

**STAFF REPORT TO THE PUBLIC COUNCIL
FOR THE DETERMINATION OF NEED**

DoN Project Number	MFEC 18032715 - TO
Applicant Name	Milford – Franklin Eye Center, LLC
Applicant Address	391 East Central Street Franklin, MA 02038
Date Received	March 28, 2018
Type of DoN Application	Transfer of Ownership
Total Value	\$1,353,758
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	Not applicable
Staff Recommendation	Approval
Public Health Council (PHC) Meeting Date	July 11, 2018

PROJECT SUMMARY AND REGULATORY REVIEW

The Applicant is Milford - Franklin Eye Center, LLC. (M-F Eye, or Applicant). M-F Eye is a physician practice that proposes to acquire a licensed ambulatory surgery center (ASC) called the Cataract Surgery Center of Milford, Inc. (CSC Milford) located at 145 West Street, Milford, MA 01757. The Applicant requests a Determination of Need (DoN) for this proposed Transfer of Ownership pursuant to 105 CMR 100.000. The current owner of CSC Milford is an ophthalmologic surgeon who is retiring from practice. The physician manager of M-F Eye will practice out of the two facilities and serve the patient panels of both facilities.

Transfers of Ownership are reviewed subject to M.G.L. c.111 §§ 51 and 53 and the DoN regulation, specifically, 105 CMR 100.735 which provides, in relevant part that “no Person shall be issued an Original License for a Hospital unless the Department has first issued a Notice of Determination of Need for such Proposed Project at the designated Location.” Transfers of Ownership are subject to Factors 1, 3, and 4 of the DoN regulation and certain standard conditions that are set out in Attachment 1.

Background

The Applicant is Milford-Franklin Eye Center, LLC (M-F Eye or Applicant), a private ophthalmology practice that does not provide surgical services on site. M-F Eye has submitted a Determination of Need for the transfer of ownership of the clinic license of the Cataract Surgery Center of Milford, Inc. (CSC Milford) which is located at 145 West Street, Milford, MA 01757. CSC Milford is a licensed outpatient ambulatory surgery center owned by a single ophthalmologic surgeon who is retiring.¹

The owner of M-F Eye is an ophthalmologic surgeon who has privileges to perform surgery at a site in Waltham, MA.² M-F Eye intends to purchase CSC Milford and grow the ASC by shifting the majority of the Applicant's surgeries there rather than in Waltham which is about 40 miles away from the bulk of the patient panel. If approved and completed the transaction will enable the Applicant to continue to serve the Patient Panels of each of M-F Eye and CSC Milford in facilities that are locally accessible. The towns of Milford and Franklin are about 14 miles apart and both are about 50 miles south of Boston.

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.

Factor 1:

Factor 1 requires that the Applicant establish that the project:

- will meet a demonstrated need of the existing patient panel;
- will add measurable public health value in terms of improved health outcomes and quality of life of the Applicant's existing patient panel, while providing reasonable assurances of health equity;
- will result in efficient and effective operations that improve continuity and coordination of care for the Applicant's patient panel, including appropriate linkages to patients' primary care services;
- is characterized by sound community engagement throughout the development of the proposed transaction; and

¹ The two ophthalmic surgeons who are employed by CSC Milford will be retained in service there following the transaction.

² The M-F Eye Patient Panel resides primarily in Franklin, Milford and the four contiguous towns and in the vicinity of Woonsocket, Rhode Island. The Applicant reports that approximately 75% of its Patient Panel lives within ten miles of the practice in Franklin.

- will be competitive on the basis of price, total medical expense (TME), provider costs, or other recognized measures of health care spending. 105 CMR 100.210(A)(1).

In addition, factor 1 requires that the Applicant provide evidence of consultation with the relevant regulatory agencies. The Applicant has provided this evidence and, as a result this will not be addressed further in the Staff Report.

Patient Panel and Need

M-F Eye: The Patient Panel resides primarily in Franklin, Milford and the four contiguous towns and in the vicinity of Woonsocket, Rhode Island. The Applicant reports that approximately 75% of its Patient Panel lives within ten miles of the practice in Franklin. Approximately 75% of patients are under the age of 45 and 25% are over the age of 45. The most common non-surgical services needed by M-F Eye's Patient Panel include comprehensive eye care, glaucoma management, retinal eye disease, pediatric eye care and outside referrals for cataract evaluations. M-F Eye performs approximately 1,200 surgeries annually (using the Waltham, MA surgical facility), about 98% of which are cataracts. Approximately 63% percent of patients have commercial insurance coverage, while 23% have Medicare, 13% have Medicaid and 1% are self-pay.

CSC Milford: The geographic provenance of the CSC Milford Patient Panel is similar to that of M-F Eye. At CSC Milford 89.62% the patient population is older than 60 years. Approximately 833 surgeries are performed annually at CSC Milford of which 70% were for cataract removal, and the remainder was for ptosis, entropion, ectropion, blepharoplasty, and eyelid malignancy cases. Approximately 56% of patients have commercial insurance, while Medicare comprises 35%, Medicaid, 2% and patients with no insurance, 7%.

The Applicant asserts that, like much of the Commonwealth, its Patient Panel is characterized by an aging population that is growing and that that growth generates a continuing need for eye care and cataract surgery.³ The Applicant argues that the combined volume of surgery done by M-F Eye and CSC Milford mitigates in favor of the transaction which, if completed, will offer a local surgical clinic to the M-F Eye patients while continuing to care for CSC Milford's patients. Upon closing of this transaction, if approved, the Applicant anticipates providing approximately 2,400 surgical procedures in 2018, serving the M-F Eye and the CSC Milford patients at a local site.

Public Health Value

The Applicant asserts that proper eye and vision health can reduce health disparities, influence poverty, health care costs, and avoidable mortality and morbidity.⁴ Further, the Applicant

³ The Applicant reports that the major causes of vision loss in Americans in the elderly are cataracts, age-related macular degeneration (AMD), diabetic retinopathy, and glaucoma. The NIH statistics (2010) indicate that risk of cataracts increases with each decade of life starting at approximately age 40. Local treatment for the visually impaired is important since independent travel for such procedures is not possible.

⁴ Christ et al., 2014; Rahi et al., 2009; Rein, 2013.

states that as the U.S. population ages, and life expectancy increases, the impact of vision loss-associated disability will grow. Studies suggest that if cataract surgery rates continue at a level consistent with meeting population growth, surgical volume will grow 128% in 25 years which when extrapolated to the US population growth projections results in approximately 4.3 million additional cataract operations per year in the United States by 2036.^{5 6}

Applicant asserts that the transaction will improve the coordination of care by adding dedicated surgical care coordinator services and extending the use of its electronic health record (EHR) system to Milford. The surgical care coordinator oversees the proper documentation within the EHR system, and facilitates locating a primary care physician or specialist, if needed, by working with the patient referral line of the area medical center. These processes, the Applicant asserts, will smooth the transition of patients through surgery and back to their provider post-operatively.

The Applicant will also implement more efficient processes at CSC Milford that, it asserts support high-quality and lower-cost cataract surgery. These processes include using a less invasive anesthetic technique, which reduces surgical and recovery times, improves efficiency and improves safety,^{7 8} and laser assisted cataract surgery. Both of these techniques are not currently in use at CSC Milford, and will reduce the surgical time to an average of seven minutes, at the same time improving throughput without sacrificing quality.

The Applicant describes staff training, standardization of instruments and equipment used, and providing improved post-operative instructions as measures that will improve quality outcomes, and efficiencies.

The Applicant reports that based upon health outcomes tracked by independent peer review, the rates of surgical site infections and of post-operative complications for surgeries performed by the Applicant surgeon are among the lowest in the country and that similar health outcomes measurements will be implemented at CSC Milford once this transaction is complete.

Competition on Price, Costs, TME

The Applicant cites studies demonstrating that ambulatory surgical facilities provide quality care and excellent outcomes at a lower cost compared to hospital outpatient departments⁹ providing value to both the payer and patients.¹⁰ This project, if approved will, according to the

⁵Carter M, Kolos A. Reduction of Ontario surgical wait times. J Policy Engagem. 2009; 1(4):9-11Google Scholar.

⁶ It is estimated that with the increased need for cataract surgery surgeons, there may be a shortage of surgeons to perform the procedures. (Ophthalmology Times, Frank Goes, MD, July 10, 2017).

⁷ Topical anesthetic eye drops replace retrobulbar blocks, which require inserting a needle behind the eye.

⁸ Advantages of topical anesthesia include no risk of ocular perforation, extraocular muscle injury, or central nervous system depression. Vision returns almost immediately, and patients are able to leave the operating room without being patched because no eyelid block is used. *Anesthesia for Cataract Surgery*
<https://www.aao.org/bcscsnippetdetail.aspx?id=c6bba5fc-cfa7-4c0f-a879-b184f4cf7f4d>.

⁹<http://www.ascassociation.org/advancingsurgicalcare/reducinghealthcarecosts/costsavings/healthcarebluebookstudy>.

¹⁰ Ambulatory Surgery Centers (ASCs) perform more than 7 million cataract procedures for Medicare beneficiaries. By specializing in specific procedures, ASCs are able to maximize efficiency and quality outcomes for patients. This

Applicant, increase the efficiencies of an existing ASC without expanding operating room capacity and without any increase in per procedure reimbursements from payers.

Health Equity-Focused

The Applicant and CSC Milford will continue to accept all insurance plans, including Medicare and MassHealth. The Applicant expresses its commitment to health equity and has hired bilingual staff that lives locally and who can support culturally competent care which, in turn, can lead to improved clinical outcomes. This transaction will keep and expand ambulatory surgical capacity in the Milford-Franklin region. The Applicant asserts that this will afford more convenient access to services without the time and cost incident to longer travel. CSC-Milford is accessible to individuals who utilize public transportation.

Community Engagement

Applicant consulted with local community representatives and its patients about the proposed acquisition and has been performing some surgeries at CSC Milford to help ensure a smooth transition to familiarize staff with the new surgeon. To document local support, the Applicant included letters from patients who have received surgery at CSC Milford.

Factor 2

Factor 2 is not applicable to transfers of ownership

Factor 3

The Applicant has certified that it is in compliance and 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. There have been no previously issued Notices of Determination of Need.

Factor 4

The DoN regulation at 105 CMR 100.210(A) (4) requires that an Applicant for a DoN provide “sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel and that the Proposed Project is financially feasible and within the financial capability of the Applicant.” Factor 4 requires that the documentation include an analysis of the Applicant’s finances, completed by an independent Certified Public Accountant (CPA Report).

led to Medicare reimbursing ASCs as a percentage of the amount paid to hospital outpatient departments (HOPDs). The Medicare program and its beneficiaries accrue annual savings of more than \$2.3 billion from procedures performed in ASCs instead of HOPDs. A commercial medical-claims data review found that annually, ASC availability reduces U.S. health care costs by more than \$38 billion, with more than \$5 billion of that savings accruing to patients from lower deductible and coinsurance payments.

In order to assess the reasonableness of assumptions used, and the feasibility of the projections for the transfer of ownership, the CPA Report reviewed M-F Eye's audited consolidated financial statements, and its current financial position (FY 2015 through 2017). The financial performance was reviewed in relation to key financial metrics from three private business intelligence organizations and to the most current three-year financial performance of M-F Eye.

The CPA Report indicates that the Applicant projects revenue growth at a rate of about 5% per year, due to an increase in the number of procedures associated with the acquisition contemplated in this DoN and the addition of another surgeon and optometrist to bring the underutilized facility up to optimal utilization. The CPA Report indicates that this revenue growth reflects a reasonable estimation of future revenues.

The CPA Report indicates that operating expenses, with the exception of three categories: payroll, medical supplies, and laser click fees, are projected to grow at an annual rate of 3% from 2017. The payroll projections, which include the addition of administrative and clinical staff, will bring growth in that category to inflation plus adjustments. The medical supplies' expense has varied widely; however, the CPA Report states that it is reasonable to think that following this transaction, these costs will be contained within eye center industry standards. The expense associated with laser click fees will rise as a function of volume growth and will increase at the same rate as number of procedures performed. The CPA Report found all of the assumptions used in the Applicant's expense projections to be reasonable.

The CPA Report reports that historical metrics for profitability, solvency and liquidity were analyzed and notes that margins were higher than industry metrics due to a projected annual EBITDA (earnings before interest, taxes, depreciation and amortization) surplus of approximately 52.6% for projected revenues for M-F Eye from 2018-2022. Further inquiry determined that this was because the two physician owners of M-F Eye receive distributions from the partnership rather than compensation through a payroll expense. The CPA performed a sensitivity analysis to account for this, estimating payroll expenses related to the M-F Eye physicians and noted no change to their opinion that the "Proposed Project would not likely have a negative impact on the Patient Panel or result in the liquidation of the Applicant's assets."

The CPA Report concludes that the Applicant's five year financial projections, as well as its revenue and expense projections are reasonable and feasible and states that "We determined that the Projections are reasonable and feasible, and not likely to have a negative impact on the patient panel or result in a liquidation of assets of MFEC".

Factors 5 and 6

Factors 5 and 6 are not applicable to transfers of ownership

Findings and Recommendation

Pursuant to 105 CMR 100.735, the staff recommends approval of the proposed project. Any approval is subject to 105 CMR 100.735(D)(3) relative to noncompliance and to certain

standard conditions that are set out in Attachment 1 including standard condition 105 CMR 100.310(L), which requires annual reporting by Holder relating to the project's achievement of the DoN factors.

Attachment 1**Standard Conditions that Apply to Transfers of Ownership**

Only a subset of all the standard conditions set out in 105CME 100.310 apply to transfers of ownership.

105 CMR 100.310: Standard Conditions

Unless otherwise expressly specified within 105 CMR 100.000, each Notice of Determination of Need issued by the Department shall be subject to the following Conditions. The Commissioner may specify additional Standard Conditions within Guideline which shall be attached to all Notices of Determination of Need, unless otherwise specified, and which shall be determined by the Commissioner as advancing the objectives of 105 CMR 100.000. Prior to issuance, such Guideline shall be developed through a public process consistent with 105 CMR 100.440 and in consultation with applicable Government Agencies, community-based organizations, relevant stakeholders, and the Public Health Council.

(A) The Notice of Determination of Need shall be subject to administrative review by the Health Facilities Appeals Board and may be stayed by the Health Facilities Appeals Board. If the Health Facilities Appeals Board is not constituted on the date of issuance of the Notice of Determination of Need, the Notice shall be considered a Final Action subject to review under M.G.L. c. 30A.

(B) Intentionally Omitted

(C) Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization only for the Proposed Project for which the Notice of Determination of Need is made, and for only the total Capital Expenditure approved.

(D) The Notice of Determination of Need shall constitute a valid authorization only for the Person to whom it is issued and may be transferred only upon the expressed written permission of the Department pursuant to 105 CMR 100.635(A)(3), except that a Notice of Determination of Need issued for an Original License pursuant to 105 CMR 100.730 and a Notice of Determination of Need for a Transfer of Ownership pursuant to 105 CMR 100.735 shall not be transferable.

(E)-(G) Intentionally Omitted

(H) The Government Agency license of the Health Care Facility or Health Care Facilities for which, and on behalf of, the Holder possesses a valid Notice of Determination of Need, shall be conditioned with all Standard and Other Conditions attached to the Notice of Determination of Need.

(I)-(J) Intentionally Omitted

(K) If the Health Care Facility or Health Care Facilities for which the Notice of Determination of Need has been issued is eligible, the Holder shall provide written attestation on behalf of the Health Care Facility or Health Care Facilities, under the pains and penalties of perjury, of participation, or their intent to participate, in MassHealth pursuant to 130 CMR 400.000 through 499.000.

(L) The Holder shall report to the Department, at a minimum on an annual basis, and in a form, manner, and frequency as specified by the Commissioner. At a minimum, said reporting shall include,

but not be limited to, the reporting of measures related to the project's achievement of the Determination of Need Factors, as directed by the Department pursuant to 105 CMR 100.210.

(M) Intentionally Omitted

(N) The Holder shall provide to Department Staff a plan for approval by the Office of Health Equity for the development and improvement of language access and assistive services provided to individuals with disabilities, non-English speaking, Limited English Proficiency (LEP), and American Sign Language (ASL) patients.

(O) The Holder shall provide for interpreter services to the Holder's Patient Panel. The Holder shall ensure that all medical and non-medical interpreters, inclusive of staff, contractors, and volunteers providing interpreter services to the Holder's Patient Panel maintain current multilingual proficiency and have sufficient relevant training. Training for non-medical interpreters should include, at a minimum:

- (1) the skills and ethics of interpretation; and
- (2) cultural health beliefs systems and concepts relevant to non-clinical encounters.
- (3) Training for medical interpreters should include, at a minimum:
 - (a) the skills and ethics of interpretation; and
 - (b) multilingual knowledge of specialized terms, including medical terminology, competency in specialized settings, continuing education, and concepts relevant to clinical and non-clinical encounters.

(P) The Holder shall require and arrange for ongoing education and training for administrative, clinical, and support staff in culturally and linguistically appropriate services (CLAS), including, but not limited to, patient cultural and health belief systems and effective utilization of available interpreter services.

(Q) All Standard and Other Conditions attached to the Notice of Determination of Need shall remain in effect for a period of five years following completion of the project for which the Notice of Determination of Need was issued, unless otherwise expressly specified within one or more Condition.

105 CMR 100.735(D) Other Conditions. A Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.735(A) shall include the following Other Condition(s):

(1) (a) Unless rescinded pursuant to 105 CMR 100.735(D)(1)(c), any Notice of Determination of Need issued to a Holder that is subject to a Cost and Market Impact Review pursuant to M.G.L. c. 6D § 13 and 958 CMR 7.00 shall not go into effect until: 30 days following HPC's completed Cost and Market Impact Review. Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization for a period of not more than three years following the approval of the Department, unless otherwise expressly noted as an Other Condition, and shall only be for the purposes of the approved project. No Notice of Determination of Need shall remain in authorization unless the Holder complies with all prescribed terms and Conditions as set forth by the Department.

(b) The Department shall receive within 30 days of issuance of the written notification made pursuant to 105 CMR 100.625(A) a written acknowledgement of receipt of such written notification by the Holder, documented in the form of an attestation, signed by the Holder's chief executive officer and board chair, and returned to the Department and all Parties of Record.

(c) Notwithstanding 105 CMR 100.735(D)(1)(a), as part of a completed Cost and Market Impact Review, the HPC may provide a written recommendation to the Commissioner that the Notice of Determination of Need should not go into effect on the basis of findings contained within the completed and publicly released Cost and Market Impact Review. Upon receipt, the Commissioner shall determine if the Cost and Market Impact Review contains information sufficient for the Commissioner to conclude that the Holder would fail to meet one or more of the specified Factors. Should the Commissioner determine that the Holder would fail to meet one or more of the specified Factors, the Department may rescind or amend an approved Notice of Determination of Need. The Department shall consider the HPC's written recommendation pursuant to the Commissioner's determination prior to the Notice of Determination of Need going into effect, and within the context of all specified Determination of Need Factors. If a Notice of Determination of Need is rescinded by the Department, the Person for which the rescinded Notice of Determination of Need was issued must file a new Application for Determination of Need, if so desired. Such Application must satisfy 105 CMR 100.210 and shall account for the concerns expressed by the Department within their findings.

(3) If it is determined by the Department that the Holder has failed to sufficiently demonstrate compliance with the terms and Conditions of the issued Notice of Determination of Need, the Holder shall fund projects which address one or more of the Health Priorities set out in Department Guideline, as approved by the Department, which in total, shall equal up to 5% of the Total Value of the approved project. In making such determination, the Department shall provide written notification to the Holder at least 30 days prior to requiring such funding, and shall provide the Holder the opportunity to appear before the Department. The Department shall consider factors external to the Holder that may impact the Holder's ability to demonstrate compliance.

(4) Upon Notice of Determination of Need issued pursuant to 105 CMR 100.735(A), where the acquired Health Care Facility is a Holder of an approved, but not yet implemented Notice of Determination of Need, the acquired Health Care Facility's unimplemented Notice of Determination of Need shall be rendered null and void, unless the acquiring Holder receives the express written approval from the Department, pursuant to a Significant Change amendment, see 105 CMR 100.635(A)(3)