New England Surgery Center, LLC

Amendment for Determination of Need Applicatoin #20072809-AS

June 22, 2022

New England Surgery Center, LLC 900 Cummings Center, Suite 122U Beverly, MA 01915

**New England Surgery Center, LLC Amendment to DoN Application# 20072809-AS**

**Table of Contents**

1. Factor 10 Amendment Narrative
2. Affiliated Parties Form
3. Copy of Notice of Intent
4. Affidavit of Truthfulness Form
5. Staff Summary for Approved DoN
6. Copy of Original Decision Letter for Approved DoN

# Attachment 1

DoN Project #20072809-AS

New England Surgery Center, LLC Significant Amendment

* + 1. Described the proposed change.

This amendment is filed for the purpose of requesting an increase in the DoN approved Maximum Capital Expenditure (MCE) that relate to the increase in project cost from the time the DoN was developed. The project scope remains the renovation of space adjacent to the current location. However, additional unanticipated and necessary critical and noncritical repairs were identified after more in-depth inspection by the architect and engineers that were not included in the original DoN's project scope. These include the addition of one HVAC roof unit, repair/upgrade/replacement of two original HVAC roof units and upgrading insufficient electrical breakers and the addition of an electrical room for additional panels. In addition, labor and construction cost increases, attributable to the COVID 19 pandemic have contributed to the need for the proposed amendment.

* + 1. Describe the associated cost implications to the Holder.

This amendment requests an increase in the approved maximum capital expenditure associated with the approved project. The Applicant is seeking an approval for a total capital expenditure of $2,946,581. This is a 86% increase from the currently approved $1,587,646. In addition to the cost elements described in 10.5.a. the Applicant will have additional interest expense associated with the increase in borrowing required to fund the increased project costs. There are no other material changes projected in operating expenses upon the completion of the project and there continues to exist the potential for savings from the variety of energy-related improvement in the project.

* + 1. Describe the associated cost to the Holder's existing Patient Panel.

There will be no cost impact for the patient panel.

* + 1. Provide a detailed narrative, comparing the approved project to the proposed Significant Change, and the rationale for such change.

On January 27, 2021, New England Surgery Center, LLC received approval of a Determination of Need (DoN) application for a Substantial Change in Service to add a second operating room, additional patient support and administrative areas to the existing facility at 900 Cummings Center, Suite 122U, Beverly, MA. The (MCE) for the project was $1,587,646. Through this Amendment, the Applicant seeks approval for an increase in the approved MCE for the project to $2,946,581. This is an increase of $1,358,935 or 86%.

The Applicant is not seeking to materially change the scope or gross square feet of the approved Project. However, there are additional unanticipated required repairs/replacements that were not requested in the approved application. The primary basis of the increase in capital expenditure relates to the increase in Project costs from the time the DoN was developed.

1. Explanation of Capital Cost Increases

This increase in costs is due to a number of factors of factors. A more detailed investigation by the architects and engineers as part of the development of the more detailed construction plans, resulted in the identification of additional work that is necessary for the completion of the project. This work could not have been foreseen without the investigations done for the development of the construction plan. The increase in costs also were impacted by the significant increase in construction related labor and

material costs.

* 1. HVAC

There are currently two roof units that supply the center as it is. Originally, the plan was to update these two units and add servicing of the new additional space to these units. Unfortunately, upon a more recent evaluation, both units were found to be at end of their operational lives and not capable of the added requirements of servicing the new space. A new roof unit, to cover the additional OR, central sterile, PACU and office area will need to be added. This will require new duct risers traveling through the occupied second and third floors of the building. The two existing units will need to be updated or replaced, and this will result in $493,000 in additional costs not originally accounted for.

* 1. Electric

Replacement and upgrading electrical systems were not a component of the project at the time of DoN approval. At that time, it was projected that any expansion could be handled with the existing panels, both normal and emergency. Subsequently, the engineers identified insufficient available electrical breakers and the lack of sufficient room in the electrical equipment room to mount additional circuit expansion. These increased electrical costs arise from increased costs in supplies, the replacement of the existing 800 Amp distribution Panel with a new 800 Amp distribution panel providing increased circuit expansion capabilities to feed new panels and other select specialty equipment. Three transfer switches were metered for a 30-day period to measure load outputs at an additional cost of $5,400. The additional equipment will need to be moved to a new emergency electrical closet adding $245,400 additional costs.

* 1. Architectural/Engineering fees

The architectural cost estimates developed for the DoN application were quoted at $75,586. During the DoN process and with an increase in available projects, the original architect took on other projects and no longer would be available. New architects were contacted and bids received. The cost increased by

$92,811 to $168,397.

1. Covid Related Construction Costs

The remainder of the requested increase in costs relates to higher than projected construction costs from the time the DoN was developed and submitted (August, 2020) to the date the construction estimate was received (October, 2021). The increases in labor, material and equipment costs attributed to the COVlD-19 pandemic were not foreseeable. There are many factors affecting construction costs.[[1]](#footnote-1) For example: Steel mill products prices have climbed 108.6% over the past 12 months and 87.6% in

2021 alone. Lumber has increased 112%[[2]](#footnote-2) Suppliers made incorrect estimates that the demand would decline with Covid-19 limiting production; material increased demand for home improvement, renovations and construction due to more time spent at home increasing the demand; import tariffs and government policies; supply and manufacturing material shortages such as copper and crude oil[[3]](#footnote-3); and significant increases in labor costs. The total construction increase is $652,724.

Comparison of Approved and Requested Expenditures

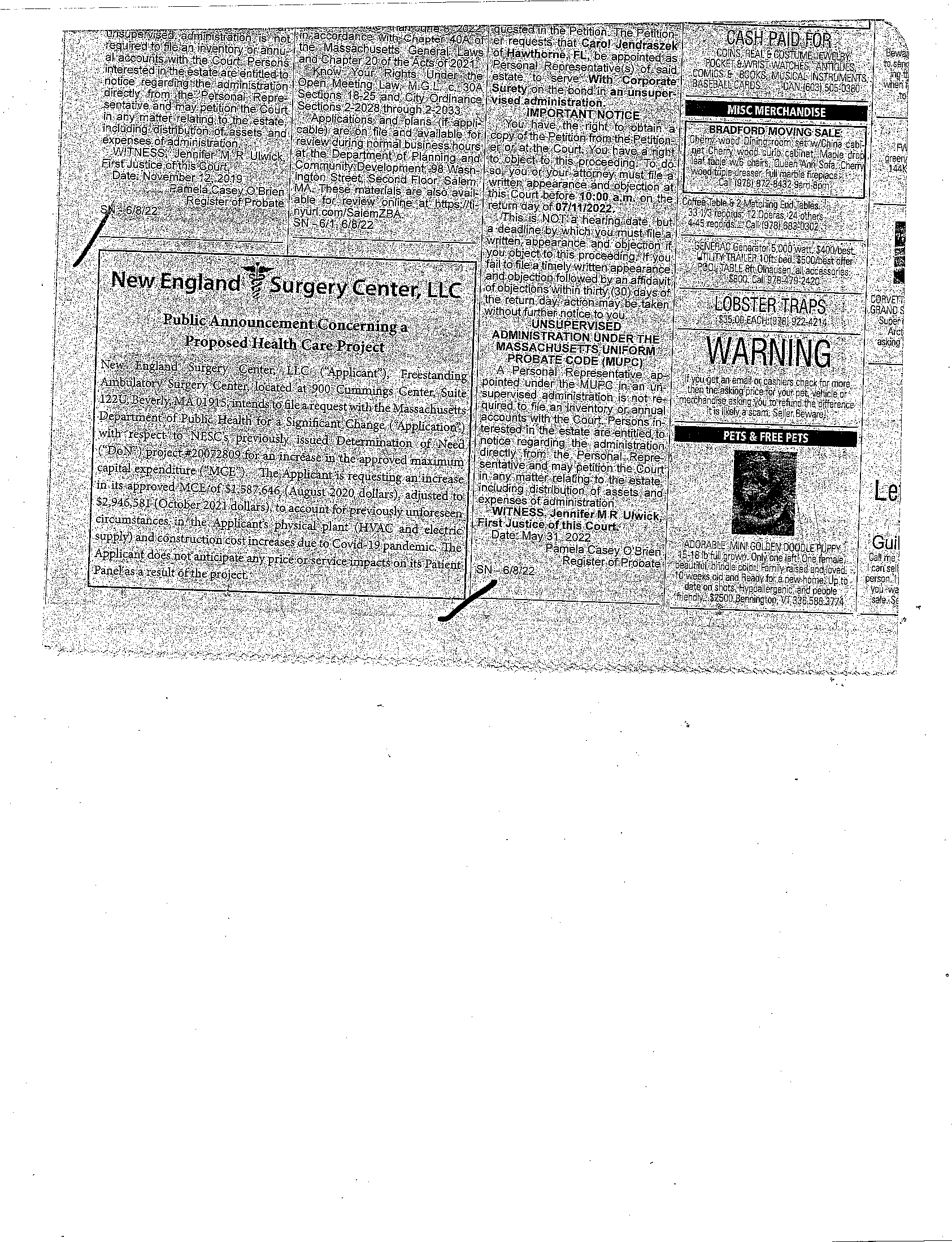
|  |  |  |  |
| --- | --- | --- | --- |
| Category of Expense | Approved (January 2021 dollars) | Renovation Increase | New Proposed MCE |
| Land Costs |  |  |  |
| Land Acquisition | $0 | $0 | $0 |
| Site Survey and Soil Investigation | $0 | $0 | $0 |
| Other Non-Depreciable Land Development | $0 | $0 | $0 |
| Total Land Costs | $0 | $0 | $0 |
| Construction Contract (including bonding cost) |  |  |  |
| Depreciable Land Development  Cost | $0 | $0 | $0 |
| Building Acquisition Cost | $0 | $0 | $0 |
| Construction Contract (including bonding cost) | $1,178,250 | $652,724 | $$1,830,974 |
| Fixed Equipment not in contract | $125,000 | $613,400 | $738,400 |
| Architectural Cost (including fee, printing, supervision etc) and Engineering Cost | $75,586 | $92,811 | $168,397 |
| Pre-filing Planning and Development Costs | $44,115 | $0 | $44,115 |
| Other (specify) |  |  |  |
| Contingency allowance | $78,195 | $0 | $78,195 |
| Net Interest Expensed During Construction | $24,000 | $0 | $24,000 |
| Financing Costs |  |  |  |
| Cost of Securing Financing (legal, administrative, feasibility studies, mortgage, insurance, printing,  etc. | $62,500 | $0 | $62,500 |
| Bond Discount | $0 | $0 | $0 |
| Other | $0 | $0 | $0 |
| Total Capital Expenditure | $1,587,646 | $1,358,935 | $2,946,581 |

Conclusion:

The Applicant has worked diligently to implement its DoN approval. It has completed plans and sought construction bids, despite encountering unexpected challenges. COVID-19 delayed original development of plans and has caused significant impact on the cost of construction supplies and related labor.

All of the factors discussed in this narrative are beyond the control of the Applicant. None of these circumstances could have been foreseen when developing the DoN. New England Surgery Center respectfully requests the consideration of its significant amendment of the approved DoN.

Attachment 3



# Attachment 5

|  |  |
| --- | --- |
| **STAFF REPORT TO THE PUBLIC HEALTH COUNCIL**  **FOR A DETERMINATION OF NEED** | |
| Applicant Name | New England Surgery Center, LLC |
| Applicant Address | 900 Cummings Center, Suite 122U  Beverly, MA 01915 |
| Filing Date | October 16, 2020 |
| Type of DoN Application | Ambulatory Surgery |
| Total Value | $1,587,646.00 |
| Project Number | 20072809-AS |
| Ten Taxpayer Group (TTG) | None |
| Community Health Initiative (CHI) | $79,382.30 |
| Staff Recommendation | Approval |
| Public Health Council | January 20, 2021 |
| Project Summary and Regulatory Review  New England Surgery Center, LLC (Applicant) is a multi-specialty, freestanding ambulatory surgery center located in Beverly, MA. The Applicant submitted an application for a Proposed Substantial Change in Service to expand their ambulatory surgical capacity. The proposal is to renovate 5,190 gross square feet (GSF) of existing space adjacent to the current location for one operating room, two pre/post-operative beds, one enclosed pediatric room, an enlarged central sterile area, and additional administrative offices and storage spaces. The total value for the Proposed Project is 1,587,646.00. The Community Health Initiative (CHI) contribution to the Statewide Initiative Fund is $79,382.30.  Review of Applications for Ambulatory Surgery is under the DoN regulation 105 CMR 100.000. The Department must determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210. This staff report addresses each of the six factors set forth in the regulation. | |

Table of Contents

[Background: New England Surgery Center and Application Overview 4](#_Toc58960194)

[Patient Panel 4](#_Toc58960212)

[Factor 1: a) Patient Panel Need 5](#_Toc58960213)

[Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity 9](#_Toc58960214)

[Factor 1: c) Efficiency, Continuity of Care, Coordination of Care 11](#_Toc58960215)

[Factor 1: d) Consultation 11](#_Toc58960216)

[Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel 12](#_Toc58960217)

[Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending 12](#_Toc58960218)

[Factor 1 Summary 14](#_Toc58960219)

[Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation 14](#_Toc58960220)

[Factor 2 Summary 16](#_Toc58960221)

[Factor 3: Relevant Licensure/Oversight Compliance 16](#_Toc58960222)

[Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis 16](#_Toc58960223)

[Factor 5: Assessment of the Proposed Project’s Relative Merit 17](#_Toc58960224)

[Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline 17](#_Toc58960225)

[Findings and Recommendations 17](#_Toc58960226)

[Other Conditions 17](#_Toc58960227)

**OVERVIEW of PROPOSED PROJECT AND FACTOR REVIEW**

| Description | What’s Needed to Meet Factor 1: Demonstration of need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending. | What’s Needed to Meet Factor 2: Demonstration of cost containment, improved public health outcomes, and delivery system transformation | Factors 3, 4 & 5[[4]](#footnote-4) | What’s Needed to Meet Factor 6: Demonstration of plans for fulfilling … responsibilities … in the DPH Community-based Health Initiatives Guideline. |
| --- | --- | --- | --- | --- |
|  | ***Staff Report finds*** | | |  |
| **MEETS** | **MEETS** | **MEETS** | **MEETS** |
| The Applicant, a multispecialty, freestanding ambulatory surgery center, is renovating existing space to add a second operating room and additional patient support and administrative areas.  The Applicant proposes to provide more patients access to outpatient surgical services in the ASC setting which will serve as a lower cost alternative to hospital outpatient departments (HOPDs). | ✓ | ✓ | ✓ | ✓ |

**Background: New England Surgery Center and Application Overview**

The Applicant is New England Surgery Center, LLC (NESC), a freestanding, multispecialty ambulatory surgery center (ASC) located in Beverly, MA. NESC offers services in Orthopedics, Otolaryngology (ENT), Urology, Pain Management, Ophthalmology, Plastics, Podiatry, and General Surgery to patients age four years and older. NESC is Medicare-certified and accredited by the Accreditation Association for Ambulatory Health Care (AAAHC). The current facility has one operating room and seven pre/post procedure beds. NESC was organized in 2007 as a Massachusetts LLC. The applicant is eligible to expand through the grandfathering provision of 105 CMR 100.715.[[5]](#footnote-5)

The Applicant is proposing to renovate existing space located adjacent to the current site to add one operating room, two pre/post-operative beds, one enclosed pediatric room, an enlarged central sterile area, and additional administrative offices and storage spaces in order to increase its Patient Panel access to NESC’s services. The additional capacity will allow the Applicant to accommodate the current shift it is experiencing towards more complex surgeries which require longer operating room (OR) time per procedure.

|  | **Current** | **Proposed** | **Total if Approved** |
| --- | --- | --- | --- |
| ORs | 1 | 1 | 2 |
| Pre/Post-operative beds | 7 | 2 | 9 |
| Pediatric room | 0 | 1 | 1 |

**Patient Panel**[[6]](#footnote-6)

The Applicant provided Patient Panel information for the period FY2017-2019 during which time the Applicant served 3,752 patients.[[7]](#footnote-7) Table 1 below presents demographic information for these patients during FY19. Staff compared the demographic profile of NESC patients to that of Essex County where the majority of NESC patients reside and found that the racial/ethnic makeup of NESC patients differs from that of Essex County.[[8]](#footnote-8)

**Table 1: Overview of NESC Patients**

|  | **FY19** |
| --- | --- |
| Total Unique Patients | 1,024 |
| **Gender**  Male | 50% |
| Female | 50% |
| **Age**  0-17 | 9% |
| 18-64 | 58% |
| 65+ | 32% |
| **Race/Ethnicity[[9]](#footnote-9)**  White | 90% |
| Black/African American | 2% |
| Hispanic/Latino | 4% |
| Asian | 1% |
| Multiracial | 2% |
| Other | 1% |
| **Patient Origin**  75% of patients came from 14 communities[[10]](#footnote-10) | Beverly (13%)  Gloucester (11%)  Lynn (8%)  Peabody (7%)  Danvers (7%)  Salem (6%)  Wilmington (6%)  Marblehead (3%)  Ipswich (3%)  Manchester (3%)  Rockport (2%)  Swampscott (2%)  Middleton (2%)  Topsfield (2%) |
| **Payer-Mix**  Commercial | 40% |
| MassHealth | 2.1% |
| Managed Medicaid | 11.4% |
| Commercial Medicare | 6.3% |
| Medicare FFS | 32.8% |
| All Other | 7.4% |

**Factor 1: a) Patient Panel Need**

**In this section, we assess whether the Applicant has sufficiently addressed** Patient Panel need for the Proposed Project. The Applicant states that the Proposed Project will expand access to its services to additional patients, and address Patient Panel need for outpatient surgery to improve health outcomes and quality of life.

**Patient Panel Need**

The Applicant attributes Patient Panel need for increased outpatient surgery capacity to two factors: capacity constraints due to more complex procedures and more providers performing cases requiring anesthesia; and an aging population.

1. **Capacity Constraints.** The Applicant describes a need for additional OR capacity as a result of heavier demand on the existing OR and a subsequent decrease in available time slots for procedures.

The Applicant notes that despite the procedure volume decrease, scheduled time in the OR remains high due to the complexity of the current case load. From 2017 to 2019, the Applicant experienced a shift from a higher volume of simple cases to a lower volume of more complex cases requiring additional operating room (OR) time. Overall case numbers are 1,621 visits in 2017, 1,500 visits in 2018 and 1,474 visits in 2019.[[11]](#footnote-11) Complex procedures, described further below, make up 13% of the 2019 case volume. The majority of patient diagnoses were related to otolaryngology, urology, ophthalmology, pain management and orthopedics.

The biggest impact on OR demand was driven by a shift noted from 2017 in which 18% of pain procedures were complex to an increase to 97% of such complex procedures in 2020.[[12]](#footnote-12) The Applicant attributes this dramatic difference to recent Medicare approval of these procedures for the outpatient setting, which has led to more complex interventional techniques performed in place of prescription opioid pain management.[[13]](#endnote-1) Also, for pain management procedures NESC has experienced a change in OR time. Per patient registration-to-discharge time increased from 30 minutes for patient pain injections to one to two hours of OR time for more advanced pain procedures. Complex surgeries include Veritflex[[14]](#footnote-13), MILD[[15]](#footnote-14), and neurostimulator implantation procedures for pain.

Additionally, the percentage of complex otolaryngology procedures increased from 8% in 2018, to 14% in 2020.[[16]](#footnote-15) The otolaryngology case shift from uncomplicated pediatric otolaryngology services to higher complexity frontal sinus cases began in 2018. High-volume pediatric care (including tubes, tonsils and adenoids) require 30 minutes of OR time compared to the frontal sinus surgeries which can require up to three hours in the OR.[[17]](#footnote-16) The Applicant asserts complex fusion sinus cases allow for better visualization of sinus anatomy and disease, and this helps to reduce the need for subsequent surgery and enhances patient safety.

The more complex cases require longer time in the OR which leads to a reduction in the number of cases that can be performed per day. Previously, eight cases would be performed on a full OR day including turnaround time. However, as the operative time per procedure has increased, the number of cases decreased to between four and seven, depending on the number of complex cases scheduled per day. This calculates to a decrease of up to 20 or more cases per month, or 100+ cases annually. The Applicant also attributes the shift to more complex procedures to the aging population in Massachusetts, which is explained further below (2a,2b).

1. Current wait times for patients to schedule a procedure vary by specialty: five to ten days for otolaryngology, and five to ten days for pain management. To shorten wait times, the Applicant plans to add new providers. The new surgeons include four general surgeons, four orthopedic surgeons, and two urologists. Operating room scheduling consists of individual and group block scheduling. The Applicant states optimal OR usage would be 75-80%, and that utilization higher than 85 to 90% leads to patient delays and staff overtime.[[18]](#endnote-2) At the time of application submission, the Applicant states the current operating room reserved time usage was 58%-62%; OR block utilization had increased from 60.3% to 63.5% between 2017 and 2019. As of October 31, 2020, OR utilization increased to 65.7%, and in November, it increased to 73.7%. The Applicant states that the time between cases has increased in order to permit adequate air exchanges to prevent COVID transmission.

While the new providers can increase access, usage of the single OR will be strained. An additional factor contributing to an increased demand on OR time is the increase in cases requiring general anesthesia. To date, total operative time per procedure increased from 71.01 minutes in 2017 to 76.83 minutes in 2019. The bulk of the procedures performed by the new surgeons will require anesthesia and will have more impact on the time per procedure at the facility. The addition of an OR will simultaneously allow for the new providers to schedule more procedures and subsequently decrease wait times for patients, as well as accommodate the longer OR times required for procedures involving anesthesia. The Applicant described trends in volume and types of cases the surgery center will be seeing by specialty due to the addition of new surgeons to increase the range of services available at the facility and reduce wait times for procedures.

1. Orthopedics – The majority of surgical services provided by the orthopedic surgeons require general anesthesia.[[19]](#footnote-17) The surgeons are projected to bring in an additional five to ten cases per week. The Applicant asserts the additional cases will bring the existing OR to near its maximum capacity resulting in a shortage of currently available OR time.[[20]](#footnote-18)
2. General Surgery – The ability of general surgeons to book additional procedures is dependent upon OR time availability for longer periods, with most cases lasting one hour.[[21]](#footnote-19) The additional volume from the new surgeons will place constraints on the single OR, reducing block time.
3. Urology – Since Application submission, the Applicant has credentialed two new urologists. With these new providers, an additional 20 urology cases, all requiring anesthesia, are being scheduled per month.[[22]](#footnote-20)
4. Otolaryngology – In 2019, OR days available for the four surgeons performing otolaryngology cases were reduced from nine full days per month to five days in order to accommodate additional orthopedic and urology cases. The Applicant asserts that the addition of the OR would allow for the return to nine full OR days per month to accommodate demand.
5. **Aging population.**

The Applicant asserts an aging population with increasing health needs will contribute to a growing demand for NESC’s services. Over 75% of the Patient Panel lives in Essex County where the age 65 and older population is expected to increase by 17.2% between 2020 and 2025.[[23]](#endnote-3) The Applicant notes Medicare patients comprise 39% of NESC’s payer mix. A population that is growing older with increased risk for conditions addressed at the Applicant’s facility will increase demand for its outpatient surgical services.

* 1. The Applicant asserts the above average prevalence of certain age-specific conditions will result in increasing demand for the multi-specialty surgical services offered at NESC.
     1. The Applicant points to an increase in the prevalence of chronic disease among adults age 65 and older in Essex County from 37% in 2007 to 39% in 2015; and notes that the prevalence of chronic disease among this age group in Essex County is higher than peer counties, the state, and the country.[[24]](#endnote-4)
     2. The prevalence of obesity in adults in Essex County increased from 19% in 2004 to 25% in 2016.[[25]](#endnote-5) Obesity is correlated with a number of health issues, including arthritis and musculoskeletal health issues that increase the need for surgical services, and is a common condition among patients with orthopedic conditions. The Applicant highlighted specific conditions and surgical needs more prevalent among obese patients including knee replacement,[[26]](#endnote-6) and a higher risk of developing kidney stones.[[27]](#endnote-7)
     3. The Applicant cited studies documenting a higher prevalence of arthritis and conditions like lumbar spinal stenosis (LSS) and sacroiliac joint (SJ) pathologies in the age 65 and older population.[[28]](#endnote-8) Arthritis, the risk of which increases with age, is a leading cause of pain and disability.[[29]](#endnote-9),[[30]](#endnote-10)
  2. The Applicant referenced a study showing personal healthcare spending[[31]](#footnote-21) varies by age with higher spending occurring in the age 65 and older segment of the population.[[32]](#endnote-11),[[33]](#endnote-12) The Applicant also argues the most commonly utilized surgical services by the age 65 and older population (urological, orthopedic, and ophthalmologic surgical services) are the primary surgical services performed at NESC, and that demand for these services is expected to increase as the age 65 and older populations grows.[[34]](#endnote-13) The Applicant also projects additional demand for its services because CMS is set to remove 300 procedures, made up of primarily musculoskeletal procedures that are within the ASC’s surgical specialties, from the Medicare Inpatient-Only list[[35]](#footnote-22)starting in 2021 as part of a proposal to eliminate the Inpatient-Only list by 2024.[[36]](#endnote-14)

***Analysis***

The Applicant outlined a need for adding operating room capacity at NESC to address decreasing OR availability, a result of several elements, and the subsequent decrease in Patient Panel access to NESC’s services. The Applicant demonstrated increasing Patient Panel demand for its services through projected population growth and increasing prevalence of certain conditions that will require the surgical services offered at NESC. Higher rates of chronic diseases in general, better chronic disease management, and the general aging population combined create a greater need for these services.[[37]](#endnote-15),[[38]](#endnote-16) NESC outlined the shift it is experiencing to more complex procedures to underscore the need for increasing OR capacity to accommodate additional procedures and to more adequately address Patient Panel need for high-quality, timely access to outpatient surgical services.

**Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity**

* **Improved outcomes**- The outpatient surgeries offered at NESC are associated with improved outcomes, including reduced pain and improved functionality.[[39]](#endnote-17),[[40]](#endnote-18),[[41]](#endnote-19),[[42]](#footnote-23) The Applicant reviewed the benefits of surgeries moving to the ASC setting, including image guided surgery (IGS), which offers 3-dimensional imaging and better visibility in guiding surgical instruments to improve precision, reduce risk of complications and reduce the recovery period.[[43]](#endnote-20),[[44]](#footnote-24) The Applicant also cited reports showing ASCs offer quality outcomes that are comparable to outcomes for outpatient surgery performed in a hospital setting.[[45]](#endnote-21),[[46]](#endnote-22) Additionally, the shift from prescription opioid medications to surgical procedures to manage chronic pain and reduce opioid prescribing is an important public health goal. [[47]](#endnote-23)
* **Improved patient experience** **-** Provision of care in the ASC setting is associated with enhanced convenience and satisfaction for patients. ASCs offer convenient locations that are easier to navigate than hospital structures, including simpler scheduling of procedures, shorter wait times, and improved accessibility to physicians.[[48]](#endnote-24),[[49]](#endnote-25),[[50]](#endnote-26) These qualities may be particularly relevant for patients age 65 and over, who find both access to, and the experience of the freestanding ASC less complicated than the hospital setting.[[51]](#endnote-27)
* **Regulatory Oversight -** The Applicant conducts regular assessments of quality of care through required reporting for certification by CMS and accreditation by AAAHC. The Applicant demonstrates favorable metrics for its 2017 and 2018 reporting through Medicare’s Ambulatory Surgical Center Quality Reporting (ASCQR) Program. The Applicant submitted patient satisfaction measures collected from patients after discharge from the period March 2017 to September 2019 in accordance with CMS and AAAHC requirements. Survey results indicate high levels of satisfaction with treatment.[[52]](#footnote-25)

***Analysis***

Access to healthcare is associated with improved outcomes and can reduce the need for additional care.[[53]](#endnote-28),[[54]](#endnote-29) Shorter wait times for procedures are correlated with increased patient satisfaction and lower rates of complications.[[55]](#endnote-30) Additionally, staff research found that surgeries performed in an ASC outpatient setting can result in fewer and lower infection rates than hospitals.[[56]](#endnote-31),[[57]](#endnote-32) ASCs are regulated to ensure the delivery of quality care, and NESC cited several reporting processes that assess quality of care, patient satisfaction and outcomes.

**Health Equity and Social Determinants of Health (SDOH)**

**Interpretation and Translation Services**

The Applicant offers an Interpreter Services Program that will be accessible to all patients receiving care in the proposed operating room. Information on interpreter services is provided on the facility’s website. In addition, the preoperative website One Medical Passport provides the option for patients to register and create an account in their primary language and asks about a patient’s need for language assistance. The Applicant states that 100% of interpreter services are provided via video or telephone and does not anticipate this changing. The Applicant contacts the Massachusetts Commission for the Deaf and Hard of Hearing to access interpreters for patients who require them. Currently, phone and video interpretive services for spoken language are provided by CyraCom are available for pre- and post-operative visits, and phone calls with patients. A remote video device and dual handset phone are stationed in the surgical area for easy access. The Applicant states that it discontinued in-person interpretation because it was cost prohibitive. After a review of language access services offered at local hospitals, it engaged Cyracom because it is cost-effective and easily available for use with patients. One percent of patients reported Spanish as a primary language and less than 1% reported Portuguese as a primary language.[[58]](#footnote-26) Pre- and post-procedure documents are routinely available in Spanish and can be translated into other languages as needed. The Applicant tracks patient utilization of interpreter services through Cyracom billing and patient self-reporting on the One Medical Passport pre-operative questionnaire. The Applicant has posted and made available posters about COVID-19 intake and care in the languages most frequently used by patients.

In response to staff inquiry about CLAS initiatives, the Applicant asserted the facility does not discriminate based on race, education, health literacy, age, sexual orientation, ethnicity, religion, physical or mental disability, language, gender expression, identity, income, or class.[[59]](#footnote-27) Annual diversity training is provided for all staff, surgeons, and new hires through HealthStream. Training is reviewed annually and updated to ensure relevance. Yearly sexual harassment training is provided through Paychex and surgeons are provided with written training materials. The Applicant states the Governing Board reviews all training annually. The facility is ADA compliant, and accommodations for patients with disabilities are assessed during pre-operative phone calls, including need for any assistance required for moving throughout the facility, such as use of a walker/wheelchair, and hearing and/or visual impairments.

**Social Determinants of Health (SDoH) Screening**

The Applicant is a physician-owned, free-standing ASC that is not affiliated with an accountable care organization (ACO) or aligned with social services or community based experts. A pre-operative questionnaire provided by NESC and completed by patients contains questions evaluating social service needs. Information identified in the questionnaire include: identifying the person who will be escorting the patient home after surgery and remaining at home with the patient for the first 24 hours, smoking habits, alcohol or drug use, level of physical activity, and whether the patient feels safe at home or suffers abuse. If abuse is indicated in the patient’s responses, the patient is directed to contact SafeLink, the Massachusetts’ statewide 24/7 toll-free domestic violence hotline. Positive social needs screens are referred to the primary care physician (PCP) who then follows up with the patient.

***Analysis***

Through a review of the facility’s interpreter services, training initiatives, and social needs screening, staff finds that the Applicant has sufficiently outlined, at a high level, a case for improved health outcomes and has provided reasonable assurances of health equity and access to care.

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

The Applicant described care coordination processes between its patients, their PCP, the surgeon’s office, and NESC both before and after surgery. The Applicant states assistance for patients starts when the procedure is booked by a surgeon’s office.

* Patients complete a standard pre-operative questionnaire that is reviewed by the pre-operative nurse and anesthesiologist. Follow up with the PCP or a specialist occurs when issues are identified.
* All patients are required to have a pre-operative history and physical completed no more than 30 days prior to surgery at the surgeon’s office or the PCP’s office and obtain clinical clearance.
* Prior to anesthesia, all patients are provided with training on post-surgery care in the pre-operative area. Patients receive a copy of written instructions at discharge.[[60]](#footnote-28) A nurse calls each patient 24 hours after surgery to review discharge instructions, pain, mobility, nausea and vomiting, signs and symptoms of infection, and satisfaction with treatment prior to and after surgery. The nurse contacts the surgeon’s office by phone to share any concerns identified during the call and the surgeon shares the information with the patient’s PCP. Results of the follow-up call from a nurse are reviewed by the Quality Improvement Committee.
* Copies of operative notes are sent to the surgeon’s office and to the PCPs office either by mail or fax.
* A billing office staff member is responsible for checking all patient benefits, and contacts each patient with information on deductibles, copays, and insurance to prevent patients from receiving a surprise bill.

NESC does not have an electronic health record (EHR); the only interface is access to Lahey Epic[[61]](#footnote-29) for viewing patient test results provided by the local hospital. The Applicant notes that while the Health Information Technology for Economic and Clinical Health (HITECH) Act provided financial incentives to physicians and hospitals for adopting EHRs, it does not include ASCs.[[62]](#footnote-30)

***Analysis***

The Applicant detailed care coordination and information sharing across different providers. Integrated processes are of particular importance in the ASC setting for managing patient referral to different points of care.[[63]](#endnote-33) EHR adoption in ASCs has been slow and the high expense of the systems is one reason cited.[[64]](#endnote-34) Staff finds NESC has adequate processes in place to facilitate care coordination and communication across providers.

**Factor 1: d) Consultation**

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

been done and will not be addressed further in this report.

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

The Department’s Guideline[[65]](#endnote-35) for community engagement defines “community” as the Patient Panel, and requires that at minimum, the Applicant must “consult” with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging “community coalitions statistically representative of the Patient Panel.”[[66]](#endnote-36)

The Applicant held two open houses (November 5 and November 11, 2019). A total of two people attended the open house on November 5th, both of whom were staff members of North Shore Physicians Group, which is located in the same building as NESC. Attendees had an opportunity to view the ASC and a copy of the proposed expansion. The Applicant states open houses were advertised in Essex County and surrounding areas, in the surgeon’s offices and on bulletin boards in the Cummings Center where the ASC is located, and on the NESC’s Facebook page and website. The Applicant submitted copies of the materials used to advertise the open houses and copies of the materials that were presented.

***Analysis***

Staff reviewed the information on the Applicant’s community engagement and finds that the Applicant has met the minimum required community engagement standard of *Consult* in the planning phase of the Proposed Project.

**Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending**

The Applicant asserts that through the Proposed Project, it will continue to compete based on price, TME, costs and other measures of health care spending through providing a lower-cost alternative for patients’ outpatient surgery needs.

The Applicant asserts improving access to outpatient surgery in the ASC setting, where the surgeries are performed with greater efficiency and less expense than those done in HOPDs is unlikely to impact TME or the cost of services. ASCs are a lower cost option for these procedures for both payers and patients as compared to HOPDs. The benefits of expanding capacity to have these surgeries take place at NESC instead of a HOPD can lead to a reduction in TME as a result of lower provider and payer costs and lower out of pocket expenses for patients. Reports show Medicare procedures performed in the ASC setting can be less expensive than those performed in the hospital.[[67]](#endnote-37),[[68]](#endnote-38),[[69]](#endnote-39) The Centers for Medicare and Medicaid Services (CMS) launched the Procedure Price Lookup (PPL) tool in 2018 on Medicare.gov allowing patients to look up and compare estimated cost differences between ASCs and HOPDs for certain outpatient procedures.[[70]](#footnote-31) The Applicant asserts the tool shows differences in Medicare costs and copayments in ASCs and HOPDs. The Applicant provided Medicare payments information for a sample of procedures that are offered at the ASC to demonstrate the cost differential between ASCs and HOPDs. In response to staff inquiry about estimated cost differences for complex procedures, the Applicant provided additional Medicare payment information for a sample of complex pain and otolaryngology procedures that are offered at the ASC. A selection of the procedures is listed in Table 2.

**Table 2: Medicare local payments for a sample of procedures (2020)[[71]](#footnote-32)**

|  | **ASC (Average)** | | | **HOPD (Average)** | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | Total | Medicare Payment | Copay | Total | Medicare Payment | Copay |
| **Orthopedics** |  |  |  |  |  |  |
| Repair of shoulder rotator cuff using endoscope | $2,947 | $2,358 | $589 | $6,816 | $5,453 | $1,363 |
| Arthroscopy, knee, surgical (medial or lateral) | $1,352 | $1,082 | $270 | $3,119 | $2,495 | $624 |
| Suture of quadriceps or hamstring muscle rupture; primary | $2,947 | $2,358 | $589 | $6,816 | $5,453 | $1,363 |
| Removal of deep bone implant | $1,045 | $836 | $209 | $2,642 | $2,114 | $528 |
| **Podiatry** |  |  |  |  |  |  |
| Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method | $4,521 | $3,617 | $904 | $6,816 | $5,453 | $1,363 |
| **Otolaryngology** |  |  |  |  |  |  |
| Nasal sinus endoscopy frontal tissue removal | $1,993 | $1,594 | $399 | $6,199 | $4,959 | $1,240 |
| Repair of nasal septum (Septoplasty) | $1,109 | $887 | $222 | $2,985 | $2,388 | $597 |
| **Urology** |  |  |  |  |  |  |
| Fragmenting of kidney stone (ESWL) | $1,045 | $1,158 | $289 | $3,439 | $2,751 | $688 |
| Cystoscopy with biopsy | $830 | $664 | $166 | $2,018 | $1,614 | $404 |
| **Pain Management** |  |  |  |  |  |  |
| Percutaneous Laminectomy for decompression of neural elements (MILD) | $2,947 | $2,358 | $589 | $6,816 | $5,453 | $1,363 |
| Percutaneous fusion stabilization of sacroiliac joint | $13,648 | $10,918 | $2,730 | $18,169 | $16,483 | $1,686\* |
| Insertion of Interlaminar/interspinous process stabilization device (Vertiflex) | $10,380 | $8,304 | $2,076 | $13,560 | $11,874 | $1,686\* |

\*Reflect a higher patient responsibility if performed in an ASC vs HOPD due to Ambulatory Patient Care Classifications (APC) pricing.APCs incentivize hospitals to provide outpatient services economically, efficiently and profitably. The HOPD is paid at a higher rate than an ASC which allows for the lower patient responsibility.

Health Capital Consultants (HCC) conducted an analysis of potential NESC competitors in its service area in support of the Applicant’s Factor 4 analysis and determined that there are no comparable multispecialty, free-standing ASCs to provide the lower cost cases offered at NESC.[[72]](#footnote-33)

The Applicant will be utilizing available shell space within the existing footprint of the building. Reconfiguration of existing space will result in lower construction costs (compared to construction of an addition). Buildout of the space will have little to no effect on the daily operations of the facility. Finally, the Applicant has changed its purchasing organization which has resulted in a 24.9% supply cost savings in 2018.[[73]](#footnote-34)

***Analysis***

It has been well-established that generally, outpatient surgeries performed in the ASC setting can be a lower-cost alternative to the same surgeries performed in the HOPD and several studies detailed the cost savings associated with performing surgeries in the ASC setting.[[74]](#endnote-40),[[75]](#endnote-41),[[76]](#endnote-42) ASCs focus on performing a narrow set of medical specialties and surgical procedures and providing care for patients with lower-acuity and less risk of complications.[[77]](#endnote-43),[[78]](#endnote-44) Staff compared total costs and copayments of select procedures offered at NESC using the Price Procedure lookup tool and found that ASCs can be a cost-effective alternative for certain procedures. It has been reported that data from the Price Procedure tool are limited because the prices are based on national averages and copayment estimates are only for patients with Original Medicare and no supplemental policy. In addition, Medicare costs and copayments are not always aligned; a patient copay may be less expensive at an HOPD, but the total cost of the procedure may be more expensive than an ASC.[[79]](#endnote-45)

**Factor 1 Summary**

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the proposed ambulatory surgery project has met Factors 1(a-f).

**Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation**

**Cost Containment**

The Applicant reiterated the cost savings achieved in ASCs outlined above through provision of Medicare local payments and copays for additional outpatient procedures. The Applicant notes that Medicare, some commercial insurers, and employers are increasing coverage for services at ambulatory surgery centers to encourage patients to seek care in the most cost-effective, appropriate setting.[[80]](#endnote-46),[[81]](#endnote-47) The Applicant states that the administrator has provided written testimony to the Massachusetts Health Policy Commission (HPC) in 2016 regarding healthcare cost trends, and how surgery centers are a cost-effective way of assisting the state in meeting the health care cost growth benchmark.

***Analysis: Cost Containment***

A review of the literature shows that the rate of outpatient surgery is increasing in the ASC setting. Studies show that payment differentials between ASCs and HOPDs are driving care to take place in the lower-cost ASC setting, where care may be more cost efficient. [[82]](#endnote-48) Another reason cited for the utilization of the ASC setting for certain surgical procedures/patients[[83]](#endnote-49),[[84]](#endnote-50) is value-based healthcare, in which provider compensation is based on health outcomes, and health outcomes are measured against the cost of the delivery of care.

Cost containment on a statewide level is impacted through pricing, which is a function of what providers charge payers and what payers agree to pay. While payment contracts between individual providers and commercial payers are confidential, contracts among providers and Medicare and Medicaid are more transparent. Since surgeries performed in the ASC setting have been shown to be efficient, cost-effective, and are of equal or higher quality than when they are performed in the HOPD, staff finds that expanding access to outpatient surgery in the ASC setting has the potential to contribute to the Commonwealth’s cost containment goals.

**Improved Public Health Outcomes**

The Applicant has addressed how surgeries performed in the ASC setting can be more efficient, convenient, and cost-effective without compromising quality of care. In addition, the Applicant discussed how surgeries performed at NESC are demonstrated to improve outcomes, including increasing functioning and reducing pain.

***Analysis: Public Health Outcomes***

Surgical procedures performed in ASCs are associated with reduced mortality, morbidity, and hospital admission rates as compared to outpatient surgery performed in the hospital setting, and patients also experience shorter surgery and recovery times; these benefits appear to extend to vulnerable (highest-risk Medicare) patients.[[85]](#endnote-51),[[86]](#endnote-52),[[87]](#endnote-53) Improving access to NESC’s services has the potential to improve outcomes and quality of life for the Patient Panel.

**Delivery System Transformation**

The Applicant mentioned its value-based contracts[[88]](#footnote-35) and participation in numerous MassHealth products as evidence of its efforts to improve access to high quality, low cost care. In response to staff inquiry about MassHealth participation, the Applicant stated NESC contracts with all MassHealth products, and that 90% of the 24 surgeons performing procedures at the surgery center are participating MassHealth Providers, but not to all products. The Applicant explained that participation in all MassHealth products is not possible for the facility or the surgeons because some plans are only for services that are not covered in an ASC.[[89]](#footnote-36) The Applicant, along with other members of the Massachusetts Association of Ambulatory Surgery Centers (MAASC), provided case information to MassHealth which supported an increase in the rate of payment ASC’s received in 2018. The Applicant asserts that prior to the rate increase, the Applicant referred most complex and non-complex procedures to HOPDs where it was more cost efficient to perform them. The change in payment structure allowed the ASC to accommodate more complex and non-complex procedures and keep more patients at its facility.[[90]](#footnote-37)

***Analysis: Delivery System Transformation***

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant described its social needs screening processes including how surgery patients are assessed and how referrals are made to the PCP and outside organizations.

**Factor 2 Summary**

As a result of information provided, staff finds that the Applicant has sufficiently met the requirements of Factor 2.

**Factor 3: Relevant Licensure/Oversight Compliance**

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and will not be addressed further in this report. As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 3.

**Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis**

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 conducted by an independent CPA. The Applicant submitted a report performed by Cohen & Company (CPA Report).

In order to assess the reasonableness of assumptions used, and the feasibility of the projections for the Proposed Project, the CPA Report reflects a review and analysis of the “Financial Feasibility Report” prepared by Health Capital Consultants, dated February 11, 2020 (HCC Report), including five-year financial projections (2020-2024). The HCC Report relied upon historical and projected performance of NESC, industry data and trends, financial data and NESC Management interviews.

The CPA reports that key revenue variable considerations were changes in utilization demand and market share, and changes in reimbursement yield. HCC took a conservative approach to estimating changes in utilization considering only projected population growth of the market service area and NESC’s historical patient age demographics. Changes in reimbursement yield were estimated based on historical per patient revenues. Changes in reimbursement from Year 1 to Year 5 were based on proposed Medicare reimbursement fees and projected long-term growth rate of NESC. The CPA reports that operating expenses were calculated using historical costs per procedure plus an inflationary factor.[[91]](#footnote-38) The CPA reviewed capital expenditure and cash flows. The Projections reflect positive cash flows in years 2 through 5 and adequate levels of capital expenditure necessary for maintenance associated with the expansion.

The Projections exhibit a cumulative net operating surplus of approximately 19.2% of cumulative projected revenue for the project for the years 2020 through 2024, and the CPA determined that the operating surplus is reasonable and based upon feasible financial assumptions. As a result of the foregoing, the CPA 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.”

As a result of information provided by the Applicant, staff finds the Applicant has reasonably met the standards of Factor 4.

**Factor 5: Assessment of the Proposed Project’s Relative Merit**

The Applicant compares the Proposed Project to the alternative of continuing operations within the existing configuration of the facility. The Applicant dismissed this alternative because the clinical and operational inefficiencies resulting from a lack of an additional OR capacity would persist and could result in cases being turned away to a higher cost HOPD where costs to the patient, Medicare and other insurers can increase.

**Staff agrees that** the above alternative of maintaining the status quo will not adequately address Patient Panel need for high-quality and convenient access to outpatient surgical services. As aresult of information provided by the Applicant and additional analysis, staff finds the Applicant hasreasonably met the standards of Factor 5.

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

It is the intent of the relevant Guidelines which implement Factor 6 to build on, and make use of, the CHNA/CHIPs supported as part of the AGO’s Community Benefits Guidelines and/or federal IRS requirements for community benefits reporting routine community health planning activities required by IRS. It is not the intent of the Regulation or these Guidelines for any entity applying for a DoN to embark upon a separate, stand-alone Community Health Needs Assessment. Because the Applicant is not required to and otherwise does not conduct regular CHNAs/ CHIPs to fulfill standards set by the IRS or the AGO’s Community Benefits program the CHI contribution shall be made to the CHI Statewide Initiative. In compliance with Factor 6 of the regulations, as a condition of approval, the Applicant will make payment in the amount of $79,382.30 (5% of the Total Value of the Proposed Project) to the DoN fund for Community Health Initiative Statewide Initiative pursuant to 105 CMR 100.210(6).

**Findings and Recommendations**

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended Condition detailed below, the Applicant has met each DoN Factor for the Proposed Project, and recommends that the Department approve this Determination of Need, subject to all applicable Standard and Other Conditions.

**Other Conditions**

1. Of the total required CHI contribution of $79,382.30
   1. $79,382.30 will be directed to the CHI Statewide Initiative paid in two equal installments to Health Resources in Action (HRiA) (the fiscal agent for the CHI Statewide Initiative)
      1. The Holder must submit $39,691.15 to HRiA within 30 days from the date of the Notice of Approval.
      2. The Holder must submit $39,691.15 to HRiA within 30 days of the first anniversary date of the Notice of Approval.
      3. The Holder must promptly notify DPH (CHI contact staff) when the payment(s) has been made.

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4. 3: Sufficient evidence of compliance and good standing with federal, state, and local laws and regulations

   4: Sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Project without negative impacts or consequences to the Applicant's existing Patient Panel 5: The … Project, on balance, is superior to alternative and substitute methods for meeting … Patient Panel needs. [↑](#footnote-ref-4)
5. An Expansion, Conversion, Transfer of Ownership, transfer of Site, or change of designated Location for a Freestanding Ambulatory Surgery Center that received an Original License as a Clinic on or before January 1, 2017. [↑](#footnote-ref-5)
6. As defined in 105 CMR 100.100, Patient Panel is the total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder. [↑](#footnote-ref-6)
7. Patient Panel by Specialty (2019): Otolaryngology (29%), Urology (20%), Ophthalmology (20%), Pain Management (12%), Orthopedics (13%), Podiatry (3%), Plastics (2%), General (1%). [↑](#footnote-ref-7)
8. US Census Bureau QuickFacts Essex County, Massachusetts: White alone (85.1%), Black of African-American alone (7.1%), American Indian and Alaska Native alone (0.9%), Asian alone (3.9%), Native Hawaiian and Other Pacific Islander alone (0.2%), Two or more races (2.8%), Hispanic or Latino (22.2%), White alone, not Hispanic or Latino (69.0%). [↑](#footnote-ref-8)
9. Based on self-reporting, and reflects 75% of patients served in 2019. [↑](#footnote-ref-9)
10. All cities/towns are in Essex County except Wilmington, MA which is in Middlesex County. [↑](#footnote-ref-10)
11. In general, many patients require multiple visits. [↑](#footnote-ref-11)
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14. Minimally invasive procedure designed to relieve back pain associated with lumbar spinal stenosis (LSS) by restoring the normal space between the vertebrae. [↑](#footnote-ref-13)
15. Outpatient procedure that helps patients diagnosed with lumbar spinal stenosis (LSS) stand longer and walk farther with less pain. The Applicant notes the MILD procedure is only performed on patients age 65 and older who have not had success with epidural steroid injections (ESI). [↑](#footnote-ref-14)
16. Collection of data for otolaryngology cases began in May, 2018. [↑](#footnote-ref-15)
17. Both require general anesthesia. [↑](#footnote-ref-16)
18. Impact Advisors. Surgical Block Utilization. Available: <https://www.impact-advisors.com/implementation/surgical-block-utilization/#:~:text=Set%20an%20initial%20conservative%20goal,yet%20have%20block%20time%20assigned> [↑](#endnote-ref-2)
19. The additional orthopedic surgeons increased the number of shoulder and knee arthroscopies; and added foot, ankle, and hand procedures, the majority requiring general anesthesia. [↑](#footnote-ref-17)
20. Additional surgeries include large mass removal, open hernia repairs, breast biopsies, and hemorrhoid procedures. [↑](#footnote-ref-18)
21. Procedures brought in by the general surgeons include excision of malignant lesions, umbilical hernia repair, removal of soft tissue tumors; all of the procedures are performed under general anesthesia. [↑](#footnote-ref-19)
22. Cases include transurethral resection of the prostate (TURP), Pyronie disease repair, and kidney stone removal. [↑](#footnote-ref-20)
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60. The Applicant mentioned that COVID protocols do not allow family or caregivers to wait in the facility, so upon discharge patients are provided post-surgery information and escorted to their transportation. [↑](#footnote-ref-28)
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71. Medicare.gov website. Local average prices are based on 2020 Medicare payments and copayments, and do not include physician fees. Payment rates for each covered surgical procedure after adjustments for regional wage variations, and wage indices, without 2% sequester. [↑](#footnote-ref-32)
72. Six potential competitors include: North Shore Plastic Surgery and Med Spa, Mass General/North Shore Center for Outpatient Care; Lahey Outpatient Center, Danvers; Lahey Medical Center, Peabody; New England Pain Care ,Inc; and Orthopedic Surgical Center of the North Shore. [↑](#footnote-ref-33)
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