Manager of Community Engagement Practices, Office of Community Health Planning and Engagement, Department of Public Health

As a result, Staff finds that the Proposed Project meets the requirements of Factor 1d.

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

The Department's Guideline[16] 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."[17]

The Applicant engaged the community in order to more fully involve patients and families regarding the Proposed Project by holding two meetings where the project was discussed: 1) CHA's Patient Family Advisory Committee and 2) the Malden Patient Advisory Committee.

1) **CHA's Patient Family Advisory Committee ("PFAC"):** The Proposed Project was presented to CHA's PFAC in June 2022 with seven members in attendance. The PFAC is composed of CHA patients and their family members as well as CHA staff. The presentation offered members an overview of current PET-CT operations and explained how the Proposed Project will benefit current and future patients. The PFAC members generally had positive reactions and did not voice any concerns with the Proposed Project.
2) **Malden Patient Advisory Committee ("PAC"):** The Proposed Project was also presented to the Malden PAC in June 2022 with four members in attendance. The Malden PAC is a group of patients and staff who work on a committee solely focused on CHA Malden Care Center. Like the PFAC presentation, the presentation sought to inform the Malden PAC members about the purpose of the Proposed Project and the effect on its patients. The Malden PAC members generally had positive reactions regarding the Proposed Project and did not voice any concerns.

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. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1e.

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 should reduce total medical expenses ("TME"), as the service will transition from outside providers to an outpatient service at a local community ambulatory site. The Applicant asserts that bringing PET-CT in-house will allow CHA to manage costs more effectively for its patients and achieve savings. As previously noted, the central location will save the cost of transportation for the Patient Panel, who currently travels to the periphery of the service area for PET-CT services. The Applicant states that the administrative cost of adding this service is minimal, and the mobile platform allows CHA to provide services appropriate to its volume. Under the Proposed Project, the Applicant projects that the cost per scan will be less than what CHA is currently paying from risk-based contracts to external providers. Additionally, the PET-CT Service will

[16] Community Engagement Standards for Community Health Planning Guideline.
[17] DoN Regulation 100.210 (A)(1)(e).

be operated in collaboration with Alliance, a national provider who will continue to seek operational efficiencies.

The Applicant notes that CHA has had the American College of Radiology ("ACR") Clinical Decision Support Tool ("CDS") called ACR Select in place for several years to ensure that orders meet Appropriate Use Criteria ("AUC"). Under the Proposed Project, all PET-CT orders will include an appropriateness review with this tool, which is built into the electronic medical record and used when CHA providers order PET-CT scans. The Applicant anticipates implementation of this tool when the Proposed Project goes live in 2023.

Analysis

The Proposed Project has the potential to reduce costs by providing PET-CT services locally to its Patient Panel, which saves patients the expense of traveling outside of their locality to complete PET-CT services. While advanced imaging improves clinical care, it can also be the source of overuse and added healthcare costs.[m] Staff notes that the Applicant has protocols planned to support appropriate use of PET-CT imaging and minimize overuse. The Applicant plans to review providers' use of the American College of Radiology ("ACR") Clinical Decision Support Tool ("CDS") for adult PET-CT orders to ensure unnecessary PET-CT imaging is not provided. Staff notes that with the high percentage of patients on risk-based contracts the Applicant may also be able curtail unnecessary PET-CT 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. As a result, Staff finds that the Proposed Project meets the requirements of Factor 1f.

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

For Factor 2, the Applicant must demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation beyond the Patient Panel.

Cost Containment

The Applicant asserts that the Proposed Project will contribute to the Commonwealth's goals for cost containment by reducing costs through increased efficiencies in operations and reduction in delays to care. The Proposed Project provides the Applicant's Patient Panel with the ability to receive needed PET-CT services at a convenient, accessible location that is integrated with CHA's primary care. The Applicant notes that this will provide a lower-cost option for PET-CT scans for CHA's Patient Panel, which has ~56% of its primary care population in risk bearing contracts. The Applicant anticipates approximately 20% savings compared to sending CHA patients to providers outside of CHA for these services. The Applicant states that the administrative cost of adding this service is minimal due to

outside management and the ability to use a part-time mobile platform, which allows CHA to provide services appropriate to its volume.

Analysis: Cost Containment
Staff finds that the Applicant has adequately explained how the Proposed Project aligns with cost containment goals through the expansion of low-cost PET- CT imaging services provided locally. As a result, Staff finds that the Proposed Project meets the requirements of Factor 2: Cost Containment.

Improved Public Health Outcomes
The Applicant states that the Proposed Project will improve public health outcomes and patient experience by reducing delays to access PET-CT services by providing convenient access for its Patient Panel in a familiar environment in their preferred language. Additionally, the Proposed Project will create a seamless experience of care through improved care coordination linked to their care teams to for more timely diagnosis and treatment of health conditions prevalent in these geographic, underserved areas.

Analysis: Public Health Outcomes
Staff finds that the Proposed Project will enable the Applicant to provide the Patient Panel more timely access to PET-CT services, which 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. As a result, Staff finds that the Proposed Project meets the requirements of Factor 2: Public Health Outcomes.

Delivery System Transformation
The Applicant notes that it integrates social services and community expertise in three ways: 1) Individually, 2) Institutionally, and 3) Community Wide.

1) **Individually:** The Applicant states that it addresses the individual needs of its Patient Panel through health-related social needs ("HRSN") screening. CHA screens patients for housing and food insecurity, economic stress, lack of access to transportation, and experience of violence. Patients who screen positive for these factors receive a geographically specific resource guide and referrals to practice-based patient resource coordinators to help connect them with needed services.

2) **Institutionally:** The Applicant noted the programs listed below that are available across its care continuum to assist its Patient Panel.

    a. CHA has a community resource database – CHA Connect (powered by Findhelp) - available to both staff and patients.
    b. Through CHA Connect, patients are able to apply for free or below-cost services and CHA documents information in the clinical record.
    c. The department of Population Health Management assists with coordinating care for patients with outside organizations including home health agencies, skilled nursing facilities, aging service access points, and substance use providers, among others.

d. CHA provides Flexible Services, a pilot program providing solutions for housing and food insecurity for ACO members who meet certain criteria.
e. CHA maintains a Patient and Family Advisory Council to provide feedback on all of the above programs and other health system initiatives to assure they are meeting the needs of our patient population.

3) **Community Wide:** The Applicant noted that it uses information from its Community Health Needs Assessments led by its Department of Community Health Improvement to engage with its local communities. CHA also develops relationships with key community-based organizations and municipal partnerships and programs to promote the health and well-being of the CHA Patient Panel.

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 (referred to as HRSN by the Applicant) and demonstrates a variety of methods for linking patients to needed community resources. The Applicant provides patients who screen positive for SDOH needs such as housing and food insecurity, economic stress, lack of access to transportation, and experience of violence, with a geographically specific resource guide and refers them to practice-based patient resource coordinators to help connect them with needed services. The Applicant also has institutional tools to assist patients and community-based partnerships to improve responsiveness to service area needs. As a result, Staff finds that the Proposed Project meets the requirements of Factor 2: Delivery System Transformation.

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: Financial Feasibility

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 is an analysis of the Applicant's six-year projections and the following supporting documentation:

1. Financial Model for CHA for the periods ending June 30, 2020, through June 30, 2027.

2. May Results Analysis and Fiscal Year 2022 Reprojection Presentation to the CHA Board Finance Committee on June 28, 2022.
3. Fiscal Year 2023 Budget Recommendation Presentation to the CHA Finance Committee on June 28, 2022.
4. Cambridge Health Alliance DoN Application # CHA-22061514-RE dated August 31, 2022, Public Announcement, and Determination of Need Application Instructions dated March 2017.
5. A Project Budget for the project titled Malden PET - CT signed by David Farmer, Senior Director of Facilities, dated August 19, 2022.
6. Projected Return on Investment ("ROI") for Mobile PET Service Project.
7. Audited Financial Statements for Cambridge Health Alliance for Fiscal Years 2018-2021
8. Proprietary market forecasting organization reports including: Integra Reports, published by MicroBilt Corporation; Definitive Healthcare data; and IBISWorld Industry Report, Hospitals in the US, dated July 2022

Revenues
The CPA Report analyzed the projected revenue which included net patient revenue, federal and state support, and other operating revenue. Net patient revenue is projected to grow between 2.0% and 6.5% annually, which the CPA states falls within historical growth rates. The CPA Report also reviewed the reasonableness of the projected revenue, for which the Applicant relied upon historical operating results and anticipated demographic trends in CHA's service area. The revenue growth anticipated is within or below the range of historical annual revenue growth rates for the Applicant between FY2017 and FY2021. Corresponding revenue for the Proposed Project is expected to increase from $414.4 thousand in year one to $1.3 million in year five. The CPA determined that the impact of the Proposed Project on the Applicant is small, with incremental revenue accounting for between 0.0 % and 0.1 % of total operating revenue for the Applicant.

The CPA concluded that the revenue growth projected by the Applicant reflects a reasonable estimation of future revenue of CHA.

Expenses
The CPA Report analyzed each of the categorized operating expenses for reasonableness and feasibility related to the projections. Incremental expenses related to the Proposed Project include salary and wages, supplies, purchased services, rental expense, and other expenses. Total expenses increase from $641.0 thousand in year one to $1.2 million in year five. The CPA notes that the projected total expenses as a percentage of CHA's total revenue range from 100.5% to 106.0% from FY2022 to FY2027, which is consistent with the historical total expenses as a percentage of total revenue which ranged from 100.5%to 106.5 % from FY2017 to FY2021. It is the CPA's opinion that the projected operating expenses reflect a reasonable estimation of future expenses of the Applicant.

Capital Expenditures and Proposed Project Financing
The CPA Report reviewed the capital expenditures projected related to the Proposed Project as well as proposed financing. The Applicant indicated routine capital/cash on hand would be utilized to fund the Proposed Project. The Applicant has a cash and cash equivalents balance exceeding $240 million throughout the projection period. As such, the CPA notes it appears the Applicant has sufficient capital to fund the Proposed Project without requiring CHA to obtain debt financing.

The CPA Report states that projections exhibit a cumulative operating EBITDA[18] surplus of approximately 1.9 % of cumulative projected operating revenue for the six years from FY2022 through FY2027. The CPA notes that based upon its review of the relevant documents and analysis of the Projections, it determined the anticipated EBITDA surplus is a reasonable expectation and based upon feasible financial assumptions. The CPA states, "We determined that the Projections are reasonable and feasible, and not likely to have a negative impact on the Patient Panel or result in a liquidation of assets of CHA."

Analysis
Staff is satisfied with the CPA's analysis of Applicant's projections for 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 two alternatives to the Proposed Project.

Alternative Option 1: Maintain the status quo by continuing to refer CHA patients to providers outside of CHA for PET-CT Services. This was rejected because the quality of care, patient access, and efficiency of care referenced throughout this report would continue to be impacted and would not improve. Patients would have longer wait times and hamper timely access to necessary diagnostic information. Further, growing patient demand would not be met. The applicant notes that this option would result in higher operating costs and ultimately higher TME for patients served based on the higher cost per scan and patient travel expenses to access services outside of the CHA system.

Alternative Option 2: Purchase a mobile PET-CT unit to be permanently located at CHA Malden Care Center. While Option 2 would expand access to the PET-CT Service, the Applicant asserts that having a full-time scanner would likely decrease efficiency because it exceeds the capacity needs of its Patient Panel. The capital costs for equipment and renovations with this alternative would be significant and there would be additional operating costs for staffing, maintaining, and operating the full-time PET-CT.

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

[18] EBITDA ("Earnings before Depreciation, Interest and Tax")

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

Summary and relevant background and context for this application: This is a DoN project that will result in a Tier 1 Community-based Health Initiative ("CHI"). The Applicant, Cambridge Health Alliance (CHA), plans to establish a mobile PET-CT service that constitutes DoN-Required Equipment. Standard practice is to contribute the full CHI contribution to the Statewide Funds for DoN-regulated equipment. In this case, the Applicant and DPH agreed to allow CHA to follow a standard CHI process, contributing to both the Statewide Funds and local DoN health priorities. The Applicant has an existing CHI infrastructure and would like to pool these funds with the larger community health improvement efforts. DPH will work with CHA to ensure that this aligns with upstream principles and health priorities.

To fulfill Factor 6 requirements, the Applicant submitted a CHI Narrative, its existing 2019/2020 Community Health Needs Assessment (CHNA) and 2021 Community Health Implementation Strategy (IS) for Everett-Malden communities, a Self-Assessment, and Stakeholder Assessments.

The Community Health Needs Assessment was conducted in 2019 by Cambridge Health Alliance, the entity that will implement CHI activities. The CHNA was conducted in partnership with Massachusetts General Hospital (MGH) and Melrose Wakefield Healthcare (MWHC) due to overlapping service areas. The 2019/2020 CHNA utilized secondary data sources and primary data gathered from qualitative interviews with key informants, group discussions and open community meetings. The CHNA describes quantitative and qualitative data collection methods and outlines key findings and themes from the service area and participating communities. These themes include economic stability and mobility, housing affordability and behavioral health. The Applicant also included CHA's 2021 Implementation Strategy (IS) to address the needs identified in the CHNA. Key focuses of the IS include access to health care and services, mental health and substance use, chronic disease and sexually transmitted infections, economic stability and mobility, access to healthy food and safe and affordable housing.

Recently, the Applicant released a new CHNA in October 2022 and employed similar strategies for engagement. Four key priorities emerged from the 2022 CHNA including housing, equitable economies, equitable access to resources, and climate health and justice. The Applicant engaged local Community Advisory Boards (CABs) to identify said priorities and will work with this group to identify implementation strategies to address these areas.

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, existing surveys, and key informant interviews, the participating community groups and residents identified the key concerns outlined in the 2019/2020 CHNA.

Stakeholder Assessments submitted provided information on the individuals' engagement levels (e.g., their personal 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 consistent with the self-assessment conducted by the Applicant.

The CHI Narrative provided information on the Applicant's decision-making structure and governing body for the CHI funding decision. The Applicant reported that during the winter of 2022 to 2023, CHA

will complete IS planning focused on developing or supporting policies, programs and practices focused on local health priorities identified by the 2022 CHNA. DPH staff requested and received additional narrative content to understand the Applicant's reasons and plans for pooling CHI funds with existing community health planning work. This narrative appropriately addressed questions and DPH staff agreed to allow this pooling investment strategy.

DPH will work with the Applicant to ensure on-going community engagement, a feasible project timeline and appropriate stewardship of any administrative allowance. Administrative allowances are used to address barriers to participation for community to engage.

Analysis

As a result of information provided by the Applicant and additional analysis, staff finds that with the conditions outlined below, and the ongoing communication 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 Commissioner approve this Determination of Need, to permit the Applicant to provide part-time, mobile PET-CT diagnostic imaging service three days a week at its CHA Malden Care Center, subject to all applicable Standard and Other Conditions.

Other Conditions

1. Of the total required CHI contribution of $33,900.00
   a. $3,254.40 will be directed to the CHI Statewide Initiative
   b. $29,289.60 will be dedicated to local approaches to the DoN Health Priorities
   c. $1,356.00 may be designated as the administrative allowance.
2. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $3,254.40 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 promptly notify DPH (CHI contact staff) when the 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

Outcome Measures

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) Access Measure – Time to the Next PET-CT Imaging Appointment: The Applicant will review the number of business days from the receipt of the patient's prior authorization for the PET-CT Service to appointment.

Measure: The number of business days to the third available appointment for the PET-CT Service.

Projections: Baseline: 5 business days or less; Year 1: 5 business days or less; Year 2: 3 business days or less; and Year 3: 3 business days or less.

Monitoring: These data will be evaluated on a quarterly basis by the Applicant and reported to DPH annually.

ii) Clinical Decision Support ("CDS") Measure: The Applicant will review providers' use of the American College of Radiology ("ACR") Clinical Decision Support Tool "ACR Select" for adult PET-CT orders (or any subsequent CDS) to ensure unnecessary PET-CT imaging is not provided.

Measure: The Applicant will collect and provide data related to the use of CDS as follows: (a) data showing yearly changes in "low utility" or "marginal utility" orders; and (b) percentage of provider response to alerts provided by ACR Select (or any subsequent CDS).

Projections for (a): Baseline: 35%; Year 1: 30%; Year 2: 25%; Year 3: 20%.

Projections for (b): Baseline: 60%; Year 1: 65%; Year 2: 70%; Year 3: 75-80%.

Monitoring: The Applicant will report this data to DPH annually

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