STAFF REPORT FOR A DETERMINATION OF NEED

Applicant Name	Medford Surgery Center, LLC
Applicant Address	700 Congress Street, Suite 204 Quincy, MA 02169
Date Received	June 11, 2018
Type of DoN Application	Ambulatory Surgery
Total Value of the project	$14,675,550.00
Ten Taxpayer Group (TTG)	1. Ten Taxpayer Group #1 1199SEIU Ten Taxpayer Group Elisabeth Daley – TTG Agent 2. Ten Taxpayer Group #2 John Curtin – TTG Agent
Public Hearing	August 22, 2018
Public Comment	Received
Community Health Initiative (CHI)	Total CHI commitment $733,777.50 – Tier 2
Staff Recommendation	Approval
Public Health Council Meeting Date	January 9, 2019

Project Summary and Regulatory Review

Medford Surgery Center, LLC (Applicant) submitted a Determination of Need (DoN) application to construct a five room (three outpatient operating rooms, and two procedure rooms) freestanding ambulatory surgery center (ASC) to be located on the grounds of MelroseWakefield Healthcare's Lawrence Memorial Hospital in Medford, MA. The capital expenditure for the Proposed Project is $14,675,550.00. The gross square feet (GSF) is 17,500.

The Department received written comment and held a public hearing on August 22, 2018. A list of speakers can be found at Attachment 3 and a description of the comments received at Attachment 4. Two groups registered as Ten Taxpayer Groups.

Applications for Ambulatory Surgery 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 within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation.

Background

Medford Surgery Center, LLC (Applicant) is a newly-formed joint venture established by Shields ASC, LLC (an affiliate of Shields Healthcare Group), MelroseWakefield Healthcare, formerly Hallmark Health, and Tufts Medical Center Physician Organization (TMCPO) to construct and operate a freestanding ambulatory surgery center (ASC) on the campus of Lawrence Memorial Hospital in Medford, MA.[1,2,3]

MelroseWakefield Healthcare is an integrated health system in the Metro Boston region with two campuses (MelroseWakefield Hospital Campus and Lawrence Memorial Hospital Campus) and satellite locations in surrounding communities north of Boston.[4] [5] MelroseWakefield Healthcare has a physician organization and visiting nurse association that provides home health and hospice service. The ASC will be affiliated with Wellforce, a Health Policy Commission (HPC) certified Accountable Care Organization (ACO) and health system with four community hospital campuses (Lowell General Main, Lowell General–Saints Campus, MelroseWakefield Hospital, and Lawrence Memorial Hospital), an academic medical center (Tufts Medical Center), and a children's hospital (Floating Hospital for Children at Tufts Medical Center).[6] Tufts Medical Center Physician Organization (TMCPO) is Tufts Medical Center's academic physician organization.

Lawrence Memorial Hospital currently operates 11 operating and procedure rooms. The Applicant states that the rooms are at the end of their useful life and need significant renovation in order to meet current standards of care. The Applicant asserts that renovation of the existing rooms is expensive and costlier than providing low-acuity surgical services to clinically appropriate patients in an outpatient setting. The Applicant is proposing construction of an ASC with three outpatient operating rooms and two procedure rooms on the Lawrence Memorial Hospital campus to specialize in orthopedic surgery; ear nose and throat (ENT)

[1] On January 1, 2017, Hallmark Health System became the third founding member of Wellforce Care Plan (Wellforce). MelroseWakefield Hospital, Lawrence Memorial Hospital and the Hallmark Physician Hospital Organization all became a part of Wellforce. Hallmark Health System changed its name to MelroseWakefield Healthcare in 2018.

[2] Freestanding Ambulatory Surgical Center (FASC) is defined in regulation 114.3 CMR 47.00 as a distinct entity that operates exclusively for the purpose of providing surgical services that do not require the availability of hospital facilities, is licensed by the Massachusetts Department of Public Health and meets the conditions for payment by the purchaser for facility services.

[3] In compliance with 105 CMR 100.740(A) the proposed project is not within the Primary Service Area of an existing Hospital that is designated as an independent community Hospital as defined by HPC's Massachusetts Hospital Cohort Designation and Affiliation status.

[4] MelroseWakefield Hospital is a 174-bed general hospital located in Melrose, MA. Lawrence Memorial Hospital, the subject of this DoN application, offers Emergency Services in the form of a satellite emergency facility (SEF) and inpatient psychiatry services (34 psychiatric beds).

[5] In 2017, Lawrence Memorial Hospital underwent an essential services process to close (10) ICU beds and (54) Medical/Surgical beds. The hospital intends to continue to operate the Emergency Department, all other outpatient services and the 34 Psychiatric beds located at the hospital. The hospital received approval from the Department in 2017 to operate a Satellite Emergency Facility (SEF) to offer Emergency Services.

[6] Wellforce was formed in 2014 by Circle Health (including Lowell General Hospital), Tufts Medical Center, the physicians of New England Quality Care Alliance (NEQCA) and the Lowell General Physician Hospital Organization.

surgery; endoscopy; and plastic surgery. The ASC will serve patients from MelroseWakefield Healthcare, TMCPO through Wellforce ACO, and other patients in the service area seeking cost-effective surgical services. The Applicant states that it will shift low-acuity procedures that would normally take place in a hospital-outpatient department (HOPD) to the ASC where it is less costly, more operationally efficient, and more convenient for the Applicant's patient panel. The Applicant argues that the proposed project will lead to the highest quality outcomes and patient satisfaction levels.

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 Proposed Project for Ambulatory Surgery. This Staff Report addresses each of these factors in turn.

Factors 1 and 2

Factor 1 of the DoN regulation asks that the Applicant address patient panel need, public health value, and operational objectives of the Proposed Project, while factor 2 focuses on health priorities. Under factor 1, the Applicant must provide evidence of consultation with government agencies who 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 each element of the Proposed Project and how each element complies with those parts of the regulation.

Patient Panel, Need, and Projected Growth

The Applicant is a newly-formed joint venture and does not have its own patient panel. Therefore, Applicant relies on patient panel data from its joint venture partners to determine need for the proposed project. The Applicant's patient panel will encompass patients from MelroseWakefield Healthcare, TMCPO through the Wellforce ACO, along with other patients in the ASC's primary service area in need of the surgical services that will be offered by the proposed ASC. Staff agrees that this is an acceptable way to identify a potential patient panel.

MelroseWakefield Healthcare Patient Panel

The MelroseWakefield Healthcare patient panel consisted of 363,042 unique patients from FY15-FY17.[7] The Applicant's patient mix is 41% male and 59% female. The age profile of the patient panel is as follows: 9.0% are in the 0-17 age cohort, 67% in the 18-64 age cohort, and 24% in the 65 and over cohort. Based on self-reported data on race, 79% of the patient panel is White/Caucasian. The top ten cities served by MelroseWakefield Healthcare during FY15-FY17 are: Medford (15%), Malden (13%), Melrose (10%), Wakefield (8%), Saugus (7%), Revere (4%), Everett (4%), Stoneham (4%), Reading (3%), and Somerville (2%).[8] Applicant states that approximately 50% of the patient panel is insured by third party commercial payers, 42% is insured through government programs, and 6% qualifies for free care, self-pay, or have some other form of insurance. [9]

The Applicant also predicts that volume for the proposed ASC will also originate from the Wellforce Care Plan's patient panel that resides in the ASC's primary service area (PSA).[10] Upon approval of this project, Lawrence Memorial will cease using the 11 ORs and procedure rooms on its campus. The Applicant provided patient panel data for Wellforce ACO members who reside in the towns of the proposed PSA.[11] The Applicant states that information is available for Wellforce patients who participate in MassHealth ACO, Medicare Shared Savings Program, and those covered by risk-based commercial contracts. The Applicant reported that in 2017, there were 4,366 MassHealth ACO members, 2,100 Medicare Shared Savings Program ACO members, and 27,618 Commercial members for a total of 34,084 patients. The gender profile of the Wellforce patient panel is roughly 50% female and 50% male, and the age profile is as follows: 45% are 0-17 years, 47% are 18 -64 years, and 8% are ages 65 and older. Reported languages spoken by the Wellforce ACO patient panel include Chinese (167), Spanish (148), Haitian/Creole (40), Hindi (42), Arabic (37), and Vietnamese (111).[12]

The Applicant reviewed MelroseWakefield Healthcare historical use rates for the surgeries that will be offered at the ASC to ascertain need for the proposed project. The Applicant stated that 8,656 patients received ambulatory surgical services across the four specialties in FY17: Orthopedics 1,054; ENT 201; Endoscopy 7,259; and Plastics 142. The Applicant noted a 5% increase in the number of patients undergoing those procedures since FY15 and maintains that MelroseWakefield Healthcare's historical utilization data for these services demonstrates

[7] The Applicant states that over 80% of its patient panel will be comprised of MelroseWakefield Healthcare patients.
[8] Applicant states that over 70% of MelroseWakefield Healthcare's cases are from the patients residing in these cities and towns. The remaining patients in the panel are either from other cities and towns in Massachusetts or are part of the 2% of patients who reside outside of Massachusetts.
[9] In 2017: Medicaid (3.52%), Medicaid MC (7.91%), Medicare (27.61%), and Medicare MC (2.64%).
[10] Wellforce Care Plan (Wellforce ACO) is made up of Wellforce ACO and Fallon Health. Wellforce ACO is comprised of doctors and healthcare providers that provide care for MassHealth and risk-based patients, some of whom are affiliated with Melrose-Wakefield Hospital, Lawrence Memorial Hospital, and Tufts Medical Center.
[11] The Applicant excluded Wellforce ACO members who have a MelroseWakefield Healthcare Primary Care Physician in order to prevent double counting volume from the MelroseWakefield Healthcare surgery and procedure volume.
[12] Applicant states that information provided on language spoken does not indicate racial background but does indicate ethnic identity of the patient panel. DoN Application Attachments, at page 6.

strong, ongoing demand. The Applicant expects the demand for these services to continue to increase in the future due to an aging population and an increase in comorbidities for patients in the 18-64 and 65 and over age groups.

The Applicant compiled patient panel data from joint venture partners and demographic projections and population health data from the Advisory Board to define a Primary Service Area (PSA) for the ASC and to make volume projections for the ASC. [13] The Applicant reported on the cities and towns that will comprise the ASC's PSA, the total population of the PSA (738,961 as of 2016), and the gender make-up of the PSA (49% male and 51% females in 2016).[14,15]

Because it is a newly formed joint venture there is no historical patient panel volume available for the ASC and therefore, the Applicant utilized data obtained from the Advisory Board as well as the patient panel of each of the joint venture partners to model volume projections for the proposed ASC. The Applicant determined that there are 120,590 potential patients within the ASC's PSA who may need one of the ASC's surgical procedures.[16]

Potential Patients within the ASC's proposed PSA

	2016
Endoscopy	51,629
Orthopedic Surgery	36,477
ENT Surgery	24,928
Plastic Surgery	7,556
Total Volume	**120,590**

Further, the Applicant assumed that 15% of these potential patients will fall within the managed population of the ASC making the relevant patient panel size for the PSA to be 18,089. Applicant estimates that the proposed ASC will service at least 20% of the ASC eligible patient panel within the PSA in Year 1 and up to 40% by Year 4.

Proposed ASC Volume projections based on service line

	Year 1	**Year 2**	**Year 3**	**Year 4**
Endoscopy	2,523	3,784	4,541	4,995
Orthopedic Surgery	977	1,466	1,759	1,935

[13] The Applicant states that the Advisory Board is a best practices firm that uses research, technology and consulting to improve the performance of healthcare organizations. The Applicant obtained population health data, including population/demographic projections, health conditions, and service line specific needs, in order to model projected volume for the ASC. DoN Application 18060613-AS Attachments, at page 6.
[14] Applicant reported that the cities and towns that will comprise the ASC's PSA are: Malden; Melrose; Saugus; Wakefield; Stoneham; Revere; Everett; Winchester; Woburn; Wilmington; Reading; North Reading; Somerville; Arlington; Winthrop; Chelsea; Lynn; Lynnfield; and Peabody.
[15] Applicant states the total population of the PSA is expected to increase by 5% to 775,602 by 2021.
[16] Applicant states the number of potential patients in the PSA is expected to increase 147,793 by 2021.

ENT Surgery	581	872	1,046	1,150
Plastic Surgery	99	149	179	197
Total	**4,180**	**6,271**	**7,525**	**8,277**

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 that establishing an ASC on the campus of Lawrence Memorial Hospital will increase access to low-cost, high-quality, community-based surgical services that will improve the patient care experience and health outcomes. The Applicant proposes to shift low-acuity surgery from the higher-cost hospital-outpatient departments (HOPDs) to the ASC which offers greater clinical and operational efficiencies than HOPDs and, the Applicant argues, produces higher patient satisfaction. The Applicant states that the proposed ASC will focus on four service lines, allowing the ASC personnel to gain proficiency and efficiency performing procedures leading to expertise in care that produces high-quality outcomes for patients.[17] The Applicant notes a lower infection rate in ASCs compared to hospitals with the Surgery Center Network reporting one surgical site infection per 1,000 for ASCs (compared to 20 per 1,000 for hospitals).[18,19]

The Applicant reports on the noted benefits of migrating lower acuity outpatient surgical procedures from HOPDs to ASCs for the patient panel.[20] The Applicant says that these benefits include reduced wait times, a convenient location, shorter recovery times and, overall, an improved care experience. The Applicant states that the ASC will offer improved throughput pre- and post-surgery allowing for an expedited, patient-centered experience. Additionally, the Applicant states that it will implement amenities that will improve the patient experience and create a higher level of patient satisfaction. Amenities include an on-line pre-registration system, available in over 70 languages that will allow patients to register from their homes,

[17] See, generally Munnich, E. L., & Parente, S. T. (2014). Procedures Take Less Time At Ambulatory Surgery Centers, Keeping Costs Down And Ability To Meet Demand Up. *Health Affairs, 33*(5), 764-769. Retrieved June, 2018, from https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2013.1281

[18] Levitt, L. (2017, June 15). The Benefits of Outpatient Surgical Centers. Retrieved June, 2018, from https://www.cfaortho.com/media/news/2017/06/the-benefits-of-outpatient-surgical-centers

[19] Hospital or ASC... What's the Difference? (n.d.). Retrieved June, 2018, from https://www.surgerycenternetwork.com/hospitals-vs-ascs

[20] *Ambulatory Surgical Centers Position Statement* (Rep.). (2010, December). Retrieved January, 2018, from American Academy of Orthopaedic Surgeons website: https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/1161 Ambulatory Surgical Centers.pdf

price transparency tools to ensure that patients have access to pricing information and access to financial counselors to assist in understanding insurance benefits. [21]

The ASC will have a hospital transfer agreement with MelroseWakefield Hospital in the event that a patient requires emergency care.[22] Discharge information and instructions will be made available to the patient in hard copy format as well as electronically, and all prior to discharge, to ensure that the patient has ample access to the information that will aid in recovery. The Applicant states that this approach has proven to be successful at other ASCs, and facilitates continuous communication with the patient, thereby improving patient satisfaction and quality of care.[23] The Applicant asserts that this will support the value-based care goals of the Wellforce ACO. The Applicant developed the quality metrics and a reporting schematic that will measure patient satisfaction and quality of care (Attachment 1).

Equity

The Applicant is developing what it describes as a robust translation program that will include multiple tools and options for translation services that will, according to the Applicant, address language barriers and support culturally appropriate care.[24] The Applicant asserts that patients will be linked with community resources to address their social determinant health needs. Wellforce ACO members will have access to a case manager prior to discharge, to screen for social determinant of health needs and a Wellforce ACO care manager to help patients with identified needs access resources. Patients who are not members of Wellforce ACO will have access to a case manager prior to discharge to identify needs and will be referred to the Director of Community services at MelroseWakefield Healthcare to access resources for identified needs.

Competitiveness and Cost Containment

The Applicant states that the proposed project is a lower-cost alternative to surgery performed in a HOPD largely because ASCs do not have the same hospital overhead; clinical efficiencies produce cost savings for the ASC; Medicare reimburses ASCs at roughly fifty-eight percent of the HOPD rate; and patients experience lower deductibles and coinsurance payments. [25,26] The

[21] Applicant states that the patient access tools that offer pre-registration functionality will interface with an electronic medical record (EMR) to combine necessary patient information and allow surgeons to share pre-operative notes and post-operative discharge instructions with primary care physicians (PCP).
[22] The state of Massachusetts requires either a hospital transfer agreement or surgeons to have admitting privileges at a designated hospital. Available at https://www.foxrothschild.com/publications/when-an-asc-dials-911-the-basics-of-hospital-transfer-agreements/.
[23] DoN Application Question Responses, at page 1.
[24] DoN Application 18060613-AS Attachments, at page 19.
[25] *Commercial Insurance Cost Savings in ASCs* (Rep.). (2016, June 14). Retrieved June, 2018, from Ambulatory Surgery Center Association website: file:///C:/Users/LClarke/Downloads/ASC Cost Savings Study.pdf and Munnich, E. L., & Parente, S. T. (2014). Procedures Take Less Time At Ambulatory Surgery Centers, Keeping Costs Down And Ability To Meet Demand Up. *Health Affairs, 33*(5), 764-769. Retrieved June, 2018, from https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2013.1281
[26] *Medicare Cost Savings Tied to Ambulatory Surgery Centers* (Rep.). (2013, September 10). Retrieved July, 2018, from University of California Berkeley website: https://www.ascassociation.org/communities/community-

Applicant states that ACSs are a high-quality option for elective and same-day surgical procedures in a lower cost setting.[27] The Applicant asserts that the ASC will reduce overall provider costs, which will directly impact TME.

Community Engagement

Prior to submitting a DoN application, the DoN Regulation requires applicants to have engaged and consulted with the community. The Community Engagement Guide describes community engagement processes on a continuum from "Inform" and "Consult" through "Community driven-led."[28] For the purposes of factor 1, engagement defines "community" as the Patient Panel, and requires that the minimum level of engagement for this step is "Consult."[29]

The Applicant described its work, saying that it presented the proposed project to the MelroseWakefield Healthcare's Patient Family Advisory Committee (PFAC) on February 27, 2018.[30,31] The Applicant reported that the presentation informed community members about the scope, aim, and details of the ASC and how it will benefit patients. Applicant submitted PFAC minutes from the February 27th meeting at which nine members were present (4 Hallmark Health System and 5 community members). The Applicant asserted that it had engaged local residents and resident groups through a community forum on April 30, 2018 at Lawrence Memorial Hospital's School of Nursing. At the forum, the Applicant asserted that it had presented the proposed project, answered questions from attendees and responded to concerns about the impact of the ASC on the community. Applicant submitted slides for the presentation at the community forum where nine community members were in attendance.

At the request of a registered TTG the Department held a public hearing on August 22, 2018. A significant portion of the testimony at the hearing, and subsequent written comment, reflected concern over what was perceived by those in attendance, as a lack of community engagement in the development of the proposed project. Participants at the hearing cited low attendance at the community forum and PFAC meeting and lack of engagement of patients from the

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home/librarydocuments/viewdocument?DocumentKey=866fa139-09d2-4cad-b1f1-a97a65b5169d and *Commercial Insurance Cost Savings in ASCs* (Rep.). (2016, June 14). Retrieved June, 2018, from Ambulatory Surgery Center Association website: file:///C:/Users/LClarke/Downloads/ASC Cost Savings Study.pdf

[27] The ASC Cost Differential. (2016, August). Retrieved August, 2018, from https://www.ascassociation.org/advancingsurgicalcare/reducinghealthcarecosts/paymentdisparitiesbetweenascsandhopds

[28] *Community Engagement Standards for Community Health Planning Guideline* (Rep.). (2017, January). Retrieved May, 2018, from Massachusetts Department of Public Health website: https://www.mass.gov/files/documents/2017/01/vr/guidelines-community-engagement.pdf

[29] *Community Engagement Standards for Community Health Planning Guideline* (Rep.). (2017, January). Retrieved May, 2018, from Massachusetts Department of Public Health website: https://www.mass.gov/files/documents/2017/01/vr/guidelines-community-engagement.pdf

[30] The Applicant states that over 80% of the proposed ASC volume will originate from MelroseWakefield Healthcare and the MelroseWakefield Healthcare's PFAC represents patients from the ASC's proposed service area.

[31] Applicant states that MelroseWakefield Healthcare's Patient Family Advisory Committee (PFAC) is comprised of members from MelroseWakefield Healthcare and community members.

Lawrence Memorial Hospital (campus), the site of the proposed project. A summary of hearing testimony and written comment can be found in Attachment 4.

In response to the concerns expressed at the public hearing, the Applicant developed a document called Community Engagement Activities and Plan (CE Plan) The CE Plan details community engagement activities that will, according to the Applicant, "inform, consult, collaborate and drive community participation in the proposed project." The CE Plan describes; establishing city-wide communication through a public website, a public email, and community list serv to inform, gain input, and answer questions about the proposed project; organizing community-based meetings to provide more information about the development of the proposed project and concerns expressed at the hearing and in written comment; and scheduling meetings with community coalitions and groups representing the business and service communities. The Applicant developed a Community Advisory Group that will consist of community members, including a representative from the registered TTG, and MelroseWakefield Staff to, "advise the organization's leadership related to the proposed Ambulatory Surgery Center development process." The Applicant states that the Community Advisory Group will meet once every three to four weeks, and will also attend city-wide community meetings to represent the work of the group and gain additional feedback on the proposed project.

DoN staff finds that the Applicant's CE Plan, if fully implemented, will inform and consult the community on the proposed project in a manner that reflects the intent of the requirements of factor 1 (e). The Applicant will report to the Department on its ongoing community engagement activities including publicity of and attendance at scheduled meetings and community events. Reporting on Community Advisory Group activities will include submittal of a Group Charter, plans for recruitment of members, and member participation in ongoing events. (See Condition 7 to the DoN).

Factor 3

The Applicant 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. The Applicant submitted such an analysis performed by Bernard L. Donohue, III, CPA, (Donohue) dated June 8, 2018 (CPA Report).

In order to assess the reasonableness of assumptions used, and the feasibility of the projections for the operation of the ASC, the CPA Report reflects a review and analysis of the Applicant's five-year (fiscal years 2019 through 2023) financial projections prepared by Shields and supporting documentation. The CPA report used key metrics (liquidity, operating, and solvency) to compare the operating results of the Projections for the fiscal years. CPA report states that the Projections exhibit a net pre-tax margin ranging from 7.6% to 15.1% for years 2 through 5 of the proposed project and that the continued operating surplus are reasonable and feasible.

Donohue found both the revenue and operating expense projections to be reasonable. Donohue utilized an outside, independent survey of ambulatory surgery centers completed using 2017 data for comparison. Donohue reviewed the projected volume at the ASC and found that the benchmark data used were reasonable and the number of projected cases and procedures per operating room and procedure room at full utilization (80% of available time achieved in Year 4) were within the ranges of currently operating ambulatory surgery centers. Donohue found the Applicant's payer mix, which is based on the multiple specialties of the ACS and reimbursement rates (Medicare, Medicaid, and Commercial Insurance rates) to be reasonable.

Donohue analyzed salaries and benefits for wage rates used and clinical staff hours provided. Salaries and benefits are projected to increase by 3% per year, clinical expenses by 1.5% per year and most other expenses by 1% or 2% per year. Donohue compared staffing hours and wage rates, and medical surgical supplies to the independent survey and all were found to be consistent with survey results and reasonable.

The CPA report found that the project and continued operating surplus are reasonable and based upon feasible financial assumptions and therefore, "the Projections are feasible, sustainable, and not likely to have a negative impact on the patient panel or result in a liquidation of assets of the Medford ASC."[32]

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 construction and operation of a five room (three operating rooms and two procedure rooms) freestanding ambulatory surgery center (ASC) on the campus of Lawrence Memorial Hospital. The Applicant looked at the relative merit of continuing to serve patients through the existing operating rooms at Melrose-Wakefield Hospital, Lawrence Memorial Hospital, and Tufts Medical Center. The Applicant asserts that this alternative would

[32] DoN Application 18060613-AS CPA report, at page 6.

not address the combined patient panel need nor the requirement to replace operating rooms and upgrade equipment. Further, this option would not offer the clinical and operational efficiencies because the hospital setting is less amenable to on-time and efficient provision of outpatient surgery than is an ASC.

The Applicant also looked at the relative merit of renovating the existing operating rooms at Lawrence Memorial Hospital. This proposal was dismissed as well because renovating the rooms would not resolve the inefficient layout of the operating rooms and renovation would disrupt other clinical programs in close proximity.[33] Additionally, the renovated rooms would be hospital-based which have higher operating costs than the ASC. The renovation would cost $16,600,000.

The Applicant asserts that the proposed project, construction of a one-story, five room free-standing ambulatory surgery center, is the superior option because it will provide access to state-of-the art technology in a new facility. The location is accessible and convenient and will have ample parking. The ASC achieves cost savings from shifting patients from hospital-outpatient surgical departments to the ASC and clinical and operational efficiencies from the specialization of services offered at the ASC. There will be a one-time capital expense to construct the ASC and anticipated annual operating expenses of $5,294,141 in the first year of operation.

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 2 project, which applies to projects with a CHI contribution between $500K and $4M. The Applicant is required to and did submit documentation showing that the existing community health needs assessment (CHNA) and community health improvement planning (CHIP) processes both evidence a sound community engagement process and demonstrate an understanding of the DoN Health Priorities sufficient for selecting strategies to fund and implement following approval of the DoN project (this means submittal of a CHNA-CHIP Self-Assessment, Stakeholder Assessments and the most recently completed community health needs assessment). Tier 2 Applicants are not required to, but may decide to, submit a Community Engagement Plan at the time of application. In this case the Applicant did submit a Community Engagement Plan.

In making its recommendation to the Department, DPH staff may require corrective actions or steps to be taken based on the information provided by the Applicant which will become conditions of approval. DPH staff may also make recommendations that, while not conditions of approval, will be kept as reference for subsequent DoN applications and/or are offered as

[33] Applicant states that the operating rooms are located in the basement, which is a distance from the main entrance and the registration desk and on a separate level from the parking area. DoN Application 18060613-AS Attachments, at page 25.

opportunities for improvement relative to the Applicant's community engagement practices. For Tier 2 Applicants that submit a Community Engagement Plan, the actions described in that Plan become conditions of approval.

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 from the existing CHNA/CHIP or other assessments as required by the Department. These processes, selection of the Health Priorities and funding decisions, are conditions of the DoN and enforceable as such.

This Application

The Applicant, because of the location of the proposed DoN project, is using the CHNA/CHIP processes of Melrose WakefieldHealthcare (which includes Lawrence Memorial Hospital in Medford, the site of the proposed DoN project) to complete the CHI process. In compliance with the requirements of the Guideline, and based on their own analysis, MelroseWakefield Healthcare submitted the following: a CHNA/CHIP Self-Assessment, 6 Stakeholder Assessments, a Community Engagement Plan describing actions for the Focus on What's Important, Choosing Effective Policies and Programs, Acting on What's Important and Evaluating Actions stages of the CHNA/CHIP cycle, and the 2016 Hallmark Health System Community Health Needs Assessment. Staff from DPH's Office of Community Health Planning and Engagement conducted the review of these materials.

CHI Summary Review:

1. Engagement levels by community health improvement planning stage
    a. The 2016 CHNA used a mixed methods approach to assessing needs and assets in the service region. While methods of engagement were varied and are to be commended, actual participation by community members was limited in number and type (e.g. community organization versus community member) and community location of outreach events.
    b. While some barriers to participation were planned for (e.g. translators) the diversity of representation in community forums and events was lacking pointing to issues with outreach and incentive to participate.
    c. The completed Community Engagement Plan addresses some of these issues and specifically references providing stipends as an option for increasing community member participation (in addition to other barriers such as childcare and transportation).
2. Advisory committee representation
    a. The Community Benefits Advisory Committee is heavily represented by internal hospital staff and missing important sectoral representation, specifically municipal staff (health departments were represented in various way in the 2016 CHNA but are not listed as members of the community benefits advisory

committee), housing, planning and transportation, private business and community health centers.

3. The 2016 Melrose Wakefield Healthcare CHNA provides useful and actionable information relative to the DPH Focus Issues (priorities include all Focus Issues except housing stability and homelessness) however lacks actionable information related to the six DoN Health Priorities (social determinants of health) and therefore raises concerns about how Health Priority strategies will be selected. Evidence from the 2014-2016 community benefits activities demonstrate significant effort to build relationships with community organizations but also shows focus on services not directly tackling the underlying issues of what are described as vulnerable populations in the CHNA.
4. The Community Engagement Plan sets out ambitious standards for community engagement noting aspirational goals of being community-led in Choosing Effective Policies and Programs and Acting on What's Important steps of the CHNA-CHIP process.

After review, staff recommends certain Conditions to the DoN (set out below).

Separately, staff also makes a series of recommendations and observations based upon the fact that, in future DoN applications coming from this Applicant, DPH will refer back to the issues noted during this review. These recommendations and observations are not Conditions to the DoN. The Holder, in its development of future CHNA/CHIPs and in future DoN Applications, should consider the following:

1. The description of barriers to community participation noted in Appendix A of the Community Engagement for Community Health Planning Guideline and to develop plans for understanding and addressing barriers in the service region.
2. Review of the DoN Health Priority Guideline to fully understand how to incorporate an analysis of the social determinants of health into needs assessments, priority setting and strategy implementation. This is particularly important for the upcoming 2019 CHNA.

Public Hearing

The Department held a public hearing on August 22, 2018. The names of those testifying at the hearing or submitting written comments are listed in Attachment 3 and a summary of comments on Attachment 4.

Written Comment

The Department received written comments related to the project. (See Attachments for list of commenters and summary of comment)

Ten Taxpayer Groups (TTGs)

Two ten taxpayer groups registered in connection with this project.

1. 1199SEIU TTG registered on June 13, 2018
2. TTG registered on July 10, 2018

Findings and Recommendations

The Applicant demonstrated that the proposed project will lead to increased access to high-quality, community-based surgical services in a more efficient and cost-effective setting. The Applicant provided evidence that the project will improve health outcomes and increase patient satisfaction levels. These findings, along with ongoing compliance with the Other Conditions set out below, support a determination that the Applicant meets the requirements of Factors 1 and 2.

The Applicant meets factor 3; based upon the CPA analysis, the Proposed Project is financially feasible in the context of factor 4; provision of surgical services in an ambulatory surgery setting is, on balance, the superior alternative for meeting the existing Patient Panel needs from the perspective of quality, efficiency, 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 pursuant to 105 CMR 100.310(J).

CHI Conditions to the DoN

1. Of the total required CHI contribution of $733,778, $177,941 will be directed to the CHI Statewide Initiative, $533,824 will be dedicated to local approaches to the DoN Health Priorities (includes resources for evaluation of strategies), and $22,013 is allowed to be used for administrative purposes to implement community engagement activities and management of CHI processes such as a issuing RFPs, etc. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $177,941 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 2-5 year period subject to choice of Health Priority strategies and final Department approval.
3. Additional members of the CHI Advisory Committee will be recruited and a list of members and their affiliations provided to the Department. These members shall represent, at a minimum, local health, housing, planning and transportation, private business and community health centers. Further, to ensure that community members or representatives of small and less resourced community organizations are part of this recruitment effort, the Applicant will develop and submit additional plans for membership and leadership development for new members. A listing of new members, their affiliations and plans for leadership development will be submitted to the department within two months from the date of the Notice of Approval.
4. Either as part of initial plans for the 2019 Melrose Wakefield Community Health Needs Assessment or as a separate activity specific to the selection of Health Priority Strategies, key informant interviews with stakeholders from sectors representing the six DoN Health Priorities will be completed prior to selecting Health Priority Strategies for submittal to the Department. The Applicant will submit plans for these

interviews to the Department within one month from the date of the Notice of Approval.

5. All activities described in the Community Engagement Plan (attached) are considered conditions of approval.
6. CHI timeline (see Attachment 2).

Other Condition:

7. The Holder will report to the Department on its ongoing community engagement activities including publicity of and attendance at scheduled meetings and community events. Reporting on Community Advisory Group activities will include submittal of a Group Charter, plans for recruitment of members, and member participation in ongoing events.
    a. The reporting under this Condition 7 shall commence on issuance of the Notice of DoN and shall continue, semi-annually until implementation of the proposed project.

Based upon a review of the materials submitted, Staff finds that the Applicant has met each DoN factor and recommends that the Department approve this Determination of Need application for construction of a freestanding ambulatory surgery center (ASC) 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 project, the Holder shall address its assertions with respect to the cost benefits of the provision of surgical services in an ASC as well as the metrics provided in Attachment 1.

Attachment 1

The Applicant developed the following quality metrics and reporting schematic, as well as metric projections for quality indicators that will measure patient satisfaction and quality care.

1. **Patient Satisfaction:** Patients that are satisfied with their care are more likely to seek additional treatment when needed. The Applicant will review patient satisfaction levels with the ASC's surgical services.

   Measure: The Outpatient & Ambulatory Surgery Community Assessment of Healthcare Providers and Systems (OAS-CAHPS) survey will be provided to all eligible patients. The OAS-CAHPS survey focuses on six (6) key areas: 1) before a patient's procedure; 2) about the ASC facility and staff; 3) communications about the patient's surgical procedure; 4) patient recovery; 5) overall experience; and 6) patient demographic information.

   Projections: As the ASC is not yet operational, the Applicant established a benchmark of 85.8% for the "Overall Rating of Care", which is the top decile for reporting providers.

   Monitoring: Any category receiving less than "Good" or satisfactory rating will be evaluated, and policy changes instituted as appropriate. Reviewed quarterly by clinical staff.

2. **Clinic Quality – Surgical Site Infection Rates:** This measure evaluates the number of patients with surgical site infections and aims to reduce or eliminate such occurrences.

   Measure: The number of patients with surgical site infections.

   Projections: The ASC plans to meet or exceed the national benchmark of 0.10% surgical site infection rates, ultimately reaching a target of 0%.

   Monitoring: Reviewed quarterly by clinical staff.

3. **Clinical Quality – Pre-Operative Time Out:** This measure ensures pre-operative compliance with practices aimed at ensuring high quality outcomes among members of the care team and promoting communication.

   Measure: The procedure team conducts a pre-operative time out.

   Projections: A pre-operative time-out will be completed 100% of the time on all surgical cases in the ASC.

   Monitoring: Reviewed by clinical staff.

Attachment 2

Timeline for CHI Activities: Melrose Wakefield HealthCare

- One-month post-approval: The Advisory Committee will begin meeting to review the CHNA priorities, assist with developing plans for additional member recruitment and leadership development and help determine the process of conducting key informant interviews required as conditions of approval. Plans for leadership development and key informant interviews submitted to the Department. Plans for the establishment of an Allocation Committee determined.
- Two-months post-approval: New members recruited and list submitted to Department.
- Four-months post-approval: The Advisory Committee has determined priorities for funding and the Allocation Committee chosen specific strategies. Melrose-Wakefield Healthcare submits Health Priorities form to the Department for review.
- 5-months post-approval: The Allocation Committee develops RFP process and works to determine how to combine with ongoing community benefits efforts or grant opportunities.
- 5-months post-approval: Allocation Committee chooses an evaluator to assist with RFP development and to serve as a technical resource for grantees and develop/implement the evaluation plan.
- 6-7 months post-approval: RFP for funding released.
- 7-months post-approval: Bidders conferences held.
- 8-9 months post-approval: responses to RFPS due.
- 10 months post-approval: funding decisions made.
- Ongoing: evaluation, monitoring and reporting.

Attachment 3

Speakers at the Public Hearing

Stephen Sbardellla
Stephanie Burke
Richard Caraviello
Ryan Fuller
Carmel Shields
Jennifer Hoffman
Cathy Liu
Karen Andrews reading for Paul Muzhuthett
Sharon Burton reading for Loretta Kemp
John Tancredi
Eileen Dern
Michael Kass
Katherine Vitiello
David Pladziewicz
Bob Penta
Kathy Harlow reading for Mei Hung
Rick Catino
Caroline Jaques
Marcia Kussin
Ellyn Boukus
Sohail Husain
Tara Miner
Ivanka Toudjarska
Rob Brogna reading for Matt Haverkamp
Sankha Basu
Nicole Bloor
Andrew Castagnetti
John Curtin
Gail Orlando
Malisa Schuyler
Deb Cronin-Waelde
Paul Gerety

Attachment 4

Summary of Hearing Testimony and Written Comment

The Department held a public hearing on August 22, 2018 pursuant to DoN Regulation 105 CMR 100.445. The hearing was located at the Lawrence Memorial Hospital College of Nursing. Elected officials, TTG members, staff members of WakefieldHospital, Lawrence Memorial Hospital partners, residents of the City of Medford and members of the general public provided testimony on the proposed project. A ten-day comment period followed the public hearing.

Comments in support of the construction of the ASC cited the benefits of the proposed project to the Medford community. Proponents of the ASC stated;

- the ASC will provide a convenient location for outpatient surgery in a new state-of-the-art facility with the latest technologies;
- surgery in the ASC will be safe, quicker and more efficient;
- ASC quality outcomes are comparable to those of surgeries performed in the hospital;
- scheduling in the ASC reduces patient waiting times and cancellations;
- the ASC will improve quality of life and increase patient satisfaction;
- the ASC will be a cost-effective alternative to the hospital setting and will reduce out of pocket costs for patients of the ASC; and
- the Community Benefits Council will support the community health improvement responsibilities of the DoN, which will support the needs identified in the 2016 community health needs assessment and DPH's Health Priorities.

Comments in opposition to the construction of the ASC expressed concern over the level of community engagement that the Applicant undertook in the development of the proposed project, the process for determining need for the project, and the impact on Lawrence Memorial Hospital services. Comments mentioned;

- a lack of information about and attendance at the community forum cited by the Applicant as evidence of sound community engagement;
- a reduction in services at Lawrence Memorial Hospital citing a significant aging population that needs access to LMH and its emergency services;
- a need for additional statistics to demonstrate need for the ASC in Medford;
- a need for representation from Medford residents and the Medford Board of Health on the Community Benefits Council; and
- requests for more time and information to complete the regulatory process.

The analysis focused on comments that addressed the proposed project's ability to meet the six required factors. Comments received that were outside of the scope of the analysis were focused on the impact of the proposed project on the neighborhood surrounding Lawrence Memorial Hospital. Comments included;

- a request for an in-depth traffic study to study the ASC's potential for increasing traffic and overflow of parking into adjoining areas;

- a discussion of the potential impact of the construction of the ASC on resident properties, safety, and pollution (noise, light, air); and
- requests for more information on the projects planned for Lawrence Memorial Hospital that were presented at a Medford community meeting organized by Wellforce.