ATTACHMENT 1

DETERMINATION OF NEED NARRATIVE AND TABLES

2. Project Description

2.1 Provide a brief Description of the scope of the project.

Cambridge Public Health Commission, d/b/a Cambridge Health Alliance ("CHA" or "Applicant"), is applying for a Determination of Need to establish a part-time, mobile positron emission tomography ("PET") - computed tomography ("CT") diagnostic imaging service three (3) days a week at its CHA Malden Care Center Care Center ("CHA Malden Care Center") to allow it to meet the needs of its Patient Panel (the "Proposed Project" or "PET-CT Service").

Massachusetts' only public hospital[1] CHA operates as a regional integrated healthcare system primarily serving Boston's metro north communities. CHA has an extensive 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. Core to its mission and legislative charge to improve the health of its patients and communities, CHA actively works to address social determinants of health and other public health issues impacting the community. It operates the Cambridge Public Health Department and has robust public and community health teams working across its service area to assess and improve community health and wellbeing. 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.

By adding PET-CT to the imaging services offered at CHA, the Applicant seeks to meet CHA's existing and future Patient Panel needs, bringing state-of-the-art imaging services to a patient population that has historically been underserved despite demonstrating higher levels of chronic disease and other health disparities. Currently, CHA does not offer PET-CT services at all. Instead, the CHA providers refer their patients to external imaging services at a wide range of non-affiliated providers. Many CHA patients in the Boston metro-north reside in a geographic area with no central or convenient access to such imaging. CHA patients have to travel to access PET-CT, creating barriers to timely, convenient and coordinated care for CHA patients who need these imaging services.

CHA will offer the PET-CT Service to its Patient Panel through a collaboration with Alliance HealthCare Radiology[3] ("Alliance"). The PET-CT Service will be provided three days a week in a state-of-the art mobile van that is located adjacent to the CHA Malden Care Center with a parking

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[1] CHA was created by and exists 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 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.

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.[4]

CHA's proposed PET-CT Service will be available to the CHA Patient Panel (defined below) and to members of the wider community. All patients who receive services through the Proposed Project will have an appropriate clinical order. Physicians will assess patients to determine if they (1) demonstrate the requisite underlying clinical condition/diagnosis and (2) meet clinical protocols that accord with the standard of care. If clinically appropriate, the Physician will order PET-CT and start the process for scheduling the ambulatory service at a time convenient for the patient at the CHA Malden Care Center. Initially, CHA will offer the PET-CT Service to support patient care in its oncology, neurology and cardiology services. As discussed later, CHA anticipates that the use of PET-CT will continue to evolve during the Proposed Project, expanding to other clinical applications as new isotopes are developed and approved for other clinical applications.

The Proposed Project will enable the CHA Patient Panel, and notably primary care patients who live in Medford, Malden, Everett, Chelsea, Winthrop and Revere (collectively "MMCREW"), to access this essential service, an established standard of care, within the CHA integrated healthcare system. Patients will be able to access PET-CT services as an ambulatory, community-based service. Patients will be able to decrease scheduling challenges, shorten commuting times and more efficiently access the results of PET-CT imaging. CHA providers will be able to improve care coordination in that all orders, results and follow-up recommendations will be integrated into and accessible using the CHA electronic medical record ("EHR").

The primary goal of the Proposed Project is to improve access to care and care coordination for all patients including the large safety net populations CHA serves. The Proposed Project will reduce health inequities by increasing access for CHA's vulnerable patient population as described in greater detail later in this application. It will also further the Commonwealth's priority to control healthcare costs through increased efficiencies in operations and reduction in delays to care.

[4] 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.

Factor 1: Applicant Patient Panel Need, Public Health Values and Operational Objectives

F1.a.i Patient Panel:

> **Describe your existing Patient Panel, including incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measure, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status and other priority populations relevant to the Applicant's existing patient panel and payer mix.**

As the sole public hospital in Massachusetts and with its integrated network of services and sites, CHA is a safety net for vulnerable and diverse patients. With 16 freestanding and school-based ambulatory clinics, CHA's services are rooted in primary care. As of FY 2022 CHA's core patient population, its primary care patient population (as distinguished from "CHA Patient Panel" or "Patient Panel" described below) exceeded 121,000 patients, which is approximately 94% of the CHA Patient Panel.

CHA Patient Panel

The CHA Patient Panel consists of (1) CHA's primary care patient population and (2) other patients who do not have a CHA primary care provider. For example, 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). These patients have a range of reasons for seeking care at CHA and may include, for example, college students who are temporarily in the CHA service area, CHA employees who decide to seek care at CHA under its self-insured health plan or children/adolescents who access CHA's expanded psychiatric services despite residing outside of CHA's service area. The CHA Patient Panel 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.

In FY 2022[5], CHA served 128,856 unique patients in total. Table 1 shows the growth in the patient panel for fiscal years 2020-2022 which includes those patients who temporarily came to CHA for services related to the COVID-19 pandemic. CHA's Patient Panel mix consists of approximately 44% males and 56% females. CHA's Patient Panel serves a significant population ages 30 to 64, which encompasses a large middle age population with higher need of diagnostic imaging as described in more detail below. *See* Table 1. The Patient Panel lives Somerville (16%), Cambridge (14%), and the MMCREW cities and towns (38%). *See* Table 1.

[5] CHA's Fiscal year runs July 1 to June 30.

Reflecting CHA's commitment to health equity[6] and access to care, CHA serves a diverse Patient Panel – 60% of CHA's patients self-identify as an ethnicity other than North American/European or African American/Black Caribbean. Most notably, 20% identify as Brazilian, 8% as Latino – Central American/Mexican, 7% as Haitian, 5% as South Asian, 5% as Latino-Caribbean or Other Latino, and 15% as Other. Over half of CHA's Patient Panel speaks a language other than English at home.[7] Forty-two percent (42%) of primary care patients at CHA have limited English proficiency and require the services of a professional medical interpreter. Patient utilization of interpreter services is growing at a rate of 18% to 20%. In fact, if FY20201 CHA served 49,000 unique patients by providing 560,000 interpreter assisted encounters in 120 languages. CHA does not track immigration status.

As a safety net, integrated community healthcare system, CHA cares for a disproportionate share of Medicaid and Health Safety Net patients, who account for over 50% of CHA's Patient Panel[8]. *See* Table 1. In addition, the CHA payor mix includes 6% Medicare. CHA does not maintain income data on its Patient Panel, but insurance coverage is a reasonable proxy for determining general income levels. CHA has among the highest concentration of patients participating in MassHealth programs of any acute hospital system in the Commonwealth. As part of MassHealth reform, CHA participates with Tufts Public Health Plans as a MassHealth ACO Partnership Plan, Tufts Health Together with CHA. CHA does not have risk data for the full CHA Patient Panel, but based on its claims data approximately 53% of the primary care patient population are on a MassHealth risk contract, 37% in a commercial risk contract, and 9% in a Medicare risk contract. *See* Table 1.

MMCREW Patient Population

CHA served 43,327 unique patients from the MMCREW communities[9] in FY 2022. This subset of patients is materially more diverse and lower income than the CHA Patient Panel. CHA anticipates that its CHA Patient Panel members and MMCREW patient population will have the highest demand for PET-CT Services, which drives the choice of location for the Proposed Project at the accessible and conveniently located CHA Malden Care Center. MMCREW is a historically

[6] "Pursuing health equity means striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health based on social conditions." *See* Paula Braveman, *What are Health Disparities and Health Equity? We Need to be Clear*, PUB. HEALTH REPS., Jan.-Feb. 2014, Suppl. 2, at 5-8, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863701. To that end, CHA seeks to ensure high quality care to those who are most directly impacted by society's injustices which lead to health inequities.

[7] CHA has four official languages on its signage – English, Spanish, Portuguese and Haitian Creole.

[8] For FY2020, Cambridge Health Alliance reported a high public payor mix of 66.6% based on gross patient service revenue to CHIA, available at: https://www.chiamass.gov/assets/docs/r/hospital-profiles/2020/cambr-ha.pdf. The public payor mix reported in this Application and Table 1 is lower than the public payor mix reported to CHIA because it is based on percentages of CHA's unique patients who make up the CHA Patient Panel.

[9] The MMCREW patient population is based on CHA's primary care panel data as those are the patients most likely to access the PET-CT Service.

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

The gender breakdown mirrors the overall CHA panel and consists of approximately 45% males and 55% females. *See* Table 2. A significant portion of the MMCREW patient population is between ages 30 to 64 (62%), including a significant middle age population ages 45 to 64. *See* Table 2. The MMCREW patient population is materially more diverse than the CHA Patient Panel. Seventy-three (73%) of the MMCREW patient population self-identify as an ethnicity other than North American/European or African American/Black Caribbean (compared to 60% of the overall CHA Patient Panel). *See* Table 2. The MMCREW patient population also has a large public payor mix with 44% Medicaid, 8% Medicare, 2% Health Safety Net. *See* Table 2. Based on CHA's claims data, approximately 62% of the MMCREW primary care patient population are in a MassHealth risk contract, 30% are in a commercial risk contract and 8% are in a Medicare risk contract. *See* Table 2.

PET-CT Patient Population

Because CHA does not currently provide PET-CT services, it lacks accurate, comprehensive data on how the current CHA Patient Panel accesses these imaging services from third-party providers. In analyzing the potential PET-CT patient population, CHA extrapolated its population health claims data[11]. There are four factors that impact this extrapolated data: (1) risk-based contracts represent approximately sixty (60%) percent of CHA's payor mix and CHA is making an assumption that the prevalence of outmigration for PET-CT services is consistent across all payor sources (e.g. self-pay, Health Safety Net, and fee-for-service); (2) population health claims data is for 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; and (4) the data cannot be broken down by referral and/or specialty that ordered the scan. With a PET-CT Service of its own, CHA will be able to consistently track such data and capture the full PET-CT patient population.

Based on CHA's population health claims CY 2019 through CY2021, PET-CT utilization has grown by 7% since CY 2019[12] despite the Pandemic. *See* Table 3. During this period, PET-CT services were accessed equally by gender. *See* Table 3. Patients of all ages utilized PET-CT services, but PET-CT was utilized most heavily by the middle-age patient population age 54 and up which accounted for approximately 71% of PET-CT utilization. *See* Table 3. This is consistent with the age distribution of the MMCREW patient population that includes a significant middle-age population. It reflects that oncology and cardiology issues are more prevalent in a middle-aged

[10] CAMBRIDGE HEALTH ALL., MASS. GEN. HOSP., & MELROSE WAKEFIELD HEALTHCARE, EVERETT-MALDEN COMMUNITY HEALTH NEEDS ASSESSMENT 20 (2019) [hereinafter CHNA].

[11] This includes Medicaid, Medicare and Commercial risk contracts.

[12] There is a dip in utilization in CY2020 due to COVID-19.

population[13]. Seventy-seven (77%) percent of PET-CT are reimbursed by government payors (Medicaid or Medicare). *See* Table 3. In addition, the chronic illnesses such as cancer and heart disease that are most indicative of PET-CT are more highly prevalent in CHA's Patient Panel.[14]

F1.a.ii Need by Patient Panel:

> **Provide supporting data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question F1.a.i that demonstrate the need that the Proposed Project is attempting to address. If an inequity or disparity is not identified as relating to the Proposed Project, provide information justifying the need. In your description of Need, consider the principles underlying Public Health Value (see instructions) and ensure that Need is addressed in that context as well.**

CHA's Proposed Project is designed to meet existing and future Patient Panel needs by providing PET-CT Services three days a week at the CHA Malden Care Center. In assessing existing and future need for PET-CT Service, CHA first looked at historical volume trends from the extrapolated population health data, the need to increase access and improve continuity of care, the aging CHA Patient Population together with CHA's focus on programs for the elderly, and the increasing number of patients with underlying oncologic and cardiac conditions for which PET-CT has proven clinical applicability.

To ensure its needs assessment had sufficient breadth, CHA also analyzed national service-line specific historic claims data from the Advisory Board Company (the "Advisory Board") to determine Patient Panel Need for the Proposed Project. *See* Table 4.

<u>Historical Demand for PET-CT Service at CHA</u>

The Proposed Project responds to CHA's assessment of historical volume trends and projections for future needs. As noted above, the Applicant calculated that, despite the COVID-19 pandemic, there was a seven (7%) percent increase in the number of PET-CT scans performed for CHA patients in the period from CY2019 through CY2021. *See* Table 3. We believe that reflects the increasing adoption of PET-CT technology and its application to a growing list of approved clinical diagnostic uses. Based on market data, the Applicant

[13] *See* Amit Khera, *Why Fatal Heart Disease is Striking Middle-Aged Patients Younger and More Often*, UTSW MED. CTR. (Feb. 19, 2020), https://utswmed.org/medblog/why-fatal-heart-disease-striking-middle-aged-patients-younger-and-more-often/; Kim-Lien Nguyen et al., *The Crossroads of Geriatric Cardiology and Cardio-Oncology*, 4 CURRENT GERIATRIC RPTS. 327 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4624825/; *Why Does Cancer Risk Increase as We Get Older?*, CANCER TREATMENT CTRS. AM. (Feb. 7, 2017), https://www.cancercenter.com/community/blog/2017/02/why-does-cancer-risk-increase-as-we-get-older.

[14] *See* CHNA, *supra* note 7, at 26.

projects[15] that it will see 13% growth in the PET-CT Service over the next five years and 24% in the 10 year period. *See* Table 4. Operationally, CHA plans to go-live with the Proposed Project one day a week in the first year and then and increase to two days within 12-15 months, and add a third day within 18 months. Applying the national average of referrals per provider for PET-CT services to the CHA Patient Panel, CHA has estimated that the PET-CT scan volume will be in the range of 296 in year 1, 624 in year 2, 912 in year 3 and 936 in years 4 and 5. *See* Table 4. This is a 26% compound annual growth rate in 5 years. *Id.* The two different measures (market data and referrals) both show significant growth and need for the PET-CT Service.

CHA plans to have the mobile PET-CT on-site and operational three (3) days a week, operating approximately from 8:00am to 5:00pm, and will explore adding evening and weekend hours[16] as the Proposed Project is implemented over first three years. Because the Proposed Project is mobile, all downtime happens when the van is offsite, allowing for maximum efficiency. In addition to clinical demand discussed above, there are two additional factors that drive the need to operate three days a week. First, each scan takes approximately 60 minutes, including room-turnover, injections as needed and administrative functions. This means that a maximum of 7 to 8 scans a day can be completed in any one day. Second, different types of isotopes are used for each type of scan, meaning that cardiac scans must be done on a different day than oncology/neurology scans. As a result, the Applicant has determined that the clinical needs of its underserved Patient Panel will support offering three (3) days of PET-CT services.

Need for Continuity of Care and Increased Access

Currently, CHA must refer all patients requiring PET-CT services to providers outside of the CHA system. No third-party is now offering PET-CT services in CHA's primary service area; this is especially pronounced in the MMCREW area. Many of CHA's patients rely on public transportation, increasing the burden on patients who must travel to access PET-CT services. Moreover, CHA patients have to carry the burden of registering in a new system, completing new paperwork, meeting new providers and/or engaging with new interpreter services. Relying upon third-party PET-CT services creates delays in care for patients. Staff must coordinate with outside imaging providers and obtain prior authorizations. There are frequently delays with prior authorizations prolonging the scheduling period. Because reports from the non-CHA imaging services only go to the ordering clinician, results must be manually imported into CHA's EHR, preventing the patient's CHA care team from having integrated, timely access to the scan results.

Bringing the PET-CT Service to CHA at its Malden location 3 days a week will not only ensure continuity of care but eliminate the current barriers to care. The Proposed Project will allow

[15] 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.

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

CHA to timely schedule PET-CT scans for patients and eliminate the delays that exist with this current process. The CHA team will schedule the patients and obtain the prior authorization. When the scans are performed, the images will automatically go into the CHA PACS system; the report will immediately go to the patient through the EHR patient portal and to the ordering provider's inbox as well as be available to other members of the patient's CHA care team. CHA radiologists will have the benefit of comparing previous images within CHA and will be able to immediately alert ordering providers of critical results. Patients will also have all their results in one place through the EHR, which will allow them to receive their results and easily communicate with their care team. Additionally, it will greatly reduce transportation barriers[17] that patients face when referred to outside providers. CHA Malden Care Center is centrally located in CHA's service area and convenient to public transportation (bus, subway and commuter rail) and has plentiful parking. In addition, having the services stay within CHA helps counter the potential barriers to follow through on testing, as well as potentially combatting the fear and distrust from having to access unfamiliar institutions, particularly among the immigrants prevalent in the CHA Patient Panel.[18]

Aging Population and Need for PET-CT Services

As noted above, the majority of PET-CT services are currently ordered for CHA patients who are 54 years and older. *See*, Table 3. This is also consistent with the statewide population projection that within the next 15-20 years, the largest part of the Commonwealth's population growth will be attributed to residents within the 50+ age cohort. Residents who are 65+ will represent roughly 21% of the Massachusetts population.[19]

CHA has a number of programs that serve an older population. CHA's Program of All-Inclusive Care for the Elderly (CHA PACE) supports frail elders, 55 years and older, who want to age at-home. This program continues to expand each year and is primarily located at CHA East Cambridge Care Center and CHA Malden Care Center where the PET-CT Service will be located. CHA PACE participants can access primary care and outpatient pharmacy in addition to the activities and support services provided at the Malden adult day center. In addition, the CHA House Calls program has a team of doctors and nurse practitioners who provide primary care to homebound adults who have difficulty traveling to a doctor's office. CHA also partners with Cataldo Ambulance Service, Inc. to provide mobile integrated care to certain patients in their homes. This includes providing personalized, in-home care options and post-discharge visits to prevent hospital readmissions.

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[17] Everett and Malden residents have longer commute times than the state - at least 1.5 hours a day, so having a convenient imaging location close to home and where the scans can be coordinated with their other medical services will improve access to care. *See* CHNA, *supra* note 7, at 19.

[18] *See* CHNA, *supra* note 7, at 20 (Research conducted by the Blue Cross Blue Shield Foundation of Massachusetts has indicated that this fear and mistrust often leads to high rates of uninsured residents, and both Everett and Malden have higher rates than the state of uninsured residents (Everett 7.1%, Malden 5.9%, MA 3.0%).

[19] TUFTS HEALTH PLAN FOUND., HIGHLIGHTS FROM THE MASSACHUSETTS HEALTHY AGING DATA REPORT: COMMUNITY PROFILES 2014, https://www.mass.gov/files/documents/2016/07/wb/healthy-aging-data-report.pdf.

As this middle-age population ages in place, and CHA continues to offer and expand services for this patient demographic, the need for imaging services such as PET-CT becomes more important for detecting, managing, and treating age-related conditions. The Proposed Project will enable CHA's Patient Panel, and in particular the vulnerable MMCREW patient populations, to access PET-CT imaging services. Making PET-CT services available at a local, outpatient ambulatory care center that is part of an integrated community healthcare system will facilitate care coordination related to the treatment of the underlying clinical condition.

Need for PET-CT Services for Cancer Patients in Massachusetts

Cancer is the leading cause of death for Massachusetts residents[20]. The American Cancer Society has projected 42,190 new cases of cancer in Massachusetts in 2022, and 12,520 cancer related deaths.[21] Research also shows that the risk of cancer increases with age and significantly rises more rapidly beginning in midlife.[22] As a result, cancer was the number one cause of death in 2019 for ages 45-64.[23]

The age adjusted incidence rate for cancer in Middlesex and Suffolk Counties, where the CHA's Patient Panel resides and the Proposed Project will be located, was 441.2 to 423.0 cases per 100,000. Also, when taken as a whole, the cancer mortality rates are higher in both Everett and Malden than the Commonwealth, and cancer was one of the chronic diseases of most concern for the MMCREW patient population.[24] In particular, breast, ovarian and prostate cancers and cancer mortality in general are higher in Malden than the Commonwealth.[25]

Oncology is the major clinical application for a PET-CT Service.[26] The national annual referral data for PET-CT scans by oncology and hematology providers is 62.7. Applying this benchmark to CHA oncology and hematology providers results in 1,380 estimated annual referrals. *See* Table 4. In addition to the above, Massachusetts has more residents over the age of 60 than under the age of 20.[27] This is both consistent with the numbers that show a significant middle-age patient population for both the CHA Patient Panel and the MMCREW patient population. It is also consistent with the observations that approximately 71% of the middle-aged patient population (54+) used PET-CT services. *See* Table 3.

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[20] MASS. DEP'T PUB. HEALTH, MASSACHUSETTS DEATHS 2019 (2022), https://www.mass.gov/doc/2019-death-report/download.

[21] AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2022, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf.

[22] Mary C. White et al., *Age and Cancer Risk: A Potentially Modifiable Relationship*, 46 AM. J. PREVENTATIVE MED. (Suppl 1), S7 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544764/.

[23] MASS. DEP'T PUB. HEALTH, *supra* note 16.

[24] *See* CHNA, *supra* note 7, at 26.

[25] *See* CHNA, *supra* note 7, at 27.

[26] SS Anand et al., *Clinical Applications of PET and PET-CT*, 65 MED. J. ARMED FORCES INDIA 353 (2009), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4921358/.

[27] *Age-Friendly Massachusetts*, MASS. EOHHS, https://www.mass.gov/service-details/age-friendly-massachusetts (last visited Aug. 24, 2022).

Need for PET-CT Services for Neurology Patients in Massachusetts

Recent studies increasingly focus on aging and neurological diseases, such as epilepsy and Alzheimer's dementia. Recent research provides, for example, that the risk of having a seizure increases after the age of 60[15]. Moreover, the incidence rate of Alzheimer's also increases with age. Millions of Americans have Alzheimer's or other dementias. As the size and proportion of the U.S. population age 65 and older continue to increase, the number of Americans with Alzheimer's or other dementias will grow. This number will escalate rapidly in coming years, as the population of Americans age 65 and older is projected to grow from 52 million in 2018 to 95 million by 2060[28]. The baby boom generation has already begun to reach age 65 and beyond, the age range of greatest risk of Alzheimer's dementia. The oldest members of the baby boom generation turned age 73 in 2019.

PET-CT has been shown to enhance a clinician's ability to diagnose and effectively treat these diseases. In neurology, PET-CT plays an important role in the evaluation of various epileptic syndromes as well as in the clinical assessment of patients with a multitude of other disorders, including cognitive impairment and dementias. 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.[29]

Need for PET-CT Services for Cardiology Patients in Massachusetts

It is also well established that age is a leading risk factor for cardiovascular disease[30]. The American Heart Association reports that the incidence of cardiovascular disease in US men and women is ~40% from 40–59 years, ~75% from 60–79 years, and ~86% in those above the age of 80.[31] Heart disease was the second leading cause of death, after cancer, in Massachusetts.[32] With respect to the CHA Patient Panel, there are higher age adjusted emergency room visits for cardiac reasons, as well as other chronic diseases that can lead to cardiovascular disease, among other things.[33]

Within the last year, there has been significant development in PET-CT for cardiovascular disease. It has become the first-line preferred test for patients unable to complete a diagnostic-level exercise stress test imaging study, who have known cardiovascular disease

[28] Mark Mather et al., *Fact Sheet: Aging in the United States*, POPULATION REFERENCE BUREAU (July 15, 2019), https://www.prb.org/resources/fact-sheet-aging-in-the-united-states/.
[29] Hongming Zhuang & Ion Codreanu, *Growing Applications of FDG PET-CT Imaging in Non-Oncologic Conditions*, 29 J. BIOMEDICAL RSCH. 189 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449487/.
[30] Jennifer L. Rogers et al., *Cardiovascular Risks Associated with Gender and Aging*, 6 J. CARDIOVASCULAR DEV. & DISEASE 1 (2019), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616540/.
[31] *Id.*
[32] *Stats of the State of Massachusetts*, CDC (Apr. 11, 2018), https://www.cdc.gov/nchs/pressroom/states/massachusetts/massachusetts.htm.
[33] *See* CHNA, *supra* note 7, at 29.

and who meet appropriate criteria for a stress-imaging test.[34] 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.[35]

The national annual referral data for PET-CT scans by cardiology providers is 4.3, which when applied to CHA results in estimated referrals in CHA's primary service area of 91. *See* Table 4. CHA's cardiology patients will benefit from access to PET-CT by allowing for efficient and accurate decision-making.

F1.a.iii Competition:

Provide evidence that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending. When responding to this question, please consider Factor 4, Financial Feasibility and Reasonableness of Costs.

The Proposed Project should reduce total medical expenses (TME), as the care will transition from referrals to tertiary hospitals and private imaging providers to an outpatient service at a local community ambulatory site. As noted above, a significant portion of CHA's primary care patient population is in a risk-bearing contract (53% Medicaid, 37% Commercial and 9% Medicare as of CY2021) and an even larger percentage of the MMCREW patient population is in a risk-bearing contract (64% Medicaid, 28% Commercial, 8% Medicare as of CY2021). Bringing PET-CT in-house will allow CHA to more effectively manage its costs for these patients and achieve savings. CHA estimates there will be approximately a 20% savings in cost. The administrative cost of adding this service is minimal; the mobile platform allows CHA to provide services appropriate to its volume. Under the Proposed Project the cost per scan will be less than what CHA is currently paying from risk-based contracts to external providers. In addition to cost savings, the Proposed Project will allow CHA to more effectively manage the care coordination of these patients, which will have a direct impact on the public health outcomes for this population. Additionally, the PET-CT Service will be operated in collaboration with Alliance, a national provider, who will continue to seek operational efficiencies, while simultaneously ensuring the highest quality of care possible.

[34] Timothy M. Bateman et al., *American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET*, J. NUCLEAR CARDIOLOGY (2016), available at https://www.asnc.org/files/Guidelines%20and%20Quality/ASNCandSNMMIJointPETPositionPaper2016.pdf.

[35] P. Knaapen et al., *Cardiac PET-CT: Advanced Hybrid Imaging for the Detection of Coronary Artery Disease*, 18 NETH. HEART J. 90 (2010), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2828569/#:~:text=Cardiac%20PET%2DCT%20is%20a,the%20one%2Dstop%2Dshop.

F1.b.i Public Health Value /Evidence-Based:

Provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need that Applicant has identified.

The Proposed Project is supported by evidence-based literature related to the utility of PET-CT technology and the benefits associated with receiving timely, convenient and coordinated health care. PET and CT are two well-established imaging systems that have been available for clinical use for several decades.

PET is a non-invasive molecular imaging modality that measures metabolic activity of organs and tissues via detection of radiotracers injected in a patient's bloodstream. It provides information about how organs and tissues are functioning on a molecular and cellular level, and allows physicians to measure chemical and biological processes. Thus, PET is used to detect biochemical changes in an organ or tissue that indicate the onset of a disease process before symptoms, abnormalities, or anatomical changes related to the disease can be seen with other imaging technology.[36] PET may also be used to track treatment progress and is commonly used in the fields of oncology, cardiology, and neurology/neuropsychology.[37]

CT provides anatomical and structural information by creating a three-dimensional picture of the inside of the body with an x-ray machine.[38] These images, when combined by a computer into a cross-sectional view show tumors or physical abnormalities in tissue morphology. CT scans can be performed on every region of the body and CT images of internal organs, bones, soft tissues, and blood vessels provide greater detail and clarity compared to conventional x-ray images. CT scans are performed for a variety of reasons, and are useful in diagnosing disease, trauma, and abnormality. CT can also be used for interventional and therapeutic procedures, treatment planning and monitoring the effectiveness of therapy, and screening purposes.

<u>PET-CT Utility</u>

PET-CT combines the two imaging systems to produce highly detailed views of the body by superimposing the precise location of abnormal metabolic activity (from PET) against the detailed anatomic image (from CT).[39] PET-CT utilizes dual-modality imaging from both PET and CT technology that are performed at the same time on the same machine. [40] The combination of two imaging techniques—called co-registration, fusion imaging or hybrid imaging—allows

[36] *Fact Sheet: What is PET?*, SOC'Y NUCLEAR MED. & MOLECULAR IMAGING, https://www.snmmi.org/AboutSNMMI/Content.aspx?ItemNumber=5649 (last visited Aug. 24, 2022).
[37] *Id.*
[38] *Computed Tomography (CT)*, NAT'L INST. BIOMEDICAL IMAGING & BIOENGINEERING (June 2022), https://www.nibib.nih.gov/science-education/science-topics/computed-tomography-ct.
[39] SOC'Y NUCLEAR MED. & MOLECULAR IMAGING, *supra* note 32.
[40] Tanay Patel & Prabhakar Rajiah, *Lung Metastases Imaging*, MEDSCAPE (Sept. 30, 2018), https://emedicine.medscape.com/article/358090-overview.

information from two different types of scans about the body's anatomy and metabolic function to be viewed in a single set of images to provide a more detailed image of tissues and organs inside the body, than either a stand-alone PET or CT can provide.[41] The result is a highly detailed image that can pinpoint the anatomic location of abnormal metabolic activity.[42] The combination of these two technologies leads to more precise information and more accurate diagnoses. [43] PET-CT scans also reduce the number of additional imaging procedures a patient may need. [44]

PET-CT services are widely used in oncology, neurology, and cardiology among other clinically appropriate applications due to the significant clinical benefit of early detection of disease through more accurate imaging and the convenience of fewer scans. The combined PET-CT technology has a higher level of accuracy than either PET or CT individually. This allows physicians to better diagnose disease, as well as plan and monitor response to treatments more effectively. It is also efficient and convenient for both physicians and patients as it avoids scanning delays associated with separate or sequential PET and CT scans as the patient has to undergo only one scan.[45] Research into the various uses and benefits of PET-CT is ongoing and uses are continually developing for expanded clinical applications. For example, application of PET-CT has expanded into pulmonary care.[46] CHA's service area has a higher rate of pulmonary disease than the Commonwealth does and further PET-CT developments in this area may be beneficial. There is also early research that it may have future uses to detect and manage multi-organ pathophysiology of long COVID.[47]

Oncology

The most well-known and well-documented use of PET-CT is for oncology. It can detect and stage cancer with its detailed images.[48] It assists with tailoring treatment plans and evaluating the effectiveness of treatment, such as chemotherapy and radiation. [49] It combines PET's

[41] SOC'Y NUCLEAR MED. & MOLECULAR IMAGING, *supra* note 32.

[42] *Positron Emission Tomography- Computed Tomography (PET/CT)*, RADIOLOGYINFO.ORG (Feb. 8, 2021), https://www.radiologyinfo.org/en/info/pet.

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] Selene Capitanio et. al, *PET/CT in Non Oncological Lung Diseases: Current Applications and Future Perspectives*, 25 EUROPEAN RESPIRATORY REV. 247 (2016), available at https://err.ersjournals.com/content/25/141/247.long.

[47] Martina Sollini et. al, *Long COVID Hallmarks on [18F]FDG-PET/CT: A Case-Control Study*, 48 EUROPEAN J. NUCLEAR MED. & MOLECULAR IMAGING 3187 (2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7937050/. *See also* CHNA, *supra* note 7.

[48] Heiko Schoder & Mithat Gonen, *Screening for Cancer with PET and PET/CT: Potential and Limitations*, 48 J. NUCLEAR MED. 4S, 12S (2007); RADIOLOGYINFO.ORG, *supra* note 38; Jun Li & Ying Xiao, *Application of FOG-PET/CT in Radiation Oncology*, 3 FRONTIERS IN ONCOLOGY 1 (2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3622875/.

[49] Landis K. Griffeth, *Use of PET-CT Scanning in Cancer Patients: Technical and Practical Considerations*, 18 BAYL U. MED. CTR. PROCEEDINGS 321 (2005), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1255942/.

incomparable ability to determine the metabolic activity of tissues with CT's high-resolution anatomic information to offer an integrated data set and improve accuracy and localization of many lesions. PET-CT allows physicians to identify the appropriate location for a biopsy, determine the efficacy of cancer treatment and assist in planning for radiation therapy.[50] The PET-CT scan's sensitivity and specificity can provide invaluable information on the extent of a tumor, as well as target localization.

Neurology

PET-CT has significant potential in the fields of neurology and neuropsychiatry due to the merging of metabolic and anatomic in one examination. PET-CT can increase understanding of the pathogenesis and mechanism of various conditions, including but not limited to, epilepsy and seizures and autoimmune encephalitis ("AE").[51] With regard to epilepsy and seizures, PET-CT provides information both during a seizure and between seizures. During a seizure, the hybrid scan shows the area responsible for the seizure as an area of increased glucose use, and between seizures, the hybrid scan shows a characteristic pattern of reduced glucose need.[52] Additionally, research indicates that PET-CT may be helpful in supporting evidence of brain dysfunction in suspected patients with AE.[53]

Cardiology

PET-CT is also becoming more widely used for early detection and treatment of cardiovascular disease[54]. PET-CT can be used to quickly and effectively evaluate patients suspected of having coronary artery disease by obtaining information on coronary anatomy as well as the heart's level of functioning.[55] Various PET radiotracers are capable of probing molecular processes and tracking biologic pathways inside the body, making PET a powerful technology for understanding

[50] RADIOLOGYINFO.ORG, *supra* note 38; Stasa Jelercic & Mirjana Rajer, *The Role of PET-CT in Radiotherapy Planning of Solid Tumours*, 49 RADIOLOGICAL ONCOLOGY 1 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4362600/; *Positron Emission Tomography and Computed Tomography (PET-CT) Scans*, CANCER.NET (Feb. 2020), https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/positron-emission-tomography-and-computed-tomography-pet-ct-scans.

[51] Julie Guerin et al., *Autoimmune Epilepsy: Findings on MRI and FDG-PET*, 92 BRIT. J. RADIOLOGY (2019), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6435058/.

[52] Ismet Sarikaya, *PET Studies in Epilepsy*, 5 AM. J. NUCLEAR MED. MOLECULAR IMAGING 416 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4620171/.

[53] John C. Probasco et al., *Abnormal Brain Metabolism on FDG-PET-CT is a Common Early Finding in Autoimmune Encephalitis*, 4 NEUROLOGY: NEUROIMMUNOLOGY & NEUROINFLAMMATION 1 (2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5442608/.

[54] Anna Rosiek & Krzysztof Leksowski, *The Risk Factors and Prevention of Cardiovascular Disease: The Importance of Electrocardiogram in the Diagnosis and Treatment of Acute Coronary Syndrome*, 12 THERAPEUTICS & CLINICAL RISK MGMT. 1223 (2016), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4982493/.

[55] Knaapen et al., *supra* note 31.

cardiac physiology, myocardial viability, and disease processes.[56] In addition, CT produces images of cardiovascular structure. Given the utility of both PET and CT imaging systems when used independently, an integrated PET-CT modality provides significant incremental benefits to the data provided by each modality alone. Specifically, the hybrid modality's simultaneous quantification of cardiac perfusion and assessment of coronary artery anatomy allows for direct comparison of the extent of stenosis and the severity of obstructed blood flow, and therefore provides a wealth of complementary information in the evaluation of coronary artery disease ("CAD").[57] Moreover, the PET-CT provides improved characterization of atherosclerotic plaque and risk stratification in patients, and thus is clinically applicable in staging and managing CAD.[58] Images from the combined scans can also aid in treatment decisions, by detailing the effects of a heart attack, or myocardial infarction, on areas of the heart and identifying areas of the heart muscle that would benefit from treatments such as angioplasty or coronary artery bypass surgery.[59]

F1.b.ii Public Health Value /Outcome-Oriented:

> **Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.**

The Applicant anticipates that the Proposed Project will provide CHA's Patient Panel with timely, convenient and integrated care at a central, accessible location and will directly and positively impact health outcomes, quality of life and patient satisfaction. Studies indicate that delayed access to healthcare services results in decreased patient satisfaction, as well as negative health outcomes due to delays in diagnosis and treatment.[60]

When determining need for PET-CT, a patient's underlying condition and diagnosis will be the basis for determining whether the patient meets appropriate clinical protocols for PET-CT through clinical decision support. If so, access to the PET-CT Service for CHA patients will lead to improved health outcomes, by allowing clinicians to gain a better understanding of an individual's condition and provide appropriate comprehensive treatment options in a timely

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[56] Caitlund Q. Davidson et al, *Searching for Novel PET Radiotracers: imaging cardiac perfusion, metabolism and inflammation*, 8 AM. J. NUCLEAR MED. MOLECULAR IMAGING 200 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056242/.

[57] Knaapen et al., *supra* note 31.

[58] Patricia M Sánchez-Roa et al., *Systemic Atherosclerotic Plaque Vulnerability in Patients with Coronary Artery Disease with a Single Whole Body FDG PET-CT Scan*, 8 ASIA OCEAN J. NUCLEAR MED. BIOLOGY 18 (2020); available at https://pubmed.ncbi.nlm.nih.gov/32064279/.

[59] RADIOLOGYINFO.ORG, *supra* note 38.

[60] Julia C. Prentice & Steven D. Pizer, *Delayed Access to Health Care and Mortality*, 42 HEALTH SERVS. RSCH. 644 (2007), available at https://www.ncbi.nlm.nih.gov/pmclarticles/PMC1955366/.

manner. By having easier access to the PET-CT Service through a patient's regular primary care provider, patient satisfaction, health outcomes and quality of life will improve.

As discussed above in the application, the PET-CT Service will be integrated into the CHA EHR. Studies show that having access to integrated health information systems, including integrated PACS information, has a direct impact on health outcomes as access to a single medical record for patients leads to enhanced care coordination by care teams. Additionally, an integrated medical record allows primary care physicians and specialists to have access to the same patient information, allowing for real-time care decisions. It also reduces duplication of services and unnecessary testing. Because the Proposed Project is integrated into CHA's EHR it will facilitate quick and easy access to patient images and reports, which will in turn effect timely care, improved outcomes, and better quality of life.

Additionally, core to its mission, the Applicant promotes health equity by providing everyone with an equal and fair and just opportunity to be as healthy as possible. This means giving all members of the community - regardless of who they are, how much money they have, or what neighborhood they live in - the same chance to achieve their best care. As emphasized throughout this application, one of the primary reasons for the Proposed Project is to address health inequities by improving access to CHA's safety net population through greater availability of a PET-CT Service at a location that is convenient and centrally located in CHA's service area and accessible by multiple means of transportation. The Proposed Project should also reduce TME for the Applicant and in the Commonwealth as a whole as it will allow CHA to more effectively manage its costs for its primary care patient population who are in risk-bearing contracts as described in F1.a.iii.

To assess whether the proposed project is achieving these aims, Applicant will use the following measures:

Measure 1

Access Measure – Time to the Next 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.

Measure 2

Clinical Decision Support ("CDS") – 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). The Applicant anticipates that it will continue to perform well with respect to ensuring unnecessary 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 on an annual basis.

F1.b.iii Public Health Value /Health Equity-Focused:

For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need- base, please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g. culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

The Proposed Project falls within 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. By providing increased access and improved patient service, the Proposed Project will address inequities arising from income status and linguistic or cultural background. As highlighted above, CHA's primary care patient population including the MMCREW area needs improved local access to essential outpatient radiology services. The demographics of the Patient Panel further show that this need must be met in a culturally competent manner and by ensuring that the patients and communities served by CHA receive timely high quality care.

The Proposed Project will enhance CHA's ability to provide timely and convenient local care to its patients. Enabling more patients to receive imaging services at CHA Malden Care Center will alleviate the burden of time associated with receiving care. As indicated, delays and wait time are a burden for many patients who can ill afford the additional time for work. Reliably available services also reduce the need to refer patients to other facilities, thereby reducing the burden of travel time (an expense), inconvenience, and out-of-pocket costs.

Through the Proposed Project CHA will be able to address health inequities arising from linguistic and cultural barriers to care. CHA serves one of the most linguistically and culturally diverse patient populations in the United States. Over half of its patients speak a language other than English at home. Almost half (approximately 42%) of CHA's primary care patient population has limited English proficiency and need access to professional medical interpreter

services. CHA provides extensive linguistic and cultural support to its patients, including patients receiving imaging services, through its Multicultural Affairs and Patient Services department ("MAPS"). MAPS regularly provides interpreter services in more than sixty languages to all CHA sites. Interpreter services also handle requests for the deaf or hard of hearing, including American Sign Language and CDI services. To help bridge linguistic and cultural gaps, MAPS provides professional medical interpreters via face-to-face, telephonic and video conference; 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. As noted above, in FY2021 alone, MAPS provided interpreter services to approximately 490,000 unique patients through 560 interpreter assisted encounters in 120 different languages. CHA's patients' use of MAPS' services is growing at a faster rate than CHA's Patient Panel

Language access is available at the information desk, and site maps are provided in English, Portuguese, Spanish and Haitian Creole. By improving CHA's ability to provide care along the continuum of care, the Proposed Project will expand CHA's ability to address health inequities.

F1.b.iv Provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life for the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

The Proposed Project will allow the CHA Patient Panel and in particular the primary care patient population including the MMCREW patient population to have convenient access to an integrated PET-CT Service through their safety net integrated community healthcare system. This delivery model is more convenient and efficient than the existing process whereby patients are referred to outside providers on the periphery of the CHA primary service area. As described earlier in this application, this is a barrier to access and creates operational and administrative inefficiencies that can delay access. For CHA, as an integrated, safety net healthcare system that focuses on health equity as part of its core mission, the Proposed Project will both improve access by increasing capacity and improve patient and referring provider satisfaction by providing faster and easier scheduling and timely delivery of imaging results.

F1.c Provide evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including how the Proposed Project will create or ensure appropriate linkages to patients' primary care services.

Through the Proposed Project, the Applicant will combine physician engagement with a strong technology infrastructure to ensure continuity and coordination of care, improved health outcomes and care efficiencies. The CHA team will schedule the patients and obtain the necessary prior authorization from the payors. The technology infrastructure for the Proposed Project streamlines access for patients and facilitates improved coordination of care among physicians and the rest of the CHA care team. When the scans are performed, the images will automatically go into the CHA PACS system; the report will immediately go to the patient

through the EHR patient portal and to the ordering provider's inbox as well as be available to the patient's CHA care team. This not only eliminates patient barriers to care but also ensures continuity and coordination of care. CHA radiologists will have the benefit of comparing previous images within the CHA EHR and will be able to immediately alert ordering providers of critical results. Patients will also have all their results in one place through the EHR, enabling them to receive their results and easily communicate with their care team.

F1.d Provide evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

The Applicant sought input from a variety of stakeholders in planning the Proposed Project. The Applicant conducted a formal consultative process with individuals at various regulatory agencies regarding the Proposed Project. The following individuals were consulted with regard to the Proposed Project:

- Rebecca Rodman, Esq., Deputy General Counsel, Department of Public Health
- Jennica Allen, Manager of Community Engagement Practices, Office of Community Health Planning and Engagement, Department of Public Health

F1.e.i Process for Determining Need/Evidence of Community Engagement: For assistance in responding to this portion of the Application, Applicant is encouraged to review Community Engagement Standards for Community Health Planning Guideline. With respect to the existing Patient Panel, please describe the process through which Applicant determined the need for the Proposed Project.

The Applicant identified the need to provide timely and convenient access to integrated, high-quality, cost-effective radiology services to CHA's patients. CHA's historical utilization data for PET-CT, which as noted above is under inclusive, demonstrates ongoing demand. Furthermore, the lack of convenient access to PET-CT in CHA's service area for the vulnerable, underserved patient population makes it even more important that these services are provided by CHA. The Applicant engaged the community in order to more fully involve patients and families regarding the Proposed Project.

The Proposed Project was presented a CHA's Patient Family Advisory Committee ("PFAC") on June 16, 2022[61] with 7 members and CHA staff in attendance. The PFAC is composed of CHA patients and their family members as well as CHA staff. The presentation sought to inform PFAC members about the purpose of the Proposed Project and what it would mean for patients. The presentation to the PFAC offered members an overview of current PET-CT operations and how

[61] Both the PFAC and the PAC were updated at subsequent meetings that the Proposed Project would be three days, not the one day as listed on the presentation.

the Proposed Project will benefit current and future patients. Details included the plans to partner with Alliance to provide the PET-CT Service. It was also explained that the Proposed Project would be integrated into the CHA EHR and provide for a more convenient, seamless experience that would result in more timely care. The PFAC members generally had positive reactions regarding the Proposed Project and did not voice any concerns with the Proposed Project.

In addition to the CHA PFAC, the Applicant also presented the Proposed Project to the Malden Patient Advisory Committee (PAC) on June 22, 2022 with four (4) members and CHA staff in attendance. The Malden PAC was started by the Family Medicine Training Program that is located at CHA's Malden location and 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 what it would mean for patients. The Malden PAC members generally had positive reactions regarding the Proposed Project and did not voice any concerns with the Proposed Project.

CHA is also in the process of scheduling a meeting with its Community Health Advisory Council (CHAC) to present the Proposed Project and engage in a discussion with the CHAC members. The CHAC is made up of members that represent local social service and advocacy organizations, community coalitions and local officials from the CHA service area. The CHAC's focus is to assess community health gaps and needs, identify community and public health priorities across CHA and help develop strategies for community health improvement.

Factor 2: Health Priorities

Addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

F2.a Cost Containment:

Using objective data, please describe, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment.

The Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment by reducing costs while improving the quality of care through increased efficiencies in operations and reduction in delays to care. The Proposed Project will enable the Applicant to ensure that its patients needing PET-CT services will be able to receive them at a convenient, accessible location that is integrated with their primary care. This ensures continuity of care and

timeliness of appropriate services and avoids risks associated with referring patients to providers outside of CHA. It should also have a negative effect on TME as described in F1.a.iii.

Additionally, the Proposed Project meets the goals of providing a lower-cost alternative since CHA is an integrated health system with a significant portion of its primary care population in risk bearing contracts. Under the Proposed Project, the cost per scan will be less than what CHA is currently paying providers outside of CHA to whom they are currently referring the patients from their risk-based contracts. 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.

In addition to the cost savings, the Proposed Project will better enable Applicant to provide the full continuum of care, which will result in clinical and operational efficiencies.

F2.b Public Health Outcomes:

Describe, as relevant, for each new or expanded service, how the Proposed Project will improve public health outcomes.

The Applicant's ultimate objective is to improve the health of the communities and populations it serves and to address health inequity by reducing barriers to care for these important diagnostic imaging services. The Proposed Project will play an important role in improving public health outcomes and patient experience by creating streamlined pathways for access to high value care. The Proposed Project will better enable the Applicant to keep more care local by ensuring the availability of a PET-CT Service for its Patient Panel. The Proposed Project will provide comprehensive and convenient access to state-of-the-art imaging services to its diverse safety net patient population in a supportive environment in their preferred language. It will create a seamless experience of care through improved care coordination. The Proposed Project will better enable patients to receive timely diagnostic services linked to their primary care provider and care teams to proactively diagnose and treat health conditions prevalent in these geographic, underserved areas.

F2.c Delivery System Transformation:

Because the integration of social services and community-based expertise is central to the goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

CHA assesses the healthcare needs of its Patient Panel and the social determinants impacting these needs on three levels: the individual, panel, and community levels.

On an individual level, CHA addresses these needs through health-related social needs (HRSN) screening. CHA screens patients for the following factors: housing and food insecurity, economic stress, lack of access to transportation, and experience of violence. CHA gives patients who screen positive for these factors a geographically-specific resource guide and refer them to practice-based patient resource coordinators to help connect them with needed services.

At an institutional level, CHA has a community resource database – CHA Connect (powered by Findhelp) – that is integrated into the EHR for staff use and is available to patients via CHA's public website and the EHR patient portal. Patients can apply for free or below-cost services and CHA documents information in the clinical record for organizations that choose to participate in using the website.

From a clinical standpoint, ambulatory complex care managers who work as part of the clinical team in developing and implementing an appropriate care plan address psychosocial issues that directly impact the quality of health care and utilization. The department of Population Health Management is responsible for creating and maintaining agreements with various organizations to coordinate the care of our patients. These organizations include home health agencies, skilled nursing facilities, aging service access points, and substance use providers among others.

Moreover, CHA participates in the MassHealth ACO program in partnership with Tufts Health Public Plans. In addition to the screening above, CHA provides Flexible Services, which is a pilot program funded by MassHealth and CMS, providing solutions for housing and food insecurity for certain ACO members who meet certain criteria. These programs, available to approximately 38,000 ACO members, provide essential support in the current economic environment. In addition, 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.

Finally, CHA uses information from its community health needs assessments led by its Department of Community Health Improvement to engage with its local communities. CHA develops relationships with key community-based organizations and municipal partnerships and programs to promote the health and well-being of the CHA Patient Panel.

F1.e.ii **Please provide evidence of sound Community Engagement and consultation throughout the development of the Proposed Project. A successful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value".**

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

- Presentation to CHA PFAC on June 16, 2022, see Exhibit A
- Presentation to the Malden PAC on June 22, 2022

Factor 5: Relative Merit

1) **F5.a.i Describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs as those have been identified by the Applicant pursuant to 105 CMR 100.210(A)(1). When conducting this evaluation and articulating the relative merit determination, Applicant 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.**

Proposal: The Proposed Project will establish a part-time mobile PET-CT Service three days a week at CHA Malden Care Center.

Quality: Care provided through the Proposed Project in collaboration with Alliance, a nationally recognized imaging provider, will provide high-quality images that allow the CHA clinical team to promptly review the scans and assess for the appropriate clinical applications.

Efficiency: The Proposed Project will improve access to care and care coordination for the CHA Patient Panel where the majority are part of its primary care patient population and will remove multifaceted barriers to timely, convenient and integrated care.

Capital Expense: The Proposed Project will entail a one-time capital expense of $430,000.00 to build out the state-of-the art parking pad to support the weight of the mobile van where the PET-CT Service will be located.

Operating Costs: The Proposed Project offers the ability for the Applicant to control the operating costs through its collaboration with Alliance. CHA estimates that by adding the PET-CT Service it will have approximately 20% savings compared to sending CHA patients to providers outside of CHA for these services. Pursuant to a management and services contract with Alliance, the operational cost is based on the volume of PET-CT scans[62]. In addition, the administrative expense to add the PET-CT Service will be minimal. CHA staff already coordinate the pre-scan approvals and post-scan administration for PET-CT referrals outside of CHA. These administrative

[62] See footnote 3 describing CHA's relationship with Alliance

duties will decrease because of this integration. Further, registration for the PET-CT Service will be done by existing CHA employees.

Alternative #1 for the Proposed Project:

Alternative Proposal: The first alternative for the Proposed Project would be to maintain the status quo by continuing to refer CHA patients to providers outside of CHA for PET-CT Services.

Alternative Quality: Based on the administrative burdens and untimely and inconvenient access to care for its patients, CHA has determined that this alternative is not feasible. This system also has unnecessary administrative burdens on the staff who must coordinate with outside imaging providers and obtain prior authorizations. Frequently there are delays with prior authorizations extending the scheduling period. There are also other operational inefficiencies as the report from the non-CHA provider only goes to the ordering clinician. Importing the results into CHA's EHR is a manual process that is often delayed up to a week or more after the scan.

Alternative Efficiency: This alternative has demonstrated that it is inefficient and does not provide convenient access and coordinated care to the CHA patients and providers in an integrated system.

Alternative Capital Expenses: Although this alternative will allow the Applicant to forego capital expenses, it will have an overall negative impact on access, efficiency, quality of care, and patient and provider satisfaction.

Alternative Operating Costs: Taking no action would result in higher operating costs and ultimately higher TME for patients served in the market.

Alternative #2 for the Proposed Project:

Alternative Proposal: The second alternative for the Proposed Project would be to purchase a mobile PET-CT unit to be permanently located at CHA Malden Care Center.

Alternative Quality: Similar to the Proposed Project this alternative would provide high-quality images that allows the CHA clinical team to promptly review the scans and assess for the appropriate clinical applications.

Alternative Efficiency: This alternative would expand access to the PET-CT Service; however, it would likely decrease efficiency because CHA would now have a full-time scanner, which exceeds the needs of its Patient Panel, and for which it would be responsible for all maintenance. Under the Proposed Project, all downtime and maintenance takes place when the mobile unit is off-site and does not interfere with the maximum efficiency that CHA will achieve with the Proposed Project.

Alternative Capital Expenses: The capital expense for this alternative would be significant. Not only would CHA have the capital expense for the construction of the mobile pad as detailed in this Application, but it would also have to invest significant capital into acquiring the PET-CT

outright or leasing it full-time instead of a part-time arrangement with Alliance that meets the needs of the Patient Panel.

Alternative Operating Costs: The operating costs with this alternative would be significant as there would be additional costs to maintaining and operating the full-time PET-CT.

Table 1

CHA Patient Panel

A. Unique Patients Served

	FY20	FY21	FY22
Unique Patients	130,291	143,749	128,856

B. Gender

	FY20	FY21	FY22
Male	56,781	63,048	56,595
Female	72,455	78,530	71,426
Other/Unspecified	1,055	2,171	835
Total	130,291	143,749	128,856

C. Age

	FY20	FY21	FY22
0 to 19	23,770	26,406	29,684
20 to 29	19,318	22,974	19,104
30 to 44	36,613	41,309	34,003
45 to 64	31,108	33,402	30,005
65+	18,427	17,487	15,225
Unspecified	1,055	2,171	835
Total	130,291	143,749	128,856

D. Ethnicity Grouping

	FY20	FY21	FY22
North American/European	54,369	58,313	46,441
Brazilian	20,686	22,188	26,409
Latino - Central American/Mexican	9,513	10,149	10,022
Haitian	8,876	9,038	9,373
South Asian	6,409	6,704	6,679
African American/Black Caribbean	4,325	4,810	4,411
Latino - Caribbean	3,518	3,814	3,440
Other Latino	3,219	3,463	3,239
All Other	19,376	25,270	18,842
Total	130,219	143,749	128,856

E. Patients by Service Area City/Town

	FY20	FY21	FY22
Somerville	17%	20%	16%
Cambridge	15%	14%	14%
Everett	11%	11%	13%
Malden	10%	9%	11%
Chelsea	3%	3%	3%
Revere	6%	5%	6%
Medford	5%	6%	5%
SSA Sub-total	13%	13%	14%
All Other	19%	19%	18%

F. CHA Patient Panel by Payer Mix

	FY20	FY21	FY22
Public/Medicaid/Medicaid MC	40%	39%	48%
Medicare/Medicare MC	9%	8%	8%
Private/Commercial/HMO	44%	44%	41%
Health Safety Net (HSN)	2%	1%	1%
Other (self pay, workers' comp)	5%	8%	2%

Table 2

MMCREW Patient Population (Primary Care Only)

A. Gender

	FY20	FY21	FY22
Male	16,933	18,349	19,418
Female	20,577	21,835	23,909
Other/Unspecified	0	0	0
Total	37,510	40,184	43,327

B. Age

	FY20	FY21	FY22
0 to 19	6,698	7,299	10,796
20 to 29	4,996	5,548	5,746
30 to 53	14,162	15,707	15,689
54 to 64	5,832	6,087	5,779
65+	5,822	5,543	5,317
Total	37,510	40,184	43,327

C. Ethnicity Grouping

	FY20	FY21	FY22
North American/European	12,353	12,764	11,662
Brazilian	6,395	6,854	11,304
Latino - Central American/Mexican	4,075	4,293	4,523
Haitian	3,552	3,588	4,206
South Asian	2,077	2,217	2,362
African American/Black Caribbean	1,109	1,221	1,197
Latino - Caribbean	1,280	1,448	1,290
Other Latino	1,291	1,397	1,371
All Other	5,378	6,402	5,412
Total	37,510	40,184	43,327

D. MMCREW Patient Population by Payer Mix

	FY20	FY21	FY22
Public/Medicaid/Medicaid MC	43%	45%	44%
Medicare/Medicare MC	9%	8%	8%
Private/Commercial/HMO	41%	39%	44%
Health Safety Net (HSN)	3%	2%	2%
Other (self pay, workers' comp)	4%	6%	2%

E. MMCREW Patient Population by Risk Contract

	CY19	CY20	CY21
Commercial	**35%**	**35%**	**30%**
Medicaid	**55%**	**57%**	**62%**
Medicare	**10%**	**8%**	**8%**

Table 3

PET-CT Patient Population[63]

A. Gender

	CY19	CY20	CY21
Male	73	66	67
Female	74	62	66
Other/Unspecified	3	1	1
Total	150	129	134

B. Age

	CY19	CY20	CY21
19 to 54	29	30	38
55-64	40	36	38
65-74	44	43	37
75+	35	19	20
Unknown	2	1	1
Total	150	129	134

A. Race

	CY19	CY20	CY21
White	99	71	87
Black	12	20	19
Asian	7	8	4
Other	18	22	19
Unknown	14	8	5
Total	150	129	134

B. PET-CT Patient Population by Risk Contract

	CY19	CY20	CY21
Commercial	21%	26%	23%
Medicaid	27%	34%	32%
Medicare	51%	40%	45%

[63] As noted in the DoN narrative, CHA extrapolated this data from its population health claims. There are four factors that impact this extrapolated data: (1) risk-based contracts represent approximately sixty (60%) percent of CHA's payor mix and CHA is making an assumption that the prevalence of outmigration for PET-CT services is consistent across all payor sources (e.g. self-pay, Health Safety Net, and fee-for-service); (2) population health claims data is for 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; and (4) the data cannot be broken down by referral and/or specialty that ordered the scan.

C. PET/CT Volume

	CY19	CY20	CY21
# of Scans	311	284	334

Table 4

PET-CT Need

A. Projected PET-CT Market Demand

Service Line	Sub Service Line	2019 Volume	2024 Volume	2029 Volume	5 Yr Growth	10 Yr Growth
Radiology	PET	3,024	3,421	3,739	13%	24%

B. Projected PET-CT Patient Panel Volume and Growth

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

C. Projected referrals[64]

Modality	Referrer Specialty	% of Modality Procedures Associated with Specialty	Average National Annual Referrals per Provider	# of Physicians with Specialty within PSA Cities	Expected Referrals within PSA Cities from Specialty	
PET	Oncology & Hematology	50%	62.7	22	1,380	
PET	Primary Care	12%	1.4	392 (Internal Medicine)	561	
PET	Pulmonology	7%	12.6	14	177	
PET	Cardiovascular	6%	4.3	21	91	
PET	General Surgery	4%	2.6	19	49	
PET	ENT	3%	7.3	13 (Otolaryngology)	95	
		82%			2,351	--> 82% of procedures
						100% of procedures --> 2,868

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[64] Neurology as referring specialty is not included in Table 4.C. This is because the potential neurology related diagnoses that use PET-CT such as dementia or seizures are commonly referred by primary care physicians.