STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	Dana Farber Cancer Institute, Inc.
Applicant Address	450 Brookline Avenue, Boston, MA 02115
Date Received	July 19, 2018
Type of DoN Application	Substantial Capital Expenditure
Total Value	$174,850,000
Ten Taxpayer Group (TTG)	One
Community Health Initiative (CHI)	Total CHI: $8,742,500
Staff Recommendation	Approval
Public Health Council (PHC) Meeting Date	December 12, 2018

Project Summary and Regulatory Review

The Applicant, Dana Farber Cancer Institute, Inc., (DFCI) proposes to open a hospital satellite facility in Chestnut Hill (DFCI-CH) at 300 Boylston Street, in Newton, Massachusetts, 02467. Pursuant to 105 CMR 100.000, the Applicant requests a Determination of Need (DoN) for a substantial capital expenditure to renovate 140,000 gross square feet (GSF) of leased space, and to acquire five pieces of DoN-required equipment. The total value for the Proposed Project is $174,850,000.

Applications for substantial capital expenditures and DoN-required equipment are reviewed under the DoN regulation 105 CMR 100.000. Under the regulation, 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 in 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

Background

DFCI is a not-for-profit acute care specialty clinical, teaching and research hospital offering sub-specialized cancer care services[1] in the Longwood Medical Area (LMA) at 450 Brookline Ave, Boston, MA 02215 (Main or LMA Campus). DFCI also operates four satellites in Massachusetts[2], and one in New Hampshire. DFCI has four physician practices in Massachusetts, provides care for adult and pediatric cancer patients, and is involved in over 800 clinical trials. It is a teaching affiliate of Harvard Medical School.

In 2011, DFCI opened a new hospital building at its LMA Campus which it asserts, based upon utilization trends, is nearing capacity. As a consequence, DFCI argues that approval of the Proposed Project is necessary to meet the demands of its patient panel. Based upon an analysis of its patient panel needs, DFCI suggests that the Chestnut Hill region is accessible and convenient to that portion of its patient panel who would receive treatment for the services proposed there.

The proposed satellite will serve adult patients who have breast, gynecologic, thoracic, gastrointestinal and genitourinary cancers. The proposed project includes the renovation of 140,000 GSF of leased space and will include at completion:

- 45 exam rooms
- 65 Infusion Therapy chairs
- Centralized phlebotomy and laboratory
- Palliative care
- Supportive services: social workers, financial counselors, resource specialists. etc.
- 5 pieces of DoN-Required Equipment
    - 2 MRI's (1.5T and 3T)
    - 2 CT's
    - 1 PET/CT
- Other imaging modalities
- Imaging consultations
- Genetic testing and counseling
- Survivorship programs
- Clinical trials

Analysis

This analysis and recommendation reflect the purpose and objective of DoN which is "to encourage competition and the development of innovative health delivery methods and population health strategies within the health care delivery system to ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation" 105 CMR 100.001.

All DoN factors are applicable in reviewing a capital expenditure project. This Staff Report addresses each of these factors.

[1] Oncology Subspecialties include medical, surgical, radiation, immunology, genetics and within those areas can include such specialties as breast, neurology, genito-urinary, dermatology, cardiology, hematology and pediatrics

[2] In Brighton, Milford, Roxbury, and Weymouth

Factors 1 and 2

Factor 1 of the DoN regulation requires that the Applicant address patient panel need, public health value, and operational objectives of the Proposed Project. Factor 2 considers how the Proposed Project will contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation. Under factor 1, the Applicant must provide evidence of consultation with government agencies that have licensure, certification or other regulatory oversight which, in this case, has been done and so will not be addressed further in this staff report. This analysis will approach the remaining requirements of factors 1 and 2 by describing how each element of the Proposed Project complies with those parts of the regulation.

Patient Panel, Need, and Projected Growth

In the three years 2015-2017,[3] DFCI's patient panel consisted of an average of 86,000 unique patients annually. Approximately 74% of the patients are Massachusetts residents. Approximately 18% of patients reside in the other northeastern states (including New York), and the remaining patients come from within and outside the United States. The Applicant's public payer mix is approximately 47% of its total patients, with 40.4% enrolled in Medicare and 6.8% enrolled in MassHealth. FY18 fiscal data show an increase in the Applicant's public payer mix, with 42.4% of patients enrolled as Medicare beneficiaries and 7.2% of patients enrolled as MassHealth beneficiaries. Staff is informed, as well, that 100% of the employed physicians participate in MassHealth. The patient panel is about 63% female. Based on self-reporting, the racial mix of the DFCI patient panel is 85% Caucasian, 4% African American-Black, 3% Asian, 2% Other, and 3% not reporting.

The incidence rate for cancer in Massachusetts is higher than the national average,[4] and it is the leading cause of death in the Commonwealth. The National Cancer Institute statistics show that advancing age is the most important risk factor for cancer overall. Eighty-eight percent of the DFCI patient panel is over the age of 40, and 10% of the patient panel is age 19-39, while 3% is age 18 and under. Additionally, over the FY 2015-2017 timeframe, the number of patients within the 65+ age cohort increased nearly 11%; the 65+ age cohort represented 43% of the Applicant's panel in FY17.

DFCI asserts that demand for outpatient treatment will continue to increase as the percentage of the population over age 65 increases.[5] DFCI notes that this cohort of older patients experiences a higher incidence of a broad range of cancers.

The annual number of patients seen by DFCI grew from 2015 to 2017 by over 5%. DFCI attributes this growth in demand to the aging population and to what it describes as the now chronic nature of cancer which requires long-term follow-up assessment and treatment. DFCI reports that the LMA facility is on a trajectory to reach capacity there within three years, notwithstanding its already extended hours.

[3] Patient Panel is defined in the regulation as 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.
[4] National Cancer Institute and MA DPH Cancer registry
[5] Population forecasts for Massachusetts predict that by 2035 nearly a quarter of the population will be age 65 and older.

In planning this project to expand capacity, DFCI states that it identified cancers that could be safely and appropriately treated at a satellite facility[6] and estimates that approximately 12,000 patients, or 14% of its Patient Panel seeking treatment for these cancers, live within 10 miles of the proposed satellite. This proposed satellite facility would, DFCI argues, shift volume away from the LMA facility to free capacity for cases that require tertiary and quaternary levels of care and also for patients who live closer to the main campus and/or rely on public transportation. As a complement to the expanded capacity for those patients who are near the main campus, staff suggests that a concerted effort to expand access to care at DFCI, irrespective of payer, will support the Project's goals.

Public Health Value

The DoN regulation requires the Applicant to demonstrate that the Proposed Project will add measurable public health value in terms of improved health outcomes and quality of life for the existing patient panel, while providing reasonable assurances of health equity.

The Applicant asserts new treatment services, new technologies, and scientific discoveries are leading to improved cancer outcomes. They cite in support, documented decreases in rates of incidence and death from certain types of cancer, as well as studies showing that early diagnosis and timely treatment leads to reduced death rates and reduced costs of treatment.[7] [8] DFCI also cites studies that show that treatment of cancer in its initial stages (stages I and II) costs less than treating late stage cancer (stages III and IV). DFCI argues that the additional capacity provided by this facility will improve timely access to care, limiting the negative consequences of delays in treatment.

Imaging Technology

The proposed project includes the addition of five pieces of DoN-required Equipment: 2 MRIs (1.5T and 3T); two CTs; and a PET/CT.[9] These are designated, under the 2017 DoN-Required Equipment and Services Guideline (the Guideline), as equipment that warrants review based on DoN application-specific information due to its potential for clinically unnecessary utilization.[10] In this Application, addition of this imaging capacity has been analyzed as an integral part of the proposed cancer program's need for expanded capacity and in the context of how the project addresses the patient panel need, public health value, and operational objectives.

The Applicant asserts that currently its MRI, PET-CT and CT units are operating at near capacity at the LMA facility. DFCI states that diagnostic imaging plays a critical role in cancer diagnosis, staging, treatment

[6] These include breast, gynecologic, thoracic, gastrointestinal and genitourinary cancers.
[7] *Econ. Impact of Cancer,* AM. CANCER Soc'y, https://www.cancer.org/cancer/cancer-basics/economic-impact-of- cancer.html (last visited July 9, 2018).
[8] Early Cancer Diagnosis Saves Lives, Cuts Treatment Costs, WORLD HEALTH 0RG., http://www.who.inUen/news- room/detail/03-02-2017-early-cancer-diagnosis-saves-lives-cuts-treatment-costs (last visited July 9, 2018).
[9] The Department of Public Health uses an inclusion framework in order to determine what equipment and services require a Notice of Determination of Need. The inclusion framework looks at: Quality: Meaning improved patient health outcomes; Access: Meaning a demonstrable increase in access and reasonable assurances of health equity, including but not limited to a decrease in price; and Cost: Meaning a reduction in the Commonwealth's Total Health Care Expenditure. In consideration of whether the use of specific equipment or service may result in increases in health care spending without associated benefits to the public in terms of improved patient health outcomes or improved access to health care, the Department has included MRI, CT, and PET-CT in its list of DoN-Required Equipment.
[10] https://www.mass.gov/files/documents/2017/01/vr/guidelines-equipment-and-services.pdf.

planning, monitoring and certain palliative therapies used for care, and that imaging is a standard aspect of cancer care. As a result, DFCI argues they must have these services integrated and co-located with the new service capacity in order to ensure timely, accurate diagnoses, staging, treatment planning, and ongoing monitoring.[11] The Applicant argues that obtaining precise images reduces patient suffering and unnecessary treatment with its associated costs, to patients and the system. DFCI will extend to the proposed satellite a set of quality metrics for reporting on patient satisfaction, access and quality of care.

Health Equity

The Applicant reviewed data for the zip codes within its Community Health Needs Assessment (CHNA) targeted areas and found that approximately 2,500 patients from these zip codes targeted within the CHNA seek services at the LMA campus annually. DFCI asserts that providing capacity for some cancer care at the proposed satellite will improve access to timely and efficient care at the LMA facility for those patients living within the adjacent neighborhoods. DFCI points to the well-documented disparities in cancer incidence and mortality among economically and racially diverse populations and affirms its commitment to addressing those disparities. Staff suggests that a concerted effort by DFCI and its physician network to provide consistent access to the high quality clinical services irrespective of payer would be fortified by an analysis of ways in which the quality care offered by DFCI clinicians can be made accessible regardless of payer. DFCI cites its involvement in outreach partnerships aimed at improving prevention, screening, education and vaccine administration, improving access to early treatment[12] and other public health programs that are intended to support access for every patient to equitable and culturally appropriate care and reduce cancer incidence and mortality.

One program that aims to reduce cancer disparities and promote health equity is the Applicant's Community Care Equity Program ("CCEP"). Established in 2012, the CCEP is designed 1) to improve local outcomes via clinical access to the spectrum of preventive medicine, treatment, and to clinical trials for medically underserved populations; 2) to unite disparities-related research across the Applicant's facilities; 3) to initiate and facilitate research in cancer disparities; and 4) to support established outreach and educational programs. DFCI asserts that by directly involving and encouraging patient centered collaborations between oncologists and primary care clinicians, it establishes trust and a high level of comfort which is reflective of its commitment to treatment equity.

DFCI will implement two internal operational strategies that it asserts improve health equity at the proposed satellite. These are next day appointments and supportive navigation services. The supportive services link patients, their families and caregivers with local resources. DFCI asserts that these services offer assistance related to the social determinants of health that may be exacerbated during treatment; including lack of housing while undergoing treatment; lack of appropriate food; a lack of transportation; language barriers; and the need for pro bono legal services. In support of what it describes as patient centered care, patients are provided with an infusion nurse who follows patients throughout their treatment. The infusion nurse initially and periodically assesses patient needs, and provides what they call a “warm hand-off” to the appropriate resource specialist who matches them with appropriate services. DFCI states that the proposed Chestnut Hill satellite will have an onsite Spanish-speaking interpreter, and that assessment of the need for additional interpreters will be made over time.

[11] DFCI also reports that its imaging units (MRI, CT and PET-CT) at the LMA facility are operating at approximately 90% supporting its argument in favor of additional capacity.

[12] DoN Application pp. 32-35 These include their mobile mammography, HPV vaccination, tobacco cessation embedded in the communities that the applicant serves such as work with community health centers and schools, and access to clinical trials.

To ensure effective administration and assessment of language access and patient navigation resources, DFCI has developed a database to track the referrals to resource specialists and the resources that patients utilize and need. DFCI asserts that the database maximizes the impact of the team approach and ensures that patients receive the resources they need thereby reducing barriers to care. To assess the impact of the proposed project DFCI will report on a set of assessment metrics related to access, patient satisfaction, and quality of care.

Competitiveness and Cost Containment

DFCI points to its electronic health records (EHR) as a tool that saves time and resources by improving communications, care coordination and efficiencies among providers. In addition, DFCI points to efforts to implement cost effective strategies in its delivery of cancer services which are available at existing satellites and will be extended to the Chestnut Hill site. DFCI describes its second opinion consultation review, through which oncology imaging sub-specialists support patient care and improve its efficacy, as well as minimize the overall cost by ensuring correct diagnoses and staging.

DFCI also points to the value-based Clinical Pathways tool, in use since 2012. This is an evidence-based, integrated clinical decision-support tool that, according to the Applicant, has demonstrated improved value by reducing unnecessary variation in decision-making based on cancer diagnosis, stage, tumor biology, line of therapy, and patient characteristics. DFCI asserts that the tool standardizes treatment and resource use, resulting in efficiencies and cost savings while maintaining comparable clinical outcomes. Findings of a study conducted of non-small cell lung cancer after using the tool revealed that the total cost of ambulatory care decreased by more than $15,000 per patient after the implementation of the clinical pathways ($67,050 before pathways versus $52,037 after pathways). Savings were achieved partially, by reducing the use of selected high-price regimens that were not associated with significant clinical benefit.[13] The Applicant asserts that when applied to a larger population the savings and efficiencies will be maintained or improved further lowering TME.

Community Engagement

The DoN Regulation requires that, prior to submitting a DoN application, the Applicant has engaged and consulted with the community. The Community Engagement Standards For Community Health Planning Guideline describes community engagement processes on a continuum from "Inform" and "Consult" through "Community driven-led."[14] For the purposes of factor 1, the relevant population defined as "community" is the Patient Panel, and the minimum level of engagement for this step is "Consult."[15]

In March 2018, during the planning phase of the Proposed Project, the Applicant along with the Patient Family Advisory Committee (PFAC)[16] Co-Chairs presented the Proposed Project to the PFAC. The

[13] David M. Jackman et al., Cost and Survival Analysis Before and After Implementation of Dana-Farber Clinical Pathways for Patients with Stage IV Non-Small-Ce/I Lung Cancer, 13, J. OF ONCOLOGY PRAG., e346, e346-e352 (2017).
[14] https://www.mass.gov/files/documents/2017/01/vr/guidelines-community-engagement.pdf
[15] Id at Page 13
[16] The adult PFAC of up to 20 members is governed by written policies and procedures and is open to all of the Applicant's adult patients, family members, and caregivers, through an application process. DFCI states that its staff regularly compares the demographic profile of the PFAC with that of their patient panel to ensure representation. The PFAC members "collectively seek to ensure that DFCI provides patient- and family-centered care with a commitment to dignity and respect, information sharing, participation and collaboration." According to DFCI, the combined mission of the DFCI adult and pediatric PFACs is: (1) to help

presentation included background, a timeline, and a brainstorming and discussion session, and the Applicant reports that all feedback from PFAC members was positive, with thoughtful contributions around the types of integrative and supportive therapies that might be provided at the CH site.

The Applicant held two community information public sessions in March 2018; one was at the LMA campus and the other was in the Chestnut Hill area. These meetings were publicized on the Applicant's website, in Patient areas at the LMA Campus and at various community locations in the Chestnut Hill area. In addition to staff, a total of five community members at both sites attended. Feedback forms were distributed and DFCI reports that feedback was positive and supportive of the plan, and within the community, there was enthusiasm for the site becoming health and wellness focused. The minutes reflect that the group expressed no concerns. Further, the Applicant posted a designated project-related email for the submission of feedback and questions. At the time of DoN submission, one staff email was received and answered; no emails were received from the community. DoN staff reviewed the slides and minutes of these meetings and found that in the context of factor 1 the Applicant met the community engagement standards in the planning phase of the Proposed Project.

Factor 3

Factor 3 requires compliance with relevant licensure, certification, or other regulatory oversight. DFCI has certified that it is in compliance and in good standing with federal, state, and local laws and regulations, including, but not limited to M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder, and in compliance with all previously issued notices of Determination of Need and the terms and conditions attached therein.

Factor 4

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 (CPA Report). The Applicant submitted an analysis performed by BDO, USA, LLP (BDO)dated July 18, 2018.

In order to assess the reasonableness of assumptions used, and the feasibility of financial projections, the CPA Report reflects a review and analysis of 26 reports including the Applicant's 2017 audited financial statements; historical and projected volume and cash flow; the 2018 DFCI financial projections; the Chestnut Hill lease; six years of financial projections for the satellite and historical volume. In addition, the CPA reviewed key industry metrics of two industry reports.[17]

Financial projections show a cumulative operating surplus of approximately 1.9% of cumulative projected revenue for DFCI for the six years reviewed, 2018-2023. For the first three years, prior to project

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disseminate information and implement services that affect the Applicant's patients and their families; (2) to support patients and their families becoming informed advocates for their own care; (3) to offer a patient and family voice; (4) to initiate ideas for policies, programs, projects, and services within the patient care environment; and (5) to provide ongoing opportunities to hear the voices, experiences, and perspectives of patients and their families.

[17] IBISWorld Industry Report, Specialty Hospitals in the US, 2017; and FMA Statement Studies, published by Risk Management Associates, March 31, 2016

implementation a net decrease in cash is projected, followed by an increase in cash flows when the project is in operation.

Approximately 66% of revenue is derived from N*et* P*atient* S*ervice* R*evenues* (NPSR), while one third is from *Research*, *Net Assets Released*, *Unrestricted Gifts,* and *Other Operating Revenues* combined. The Applicant presented estimates of increases in NPSR ranging from 7% to 10% annually (with the exception of the first full year of operations where the Applicant estimates it will be 18.0%) based on anticipated changes in volume of visits. On a per visit basis, only the *Infusion* and *All Other* components of NPSR are projected to increase due to anticipated increases in pharmaceutical (under *All Other*) prices which will occur at all sites with or without the project. While volume increases are anticipated for imaging and radiation therapy services, they only account for approximately 10% of total NPSR. Projected growth in NPSR for imaging ranges from -5.6% to 1.7% while growth for radiation therapy is 1.3-2.7%.[18]

BDO reports that almost 50% of expenses relate to direct patient care expense; and that projected direct patient care expenses for each service and year were within range or above historic metrics except for laboratory services, which were slightly below the historic per visit projections.[19]

BDO also analyzed the capital expenditures, cash flows, and financing to determine whether DFCI would have sufficient funds and cash flow for the Proposed Project. The Proposed Project represents approximately 17.8% of cumulative capital expenditures. The renovation cost of $101 million includes a 14% contingency and will be funded through net assets and cash flows with no debt financing. Based on that review, the report stated that the capital obligations, expenditures, and resulting impact on cash flows are reasonable.

The CPA Report determined that the Proposed Project is financially feasible, within the financial capability of Partners and based upon feasible financial assumptions.

Factor 5

Factor 5 requires the Applicant to "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 and addressing, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes."

The Proposed Project is a renovation within an existing multi-use structure on Route 9 in Newton. Following a geographic patient origin analysis of where patients live, the Applicant determined that the satellite should be situated along the Route 9 corridor outside of Boston because of its easy access to major highway exchanges linking the north, south and west. After looking at a number of available sites, the Applicant selected the one in Chestnut Hill because of its accessible layout and of ease of renovation to accommodate the proposed services, parking within a covered garage, and because it is in close enough proximity to the Main Campus to allow for effective clinical collaboration and efficient leveraging of resources.

[18] While Radiation therapy is not a component of this satellite project, associated revenue and expenses have an impact on the overall DFCI financial performance.
[19] Laboratory per/visit expense projected $141-$145 vs. $147 in FY 2017.

The Applicant looked at the relative merit of building additional capacity at the main campus in the LMA. Expansion at the LMA Campus was eliminated because the capital costs of new construction were significantly higher there than renovating the existing CH site, as were operating costs attributable to higher space and utility costs. Additionally, accessibility to the LMA Campus for those coming by car is more difficult and parking more expensive than at the CH site where it is free.

In sum, the Applicant asserts that of the all the sites and options considered, the Proposed Project is the superior option because it will enable the provision of high quality services in a site designed and equipped for the diagnostic (imaging and laboratory), infusion therapy, and other treatments (including palliative care) in an efficient cost effective site.

Factor 6

Background

The Community Health Initiative (CHI) component of the DoN regulation requires approval of the Applicant's plans for fulfilling its responsibilities set out in the Department's Community-based Health Initiatives Guideline (Guideline). This is a Tier 3 project, which applies to projects with a CHI contribution greater than $4,000,000. The Applicant, as required, submitted documentation showing that the existing community health needs assessment (CHNA) and community health improvement planning (CHIP) processes, evidence a sound community engagement, and demonstrate an understanding of the DoN Health Priorities sufficient for selecting strategies to fund and implement following approval of the DoN project. Tier 3 Applicants are further required to submit a Community Engagement Plan at the time of application because the Guideline states that additional community engagement must take place to develop priorities prior to submitting the Health Priorities strategy selection form to DPH. The Applicant submitted a Community Engagement Plan.

If the DoN is approved by the Department, the Applicant (then Holder of a DoN) will work with its CHI Advisory Committee (which needs to meet the Departments standards) to complete any additional community engagement requirements and select Health Priority strategies for funding and implementation These Health Priority strategies may come from the existing CHNA/CHIP or other assessments as required by the Department. Fulfillment of these processes, including the selection of the Health Priorities and the funding decisions, are conditions of the DoN and enforceable as such.

This Application

The Applicant submitted the following: a CHNA/CHIP Self-Assessment, 6 Stakeholder Assessments, a Community Engagement Plan[20], and the 2016 Dana Farber Cancer Institute's Community Health Needs Assessment. Staff from DPH's Office of Community Health Planning and Engagement as well as 5 members from DPH's Cross-Bureau Community Engagement Workgroup conducted the review of these materials. Summary review comments provided to the Applicant and the Applicant responses are included as Attachment 1. Staff points out the Applicant will not use the 2016 CHNA as a foundation for CHI decisions, rather that CHI decisions shall be made as part of the 2019 CHNA cycle. For the first time, the hospitals which comprise the Consortium of Boston Teaching Hospitals (COBTH) are conducting a joint CHNA/CHIP

[20] The Community Engagement Plan describes actions for the "Acting on What's Important" and "Evaluating Actions" stages of the CHNA/CHIP cycle

process which will be completed by September 2019. DPH is highly supportive of joint CHNA/CHIP processes in similar geographies and believes this represents the best opportunity for both leveraging CHI resources across health systems, and for leveraging and coordinating related community engagement activities. At the time of this Application there was not enough known about the 2019 CHNA/CHIP process to include details in the submitted Community Engagement Plan and accordingly DPH will require a new Community Engagement Plan to be submitted and reviewed in December 2018, that will coordinate with the community engagement activities planned for the 2019 CHNA/CHIP. With the CHI Conditions set out below, the Proposed Project can be found to comply with the provisions of factor 6.

Public Hearing

At the request of the Ten Tax-payer group representing Sturdy Memorial Hospital (Sturdy), a public hearing was held at the Department of Public Health on September 20, 2018. Twenty-two individuals commented on the project. Most comments were from clinical staff and those involved in the DFCI work supporting the Social Determinants of Health (SDoH). These speakers spoke in favor of the project citing the need for more services at DFCI in order to ensure timely appointments and increased access to innovative treatments that are being developed. They also addressed the importance of the project as a way to minimize health inequities and disparities in cancer treatment through attention to the SDoH.

The Chief Executive Officer and the Oncology Program and Clinical Manager from Sturdy Memorial Hospital (Sturdy)[21] both testified and addressed a separate project being developed by DFCI at a location in Foxboro, MA. They indicated that the DFCI Foxboro satellite is reportedly only a portion of a 300,000 square foot health facility being developed in conjunction with Partners HealthCare. They indicated their concern that the proposed Foxboro project would be likely to draw patients away from the Sturdy cancer center. They describe the Sturdy cancer center as providing a full continuum of integrated cancer care serving eleven surrounding communities, including Foxboro. They acknowledge that approximately 15% of their more complex tertiary patients do receive treatment at existing DFCI sites with whom they say they have a strong relationship. They claimed that neither Sturdy nor the public was invited to participate in any of the planning phases of the new Foxboro site and that as a result, they have no way of knowing whether the intent of the new site, like the Chestnut Hill site, is to free up capacity at the main campus. The CEO of Sturdy stated that DPH and HPC have designated independent community hospitals such as Sturdy as "deserving of protected status." They pointed to the DoN regulation which requires that new ambulatory surgical capacity located within the service area of independent community hospital must, either be a joint venture partner, or obtain a letter of support from a community hospital. In that context they wondered whether it would not also make sense, given the complexity and expense of operating a cancer center, to offer similar protections in the case of other ambulatory capacity.

The Applicant, speaking only with respect to the proposed project that is the subject of this DoN, stressed that the volume projections for this DFCI-CH satellite took into account the patient panel data from its LMA Campus only and stated that there is no anticipated impact of this project on its two existing South Shore satellites.

[21] Sturdy is an independent 132-bed disproportionate share hospital (DSH) meaning that it serves a disproportionate number of patients on public insurance programs, including MassHealth and Medicare.

Findings and Recommendations

The Applicant has provided evidence that the Proposed Project is likely to improve patient access to care by accommodating the growing demand for a number of sub-specialty cancer services in a suburban satellite. The proposed project will help to meet the needs of the aging population in a broad geographic region. The Applicant complies with factor 3; based upon the CPA analysis, the Proposed Project is financially feasible in the context of factor 4; expansion into a renovated facility is, on balance, the superior alternative for meeting the Patient Panel needs from the perspective of quality, efficiency, and capital and operating costs as required by factor 5; and the Applicant is in compliance with the requirements of the CHI planning process for the purposes of factor 6 subject to the CHI Conditions and Timeline and the Community Engagement Plan pursuant to 105 CMR 100.310(J).

Based upon a review of the materials submitted, Staff finds that with the conditions below and set out in Attachment 2, the Applicant has met each DoN factor and recommends that the Department approve this Determination of Need application for an expansion satellite clinic including 65 infusion chairs, 45 exam rooms, and DoN-required equipment (2 MRI's, 2 CT's, 1 PET/CT) subject to all standard conditions (105 CMR 100.310). In compliance with the provisions of 105 CMR 100.310(L) and (Q), which require a report to the Department, at a minimum on an annual basis, including the measures related to achievement of the DoN factors for a period of five years from completion of the Proposed Project, the Holder shall address its assertions with respect to the cost and quality and access benefits of this satellite site with appropriate metrics.

<u>Other Conditions (CHI)</u>

1. Of the total required CHI contribution of $8,742,500, $2,141,912 will be directed to the CHI Statewide Initiative, $6,425,738 will be dedicated to local approaches to the DoN Health Priorities (includes resources for evaluation of strategies), and $174,850 is allowed, pending full explanation in the revised Community Engagement Plan, to be used for administrative purposes to implement community engagement activities and management of CHI processes such as issuing RFPs, and related activities. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $2,141,912 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative). The Holder must submit the funds to HRiA within one month from the date of the Notice of Approval. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

2. Funds will be distributed over a 3-5-year period subject to choice of Health Priority strategies and final Department approval and based on the CHI Timeline (Attachment 2).

3. A revised Community Engagement Plan will be submitted by December 15th, 2018. All activities described in the revised Community Engagement Plan to be submitted and approved by DPH by December 15th are conditions of approval.[22]

[22] In this context, DPH notes and understands the nature of the care provided by the Applicant (a comprehensive cancer care institute) while noting its intention to broaden community engagement activities beyond those employed for the Applicant's 2016 CHNA.

4. The Community Engagement Plan will include memorandum of understanding or a charter type document formally describing the decision-making role of the advisory committee members.

5. The Community Engagement Plan will include a new member representing the Transportation and Planning sector.

6. The 2019 CHNA/CHIP will include an analysis of social determinant of health information consistent with DPH's Health Priorities and the 2019 CHNA/CHIP will be the basis for choosing funded strategies.

7. Compliance with the CHI timeline, set out at Attachment 2, shall be a condition to this DoN. (see Attachment 2).

8. Pursuant to the Standard Condition set forth in 105 CMR 100.310(L), the Holder shall annually report on the payer mix of its patient panel. If there is a material decrease in the Holder's public payer mix, the Holder shall provide justification for such change and propose a remedial plan to increase public payer mix.

ATTACHMENT 1
These are NOT conditions to the DoN.

Summary Feedback and Questions regarding Dana Farber Cancer Institute's CHI Application materials

As described in the Community Engagement Plan form we will need the submitted Community Engagement Plan to be revised to include plans for the "Focus on What's Important" and "Choose Effective Policies and Programs" stages of the CHNA/CHIP process. Tier III applicants are expected to utilize the existing CHNA as a basis for decision-making but not exclusively, e.g. additional engagement is necessary for Tier III projects to develop issue priorities and strategies. In elaborating on these stages, we are interested in learning how you are thinking about the 2019 CHNA cycle and what from that process could be leveraged to assist with DoN-CHI community engagement? Please note that the Community Engagement Plan becomes a formal reporting tool so the more detail that is included the easier it will be to follow. We also recognize that the advisory committee(s) will and should play a role in community engagement and that it may change as a result of the committee's feedback.

- Background question regarding the cycles of community health improvement planning: To help us think about how the 2016 CHNA will be used as a basis for DoN-CHI decision-making, we would find it helpful to understand how the 2013-2016 cycle of community health needs assessment, planning and implementation informed how the 2016-2019 cycle has been implemented. What was trying to be accomplished, what was accomplished, what did you learn, etc.? We are trying to understand how or if a continuous improvement planning process is used that will be informing how the DoN-CHI decisions will be made?

- Advisory Committee questions

    - Structure and decision-making: We were somewhat confused about the three different advisory committees referenced in the application materials. Could you provide a visual and/or additional narrative describing how the three committees work, whether they are internal or external (and what that actually means), what type of decision-making role they have and over what decisions they have authority or are involved with?

    - Representation of issues identified in the 2016 CHNA: the 2016 CHNA elaborates on many social determinants of pressing need and concern for the community. Can you describe how the advisory committee(s) represents those issues and if additional recruitment is necessary how that will happen? We have noted that Transportation and Planning is lacking from the DoN Advisory Committee. Can you provide information on recruitment for that person(s)?

- While completing and adding to the Community Engagement Plan the following elements and thoughts were raised by the review committee:

    - Reducing Barriers and Communication: there is mention of a robust communication plan that has been developed. Can you provide us with that plan? Committee members noted a lack of detail on how barriers will be reduced for community members of all types to participate in the DoN-CHI process. For example, what types of incentives could be used to

engage people (e.g. how can “bidders conferences be re-thought as capacity building opportunities) and how will specific barriers be reduced?

- Build Leadership Capacity: can you provide some additional information or ideas on how leadership capacity of community members and the advisory committee(s) could be enhanced through the DoN-CHI process?

- Reporting: There was a general comment that plans for reporting to different community/population groups were too generic. Can you provide some additional thinking on how reporting plans can be enhanced for different population groups?

- Social Determinants of Health and Prioritization of issues and strategies:

  - A general comment from the reviewers is that while the 2016 CHNA identified many social determinants (both through quantitative data and from community members) as pressing concerns that the choice of practices and strategies for implementation did not directly address those issues. This disconnect is important to address and understand in the context of DoN-CHI decision-making. Please provide some additional information on how this issue will be addressed moving forward.

- Administrative allowance: please provide additional detail and information about how the administrative resources will relate to the actions described in the Community Engagement Plan.

ATTACHMENT 2
CHI Timeline for Dana-Farber Cancer Institute
Required Pursuant to Condition 7

- By December 15th complete and submit a revised Community Engagement Plan to DPH based on the community engagement activities planned for the COBTH 2019 CHNA/CHIP.
- One to three months post-approval: Dana-Farber begins working with a third-party evaluator to evaluate all aspects of engagement and the CHI activities.
- One to five months post-approval: Additional community engagement activities are carried out to supplement the Collaborative's community engagement activities.
- Six to seven months post-approval: 2019 CHNA and additional community engagement activities completed; summary report on community engagement activities is submitted to DPH.
- Seven to eight months post-approval: The External DoN Advisory Committee begins selection of the Health Priorities for CHI funding based on the priorities identified through the 2019 CHNA/CHIP.
- Eight to nine months post-approval: The External DoN Advisory Committee selects Health Strategies for noted Health Priorities and submits the Health Priorities and Strategies Selection Form to the Department of Public Health for review and approval.
- Ten months post-approval: The External DoN Advisory Committee conducts a conflict of interest disclosure process to determine which members of the Committee will move on to the External DoN Allocation Committee. External DoN Advisory Committee members with no conflict of interest will move on to the External DoN Allocation Committee. Additionally, the External DoN Allocation Committee will be supplemented with content experts and others to facilitate the solicitation process.
- Eleven to twelve months post-approval: The External DoN Allocation Committee is developing the RFP process and determining how this process will work in tandem with ongoing community benefit activities and engagement being conducted by Dana-Farber's Community Benefits Office.
- Eleven to twelve months post-approval: Dana-Farber's Community Benefits Office will begin working with HRiA to provide technical assistance to applicants submitting RFP responses. HRiA will begin this work at the Bidders conferences for the RFP.
- Twelve to thirteen months post-approval: The RFP for funding is released.
- Thirteen to fourteen months post-approval: Bidders conferences are held on the RFP.
- Fifteen to sixteen months post-approval: Responses are due for the RFP.
- Seventeen to eighteen months post-approval: Funding decisions are made, and the disbursement of funds begins.