STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	Chelmsford Surgery Center, LLC
Applicant Address	700 Congress Street, Suite 204, Quincy, Massachusetts 02169
Filing Date	February 2, 2021
Type of DoN Application	Ambulatory Surgery
Total Value	$6,335,872.00
Project Number	# 21010715-AS
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	$316,793.60
Staff Recommendation	Approval
Public Health Council	Yes

Project Summary and Regulatory Review

Chelmsford Surgery Center, LLC (Applicant) based at 700 Congress Street, Suite 204, Quincy, Massachusetts 02169, submitted this Application for a Notice of Determination of Need (DoN) for the development of a freestanding ambulatory surgery center (ASC) to be located at 10 Research Place, North Chelmsford, Massachusetts 01863 (Proposed Project). The Applicant is a newly formed joint venture established for the purpose of developing the freestanding ASC. The Proposed Project will convert three (3) hospital-based outpatient operating rooms (ORs) to a freestanding ASC and add a fourth OR.

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 and Application Overview

Chelmsford Surgery Center, LLC (Applicant) submitted this Application for the development of a freestanding ambulatory surgery center (ASC) to be located at 10 Research Place, North Chelmsford, the Proposed Project. The Applicant is a newly formed joint venture established for the purpose of developing this freestanding ASC.

The Applicant's members are:

- Chelmsford ASC Holding Company, LLC, a company formed by Shields Health Care Group (Shields),
- Lowell General Hospital (LGH), and
- Community-based specialty physicians (Participating Physicians), with representation from Lowell General Physician Hospital Organization (LG-PHO)

Shields Health Care Group was founded in 1972 in Brockton, Massachusetts by the Shields family, the company established itself as a provider of different specialized healthcare services including dialysis, imaging, including fixed and mobile MRI, CT and PET-CT, and more recently Ambulatory Surgery Centers. The Applicant asserts that it "operates the largest, most efficient and effective outpatient services in the New England Region," and that it "is recognized as part of the solution towards driving down healthcare costs."

Lowell General Hospital is a high Public Payer Hospital as designated by the Center for Health Information and Analysis (CHIA) as 65.7% (2018) of payments come from public payers. The hospital is spread across two campuses, the Main Campus located at 295 Varnum Avenue in Lowell, and the Saints Campus located at One Hospital Drive in Lowell. Both campuses represent the not-for-profit community hospitals servicing the Greater Lowell Area and surrounding communities. Lowell General Hospital currently operates a hospital outpatient department (HOPD) surgery center consisting of three (3) operating rooms (ORs) located at 10 Research Place in Chelmsford. As described further herein, the Applicant will transition this existing surgery center into the Proposed Project.

LGH is a member of Circle Health, an integrated community healthcare delivery system composed of Circle Home, Lowell General Hospital, Lowell Community Health Center, and the community of local physicians. Circle Health is a member of Wellforce Inc., the health system formed by Tufts Medical Center, Circle Health and MelroseWakefield Healthcare. Wellforce includes 2,500 physicians, 3 community hospital campuses, an academic medical center and a children's hospital and is a Health Policy Commission's (HPC) Certified Accountable Care Organization (ACO).[1] The Applicant asserts that "Wellforce is the high quality, lower-cost system in Massachusetts that focuses on care integration, population health management, patient access and operational performance."

[1] Wellforce, Inc., inclusive of Wellforce Care Plan, LLC; Lowell General Hospital/Lowell General Physician Hospital Organization; Circle Health Alliance, LLC; New England Quality Care Alliance, Inc.; and New England Quality Care Alliance Accountable Care, Inc.

Lowell General Physician Hospital Organization is a non-profit organization comprised of approximately 400 member physicians and partners with Lowell General Hospital. The LG-PHO was established in 1995 with the goal of developing a local integrated delivery system.

The Applicant, Chelmsford Surgery Center, LLC, was formed to develop and operate a freestanding ASC that will offer lower-cost surgical services within the community setting serving the communities in and around Lowell, Massachusetts, allowing the Applicant to satisfy the existing and anticipated future demand for surgical services in the primary service area (PSA). Through the Proposed Project, the Applicant will accomplish two goals - it will 1) transition the existing HOPD surgical center[2] into a freestanding ASC, and 2) expand the current center from three to four operating rooms (OR) and include , as required for licensure,[3] the pre-operative space and post anesthesia care unit (PACU), central sterile processing, clean supply areas, lobby/waiting area with ample space to accommodate social distancing requirements, as well as consultation, administrative and patient support areas. The total capital expenditure for the project is $6,335.872 for the construction of a new OR, updates to non-DoN required equipment and renovations to existing space. The Proposed Project will provide orthopedic, total joint (MSK-joints), podiatry, spine, hand, gynecology (GYN), and plastic surgical services.

In planning the Proposed Project, the Applicant assessed the location of the existing hospital-based surgical center and found it accessible and convenient to patients in the noted service area by both public bus route, as well as proximity to nearby highways and thoroughfares. Thus, the Applicant will transition the existing HOPD surgical center to a multi-specialty freestanding licensed ASC at the same site. Following implementation of the Proposed Project, the current Lowell General Hospital's licensed HOPD rates will transition to the Medicare free-standing ASC fee schedule,[4] resulting in a lower cost site of care.

Factor 1: Patient Panel & Need

Patient Panel[5] Demographics

As the Applicant is a newly formed joint venture, it does not have its own Patient Panel. Consequently the Applicant relies on data from its joint venture partners, LGH and LGH-PO and their affiliated relevant specialty physician groups to define its patient panel. The Applicant reports these data are based on existing freestanding ASC-eligible patients. Staff agrees that, since this is a new entity, this is an acceptable way to identify an anticipated patient panel, assess need, and develop projections.

[2] Which is referred to as Drum Hill

[3] Separate from DoN, architectural plans are reviewed by Plan Review within the Bureau of Healthcare Safety and Quality

[4] 2021 *HOPD and ASC Medicare Fee Schedule*

[5] 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…(2) If the Proposed Project is for a new facility and there is no existing patient panel, Patient Panel means the anticipated patients

The Proposed Project's Primary Service Area consists of the ten towns in zip codes representing approximately 75% of the patients currently served by Lowell General Hospital.[6] Staff researched the Applicant's CHNA, which provides a snapshot of the racial profile of the Greater Lowell area and is in Table 1. The city of Lowell reflects greater diversity than the surrounding towns including Chelmsford.

Table 1: Demographic Information of Greater Lowell CHNA[7] 2013-2017

City/Town	White	Black	Asian	Hispanic	Born Outside of the US
Lowell	60.8	7.3	21	20.3	26.7
Chelmsford	87.2	0.8	9.5	3.7	11.2
Weighted Avg. of Gr. Lowell CHA Service Area	77.1	4.1	12.8	10	15.6
Massachusetts	78.9	7.4	6.3	11.2	16.2

In 2019 Lowell General Hospital's Outpatient Surgical Patient Panel,[8] consisted of 10,904 unique encounters. Due to the COVID-19 outbreak, during which non-elective surgical volume was halted in the Commonwealth, demographic data for that year is not a reflection of the anticipated Patient Panel. Consequently, the Applicant relies on the two prior full years of Patient Panel information.[9] The demographic data within that population reflects an aging population. In 2019, 46.4% of the Patient Population was over the age of 55 which is an increase of 1.6% from the prior year. In 2019, nearly a quarter of patients served were age 65 and above which is a 1.4 % increase over 2018.

Table 2: Anticipated Patient Panel

Age Cohort	2018	% of Total in 2018	2019	% of Total in 2019
0-19	1,037	9.34%	1,010	9.26%
20-54	5,092	45.88%	4,837	44.36%
55-64	2,404	21.66%	2,388	21.90%
65+	2,565	23.11%	2,669	24.48%
Total	11,098	100%	10,904	100%

Staff, however, noted in Table 2 that the total number of unique encounters in every age cohort declined except in the persons aged 65+ and further, that the overall total decreased 1.75% from 2018-2019. This decline is also reflected in the volume shift. Following staff inquiry, the Applicant reported that it is the result of the departure of two active surgeons and is further explained below

[6] The cities and towns are: Lowell, Dracut, Chelmsford, North Chelmsford, Tewksbury, Tyngsboro, Westford, Billerica, North Billerica, and Methuen.
[7] Greater Lowell CHNA is comprised of all of the above except N. Chelmsford and N. Billerica, and Methuen.
[8] Including the Drum Hill Surgery Center, Lowell General's Main Campus and Lowell General Saints Campus
[9] The Applicant also reports that 2017 data was not available due to a change from electronic health systems used.

under projections. Through the current LLC structure, LGH, in partnership with Shields ASC, is now able to offer equity interest to physicians in the region and anticipates that physicians who are currently transferring surgical cases elsewhere will return to provide their patients with these services in the local market.

Table 3 shows the payer mix of the outpatient surgical patients for LGH. It includes patients covered by risk contracts[10] that are held by the joint venture participants, as well as Fee-For-Service (FFS) patients seen by the participating physicians over the last twenty-four months. Approximately 53% of the anticipated volume at the proposed ASC falls under a managed arrangement with the Lowell PHO under Wellforce, an HPC Certified ACO.

Overall, LGH sees a mix of Medicare-eligible patients, of which 77% are eligible based on age and 23% based on disability status. However, the Outpatient Surgical Payer Mix at all LGH sites is comprised of 36.5% of patients with all government-sponsored health insurance, and 5.4% includes Health Safety Net, TriCare, and self-pay, as Table 3 shows.

Table 3: 2019 ALL sites LGH Outpatient Surgical Volume: Payer Mix (Inclusive of Drum Hill Surgery Center and other LGH Outpatient Surgery Sites)

APM Contract	Contract Percentages	Payer Mix	Payer Percentages
ACO and APM Contracts	57%	Commercial PPO/Indemnity	37.50%
		Commercial HMO/POS	20.60%
		MassHealth	1.60%
		Managed Medicaid (Private Medicaid/Medicaid MCOs)	7.70%
Non-ACO and Non-APM Contracts	43%	Commercial Medicare (Private Medicare/Medicare Advantage)	9.40%
		Medicare FFS	17.80%
		All Other (e.g. HSN, Self-Pay, TriCare)	5.40%

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 attributes anticipated need by the Patient Panel for increased outpatient surgery capacity to many local factors and national regulatory trends.

- The growth in the population, especially the 55 plus age cohort, places greater demand on the existing surgical supply. Nationally, the 55 plus age cohort has experienced the greatest increase in number of surgical procedures since 1990 of all age cohorts.[i] In the Commonwealth, between 2020 and 2035, the 55+ age cohort will increase approximately 14% and will comprise 35% of its population; no other age cohort will experience the same increase in growth as the 55+ cohort.[ii]

[10] Also referred to as managed patients

- Census data for the Applicant's PSA forecast the 55+ population will increase 5% by just 2025.[iii]
- The 2019 data (Table 2) indicate nearly half of the Applicant's surgical patients are over age 55, and nearly one quarter are over age 65. Medicare patients comprise 27% of the Applicant's payer mix.

- As the population ages, the need for orthopedic related surgical services rises as the prevalence of conditions such as arthritis and obesity which result in joint damage increases. The Applicant's facility will offer a wide range of orthopedic services to meet this increase in demand due to health risk factors described below.

    - Among the 65 and older population[iv] there is a higher prevalence of arthritis and conditions like lumbar spinal stenosis (LSS) and sacroiliac joint (SJ) pathologies. Arthritis, the risk of which increases with age, is a leading cause of pain and disability.[v,vi]
    - Obesity is correlated with health issues,[11] including progressive wear and tear diseases of the joints leading to arthritis and musculoskeletal conditions leading to subsequent need for surgical orthopedic services, specifically spine, hip, and knee replacement.[vii] The percentage of adults in the United States with obesity has more than doubled over the past 30 years—from 15 percent in 1980 to 35 percent in 2010.[viii] Staff notes that in Massachusetts the prevalence of obesity is 25.2% according to the 2019 Self-Reported Obesity, BRFSS.[12] Individuals with obesity are 20 times more likely to need a knee replacement than those who are not overweight. From 2002 to 2009, the number of total knee arthroplasty (TKA) procedures performed on patients with obesity doubled.[ix]

- Need to manage care for the Applicant's ACO patient population- with approximately 57% of the patients currently participating in an ACO, managing costs and quality to provide value-based care, is essential. This is discussed further under Factor 1(b) and (c).

- In an effort to control costs, and to allow for more discretion on the part of physicians, there are increasing numbers of procedures that the Center for Medicare and Medicaid Services (CMS) is shifting to the outpatient setting. CMS is both expanding its ASC covered procedures list and eliminating their Inpatient-Only (IPO) list.[13, x] In calendar year 2021, CMS added 11 procedures to the ASC approved procedure list, including total hip replacements and CMS removed 300 procedures, made up of primarily musculoskeletal procedures, from the Medicare IOP list.[14] Over the next three years the IOP list is slated to be eliminated.[15] Further, it is anticipated that more procedures will be added to the ASC list over time, which will ultimately create demand for both outpatient and ASC services, not only in the Chelmsford PSA, but

[11] In addition to contributing to arthritis and other musculoskeletal health issues, obesity also is linked to diabetes, heart disease, sleep apnea, liver disease, pancreatitis, certain tumors and cancers, and psychiatric disorders

[12] After 2011, the reporting methodology changed so the before and after data are not comparable Behavioral Risk Factor Surveillance System: https://www.cdc.gov/brfss/

[13] Introduced approximately 20 years ago, the List designates surgeries and procedures that require inpatient hospital care to be reimbursed under Medicare.

[14] Procedures removed from the IPO list are not automatically approved for ASC. To be reimbursed in the ASC setting, the procedure must separately be approved for ASCs. Removal from the IPO list makes a procedure eligible for reimbursement in a Hospital Outpatient Department (HOPD).

[15] Ultimately, this may allow nearly 1,700 procedures to be conducted in outpatient facilities and covered by Medicare.

nationwide. As the number of ASC approved procedures increases the demand for surgical capacity will increase.

- Further impacting the capacity needs of ASC's resulting from the expansion of ASC approved procedures is that procedure times for more complex approved cases are longer. Newly approved procedures, such as Total Joints and Spine, have 62.5% longer average case times compared to others. These two procedures alone have, average times of 120 minutes compared to 75 minutes for an average orthopedic procedure. The Applicant anticipates that over time it will perform over 140 Total Joint and over 200 spine cases annually. (See projections in Table 4)

- The technological advancements and specialty-focused surgical sites of care have enabled a shift of higher acuity and complex cases from inpatient to freestanding ambulatory surgical sites of care. The Applicant asserts that if the number of operating rooms remained at three, the surgery center would soon reach capacity trying to accommodate these higher acuity and more complex cases. As described below, the addition of a fourth OR will allow the surgery center to meet the current need for the select specialties, as well as expand its ability to provide care for patients as more complex procedures are approved for ASCs.

Current Volume

To determine current baseline volume for the proposed ASC, the Applicant first analyzed historical surgery volume from affiliated sites of its joint venture partners, by the specialties to be offered.[16] ASC eligible cases were identified by including those cases reimbursed by CMS on the Medicare Freestanding ASC fee-schedule, with an acuity level (ASA) less than 3,[17] and Total Joint and Spine procedures from LGH that now meet the ASC eligible criteria, and were discharged within under 24 hours.

Table 3 below shows a decline in volume for 2019 and 2020. While it is known that due to the COVID-19 outbreak non-elective surgical volume was halted in the Commonwealth, resulting in a volume decline in 2020, staff requested an explanation for the decline in 2019. The Applicant explained that two physicians, each averaging ~150 cases per year, acquired interest in an ASC located in New Hampshire. Therefore, they referred their Massachusetts-based patients out-of-state for their surgical procedures. The Applicant reports some of the care delivered was out-of-network for Massachusetts-based insurance carriers, resulting in substantially higher prices for the patients, insurers, and employers providing employer-sponsored health benefits.

[16] These include Lowell General Hospital, Saints Campus and the current site, called Drum Hill.

[17] The American Society of Anesthesiologists Physical Status Classification System, in use for over 60 years, is to assess and communicate a patient's pre-anesthesia medical co-morbidities. The classification system alone does not predict the perioperative risks, but used with other factors (e.g., type of surgery, frailty, level of deconditioning), it can be helpful in predicting perioperative risks. ASA I- A normal healthy patient; ASA II- A patient with mild systemic disease; patients not accepted above ASA III-A patient with severe systemic disease.

Also presented in Table 4 below, the volume for Quarter 1 of 2021 and a 12-month annualized volume was provided at staff request following the submission of this DoN. It demonstrates an upward trend in ASC appropriate surgical volume. Despite the two year down-turn, the annualized volume after the first quarter of 2021 shows that the surgeries are tracking to exceed their 2018 peak of 3,188. The ASC eligible surgeries are counted from those currently performed at the proposed site, (the HOPD) accounting for ~75% of the total, 19% at the Main and Saints Campuses, and those <24 hour inpatients from the Main campus accounting for ~5%.

Table 4: Historical ASC Eligible Case Volume[18]

Service Line	2018	2019	2020	*2021 Q1*	*2021(A)*
MSK - Joints	167	125	84	*32*	*128*
Orthopedics	1,715	1,469	1,247	*460*	*1,840*
Hand	884	869	760	*248*	*992*
Plastics	104	102	82	*32*	*128*
Podiatry	138	117	93	*39*	*156*
Spine	36	32	38	*11*	*44*
GYN	144	198	110	*25*	*100*
Total Cases	**3,188**	**2,912**	**2,414**	**847**	**3,388**

Volume Projections

After determining the current volume of ASC eligible patients from all three sites, the Applicant overlaid demographic projections and population health data from the Advisory Board[19] to develop five year projections. Found across the bottom of Table 5, Staff calculated year over year percentage changes in the Applicant's volume projections. Year 1 estimated decline over 2021 during renovations, recapturing pre-Covid volume and growth due to the shift in procedures from the Hospital, in Years 2 and 3 and leveling off at 2% growth projection for Years 4 and 5. Growth in Year 3 and beyond assumes cases migrating from the Lowell General Main Campus and Saints Campus. As the growth in the 2021 annualized surgical volume suggests, the Applicant states its volume projections are conservative and that they affirm the need for a 4th OR.

[18] Upon request, the applicant provided detailed charts by campus site and by specialty.

[19] Advisory Boards data researchers develop national demand models from several data sources, including Medicare data from CMS, national sample data from AHRQ, and other proprietary commercial claim sets. It then incorporates national disease prevalence rates with service area demographic factors such as population and socioeconomic characteristics of the PSA.

Table 5: Chelmsford ASC Volume Projections[20]

Service Line	Year 1	Year 2	Year 3	Year 4	Year 5
MSK - Joints	28	77	133	136	139
Orthopedics	1,104	1,366	1,565	1,596	1,628
Hand	722	878	988	1,008	1,028
Plastics	72	85	109	111	114
Podiatry	62	85	124	127	129
Spine	136	171	215	219	223
GYN	160	195	215	219	223
Total Cases	**2,284**	**2,858**	**3,348**	**3,415**	**3,484**
% change	-33%	25%	17%	2%	2%

The projections the Applicant reports take into account the construction timeframe associated with adding a 4th OR as well as a ramp up period that includes accreditation and payer contracting. Therefore, the Applicant states that based on these projections, a 4th OR would be required by Year 3 to handle the projected need. The Applicant asserts that with three ORs, Chelmsford Surgery Center would be operating at 96% of capacity by Year 3, while with four ORs, it should operate at 72-75% utilization years 3-5, which is more closely aligned with industry norms.[21] Table 6 shows how the increase of one OR increases minutes available by 120,000 minutes, and thereby impacts the utilization percentages.

Table 6: Comparison of Utilization of Three vs Four ORs

Year 3	Year 4	Year 5		Year 3	Year 4	Year 5
120,000	120,000	120,000	***Annual Minutes per OR[20]***	120,000	120,000	120,000
3	3	3	**# of OR's**	4	4	4
360,000	360,000	360,000	**Total OR Minutes Available**	480,000	480,000	480,000
347,133	354,111	361,144	**Total OR Time Needed[22]**	347,133	354,111	361,144
96%	98%	100%	**Combined Utilization %**	72%	74%	75%

[20] Upon request, the applicant provided detailed projection charts by campus site and by specialty.
[21] Assuming operating 8 hours per day, 5 days per week, 50 weeks per year, means each OR has 480 minutes available per week and 120,000 minutes per year.
[22] The Applicant calculated the number of minutes needed by specialty based on average time per procedure

Analysis

Since the utilization was highly variable over the past three years, Staff communicated with the Applicant to gather additional data and information to verify its volume and demonstrate that the additional OR is needed. Staff notes that the current annualized volume data suggests the Applicant is on track to exceed the projections by Year 3. The Applicant outlined a need for forming this joint venture ASC and adding operating room capacity at Chelmsford to address increasing demands for OR availability, a result of several elements including: 1) the need to locally accommodate the existing patient demands for surgery, 2) the need to ensure ACO accountability while accommodating access, 3) the need to ensure access to ASC services as numerous and more complex procedures are moved to the Medicare ASC covered procedures list (CPL) and become eligible for payment, and 4) the need to address the projected population growth, including the aging population cohort, that will benefit from the surgical services offered at Chelmsford. Given the Applicant's current trajectory and the increasing shift in procedures to ASC's, Staff finds that the Applicant's volume projections are reasonable.

At staff's request, the Applicant provided detailed calculations for capacity utilization comparing their current and projected utilization of three ORs versus four ORs. Staff summarized that information in Table 6. Because procedure times vary considerably by type of procedure, utilization was based on the number of minutes per type and volume by specialty. The calculation was done as follows: the total minutes needed to meet demand was summed and then divided by the total available OR minutes. Staff confirmed the Applicant's claim that 70+ % utilization comports with industry norms,[xi] and believes that the Applicant's capacity projections reasonably justify the need for an additional OR.

Higher rates of chronic diseases in the general as well as aging population create a greater need for these services.[xii,xiii] The detrimental effects of obesity on surgical outcomes and complication rates are well documented in medical literature. These effects include higher rates of infection and prosthesis failure/loosening of the implant when compared to patients of normal weight. These risks must be considered by referring physicians, surgeons, and the patient against the potential health benefits of increasing mobility following surgery.

Staff emphasizes the likely approval by CMS of the increasing numbers of procedures for Medicare payments in ASCs and underscores the need for increasing OR capacity to more adequately address patients' 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 orthopedic surgeries offered at Chelmsford are associated with improved outcomes, including reduced pain and improved functionality. The Applicant reviewed the benefits of surgeries moving to the ASC setting. The Applicant also cited reports showing ASCs offer quality outcomes that are comparable to outcomes for outpatient surgery performed in a hospital setting.[xiv,xv] Patients who undergo surgery in the ASC setting experience multiple benefits including lower rates of revisit to the hospital within one week post-surgery,[xvi] half the Infection rates for procedures performed in ASCs than for the same procedures performed in the hospital setting, and improved pain levels and less nausea when

receiving surgery in an ASC.[xvii] There also are better thirty day outcomes associated with procedures performed in ASCs, including reductions in pneumonia, renal failure, and sepsis as well as no demonstrated increase in morbidity, mortality, or readmission.[xviii]

- **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.[xix, xx, xxi] These qualities are 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.[xxii]

To assess the impact of the proposed Project, the Applicant developed quality metrics, a reporting schematic and quality indicator metrics that will measure patient satisfaction and quality of care. The measures are to be reported following DoN approval as a condition of approval.

Analysis

Research has shown that access to healthcare is associated with improved outcomes and can reduce the need for additional care.[xxiii, xxiv] Shorter wait times for procedures are correlated with increased patient satisfaction and lower rates of complications.[xxv] Additionally, staff research found that surgeries performed in an ASC outpatient setting can result in fewer and lower post-surgical infection rates than hospitals.[xxvi,xxvii]

Health Equity and Social Determinants of Health (SDOH)

The population within the PSA of the Proposed Project reflects diversity that necessitates implementation of culturally appropriate support services to ensure improved patient experience and higher quality outcomes. Upon additional research, staff notes that approximately 3.3% of households in greater Lowell, and about 14% of all households in Lowell proper speak limited English. Most commonly spoken languages are Portuguese, Creole, African languages, Vietnamese, French, Laotian, Khmer and others.[23] As noted previously, this Proposed Project is located only 2.8 miles from Lowell. Patients with limited English proficiency (LEP) are among the most vulnerable populations experiencing high rates of medical errors with less desirable clinical outcomes than English-proficient.[xxviii]

The Applicant states it will employ culturally competent staff and plans to develop a robust translation services program that offers multiple options and tools to address language barriers. These include two services, Language Line and lnDemand interpreting, to provide for translation services. Language Line provides phone and video interpretation services from trained professional linguists in more than 240 languages 24 hours a day, 7 days a week.[24] lnDemand offers medical interpreting options, such as video interpretations, allowing clinicians to provide their limited English proficient, and deaf and hard of hearing patients with access to quality healthcare. The Applicant asserts these methods will eliminate language barriers for patients and ensure culturally appropriate care.

[23] As reported in the Applicants Community Health Needs Assessment
[24] Performing ~35 million interactions per year

The Applicant also plans to implement patient access tools, such as pre-registration functionality and a cost transparency application, to improve patient experience and ensure high rates of patient satisfaction. The price transparency tools ensure that all patients have access to current pricing information to determine if specific procedures are affordable. Further, the Applicant will provide financial counselors for assistance in understanding insurance benefits.

Analysis

Through a review of the Applicant's interpreter services, training initiatives, and social needs screening that the Applicant has employed at its other sites, 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. Staff finds that the Applicant's description of the Language Access and Assistive Services Plan is sufficient, with the understanding that, the Applicant will as part of the Standard Conditions of DoN approval need to report on and comply with requirements of the Office of Health Equity.

Staff notes that with the COVID-19 epidemic, it has been well documented that communities of color and low income communities have been the hardest impacted, thereby highlighting inequities to access across communities. The Applicant did not provide current racial or social economic analysis of the anticipated Patient Panel. Because of the wide variation in the demographic profile within the PSA presented in their 2017 CHNA, and to ensure equitable access, as a Condition of Approval, staff recommends the applicant be required to report annually on the racial socio-demographic profile of their newly developing Patient Panel.

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

It has been documented that ASCs offer greater clinical and operational efficiencies over traditional hospital outpatient surgery since an ASC can limit its efforts to performing a narrow subset of surgical procedures in a limited number of medical specialties. Additionally, ASCs often focus on specific categories of lower acuity surgical cases, serving patients who have less risk for complications following surgery.[xxix]

The Applicant described how it will support processes to ensure continuity of care, pointing to how its technology infrastructure and physician engagement interrelate to ensure continuity of care, improved health outcomes and care efficiencies. The technology infrastructure also includes streamlined patient access tools that offer pre-registration functions that interface with an electronic medical record (EMR) system to amalgamate essential patient health information, such as a patient's pre-operative medications, medical history, allergies and medications for review by surgeons and anesthesiologists. The EMR enables surgeons to share operative notes and post-operative discharge instructions with primary care physicians (PCPs), so both physicians may track a patient's progress post-discharge and ensure appropriate medication dosing, as well as necessary post-operative prescriptions.

The Applicant's administrative leaders will engage surgeons in developing policies and procedures that assist in increasing communication with PCPs. For example, in the event

that a patient is unable to have surgery because of a failure to follow instructions by the surgeon, communication between the surgeon and PCP may address the issue, so the patient is aware of appropriate preparation for surgery. Developing strategies for timely communication amongst providers ensures higher quality outcomes for patients, especially those with co-morbidities that struggle with psycho-social support needs. An assigned care manager will follow-up with the patient to determine if they have any needs post discharge. Accordingly, these efforts will ensure patients have efficient and coordinated care.

Upon discharge, a nurse manager will review and provide detailed written discharge instructions from their care team in a brightly colored folder to minimize the chance that the patient misplace the instructions. Additionally, the surgeon has the ability to record the post-operative message in the EMR, which details the surgery and post-operative instructions. The electronic information will also be emailed, using HIPAA-compliant protocols, so that in the event that the patient or family misplaces the hard copy, they will have the same instructions in their email inbox. This affords the ASC and the surgeon the opportunity to guarantee the patient is equipped with the appropriate discharge information to ensure a safe, rapid recovery. The Applicant reports that this two pronged approach has proven to be successful at other ASCs, and facilitates continuous communication with the patient, thereby improving patient satisfaction and quality of care.

The ASC's EMR will allow for the perioperative record to be exported and shared with the patient's PCP and others on the patient's care team electronically. Additionally, the medical record is also present in the surgeon's clinic allowing the surgeon to discuss the patient's outcomes when not physically at the ASC.

Analysis

The Applicant provided a detailed description of care coordination and information sharing across different providers from admission through post-operative care. Integrated processes are of particular importance in the ASC setting for managing patient referral to different points of care.[xxx] While EHR adoption in ASCs has been slow and the high expense of the systems is one reason cited,[xxxi] the Applicant has experience in establishing such systems with other partners. Staff finds Chelmsford has adequate processes in place to facilitate care coordination and communication among providers, patients and their families.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, 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 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."[xxxii]

The Applicant and the Participating Physicians conducted two community forums. The presentations aimed to inform the community members about both the Proposed Project and the ongoing shift to outpatient surgery as part of the evolving healthcare delivery process. Information provided included the benefits of receiving surgical procedures in an ASC setting, such as convenience, and "cost-efficiencies." These forums were publicized as a legal notice on Shield's and LGH's websites, practice locations and via email to patients.

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 by providing a lower-cost alternative for patients' outpatient surgery needs that does not compromise quality.

The Applicant asserts that the Proposed Project is unlikely to negatively impact TME or the cost of services since procedures performed as outpatient surgery in the ASC setting are done with greater efficiency and less expense than those done in HOPD surgery centers.

Numerous reports show Medicare procedures performed in the ASC setting can be less expensive than those performed in the hospital.[xxxiii, xxxiv, xxxv] As a result, ASCs, are a lower cost option for both payers and patients as compared to HOPDs. Expanding capacity to accommodate the expanding number of surgeries approved for[xxxvi] ASC instead of a HOPD can lead to a reduction in TME resulting from lower provider and payer costs and lower out of pocket expenses for patients.

Generally, ASCs work to achieve several main goals. The first goal is to ensure that patients have the best surgical experience possible, with high-quality outcomes. The second is to provide cost-effective care that leads to savings for government and third-party payers, as well as patients. When surgery is performed in an ASC rather than an HOPD, the Medicare program and its beneficiaries share an estimated $2.6 billion in savings each year. ASC reimbursement rates are nearly 48% of the amount paid to HOPDs.[xxxvii] Studies estimate that if half of the eligible surgical procedures were shifted from HOPDs to ASCs, Medicare could save an additional $2.5 billion annually and the savings to commercial payers could be as high as $55 billion annually.[xxxviii] Similarly, Medicaid and other insurers benefit from lower prices for services performed in the ASC setting. Patients' copayments for procedures performed in the ASC are often lower for comparable procedures than in a hospital setting.[xxxix]

At staff's request, the Applicant provided a comparative chart of the relative prices for its outpatient services as shown in Table 7 below.

Table 7: Outpatient Relative Price

	Outpatient Relative Price 2018				Percent of Total Network Payments 2018			
	Blue Cross	Fallon	Harvard Pilgrim	Tufts	Blue Cross	Fallon	Harvard Pilgrim	Tufts
Lowell General	0.84	0.81	0.84	0.89	1.49%	1.64%	1.38%	2.00%
Lahey Hospital	0.98	0.79	1.04	0.93	3.36%	1.91%	5.84%	4.33%
Lawrence General	0.74	0.72	0.79	0.78	0.43%	0.23%	0.42%	0.43%
Steward Holy Family	0.84	0.94	0.92	0.95	0.54%	0.28%	0.58%	0.83%
Weighted average, based on percent of total network payments	0.94	0.80	1.01	0.92	4.33%	2.42%	6.84%	5.59%

Analysis

Staff points out that Table 7 shows that LGH outpatient services payment rates from the four payers is below the relative price of the other hospitals in its *Community Hospital* cohort.[25] This indicates that LGH's outpatient services are generally lower than others in its cohort. In forming the ASC, staff would not expect these rates to increase when negotiating contracts. On the right of Table 7, Staff notes that the total share of payments by each of the payers to LGH's outpatient services is low ranging from 1.38% to 2%. Therefore, any increase in prices that may occur is unlikely to have a measureable impact on TME.

Studies have demonstrated that outpatient surgeries performed in the ASC setting are 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.[xl,xli,xlii] 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.[xliii,xliv] Staff has compared total costs and copayments of select procedures using the Price Procedure lookup tool and found that ASCs can be a cost-effective alternative for certain procedures.[26]

Personal healthcare spending[27] varies by age with higher spending occurring in the age 65 and older segment of the population. [xlv, xlvi] The most commonly utilized surgical services by the age 65 and older population includes a broad range of surgical procedures with

[25] The Center for Health Information and Analysis defines the cohorts and publishes these data annually. The most recent year available is 2018.

[26] The Price Procedure tool data are limited because the prices are based on national averages and copayments are estimates for patients having only Original Medicare with no supplemental policy. In addition, a patient copay while generally less in an ASC, may be less expensive at an HOPD, while the total cost of the procedure may be less expensive at an ASC.

[27] Personal health care consists of all the medical goods and services used to treat or prevent a specific disease or condition in a specific person.

orthopedic services among them. The personal spending for surgical care is in the form of copayments and deductibles and spending for drugs and prosthetics that may or may not be covered. Demand for these services is expected to increase as the age 65 and older populations grow.[xlvii]

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).

Staff, highlights that, through standard conditions, the Applicant is required to meet the requirements of the Department's Health Equity Program that comply with CLAS standards in a timely manner. Further, Staff recommends reporting of outcome measures, demographic data including by race, payer, and age including the aging population by 10 year intervals; and payer-mix described at the end of this report as additional conditions.

Factor 2: Health Priorities

Cost Containment

The Applicant states that the proposed Project meets the cost containment goals of Massachusetts by providing qualifying lower acuity patients with high quality surgical services in a cost-effective setting. As previously discussed, ASC reimbursement rates are 48% of the amount paid to HOPDs.[28] Studies provide that if half of the eligible surgical procedures were shifted from HOPDs to ASCs, Medicare would save an additional $2.5 billion annually. Similarly, Medicaid and other insurers and patients benefit from lower prices for services performed in the ASC setting given lower levels of reimbursement and less coinsurance payments.

As outlined above, the Applicant reiterated that cost savings are achieved in ASCs through provision of an array of low intensity procedures to patients with low acuity in an efficient manner. The Applicant notes that Medicare, more commercial insurers, and employers are increasing coverage for procedures performed at ASCs to encourage patients to seek care in a more cost-effective, appropriate setting.[xlviii, xlix]

The selection of an ASC for certain surgical procedures[l, li] by an ACO provider is value-based healthcare, in which provider compensation is based on health outcomes. Since the Applicant's member is an ACO, Chelmsford has inherent incentives to provide value-based care.

Analysis: Cost Containment

[28] Based on the *2018 HOPD Medicare Fee Schedule.*

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 HOPD surgery centers are driving care to take place in the lower-cost ASC setting, where care may be more efficient resulting in aforementioned cost-savings.[lii] Further, in addition to the savings to Medicare (cited above) by shifting services away from the hospital setting, the transition of surgical procedures from an inpatient setting to an outpatient setting saves commercial payers $38 billion annually, according to an Ambulatory Surgery Center Association (ASCA) study.[liii, 3]

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.[29] 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 surgery center, 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

As addressed in greater detail in Factor 1(b) the Applicant has addressed how surgeries performed in the ASC setting can have improved outcomes, be more efficient, convenient, and cost-effective while not compromising quality of care. In addition, the Applicant discussed how surgeries performed at Chelmsford are demonstrated to improve outcomes, including increasing functioning and mobility.

Analysis: Public Health Outcomes

As discussed in further detail in Factor 1(b), 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 fewer infections and readmission rates; these benefits appear to extend to vulnerable (highest-risk Medicare) patients as well .[liv,lv,lvi] Improving access to Chelmsford's services has the potential to improve outcomes and quality of life for the Patient Panel.

Delivery System Transformation

The Applicant has reported that 57% of the existing payments derive from ACO and APM contracts that include value-based payment methodologies where provider compensation is based on health outcomes. The Applicant asserts that with the proliferation of ACOs, value based care (VBC), and Alternative Payment Models (APMs), there will be an increased demand for services offered through the Proposed Project as volume is pushed to lower-cost sites of care. Currently, over a third of U.S. healthcare payments are tied to APMs, with

[29] Also referred to as reimbursement

a recent goal of the CMS to align greater than 50% of Medicare payments to APMs in the years ahead.[lvii]

As described previously in this report, patients will be provided with access to care management services. Patients will meet with a case manager who will screen patients for social determinant of health needs. If after screening a patient needs additional services, the individual will be linked to a care manager, who will help the individual gain access local resources. To facilitate these referrals, the care manager will develop relationships with primary care practices and social work resources within the ACOs that refer patients to the ASC. These efforts will ensure patients are linked with appropriate community resources to address social determinant of health needs.

Analysis: Delivery System Transformation

Central to the goal of Delivery System Transformation is participation in innovative health care delivery models of care. One such model is an ACO, and as described previously in this report, LGH and LG- PHO are members of Wellforce ACO. Through its ACO contracts, the Applicant has built-in incentives to better manage their patient population through the integration of care with the PCP and outside social service 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: 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: Financial Feasibility

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 Bernard L. Donohue III, CPA (CPA Report) dated January 11, 2021.

In order to assess the reasonableness of assumptions used, and the feasibility of the Proposed Project, the CPA Report analyzed historical and projected performance of the Applicant's member hospital (LGH), and key financial metrics as compared to industry data and trends. The CPA Report includes an analysis of the Applicants five year financial

projections incorporating a review of CMS payment systems, Management interviews, and industry surveys and benchmarks.

To determine whether revenue projections were reasonable, the CPA reviewed the reimbursement mechanisms for each payer and applied those against the Applicant's projections to affirm that they aligned with volume projections. It found that for Medicare payments, the implications of the most current Medicare rates[30] which include a 2% rate reduction had not been accounted for in the projections. However, when the adjustments were applied, the impact was only a 0.5% reduction in total revenue. Further, the volume projections that are based on the LGH's current volume were reasonable relative to industry benchmarks and standards.[31] As a result of this assessment, the CPA found the Applicant's projected revenue was a reasonable estimation of future revenues.

To determine whether the Applicant's projections for expenses were reasonable, the CPA evaluated whether the projections for key categories of expenses were in sync with key industry benchmarks.[32] Salaries and benefits relative to the hours of clinical staff needed as well as administrative staff, including wage rates for the northeast and raises, clinical expenses and other expenses were projected to raise approximately 3% annually and were all considered by the CPA as reasonable.

Capital expenses including building and equipment leasing and financing terms were reviewed with their impact on cash flow and considered to be reasonable. Finally, the Projections forecast a net pre-tax profit margin ranging from 25.9% to 25.1% for years 2 through 5. Therefore, based on an analysis of the projected financial statements, the CPA determined that the Proposed Project and continued operating surplus are "reasonable expectations and based on feasible financial assumptions." As a result of the foregoing, the CPA determined that "the projections are feasible and sustainable, and not likely to have a negative impact on the Patient Panel or result in a liquidation of assets of Chelmsford ASC."

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

Factor 5: Relative Merit

The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

The applicant described one alternative to the Proposed Project, the status quo.

[30] The Medicare Out Patient Prospective Payment System (OPPS) published December 2, 2020
[31] Becker's ASC website, VMG Health Intellimarker Multispecialty ASC Study for 2017
[32] Becker's ASC website, VMG Health Intellimarker Multispecialty ASC Study for 2017

This alternative was rejected as it would not address current needs and does not address the needs to upgrade ORs and equipment in order to stay operational, thereby potentially negatively impacting the need for low-cost and high-quality outpatient surgical services in the community.

Given the need to upgrade the ORs, the status quo would not ensure the most efficient operations due to inefficient patient flow and outdated equipment. The specialization of services offered at the ASC will allow the Applicant to achieve clinical and operational efficiencies for eligible lower-acuity cases, enabling it to maintain a more uniform schedule, enhanced throughput and improved quality patient outcomes over those ocuring within the hospital-based setting. These efficiencies enable it to achieve cost savings through better staff scheduling, reductions in hospital overhead charges. Shifting volume from higher HOPD rates to a lower freestanding rate structure will generate downstream savings for TME.

Factor 5 Summary

As a result of information provided, staff finds that the Applicant has sufficiently met the requirements of Factor 5.

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

Summary and relevant background and context for this application: The Applicant is applying for a DoN project that will result in a Tier 1 CHI project. The Applicant submitted its 2019 Community Health Needs Assessment (CHNA) for Lowell General Hospital, a Self-Assessment, Stakeholder Assessments, and the 2020 Greater Lowell Community Health Improvement Plan (CHIP).

The Community Health Needs Assessment was conducted in 2019, as a joint effort of Lowell General Hospital, the Greater Lowell Health Alliance, and UMass Lowell, and outlines community health needs, assets, and planning for the community over the next 3 years. In creating the final CHNA, the Applicant utilized listening sessions, key informant interviews, community surveys, and additional data collection methods. The CHNA outlines health needs and priorities identified by participants, and key findings include mental health issues, substance use disorder, chronic disease, and violence and trauma. Populations of focus include immigrants and refugees, low-income families and individuals, and elderly community members.

The Self-Assessment provided a summary of community engagement processes and socio-demographic information, data and highlights related to topics and themes of community needs. Through data analysis, twenty listening sessions, nineteen key informant interviews, and a survey available in six languages, the participating community residents and stakeholder groups and residents identified the key concerns outlined in the 2019 CHNA.

Stakeholder Assessments provided information on the individuals' engagement levels (e.g. their personal participation and role) and their analysis of how the Applicant engaged the

community in community health improvement planning processes. The information provided in these forms were largely consistent with the self-assessment conducted by the Applicant.

The Community Health Improvement Plan is the most recent annual report from the Greater Lowell Health Alliance. The CHIP outlines goals, objectives, and strategies for community health improvement. The 2020 CHIP identifies a goal of Health Equity, a key component of Cultural Competency and Responsiveness, and seven priority areas. These areas are Alcohol and Substance Misuse, Housing and Built Environment, Infectious Disease, Maternal and Child Health, Mental Health, Safety and Violence, and Wellness and Chronic Disease. These seven areas include twenty-one focus areas. The CHIP utilized information from the most recent Community Health Needs Assessment (2019) and additional input from individual and organizational stakeholders.

As a result of review of these materials DPH Staff will work with the Applicant in areas including decision making and priority strategies.

Decision Making
This is the Applicant's first DoN since the adoption of the 2017 Community Health Initiative Guidelines, and given that the Applicant has a longstanding relationship with the Greater Lowell Health Alliance (GLHA) in community health planning processes, the CHI will be implemented as a joint activity. The GLHA works closely with Lowell General Hospital (LGH), and there is mutual participation across community decision making bodies. Lowell General Hospital has a Community Benefit Advisory Council, and GLHA convenes several task forces in addition to its larger body. Given this overlap, the Board of Directors of the GLHA will be integrally involved in decision making for the CHI process. The composition of this body is robust, and while this is allowable, DPH has required the Applicant and the GLHA commit to ensuring that the task forces and subcommittees are engaged and have meaningful say in all processes, including investment strategies.

CHI Focus Areas
The CHNA is foundational to the CHIP, and the 2020 CHIP has seven priority areas and 21 subcategories of focus. The CHIP represents the operationalization of the needs identified in the CHNA, and in order to ensure alignment with health priority guideline principles, the Applicant will be expected to focus on the areas that are related to the Social Determinants of Health and upstream community conditions. DPH staff will work with the Applicant to encourage prioritization of strategies within Housing and Built Environment, Safety and Violence, and other strategies where this link is clearest.

As the Applicant continues to work closely with the Greater Lowell Health Alliance, the Applicant may wish to directly support the work of GLHA to carry out community health planning activities. This is allowable only through the use of the administrative allowance. If the Applicant intends to provide support beyond this amount to the GLHA, they will need to propose a process that is both transparent and decided upon by the committee members, and will need to submit a rationale to DPH staff.

The anticipated timeline for the CHI activities includes continued meeting of the committees, and additional outreach and planning prior to approval, with further planning and funding strategy decision making to take place 3-4 months post approval, ultimately resulting in a publicly available grant-making process led by the GLHA. DPH staff will work with them on best practices for transparent grant-making. The timeline, ongoing engagement processes, and use of administrative funds are all appropriate and in line with CHI planning guidelines.

Summary Analysis: As a result of information provided by the Applicant and additional analysis, staff finds that with the conditions outlined below, and the ongoing communication on items outlined above, the Applicant will have demonstrated that the Proposed Project has met Factor 6.

Conclusion

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.

Conditions to the DoN

1. Of the total required CHI contribution of $316,794.00
    a. $30,412.22 will be directed to the CHI Statewide Initiative
    b. $273,710.02 will be dedicated to local approaches to the DoN Health Priorities
    c. $12,671.76 will be designated as the administrative fee.

2. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $30,412.22 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
    a. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
    b. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

Pursuant to 105 CMR 100.310(A)(12), ongoing reporting is required to DoN. In order to measure the impact of the Proposed Project, staff recommends ongoing evaluation of access and quality measures described in numbers 3, and 4 below. The Applicant will also report such measures as required by DPH- Bureau of Health Care Safety and Quality (BHCSQ) to DoN.

3. To assess access the Applicant will track and report annually on the payer mix, age and racial profile of the developing Patient Panel.
    a. The payer-mix will include payments from ACO and managed care contracts as well as commercial and public payers as reported in this document above.

b. The report the on ages will be segmented into the following age cohorts: 0-17, 17-64, 65-74, 75-84, 85+.
c. Further the Applicant will track and report on the racial profile of the Patient Panel.

4. To assess the impact of the proposed Project, the Applicant developed quality metrics and a reporting schematic, as well as metric projections for quality indicators that will measure patient satisfaction and quality of care. Annually, the Applicant shall report results of the measures and discuss any indicated corrective actions taken. These measures are discussed below:

a. **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
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 a less than "Good" or satisfactory rating will be evaluated, and policy changes instituted as appropriate. Metrics will be reviewed quarterly by clinical staff.

b. **Clinical 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 achieve or be better than the national benchmark of 0.10% surgical site infection rates, ultimately reaching a target of 0%.

Monitoring: Reviewed quarterly by clinical staff.

c. **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 quarterly by clinical staff.

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